Maine Department of Environmental Protection

Department Rule Chapter 90

Regulation of Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Basis Statement and Response to Comments

April 2025

The PFAS in Products Program is established at Title 38 M.R.S. § 1614. This rule explains how the Department of Environmental Protection (Department) will implement the law and establishes expectations for the regulated community wishing to submit proposals for Currently Unavoidable Use (CUU) designations. On August 5, 2024, before initiating rulemaking for the proposed Chapter 90, the Department published a concept draft of the proposed rule for public input. Numerous stakeholders commented on the concept draft, which resulted in the Department making several revisions that remain in the proposed rule presented to the Board of Environmental Protection (Board) for adoption. At its meeting on December 19, 2024, the Board voted to post proposed rule Chapter 90, *Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances*, for public comment and to hold a public hearing. The public hearing was held on January 16, 2025, during which the Board received testimony from the public. A 30-day period was provided to submit comment on the proposed rule; the public comment period closed on January 28, 2025. The Department received and reviewed 57 comments totaling 419 pages. Based on comments received, the proposed rule was further revised to correct typographical errors, eliminate superfluous language, and to add clarifying language. None of these changes are deemed significant.

Summaries of public comments and the Department's responses are provided below.

RESPONSE TO COMMENTS

Commenters

1) AGC Chemicals Americas
2) Air-Conditioning, Heating, Refrigeration Institute (AHRI)
3) Alliance for Automotive Innovation (AAI)
4) Alliance of Nurses for Healthy Environments (ANHE)
5) American Apparel & Footwear Association, National Council of Textile Organizations (AAFA & NCTO)
6) American Coatings Association (ACA)
7) Association of Equipment Manufacturers (AEM)
8) Association of Home Appliance Manufacturers (AHAM)
9) Bath Iron Works Corporation (BIW)
10) Business and Institutional Furniture Manufacturers Association (BIFMA)
11) Can Manufacturers Institute (CMI)
12) Chemical Users Coalition (CUC)
13) Complex Products Manufacturers Coalition (CPMC)
14) Conservation Law Foundation (CLF)
15) Consumer Technology Association (CTA)
16) Cookware and Bakeware Alliance (CBA)
17) Cookware Sustainability Alliance (CSA)
18) CropLife America and RISE
19) Defend Our Health (DOH)
20) Defend Our Health (DOH) - hearing
21) Electric Hydrogen
22) Emerson Electric
23) Farella Braun + Martel LLP (client)
24) Fire Equipment Manufacturers Association (FEMA)
25) Freudenberg Sealing Technologies (FST)
26) Halon Alternatives Research Corporation (HARC)
27) Heating, Air-conditioning & Refrigeration Distributors International (HARDI)
28) Hitachi Energy
29) Honeywell
30) Household & Commercial Products Association (HCPA)
31) International Safety Equipment Association (ISEA)
32) Japan Refrigeration and Air Conditioning Industry Association (JRAIA)
33) Japanese 4 Electronic and Electrical Industry Associations (JP4EE; JEMA, CIAJ, JBMIA, JEITA)

Commenters continued

34) KEMET Corporation
35) Maine Conservation Voters
36) Maine Organic Farmers and Gardeners Association (MOFGA)
37) Maine State Chamber of Commerce (MSCC)
38) National Electrical Manufacturers Association (NEMA)
39) Natural Resources Council of Maine (NRCM)
40) Natural Resources Defense Council (NRDC)
41) Performance Fluoropolymer Partnership (PFP) ACC (American Chemistry Council)
42) Personal Care Products Council (PCPC)
43) PFAS Pharmaceutical Working Group (PPWG)
44) Rep. Gramlich (Hearing)
45) Semiconductor Industry Association (SEMI and SIA)
46) Sen. Henry Ingwersen
47) SEW Eurodrive, Inc.
48) Slingshot
49) Sustainable PFAS Action Network (SPAN)
50) Syensqo
51) Taconic
52) Trelleborg Sealing Solutions (TSS)
53) Truck & Engine Manufacturers Association (EMA)
54) Valmet
55) VDMA
56) W. L. Gore & Associates, Inc.
57) Window & Door Manufacturers Association (WDMA)

SUMMARY OF COMMENTS AND DEPARTMENT RESPONSES

Applicability Section 1

Components

1. Comment: Commenter states that the proposed regulation is inconsistent, as the "Applicability" section removes product components from the rule's scope, but the "Notification" section still requires reporting PFAS in components. Commenter believes this suggests component manufacturers must comply with the regulation and ask for clarity. Commenter supports exempting components from the notification requirements because suppliers often withhold information due to confidentiality concerns. Commenter requests the Department clarify the exclusion of embedded components in the regulation as regulated entities must parse through tens of thousands of stock-keeping-units (SKU), each having hundreds of associated components and spare parts, to understand whether their product is regulated. This introduces hundreds of millions of potential changes for any given component to contain one of the thousands of PFAS included in Maine's definition. Component suppliers are often unable to disclose the chemical composition of their components to manufacturer customers for confidentiality reasons. Components in our sector are not generally accessed by the public, nor are they disposed of in waterways which avoid exposure through drinking water. The burden of this regulation would be nearly impossible for manufacturers to comply with. (Commenter 12, 32)

Response: The commenter is correct that product components have been removed from the applicability section of the proposed rule. Product components containing intentionally added PFAS are not subject individually to the notification for a currently unavoidable use (unless the product component is sold independently in which case it is considered a "product") or notification requirements based solely on their incorporation into another product covered by a currently unavoidable use determination. However, statute defines products as "including its product components"; therefore, a product which contains product components containing intentionally added PFAS is subject to currently unavoidable use and notification requirements of the proposed rule if it is covered by a currently unavoidable use

determination and is sold in Maine. No change to the rule.

Repair Parts

2. Comment: Commenter requests exempting replacement parts needed for routine repairs, particularly for durable goods like appliances, to reduce waste, especially those sold prior to the sales prohibitions taking effect. (Commenter 12)

Response: Exemptions to this rule are provided by statute. The statute does not allow the Department to establish additional exemptions through rulemaking. Manufacturers of replacement parts, which are sold independent of the final product, may request a currently unavoidable use determination consistent with the timeline and requirement in the adopted rule. No change to the rule.

Sell Through

3. Comment: Commenter suggests clarifying that previously manufactured products can continue to be sold in Maine until existing stocks are depleted without enforcement concerns. Commenters request a sell-through provision or existing stock exclusion. (Commenter 6, 12, 49)

Response: With regard to each sales prohibition, the statute states "… effective January 1, 20[XX], a person may not offer sell, offer for sale, or otherwise distribute for sale in this State …". Allowing the sale of products after said date would be inconsistent with the statutory language and beyond the Department's authority. No change to the rule.

Definitions Section 2

Alternative

4. Comment: Commenter is concerned that the phrase "has not been shown" in the statutory definition could allow substances to be deemed acceptable without sufficient data on its impacts. Commenter requests the Department require evidence or substantiation that an alternative does not pose the same or greater harm as PFAS. Commenter requests more detail

on the methodology for verifying harm. (Commenter 41)

Response: The Department recognizes that alternatives being considered need to meet statutory standards established in the definition of "alternative", which includes the consideration that the alternative has not been shown to pose the same or greater potential harm to human health or the environment as the PFAS it would replace. However, the Department does not have the authority to be more stringent than those requirements found in statute. No change to the rule.

5. Comment: Commenter states the concept of a comparable cost within this definition is too vague and should not be a consideration within the test of "reasonably available." Commenter states that the section of the definition regarding performance is irrelevant and should also be removed. Commenter recommends the following definition, "…means an alternative to the use of PFAS or to the product containing PFAS which is readily available in sufficient quantity or may become readily available in sufficient quantity in the relevant timeframe." (Commenter 19)

Response: Consideration of performance as an aspect of evaluating alternatives that are compared to the use of PFAS is founded in the statutory definition which describes an appropriate alternative as one that results "...in a functionally equivalent product…" and is also a component of full chemical alternative analysis, from which certain sections of rule language are modeled. This aspect of comparative analysis is important to understanding an alternative's viability when compared to the currently used PFAS. No change to the rule.

Article

6. Comment: Commenter suggests adding the following definition "Article" is a solid-state product and the chemicals in the articles are designed to be kept in the products in many cases. Especially for the longer life products such as electrical and electronic equipment, the performance and safety must be kept during their expected useful life, therefore the users are seldom exposed to chemicals in products in use phase. (Commenter 33)

Response: The Department notes that the word "article" is used in the context of textiles and upholstered furniture, as they are defined in statute using this term. The Department finds the statutory definitions are sufficiently clear and that the rule does not warrant the addition of this term. No change to the rule.

Chemically Formulated

7. Comment: Commenter seeks clarification on whether the Department is defining "chemically formulated" solely for its use in "Air care product" and "Automotive maintenance product" or for other purposes. Commenter states that this term is not used in the rule, making it unclear why it is in draft. (Commenter 36, 41)

Response: The Department's intention is to clarify undefined language used in statute, in this case that of "chemically formulated." Though this term is used only to describe two product categories within the rule, the Department may rely on this definition to interpret any relevant provision of the regulation. No change to the rule.

8. Comment: Commenter states the proposed definition does not account for uses when the natural substance is unchanged by the intentional addition of PFAS. Commenter requests clarity for the term "naturally occurring biological process" due to its vague application here. Commenter suggests the following amendment: "…a process that chemically changes the properties of a substance extracted from naturally occurring plant, animal, or mineral sources except that such a term does not apply to substances created by living organisms through metabolic processes." Commenter believes the definition should include instances when the process does not chemically change a natural substance. (Commenter 19, 44, 46, 48)

Response: The term "chemically formulated" is used in statute to describe just two categories of regulated products, "air care product" and "automotive maintenance product". It is the Department's understanding that this term is intended to describe how PFAS may be added to a product to specifically change the original substance properties to create a certain characteristic for the final product in those two product categories alone. The Department finds the commenter's concern for metabolic process within the definition is

sufficiently covered by the already existing language of "created by naturally occurring biological process." No change to the rule.

Cleaning Product

9. Comment: Commenter suggests it may clarify the scope of this definition to note that industrial cleaning products are not within the scope of the regulation. Commenter notes the definition of "general cleaning product" was removed from the current draft and recommends this be included. (Commenter 30)

Response: The Department's proposed rule relies on the definition of the term "cleaning product" as defined in statute, which lists specific places where regulated cleaning products may be used. The Department acknowledges the statutory definition does not include industrial cleaning products and, therefore, interprets the rule as not being applicable to industrial cleaning products. The inclusion of an additional definition for "general cleaning products" is not necessary because the currently defined term already includes this category in statute. No change to the rule.

Clothing Item

10. Comment: Commenter seeks clarification on whether the Department is defining "clothing item" solely for its use in "outdoor apparel for severe wet conditions" or for other purposes. Commenter states that this definition is narrower than, and inconsistent with, Maine law, which does not separately define "clothing." Commenter requests that this definition be revised to be consistent with the law, which covers any item of clothing except for some outdoor apparel. (Commenter 36, 41, 46)

Response: The Department agrees with commenters that this definition does not add clarity and has, therefore, removed the definition of "clothing item."

Commercially Available Analytical Method

11. Comment: Commenter requests flexibly to modify commercially available analytical methods. Commenter requests flexibility for manufacturers to use modified or proprietary in-house methods when no commercially available methods exist. Commenter notes that there are not methods available for articles and chemically formulated products. Commenter requests the Department, to the extent possible, identify appropriate methods that would comply with the regulation's requirements. (Commenter 6, 41)

    Response: The statute does not allow for methods which are not commercially available. The Department interprets "commercially available" to mean that either the method itself is available for purchase or made generally publicly available, or a laboratory may be hired to perform the analysis thus fulfilling the commercial transaction for use of the method. Any modified method that does not meet this criterion would not be considered commercially available. The Department understands that currently there are limited methods available for determining PFAS concentrations in products; however, modification of an existing method creates a new method. Unless the new method is made commercially available it fails to meet the criteria for a commercially available analytical method. No change to the rule.

12. Comment: Commenter suggests removing the distinction between a third-party laboratory and an in-house laboratory with respect to modification of methods. Specifically, the commenter suggests the following language, "Commercially available analytical method means any test methodology used by a laboratory that performs analyses or tests ~~for third parties~~ to determine the concentration of PFAS in a product and can be used by a third-party laboratory or other laboratory. Commercially available analytical methods ~~do not need to be performed at a third-party laboratory; however, the method~~ must remain unmodified when used to determine the concentration of PFAS in a product. ~~not performed by a third-party laboratory~~." (Commenter 6)

    Response: Please see response to comment #11.

13. Comment: Commenter urges the Department to clarify what qualifies as an acceptable analytical method, given that many labs use Total Organic Fluorine (TOF) tests rather than identifying specific PFAS. Commenter cautions against the use of TOF as an indicator of intentionally added PFAS. (Commenter 6, 12)

Response: The Department interprets the text of the statute and legislative history as requiring analysis for PFAS and allowing for TOF analysis to substitute when specific methodologies for either the PFAS analyte or product substrate is unavailable.
The Department acknowledges that TOF analysis may yield results that are higher than those obtained from methodologies specifically targeting PFAS. The Department interprets the statutory language to mean the use of TOF analysis is permissible only when the PFAS concentration is not available. In this respect, it remains more accurate than the next option, which is the total weight of the product. No change to the rule.

14. Comment: Commenter suggests refining the definition of "Commercially available analytical method" to better reflect current testing capabilities and PFAS properties. Given the proprietary nature of many PFAS compounds, standardized analytical methods are lacking, and setting clear standards would help laboratories develop reliable testing. Commenter proposes amending the definition to: "Any test methodology that provides quality control parameters, required frequency, and performance criteria that must be met to satisfy method objectives and assure data quality that is used by a laboratory that performs analysis 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 <u>as long as the method is under the laboratory's scope of accreditation.</u> <u>The laboratory performing the testing should have ISO/IEC 17025 Testing and Calibration Laboratories certification or be accredited through the National Environmental Laboratories Accreditation Conference (NELAC) whose standards are based on ISO requirements.</u>" (Commenter 37)

Response: In response to comments received, the Department has clarified the laboratory accreditation requirements of 22 M.R.S. § 567 apply to data submitted to the Department. See Department rule Chapter 263, Maine Comprehensive and Limited Environmental Laboratory Accreditation Rule, for additional information.

15. Comment: Commenter states that the definition lacks validation criteria. Commenter suggests the Department should establish baseline criteria or performance standards for test methodologies and laboratories. Commenter proposes revising the definition to require independent validation, quality control parameters, and performance criteria. Additionally, commenter suggests that any laboratory conducting PFAS testing should be certified under ISO/IEC 17025 or OECD Good Laboratory Practice. (Commenter 41)

    Commenter recommends that acceptable analytical methods be based on established EPA methods or other rigorous regulatory standards. Third-party labs conducting testing should be certified or follow Good Manufacturing Practice (GMP) or Good Laboratory Practice (GLP) standards. (Commenter 49)

    Commenter is concerned that this definition as drafted may lead to incorrect testing methods for particular PFAS compounds or inconsistent results. . Because this is a rapidly developing area, commercially available analytical methods, unmodified or modified, may not be suitable for testing certain PFAS chemicals. Commenter strongly encourages the inclusion of science-based criteria for appropriate regulatory testing methods and approaches which must distinguish between screening approaches and rigorous analytical techniques. (Commenter 30)

    Commenter states that because current commercially available methods are inadequate the proposed definition for the detection of specific PFAS in complex matrices will be difficult for manufacturers. Some of the reasons for this include the broad definition of PFAS in Maine which could represent hundreds of target chemicals within a highly complex chemical class of compounds with diverse functional groups. Testing methods for cosmetic products, though some exist, will need to be validated and verified, which will require modification, and most are not commercially available. (Commenter 42)

    Commenter requests the Department clarify that commercially available analytical methods must be a method that has been validated using a standard procedure (e.g. ASTM, ISO, NIST) and that the laboratory performing the analysis must be able to demonstrate that it

meets good laboratory practices regulations or holds a quality certification such as ISO-IEC 17025 or other certification acceptable to the Department. (Commenter 56)

Response: The Department finds that it does not have the authority to restrict appropriate methodologies further than the commercially available criteria found in statute. The Department agrees that requiring laboratories to perform to a certain standard will ensure that the methods are accurately replicated. The sole statutory criterion is that a method must be commercially available. The Department is interpreting this to mean a laboratory is offering to perform the methodology for compensation, offering the method itself for sale, or the method is otherwise publicly available.

16. Comment: The commenter highlights concern about laboratory capacity. Commenter urges the Department to accommodate manufacturers using documented in-house methods or face delays due to third-party lab constraints. Commenter recommends the Department allow for both in-house and external testing. (Commenter 29, 41)

Response: The statute does not allow for the use of any method that is not commercially available. A manufacturer may utilize an in-house laboratory provided that the method applied to the analysis is commercially available. No change to the rule.

17. Comment: Commenter states methods detecting only fluorine should not be used, as they can be misinterpreted as indicating the presence of PFAS. (Commenter 49)

Response: The Department interprets the statute, along with its accompanying legislative history, as allowing for total organic fluorine when methods are not available for the specific PFAS or product. This is an allowed method for determining the potential concentration of PFAS in a product, it is not intended as a PFAS screening. No change to the rule.

18. Comment: Commenter believes that regulated manufacturers should be required to use a third-party laboratory to analyze for PFAS to avoid conflicts of interest and ensure accuracy. . Commenter states that lab analysis submitted to the Department should include both the methods used and the results in full. Commenter states the draft definition is vague regarding

the alteration of third-party lab protocols and needs clarity and specification. (Commenter 19, 35, 36, 44, 46, 48)

Response: The statute speaks to the nature of the analytical methodology's availability not the laboratory location. Therefore, there is no statutory basis for limiting the nature of the laboratory performing the analysis. No change to the rule.

19. Comment: Commenter states the lack of adequate commercially available test methods makes the Department approved PFAS concentration ranges more important. Commenter requests clarity on how the Department will establish such approved ranges. (Commenter 42)

Response: The Department understands the usefulness of publishing concentration ranges prior to the notification requirement becoming effective. Statute allows for reporting in a range when the report is based on information received from a supplier. Given the broad range of products and compounds covered by this rule, the Department has determined that using the already defined range within "Significant change" of 10% increments by weight is reasonable. These reporting ranges will be established in the reporting database and listed in the program frequently asked questions. The Department is aware that few commercially available analytical methods are currently available. In the absence of such a method, the statute allows reporting based on calculation or total organic fluorine (TOF) analysis. For clarity and consistency, estimated concentrations for the product should be reported as a percentage by weight. No change to the rule.

Complex Product

20. Comment: Commenter encourages the inclusion of a definition for "complex product" or clarifying language to differentiate between a product, product component, or complex product. Commenter states that the Department should distinguish complex consumer goods from complex durable goods instead of using the term "Complex Product" in terms of the number of components, product lifespan, and the intended recipient of the product (i.e., consumers versus non-consumers). "Complex durable good" should be defined in the rule as "a consumer product that is a manufactured good composed of 100 or more manufactured

components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use. This includes replacement parts for complex durable goods not subject to a phase out under this chapter." (Commenter 13, 30)

Commenter requests clarification about whether product components incorporated into complex products are exempt from the reporting requirement and whether this applies to components sold as replacement parts for finished goods. Commenter encourages the Department to avoid duplicative reporting and not require separate notification for replacement parts. (Commenter 15)

Response: Because the term "complex" is not used in the statute and had few uses within the proposed rule, the term "complex" has been removed.

Consumer Product

21. Comment: Commenter supports the proposed definition of "consumer products" in the rule. (Commenter 41)

Response: The Department acknowledges the commenter's support. No change to the rule.

Cookware Product

22. Comment: Commenter states there is no exemption for industrial or commercial cookware and excluding such from the definition goes against legislative intent. Commenter states that because the statutory definition does not explicitly exempt industrial or commercial cookware, commenter states that the draft rule must remove this wording. Commenter claims electric cookware poses little risk to humans and the environment compared to non-electric cookware. Commenter states "Cookware product" as defined at 38 M.R.S. § 1614(1)(A-10) is limited to houseware intended to be in direct contact with food or beverage, and that "Houseware" does not include electric cookware products, such as microwave ovens, are classified as electronic equipment. (Commenter 4, 19, 33)

Response: Statute defines cookware as "a durable houseware product." The Department understands the common meaning of houseware to mean equipment, tools, and machinery used in a residential house. Therefore, any cookware that is not intended to be used in the residential house setting cannot meet the statutory definition. No change to the rule.

23. Comment: Commenter understands that the definition of "cookware product" includes small articles and utensils but excludes large appliances, refrigerators and ranges, and small appliances, coffee makers and toasters. Commenter is concerned that major appliances may be captured which would be contrary to the law's intent. From this commenter's perspective, "cookware" refers to products designed to be used primarily on a stovetop or inside an oven, not the cooking appliance itself. Commenter requests that this definition include a clear list of products to clarify its scope. Commenter requests a narrowing of the product scope due to the uncertainty of which products may be subject by how the Department will define durable houseware items. (Commenter 8, 41)

Response: Statute defines "cookware product" as "…product intended to be used to prepare, dispense or store food, foodstuffs or beverages." Icemakers incorporated into refrigerators would satisfy the meaning of this definition of cookware, as would a toaster and a coffee pot are also meant to prepare food or beverage. The Department's inclusion of food and beverage contact within the definition provides clarity on the scope of applicability. To avoid unnecessarily duplicating statutory language verbatim, the Department chose to offer only new language related to program implementation in the proposed rule. Commenter's request for a clear list of products may be fulfilled by way of review of the statutory definition at 38 M.R.S. § 1614 (1)(A-10), which lists specific cookware products the Legislature envisioned being captured in law. No change to the rule.

24. Comment: Commenter suggests amending the definition to include, "…nor does it include any polymer-coated durable items which the United States Food and Drug Administration authorizes for food contact" (Commenter 17)

Response: Exemptions are established in statute and duplicated in Section 4 of the rule for

convenience. The Department does not have the authority to add or amend this list of exemptions. No change to the rule.

Exclude Internal Components

25. Comment: Commenter is concerned that the proposed definition is unjustifiably expansive to include any product that touches food, including internal components. Commenter is concerned that potential compliance problems will be aggravated by the short January 2026 timeline. Because additional time is needed to identify substitutes and implement their use, commenter asserts that failing to make necessary correction to this definition could lead to the unavailability of essential household products for Maine consumers. Commenter argues that internal components of these complex household appliances do not contact food or otherwise present risks to consumers. Pointing out that time necessary for the design to production of appliances can take several years, commenter shares concern for the fast-approaching January 2026 effective date and potential for regrettable substitutions. Commenter requests that this definition clearly exempt all internal components, specifically any surfaces that do not come into contact with food during cooking, for cookware products from the 2026 prohibition. (Commenter 8)

Response: Where appropriate, the Department did not duplicate statutory language, choosing instead to focus effort on providing stakeholders with implementation insight. Commenter's requests for clarity and limiting of scope to only surfaces that come into direct contact with food and beverages <u>during cooking</u> (emphasis added) may be best addressed by a plain read of existing statutory language at 38 M.R.S. §1614(1)(A-10), which states that products captured by this cookware definition include, "…durable houseware product intended to be used to prepare, dispense or store food, foodstuffs or beverages…". The Department would be inappropriately limiting the law's applicability if this definition were amended to limit the scope to only products used during the process of cooking, as suggested. No change to the rule.

Exempt Spare/Replacement Parts

26. Comment: Commenter requests special consideration for replacement or spare parts so that fixable cookware may live out its expected lifespan and to avoid unnecessary negative impact on the waste stream should large quantities of spare parts require disposal because of capture by a sales prohibition. Commenter requests an exemption for spare parts. (Commenter 8, 15)

Response: The Department has provided a definition reflective of the legislative intent of providing protection to consumers of unnecessary exposure to these chemicals so that consumable food or beverages do not come into direct contact with cookware surfaces containing intentionally added PFAS. The Department does not foresee a market interruption in the use of spare parts due to the definition as written. No change to the rule.

Cosolvent

27. Comment: Commenter notes that the term "cosolvent" does not appear elsewhere in the proposed rule or the statute. If the Department is defining this term for any purpose related to the statute's implementation, clarification is requested. Commenter states that the purpose of this definition is unclear and appears to be surplusage. If there is a reason for it, then it should be revised to delete, "in small amounts". (Commenter 36, 41, 48)

Response: The term "cosolvent" is found in the term "aerosol propellant" referenced in statute. No change to the rule.

Distribute for Sale

28. Comment: Commenter disagrees with the proposed definition of "distribute for sale". Commenter believes it could be interpreted to include the United States Postal Service and other transportation companies that merely transport products. (Commenter 41)

Response: When utilizing the United State Postal Service, or other common carrier, no agency relationship is formed. Therefore, responsibility for shipping a product or causing it

to be transported remains with the sender initiating the transaction. A common carrier would be subject to the rule when a sales transaction takes place, for instance when selling materials and packaging supplies. No change to the rule.

Electronics

29. Comment: Commenter understands that the Department is defining the term "electronics" because it appears without definition in the statute. If the Department is defining this term for any other purpose, clarification is requested. (Commenter 41)

    Response: The Department's intention is to clarify undefined language in statute, in this case "electronics." The Department may rely on this definition to interpret any relevant provision of the rule. No change to the rule.

30. Comment: Commenter suggests expanding the language for "electronics" to mean "technology having electrical, digital, magnetic, wireless, optical, electromagnetic, electrochemical, or similar capabilities." Commenter seeks clarification if the definition includes passive electronic components, like capacitors (their primary product line)? If not, does the definition of "semiconductor" cover these components? (Commenter 13, 21, 34)

    Response: The Department does not consider the inclusion of "electrochemical" as adding clarity to this definition. Where a capacitor is a component of an electronic product the Department will adhere to the rule's description of a semiconductor or electronic product as defined in the rule. No change to the rule.

31. Comment: Commenter suggests amending the language in Section 2: "Electronics" means technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities, including electrical equipment such as, but not limited to, power grid equipment, motors and generators, arc welding, batteries, electrical conduits, fuses, enclosures, connectors, wiring devices, low voltage distribution equipment, power electronics, residential and commercial controls, wires and cables, industrial automation controls, commercial and industrial lighting equipment, residential light fixtures (luminaires), electric vehicle and

transportation management equipment. (Commenter 38)

Comment: Commenter suggests listing examples in the definition of "electronics" for clarification (similar to the juvenile products definition), to include the following:

- Outdoor, commercial, and industrial lighting;
- Residential light fixtures (luminaires);
- Electric hydrogen technology;
- Lithium and other batteries;
- Personal and commercial communication devices;
- Smart home systems;
- Global positioning and navigation systems;
- Solar panels;
- Electrical equipment such as but not limited to power grid equipment, motors and generators, arc welding equipment, electrical conduits, fuses, enclosures, connectors, wiring devices, low voltage distribution equipment, power electronics, residential and commercial controls, wires and cables, industrial automation controls, electric vehicle, and transportation management equipment; and
- Food manufacturing equipment. (Commenter 13)

Response: The Department does not have sufficient justification to make such determinations in rule, nor is it necessary. The draft definition allows such determinations without rulemaking. No change to the rule.

Environmental Control Technology

32. Comment: Commenter ask that the Department add "including technologies to help control the environment" to the definition of "Environmental Control Technology".
Commenter understands that the Department is defining the term "environmental control technology" because it appears without definition in the statute in the definition of "textile article." If the Department is defining this term for any other purpose, clarification is requested. (Commenter 37, 41)

Response: The Department understands the environmental control technology to broadly mean those technologies meant to control or mitigate human impacts on the environment, such as emissions control devices like bag houses. The Department does not find support that the definition should be extended to devices that modify or control the environment. No change to the rule.

Essential for Health, Safety and the Functioning of Society

33. Comment: Commenter requests the Department add "Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, delivery of medicine, lifesaving equipment, public transport, and construction" to the definition. The commenter bases this on Department language from a previous rulemaking. (Commenter 6)

    Response: In consideration of the legislative history that has occurred since the document referenced by the commenter, the Department finds the suggestion to change to the definition unsupported. First, the Legislature has reviewed these and other product categories suggested for inclusion, which resulted in a series of tailored exceptions. Second, the proposed language was included in a prior Department rulemaking, which served as the basis for the new statutory definition. The Legislature declined to include the suggested language in statute. No change to the rule.

34. Comment: Commenter believes the statutory definition, which includes the phrase "the unavailability of PFAS for use in the product would cause the product to be unavailable," could be interpreted in a way that deprives Maine residents of essential products if similar PFAS-free alternatives exist, even if those alternatives fail to provide adequate health or safety protection. The commenter urges the Department to find that PFAS use in a product will be considered essential if its unavailability would result in adverse health or safety outcomes or significant disruptions to the daily functions on which society relies. (Commenter 41)

    Response: The statutory definition of alternative requires that a resulting product would be

functionally equivalent. The Department is proposing a definition of functionally equivalent that would require the alternative to perform in the same manner and to the same standard as the PFAS containing product. Taken together, a product that fails to provide adequate health or safety protection would not meet the criteria of being functionally equivalent. No change to the rule.

35. Comment: Commenter understands that the phrase “function provided by the PFAS” in the statutory definition to include a temporal dimension, meaning that the duration and reliability of a product or product component throughout its service. Commenter recommends more precise criteria for defining "essential for health, safety, or the functioning of society" to improve consistency and usability in the currently unavoidable use process. (Commenter 41, 57)

    Response: Statutory definition was created with significant stakeholder input. The Department finds that it offers sufficient guidance to make currently unavoidable use determinations, while allowing the flexibility necessary to be applied to thousands of chemicals and products. No change to the rule.

Finished Product

36. Comment: Commenter understands that the Department is defining this term because it appears without definition in the statute in the definition of “cleaning product.” If the Department is defining “finished product” for any other purpose, commenter requests clarification. (Commenter 41)

    Response: The Department’s intention is to clarify the undefined language in statute of “cleaning product.” The Department may rely on this definition to interpret any relevant provision of the rule. No change to the rule.

Fully Fluorinated Carbon Atom

37. Comment: Commenter understands that the Department is defining this term because it appears without definition in the statute in the definition of "perfluoroalkyl and polyfluoroalkyl substances" or "PFAS." If the Department is defining "fully fluorinated carbon atom" for any other purpose, commenter requests clarification. (Commenter 41)

    Response: The Department's intention is to clarify undefined language in statute of "perfluoroalkyl and polyfluoroalkyl substances." The Department may rely on this definition to interpret any relevant provision of the rule. No change to the rule.

38. Comment: Commenter understands that the Department is indicating that (a) any substance with at least one perfluorinated methyl group (-CF3) or a perfluorinated methylene group (-CF2-) is a PFAS, and (b) a substance with a -CFR'R'', where R' and R'' are neither fluorine nor hydrogen, is not a PFAS. Commenter requests that the Department elaborate in more detail on the implications of the definition of "fully fluorinated carbon atom" for the identification of substances that would be considered PFAS under the statute. (Commenter 41)

    Response: For the purposes of the statute, any carbon atom which is bonded to at least one fluorine and all bonds to that carbon atom are to either fluorine or carbon atoms, will be considered fully fluorinated. No change to the rule.

Functionally Equivalent

39. Comment: The commenter requests that the Department clarify the definition of "functionally equivalent product" to include service life and reliability under foreseeable use conditions. Commenter supports the proposed definition of "functionally equivalent" in the proposed regulation and recommends that the Department include a note clarifying that the concept of "functionally equivalent product" includes the duration of a product's or product component's service life. (Commenter 41)

Response: If the standard that the existing product is meeting includes a lifespan or duration component, such a function will be included in the Department's Currently Unavoidable Use assessment. No change to the rule.

Fluorinated Container

40. Comment: Commenter states the statute makes no distinction or exceptions for the purpose of fluorination in containers. The proposed definition is a restriction of the scope of the term and, because of this, is contrary to statute. Containers which are fluorinated should be included in the application of this rule regardless of whether the fluorination purpose is to create a barrier, prevent odor, prevent distortion, or for any other purpose. The draft rule proposes to narrow this definition, which is not within the agency's authority. (Commenter 19)

    Commenter is concerned that the proposed definition limits the prohibition's scope, and there may be other reasons to treat a container with fluorine. Because the law does not include this limiting phrase, it should be deleted from the proposed definition. Fluorinated containers should be covered regardless of purpose for the fluorine treatment. (Commenter 36, 46)

    Response: The Department's understanding of the fluorination process for containers is that it is intended to protect the product within it by creating a barrier or coating. In response to the commenter's request for clarity, the definition has been revised to include "coating."

Intentionally Added PFAS

41. Comment: Commenter agrees with the interpretation of "intentionally added PFAS" provided in the note accompanying the definition. (Commenter 41)

    Response: The Department acknowledges the commenter's support.

42. Comment: Commenter expresses concern for unintentional cross-contamination of PFAS from facilities producing components for other industry sectors which allow for its use. Commenter urges the Department to exempt articles that contain de minimis quantities of

PBT or non-PBT PFAS of 0.1% by weight or less. Commenter states that not having a de minimis exemption puts unreasonable burden on manufacturers. (Commenter 8)

Response: Contaminants and cross contaminants are not intentionally added, as is required by statute for regulatory applicability. No change to the rule.

Intrinsic to the Design or Construction of a Building

43. Comment: Commenter suggests the definition, in part, should be amended to read "… structural elements and <u>other</u> elements meant to block light, wind, or precipitation", in order to remove emphasis on structural elements. Commenter also notes that it is likely the determination between instinct to the design of a building and decorative elements will be made on a case-by-case basis. (Commenter 6)

Response: The Department agrees that the inclusion of the word "other" clarifies the definition and has made this change to the definition in rule. The Department acknowledges that this determination may need to be made on a case-by-case basis and will rely on this definition in conjunction with the definition and use of architectural fabric in the statute to make those determinations.

44. Comment: Commenter understands that the Department is defining this term because it appears without definition in the statute in the definition of "architectural fabric structure." If the Department is defining "intrinsic to the design or construction of a building" for any other purpose, commenter requests clarification. (Commenter 41)

Response: The Department's intention is to clarify undefined language in statute of "architectural fabric." The Department may rely on this definition to interpret any relevant provision of the rule. See response to comment #43.

Laboratory Equipment

45. Comment: Commenter understands that the Department is defining this term because it appears without definition in the statute. If the Department is defining "laboratory equipment" for any other purpose, commenter requests clarification. (Commenter 41)

Response: The Department's intention is to clarify undefined language in statute of "laboratory equipment." The Department may rely on this definition to interpret any relevant provision of the rule. No change to the rule.

46. Comment: Commenter is concerned that the definition focuses on "analysis" when laboratory equipment may be used for additional purposes. Commenter recommends that the Department modify the definition in the proposed rule as shown here: "Laboratory equipment" means any analytical or monitoring instrument or other support equipment that is required to conduct research or generate the results of an analysis. Laboratory equipment includes, but is not limited to, any tool, apparatus, gear, or appliance that is intended to be used in the creation, separation, sampling, or monitoring of a substance, a mixture of substances, a process, or electromagnetic phenomena, such as incubators, fume hoods, laboratory water equipment, reaction vessels, gas generators, sensors, preparatory or purifying equipment, or single-use laboratory equipment. (Commenter 41)

*Response: The Department agrees that the addition of "…*separation, sampling, or monitoring*…" and "…*electromagnetic phenomena*…" adds clarity to the definition and has amended the rule.*

Manufacturer

47. Comment: Commenter requests that the Department clarify which entity is responsible for reporting when both a manufacturer and a brand owner meet the definition of "manufacturer." Commenter states the Department should explicitly specify the responsible party and provide real-life examples in guidance developed with input from the manufacturing community. Commenter states that when two companies fit this description of

a manufacturer: one makes the product and the other brands it, who is responsible for reporting? (Commenter 29, 49)

Response: The Department anticipates clarifying this in the upcoming frequently asked questions section of the program webpage. No change to the rule.

Offer for Sale

48. Comment: Commenter requests clarification on "Offered for sale." Does the Department expect online retailers to block sales to Maine? (Commenter 41)

Response: Online retailers must comply with Maine laws and rules. It is not necessary to block IP addresses with geolocation in Maine for an entire retail site; however, a transaction containing products that are subject to the rule with intentionally added PFAS must not be able to be completed once the consumer has indicated a shipping address in Maine. No change to the rule.

49. Comment: Commenter asks the Department should confirm that a sale is only considered "in Maine" if the product is physically delivered there. (Commenter 41)

Response: The Department understands that a sale, in the context of a person "may not sell" in Maine, does not occur unless the transaction physically occurs in Maine, or the sale includes delivery into Maine. No change to the rule.

PFAS

50. Comment: Commenter states the definition encompasses a broad group of chemicals that do not all share the key properties of persistent, bioaccumulative, and toxic (PBT), which should be the focus of PFAS regulation. Certain polymers that meet Maine's definition of PFAS (such as fluoropolymers) are unlikely to be released into the environment or cause harm to human health. Because Maine's definition of PFAS is so broad, even industries with strong knowledge of the chemical make-up of components will have difficulty ensuring an accurate dataset of chemicals within their supply chains. Commenter states this rule should focus on

the non-polymer PBT PFAS to ensure protective efficacy for human health and the environment, without putting unnecessary and ineffective burden on industries whose products may contain low-exposure PFAS which are not persistent, bioaccumulative, or toxic. (Commenter 32)

Response: The definition of PFAS is statutory and the Department does not have the authority to modify it in a manner to implement the suggested approach. No change to the rule.

51. Comment: Commenter urges the Department to limit the rule to a defined list of PFAS with CAS Numbers to ensure effective tracking through complex supply chains. (Commenter 43)

    Response: By its language, the statute applies to listed products which contain intentionally added PFAS, with PFAS being defined "as substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." The Department does not have the authority to further limit the scope of this rule as suggested. No change to the rule.

52. Comment: Commenter states that this definition is based solely on chemical structure and thus disregards the remarkably different physical, chemical, and biological properties that shape the potential human and ecological risk profiles of chemistries that meet that definition. Commenter argues this fails to implement a risk-based approach to defining PFAS and will result in arbitrary application of the statute. (Commenter 18)

    Response: The definition of PFAS is statutory in nature and the Department does not have the authority to modify it in a manner to implement a risk-based approach. No change to the rule.

53. Comment: Commenter states the Department should develop a focused definition of "contaminant" to distinguish unintended PFAS presence in final products. (Commenter 37)

    Response: The term contaminant appears once in an explanatory note. Any PFAS which does not meet the statutory definition of intentionally added PFAS is not covered by the proposed

rule. No change to the rule.

54. Comment: Commenter states the rule fails to differentiate between various PFAS chemistries, particularly fluoropolymers, which they claim pose minimal risks to human health and the environment. Commenter states that fluoropolymers, particularly polytetrafluoroethylene (PTFE), are used pervasively in almost every major manufacturing sector due to their inert and thermally stable properties. Commenter adds that PTFE is used in certain appliances and may be included in material that contacts food, often as a coating for the purpose of water, scratch and heat resistance, as well as long-life durability. Commenter states that unlike non-polymeric PFAS, fluoropolymers have not been demonstrated to have negative health concerns. Commenter cites a February 2024 statement by the Environmental Working Group, which proclaimed that cookware is not a major source of exposure to PFAS. As a result, commenter believes that fluoropolymers require special consideration relative to any prohibition. (Commenter 8, 50)

    Response: PFAS is defined in statute and the Department does not have the authority to modify it in such a way as to different between chemistries. No change to the rule.

55. Comment: Commenter states the broad definition of PFAS includes many chemicals that do not share the properties of persistent, bioaccumulative, and toxic (PBT), which should be the chemical properties Maine's chemical regulation prioritizes. An example of applying this PBT focus, commenter points to EPA's Significant New Alternative Policy (SNAP) criteria for evaluating alternatives for acceptable use conditions using assessments of the potential exposure risks, toxicity and environmental impact of the chemical. In this specific case, commenter states that the EPA SNAP approval process has determined that the chemical makeup of low global warming refrigerants (A2Ls) present minimal risk to humans and the environment, in addition to their use in a sealed application providing a useful life of 15 years. Commenter is also concerned that fluoropolymers such as polytetrafluoroethylene (PTFE) that meet the statutory definition of PFAS are unlikely to have the potential for human or environmental release or exposure during the use of the product, therefore presenting minimal risk associated with the actual product. (Commenter 2)

Response: Given the continuing discovery of impacts from PFAS on Maine people and property, the Maine Legislature has generated a definition of PFAS that ensures a categorical regulation that avoids regrettable substitutions within the same chemical classification. The Department does not have the authority to restrict the statutory definition. No change to the rule.

56. Comment: Commenter states the scope of this definition for PFAS is by far too broad and inappropriate. The establishment of a comprehensive information obligation for "intentionally added" PFAS for at least five years prior to a comprehensive PFAS restriction represents the only reasonable approach. (Commenter 52)

Response: PFAS is defined in statute and the Department does not have the authority to modify it in such a way as to different between chemistries. No change to the rule.

Product

57. Comment: Commenter argues that product packaging should be exempt from the proposed rule until the 2032 prohibitions take effect, as current requirements create significant compliance challenges. Commenter notes that industries are still assessing PFAS use in products, and extending the same requirements to packaging adds an undue burden on regulated entities. (Commenter 12)

Response: Section 4(B) of the statute exempts packaging when applied to a product. Packaging is only subject to the statute and proposed rule when it itself is the product being sold, offered for sale, or distributed for sale. No change to the rule.

Product Component

58. Comment: Commenter requests clarification of the exclusion of components embedded within complex products. Commenter states the statutory definition of “products,” Section 3 and Section 6(A) of the draft rule provide conflicting directions regarding notification

requirements for embedded components. Commenter requests the Department resolve the inconsistencies. Related, commenter notes that the draft rule does not define "complex product". To remove this ambiguity, commenter requests the Department consider adding this definition to align with Directive 98/71/EC of the European Parliament and of the Council (Directive – 98/71). (Commenter 8)

Response: See response to comment #20.

59. Comment: Commenter requests removal of the "note" underlying the definition of "product" because food packaging is specifically exempt under the statute. Commenter states that language in the "note" is not in the underlying statute. Commenter states food packaging is not intended to be within the scope of the law and the rule should ensure that the implementing rule does not vary from the definition in statute, without any additional language added. Such food packaging as is described in the "note" makes the application of this definition unclear and could be read to mean that the law's exemption only applies to the food packaging once it contains food, and that the sale of empty packaging materials would not be exempt. Such food packaging is under the purview of the food packaging law (32 M.R.S. 1731-1738) and exempt from this one. Commenter requests that the Department adopt the statutory definition of "product" and delete the draft "note." (Commenter 11)

Response: The Department's note is consistent with the language in statute; food packaging is exempt except when the package is the product of the manufacturer. No change to the rule.

60. Comment: Commenter states that "Product" is defined at 38 M.R.S. §1614(1)(G) – not paragraph (H) (Commenter 36)

Response: The Department has corrected the typographical error in the rule.

Reasonably Available

61. Comment: Commenter states that cost should not be the focus of this definition and should not be included. Commenter recommends that the definition consider the cost impact on

small businesses and end users, including potential energy cost differentials from less efficient equipment. Commenter states that a cost threshold is not appropriate in this context because sources of cost differentials can vary dramatically. (Commenter 4, 40, 49)

Commenter states this assessment should consider adequate supply of alternatives and potentially cost to the public. Commenter claims costs to manufacturers are variable and subject to market pressures, including the Department's actions. Commenter states that an alternative that is currently more expensive than the PFAS it is intended to replace may change in price as demand increases. Commenter claims this variability is why cost considerations should not be determinative and any consideration of cost should focus on impact on the public rather than the manufacturer. Commenter states the Department should adopt definitions that make clear that alternatives can include materials, processes, designs, products, or chemicals that achieve the desired result. Commenter claims minor costs should not influence analysis, even when considering costs to the public and any cost should be considered alongside societal costs of PFAS exposure and clean up. Commenter recommends amending the rule as follows: "Reasonably available" means an ~~PFAS~~ alternative to the use of PFAS or to the product containing PFAS which is readily available in sufficient quantity or can become readily available in sufficient quantify in the relevant timeframe. ~~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.~~ (Commenter 40)

Commenter suggest considering the cost of PFAS alternatives compared to existing PFAS on a per-volume basis, costs of the manufacturing process and any necessary equipment changes. Commenter states that when evaluating costs, the Department should consider the increased expenses in the manufacturing process and the impact on small businesses and end-users. (Commenter 29)

Response: Cost alone is not a determining factor within the Currently Unavoidable Use structure. However, differences in cost have the potential to result in prohibitively expensive products. Such costs could make products effectively unavailable to the average consumer. Further, the definition "reasonably available" is used in conjunction with the proposed

definition of "functionally equivalent" and the statutory definition of alternative. Taken together, they require a reasonably available alternative to perform to the same standard as the PFAS containing product. No change to the rule.

62. Comment: Commenter states that "intended to replace and perform as well as or better than PFAS in a specific application of PFAS in a product or product component" is irrelevant to this definition and should be removed. (Commenter 4)

Response: The definition of "reasonably available" is intended to be read in conjunction with similar definitions which will be used to determine Currently Unavoidable Use and not as a stand-alone term. No change to the rule.

63. Comment: Commenter supports the proposed definition of "reasonably available" in the proposed regulation. (Commenter 41)

Response: The Department acknowledges the commenter's support.

64. Comment: Commenter states DEP should establish a transparent framework for determining reasonable availability, using criteria similar to those in subsection (i) of the federal American Innovation and Manufacturing (AIM) Act of 2020 (42 USC 7675). Commenter recommends more detailed guidance for determining when alternatives are "reasonably available." Commenter argues that strengthening these provisions will improve precision and help manufacturers navigate compliance effectively. (Commenter 49, 57)

Commenter claims statutory definitions for "reasonably available", "alternative" and "essential for health, safety or the functioning of society" do not mention cost or performance standard as a factor in determining if alternatives are available. Commenter states under the definition of "essential for health, safety or the functioning of society" a product must be "unavailable" to trigger the analysis of essentiality. Commenter claims adding "comparable cost" as a consideration for alternative availability would potentially allow manufacturers to avoid reformulating their products or processes even where alternatives do, in fact, exist at a cost that is financially viable for the company. Commenter states both cost and performance

factors should be removed. Commenter states the draft definition creates a significant loophole and fails to create the imperative necessary to change corporate behavior. (Commenter 36, 46, 48)

Commenter states the criterion of an alternative's performance does not relate to its availability. Commenter states it's unclear why this criterion is part of considering whether an alternative is reasonably available. Performing as well or better than PFAS is not necessary for an alternative to work and could unintentionally eliminate the potential of alternative materials, designs or processes. Commenter claims Maine statute includes a broad definition of alternative that is focused on the functional equivalence of the product, not just PFAS, and includes other materials, designs, or processes. Commenter states the statutory definition expressly contemplates the removal of PFAS an alternative itself, even if the alternative (no PFAS) does not perform as well or better than PFAS, as long as the product itself still serves an equivalent function. Commenter states that functionally sufficiency of an alternative is more appropriate, particularly in the context of implementing the essential use concept. Functional substitution is a method of identifying and evaluating alternatives to a substance that focuses on the function of the product and encourages broader consideration of how this function can be achieved. Commenter states that a product without PFAS need not perform as well or better than a product with PFAS to achieve the required function. (Commenter 40)

Response: The Department relies on Maine statute, which defines "alternative" as that which results in a "functionally equivalent product". The Department finds that a product that does not perform to the same standard as the product containing intentionally added PFAS that it replaces is not functionally equivalent and, therefore, cannot be considered a reasonable alternative for the purposes of Currently Unavoidable Use determinations. No change to the rule.

Semiconductor

65. Comment: Commenter states that because this is an exemption to the law, commenter suggests the term should be narrowly defined, clearer and more detailed. Commenter appreciates the Department's efforts to align the semiconductor definition with federal law.

Commenter suggests replacing the final sentence with: "Semiconductor means both a semiconductor material and a type of product that is a discrete assembled functional object containing semiconductor material which is capable of being incorporated into electronic equipment, such as a CPU." (Commenter 4,12, 46)

Response: The Department finds that the rule aligns with other regulatory definitions of semiconductor, including those found in federal programs. This definition is the result of the Department's stakeholder engagement process and reflects the Department's understanding of the legislative intent. No change to the rule.

66. Comment: Commenter appreciates the Department aligning the definition with industry recommendations and 17 U.S.C. § 901(a)(1). Commenter requests that the definition remain unchanged in the final rule. (Commenter 37)

Response: The Department acknowledges commenter's support.

67. Comment: Commenter appreciates the Department's alignment of the semiconductor chip product definition with federal standards but requests additional revisions. Commenter suggests modifying the language to clarify that a semiconductor is both a material and an assembled functional product capable of being incorporated into electronic equipment. (Commenter 49)

Response: The Department finds that defining semiconductor as a finished assembled product capable of being incorporated into electronic equipment, such as a CPU, would likely include one or more of the commonly associated materials which are not covered by the definition. No change to the rule.

68. Comment: Commenter states the proposed definition is broad and should be amended so as not to cause confusion about the application of this exemption. Commenter suggests that only semiconductor devices, "…whose primary purpose is to control the flow of electric current, amplify signals, act as a switch, or perform energy conversions" should be considered

exempt. (Commenter 19)

Commenter suggests the proposed definition should rely on the National Institute of Standards and Technology (NIST) definition, "material that can act either as a conductor or an insulator of electricity, depending on small changes in voltage." Commenter states microelectromechanical systems (MEMS) encompass components like grids and nozzles, which may lack electronic elements but are still manufactured using semiconductor processes. Commenter recommends eliminating the ambiguous term related and creating a modified definition "Semiconductor" "means 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…" (Commenter 36, 45)

Response: The Department finds that the rule aligns with other regulatory definitions of semiconductor, including those found in federal programs. This definition is the result of the Department's stakeholder engagement process and reflects the Department's understanding of the legislative intent. No change to the rule.

69. Comment: Commenter states the purpose of this note is to make clear that a "semiconductor" is not just a material but also a type of product subject to the semiconductor exemption. "Semiconductor" "means <u>both a material and a type of product that is a discrete functional object as described in the definition. Semiconductor products (discrete functional objects) include, but are not limited to, integrated circuits, micro electromechanical systems, solar cells, patterned flat panel display substrates, light emitting diodes, sensors/detectors, and other products</u>." Commenter suggests removing the note after the definition to avoid confusion. (Commenter 12, 31, 49)

Response: The Department has clarified the intent that all members of a product type are not considered semiconductors solely because some members of that type are semiconductors, such as capacitors.

Significant Change

70. Comment: Commenter suggests reporting on an annual basis to incorporate into a regulatory calendar rather than when a significant change occurs. (Commenter 6)

Response: Statute provides for notification to occur under currently unavoidable use determinations which are valid for a period of 5 years. Statute also requires that the notification be updated with there is a significant change. The Department lacks authority to require annual reporting. Further annual reporting would add a burden to members of the regulated community and the Department for products that did not undergo significant change. No change to the rule.

71. Comment: Commenter suggests that the threshold for reporting an increase of 10% in PFAS be clarified to only intentional increases. Commenter suggests there may not be analytical methods that measure such a change. (Commenter 6)

Response: If the increase in PFAS is unintentional, then that quantity of PFAS would not meet the definition of intentionally added PFAS and, therefore, would not be subject to any provision of the proposed rule applying to intentionally added PFAS. No change to the rule.

72. Comment: Commenter specifically suggests the following language "Significant change" means a change in the composition of a product which results in the <u>intentional</u> addition of a specific PFAS; a change in the amount of PFAS of more than a 10% increase, above the method variability allowed by the commercially available analytical method used <u>or excluding any inadvertent variances occurring during the product's usual manufacturing process</u> of the concentration that has been reported when compared to the existing notification; or a change in responsible official or contact information." (Commenter 6)

Response: *The Department agrees with the clarification that inclusion of additional PFAS within a product must be intentional for it to trigger the significant change reporting*

requirement and has amended the rule in this way.

73. Comment: Commenter expresses concern that a 10% deviation is too small given variability in testing methods and the low levels of PFAS likely to be reported. Commenter suggests addressing analytical and reporting variability and recommends defining a "significant change" as at least a 50% increase or decrease. Additionally, commenter suggests that the final rule explicitly include the phrase "intentionally added" and proposes the following revised definition: "Significant change" means a change in the composition of a product which results in the addition of a specific intentionally added PFAS; a change in the amount of intentionally added PFAS of more than 50% increase or decrease, above the method variability, etc." (Commenter 41)

Response: The threshold for significant change is not an absolute increase of 10%; rather, it is an increase of 10% above the allowed method variability. As an example, if a commercially available analytical method were to allow a 25% difference between duplicates, then a significant change would occur when the method reports a 35% (25% + 10%) increase in PFAS. No change to the rule.

74. Comment: Commenter urges amending this definition to reflect a significant change of the quantity of PFAS as a change that would result in moving between the Department's defined reporting ranges. Commenter recommends revising to match the Departments PFAS reporting ranges because an amount that causes the total amount of PFAS to move from one range to another will help with enforcement. (Commenter 19, 36)

Response: The Department finds that it would be inappropriate to use reporting ranges in this portion of the rule as the Department intends to establish these ranges outside of rulemaking and within the reporting database. No change to the rule.

Textile Article

75. Comment: Commenter requests the rule exclude personal protective equipment (PPE). Commenter acknowledges that PPE is not customarily or ordinarily used in households or

businesses. Commenter states that excluding PPE would provide sufficient time for the identification and commercialization of feasible alternatives. Commenter requests that without the exclusion of PPE from this definition, PPE should be subject to the same treatment as outdoor apparel for severe wet conditions. This would delay prohibition until 2032. (Commenter 5)

Commenter requests clarification that this definition excludes PPE, including equipment worn to minimize exposure to occupational hazards that can cause serious injury or illness from contact with or exposure to workplace or professional hazards. PPE is distinguishable from the list of regulated items included in the definition, it is not marketed for general consumer use, and it is necessary for compliance with occupational safety and health regulations and other industry standards (such as NFPA). Confirming that the proposed definition of "textile article" does not include PPE would provide clarity that a ban on the use of PFAS in PPE would go into effect on January 1, 2032. Should the Department determine the PPE is included within the scope of "textile articles" then commenter requests that it be managed in line with the requirements for "outdoor apparel for severe wet conditions." This is, in part, because there are categories of PPE that are designed to meet the same conditions as the outdoor apparel described in rule. (Commenter 56)

Response: Exemptions are established in statute. The Department does not have authority to modify or add additional exemptions. No change to the rule

Unit

76. Comment: Commenter suggests defining "unit" for chemical producers as total volume by weight. Commenter states the term can vary based on product, as chemicals are sold in different sized cylinders and containers and are counted as units in end-products. (Commenter 28)

Response: The term "unit" is used once in the rule in Section 3(A)(1)(b), (the reporting requirement that describes the estimated number of products sold). The type of unit used to

fulfill this reporting requirement will depend on the product type. No change to the rule.

Section 3. Notification

77. Comment: Commenter suggests the Department should exempt pesticide manufacturers from the notification requirement on the basis that the Board of Pesticide Control has access to the formulation and reporting to the Department would be duplicative. (Commenter 18)

Response: Exemptions listed in the rule are statutory. The Department does not have the authority to grant additional exemptions. No change to the rule.

78. Comment: Commenter suggests minimizing notification requirements to the extent they are duplicative with the information submitted in support of a currently unavoidable use determination. Commenter recommends consolidating the product notification process under Section 3 with the CUU determination process under Section 9. Commenter states allowing manufacturers to submit required product information as part of their CUU request. (Commenter 12, 41)

Commenter states the Department should consider the extent to which Section 3 Notification can be streamlined by the proposed requirement in Section 3(A)(1)(g) to provide "[i]dentification by citation to a specific section of this chapter of the applicable determination by the Department that the use of PFAS in the product subject to the notification if a currently unavoidable use." Commenter states both Section 3 and Section 9 require a brief description of the product that includes the GPC or HTS code, the intended use of the product, and the purpose of the PFAS. Commenter is not clear why companies should re-submit this information unless it has changed. (Commenter 13)

Commenter urges the Department to minimize notification requirements for materials subject to CUU determinations, as the Department will already possess extensive information from the CUU application process, including product content details. (Commenter 49)

Response: An entity submitting a proposal for a CUU may differ from the organization

complying with the notification requirement, as any manufacturer may avail themselves of the CUU determination. Therefore, it is beneficial to all parties to separate these two processes. Categories of information required in a notification are established in statute. No change to the rule.

79. Comment: Commenter suggests including product components contradicts the removal of components from applicability sections and needs clarification or removal. They also question how manufacturers would know if a component supplier submitted the required notification. Commenter notes that the proposed rule is unclear on whether product components are subject to the law. Commenter states that while "components" was removed from the "Applicability" section—a change the commenter supports—references to components still appear in definitions, notes, and other sections. Commenter states the Department should ensure consistency throughout the rule to clarify that components are not subject to regulation. (Commenter 12, 49)

Response: Product components that are not independently sold, offered for sale, or distributed for sale in Maine are not subject to the notification requirement. However, products are defined by statute as including their product components; therefore, a product is subject to the requirement based upon the intentionally added PFAS content of its components. No change to the rule.

80. Comment: Commenter highlights the complexity of global supply chains and the challenge of ensuring supplier compliance with new regulations. Commenter requests that the Department include a provision protecting manufacturers from penalties if they make a good-faith effort to identify PFAS in their products before the prohibition deadline. Commenter states that the proposed reporting requirements for product attributes, ingredients, and lifecycle data will be challenging due to complex supply chains and limited access to long-term end-user data. Commenter suggests allowing the use of aggregated industry data instead of individual manufacturer data, focusing data collection on products with the highest environmental risks, and simplifying requirements for data from component suppliers. (Commenter 12, 57)

Response: Notification requirement is based on information known or reasonably ascertainable by the manufacturer. A manufacturer is expected to perform due diligence for the collection of required information and may report data sets based on what is known or reasonably ascertainable. No change to the rule.

81. Comment: Commenter supports the Department extending the "known or reasonably ascertainable" standard to the notification process. (Commenter 41)

Response: The Department acknowledges the commenter's support.

82. Comment: Commenter is concerned about the overwhelming task of identifying unique products and components which are expected to be captured by this reporting requirement. Commenter represents a manufacturing industry that has over 4 million unique products which correlate with tens of thousands of stock-keeping units (SKUs), each having hundreds of associated components and spare parts. Commenter claims this means there are hundreds of millions of potential chances for any given product or component to contain one of the several thousands of PFAS included in Maine's statutory definition related to this rule. Commenter is also concerned that component suppliers will be unable to disclose the chemical composition of their components due to its classification as confidential intellectual property. Commenter is concerned that compliance may be complicated and delayed as it is extremely difficult to ensure the accuracy of chemicals within the supply chain. Commenter suggests that focusing this rule on non-polymer PBT PFAS will ensure protection of human health and the environment without the unnecessary and ineffective burden on industries whose products may not contain low-exposure PFAS that are not PBT chemicals. (Commenter 8)

Response: The notification requirement is based on information known or reasonably ascertainable by the manufacturer. A manufacturer is expected to perform due diligence for the collection of required information and may report data sets based on what is known or reasonably ascertainable. No change to the rule.

83. Comment: Commenter states Section 3(A) provides that "the applicable effective date" of notification will be "listed in section 5." Commenter was unable to locate this date or a proposed placeholder provision for it in proposed Section 5. (Commenter 13)

Response: Section 5 of the rule provides a schedule of prohibitions that become effective in 2023, 2026, 2029, 2032, and 2040. Please see rule Section 5 for details. No change to the rule.

84. Comment: Commenter states the Department should establish clear methods and standards for reporting known PFAS compounds to ensure manufacturers comply with requirements. (Commenter 29)

Response: The rule reporting requirements describe information requirements which are established in statute. No change to the rule.

Complex Products

85. Comment: Commenter requests that a definition be provided for the term "complex products" which is used in the note. Commenter requests the Department clarify the definition of "complex product" to align w/ Directive 98/71/EC of the European Parliament and of the Council (Directive 98/71) which defines "complex product" as a product which is composed of multiple components which can be replaced permitting disassembly and reassembly of the product. (Commenter 32, 41)

Response: Because "complex" is not used in the statute and had few uses within the proposed rule, the term "complex" has been removed.

Sell Through

86. Comment: Commenter proposes that the prohibition apply to products by their date of manufacture. Commenter suggests the following: <u>Upon the applicable effective date listed in Section 5 a product containing intentionally added PFAS and manufactured on or after the</u>

date is prohibited from being sold, offered for sale, or distributed for in the State of Maine, including any products to which a currently unavoidable use determination may apply…(Commenter 33)

Response: Language regarding effective dates of prohibitions is established in statute. The Department does not have the authority to modify this section to allow regulated products to remain for sale in violation of Maine law. No change to the rule.

87. Comment: Commenter understands "100 employees" to mean full-time equivalents company-wide, not just in Maine. If the Department interprets this differently, clarification is requested. (Commenter 41)

Response: The statute does not impose a geographic limitation on the location of "employee" in this section. Any employee, full or part-time, regardless of their location, counts toward the 100-employee threshold. No change to the rule.

Brief Description

88. Comment: Commenter requests the Department clarify section 3(A)(1)(a) "the general type of the product". Commenter questions the necessity of including "general type of the product" in notifications, as it appears redundant with the GPC brick category or HTS descriptor and code. The term is open to broad interpretation, making comparisons difficult. Commenter recommends its removal from the final rule. (Commenter 12, 41)

Response: The requirement for a description of the "general type of the product" is established in statute. The Department does not have the authority to remove this section and sees the value in identifying variations in products. No change to the rule.

89. Comment: Commenter suggests using industry sectors instead of HTS/GPC and NAICS codes for product descriptions in proposed rules. Commenter argues that PFAS's widespread use and extensive classification make broader categorization more practical and efficient. (Commenter 12)

Response: The statutory intent is the reduction and/or elimination of intentionally added PFAS, broad determinations run contrary to this intent. Further, the Department is limited to currently unavoidable use determination in the narrow context of "identifying specific products or product categories containing intentionally added PFAS for which it has determined the use of PFAS in the product is a currently unavoidable use." An industry or sector wide determination would be overly broad. No change to the rule.

90. Comment: Commenter suggests clarifying Sections 3. A(1)(c), (d), and (e) of the rule by adding "intentionally added" before each occurrence of "PFAS." (Commenter 41)

Response: The Department agrees and has made the suggested inclusion.

91. Comment: Commenter requests the Department provide additional clarification on the use of GPC brick code or HTS code and NAICS codes for both Section 3 reporting and Section 9 CUU purposes to ensure that manufacturers can report using reasonable grouping of similar products. It is commenter's understanding that manufacturers may group multiple relevant GPC or HTS codes into a single CUU proposal or a single notification, in combination with identification of NAICS by primary sector. Commenter requests the Department confirm this understanding. Commenter states the Department should align with the EPA's TSCA PFAS reporting rule, using broad product categories instead of requiring granular classifications like GPC or HTS codes. Commenter further states these codes are suited for trade purposes, not regulatory determinations, and would create unnecessary burdens for both manufacturers and DEP. (Commenter 43, 56)

Response: Maine's PFAS in products program is not a broad-based reporting program. Under the amended statute, there is now a prohibition on sales with specific determinations for currently unavoidable uses. Granular classifications are necessary to ensure only those uses which are currently unavoidable are permitted. Addressing the commenter's request for clarification, a separate CUU proposal must be submitted for each individual product category and its associated industrial sector. Please see rule Section 9(a) for details. No

change to the rule.

92. Comment: Commenter states CUU product notifications should be exclusively by CASRN. Commenter urges the Department not to backtrack (FAQ October 28, 2022) on its commitment to CASRNs and remove Section 3(A)(d)(ii) on this basis. (Commenter 13)

Response: The statute has been amended since 2022, establishing the requirement that in the absence of a CASRN the chemical may be reported by a description approved by the Department (38 M.R.S. §1614(2)(A)(3)). Whichever method is applicable, statute requires that the identity of the PFAS be reported and does not limit the scope of covered PFASs. No change to the rule.

Total Units/Sales Volume

93. Comment: Commenter asks the Department to clarify Section 3(A)(1)(b) and whether sales data requirements apply to the past calendar year or future projections. They argue that sales projections are confidential and could cause economic harm, urging DEP to focus on historical data in ranges and explicitly state this in the final rule. Commenter requests the Department clarify what information will be specifically required in the estimate for sales data. Commenter is concerned about this obligation for companies reporting sales data, which is typically confidential. If sales data is required, it should be limited to aggregate data within the past year and not include future forecasts. Additionally, commenter states recent historic sales data should be explicitly protected as CBI by the Department. (Commenter 12, 15)

Commenter states requests should be more flexible for imported products and should include consideration of the confidentiality. Commenter suggests language: An estimate of the total number of units sold annually in the State of Maine or nationally. <u>For the products imported from outside of the United States, such estimation may be reported by using any of the following units of measurement provided that such unit used in the reporting is clearly specified by using following code:</u>

<u>Code Unit of measurement</u>

LB Pounds.

TN Tons.

QT Quantity of imported products.

Other (must specify).

Commenter states the Department must not publish this part of each notification when the submitter of the notification clearly states that such estimation belongs to confidential business information (CBI) of the submitter, and that the data aggregated from the notifications may be published. (Commenter 33)

Response: The requirement for sales data is established in statute at 38 M.R.S. § 1614 (2)(A)(1), which states that "…the estimate of the total number of units of the product sold annually in the State or nationally" (emphasis added). This indicates that the data from the reporting manufacturer is gathered from past sales. Confidential Business Information (CBI) claims for information submitted will be handled in accordance with Maine law at 38 M.R.S. § 1310-B. No change to the rule.

Identity of Each PFAS

94. Comment: Commenter requests that in addition to CAS number or the IUPAC name in Section 3(A)(1)(d), manufacturers be allowed to report "One of the following identifiers: EPA Accession Number, PMN number or Low Volume Exemption (LVE) number" Commenter states the rule should require the Department to issue a complete list of CAS numbers subject to the notification obligation at least 12 months before the reporting deadline to help manufacturers streamline their compliance process. (Commenter 1, 41,15)

Response: Language for this section is established in statute and requires reporting by CAS number, allowing for alternatives only in the absence of a CAS number. Maine law requires the reporting of all PFAS, as defined by statute, regardless of whether the compound has been assigned a CASRN. No change to the rule.

95. Comment: Commenter states that supplier often will not disclose the CAS number and request yes or no or "the use of a PFAS" designation as to whether the product contains

PFAS. Commenter notes that even if components are not covered, suppliers may be unwilling or unable to disclose material composition due to confidentiality concerns. (Commenter 10, 12, 49)

Commenter states upstream suppliers may not be able to disclose additional information beyond identifying the substances as PFAS due to trade secret and confidentiality reasons. Commenter suggests adding the language: If the specific chemical identity of the PFAS imported in a product (an article) is not known to or reasonably ascertainable to the submitter of the notification (e.g. if the chemical identity is claimed as confidential business information by the submitter's supplier, or if the submitter knows they have a PFAS but is unable to ascertain its specific chemical identity), the submitter may provide a generic name or description of the PFAS. (Commenter 33)

Response: Statute requires the Department to collect the CAS number, or in its absence a description approved by the Department. The Department interprets absence to mean a CAS number has not been assigned to the chemical and not that the identity has been withheld. Further the Department finds that a yes or no response is not sufficient to meet the statutory requirement of a description. In the absence of a CAS the identity of the chemical must still be provided in the notification. Content levels are required by statute to be reported based on a commercially available analytical method, in the absence of an appropriate method the statute allows the manufacturer to report total organic fluorine or to the total weight of the product. Regarding supplier relationships, the notification requirement is based on information known or reasonably ascertainable by the manufacturer. A manufacturer is expected to perform due diligence for the collection of required information and may report data sets based on what is known or reasonably ascertainable. No change to the rule.

Amount of Each PFAS

96. Comment: Commenter suggests a range-based reporting structure for PFAS amounts, specifically with regards to upholstered furniture. Commenter requests clarification on whether Department-approved ranges for products or categories will be communicated to manufacturers before appearing in the online notification system. To ensure a robust

compliance strategy, manufacturers need advance awareness of these ranges before the notification deadline. Comment supports the inclusion of a range-based reporting option stating it will be expedient and assist where standard characterization methods are not provided. Commenter supports concentration ranges but urges the DEP to drop the requirement for Department-approved ranges, which represents an added administrative burden on the Department that is not necessary for effective implementation of the law. (Commenter 10, 13, 41, 54)

Response: Statute allows for reporting in a range when the report is based on information received from a supplier. Given the broad range of products and compounds covered by this program, the Department has determined that using the already defined range within "Significant change" of 10% increments by weight is reasonable. These reporting ranges will be established in the reporting database and listed in the frequently asked questions section of the program webpage. No change to the rule.

97. Comment: Commenter states that technical limitations, including the lack of standardized methods and instrumentation, make it difficult to accurately identify and quantify PFAS. Current standardized testing methods detect fewer than 50 PFAS molecules. Commenter states DEP should provide further guidance and flexibility on reporting requirements, particularly regarding CAS numbers, chemical identity, and specific content levels. (Commenter 49)

Response: The Department is aware that few commercially available analytical methods are currently available. In the absence of such a method, the statute allows reporting based on calculation or total organic fluorine analysis. No change to the rule.

98. Comment: The commenter requests clarification on how to calculate the exact concentration of PFAS in a product. Commenter asks whether the concentration should be based on the entire finished good or only on the specific component containing PFAS. (Commenter 12) Commenter states that Section 3(A)(1)(e) requires clarification as the Department has not specified how an exact concentration can be calculated. Commenter requests the Department provide examples and details on expectations for this calculation and clarify the phrase

"falling within a range approved by the Department" and how this will be implemented. Commenter states that because there are no currently standardized methods to calculate the use of PFAS in complex goods, commenter requests clarity on what constitutes "commercially available analytical methods" related to this section. (Commenter 15)

Commenter requests that Section 3.A(1)(e) be amended to expressly include engineering calculations based on product knowledge and/or supplier information for reporting the amount of intentionally added PFAS in a product notification. This could be accomplished by the following amendment:
(e) The amount of each of the intentionally added PFAS in the product or any product component:
(i) Reported as an exact measured quantity as a concentration, determined using commercially available analytical methods;
(ii) Reported as a calculated quantity of specific PFAS or total PFAS, determined using engineering calculations, based on product knowledge and/or information provided by suppliers. (Commenter 56)

Response: Statute allows for reporting in a range when the report is based on information received from a supplier. Given the broad range of products and compounds covered by this program, the Department has determined that using the already defined range within "Significant change" of 10% increments by weight is reasonable. These reporting ranges will be established in the reporting database and listed in the program frequently asked questions section of the program webpage. The Department is aware that few commercially available analytical methods are currently available. In the absence of such a method, the statute allows reporting based on calculation or total organic fluorine (TOF) analysis. For clarity and consistency, estimated concentrations for the product should be reported as a percentage by weight. No change to the rule.

Total Organic Fluorine

99. Comment: The commenter questions the requirement to report Total Organic Fluorine (TOF) when exact PFAS amounts are unknown. Commenter states that TOF does not conclusively

indicate PFAS presence or quantity. (Commenter 12)

Commenter does not support the use of (TOF) as a proxy for PFAS content, as it may detect inorganic fluorides or other organofluorine substances that do not meet Maine's PFAS definition. Commenter states TOF should only be used as a screening method, not for definitive conclusions about PFAS type, source, or concentration. The commenter references U.S. EPA guidance cautioning against the limitations and uncertainties of TOF analysis. Commenter states the Department should ensure TOF protocols used by manufacturers account for inorganic fluorine using standardized, validated methods. (Commenter 41)

Commenter states it is not possible to measure individual PFAS in complex products using current testing methods. Commenter claims testing for TOF in these products is also challenging due to complicated sample preparation and upstream suppliers may not be able to share information about PFAS content because of trade secrets. Commenter suggests language: For amount of PFAS in the imported products (articles), submitters of the notification may select from among the ranges of concentrations listed in the following table (source: TASCA). (Commenter 33)

Code	Concentration range (% weight)
AM1	Less than 0.1% by weight.
AM2	At least 0.1% but less than 1% by weight.
AM3	At least 1% but less than 10% by weight.
AM4	At least 10% but less than 30% by weight.
AM5	At least 30% by weight.

Response: TOF is not required as a PFAS screening tool; instead, TOF is available as a reporting option when the presence of PFAS is known but the concentration is unknown. TOF is provided as an alternative reporting option when there is no commercially available analytical method. The legislative intent was to allow for reporting compliance in such circumstances. The Department acknowledges that it is an imperfect metric. No change to the rule.

100. Comment: Commenter suggests that manufacturers be allowed to choose one of the identified approaches for determining the amount of PFAS in a product or component and requests that the Department add "or" at the end of items (i), (ii), and (iii) to clarify this

option. (Commenter 41)

Response: A manufacturer may select between options (i) or (iii) if both are available. However, option (ii) is only available when option (i) is not available. No change to the rule.

101. Comment: Commenter requests clarification on how the Department will use "the total weight of the product" to estimate the amount of intentionally added PFAS in products that are not entirely PFAS. For those using this option, the Department should consider requesting an estimate of the percentage of PFAS content. (Commenter 41)

Response: This option is only available to manufacturers when neither a commercially available analytical method for the analyte and substrate nor total organic fluorine analysis is viable for the product. The Department has no current plans to attempt to extrapolate PFAS content from total product weight for every product utilizing that pathway. No change to the rule.

Waiver of Notification

102. Comment: Commenter requests clarification if a publicly available source of substantially equivalent information is not controlled by the Department, is it reasonable to expect it to be updated in response to Department requests? Commenter states it would be more practical to require the reporting manufacturer to update the information rather than expecting the external source to do so. (Commenter 41)

Response: A waiver to the initial notification requirement does not relieve the notifier of the obligation to update the Department in the event of a significant change. In the event that the publicly available substantially equivalent information does not update in a timely manner with the significant change, the notifier must update the Department. The Department has updated significant change to include the event that information relied on for a waiver is no longer substantially similar due to a significant change.

Resubmitting Report After Database Available

103. Comment: Commenter requests the Department clarify notifications submitted after April 16, 2024, but before the reporting system is available, must be resubmitted. Commenter suggests the Department clarify that notifications submitted in 2023 under the original statute do not need to be resubmitted unless the products receive a CUU determination and are placed in commerce in Maine. (Commenter 41)

Response: Any notification received prior to the most recent statutory amendments was a general notification under a different scope of requirement. Since the effective date of the most recent amendments, notifications are only for products covered by a currently unavoidable use determination. Because no currently unavoidable use determinations have been made, no existing notifications satisfy the statutory obligations. Subsequent to completion of a currently unavoidable use determination rulemaking, and prior to the sales prohibition effective date, all manufacturers wishing to avail themselves of the CUU determination must submit a complete notification. No change to the rule.

Notification Section 3(C)

104. Comment: Commenter states the rule should clarify that affiliates and subsidiaries under the same corporate parent manufacturer may submit combined reports. (Commenter 15)

Response: Reports must be submitted by the regulated manufacturer responsible for providing the Department with accurate information that meets the notification requirements. No change to the rule.

Notification – Significant Change Section 3(D)

105. Comment: Commenter suggests modifying the language to differentiate between manufacturers who are also formulators and those who rely on information from a formulator further down the supply chain. The proposed revisions clarify reporting requirements as follows:

(c) Prior to the start of sales of a product with a new formulation or when there is a significant change in the amount or type of PFAS present in the product.
Within 60 days of when it is known that there is a significant change in the amount or type of intentionally added PFAS present in the product. (Commenter 41)

Response: A reporting manufacturer is responsible for providing accurate information to the Department, including updating reported information when a significant change occurs. No change to the rule.

106. Comment: Commenter urges the Department to confirm that for companies that manufacture and report a final piece of equipment, the 10% change in composition should be calculated based on the entire piece of equipment. (Commenter 13)

Response: Changes in the amount of intentionally added PFAS should be calculated based on the value initially reported in the notification. No change to the rule.

107. Comment: Commenter supports the ability to submit a single notification for multiple products. (Commenter 10)

Response: The Department acknowledges the commenter's support.

Notification – Supporting Evidence Section 3(F)

108. Comment: Commenter states the phrase "evidence sufficient to demonstrate" is vague. Without a clear understanding of the Department's expectations, reporting manufacturers may not be able to respond to a request from the Department in a timely and complete manner. Commenter also requests clarification of what is considered a timely response and suggests modifying the text as follows: A manufacturer shall ~~provide~~ maintain records documenting the basis for the information contained in the notification and, upon request by the Department ~~evidence sufficient to demonstrate the accuracy of the information reported in subsection A~~ provide such records to the Department within 60 days. (Commenter 41)

Response: The phrase "sufficient to demonstrate" allows manufacturers flexibility to determine which supporting information to rely on, while also establishing a threshold that the manufacturer must demonstrate the validity of the information provided to the Department. The term "basis," as suggested by the commenter, does not convey the same threshold. No change to the rule.

Exemptions Section 4

109. Comment: Commenter suggests the Department should include an exemption or categorical currently unavoidable use determination for fluoropolymers. Specifically, commenter suggests the following language should be added to Section 9(B) "Fluoropolymers (defined as polymeric substances for which the backbone of the polymer is either a per- or polyfluorinated carbon-only backbone or a perfluorinated polyether backbone), and products consisting of fluoropolymers." (Commenter 1)

Commenter requests that the Department exclude fluoropolymers and fluoropolymer-based products from the proposed regulations. Fluoropolymers are large, stable molecules that meet criteria for "polymers of low concern" and are insoluble, non-bioavailable, and non-bioaccumulative. Unlike certain PFAS, they do not pose environmental mobility risks or transform into non-polymer PFAS. Additionally, fluoropolymers are essential for numerous products due to their chemical resistance and dielectric properties. Excluding them would simplify program administration and reduce regulatory burden. (Commenter 41)

Commenter urges that if the Department proceeds with the currently unavoidable use construct it should expand exemptions for fluoropolymer-based products, emphasizing their irreplaceable role in key industries. The commenter highlights applications in automotive, aerospace, batteries, renewable energy, industrial equipment, and electronics. Commenter stresses that many fluoropolymer-based products lack viable alternatives and that regulatory certainty is crucial for maintaining supply chains and supporting domestic investment. (Commenter 50)

Commenter advocates for a time-unlimited exemption from regulatory action for all fluoroelastomers and fluoropolymers, including necessary monomers and processing aids needed for manufacturing of these. Commenter states this exemption would clarify the current focus on products and uses, effectively limiting the proposed PFAS restrictions while ensuring sustainability and quality of life for society. Alternatives for fluoroelastomers and fluoropolymers do not exist! (Commenter 52)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

110. Comment: Commenter states that products that are identical to those used in the circumstances listed in stated should be treated in the same manner. Specifically, commenter suggests the addition of the following language to section 9(B) "Components of the products enumerated in Section 4(A)(5)-(13) when used to perform the same or similar functions in other products." (Commenter 1)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

111. Comment: Commenter states the regulation should explicitly exempt replacement parts for products exempted by statute. Specifically, they suggest the addition of "[r]eplacement parts for products described in Subsections 5 through 13, above" to Section 4(A). (Commenter 1, 41)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the

Department the authority to create additional exemptions. No change to the rule.

112. Comment: Commenter requests that pesticides be exempted from this regulation or the Department issue a CUU for all pesticides. (Commenter 18)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

113. Comment: Commenter requests the Department expand exemptions to include PFAS-containing equipment used in manufacturing, as long as the PFAS is not present in the final product. (Commenter 51)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

114. Comment: Commenter requests a categorical exemption for building products, specifically windows, doors, and skylights, arguing they are essential for structural integrity, energy efficiency, and occupant safety. Commenter states that these products must meet building codes and should be exempt if no viable PFAS-free alternatives exist. (Commenter 57)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Exemptions – Preemption Section 4 (A)(1)

115. Comment: Commenter supports the use of the word "governs" in this section and reiterates concerns that manufacturers subject to export controls may be legally prohibited from disclosing formulation information. Commenter states in such cases, applying for a CUU determination and submitting a notification and fee may be impossible. (Commenter 41)

Response: The Department acknowledges the commenter's support.

116. Comment: Commenter urges the Department to include products that meet Occupational Safety and Health Administration (OSHA) standards as a separate exemption in Section 4 (e.g., CA, NY, CO, RI). (Commenter 31)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Exemptions – Fire Suppressing Foam Section 4 (A)(4)

117. Comment: Commenter requests exemption (or currently unavoidable use determination) for F-gas fire suppression agents listed in the EPA's SNAP list for Substitutes in Fire Suppression and Explosion Protection. (Commenter 24)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Exemptions – Medical Device Section 4 (A)(5)

118. Comment: Commenter asks for the Department to acknowledge that medical imaging equipment is exempt. (Commenter 13)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Exemptions – Product for Public Health Section 4 (A)(7)

119. Comment: Commenter encourages the Department to interpret this exemption broadly; commenter references PFAS-containing ion exchange membranes used in wastewater treatment as an example. (Commenter 1)

Response: The Department will assess this issue on a case-by-case basis when all relevant details have been presented and analyzed. No change to the rule.

Exemptions – Federal Standards Section 4 (A)(8)

120. Comment: Commenter requests the Department clarify why textile articles and refrigerants in federally regulated products require notification. (Commenter 12, 49)

Response: These exclusions to the exemption are found in statute and are reflective of the Legislature's intent for these components. No change to the rule.

121. Comment: Commenter states it is unclear if the equipment (electronics) used to build warships is excluded. Commenter suggests amending the language in Sect. 4.A. (8): A product, <u>including its component parts and including its packaging, notwithstanding Sections 4(A)(2) and S(B), (C), (E), and (F),</u> required to meet standards or requirements of the FAA, the National Aeronautics and Space Administration (NASA), the United States Department of Defense (DOD) or the United States Department of Homeland Security (DHS). (Commenter 9)

Response: Because exemptions are established in statute the Department does not have the

authority to create or modify exemptions. No change to the rule.

122. Comment: Commenter requests clarification on the timing and process for submitting notifications for textiles and refrigerants in otherwise exempt items. They recommend exempting these components to reduce regulatory complexity and ease the administrative burden on the Department. (Commenter 12, 49)

Response: As these components are not exempted from the program, they are subject to the sale's prohibitions for in the proposed rule. Therefore, to continue sales after the relevant effective date a product must be covered by the Department currently unavoidable use determination. Manufacturers may apply for a currently unavoidable use determination consistent with the timelines in the finally adopted rule. Notifications must be received prior to the sales prohibition. No change to the rule.

Exemptions – Motor Vehicle Section 4 (A)(9)

123. Comment: Commenter is asking if the gearboxes and 'partly completed machinery' are exempt? Commenter states the EU Machinery Directive 2006/42/EC defines 'partly completed machinery' as an assembly that nearly forms a machine but cannot operate independently. Commenter explains that while some of these may be powered by electric drives, it varies. If a complete system includes non-electrical components, should it still be labeled as 'electronics,' or should mechanical components also be included in the classification? (Commenter 55)

Response: With the information provided, the Department is unable to provide a specific response to the comment. The Department will rely on federal agency's interpretation of what is subject to this standard. No change to the rule.

Exemptions – Watercraft Section 4 (A)(10)

124. Comment: Commenter notes a typo expect should read as except. (Commenter 41)

Response: The Department has corrected the typographical error in Section 4(A)(10).

125. Comment: Commenter is concerned about many product components in their product and eventual unavailability of the components due to regulations. Commenter suggests amending the language in Sect. 4.A. (10): A watercraft as defined in 12 M.R.S. § 13001(28)(2), including its component parts and including its packaging, notwithstanding Sections 4(A)(2) and S(B), (C), (E), and (F)., or a seaplane. (Commenter 9)

Response: Because exemptions are established by the Legislature the Department does not have the authority to expand them. No change to the rule.

Exemptions – Semiconductor Section 4 (A)(11)

126. Comment: Commenter states the note in this section is unclear, and potentially inaccurate. Commenter states the note should clarify that electronic equipment used in the manufacture of semiconductors is also exempt. Commenter suggests amending the language in Sect. 4.A. (11): NOTE: "While semiconductors incorporated into electronic equipment are exempted from this Chapter, electronic equipment in their entirety is not exempt unless otherwise specified in this Chapter (for example, the electronic equipment is used in the manufacture of semiconductors, is considered a non-consumer electronic product under Subsection 12, or (as described in Subsection 13) is otherwise considered equipment directly used in the manufacture or development of products described in Subsections 5 through 12)." (Commenter 45)

Response: The Department has clarified that other exemptions may apply.

Exemptions – Non-Consumer Electronics Section 4 (A)(12)

127. Comment: Commenter points out that the term "non-consumer electronics" in section 4.A.(12) includes many technologies. To be more complete, it should also include "electrochemical" technology. (Commenter 21)

Commenter requests to add power grid equipment (transmission and distribution of electricity). Commenter suggests amending the language in Sect. 4.A. (12): Non-consumer electronics, non-consumer power grid equipment, and non-consumer laboratory equipment not ordinarily used for personal, family or household purposes. (Commenter 28)

Commenter suggests amending the language in Sect. 4.A. (12): Non-consumer electronics, non-consumer laboratory equipment not ordinarily used for personal, family or household purposes, power grid equipment and other electrical equipment; and (Commenter 38)

Commenter suggest including capacitors in the exemptions if they meet the criteria for Currently Unavoidable Use (CUU). (Commenter 34)

Commenters have concerns about larger products in their portfolio. Although they aren't used for exempt items or classified as electronic, they pose no greater risk to consumers than our smaller exempt products. Commenter seeks clarification on the rule's intention regarding these products and whether we can consider all our products exempt since they operate in similar environments isolated from public exposure. (Commenter 47)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

128. Comment: Commenter suggests that consumer electronics should be also exempted in addition to exemptions listed in Subsection 4. Some high-performance models require PFAS for their essential functions, and PFAS materials are significantly more expensive compared to non-PFAS options. Commenter states that consequently, PFAS is used only when its unique benefits are crucial for performance. Additionally, PFAS in electronic products has a low vapor pressure, meaning it does not evaporate at room temperature. (Commenter 33)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614

(4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

129. Comment: Commenter is asking if non-consumer electronics, particularly in mechanical and plant engineering (e.g., production machines, logistics and intralogistics applications) are exempt? (Commenter 55)

Response: With the information provided, the Department is unable to provide a specific response to the comment. The Department will rely on federal agency's interpretation of what is subject to this standard. No change to the rule.

Exemption – Used Product Section 4 (A)(3)

130. Comment: Commenter recommends extending the sales prohibition exemption to replacement parts for repairs and maintenance. Commenter supports the exemption for used products and recommends extending it to replacement parts for routine repair and maintenance. (Commenter 12, 49)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

131. Comment: Commenter suggests leased products like rental cars should be considered used products. (Commenter 12)

Response: A leased vehicle has been utilized for its intended purpose by at least one operator and, therefore, meets the Department's proposed definition of used.

Exemptions – Equipment Use in Manufacture Section 4 (A)(13)

132. Comment: Commenter requests the Department expand this exemption to cover all equipment used in manufacturing or development, as long as it is not incorporated into the final product. (Commenter 51)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

133. Comment: Commenter states the equipment exemption must be expanded to include all parts involved in the manufacture or development of exempted products. Commenter suggests amending the language in Sect. 4.A. (13): "Equipment and product components, including motors, electronic and mechanical equipment and other machinery, whether permanently or temporarily attached, directly used in the manufacture or development of products, or in the final products themselves, described in subsections 5 through 12, above." (Commenter 9)

Commenter suggests adding language to Sect. 4.A. (13): "Equipment "directly used" in the manufacture or development of products described in Subsections 5 through 12 includes equipment and related materials used for the servicing, maintenance, operation and upgrading of products described in Subsections 5 through 12." (Commenter 45)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Prohibitions

134. Comment: Commenter stresses that any sales prohibition established in rule by the Department should undergo adequate public participation. (Commenter 6)

Response: Any additional sales prohibitions proposed by the Department must be done through the major substantive rulemaking process, this requires an open public rulemaking process and an open public review of adopted rules by the Legislature prior to becoming effective. In addition, the Department may conduct pre-rulemaking outreach for interested parties when appropriate. No change to the rule.

Prohibitions - Section 5 (H)

135. Comment: The commenter seeks confirmation that retailers, not manufacturers, bear responsibility if they continue selling prohibited PFAS-containing products after receiving notification. Commenter also requests clarification on how the rule applies to wholesalers and distributors. Commenter states the retailer sells PFAS-containing products after the sales ban begins, despite the company's notification, the retailer should be responsible for the violation. Commenter states the rule should clearly specify who is accountable in this circumstance. Commenter states the rule should clarify whether only the retailer will be held responsible for violation of the rule in this circumstance. (Commenter 12, 15, 33)

Response: A retailer is in violation of the sale's prohibition if they continue to offer a product for sale after receiving notice from the manufacturer that the item is prohibited from sale. Further, a manufacturer which has provided such notice to all retailers has satisfied its obligations under Section 8 Certificate of Compliance of the proposed rule. No change to the rule.

136. Comment: Commenter strongly recommends the draft amend the prohibition effective dates to no earlier than one year from the publication of the final rule based on the manufacture date of the product. Commenter claims this timeline would allow affected parties to contact suppliers and gather the accurate data available to fulfill the reporting requirement.

Commenter states modifying this lead time would also avoid inventory becoming stranded causing a shortage of equipment and increased costs to consumers in Maine. Commenter states this additional time will also allow the Department to effectively staff and train personnel who will manage reporting and certification requirements. (Commenter 32)

Response: Because sales prohibition start dates are specified in statute, the Department does not have the authority to amend the law in the manner suggested. No change to the rule.

Prohibitions - 2026

137. Comment: Commenter states that producing upholstered furniture consistent with the sales prohibition may be difficult. Commenter specifically points out that there are few, if any, non-PFAS containing alternatives for non-fabric components (commenter references, electronics, gear lubricants, and mechanical parts specifically). (Commenter 10)

Response: The Department encourages any manufacturer that believes that the use of PFAS in its product is a currently unavoidable use, and for which there is no reasonably available alternative, to submit a proposal for a currently unavoidable use determination according to the timeline in the rule. No change to the rule.

138. Comment: Commenter states based on empirical data indicating that fluoropolymers such as PTFE do not bioaccumulate, nor show evidence of being toxic to humans, in addition to being authorized for use in food contact applications by the FDA and European Food Safety Authority, commenter requests this category be amended as follows: (2) A cookware product <u>surface that is intended to be in direct contact with food or beverage while cooking</u> and containing intentionally added PFAS. <u>This prohibition under this subparagraph does not include polytetrafluoroethylene (PTFE), fluorinated ethylene propylene (FEP), and perfluoro alkoxy alkane (PFA) used on food contact surfaces of cookware.</u> (Commenter 17)

Response: Because the definition of cookware is established in statute the Department does not have the authority to narrow the scope of this definition, nor the applicable scope of how PFAS is defined. No change to the rule.

139. Comment: Commenter states that because the June 1, 2025 deadline for CUU proposals within these categories will not provide sufficient time to collect the necessary information to draft and file a CUU request pending finalization of the Departments rulemaking process. Commenter requests that the deadline for submission of CUU requests be extended to six months after chapter 90 is finalized and in force. (Commenter 56)

Response: The Department understands that the June 2025 deadline may be difficult to achieve. However, the Department must complete a routine technical rulemaking process to determine currently unavoidable use requests prior to the effective date of the sales prohibition. The time necessary to finalize such determinations may be approximately six months or more. No change to the rule.

140. Comment: Commenter states that exempt products that meet OSHA standards should not be regulated. Commenter states while the definition of "textile article" excludes some items, it should also exempt those that are part of personal protective equipment (PPE) and safety gear. Commenter claims these products are vital for keeping the State's workforce safe from workplace hazards and this exemption should be added to prohibitions Section 5(C)(7). (Commenter 31)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

141. Comment: Commenter states the proposed rule should be updated to clarify the restrictions in Section 5 on textile and refrigerant bans. Commenter states this should remove the provisions in Section 4(A)(8) and 4(A)(10) that state "any textile article or refrigerant included in or as part of" exempted combatant ships is not exempted. (Commenter 9)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614

(4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Prohibitions - 2040

142. Comment: Commenter urges the Department to extend the SNAP exemption to fire suppression and explosion protection agents, arguing they are similar to already exempted applications. Commenter highlights that these agents have a critical societal role, lower emissions, high recyclability, and lack of consumer use, suggesting their exclusion was an oversight or misunderstanding. (Commenter 26)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

143. Comment: Commenter urges the Department to clarify the definition of "cooling, heating, ventilation, air conditioning or refrigeration equipment," because this wording creates regulatory ambiguity for the HVACR and water heating industry. Commenter is concerned that the draft definition does not specify that water heating, water cooling, dehumidifiers, air cleaners, and all other space conditioning equipment are also included in the scope of the category. Commenter suggests that the scope of this definition be clarified to avoid confusion about the inclusion of all equipment used to improve the indoor air environment. Commenter states that the HVAC category as described in LD 1537 (2024) creates regulatory ambiguity for the HVACR and water heating industry because it does not specify that water heating, water cooling, dehumidifiers, air cleaners, and all other space conditioning equipment are also included in the scope of the category. Commenter requests clarification that the scope of this category includes all equipment used to heat or cool water and improve the indoor air environment. Commenter requests the rule specify that the following are within the scope of this provision: Water heaters; Heat pumps; and related residential equipment. (Commenter 8, 13, 32)

Response: The Department finds it sufficient to rely on the common understanding of these terms. No change to the rule.

144. Comment: Commenter claims because some HVACR and water heating applications are not regulated under EPA's SNAP, commenter requests that the rule provides a compliance pathway for products which utilize these refrigerants which are not covered under this federal program. Commenter notes that though refrigerants for servicing subject to acceptable use conditions under EPA's SNAP are excluded, some HVACR and water heating applications are not regulated under that federal program and should be excluded from this rule. Commenter requests the rule be amended to provide a compliance pathway for products utilizing these refrigerants for applications not covered under EPA's SNAP. Commenter states the Department should harmonize refrigerant requirements and restrictions under the PFAS in Products program to those of the EPA SNAP program. (Commenter 7, 8, 32, 53)

Response: Products not excluded from the rule are subject to the sales prohibitions. Manufacturers may request a currently unavoidable use proposal which, if granted, provides for continued sales within the State of Maine. No change to the rule.

145. Comment: Commenter states the language in section 5.E and 5.F. is confusing and suggests amending the language in Sect. 5.E. "Except as provided in subsection H and section 9(B), effective January 1, 2032, a person may not sell, offer for sale, or distribute for sale in the State of Maine any product that is not ~~already~~ prohibited for sale under subsections A, B, C, D, or G that contain intentionally added PFAS. … ~~(2) Products subject to subsection F, below"~~ (Commenter 29)

Response: Exemptions found in the text of the rule are established in statute and provided for the readers' convenience and are a verbatim repetition of those found at 38 M.R.S. § 1614 (4). These exemptions were established by the Legislature, which has not granted the Department the authority to create additional exemptions. No change to the rule.

Fees

146. Comment: Commenter suggests that fees for products with approved CUU determinations be collected as part of a consolidated notification/CUU submission. Commenter also suggests a refund process should be implemented, and product notification submissions should be rejected if the CUU request is denied. (Commenter 41)

Response: Currently unavoidable use determinations may be utilized by one or multiple additional manufacturers after the Department has made the determination. Further, the statute requires a manufacturer, regardless of whether they were the currently unavoidable use applicant, to submit a notification to the Department. Therefore, the Department finds the most efficient point of collecting fees is at the time of notification for all manufacturers. No change to the rule.

147. Comment: Commenter requests clarification on fee structure. It is commenter's understanding that the fee is a one-time charge for notifying either an individual product or a group of products within a specific GPC brick (or HTS code if no GPC code applies). Commenter requests the Department's confirmation. (Commenter 41)

Response: The fee is due once for each notification whether that notification covers one or multiple products. Upon the expiration of the currently unavoidable use determination and in the event a subsequent determination is made covering the same products, a new notification and payment of the associated fee will be required. No change to the rule.

148. Comment: Commenter requests confirmation that "updates" in the draft regulation cover all types of updates described in Section 3D and that no additional fee is required if a new product falls within an existing category with an affirmative CUU designation, as the fee has already been paid. (Commenter 41)

Response: The fee is due only once for each notification whether that notification covers one or multiple products. A product that triggers a significant change update to an already submitted notification does not generate a new fee if the new product matches the

information originally reported. However, if the product does not match the information originally reported for the applicable currently unavoidable use, then a new notification must be submitted which generates a new fee. No change to the rule.

149. Comment: Commenter suggests allocating fees to support research into safer alternatives to promote long-term environmental and economic benefits. (Commenter 57)

Response: The statute requires the Department to set the fee at a level to cover its reasonable cost associated with program implementation. Statute states that the Department will develop such a program to the extent funds are available, which the Department interprets to be what is available after program implementation costs are covered. No change to the rule.

150. Comment: Commenter suggests the fee as proposed could result in a significant financial burden to manufacturers, depending on what the Department considers an individual product; particularly if there is a distinction between products in the same product line that differ by model number or identifier. Commenter supports a product line bundle notification system to reduce this burden so that Maine consumers may maintain product diversity. Commenter supports the recognition by the Department of notifications previously submitted for the same use case, and opposes fees collected from the notification of exempted equipment. (Commenter 8)

Response: Because notification is based on a currently unavoidable use designation, which is grouped by product category and industry sector, multiple products may be included in one notification. Exempt equipment is not subject to reporting under the rule. No change to the rule.

151. Comment: Commenter states that because there are numerous circumstances when two different entities meet the definition of a "manufacturer" is unclear who will, specifically, be held responsible for the reporting requirement and fee payment. Commenter recommends additional guidance to clarify. (Commenter 30)

Response: This will be clarified in a forthcoming frequently asked questions section of the program webpage. No change to the rule.

152. Comment: Commenter recommends fee mitigation strategies be incorporated into the rule. As examples they suggest waiving the fee for manufacturers after the first notification or to cap the total fees any one manufacturer might pay. Commenter urges the Department to establish a cap on total fees assessed on businesses, as individual notification fees for Currently Unavoidable Use determinations. Commenter states the Department should cap fees per manufacturer or annually and ensure they align with program needs. (Commenter 6, 37, 41)

Response: The fee is established to cover the Department's reasonable costs to implement the program, limiting the fees paid by manufacturers submitting multiple notification would shift that burden onto entities submitting fewer notifications. Similarly, waiving the fee on all subsequent notifications effectively sets a fee per manufacturer regardless of number of notifications submitted and would result in an increased base fee and a similar shifting of the burden. Because by statute the notification occurs only once per currently unavoidable use determination an annual schedule is not possible. No change to the rule.

153. Comment: Commenter suggests lowering the fee to 500 dollars as this cost is borne by the manufacturer and ultimately passed on to consumers. Commenter states the proposed fee of $1,500 should be reduced to $150 or less for notification and re-notification once a CUU determination is granted. Small businesses should not be asked to pay a fee. (Commenter 10, 13)

Response: The fee is established to cover the Department's cost in implementing the program. A reduction in the fee would result in a funding shortfall. Regulated manufacturers with fewer than 100 employees are exempt from the notification requirement. No change to the rule.

154. Comment: Commenter warns that proper oversight is necessary to ensure that internet retailers are in compliance with the fee requirement or it may result in a competitive disadvantage. (Commenter 10)

Response: If the Department becomes aware of manufacturers or retailers who have received notice of the sales prohibition from manufacturers, both in-person and online, the Department will undertake appropriate enforcement and compliance efforts. No change to the rule.

155. Comment: The commenter appreciates the fee reduction from the concept draft but argues that multiple notifications could still be costly. Commenter suggests a single fee per reporting entity, regardless of the number of product notifications submitted. (Commenter 12)

Response: Since the fee is established to cover the Department's reasonable costs, limiting the fees paid by manufacturers by submitting multiple notification would shift that burden onto entities submitting fewer notifications. No change to the rule.

156. Comment: Commenter states the Department has not provided analysis showing that the $1,500 notification fee reflects "reasonable costs." Commenter states a cost forecast is needed to assess the fee and alternatives. Commenter suggests fees should not exceed actual costs, and the Department should have flexibility to adjust them. A detailed economic analysis of program costs and expected notifications should accompany the final rule, along with an annual audit of collected fees and expenses. Commenter requests to better understand the justification for the proposed fee amount and how it would cover the Department's reasonable costs in administering and implementing the program. Commenter requests clear and transparent documentation so that stakeholders can better understand how this amount was determined. (Commenter 30, 41)

Response: The Department set its proposed fee based on estimated costs and an estimate of the number of currently unavoidable use requests that it is likely to receive. The Department estimates that a reporting system will cost $200,000 to develop and $50,000 per year to maintain. The annual cost of staff, both dedicated to the program and assigned as needed,

will be $200,000 per year. The Department also estimates $50,000 per year anticipating that contracted assistance may be necessary. Based on the number of currently unavoidable use applications submitted under the prior statutory structure and feedback from the regulated community, the Department estimates the $1,500 will cover these costs. No change to the rule.

157. Comment: Commenter argues that companies should be charged on a per-volume basis to ensure fair and equitable cost distribution. (Commenter 57)

Response: The Department finds that, across all industries sectors and product types, a sales volume forecast covering the five-year life of a currently unavoidable use determination to be too variable to accurately set a fee level reflecting the Department's reasonable cost of implementation. Further, the Department anticipates that the sales volume of a product will have little or no impact on the burden it places on administering the program. No change to the rule.

158. Comment: Commenter recommends minimizing fees for updates that reflect reductions or eliminations of PFAS use to incentivize innovation and compliance. (Commenter 57)

Response: The draft rule states "[n]o fee is required for information updates to an existing notification or changes to inactive status." No change to the rule.

159. Comment: Commenter states that products or components containing de minimis levels, less than 0.1% by weight, of any PFAS should be exempt from the regulation. Commenter states manufacturers must rely on the accuracy of information from every supplier throughout their entire supply chain on trace amounts of a chemical, even those with unintentional cross-contamination. Commenter states the absence of a *de minimis* exemption puts an unreasonable burden on manufacturers. (Commenter 32)

Response: The statute establishes that regulated products are those with intentionally added PFAS, without specifying a de minimis test. The Department does not have the authority to

create a de minimis threshold. No change to the rule.

Failure to Provide Notice

Certification

160. Comment: Commenter requests more information on certificates of compliance. It is difficult to determine whether the proposed 30-day allotted time for completion of a certificate of compliance is sufficient when no forms have been provided by the Department. Commenter states that if a manufacturer must test raw material to confirm compliance, that analytical testing may take more than the proposed 30-days. Commenter requests that the Department provide detailed information and/or the actual certification form before the formal rulemaking so that stakeholders can offer informed feedback. (Commenter 30)

Response: Maine statute has established a 30-day timeline for manufacturer response to the Department's request for certification. Laboratory testing is not specifically required to comply with a request for certification of compliance with the law. No change to the rule.

161. Comment: Commenter states the language in section 7.A. implies a 2032 reporting requirement for refrigerants, despite a 2040 ban. Commenter suggests adding language to clarify it applies to "prohibited" products with intentionally added PFAS. (Commenter 53)

Response: Currently unavoidable use determinations are only required for products subject to sales prohibitions. Since refrigerants with intentionally added PFAS will not be prohibited for sale until 2040, they are not subject to a 2032 notification requirement. No change to the rule.

Certificate of Compliance

162. Comment: Commenter notes that the 30 day response period in A(1) may be insufficient if testing is required or if the recipient needs more time to demonstrate due diligence. Commenter recommends extending the limit to 120 days in both cases. (Commenter 41)

Response: A certificate of compliance is required only when the Department has reason to believe that a product contains intentionally added PFAS. The 30-day timeline is provided by statute and the Department lacks authority to extend the timeline as requested by the commenter. No change to the rule.

Currently Avoidable Use

163. Comment: Commenter requests the Department create a clear time frame for determinations on CUU requests. (Commenter 6)

Response: The Department must make currently unavoidable use determinations in compliance with in the Maine Administrative Procedure Act's requirements for routine technical rulemaking. Final determination occurs when a rule is adopted by the Board of Environmental Protection and assigned an effective date by the Maine Secretary of State. That process is variable depending on the amount of public engagement, whether a reposting is required, and whether the Board requires additional deliberative sessions. The Department anticipates conducting at least one such rulemaking per year. No change to the rule.

164. Comment: Commenter requests the Department evaluate CUU requests on a rolling basis rather than a deadline of 18 months prior to the sales prohibition's effective date. Commenter finds the 36- to 18-month window for unavoidable use determinations too narrow and inflexible, given ongoing PFAS reviews and alternative development. One commenter, PPWG, provides specific language. (Commenter 6, 12, 43, 49)

Commenter argues that the 36-month CUU submission window is too short for industries requiring halogenated clean agents, as project designs and fire suppression approvals take decades. They highlight 30 years of unsuccessful efforts to develop alternatives and cite industry consensus, including a UNEP report. (Commenter 26)

Commenter suggests allowing CUU requests to be submitted up to 5 years/60 months before the effective date of a sales prohibition, rather than the 36 months proposed by the Department. (Commenter 26, 37)

Commenter states that the timeline for currently unavoidable use proposals is too short. Commenter suggests that four to five-and-a-half years is not enough time to complete the necessary work. Commenter urges a minimum of a 25-year transition period. (Commenter 54) Commenter objects to the Department's proposal to delay consideration of CUU proposals until 36 months before the applicable sales prohibition. Instead, manufacturers should be allowed to submit CUU proposals as soon as the regulations are finalized. To ensure final determinations are based on current information, commenter suggests manufacturers be required to certify that no material changes have occurred prior to that 36-month period. (Commenter 41)

Commenter states that businesses should be allowed to submit CUU proposals more than 36 months before sales restrictions. (Commenter 3, 13, 29, 33)

Response: The Department estimates that 18 months is adequate time to undertake the routine technical rulemaking. The Department requires sufficient time to review all proposals, request additional information if needed, and draft a rulemaking proposal. The Department's experience is that 6 months from a rulemaking being proposed, and an effective date being assigned is a reasonable timetable. Further, the Department aims to complete the rulemaking several months prior to the sales prohibition coming into force to allow time for compliance. Manufacturers may submit requests after 18 months; however, the Department may not be able to act on them until a subsequent rulemaking. Based on stakeholder concern, the Department is moving the earliest timeframe for the submission of a currently unavoidable use to no more than 5 years from the date of a sales prohibition.

165. Comment: Commenter suggests the Department offer the option for CUU designations with extended or no expiration dates on a case-by-case basis. (Commenter 6)

Response: Statute limits currently unavoidable use determinations to 5 years. The Department lacks authority to provide for longer determination applicability. No change to the rule.

166. Comment: Commenter suggests that upon timely submission of a currently unavoidable use request the sales prohibitions should go into effect either on the date found in statute or 12 months after the Department and Board's final decision, whichever is later. Specifically, the commenter suggests the following language be added to the end of Section 9(A) "For products included in a currently unavoidable use proposal submitted within the timeframes referenced above, the prohibition on sales will become effective either: (i) the date specified in the statute; or (ii) twelve months after the date on which DEP and the Board of Environmental Protection render a final determination on the product's CUU application, whichever date is later." (Commenter 1)

Response: The statute does not authorize the Department to extend the effective date of a sales prohibition or exclude products from them, other than through a currently unavoidable use determination made in rule. No change to the rule.

167. Comment: Commenter suggests that currently unavoidable use determinations should automatically renew, unless new information indicates that a prior determination is no longer valid. Specifically, commenter suggests replacing the last 2 paragraphs of Section 9(A) with the following "Upon the expiration date listed in Section 9(B), a currently unavoidable use determination shall be automatically renewed for an additional five years upon the submission of a renewal request unless information submitted with the renewal request leads the Department to conclude that a new CUU proposal must be submitted to renew the CUU determination. A renewal request under this paragraph must identify any changes to the information included in the most recent CUU proposal or renewal request submitted to the Department and must be submitted no later than 24 months prior to the expiration date of the CUU determination in effect. Within three months of receiving a renewal request the Department shall notify the submitter if the new information included in the renewal request requires the submission of a new CUU proposal. If the Department notifies a submitter that a new the CUU proposal is required, the proposal must be submitted to the Department within three months of that notification and the Department will have three months to review the proposal. If a renewal request is not received within the time frame specified above, a new CUU proposal will be required, unless the Department in its discretion waives the deadline for submission of a renewal request." Commenter requests more flexibility for

resubmissions, treating them as renewals with minimal additional information requirements or otherwise streamlining the process. (Commenter 1, 12, 37)

Commenter states it makes no sense to require risk-based criteria for this determination. It is settled science that PFAS, in almost any amount, is a risk to human health. Commenter states the statute is not intended to establish a risk-based framework. (Commenter 46, 48)

Response: The statute provides that products subject to a currently unavoidable use determination are excluded from the sales prohibition for a period of 5 years from the date of the determination or the effective date of the sales prohibition, whichever is longer. The statute does not allow for renewal or extensions at the end of the 5-year period; instead, the Department must issue a new separate determination. That determination must be based upon current information. If a manufacturer believes that nothing has materially changed since applying for the prior currently unavoidable use determination, the organization may resubmit an updated version of that proposal, which also includes a description of any changes since the time of the first currently unavoidable use determination and a summary of efforts made during that time to develop or discover alternatives or to make existing alternatives reasonably available. No change to the rule.

168. Comment: Commenter argues that requiring extensive research for CUU applications creates an unreasonably high burden, potentially preventing approvals for essential products. Commenter suggests that the Department, rather than applicants, collect necessary data. (Commenter 23)

Response: The Department understands the legislative intent of the statute to be the removal of intentionally added PFAS from all products other than the limited circumstances of exemptions found in statute and currently unavoidable use determinations. The Department finds that the statute assigns the burden to manufacturers wishing to continue to intentionally add PFAS to regulated products. No change to the rule.

169. Comment: Commenter states that requiring confidential business information in the CUU request while not allowing its protection is inconsistent and may lead to inaccurate data.

Commenter believes permitting CBI submission is essential for making informed CUU decisions that protect public health, safety, and societal functions. (Commenter 23)

Response: The Department does not require confidential information as part of a currently unavoidable use proposal and will accept requests with such claims. The Department also allows for information that is requested to be absent from a proposal, however, the requestor must explain why information is omitted. Because the rulemaking process, response to comment, and associated Board materials are public documents, the determination must be sufficiently supported and defensible by the non-CBI contents of the currently unavoidable use proposal. If the Department cannot publicly justify its rulemaking proposal, the Department will be unable to support currently unavoidable use determination. The Department suggests that a requestor provides as much, if not all, requested information as possible, which is not CBI. No change to the rule.

170. Comment: Commenter asks how will currently unavoidable use determination requests that were submitted prior to the proposed rule being adopted be handled? (Commenter 26)

Response: Given the significant statutory changes, including additional sales prohibitions and exclusions, as well as the Department's proposed timelines for submission and submission criteria, currently unavoidable use determination requests that were submitted prior to the statutory amendments will not be further reviewed by the Department. No change to the rule.

171. Comment: The commenter urges the Department to begin accepting CUU proposals immediately upon finalizing the rule and requests clarity on the expected CUU rule-making timeline. (Commenter 41)

Response: Statute limits currently unavoidable use determinations to 5 years. The Department lacks authority to provide for longer determination applicability. No change to the rule.

172. Comment: Commenter states if a CUU application is submitted within the prescribed timeframe but the Department does not issue a determination before the ban date, the prohibition should be delayed until three months after the CUU rule-making process is completed. (Commenter 41)

Response: The Department has carefully selected the minimum timeframes of 18 months for novel determination requests and 12 months for products which the Department has previously addressed to ensure determinations will be made in advance of the sales, prohibition. The statute does not give the Department the authority to extend the sales prohibition effective dates. No change to the rule.

173. Comment: Commenter requests the establishment of an appeals mechanism for CUU denials. Commenter states the Department's existing licensing appeal procedure could serve as a model. (Commenter 41)

Response: The Department will review each request and if it finds a request lacking in information the Department will contact the requestor for additional information. If the Department declines to act on a proposal in any rulemaking cycle, the requestor may submit a subsequent request containing additional information and/or their justification as to why the Department was in error to decline their request. As the currently unavoidable use determination is a routine technical rulemaking, the appropriate appeals process is through the Maine Administrative Procedure Act. All applicants will have the opportunity to submit comments and represent their proposal to the Board of Environmental Protection during the rulemaking process. No change to the rule.

174. Comment: Commenter requests clarification on "separate proposal" requirements. If a product serves multiple industries for the same function, a single CUU submission should suffice instead of separate ones for each industry. (Commenter 41)

Response: The Department understands that separate proposals will result in multiple requests for currently unavoidable use determination and in many cases those proposals may have significant overlap. However, the varying uses of a product across industries may have

different alternatives based on the function of the product or different importance to the health, safety or functioning of society. Grouping multiple uses together increases the likelihood that the Department will be unable to act on a proposal. No change to the rule.

175. Comment: Commenter disagrees with the assumption that all manufacturers have complete supply chain information for CUU proposals. Commenter states that requirements like providing NAICS codes may be difficult for component manufacturers who don't know all sectors using their products. To address this, the commenter suggests applying the "known or reasonably ascertainable" standard to all required elements, ensuring manufacturers report what they know and demonstrate efforts to obtain missing information. (Commenter 41)

Response: If a manufacturer cannot provide information on the industry sectors that use the product the Department will be unable to assess whether that use of PFAS in the product is a currently unavoidable use based on its importance to health, safety or the functioning of society. The Department does allow for information to be omitted from a determination request; however, the requestor must explain why this information is omitted. No change to the rule.

176. Comment: Commenter recommends allowing an 18-month compliance extension if the Department fails to make a CUU determination before a sales ban takes effect. This would accommodate manufacturers developing new products close to the ban date, ensuring they can still submit CUU proposals. (Commenter 41)

Response: The Department has set the minimum timeframes of 18 months for novel determination requests and 12 months for products which the Department has previously addressed to ensure determinations will be made in advance of the sales prohibition. The statute does not give the Department the authority to extend the sales prohibition effective dates. No change to the rule.

177. Comment: Commenter requests that the Department clarify CUU renewal procedures to streamline the process. Commenter suggests a certification program allowing manufacturers to update necessary information while confirming unchanged details from prior CUU

applications. Commenter states renewals should be presumed valid unless significant evidence shows alternatives are available or PFAS use is no longer essential. If a renewal is denied, manufacturers should have a one-year grace period to transition, ensuring supply chain stability and regulatory predictability. (Commenter 41, 43)

Response: The statute provides that products subject to a currently unavoidable use determination are excluded from the sales prohibition for a period of 5 years from the date of the determination or the effective date of the sales prohibition, whichever is longer. The statute does not allow for renewal or extensions at the end of the 5-year period, instead the Department must issue a new separate determination. That determination must be based upon current information. If a manufacturer believes that nothing has materially changed since applying for the prior currently unavoidable use determination, the organization may resubmit an updated version of that proposal. That proposal must include a description of any changes since the time of the first currently unavoidable use determination and a summary of efforts made during that time to develop or discover alternatives or to make existing alternatives reasonably available. No change to the rule.

178. Comment: Commenter appreciates the Department's proposal to allow manufacturers to explain any missing information in a CUU proposal. (Commenter 41)

Response: The Department acknowledges the commenter's support.

179. Comment: Commenter acknowledges the Department's recommendation to exclude proprietary information from CUU proposals but emphasizes that such information may be necessary for regulatory determinations. Commenter states the Department should not reject proposals solely for including proprietary data and must establish procedures to protect legitimate, substantiated proprietary claims, similar to other regulatory processes (Title V Permits under the Clean Air Act is cited as an example). (Commenter 41)

Response: The Department's rulemaking is controlled by the requirements of the Maine Administrative Procedure Act and the statutory authority for this rulemaking (38 M.R.S. § 1614) does not authorize alternative rulemaking procedures. Therefore, the Department is

unable to establish a protocol as suggested by the commenter. Rulemaking must be supported by sufficient information which can be used publicly in compliance with the Department's rulemaking obligations and used to justify the Department's position in response to public comments. No change to the rule.

180. Comment: Commenter notes that the Department appears to place no limitation on the number of CUU renewals a manufacturer can request, and it anticipates a 12-month period between a CUU renewal determination and expiration. Given the complexity of transitioning to alternatives, a 12-month period is unrealistic. The commenter requests that the Department consider subsequent proposals no sooner than 36 months prior to, and no later than 24 months before, the expiration date of the current CUU determination. (Commenter 41)

Response: The Department has set the 12-month minimum anticipating that new currently unavoidable use proposals related to expired currently unavoidable use determinations will require less time for review and, therefore, allow for proceeding to rulemaking in a more efficient manner. Organizations are permitted to submit their requests prior to the 12-month minimum. The Department finds that extending the window from 24 to 36 months would result in processing requests less than halfway through a determination process. The Department finds this timeframe too short to adequately allow for the market to investigate alternatives prior to resubmission. No change to the rule.

181. Comment: Commenter urges the Department to make CUU determinations for broad product categories. Commenter states a category-based approach would be more efficient, ensure consistent treatment, and prevent the omission of critical products and that this method would better align with the statute's objectives. (Commenter 43)

Response: The Department understands the legislative intent to eliminate intentionally added PFAS from products sold in Maine, unless their use is currently unavoidable. The threshold for such determination is essential for the health, safety or functioning of society. The Department anticipates that broader categories will require significantly more documentation and increase the chances of the Department declining rulemaking. To ensure timely review and avoid declining a proposal that may have a portion that meets the standard

for essential for health, safety and the functioning of society, the Department finds narrowly tailored proposals to be advantageous. No change to the rule.

182. Comment: Commenter urges the Department to prioritize CUU reviews for medical, pharmaceutical, and animal health products to prevent delays. (Commenter 43)

Response: Prosthetic devices, orthotic devices, any product that is a medical device, drug or biologic or that is otherwise used in a medical setting or in medical applications that are regulated by or under the jurisdiction of the United States Food and Drug Administration, and veterinary product are exempted from the scope of this program by statute. The Department is establishing timetables for when it will review currently unavoidable use determination requests and encourages manufacturers to submit their requests as soon as it is practicable. No change to the rule.

183. Comment: Commenter provides specific language suggestions which will help the state ensure objective determinations and allow the Department to grant CUU status when sufficient evidence exists. Commenter states the language would allow CUU determinations that would extend to essential supply chain processes to prevent disruptions. (Commenter 43)

Response: The Department finds the proposed language to be duplicative of statutory definitions and proposed rule language. Regulated manufacturers whose products do not qualify for statutory exemption must submit a proposal for currently unavoidable use if they wish to continue selling products in Maine containing intentionally added PFAS. No change to the rule.

184. Comment: Commenter urges the Department to establish clear timelines for issuing determinations on CUU proposals. Commenter suggests if the Department fails to respond before the compliance deadline, the proposal should be automatically approved for at least six months, similar to EU RoHS. Commenter requests that the regulation include clear deadlines for DEP action on CUU proposals. Commenter also recommends provisions allowing applicants to provide additional information through interactions with DEP reviewers if needed. (Commenter 43, 49)

Commenter states Section 9(A) proposed timeline will leave manufacturers with little time to comply with CUU determinations that are released close to the deadlines within the rule. Commenter requests manufacturers of products waiting for CUU determinations have an exemption from applicable prohibitions while the Department is evaluating proposals. After a final determination is made to either grant or deny a CUU request, manufacturers should have sufficient time to comply. Commenter states this will include time to prepare for necessary notification requirements, or compliance with a sales prohibition. Because manufacturers are still gathering information on the uses of PFAS across the supply chain, we request that CUU proposals be received after the 18-month mark up to the sales prohibition and should be able to submit before the 36-month window. Commenter also requests flexibility with renewing expired determinations. (Commenter 15)

Response: The Department must make currently unavoidable use determinations through the Maine Administrative Procedure Act routine technical rulemaking requirements. Final determination occurs when a rule is adopted by the Board of Environmental Protection and assigned an effective date by the Maine Secretary of State. That process is variable depending on the amount of public engagement, whether a reposting is required, and whether the Board requires additional deliberative sessions. The Department anticipates conducting at least one such rulemaking per year. No change to the rule.

185. Comment: Commenter asks the Department to make a currently unavoidable use determination for fluoropolymers in industrial uses thereby exempting them from the ban. (Commenter 54)

Response: The Department understands the legislative intent of the statute to be the removal of intentionally added PFAS, where not a currently unavoidable use, from products sold in Maine. The threshold for such determination is essential for the health, safety or functioning of society. The Department anticipates that for broader categories significantly more documentation would be necessary and increase the chances of the Department declining rulemaking. To ensure timely review and avoid declining a proposal that may have a portion

that meets the standard for essential for health, safety and the functioning of society, the Department finds narrowly tailored proposals to be advantageous. No change to the rule.

186. Comment: Commenter states that additional language is necessary to require manufacturers to clearly articulate the specific characteristics necessary for the relevant product's function in the health, safety or functioning of society. Commenter urges that clarity is needed to provide specific criteria to guide industry when comparing known risks of PFAS with any risks posed by alternative materials. (Commenter 44)

Commenter is concerned that there are no rules that provide detail on what the Department will consider "essential for health, safety or the functioning of society" or how to determine if "alternatives are not reasonable available." Commenter strongly recommends the Department finalize a rule that clearly defines "alternative," "essential for health, safety or the functioning of society," and "reasonably available" to provide clarity to stakeholders. (Commenter 30)

Commenter states the Department should provide clearer guidance regarding what standard will be applied to determine if an alternative is "reasonably available." (Commenter 15) Commenter recommends simplifying to exclusively focus on requiring evidence to demonstrate that no safer alternatives to PFAS exist, including alternative designs or products that achieve the same primary function. Recommend removing A(4)(d) due to reference of a cost-based assessment and A(4)(e) because the law does not envision or require risk-based criteria for a CUU designation. (Commenter 19)

Response: Maine statute and the proposed rule provide a guide for currently unavoidable use determinations through the definition of the critical terms referenced by the commenter, which provides a strong framework for the Department's decision-making process. No change to the rule.

187. Comment: Commenter encourages the development of guidance relevant to pesticide products that address public health which contain an active ingredient considered a PFAS under Maine law and regulated in the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA). Commenter states this would provide clarity on whether these products will be exempt via Federal preemption or whether a CUU proposal must be submitted. It is unclear if this would apply to a pesticide product addressing public health pests containing an inert ingredient considered a PFAS under Maine law. (Commenter 30)

Response: Pesticides not used in the context of the statute's veterinary exemption are regulated by the rule. No change to the rule.

188. Comment: Commenter states that because the CUU criteria proposed are tailored to an individual manufacturer's request, commenter suggests adjusting proposal requirements to reflect that the submitter is an organization rather than an individual company. Commenter encourages the inclusion of additional language for separate processes to account for collective CUU proposal submissions. (Commenter 30)

Response: Currently unavoidable use proposal criteria are written in such a way that regardless of who submits the request, the Department has consistent levels of information on which to base its determination. No change to the rule.

189. Comment: Commenter states the CUU proposal criteria request more information than the statute requires and therefore adds a compliance burden for much of the proposed data as it would exceed information necessary to make a CUU determination. Commenter requests the Department consider making some of these requirements optional if they are not necessary to determine whether a use of PFAS is unavoidable. Commenter requests that the agency make clear the criteria it will use to make an affirmative finding for a CUU and how the requested information will relate to and inform that decision. Commenter states that information requests outside of this decision making should be removed to avoid confusion. Criteria for CUU should align with international scientific work, such as the European Union guiding principles and criteria for the essential use concept. (Commenter 15, 19)

Response: The Department has carefully considered the information necessary to make this determination. Currently unavoidable use proposal criteria are written in such a way that regardless of who submits the request, the Department has consistent levels of information on

which to base its determination. No change to the rule.

190. Comment: Commenter states the rule must include clear requirements for information to be submitted by manufacturers seeking an exemption from the law under CUU, current draft is too vague. Commenter states the burden is on the manufacturer to establish the scientific and health basis for any exemption, and the rule should detail what information and analysis meets this standard. Commenter states that some language in Section 9.A(7) is inappropriate and potentially confusing by suggesting scenarios that might justify a claim that an exemption should be granted in Maine despite compliance with a similar PFAS prohibition in another jurisdiction. Recommend striking second sentence of 7(a) and 7(b) should read, "Documentation that products containing PFAS alternatives in other jurisdictions would not perform as intended in the State of Maine." (Commenter 36)

Response: The Department has carefully considered the information necessary to make this determination. Currently unavoidable use proposal criteria are written in such a way that regardless of who submits the request, the Department has consistent levels of information on which to base its determination. No change to the rule.

191. Comment: Commenter states that legislatively defined, CUU determinations are based only on whether the use of PFAS in the product is necessary for the health, safety, or functioning of society; data on the impacts of PFAS itself on health and the environment would be unnecessary. Commenter recommends removing A(9) and any other requirements of risk-based or exposure related information. Commenter states that rather than ask for an open-ended comparison of risks, industry should be required to demonstrate that each of the alternatives identified in 4(a) have higher risks to human health and the environment than PFAS. (Commenter 19)

Commenter states it makes no sense to require risk-based criteria for this determination. It is settled science that PFAS, in almost any amount, is a risk to human health. The statute is not intended to establish a risk-based framework. (Commenter 46, 48)

A(4)(e) Commenter states that Maine Legislature did not enact a "risk-based" framework but

rather an "essential use-based" framework. Commenter believes the draft opens the door to unnecessary and unintended CUU designations. (Commenter 35)

Response: The statutory definition of "essential for health, safety or the functioning of society" establishes a review process which focuses on the risk of negative outcomes by the product's unavailability. Because of this, the Department has determined it is necessary to understand both the impacts caused by the presence and lack of availability of the PFAS in the regulated product. No change to the rule.

192. Comment: Commenter states this section should consider the potential overlap between future refrigerant regulations and the use of refrigerants containing PFAS. Commenter claims this industry often has multiple overlapping systems in place to ensure the safety of refrigerants. For instance, there may be times when EPA's Significant New Alternatives Policy (SNAP) program may prevent the use of non-PFAS refrigerants if there is no safe method for their use. Therefore, commenter recommends that the draft rule include state and federal regulations or codes as a valid unavoidable use category to ensure that if separate Maine or Federal regulations restrict alternative refrigerants this qualifies for the unavoidable use exemption. (Commenter 27)

Response: The regulatory programs cited by the commenter have varying objectives and do not specifically align with this program's objective to remove PFAS in non-essential uses. The Department is establishing timetables for when it will review currently unavoidable use determination requests and encourages manufacturers to submit their requests as soon as it is practicable. No change to the rule.

193. Comment: Commenter states the draft conflates several concepts, risks confusion as to what qualifies for a CUU exemption and creates unnecessary burdens for both regulated entities and the agency. Commenter recommends that criteria for CUU decisions be clearly stated and align with scientific literature and the guidance prepared by the EU Commission. Commenter recommends the following language in a new Subsection 9.A. Commenter suggests use of PFAS is a currently unavoidable use only if all of the following criteria are met: (1) There are no safer alternatives to PFAS that are reasonably available. (2) The

function provided by PFAS in the product is necessary for the product to work. (3) The use of PFAS in the product is critical for health, safety, or the functioning of society. (Commenter 40)

Response: The Department finds that commenter's proposed language is consistent with statutory and rule definitions. No change to the rule.

Confidential Business Information (CBI) in CUU

194. Comment: Commenter asks that the Department consider confidential information the same as publicly disclosed information when conducting currently unavoidable use rulemaking. Commenter suggests the confidential information could be made available to the Board and the Department and the public would be provided summaries and general information. (Commenter 6)

Commenter expresses concern over the Department's recommendation against including confidential business information (CBI) in CUU proposals, as required details like chemical identities and functions are proprietary and commercially sensitive. Commenter states given the medical, pharmaceutical, and animal health industries' reliance on protecting such information, the Department should establish mechanisms to safeguard CBI. Suggested approaches include allowing companies to submit both redacted and unredacted versions of proposals, conducting in-camera reviews, and ensuring the notification portal has a robust CBI framework. (Commenter 43)

Commenter argues that the Department's stance of not allowing confidential information in CUU applications is impractical and unworkable. Commenter states that without confidentiality protections, manufacturers may be unable to utilize the CUU process. Commenter mentions products tied to national security, which are subject to strict secrecy requirements beyond the exemptions for DOD, NASA, or FAA-specified items. (Commenter 49)

Commenter states that some information requirements may trigger proposers to request

confidentiality within the criteria for CUU proposals. This includes the request for an assessment of the cost difference between obtaining PFAS for us in a product and without use of PFAS. Commenter believes it is important that the Department be able to claim certain information as confidential within the process and justify a rulemaking on portions of what can be made public within the rulemaking process. (Commenter 30)

Response: The Department's rulemaking is controlled by the requirements of the Maine Administrative Procedure Act and the statutory authority for this rulemaking (38 M.R.S. § 1614), does not authorize alternative rulemaking procedures. Therefore, the Department is unable to establish protocol as suggested by the commenter. It is incorrect to say that the Department does not allow proprietary information submitted in the CUU process to remain confidential; as the rule notes, a mechanism for protection of proprietary information is available. It is also true that all rulemakings must be supported by sufficient information which can be made public to support the Department's rulemaking decision and used to justify the Department's position in response to public comments. No change to the rule.

195. Comment: Commenter states that with respect to CUUs, and also notifications, commenter notes that pesticide formulations are protected by state and federal law. Commenter further states "the proposed rule does not provide adequate assurances … it is foreseeable that important pesticide products may not be …" Commenter makes mention of the Confidential Statement of Formula submitted to federal regulators as part of the product registration. (Commenter 18)

Response: Such documents will be handled in accordance with Departmental policies governing records that may contain confidential information, SOP Number OC PE 0006. The Department also allows for information that is requested to be absent from a proposal, however, the requestor must explain why the information is omitted. No change to the rule.

196. Comment: Commenter appreciates the Department's recognition of the need to keep proprietary information in CUU proposals confidential and handle it accordingly. (Commenter 37)

Response: The Department appreciates the commenter's support.

197. Comment: Commenter urges the Department to allow CBI claims in CUU proposals and the reporting portal; without protections, companies may withhold proposals to avoid exposing sensitive data, leading to reduced participation and regulatory gaps. (Commenter 43)

Commenter argues that prohibiting confidential information in CUU submissions is impractical, as product composition is often a trade secret. They warn this policy could make the CUU process unusable. (Commenter 12)

Commenter recommends removing parts of the proposed regulation that suggest companies should not submit confidential business information (CBI). Commenter states that if companies cannot claim information as CBI, they may avoid requesting exemptions for Commercial Use of Unregistered (CUU) products. (Commenter 13)

Commenter states the Department should protect confidential information when reviewing CUU determinations to ensure comprehensive reviews and create a way to share private information securely with the BEP/state during the rulemaking process without making it public. (Commenter 29)

Response: The Department does not require confidential information to be provided as part of a request and it will accept request which contain such claims. The Department also allows for information that is requested to be absent from a proposal, however, the requestor must explain why this information is omitted. With respect to currently unavoidable use determination requests, the Department's rulemaking is controlled by the requirements of the Maine Administrative Procedure Act and the statutory authority for this rulemaking (38 M.R.S. § 1614), does not authorize alternative rulemaking procedures. Therefore, the Department is unable to establish protocol as suggested by the commenter. All rulemakings must be supported by sufficient information which can be made public to support the Department's rulemaking decision and used to justify the Department's position in response to public comments. Regarding the notification requirement, and all confidential business information in general, the statue at 38 M.R.S. § 1614 (12) requires the Department to

handle CBI in the same manner indicated in 38 M.R.S. § 1310-B. No change to the rule.

Currently Unavoidable Use Proposals

198. Comment: Commenter suggests that the known or reasonably ascertainable standard be applied to the currently unavoidable use submissions. Commenter requests that Section 9(A) be amended to read "A proposal must at a minimum contain the following information to the degree it is known or reasonably ascertainable". Commenter requests more consideration for manufacturers with complex supply chains, where the end use of products is unknown. (Commenter 1, 25)

Response: The Department allows for information that is requested to be absent from a proposal, however, the requestor must explain why this information is omitted. No change to the rule.

199. Comment: Commenter is concerned the June 1, 2025, submission deadline for filing a CUU proposal is not enough time for producers to collect necessary information, draft and file requests. Commenter is concerned about continued access to these important products that help keep many Mainers, including first responders, safe. Commenter is concerned that without a longer timeline, these products may not be allowed in the marketplace and will be disposed of. (Commenter 5)

Commenter states that there is not enough time for the CUU process to have useful or effective impact relative to the sales prohibitions that begin Jan 2026. Commenter states that because the Department anticipates that manufacturers would only have certainty about their product's CUU status mere days or weeks before the January 1 compliance date, the proposed timeline for CUU submittal and evaluation has the potential to create significant commercial disruption. In addition, commenter is concerned products denied a CUU determination should be given additional time to comply with the prohibition. Commenter requests the Department provide interim exemption approvals to give certainty to manufacturers while the Department evaluates final CUU designation. Commenter suggests amending the draft rule to provide the CUU submitter an interim exemption up to 180 days

from the date a CUU proposal is submitted. Commenter also suggests providing an assurance that products denied CUU status be granted up to 2 years from the date of rejection to meet the applicable prohibition requirements, in addition to the Department's enforcement discretion. (Commenter 8)

Response: The Department requires six months to review proposals and move through the routine technical rulemaking process. The Department does not have the statutory authority to delay implementation or issue broad exemptions. No change to the rule.

200. Comment: Commenter requests the Department adopt criteria proposed by European Union for the determination of essential for "health or safety" and, separately, for "the functioning of society." (Commenter 14)

Response: The Department finds that the European Commission's "Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals" may be a valuable reference as we review CUU proposals. However, Maine is not bound by European law, it was not incorporated in the statute and the Department finds it would be inappropriate to incorporate it into the rule. No change to the rule.

201. Comment: Commenter urges the Department to adopt a risk-based approach to fluoropolymers more broadly when considering CUU exemption requests. (Commenter 13)

Response: Maine statute does not give the Department the discretion to differentiate between types of PFAS. No change to the rule.

202. Comment: Commenter states the Department should include an exemption from the 2032 ban and the need for a CUU determination for PFAS in quantities of less than 0.1% by weight of the final product. (Commenter 13)

Response: Maine statute does not give the Department the discretion to differentiate between types of PFAS or set a de minimis. No change to the rule.

203. Comment: Commenter states the Department should issue a standardized form to submit CUU requests. (Commenter 13)

Response: The Department has provided the details of criteria for currently unavoidable use proposals in rule, anticipating that organizations wishing to submit a proposal will rely on language in the rule. The Department anticipates providing a form based on the rule after it is adopted. No change to the rule.

204. Comment: Commenter suggests adding the language to Section 9, CUU decisional criteria: First, "the function provided by the PFAS is necessary for the product to perform as intended". This requires information sufficient to understand how the PFAS functions in the product. Second, "the unavailability of the PFAS . . . would cause the product to be unavailable". Commenter states information on product performance and competing alternatives would be required. Third, the unavailability of the product would result in either "a significant increase in negative health outcomes," "an inability to mitigate significant risks to human health or the environment," or "a significant disruption of the daily functions on which society relies." Commenter states this requires information on the purpose of the product and an outcomes assessment if it were no longer available in Maine. (Commenter 13)

Response: The proposed rule provides sufficient criteria for the necessary rulemaking process. The Department finds the suggested language does not add clarity. No change to the rule.

205. Comment: Commenter states the rule should reduce the information required for a CUU exemption request by only requiring the information required should be limited to that necessary to make the finding required by the statute. (Commenter 13)

Commenter criticizes the CUU determination process for collecting information that should have been reviewed before the PFAS ban, placing a burden on those seeking CUU determinations. (Commenter 53)

Response: The Department finds the information requested to be necessary to support the

routine technical rulemaking process as required by statute. Sales prohibitions are set by the Legislature; Maine statute does not provide the Department with the authority to make changes. No change to the rule.

206. Comment: Commenter states the Legislature did not list health and environmental effects as a consideration for reaching CUU determination. While Maine's law otherwise directs the Department to address the impacts of PFAS on humans and the environment, the CUU determination is an exception for essential uses if there are no current alternatives. Commenter states the Department should consider removing this provision. (Commenter 13)

Response: The rule reflects both statutory definitions of alternative and essential for the health, safety and functioning of society which provides for consideration of the reduction for the potential for harm to human health or the environment. No change to the rule.

207. Comment: Commenter requests the Department retain the discretion for deciding whether a CUU determination should be time-limited or not. Commenter states the statute does not require that CUU determinations be time-limited and includes several exemptions that are not time-limited, asks the Department to consider making CUU exemption determinations that are not time-limited for critical sectors in which there is little or no potential to expose consumers or the environment and alternatives cannot be identified. (Commenter 13)

Response: The statute at Section 5 (F)(1)(a) and (b) place a 5-year limit on currently unavoidable use determinations and does not provide the Department with the authority to make changes. No change to the rule.

208. Comment: Commenter requests the Department clarify that testing is not a requirement of this rule. Commenter states that testing would be cost-prohibitive and difficult because test methods are still under development. (Commenter 13)

Response: The statute specifies the conditions under which testing is required and provides for alternative methods when no commercially available analytical methods are available.

No change to the rule.

209. Comment: Commenter suggests adding language that products covered by a CUU determination are not subject to prohibition for the entire life of the product. This includes any maintenance, which may involve repairing or replacing individual parts. Commenter suggests new language "Products sold under a CUU determination are exempt from prohibition for the life of the product, including maintenance of the product." (Commenter 21)

Response: Parts and materials sold as a product for the maintenance and servicing of a regulated product are considered a separate product and subject to the rule. Maine statute places a 5-year limit on currently unavoidable use determinations and does not provide the Department with the authority to make changes. No change to the rule.

210. Comment: Commenter states that building a new manufacturing facility or modernizing an existing one usually requires 5 to 10 years of advance planning. Commenter states timelines are influenced by the scale and complexity of the project, regulatory and permitting approvals, and market conditions. Commenter recommends extending the CUU submission period to 60 months to provide companies with sufficient time to prepare and adapt. This new timeline can create a stable regulatory environment in Maine and may lead to economic growth and encourage technological innovation. (Commenter 22, 25)

Response: Statute limits currently unavoidable use determinations to 5 years. The Department lacks authority to provide longer time for requirements. No change to the rule.

Currently Unavoidable Use – GPC/HTS

211. Comment: Commenter requests broader product categories than the proposed codes. During the Department's prior rulemaking this commenter submitted the requested information for a CUU proposal and found over 600 relevant HTS codes for regulated products. Commenter believes this process would be simplified if the Department would issue CUUs based on industry sector. Commenter proposes that the CUU proposals should be accepted more

broadly and not limited to specific HTS/GPC and NAICS combinations. CUU proposals should be focused on entire industry sectors, like the electronics sector. (Commenter 15, 33)

Response: The statutory intent is the reduction and/or elimination of intentionally added PFAS, broad determinations run contrary to this intent. Further, the Department is limited to currently unavoidable use determination in the narrow context of "identifying specific products or product categories containing intentionally added PFAS for which it has determined the use of PFAS in the product is a currently unavoidable use." An industry or sector wide determination would be overly broad. No change to the rule.

Essential for Health, Safety or the Functioning of Society

212. Comment: Commenter suggests that the criteria for determining what is "essential for health, safety, or the functioning of society" should also consider the broader societal impacts beyond the direct use of the product. Additionally, when evaluating whether alternatives are "reasonably available," the Department should consider the direct and indirect costs and risks throughout the supply chain. Commenter suggests clarifying that a proposal must show that the product itself is essential for health, safety or the functioning of society, and also why the availability of PFAS identified in the specific product is essential for health, safety or functioning of society. (Commenter 14, 43)

Response: The rule provides currently unavoidable use proposal criteria sufficient for the Department's assessment against statutory definitions, definitions proposed in rule, and the routine technical rulemaking process. No change to the rule. .

213. Comment: Commenter requests the Department replace "may" with "must" to conform with requirements of statute at § 1614(1)(B-1) making the description of a negative impact due to unavailability required. (Commenter 14)

Response: The section cited by commenter provides an optional format of the information requested but it does not clarify that the information that is requested is optional. No change

to the rule.

PFAS Use

214. Comment: Comment states, with respect to current unavoidable use criteria addressing the specific use of PFAS and description of alternatives, that proposals must be allowed in a more general format as suppliers are often unable to indicate why PFAS is used or if there are alternatives. (Commenter 54)

Response: The Department anticipates that it will be unable to make a determination of whether the use is currently unavoidable if the fundamental reason the PFAS is added is not disclosed. Not only is an assessment of alternatives not possible without this point of comparison, but a product containing PFAS cannot be said to perform better than a non-PFAS containing product without a point of comparison. Given that the statutory intent is the reduction or elimination of intentionally added PFAS, the reason for intentionally including PFAS is necessary as part of the justification for its continued use. No change to the rule.

215. Comment: Commenter states that Section 9(A)(3)(b) should also require a description of why the characteristic(s) described is necessary for the product to perform as intended. Without this requirement the description may merely show that a certain characteristic of the product depends on PFAS, without adequately showing that this characteristic is actually essential for the product to function. Commenter states proposals should describe why this characteristic(s) is necessary for the products' function in health, safety, or the functioning of society. Commenter states the intent of law to ensure that these chemicals are used only when absolutely essential. For this reason, industry must be required to provide clear information about why this characteristic is necessary for the products' function for the health, safety or functioning of society. (Commenter 14, 19, 48)

Response: The Department considers the requested information to be sufficient to address these questions. Should there be a case where questions remain, the Department has the ability to request additional information. No change to the rule.

216. Comment: Commenter requests clearer guidance regarding what qualifies as "essential for health, safety or the functioning of society." Commenter recommends the Department establish clear criteria for making CUU decisions so that the required information clearly connects to the corresponding criteria. This would serve the purpose of eliminating unnecessary questions and streamlining the process for all parties. Commenter states the EU guiding principles and criteria for the essential use concept should be reflected in the rule. (Commenter 14, 46)

Response: The Department finds the statutory definition is sufficient for assessment criteria and the European Commission's "Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals" may be a valuable reference as we review currently unavoidable use proposals. However, Maine is not bound by European law, it was not incorporated in the statute and the Department finds it would be inappropriate to incorporate it into the rule. No change to the rule.

Availability of Alternatives

217. Comment: Commenter is concerned that complex product manufacturers may not have the required data on PFAS alternatives and their effects. The commenter requests clarification on the level of due diligence required and the consequences of incomplete information. (Commenter 12)

Response: A requestor of a currently unavoidable use determination may omit any information that they do not have access to, the proposed rule requires them to explain the absence of the omitted materials. The absence of information will not automatically result in the Department declining to initiate rulemaking; however, the totality of the request must be sufficient to justify the rulemaking. No change to the rule.

218. Comment: Commenter interprets Section A(2) as requiring manufacturers to justify PFAS use based on performance and safety considerations. Commenter requests clarification if the Department interprets this requirement differently and suggests the final regulation explicitly state its intended meaning. (Commenter 41)

Response: The Department is requesting information that would justify a determination that the use of PFAS in a product meets the criteria set out in the statutory term "essential for health, safety or functioning of society" meaning that the PFAS is necessary for the product to perform as intended, without the PFAS the product would be unavailable, and if the product where unavailable it would result in the negative outcomes found in the definition. Safety and performance are aspects of this, but only within the subset of products that would result in the defined negative outcomes should they be unavailable. No change to the rule.

219. Comment: Commenter emphasizes that the evaluation of "reasonably available alternatives" must consider real-world commercial availability, total transition costs across supply chains, and potential risks throughout a product's lifecycle. These risks include sustainability impacts, product safety, efficacy, availability, and disposal. (Commenter 43)

Response: The Department notes that the definition of reasonably available references costs and currently unavoidable use request criteria include information on the lifecycle impact on human health and impacts on the environment. All of these criteria will be reviewed when assessing whether to make a currently unavoidable use determination. No change to the rule.

220. Comment: Commenter cites section A(3)(b), that "A justification for the need for PFAS for the function of the product alone should not be sufficient for a currently unavoidable use (CUU) exemption." (Commenter 4)

Response: For the Department to make a currently unavoidable use determination it must be determined that the use of the PFAS in the product is a currently unavoidable use. According to statute, that means "that the unavailability of the PFAS for use in the product would cause the product to be unavailable, which would result in: (1) A significant increase in negative health outcomes; (2) An inability to mitigate significant risks to human health or the environment; or (3) A significant disruption of the daily functions on which society relies." The Department will assess impacts that might occur as a result of the product being unavailable, not just that PFAS is necessary for the product, when assessing currently

unavoidable use requests. No change to the rule.

221. Comment: Commenter states that requiring information on production volume and cost is impractical, as exchanging such data with competitors could raise antitrust concerns. Commenter believes PFAS manufacturers cannot provide this information and suggest it should not be required. (Commenter 23)

Response: The Department allows for information to be omitted from a determination request however the requestor must explain why this information is omitted. The Department requests information on whether alternatives are available in sufficient quantity and cost difference to support a finding that any identified alternatives are not reasonably available. If the request does not supply sufficient documentation to support the use of PFAS in the product is essential for health, safety or the functioning of society and that there are no reasonably available alternatives it will not be able to a currently unavoidable use determination. The Department encourages manufacturers to provide as much information as they are able to in support of a currently unavoidable use request. No change to the rule.

222. Comment: Commenter requests clarification on the due diligence standard for providing "known or reasonably ascertainable" information, including the level of effort required and potential consequences if such information cannot be supplied. (Commenter 49)

Response: "Known or reasonable ascertainable" is defined in statute and is a frequently used and understood term in environmental regulation at the state and federal levels. The definition and common usage are sufficient without further defining the term. If a manufacturer has a specific question about their circumstances, they are welcome to contact Department staff prior to submitting a determination request. No change to the rule.

223. Comment: Commenter argues that alternative assessments should acknowledge responsibly manufactured PFAS chemistries. Commenter highlights concern about fluorosurfactant process aids but emphasize their investment in eliminating these substances from U.S. fluoropolymer production while maintaining product performance. (Commenter 50)

Response: The statutory definition and its use in the statute does not give the Department the authority to differentiate between classes of or individual PFAS. No change to the rule.

224. Comment: Commenter states that information in subsections (c) and (d) can only be determined after subsections (a) and (b) and accomplished. As a result, commenter requests a longer timeframe and reference their suggestion of 25 years. (Commenter 54)

Response: Statute sets the effective dates of sales prohibitions, 2023; 2026; 2029; 2032; and 2040, and does not grant the Department the ability to extend these effective dates. The Department encourages any manufacturer that believes their products meet the criteria of a currently unavoidable use to submit a request to the Department containing as much information as possible during the timeframes found in the adopted rule. No change to the rule.

225. Comment: Commenter states, with respect to subsection (e) comparison of risks, there is a dearth of standardized test methods and recommends the Department set standard test methods in the rule. (Commenter 54)

Response: The Department acknowledges the commenter's desire for a standardized test. However, the Department finds that maintaining flexibility to address thousands of chemicals across potentially tens of thousands of products is necessary. No change to the rule.

List Applicable State and Federal Laws

226. Comment: Commenter recommends removing the requirements of product status in other states, comparable products in those jurisdictions, and product substitutability, as these may not be relevant or could duplicate existing criteria. (Commenter 23)

Response: The Department anticipates whether a product is subject to a sales prohibition in another jurisdiction and whether it has been granted or denied a currently unavoidable use determination, or similar, to be highly relevant. Suitability, specific to the condition in Maine, is offered as a method to justify why Maine's analysis should reach a different outcome than

other jurisdictions. No change to the rule.

227. Comment: Commenter states the Department should work with other programs (EPA, FDA) to ensure clear regulations and avoid duplication. Commenter states that PFAS products that meet federal standards for military or aviation use should be essential. This will help the Department target non-essential uses in consumer products, and it ensures fairness and stability for businesses that have passed federal reviews for their PFAS products. (Commenter 29)

Response: The regulatory programs cited by the commenter have varying objectives and do not specifically align with this program's objective to remove PFAS in non-essential products. The Department is establishing timetables for when it will review currently unavoidable use determination requests and encourages manufacturers to submit their requests as soon as it is practicable. No change to the rule. No change to the rule.

Department Designating Currently Unavoidable Use

228. Comment: Commenter states that there should be very specific criteria to meet this requirement for supporting documentation, such as primary literature citation, copies of cited studies, results and methodology of a systematic literature review, data analysis, and other scientific methodologies. (Commenter 19)

Response: The Department has provided sufficient criteria in the rule to make determinations through the rulemaking process. Where there are deficiencies in a proposal, the Department has the authority to request supplemental information. No change to the rule.

229. Comment: Commenter states the Department could consider modelling the determination approach to the EPA's SNAP program (Identification of Alternatives, Regulatory Determination, Sector-Specific Guidelines, Stakeholder Engagement, Technology Assessment and Innovation, Compliance Monitoring and Enforcement) (Commenter 29)

Response: The regulatory programs cited by the commenter have varying objectives and do

not specifically align with this program's objective to remove PFAS in non-essential products. The Department is establishing timetables for when it will review currently unavoidable use determination requests and encourages manufacturers to submit their requests as soon as it is practicable. No change to the rule.

230. Comment: Commenter states that a CUU which is submitted by an individual company or group and granted by the Department should be able to be used by all other entities using the granted uses. (Commenter 33)

Response: Anyone may utilize a currently unavoidable use by submitting the required notification. Applicability of the currently unavoidable use is not limited to the specific applicant. No change to the rule.

231. Comment: Commenter requests an appropriate transition period is given in case of not granting the CUU proposal. Commenter requests that CUU is tentatively granted during examination of the CUU proposal by the Department. (Commenter 33)

Response: Language regarding effective dates of prohibitions is established in statute. The Department does not have the authority to modify this section to allow regulated products manufactured after a prohibition is in effect to remain for sale in opposition to Maine law. No change to the rule.

Proprietary Information

232. Comment: Commenter argues that the cited provision on protecting confidential information does not specifically apply to the PFAS-in-products law. Commenter requests that the Department clarify how confidentiality will be ensured and provide the statutory basis for its interpretation. Commenter states that the Department 's cited provision on protecting confidential information does not explicitly apply to the PFAS-in-products law (38 M.R.S. § 1614). Commenter requests the Department clarify how confidentiality will be ensured under the Proposed Regulations and provide the statutory basis for this interpretation. (Commenter 12, 49)

Commenter states that requirements to disclose confidential business information need greater structure and clarity to protect manufacturers and suppliers. Commenter urges the Department to specify security measures to prevent theft, loss, or unauthorized access to sensitive data, as improper handling could compromise intellectual property and create a competitive disadvantage. (Commenter 57)

Response: Such documents will be handled in accordance with the Departmental policies governing records that may contain confidential information, SOP Number OC PE 0006, as well as at 38 M.R.S. section § 1614 (12). No change to the rule.

233. Comment: Commenter appreciates that the Legislature has directed the Department of Environmental Protection (DEP) to protect proprietary information in administering the program. (Commenter 23)

Response: The Department acknowledges the commenter's support.

234. Comment: Commenter appreciates the note in Section 9 discouraging claims of confidentiality within CUU proposals. In Section 19, Proprietary Information, the Department should make clear that information on health or environmental impacts must never be classified as confidential. (Commenter 36)

Response: All claims of confidentiality will be assessed in accordance with the Department's SOP on such matters. No change to the rule.

235. Comment: Commenter is concerned about the interpretive note in Section 9A that states the Department may not be able to justify a rulemaking to approve a CUU proposal that contains claims of confidentiality. However, the Department's criteria required for CUU requests could require the disclosure of trade secrets and other competitively sensitive information. Commenter states that companies will be placed in an untenable position of having the relinquish trade secret information they could erode its competitive position globally if such proprietary information is not protected. Commenter requests that the Department either

clarify the level of technical detail needed to complete a CUU proposal pursuant to Section 9 or establish a means for redacting confidential details from publicly available aspects of the rulemaking process, similar to Title V air permits. (Commenter 56)

Response: The Department's rulemaking is controlled by the requirements of the Maine Administrative Procedure Act and the statutory authority for this rulemaking (38 M.R.S. § 1614), does not authorize alternative rulemaking procedures. Therefore, the Department is unable to establish protocol as suggested by the commenter. All rulemakings must be supported by sufficient information which can be made public to support the Department's rulemaking decision and used to justify the Department's position in response to public comments. No change to the rule.

Miscellaneous

236. Comment: Commenter urges the Department to coordinate with the Board of Pesticide Control, specifically with regards to BPC's process for how information can be submitted and protected. (Commenter 18)

Response: Exemptions listed in the rule are statutory. The Department does not have the authority to grant additional exemptions. No change to the rule.

237. Comment: Commenter acknowledges Maine's strict PFAS regulations but warns that overly stringent rules could eliminate essential applications and drive industries to other states. Commenter urges Maine to align its regulations with other states and the federal government to ensure balanced and practical policies. (Commenter 23)

Response: The Department finds that its proposed rule is consistent with Maine's statute. Within that confine, the Department has aimed for alignment with similar regulatory programs. No change to the rule.

238. Comment: The commenter expresses concern that applying statutory sales prohibition to upstream suppliers or non-exempt products used in research and development or distribution

could affect the availability of exempted products. Commenter claims this could contradict the Legislature's intent to ensure access to these critical products. Commenter urges that the CUU standard in the statute should not be narrowly applied, as it could impact exempted products and create uncertainty in the market. (Commenter 43)

Response: Because notification is based on a currently unavoidable use designation, which is grouped by product category and industry sector, multiple products may be included in one notification. Exempt equipment is not subject to reporting under the rule. No change to the rule.

239. Comment: Commenter urges the Department to include a 0.1% by weight de minimis threshold for PFAS, aligning with other regulations and reducing the due diligence burden on supply chains. (Commenter 43)

Response: Maine statute does not give the Department the discretion for an additional exemption for de minimis PFAS content. No change to the rule.

240. Comment: Commenter wants a definition of "reasonably available alternative" as follows: "Reasonably available alternative" means a substance, material, technology, process, or otherwise that is currently available at commercial scale and that, when used in place of intentionally added PFAS, does not result in:

(a) A decrease in availability, performance, life expectancy, quality, or durability of the product or of any upstream or downstream manufacturing, distribution, or research and development activities associated with that product;

(b) A significant increase in manufacturing, design, testing, capital investment, or other costs for the product or for any upstream or downstream manufacturing, distribution, or research and development activities associated with that product; or

(c) Risks to human health or the environment that would not be present, or present in lesser degrees, with use of the intentionally added PFAS, including but not limited to risks from toxicity, energy consumption, product safety, product unavailability, and disposal."

Commenter argues that the Department's proposed definition lacks clarity and should be revised to account for supply chain impacts. The definition should ensure that alternative

assessments consider potential disruptions to exempted products under 38 M.R.S. § 1614(12). (Commenter 43)

Response: The Department finds the statutory definition of alternative and reasonably available to be sufficient. No change to the rule.

241. Comment: Commenter highlights the complexity of global supply chains and the challenge of obtaining PFAS information from upstream suppliers in a timely manner. Commenter states to address this, they request that the Department include a provision ensuring manufacturers are not penalized if they make a good-faith effort to determine PFAS presence but receive supplier notifications only after a restriction takes effect. (Commenter 49)

Response: The proposed rule applies the known or reasonably ascertainable standard in several locations. In addition, the Department allows for information to be omitted from currently unavoidable use determination requests so long as its absence is justified by the manufacturer. No change to the rule.

242. Comment: Commenter appreciates the removal of a burdensome reporting requirement but opposes the broad application of a "currently unavoidable use" framework to an entire class of chemicals. (Commenter 50)

Response: Both the definition of PFAS and the currently unavoidable use framework are established in statute. The Department lacks authority to deviate from statute in these aspects. No change to the rule.

243. Comment: Commenter argues that fluoropolymer manufacturers require sufficient market demand to justify high operational costs and remain competitive globally. Limiting approvals to only certain "currently unavoidable" uses risks disrupting the broader supply chain. Commenter warns that restricting PFAS use without assessing individual chemical risks could undermine critical industries by shifting supply to foreign manufacturers. (Commenter 50)

Response: Both the definition of PFAS and the currently unavoidable use framework are established in statute. The Department lacks authority to deviate from statute in these aspects. No change to the rule.

244. Comment: Commenter states that Maine's broad PFAS restrictions conflict with its goal of achieving GHG neutrality by 2045. Commenter states that without exemptions, energy developers would lose access to critical technologies, increasing reliance on fossil fuels and raising energy costs. (Commenter 50)

Response: Both Maine's greenhouse gas goal and its PFAS sales prohibition are established in statute. The Department understands that the PFAS sales prohibition will impact certain components or technologies; however, the Legislature has provided for currently unavoidable uses to permit continued use of PFAS where it is necessary for health, safety or the functioning of society and where there are no reasonably available alternatives. No change to the rule.

THIS PAGE INTENTIONALLY LEFT BLANK