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VIA EMAIL [KERRI.MALINOWSKI@MAIN.GOV]

Kerri Malinowski Farris
Maine Department of Environmental Protection
Office of the Commissioner
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July 18, 2022

Ms. Malinowski Farris:

Thank you for the opportunity to comment on the Maine Department of Environmental Protection's (DEP's) concept draft rule for the Maine "PFAS in Products" program (the "Program") that was discussed during the DEP-conducted stakeholder meeting on June 30th, and that will implement the notification requirements set forth in 38 MRS § 1614.

As a company proud to have its global headquarters in Maine, where we employ roughly 3,400 of our 10,000 global employees, IDEXX is a strong supporter of legislative and DEP initiatives to monitor, notify, and reduce the use of chemicals in our environment. Accordingly, we were pleased to have the opportunity to participate in the June 30th stakeholder meeting.

Our focus on human and animal health diagnostic products allies us with the Program's environmental protection goals. However, we share the concern raised by many other stakeholders that – absent significant exemption or extension provisions – the January 1, 2023, Program notification deadline is untenable given both the lack of required information within the complex global supply chain and the difficulty of obtaining such information where it does exist.

IDEXX's diagnostic products help enable the health and well-being of people, livestock, and pets, and help ensure the safety of milk and water, here in Maine, throughout the United States, and in more than 175 countries globally. Our essential human, production animal, pet, and environmental diagnostic industry (the "Human and Veterinary Diagnostic Sector") depends heavily on products and components from the electronics and semiconductor sectors. We share the same suppliers and supply chains as these sectors, and therefore also share the concern raised during the stakeholder meeting across these and other industry sectors that suppliers and supply chains simply are not prepared to provide the information Maine manufacturers will require to comply with the concept draft as currently written.

By way of background, IDEXX manufactures human, animal (pet and livestock), dairy, and water diagnostic products, including complex electronic instruments. Our products test for, among other things, infectious diseases that can be zoonotic (spreadable from animals to humans, such as SARS CoV2) or cause significant impact to the food supply (such as African Swine Fever). Many of our products are used to screen the health of herd populations or have been used to help eradicate certain diseases, and our diagnostic tools provide the information necessary to control diseases and improve the productivity and efficiencies of the food sector.

IDEXX offers not only diagnostic solutions to much of the animal production chain but also provides services that, for example, help animal producers manage vaccination more efficiently, reduce the use of antibiotics, re-introduce animals in herds after treatments, optimize reproduction cycles, and ensure early and definitive identification of highly contagious and life-threatening diseases that threaten human and animal populations.

The United Nations Food and Agriculture Organization ("FAO") recognizes the importance of such control of animal disease, and prepared a 2016 study, "Economic Analysis of Animal Diseases," focused on transboundary animal diseases that can be screened with IDEXX's products. In that study, FAO found that transboundary animal diseases ("TADs") result in multiple economic impacts, including livestock production losses, considerable disruption to trade, as well as economic impacts from human sickness and costs to public health systems where the TADs are zoonotic. Governments spend scarce resources controlling outbreaks of TADs and applying prevention measures, farmers must deal with the impacts in their livestock production systems, and consumers experience the effects of local or widespread market disruptions caused by TADs.

It is inherent to IDEXX's mission within the Human and Veterinary Diagnostic sector that we focus on sustainability and reduction of our environmental footprint while ensuring that we can continue to serve our customers in the human and animal health industries. We believe it is critical, therefore, that changes in regulatory requirements that impact the products IDEXX manufactures must address the realities of information availability and information-gathering across the supply chain. Accordingly, an appropriate balance needs to be struck among:

- Achievable environmental protection objectives
- Fair expectations
- Conditions and timelines that correspond to the realities within which the Human and Veterinary Diagnostics Sector operates
- Ensuring product quality and performance in compliance with applicable regulatory requirements and generally
- Visibility – or lack thereof – in our supply chains

IDEXX's specific comments on the 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.

IDEXX requests that products regulated by the U.S. Food & Drug Administration ("FDA") be exempted from the concept draft rule. These products – essentially, veterinary in-vitro diagnostic products – are medically necessary in diagnosing diseases or other conditions in the food chain (including livestock and dairy), as well as pets in Maine and globally. We note that, due to the comprehensive FDA regulatory framework, both the U.S. Environmental Protection Agency ("EPA") and the Occupational Health and Safety Administration have implemented a large swath of exemptions from their analogous reporting requirements. For example, EPA has consistently taken the position that if a chemical is being exclusively manufactured, processed, distributed in commerce, and used for uses falling within the FDA's jurisdiction,

EPA would not assert jurisdiction under the Toxic Substances Control Act.[1] DEP should likewise exempt products falling within the FDA's jurisdiction from the Program.

2. Timing of notification.

The information-gathering required to comply with the concept draft rule and 38 MRS § 1614 will take significant time. IDEXX is fully reliant on our supply chain to assess and notify us of the presence of PFAS. In the vast majority of cases, our suppliers are outside the State of Maine, and while they may be monitoring European Union and EPA developments, many are currently unaware of Maine LD 1503 and 38 MRS § 1614 (indeed, it is our experience that suppliers are reluctant to take action to assess their use of PFAS until the European Union and EPA frameworks are better defined).

More specifically, as noted above IDEXX (and the Human and Veterinary Diagnostics Sector generally) is heavily reliant on the electronics and semiconductor sectors for components and parts we use to manufacture our instruments. PFAS is used in significant numbers of such components and parts, including lubricants, bearings, bushings, flat and liquid crystal displays, and capacitors; plastic/rubber parts such as hoses, valves, tubes, seals, and gaskets; and in vital components used in the manufacture of films/etchings, coatings, fluids, and the photo resistance process.

Under the concept draft rule as proposed, IDEXX would need to obtain PFAS information from roughly 1,000 global suppliers for approximately 9,000 components. IDEXX is entirely dependent on our suppliers for PFAS concentration information, test reports, and descriptions of PFAS function (which frequently requires information from a technical resource over which IDEXX has no control). We also note that a single PFAS could have multiple functions in a final piece of electronic equipment, as it may be used in multiple subcomponents.

In an effort to understand what information our suppliers already have that is required under 38 MRS § 1614 (and if not currently available, how quickly they estimate can obtain it), IDEXX surveyed 100 of the roughly 1,000 global suppliers that currently provide parts and components to us. We asked the following questions:

[1] EPA Guidance Letter Re: FDA Exemption (June 10, 1994); H.R. No. 94-1341, 94th Cong., 2d Sess. 10, (1976); Inventory Reporting Rule, 42 Federal Register 64585, Comment 41 (Dec. 23, 1977); New Chemical Branch's prenotice communications 54, 57, 75, 83, 203, 261, 369, 416, 613, 621, 983, 1043, 1096, 1309, 1447, 1593, 1616, 1651, 1717, 1947, and 1970.

Do the components you supply to IDEXX contain any known PFAS? (Yes/No/Unknown)

If yes, please provide chemical name/description (CAS#)

Are there alternatives that perform similarly to the PFAS chemical? (Yes/No)

If Unknown, how long do you think it would take your organization to assess the use of PFAS in the materials provided to IDEXX. (6 months/1 year/Longer)

If Longer, please provide length of time.

These 100 suppliers surveyed represent suppliers with whom IDEXX has direct relationships due to the criticality of the products they supply. Of the 100 surveyed, we received responses from only 44. Of the 44 respondents, 10 do not know if their components contain PFAS and they anticipate it taking 6 months to a year or more to obtain the information. Accordingly, only 34 of IDEXX's direct suppliers reported either that there was no PFAS in their products or reported knowledge of the chemical name/description (CAS#) of PFAS in their products. 56 of IDEXX's direct suppliers either do not know if their products contain PFAS or did not respond, and PFAS information from approximately 900 global suppliers – with whom IDEXX may not have a direct relationship and from whom IDEXX may source products indirectly such as through distributors or contract manufacturing of circuit boards – remains unknown. As noted elsewhere in these comments, manufacturing supply chains are complex and often involve indirect sources. IDEXX therefore has an approximate 96% information gap (only 34 suppliers out of 1,000 have reported PFAS information to IDEXX) that the concept draft rule as currently drafted appears to require IDEXX to complete in the mere 5 months that remain prior to the reporting deadline. This is unmanageable, as suppliers not located in Maine (the vast majority) are not currently able to provide the required PFAS information, and it likely will take IDEXX multiple years to obtain the required information from them.

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. 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.[2]

3. Extension of notification deadline.

For the reasons noted in (2) above, IDEXX requests that the concept draft rule provide an extension of the notification requirements and sales prohibitions for products that manufacturers cannot fully determine as "contains PFAS" or "does not contain PFAS". IDEXX does not manufacture any of the subcomponents of

[2] See https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:en:PDF.

the electronic and electrical instruments that we manufacture, and we will need to either obtain from our suppliers (who in many cases are not currently able to provide such information) or test each part. We believe it will take many suppliers three years or more to provide such information. Further, it is not practical for IDEXX to conduct testing itself: Testing each of our products, when each product contains many individual components, is estimated to be over $500,000 per product. Testing of IDEXX's leading 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. Testing all of IDEXX's approximately 800 products, which include 12,000 components or sub-materials that would need to be tested, would be astronomical. Furthermore, our preliminary estimates indicate that the time to complete such testing could be years.

Accordingly, the concept draft rule should allow for extension of the notification deadline to accommodate productive efforts to obtain the requires information. It would be reasonable for an initial transition period to allow companies to gather this information, and additionally have a process to request additional time (based on efforts of discovery) such as an annual progress update, until a full declaration can be achieved. Product notification could be broken down into three categories: PFAS-free, Known PFAS (reporting the percentage per product), and Unknown.

4. Extent of product notification.

Based on the current information gap regarding roughly 96% of our suppliers, it is currently difficult to determine the total number of product notifications IDEXX would need to make under the current draft rule. However, if we limited the effort to only the components of the specific instruments listed above, we would need to obtain PFAS information for 9,000 subcomponents (and perhaps for 12,000 components inclusive of sub-materials). We also note it is unclear under the concept draft rule whether we would also have to consider packaging, plastic consumables, and similar products related to those we manufacture.

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 concept draft rule. We look forward to working with the DEP to develop a robust and reasonable notification process.

Sincerely,

Diana L Rondeau

Diana Rondcau
Associate Director Product Regulatory Compliance

Attachment A: IDEXX comments for Concept Draft

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

Attachment:
IDEXX Comments for Concept Draft

IDEXX Comments on Concept Draft for the Maine PFAS in Products Program

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 a fabric product marketed or intended for use as a floor covering. Carpet or rug does not include products that are placed on the floor that do not have a primary purpose of covering or protecting the floor.

   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.

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

IDEXX Comment: It is unclear which EPA methods are approved for PFAS.

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

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

   G. **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 subsequent to its delivery.

   H. **European article number (EAN).** "European article number" or "EAN" means a 13-digit barcode used for product identification purposes, also referred to as an international article number.

I. **Fabric.** "Fabric" means a textile made by weaving, knitting, or felting natural or synthetic fibers.

J. **Fabric treatment.** "Fabric treatment" means a consumer product meant to be applied to fabric or leather 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.

K. **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. Products containing intentionally added PFAS include products that consist solely of PFAS. Intentionally added PFAS does not include PFAS that is used in or that comes in contact with a product during the manufacturing process but is not present in the final product.

IDEXX Comment: It is unclear whether packaging of a manufactured product that included "intentionally added PFAS" would require reporting, where a manufacturer is not manufacturing that packaging but its products are sold into Maine within that packaging.

L. **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.

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

N. **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: The EPA's consolidated list contains 6,330 PFAS CAS-name substances, and 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. IDEXX requests 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. Such a precise list of CAS numbers subject to this rule would aid in obtaining

PFAS information from suppliers, as well.

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

P. 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.

Q. Product component. "Product component" means an identifiable part of a product, regardless of whether the manufacturer of the product is the manufacturer of the product component.

R. 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.

S. 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 __%, plus or minus of the current concentration when compared to the existing notification; or a change in contact person or contact information.

IDEXX Comment: It is unclear how the DEP or State of Maine will use composition of chemicals. 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. How will the individual components roll up into the final product notification? How would the change at the subcomponent level 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).

T. Substantially equivalent information. "Substantially equivalent information" means information that a consumer can reasonably identify and understand as conveying the same information which it is represented as being equivalent. Substantially equivalent information must all be in a single document or location.

U. Universal product code (UPC). "Universal product code" or "UPC" means a standard for encoding a set of lines and spaces that can be scanned and interpreted into numbers for product identification purposes. Universal product code includes any industry-accepted barcode used for product identification purposes in a manner similar to a UPC, including, but not limited to, an EAN.

V. 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.

IDEXX Comment: As described in our cover letter to these comments, a January 1, 2023 notification deadline for products that contain a number of components and subcomponents for which the PFAS information (if any) lies with the supplier is untenable. IDEXX estimates that the rule, without IDEXX's proposed exemption and/or deadline extension, would require obtaining PFAS concentration information for 9,000 subcomponents from approximately 1,000 suppliers. Based on a recent survey of a sample of those suppliers, it is evident that it will take the suppliers months if not years to gather and transmit to IDEXX the required information. Furthermore, EPA lists 6,330 PFAS CAS-name substances but it is unclear if each will be subject to the notification requirement, particularly given that this rule and the online notification system are still under development.

(1) Extension of notification deadline. The Department will issue an extension to the notification deadline if the following conditions are met:

IDEXX Comment: IDEXX requests that the concept draft rule provide an extension of the notification requirements and sales prohibitions for products that manufacturers cannot yet fully determine as "contains PFAS" or "does not contain PFAS" where those manufacturers rely upon their suppliers for such information. 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, and responses are expected to be variable.

Furthermore, requiring manufacturers to test 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. Testing all of IDEXX's approximately 800 products, which include 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 concept draft rule should allow for extension of the notification deadline to support the efforts of discovery of 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 efforts of discovery) such as an annual progress update until a full declaration can be achieved. Product notification could be broken down into three categories: PFAS-free, Known PFAS, and Unknown, reporting the percentage of each category per product.

(2) 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;

(i) Details sufficient to allow a consumer to readily differentiate the product from any other similar products, such as the marketed name of the product,

(ii) The UPC, if applicable;

(iii) The general type of the product, and

(iv) Its intended use.

If the Department determines that multiple products can be reported together as a category as provided for in subsection 3(C), the description must be sufficient to allow a consumer to readily ascertain which products are within the category and to differentiate them from any other similar products.

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

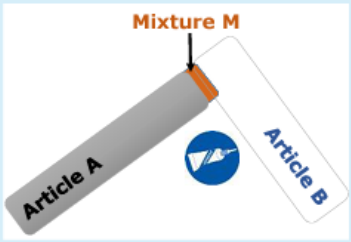
(c) The amount of each of the PFAS as a concentration, identified by name and its chemical abstracts service (CAS) registry number, of each PFAS in the product or any product component. reported as an exact quantity determined using commercially available analytical methods, or as falling within a range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

(i) If reporting PFAS as falling within a Department-approved range, unless there is evidence indicating a different amount, 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.

(ii) The name and address of the manufacturer, and the name, address, email address, and phone number of a contact person for the manufacturer. The contact person provided must have the authority, in the event of noncompliance, to carry out or direct someone else to carry out the steps in Section 8 below.

IDEXX Comment: How manufacturers will determine the amount of each PFAS as a concentration is unclear. Complex articles (by the EU definition) are an object made up of more than one article, which are joined or assembled together (complex object). IDEXX requests clarification on how weight by weight percentage should be calculated with complex objects (such as electrical products that contain many subcomponents). Ideally, alignment with the EU interpretation will aid in our ability to engage with suppliers, and to use existing process to support notification requirements.

Furthermore, there is no defined de minimus amount for concentration – only the broad definition of "intentionally added," which includes degradation by-products. Would the testing methods define the threshold (e.g., any measurable amount would need to be reported)? The EPA site provided for acceptable test methods did not include specific PFAS defined methods:

Scenario	Calculation of the concentration of a Candidate List substance (w/w)	Description/Example(s)
II. Candidate List substance as such or in a mixture used for joining two or more articles (complex object)	The concentration of the Candidate List substance is calculated over the total weight of the complex object, i.e. by dividing the weight of the Candidate List substance in the complex object by the total weight of the complex object.	Complex object made by joining two articles A and B using a mixture M (e.g. adhesive, solder) which contains a Candidate List substance.  The total weight of the complex object is obtained by summing up the weight of article A, the weight of article B, and the weight of mixture M. In most common cases, the weight of the mixture M should be of its dry form in the complex object.

Finally, any reporting range should at a minimum account for manufacturing variance, test method accuracy, and have options for CBI if applicable. For comparison, the EU SCIP (Substances of Concern in Articles) allows notification of broad concentration ranges for SVHCs (0.1% to 100%).

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 amount as determined by a commercially available analytical method, or

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

IDEXX Comment: It would be reasonable to allow some product categories. As an example, for IVDs, similar platforms that test different markers but have the same chemical composition would be a product category that might make sense for IDEXX's industry.

IDEXX also would like the DEP to be aware of shared subcomponents. For an example, we might use the same cable or Printed Circuit Board that may contain PFAS and could be used in multiple human or animal medical devices (analyzers). Would it be possible to prepare notifications for more than one product that might have similar information?

Finally, with regard to reporting ranges, any reporting range should at a minimum account for manufacturing variance, test method accuracy, and have options for CBI if applicable. For comparison, the EU SCIP (Substances of Concern in Articles) allows notification of broad concentration ranges for SVHCs (0.1% to 100%).

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

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

(a) Within 30 days, when requested to do so by the Department;

(b) Within 30 days, when there is a change in contact person 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. These updates 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

(d) Within 30 days, when updating the notification to inactive status for a product that no longer contains intentionally added PFAS.

E. If a product is imported into the State of Maine, rather than into 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 notice the product has not been submitted to the Department, it is the responsibility of the person bringing the product into the State of Maine to ensure the Department receives notice 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.

IDEXX Comment: It is unclear what evidence will be acceptable to the DEP (e.g., supplier certifications or test reports?). IDEXX suggests that supplier certifications certifying components as PFAS-free, Known PFAS (reporting the percentage), and Unknown be sufficient to demonstrate the accuracy of the information reported in Subsection A, and that the DEP develop a form for such supplier certification.

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 subject to Title 32, §26-A, *Reduction of Toxics in Packaging,* and

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

IDEXX Comment: IDEXX requests that the concept draft rule include an exemption from the notification requirements for FDA controlled products. Veterinary IVDs are medically necessary in diagnosing diseases or other conditions in the food chain including livestock and dairy, as well as Maine's pets. Similarly, due to already existing strict regulations on FDA controlled products, OSHA and EPA have granted a large swath of exemptions from their authority, as described in our cover letter.

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 $_____.

(1) The fee must be paid for each individual product registered regardless of whether it is registered independently or as part of a category.

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

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

7. Failure to Provide Notice.

A. 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.

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 the certificate, 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 this State 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.