May 19, 2023

Submitted via electronic mail

Maine Department of Environmental Protection
17 State House Station
Augusta, Maine 04333
Rulecomments.dep@maine.gov

Re: Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances

Dear Chair Lessard and members of the Maine Board of Environmental Protection:

The Animal Health Institute (AHI) appreciates the opportunity to comment on the Maine Department of Environmental Protection's (DEP's) Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances, implementing LD 1503, "An Act to Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution." AHI is the trade association representing companies that develop, manufacture, and distribute animal health products.

AHI participated in the stakeholder meetings the Department held as it developed this rule, and submitted comments on the second concept draft of this rule as well as in-person comments at the public hearing on April 20, both of which we incorporate here by reference. We acknowledge the changes the legislature is currently making to Chapter 447, and focus our comments on the process for determining what is an unavoidable use.

It is of utmost importance that the DEP, and the legislature, address what is likely an unintentional ban of products now in which the use of PFAS is essential for health, safety, or the functioning of society and for which alternatives are not reasonably available under 38 MRS §§ 1614(5)(D) and (7)(A). As many stakeholders have noted in comments over the last year, the statute and proposed rule reach hundreds of thousands of products that contain a multitude of components and sub-components, each of which may use one or more PFAS substances. For example, AHI members develop, manufacture, and distribute a range of animal health products, including pharmaceuticals, biologics (including vaccines), flea and tick preventatives, and medical devices (including diagnostics), to veterinarians, pet owners, and food animal livestock owners. Based on LD 1503's very broad definition of "PFAS" as substances "containing at least one fully fluorinated carbon atom," certain animal health products from each of these categories contain PFAS either as an active ingredient (AI) or an essential, functional component of product packaging.

Some active ingredients approved by the U.S. Food and Drug Administration (FDA) and U.S. Environmental Protection Agency (EPA) are fluorinated molecules that are administered in animals, either orally or topically. Other veterinary products regulated as biologics by the U.S. Department of Agriculture (USDA) contain fluorinated molecules as essential, functional components of their administering components (e.g., vaccine syringes) that are federally evaluated and approved together with the health product. **No current alternatives to PFAS are available for these products, making the use of PFAS unavoidable.**

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A determination that animal health products regulated by the FDA as drugs or medical devices; USDA as biologics; or EPA as pesticides, are unavoidable uses must be made before banning these essential products. The potential removal of such animal health products from the market jeopardizes the availability of safe and effective animal treatment options and should receive the same careful consideration from DEP as for human health products. These products are important to Maine's farmers, veterinarians, and pet owners to protect the health and welfare of their livestock and companion animals. These products also provide vital human public health benefits.

Preventing and controlling pests in livestock and companion animals is an essential component of preventing the spread of zoonotic diseases like cat scratch disease and Lyme disease, which are carried by fleas and ticks and can be transmitted to humans via animals. The challenge of keeping animals and humans safe from these diseases grows as climate change expands the habitable regions of the pests and lengthens their breeding season. The health of food-producing animals is also integral to a safe food supply. In short, these animal health products provide vital public health and commercial benefits to end users in Maine.

38 MRSA § 1614(7)(A) states that the prohibition on the sale of products for which the manufacturer has not provided notification to Maine does not apply to products exempted by the Department upon a determination that the use of PFAS is a "currently unavoidable use." Similarly, effective January 1, 2030, 38 MRSA § 1614(5)(D) provides that a person may not sell any product that contains intentionally added PFAS, unless the Department has determined that the use of PFAS in the product is a "currently unavoidable use".

Now that it appears that the legislature will extend the deadline to comply with the manufacturer reporting requirement to 2025, we are asking the Department to grant this exemption from the reporting requirement and product ban for categories of products and to do so prior to the new reporting deadline. AHI appreciates the regulatory challenges that come with implementing LD 1503, especially given the broad definition of PFAS, and seeks a determination, before the notification requirement takes effect, from DEP that **animal health products regulated by the FDA as drugs and medical devices, by the USDA as biologics, or by the EPA as pesticides as a category** are unavoidable uses and therefore exempt from the requirements of LD 1503 and Chapter 90. We are happy to meet with you to provide additional information.

Sincerely,

Mandy Hagan
Director, State Government Affairs

cc: Commissioner Loyzim (via email)
Mark Margerum (via email)