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Via Email: PFASproducts@maine.gov

November 10, 2022

Commissioner Loyzim:

Thank you for the opportunity to comment on the Maine Department of Environmental Protection's ("DEP's") second concept draft rule for the Maine "PFAS in Products Program" (the "Program") that was discussed during the DEP-conducted stakeholder meeting on October 27th and that will implement the notification requirement set forth in 38 MRS § 1614(2). IDEXX previously submitted comments on the first concept draft rule for the Program on July 18, 2022 and incorporates those comments herein.

As you are aware, IDEXX's global headquarters are here in Maine, where approximately 90% of our world-wide manufacturing occurs and where we spend approximately $150 million on research and development locally each year. In Maine, IDEXX receives materials necessary for its manufacturing that may be subject to the Program, and similarly manufactures products in Maine that may be subject to the Program but that are essential to the functioning of society, such as diagnostic tests for infectious diseases, diagnostic instruments for blood chemistry, hematology, urology, and blood gases, and drinking water safety. IDEXX sells both human and veterinary In Vitro Diagnostic products in Maine.

Reduction of harmful environmental contaminants is at the core of our business, and it is for that reason that IDEXX was pleased to have the opportunity to participate in the June and October stakeholder meetings. IDEXX hopes that the comments it provides below enable the DEP to craft a rule that achieves our shared environmental protection objectives while also ensuring that essential products such as IDEXX's remain available and of the same high quality and performance within IDEXX's heavily regulated marketplace. It is inherent to IDEXX's mission that we maintain the ability serve our customers in the human and animal health industries without interruption. Accordingly, changes in regulatory requirements that impact the products IDEXX manufactures – products that are already subject to multiple regulatory regimes and that therefore cannot easily be changed or replaced – must address the realities of information availability across the supply chain as well as the importance of these products to societal health and safety.

IDEXX's specific revisions to the second concept draft rule are in the attached redline of that rule. At a high level, however, IDEXX has the following comments:

1. Exemption from notification.

Because IDEXX's products are essential for health, safety, and the functioning of society and any use of PFAS within those products likely unavoidable, it is highly likely that its products will be exempted from the notification requirement on the grounds that the use of PFAS in those products is a "Currently

Unavoidable Use." 38 MRS § 1614(7)(A). IDEXX understands, however, that the Department's rulemaking process for designating products in which the use of PFAS is "currently unavoidable" is a separate major substantive rulemaking process that the Department does not anticipate commencing until late 2023 or early 2024. Nevertheless, it is critical that the DEP include in the present rulemaking an exemption for products such as IDEXX's, which are essential to maintaining the health and safety of consumers around the world.

IDEXX's understanding is that the 38 MRS § 1614(5)(C) major substantive rulemaking will focus on the function of the PFAS substances within a product, and not the essentiality of the product itself. In other words, whether a product will be determined to be exempt under the 38 MRS § 1614(7)(A) "currently unavailable use" exemption hinges on whether it contains PFAS "for which alternatives are not reasonably available." Understandably, given the complexity of such determination and the limited information available across the supply chain, the Department has not initiated that analysis. However, it is illogical to subject products that are "essential for health, safety or the functioning of society" – that may or may not contain currently unavoidable uses of PFAS – to the notification requirement and accompanying sales prohibition in the interim. Accordingly an exemption for essential products is necessary now.

In fact, the Legislature explicitly directed the DEP to "collect information regarding the use of PFAS in and to phase out the sale of certain nonessential products containing PFAS." *An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*, L.D. 1503 (the Act), Emergency preamble (emphasis added). For this reason, the Legislature made clear that the only portion of the Act that is subject to major substantive rulemaking is the adoption of rules identifying products by category or use that may not be sold, or that are exempt from such sales ban, effective January 1, 2030. 38 MRS §§ 1614(5)(C)-(D) and (10). Nothing in the Act or in its implementing statute constrains the DEP's ability to adopt additional and reasonable exemptions to the January 1, 2023 notification requirement and sales prohibition.

The Department's obligation to adopt rules to implement every other provision, including the 38 MRS § 1614(1) "Definitions," the 38 MRS § 1614(4) "Exemptions," and the 38 MRS § 1614(7) "Failure to provide notice," is instead subject to the present routine technical rulemaking process. In other words, the DEP is free to clarify in this rulemaking what products qualify for exemptions in the section 4(A) exemptions or in the section 7(A) prohibition exemptions. Doing so will ensure that the Department's present efforts to "collect information" via 38 MRS § 1614(2) applies only to "nonessential" products. Accordingly, IDEXX makes two requests.

First, IDEXX requests that the section 2(I) definition of products "Essential for Health, Safety, or the Functioning of Society" be revised to make clear that it includes those products required for the delivery of essential human, production animal, pet, and environmental diagnostics (the "Human and Veterinary Diagnostic Sector"). Such products enable the health and well-being of people, livestock, and pets, and ensure the safety of milk and water, here in Maine, throughout the United States, and in more than 175 countries globally. If IDEXX's products became unavailable there is no doubt that a significant increase in negative healthcare outcomes, an inability to mitigate significant risks to human health or the environment, and a significant interruption to the daily functions on which society relies (such as access to safe drinking water) would ensue.

Second, IDEXX requests that products defined as "Essential for Health, Safety, or the Functioning of Society" be included in the section 4(A) exemptions and/or in the section 7(A) sales prohibition exemptions. Such revisions will ensure that there is no interruption in the provision of products that enable the health and safety of people, livestock, and pets and will promote DEP's core value: a clean environment where public health and natural heritage are protected.[1]

Consumers in Maine deserve no interruption in the supply of products that are essential to their health and well-being. Certainly, the Legislature's intent was not to hamstring such supply with a notification requirement and accompanying sales prohibition effective in 2023 pending a separate rulemaking exempting PFAS uses effective in 2030. At a minimum, the DEP should exempt from the notification requirement and sales prohibition those products that are "Essential for Health, Safety, or the Functioning of Society" until the conclusion of the Department's rulemaking designating products as exempt under the "Currently Unavoidable Use" exemption.

2. Extension of notification.

Should IDEXX's products not be exempted from the notification requirement, IDEXX requests that the second concept draft rule provide for extensions of the January 1, 2023 notification requirement, as did the first concept draft rule. While IDEXX understands that the January 1, 2023 notification deadline, as well as the prohibition on the sale of products that do not meet that deadline, are statutory, so too does the statute expressly provide for an extension of this deadline. 38 MRS § 1614(3) ("The department may extend the deadline for submission by a manufacturer of the information required under subsection 2 if the department determines that more time is needed by the manufacturer to comply with the submission requirement."). There is no prohibition on a blanket extension by rulemaking where "more time is needed," as countless manufacturers have made clear is the case here. Indeed, the DEP has granted approximately 1,000 extensions of the January 1, 2023 notification deadline to-date.[2] IDEXX, like many other manufacturers, has demonstrated that a short extension of this deadline is inadequate given the realities of information gathering across the supply chain. As IDEXX explained in its July 18, 2022 comments, using the example of electrical instruments, IDEXX does not manufacture any of the subcomponents and will need to either query our supply chain or test each part. Relying on suppliers to declare or test will take an estimated 1-3 years (at least), and responses are expected to be variable.

[1] A section 4(A) exemption from the provisions of the Chapter should also extend to those products already subject to other regulatory regimes, similar to the exemption for products subject to Title 32, §26-A and Title 32, §26-B. Such an exemption would align with the intent of the second concept draft as well as the exemptions of the U.S. Environmental Protection Agency and the Occupational Health and Safety Administration, both of which have implemented a large swath of exemptions from their analogous reporting requirements in recognition of the comprehensive Food and Drug Administration regulatory framework. By way of example, the comprehensive European Union RoHS framework has typically allowed for a 7-year transition period specifically for medical device and laboratory analysis equipment because of the complexity of our products and supply chain. *See* https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:en:PDF.

[2] *See* https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/Approved-manufacturers.pdf.

Furthermore, requiring manufacturers to test each individual component prior to the January 1, 2023 notification deadline is not practicable. Testing for each individual product, when that product contains many individual components, is estimated to be over $500,000 per product. Testing of IDEXX's "premium" instruments (Catalyst One, ProCyte One, SediVue Dx, ProCyte Dx, SNAP Pro, QuantiTray Sealor Plus, VetStat, VetLab UA) alone would cost between $3,400,000 and $5,500,000. The cost of testing all of IDEXX's approximately 800 products, including the 12,000 components or sub-materials that would need to be tested, would be astronomical. Time to complete testing could also take many months if not years.

Accordingly, the draft rule should allow for extension of the notification deadline to support the efforts required to obtain this information. It would be reasonable for an initial transition period to allow companies to gather this information, and additionally to have a process to request additional time (based on good faith efforts) such as an annual progress update until a full declaration can be achieved. A transition period where a manufacturer has made the showing that more time is needed to comply with the notification requirement or where the manufacturer does not manufacture its product's components (but nevertheless would be obligated to notify the DEP of the contents of those components) would both recognize the realities of this information gathering and avoid the expenditure of the DEP's time and resources granting further extensions, which no doubt will be required.

3. Well-defined analytical methods.

The statute requires reporting of PFAS in an "exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the department." 38 MRS §1614(2)(A)(3). While the second concept draft rule attempts to define what analytical methods are acceptable, the proposed definition, particularly in its reference to "methods approved by the U.S. Environmental Protection Agency (EPA)," does not provide the needed clarity. EPA is still in the process of developing validated analytical methods for drinking water; groundwater; surface water; wastewater; and solids, including soils, sediments, biota, and biosolids, which may eventually become standard methods or research methods, but which do not include methods for products that are subject to the Program.[3] Because EPA's standard analytical methods – those methods that have been through a laboratory validation process following a rulemaking – apply only to aqueous and stationary (air) sources and only for a limited number of PFAS substances, IDEXX continues to research analytical methods, including those of the ASTM and ISO.

IDEXX's ISO 17025 accredited analytical laboratories report that they are prepared to apply CEN/TS 15968 for textiles and synthetic leathers, and an in-house method with Soxhlet extraction for plastic samples. For raw chemicals, the test method is GB/T 29493.2. However, current methods test only for 70 PFAS compounds, as recognized by national regulatory frameworks, such as EU POPs regulation (26 compounds), and EU REACH Annex XVII (18 compounds), and some chemicals (26 compounds) commonly seen in industry. Based on the Maine statute definition, chemical experts such as the American Chemical Society estimate roughly 7,000 or more unique chemicals under this definition (many of which chemical experts

[3] *See* https://www.epa.gov/water-research/pfas-analytical-methods-development-and-sampling-research.

agree are non-toxic).[4] This leaves a substantial gap in industry's ability to determine that their products or product components are PFAS-free

Without a recognized and defined method, however, manufacturers would be required to develop a way to identify unknown compounds within their products or product components, which manufacturers cannot develop based on the definition provided. Instead, the Program appears to require a non-targeted analyses where PFAS substances within a product are unknown.

4. Multitude of individual reports and excessive fees.

The proposed use of Global Product Classification brick codes for reporting, rather than the UPC codes, does not appear to address the issue of a product that contains multiple components with different CAS level PFAS. Furthermore, a conservative estimate of the individual reports that IDEXX may have to file would be one report for each of IDEXX's approximately 800 portfolio products, each of which may contain one or more of the over 7,000 unique PFAS compounds. A cross-link to notifications by product component manufacturers would require a herculean effort to identify those notifications across the approximately 12,000 components or sub-materials sourced from IDEXX's vendors, particularly given the unclear guidance on who is required to report – the manufacturer of the aggregate product, or the manufacturer of each product component. Even if this guidance were clear, whether a product is "branded" by a manufacturer is not. For example, IDEXX distributes many catalog items, such as off the shelf centrifuges, routers, PCs, touchscreens, incubators, and collection tubes, that IDEXX does not "brand" but that are used in conjunction with our portfolio products. And even if it were clear that IDEXX is obligated only to provide notice of its portfolio products, a fee of $250 for the first three notifications and an additional $50 for each additional notification would be over $40,000. Such an exorbitant fee paid by a multitude of Maine manufacturers certainly would far exceed the DEP's reasonable costs in administering the Program.

IDEXX understands and supports the need and legislative mandate to obtain information on intentionally added PFAS in products sold in Maine, but strongly suggests that the DEP consider improving the efficacy, visibility, and certainty of the Program through prioritization of manageable lists, with a reasonable timeline for Maine manufacturers to complete assessments throughout our supply chain. IDEXX again thanks the DEP for the opportunity to provide these general comments, as well as the attached specific comments on the 38 MRS § 1614 second concept draft rule. We look forward to working with the DEP to develop a robust and reasonable notification process.

Sincerely,

Diana L Rondeau

Diana Rondeau
Associate Director Product Regulatory Compliance

[4] *See* https://www.acs.org/content/acs/en/education/resources/highschool/chemmatters/past-issues/2020-2021/december-2020/open-for-discussion-balancing-act.html; *see also* https://www.npr.org/sections/health-shots/2019/04/22/708863848/scientists-dig-into-hard-questions-about-the-fluorinated-pollutants-known-as-pfa.

Attachment A: IDEXX comments for Concept Draft

cc: Matt Forsyth, Esq., IDEXX
Lisa Gilbreath, Esq., Pierce Atwood

1. **Applicability.** The proposed rule would detail the notification requirements and sales prohibitions for products containing Intentionally added PFAS under Maine's *Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution*, 38 M.R.S. §1614.

2. **Definitions.**

   A. **Alternative.** "Alternative" means a substance or chemical that, when used in place of PFAS, results in a functionally similar product and that, when compared to a PFAS that it could replace, would reduce the potential for harm to human health or the environment, or has not been shown to pose the same or greater potential for harm to human health or the environment as that PFAS. Alternatives include reformulated versions of products, including versions reformulated by removal or addition of one or more chemicals or substances, that result in the reduction or removal of intentionally added PFAS from the product. Alternatives also include changes to the manufacturing process that result in the reduction or removal of PFAS from a product.

   B. **Brand name.** "Brand name" means a name, symbol, word, or mark that identifies a product, and attributes the product to the owner of the brand.

   C. **Carpet or rug.** "Carpet or rug" means any consumer product made from natural or synthetic fabric marketed or intended to be used as a floor covering inside commercial, industrial, or residential buildings. This includes carpeted door mats intended for indoor use.

   D. **Commercially available analytical method.** "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. Commercially available analytical methods do not need to be performed at a third-party laboratory; however, they must remain unmodified. Commercially available analytical methods include methods approved by the U.S. Environmental Protection Agency (EPA) when used in accordance with that approval.

IDEXX Comment: EPA is still in the process of developing validated analytical methods which at present do not include methods for products that are subject to the Program.[1]

NOTE: Information about EPA approved methods is available at https://www.epa.gov/measurements-modeling/collection-methods.

[1] *See* https://www.epa.gov/water-research/pfas-analytical-methods-development-and-sampling-research.

E. Consumer. "Consumer" means any person who purchases goods or services in Maine which are sold by manufacturers, wholesalers, or retailers.

F. Currently Unavoidable Use. "Currently unavoidable use" means a use of PFAS that the department has determined by rulemaking to be essential for health, safety or the functioning of society and for which alternatives are not reasonably available.

G. Department. "Department" means the Department of Environmental Protection composed of the Board of Environmental Protection and the Commissioner of the Department of Environmental Protection.

H. Distribute for sale. "Distribute for sale" means to ship or otherwise transport a product with the intent or understanding that it will be sold or offered for sale by a ~~receiving party~~Consumer subsequent to its delivery.

I. Essential for Health, Safety, or the Functioning of Society. "Essential for Health, Safety or the Functioning of Society" means Products that if unavailable would result in a significant increase in negative healthcare outcomes, an inability to mitigate significant risks to human health or the environment, or would significantly interrupt the daily functions on which society relies. Products that are Essential for Health, Safety or the Functioning of Society include those that are required by Federal or State Laws and Regulations. Essential for the Functioning of Society includes but is not limited to climate mitigation, critical infrastructure, delivery of medicine and medically-necessary services, production of human and veterinary diagnostic sector products (such as human, production animal, pet, and environmental diagnostics), lifesaving equipment, public transport, and construction.

J. Fabric. "Fabric" means a textile made by weaving, knitting, or felting natural or synthetic fibers. For the purposes of this rule fabric includes leather.

K. Fabric treatment. "Fabric treatment" means a consumer product intended to be applied to fabric to give or enhance one or more characteristics, including but not limited to stain resistance or water resistance. Fabric treatments do not include fabric dyes.

L. Fully Fluorinated Carbon Atom. "Fully fluorinated carbon atom" means a carbon atom on which all the hydrogen substituents have been replaced by fluorine.

M. Intentionally added PFAS. "Intentionally added PFAS" means PFAS added to a product or one of its product components in order to provide a specific characteristic, appearance, or quality or to perform a specific function. Intentionally added PFAS also includes any degradation byproducts of PFAS serving a functional purpose or technical effect within the product or its components. Products containing intentionally added PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is present in the final product as a contaminant.

N. Manufacturer. "Manufacturer" means the person that manufactures a product, or whose brand name is affixed to the product. In the case of a product that is imported into the United States where the person that manufactured or assembled the product or whose brand name is affixed to the product does not have a presence in the United States, manufacturer includes either the importer or the first domestic distributor of the product, whichever is first to sell, offer for sale, or distribute for sale the product in the State of Maine.

NOTE: Certain online retail platforms may allow for purchase of products directly from a producer. When no other person meets the definition of manufacturer under this Chapter, the importer will be considered the manufacturer.

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

P. Perfluoroalkyl and polyfluoroalkyl substances (PFAS). "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means all substances that include any member of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.

~~NOTE: The U.S. EPA maintains a webpage of chemicals that have been identified as PFAS (available at: https://comptox.epa.gov/dashboard/chemical-lists/pfasmaster) which provides clarity on what is considered a PFAS. Any product sold, offered for sale, or distributed for sale in the State of Maine which contains intentionally added PFAS must be reported to the Department regardless of whether the substance is found on any list.~~

IDEXX Comment: DEP has stated in stakeholder meetings that it is unable to revise this definition because it is set by statute; however, other definitions that appear in 38 MRS § 1614(1) have been revised in this second concept draft rule (compare the following definitions with those in 38 MRS § 1614(1): "Carpet or rug," "Fabric treatment," "Intentionally added PFAS," Manufacturer," Product component"). There is no reason why DEP cannot similarly clarify the definition of PFAS by creating a list by CAS number of those substances that are subject to the Program. EPA itself acknowledges that there is no precisely clear definition of what constitutes a PFAS substance given the inclusion of partially fluorinated substances, polymers, and ill-defined reaction products. Hence the above-referenced website includes a number of lists, which continue to grow. Clarification as to what precise PFAS CAS numbers are subject to this rule, rather than reference to what is actually a number of lists EPA maintains while acknowledging no clear definition of PFAS, is critical. Such a precise list of CAS numbers subject to this rule would aid in obtaining PFAS information from suppliers, as well.

Q. Person. "Person" means any individual, partnership, corporation, firm, federal, state, or local government entity, or public or private organization of any character.

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

S. Product component. "Product component " means an identifiable part of a product, including its packaging, regardless of whether the manufacturer of the product is the manufacturer of the product component.

T. Publicly available. "Publicly available" means information that is lawfully made available to the general public from federal, state, or local government records, widely distributed media, or disclosures made to the general public that are required by federal, state, or local law.

U. Significant change. "Significant change" means a change in the chemical composition of a product which results in the addition or removal of a specific PFAS; a change in the amount of PFAS of more than a 25~~10~~% increase of the current concentration of the final product (and not of a product component) when compared to the existing notification; or a change in responsible official or contact information.

IDEXX Comment: This definition does not account for changes in concentrations within subcomponents. For electrical products that may contain up to 1,500 or more subcomponents, each of these components may have a determined weight by weight percentage. A change at the subcomponent level may or may not change the overall product notification. IDEXX suggests that it would be more reasonable to update the product once all PFAS is removed. In the alternative, IDEXX requests that this definition provide guidance on subcomponents (e.g., the smallest article in the larger article, per the EU definition), or a specified plus/minus change in existing percentage at the aggregate level rather than the component level (e.g., a 25% change in overall PFAS in a product would warrant a "significant change" notification).

V. Substantially equivalent information. "Substantially equivalent information" means information that the Department can reasonably identify as conveying the same information required in Section 3(A). Substantially equivalent information must all be in a single document or location.

W. Used. "Used" means the condition of a product having been installed, operated, or utilized for its intended purpose by at least one owner or operator. Used does not apply to a product that has been returned to a retailer or that is otherwise offered for resale without the product having been installed, operated, or utilized.

3. Notification.

A. Beginning January 1, 2023, and prior to sale or distribution for sale in Maine of a product that contains intentionally added PFAS.

(1) A manufacturer of such a product must submit to the Department a notification that includes.

(a) A brief description of the product, including at minimum;

IDEXX Comment: the "minimum" amount of information required should be that set forth in statute, 38 MRS § 1614(2)(A), and should not include the additional information required below (such as estimated sales volume and intended use of the product) unless it clarifies or limits the information required (such as reporting in a range or cross-linking other reports).

(i) Global Product Classification brick category and code;

IDEXX Comment: Brick codes are not useful where a product contains multiple components with different CAS level PFAS.

(ii) Estimated sales volume in the State or nationally for the full calendar year following the year in which the product is being reported;

(iii) The general type of the product, and

(iv) Its intended use.

(b) Whether the product contains known quantities of intentionally added PFAS ("Known PFAS") or contains unknown quantities of intentionally added PFAS ("Unknown"), including a reporting of the percentage of each category within the product.

(c) The purpose for which PFAS are used in the product, including PFAS in any product component;

(d) The amount of each of the PFAS as a concentration, identified by name and its chemical abstracts service (CAS) registry number, of each PFAS in the product or any product component reported as an exact quantity determined using commercially available analytical methods, or as falling within a range approved by the Department; and

(i) If reporting PFAS as falling within a Department-approved range found in the Department's online notification system, the manufacturer may rely on

calculations specific to the inputs and outputs of their manufacturing process or that of a product component's manufacturer to determine the amount of PFAS present.

For product components for which the Department has previously received notifications which are used in more complex products containing the reported components the manufacturer may report total PFAS in the product including its components, or may refer to the notifications for product components and any PFAS in the remainder of the product.

(e) The name and address of the reporting manufacturer, and the name, address, email address, and phone number of a responsible official for the manufacturer. The responsible official provided must have the authority to carry out or direct someone else to carry out the steps in Section 8 below.

NOTE: Claims of Confidential Business Information may be made at the time of reporting and will be managed under the Uniform Trade Secrets Act 10 M.R.S. §1542(4)(A)&(B).

For notifications submitted to the Department prior to the effective date of this rule and/or the availability of the digital reporting system, the notification must be submitted into the digital database within of 90 of days of the effective date of this rule.

(2) Waiver of Notification. The Department may waive all or part of the notification requirement under Subsection 1if the Department determines that substantially equivalent information is publicly available, except that the Department will not issue a waiver for the information required in Subsection 1(d) above.

(a) The Department will evaluate issuing a waiver to the notification requirement if the manufacturer submits a request containing the following:

(i) A description of the product(s) for which a waiver is requested;

(ii) A list of which requirements of Subsection 1 the manufacturer seeks a waiver for;

(iii) A description of any publicly available records which contain information duplicative of the information required in Subsection 1, above; and

(iv) A link to or copy of all publicly available substantially equivalent information described by the manufacturer.

(b) If the Department issues a partial waiver the manufacturer must still complete the notification for any requirements that were not waived, include directions to where the publicly available substantially equivalent information can be found, and pay the fee established in Section 6.

(3) Extension of Notification.

(a) The Department shall grant a two-year transition period to allow a manufacturer to gather the information required under Subsection 1 if the Department determines that more time is needed by the manufacturer to comply with the submission requirement. Such determination may be made in a previously-granted extension of time.

(b) The Department shall grant a two-year transition period to allow a manufacturer to gather the information required under Subsection 1 if the Department determines that a manufacturer does not manufacture its product's components. Such determination may be made in a previously-granted extension of time

(c) Upon the filing of annual progress updates at the conclusion of the two-year transition period, the Department shall grant an extension of that transition period until a full declaration of the information required under Subsection 1 is possible.

B. The information required in Subsection A above must be submitted in a form approved by the Department. Electronic submission of complete information to the Department's online notification system satisfies this requirement.

NOTE: The Department's online notification system is available at HTTPS://_____.

C. If, through the notification system, the Department determines that reporting as a category or type is feasible and consistent with the purposes of the program, a group of products may be reported together by category only if;

(1) All products to be so reported fall within the same Global Product Classification brick,

(2) The same PFAS are present in every product, and

(3) Each PFAS is present in every product, either:

(a) In the same a substantially similar amount as determined by a commercially available analytical method, or

(b) If reporting by range of concentration is available, within the same concentration range.

D. A manufacturer must update the information in the notification whenever there is a significant change in the reported information or when requested to do so by the Department.

(1) In the event of a significant change, a manufacturer must update their notification:

(a) Within 60 days, when requested to do so by the Department;

(b) Within 30 days, when there is a change in responsible official or contact information; or

(c) Prior to the start of sales of a product with a new formulation, when there is a significant change in the amount or type of PFAS present in the product. The update must include the date after which the prior formulation will not be sold, offered for sale, or distributed for sale in the State of Maine; or

(2) A manufacturer may update the notification to inactive status whenever a product is modified such that it no longer contains any intentionally added PFAS.

E. If a product is imported directly into the State of Maine from outside the United States to be sold, offered for sale, or distributed for sale outside of the sales and distribution channels controlled by the manufacturer and the manufacturer has not submitted notification of the product to the Department, it is the responsibility of the person importing the product into the State of Maine to submit notification of the product to the Department as required by Subsection A.

F. A notification is not effective until the Department has received payment of the fee required in Section 6.

G. A manufacturer must provide, upon request by the Department, evidence sufficient to demonstrate the accuracy of information reported in Subsection A.

4. Exemptions.

A. The following are exempt from the requirements of this Chapter:

(1) A product for which federal law or regulation controls the presence of PFAS in the product in a manner that preempts state authority. For this purpose, the provisions of this Chapter are severable, and if any phrase, Section or Subsection is preempted by

federal law or regulation, the validity of the remainder of this Chapter shall not be affected.

(2) A product that is "Essential for Health, Safety, or the Functioning of Society."

~~(2)~~(3) A product subject to Title 32, §26-A, *Reduction of Toxics in Packaging,* and

(4) A product subject to Title 32, §26-B, *Toxic Chemicals in Food Packaging.*

~~(3)~~(5) A product that is subject to regulation by the U.S. Food and Drug Administration.

5. Prohibition on Sale of Products Containing Intentionally Added PFAS.

A. Effective January 1, 2023, a person may not sell, offer for sale, or distribute for sale in the State of Maine a carpet or rug that contains intentionally added PFAS. This prohibition does not apply to the sale or resale of a used carpet or rug.

B. Effective January 1, 2023, a person may not sell, offer for sale, or distribute for sale in the State of Maine a fabric treatment that contains intentionally added PFAS. This prohibition does not apply to the sale or resale of a used fabric treatment or used product to which fabric treatment has been applied.

C. Effective January 1, 2030, a person may not sell, offer for sale, or distribute for sale in the State of Maine any product that contains intentionally added PFAS. This prohibition does not apply to the sale or resale of a used product.

6. Fees.

A. Fee amount. To cover the administrative costs incurred by the Department to administer the program, a manufacturer required by Section 3 to provide notice shall, as part of submission of notification, pay a fee of $250 for the first three notifications submitted under Section 3(A) and an additional $50 for each additional notification.

(1) A fee is only required for new product notifications. No fee is required for product updates or changes to inactive status.

(2) For notifications submitted to the Department prior to the effective date of this rule and/or the availability of the digital reporting system, the fee must be paid within 90 of days of the effective date of this rule.

B. Fees will be considered paid when funds are transferred to the Treasurer.

7. Failure to Provide Notice.

A. Unless granted an extension in accordance with 38 M.R.S. §1614(3) or a waiver in accordance with section 3(A)(2) above, a Person may not sell, offer for sale, or distribute for sale in the State of Maine a product containing intentionally added PFAS if the manufacturer has failed to provide the information required under Section 3.

(1) The prohibition in this Section does not apply to a retailer in the State of Maine unless the retailer sells, offers for sale, or distributes for sale in the State a product for which the retailer has received a notification pursuant to Section 8(A)(2) that the sale of the product is prohibited.

(2) The prohibition in this Section does not apply to products that are "Essential for Health, Safety, or the Functioning of Society."

~~(2)~~(3) The Department may exempt a product from the prohibition under this subsection if the Department has determined that the use of PFAS in the product is a currently unavoidable use.

NOTE: Violations of this Chapter are subject to the Department's enforcement authority under 38. M.R.S. §§347-A-349.

8. Certificate of Compliance.

A. If the Department has reason to believe that a product contains intentionally added PFAS and is being sold, offered for sale, or distributed for sale in violation of Section 7, the Department may direct the manufacturer of the product to, within 30 days:

(1) Provide the Department with certification, on forms provided by the Department, attesting that the product does not contain intentionally added PFAS; or

(2) Notify persons who sell, offer for sale, or distribute for sale that product in Maine that the sale of that product is prohibited in Maine, and provide the Department with a list of the names and addresses of those notified.