

**IDEXX Laboratories Inc**

1 IDEXX Dr  
Westbrook, ME 04092  
1-207-556-0300

May 19, 2023

**VIA ELECTRONIC MAIL**

rulecomments.dep@maine.gov

Re: IDEXX Comments on Proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Chair Lessard and Members of the Board of Environmental Protection:

Thank you for the opportunity to comment on the Maine Department of Environmental Protection's ("DEP's") proposed Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances. IDEXX previously submitted comments on the first concept draft rule on July 18, 2022, and on the second concept draft rule on November 10, 2022, and provided oral comments at the Board's April 20, 2023 public hearing on Chapter 90. IDEXX incorporates those comments herein.

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 development and manufacturing of products that may ultimately incorporate one or more PFAS substances, 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.

While IDEXX does not directly work with PFAS chemicals or intentionally add them to our products, as Chapter 90 is presently written IDEXX likely would have the obligation to notify the DEP of any PFAS content of its products. Due to the complexity of our supply chain, as well as the current unavailability of analytical testing methods for the vast majority of PFAS substances addressed by Maine law, however, full compliance with the notification requirement without a significant extension of time and advancements in available testing methodologies is a near impossibility. In that case, Chapter 90 Section 7 could effectively ban one or more of IDEXX's essential products. This unintended and serious adverse consequence for both veterinary and human health must be addressed in this rulemaking and the upcoming work sessions in which we understand the ENR Committee of the Maine Legislature will engage with stakeholders and the DEP on PFAS regulation in Maine.

IDEXX sources over 12,000 components from suppliers that are critical to the manufacturing of our products. At this time, there is a lack of technical capability to perform the tests required to determine PFAS concentrations in these items. Industry tests are developed only in response to national regulations, such as the pending EPA and EU-wide requirements, and current capabilities are limited in testing certain

products. This means that while Chapter 90 calls for identifying all of the more than 14,000 PFAS compounds, right now internationally recognized labs offer screening tests for only about 70 compounds. Additionally, even if the testing was possible, the timeline to conduct this exercise on over 12,000 unique components would be substantially long, likely requiring multiple years.

Importantly, IDEXX cannot easily switch out certain products or product components of our final products. Because our diagnostic tests are critical to the safety of our pets, food, and water supplies, they already are subject to stringent regulatory frameworks around the world that govern our ability to make product changes. For example, the IDEXX diagnostic kit used to test for mad cow disease is written into EU laws. Changes to this and many other products require approval of regulatory agencies both in the US and abroad. To change the components of a test that may contain PFAS we generally need 5 years to test feasibility, validate product performance, determine product stability, and obtain regulatory approval.

This combination of an inability to test components and an inability to quickly change product components leaves IDEXX and many other companies in a position where products that improve health outcomes for people and animals may not be available in Maine. Further, we are concerned that suppliers cannot or will not sell their products that are essential to Maine manufacturers and research institutions. That cannot have been the intent of the Legislature.

IDEXX believes that there is a legislative and subsequent regulatory fix available that will protect the public from PFAS while also ensuring access to life-saving and critical products. We look forward to working with the DEP and the ENR Committee in their development of legislation that would amend 38 MRS § 1614 such that it provides the DEP with information on the presence of PFAS in consumer products sold in Maine while allowing essential products to be manufactured and sold in Maine while currently unavailable PFAS information is obtained. Indeed, the DEP has recognized the limitations of testing and the realities of complex supply chains in granting thousands of extensions of the required notification, allowing essential products to remain available in Maine.

We therefore request that the regulations under development prioritize the continued availability of essential products for which PFAS information is unavailable or in which PFAS is used in a currently unavoidable manner, and that any finally adopted regulations be consistent with those of other governing bodies, including the EU Commission, such that they can be feasibly implemented so as not to put human and animal safety at risk. To do so, the DEP must make two foundational determinations prior to requiring notification of PFAS in all products and banning the sale of those products for which compliance is an impossibility. First, the DEP must clearly set forth the applicability of the rule to products that are not available for personal use in the home, and therefore are not “consumer products” as that term is generally defined. And second, the DEP must determine what products are exempted from the notification requirement because they are subject to federal or international regulation that preempts any state ban of those products, because the PFAS substances in those products are unknowable at this time, or because those products are essential to the functioning of society.

IDEXX again thanks the DEP for the opportunity to provide these comments and requests that it participate in any workshop meetings of the ENR Committee concerning PFAS in products in Maine.

Sincerely,



Diana Rondeau