November 10, 2022

Submitted via electronic mail

Commissioner Melanie Loyzim
Maine Department of Environmental Protection
17 State House Station
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Re: Maine Department of Environmental Protection Second Concept Draft, Maine PFAS in Products Program

Dear Commissioner Loyzim:

The Animal Health Institute (AHI) appreciates the opportunity to comment on the Maine Department of Environmental Protection's (DEP's) Second Concept Draft for the Maine PFAS in Products Program 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.

As explained in more detail below, AHI seeks DEP's recognition that animal health products federally regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Virus-Serum-Toxin Act (VSTA)—including pharmaceuticals, biologics, and medical devices (including diagnostics)—containing per- and polyfluoroalkyl substances (PFAS) are exempt from LD 1503 under 38 MRS § 1614(4)(A). This section exempts from LD 1503 "product[s] *for which federal law governs the presence of PFAS . . . in a manner that preempts state authority*" (emphasis added). AHI also requests that DEP institute a policy of enforcement discretion regarding enforcement of all LD 1503 requirements for animal health products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In parallel to these requests, AHI strongly urges DEP to adopt a blanket extension to the reporting requirement at 38 MRS § 1614(2)(A) for all products.

I. Background Regarding Animal Health Products Containing PFAS

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.[1] No current alternatives to PFAS are available for these products, making the use of PFAS unavoidable. For example, some active ingredients approved by the U.S. Food and Drug

[1] 38 MRS § 1614(1)(F).

Administration (FDA) and U.S. Environmental Protection Agency (EPA) are fluorinated molecules that are administered in animals, either orally or topically. Other veterinary products 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.

Unlike human drugs and medical devices (including diagnostics), which are all regulated by FDA, our members' animal health products are overseen and regulated by three distinct federal agencies:

- **Small molecule pharmaceuticals and medical devices (including diagnostics)** at FDA under the FFDCA.
- **Biologics (including vaccines and certain diagnostic kits)** at the Animal and Plant Health Inspection Service (APHIS) within the U.S. Department of Agriculture (USDA) under the VSTA; and
- **Flea and tick preventatives** administered topically (including via collars) at EPA under FIFRA.

While regulatory responsibility is divided among the above agencies, animal health products are all subject to intense federal oversight and regulatory frameworks focusing on product safety. As such, the FDA- and USDA-regulated animal health product categories are exempt from LD 1503 under 38 MRS § 1614(4)(A) and the DEP should use enforcement discretion to include the FIFRA-regulated products under this exemption.

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.

The broad definition of PFAS used in LD 1503 is based purely on chemical structure and nomenclature, without any consideration of risk data. The PFAS definition in LD 1503 encompasses thousands of different chemical combinations that, depending on concentrations, end-use, and a variety of other factors, may not be harmful to human health or the environment and may have beneficial uses (e.g., medicinal uses) that greatly outweigh potential harms. Simply being categorized as PFAS does not equate to being harmful. For some diseases or conditions, active molecules that contain a limited number of fluorine atoms deliver superior treatment efficacy or provide the only treatment option. The safety and efficacy of both veterinary and human medicines have been extensively evaluated and reviewed prior to authorization under regulatory frameworks by federal agencies (e.g., FDA, USDA). Further, it is not just some important medicines that contain PFAS but also certain medical devices (including diagnostics) and flea and tick preventatives, which are governed by comprehensive federal regulatory frameworks and programs. Other states have recognized the importance of all these

products and exempted them from legislation regarding similar reporting requirements for products containing PFAS.[2]

In an August 26, 2022, response to a July 7, 2022, request signed by AHI along with other affected parties, DEP noted that industry requires guidance on LD 1503's scope and reporting methods to be able to comply with the fast-approaching reporting deadline. As explained below, AHI requests DEP's confirmation that animal health products containing PFAS are outside the law's scope.

II. Animal Health Products Heavily Regulated Under the FFDCA and VSTA Are Exempt from LD 1503 Because Federal Preemption Prohibits State Regulation

A. Federal regulatory oversight of animal pharmaceuticals, biologics, and medical devices (including diagnostics)

The FFDCA provides FDA sole authority to review applications, approve new animal drugs, deem unapproved new animal drugs to be unsafe and adulterated or misbranded, and regulate animal drug facility registration and drug listing.[3] Similarly, FDA regulations at 21 CFR Parts 510–530 prescribe extensive requirements for new animal drug applications and allowable uses for specific types of drugs. The FFDCA also provides FDA regulatory oversight of medical devices (including diagnostics) intended for animal use.[4] Animal device manufacturers must assure that devices are safe, effective, and properly labeled. Medical device labeling may not be false or misleading and must be adequately labeled for the intended use(s).[5] An animal device that is also a radiation emitting electronic product must comply with all requirements for animal devices in addition to the FDA's extensive requirements for radiation-emitting electronic products at 21 CFR Parts 1000–1050.

Similarly, the VSTA authorizes USDA to review, license, and regulate animal biological manufacturers and their products and ensure animal biologics are pure, safe, potent, and effective.[6] USDA holds sole responsibility for issuing licenses and determining allowable uses for biologics, the extensive regulations for which are detailed at 9 CFR Parts 101–124. Importantly, the VSTA makes it unlawful to prepare, sell, barter, or exchange dangerous or harmful biologics intended for use in the treatment of animals.[7]

Human or animal drugs, biologics, and medical devices must be safe, effective, and suitable for their intended use(s). FDA and USDA can take appropriate regulatory actions if such products are unsafe, adulterated, or misbranded. Federal laws and regulations provide robust procedures for animal health product testing, review, and approval and ensure products only enter the market after successful completion of a scientific assessment (including an environmental assessment) and approval by the agency. These assessments must be generated for every

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2 *See, e.g.*, Cal. AB-2247, "Perfluoroalkyl and polyfluoroalkyl substances (PFAS) and PFAS products and product components: publicly accessible data collection interface," § 25258.4(c); Colo. HB 22-1345, "Perfluoroalkyl And Polyfluoroalkyl Chemicals Consumer Protection Act," § 25-15-603(20)(c).

3 FFDCA §§ 501–02, 510, 512.

4 FFDCA § 201(h)(1).

5 FFDCA § 502(f).

6 21 U.S.C. §§ 151, 154, 156, 157. While USDA and FDA both have authority to regulate animal biologics, USDA holds primary responsibility. *See* APHIS Agreement #04-9100-0859-MU, FDA Serial #225-05-7000.

7 21 U.S.C. § 151.

product regardless of volume. These approvals take years of careful development, as well as a substantial amount of capital investment by companies.

Accordingly, animal health products and the overall safety of such products, which are tightly regulated under the FFDCA or VSTA, fall under the 38 MRS § 1614(4)(A) exemption and are not subject to the requirements of LD 1503.

B. Federal preemption

DEP's current understanding and public articulation of federal preemption with regards to LD 1503 is incomplete. DEP's website states, "Federal preemption is either found in the text of a federal law or federal regulation" (i.e., express preemption).[8] DEP further noted in its October 27, 2022, stakeholder meeting that it would also find preemption where a federal program is so expansive so as not to leave room for state regulation (i.e., field preemption). Importantly, however, DEP glaringly ignores the well-established legal principle of implied conflict preemption, where an entity cannot comply with both federal and state law or where a state law is "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[9]

Here, LD 1503's prohibition on the sale of products containing PFAS as applied to animal pharmaceuticals, biologics, and medical devices (including diagnostics) directly conflicts with federal regulatory oversight of the products. Regulated entities are unable to comply simultaneously with both federal regulation and the state's ban, and the state law stands as an obstacle to the FFDCA's and VSTA's goals of ensuring the safety and effectiveness of animal health products.[10] FDA's and USDA's authority further preempt LD 1503's ban on PFAS in animal pharmaceuticals and biologics because it would limit uses that have been reviewed, considered, and ultimately approved by FDA and USDA, unjustifiably negating the agencies' determinations that the products are safe and frustrating Congress's intent to provide safe and effective health products for animals. Moreover, subjecting animal pharmaceuticals, biologics, and medical devices (including diagnostics) to LD 1503 would undermine FDA's and USDA's ability to make safe and effective animal health products available to promote and protect the public health.[11]

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[8] Maine DEP, *PFAS in Products*, https://www.maine.gov/dep/spills/topics/pfas/PFAS-products/index.html (last visited Nov. 6, 2022).

[9] *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *see also Freightliner Corp. v. Myrick,* 514 U.S. 280, 287 (1995) (explaining that conflict preemption exists (1) where it is "impossible for a private party to comply with both state and federal requirements," or (2) where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). Implied preemption may exist even in the absence of express preemption. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874 (2000).

[10] The FFDCA created the FDA and required it to "protect the public health" by ensuring that "human and veterinary drugs are safe and effective." FFDCA § 1003(b)(2)(B). The FDA must approve new drugs before they are introduced to the market. To do so it employs "a structured risk-benefit assessment framework." It will not approve a new drug if it concludes the drug is unsafe, or if there is insufficient information from which to determine whether the drug is safe. 21 CFR § 314.125(b)(3)–(4). But if a new drug passes the benefit-risk assessment, the FDA "promote[s] the public health" by making it available to the public. FFDCA § 1003(b)(1). Similarly, the VSTA was enacted to assure the safe and effective supply of animal vaccines and other biological products. *See* S. Rept. 62-1288 (1913).

[11] *See Zogenix, Inc. v. Patrick*, 2014 WL 1454696 (D. Mass. Apr. 15, 2014) (noting that permitting a state to "countermand the FDA's determinations and substitute its own requirements" in banning an approved drug "would undermine the FDA's ability to make drugs available to promote and protect the public health"); *see also Animal Legal Defense Fund v. Provini Veal Corp.,* 626 F. Supp. 278, 283 (D.

Additionally, the subject of federal preemption for human drugs has been heavily litigated.[12] Courts' rationale preempting state action regarding human drugs provides convincing precedent that FDA and USDA have sole purview over animal health product availability, labels, and conditions of use.

Because the FFDCA and VSTA "govern the presence of PFAS" in animal pharmaceuticals, biologics, and medical devices (including diagnostics), such products fall within 38 MRS § 1614(4)(A) and are exempt from the requirements of LD 1503. Further, since the Maine legislature did not include language in LD 1503 that this exemption for preempted products is severable as to the law's various requirements, AHI interprets federal preemption as applying to both the general products ban and the notification requirement at 38 MRS § 1614(2)(A). We note DEP's inclusion of severability language in the proposed rule and object to DEP making law where the legislature clearly did not.

III. DEP Should Exercise Enforcement Discretion to Consider Veterinary Products As a Single Category of Federally Regulated Health Products, Similar to Human Medical Products

AHI requests DEP exercise enforcement discretion for FIFRA-registered animal health products containing PFAS as these products provide important health benefits described above and, at present, manufacturers are not able to meet the reporting requirements of LD 1503. As with animal health products regulated under the FFDCA and the VSTA, entities and products regulated under the FIFRA would be unable to comply simultaneously with both federal requirements and the state's ban. Further, the intricacies of federal oversight and preemption should not single out a specific class of veterinary products, namely the flea and tick products that fall under EPA jurisdiction. While all human medications fall cleanly within FDA jurisdiction under the FFDCA, animal medicine producers must grapple with three different federal agencies and statutes. As a matter of treating animal health the same as human health, we request DEP use enforcement discretion to extend the same exemption status to FIFRA-registered products as what clearly exists for FFDCA- and VSTA-approved products.

Mass. 1986) (holding federal regulation by FDA and USDA in the area of antibiotic-treated animal feed impliedly preempted state action affecting the use of antibiotics in animal feed).

[12] *See Zogenix, Inc.*, 2014 WL 1454696 at *1–2; *Zogenix, Inc. v. Patrick*, 2014 WL 3339610 (D. Mass. July 8, 2014), vacated in part on other grounds, 2014 WL 4273251 (D. Mass. Aug. 28, 2014) (holding that an effective state ban on an FDA-approved drug necessarily "frustrated" the FFDCA's statutory scheme"); *see also Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013) (holding that "stop selling" tort claims, or claims that a drug manufacturer would violate their duty under state law by marketing their products in their FDA-approved form with their approved label, are preempted and analogizing such claims to a state's statutory prohibition on sales); *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012) ("Any such state law duty [to cease marketing a drug] would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce"); *Aucoin v. Amneal Pharmaceuticals, LLC*, 2012 WL 2990697, at 9 (E.D. La. July 20, 2012) ("To require a generic manufacturer to remove a drug from the market would repudiate the label approved by the FDA"), *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 659 (D. Md. 2011) ("No state law duty that would compel generic manufacturers to stop production of a drug could exist, as it would directly conflict with the federal statutory scheme in which Congress vested sole authority with the FDA to determine whether a drug may be marketed in interstate commerce").

IV. Impracticality of Reporting Requirements of 38 MRSA §1614 Will Overstate Risk of FIFRA-Regulated Products and Must Be Addressed Prior to Requiring Compliance

38 MRSA § 1614(2)(A)(3) requires that companies include in their notification to the state "[t]he amount of each of the PFAS, identified by its chemical abstracts service registry number, in the product, reported as an exact quantity determined using commercially available analytical methods or as falling within a range approved for reporting purposes by the department." As DEP acknowledged in its August 26, 2022, correspondence, collecting the analytical information from manufacturers and suppliers is both time and labor intensive. The type of analytical testing required to obtain the information is not readily available and would impose significant costs and disruptions to an already-strained product supply chain. This is assuming such analytical information can even be obtained within a reasonable degree of certainty. In fact, EPA is still in the process of developing and validating analytical methods for wastewater, groundwater, certain PFAS in drinking water, and other environmental media.

Furthermore, and as outlined in detail above, FIFRA-registered animal health products contain a low level of PFAS and provide essential public health outcomes for humans, livestock, and companion animals by stopping the spread of flea and tick diseases. These outcomes distinguish these products from other products containing high, measurable quantities of PFAS that are the focus of the state's regulatory purview. AHI thus urges DEP to use discretion in enforcing LD 1503's requirements for FIFRA-registered products.

AHI reiterates the concern mentioned by DEP in its August 26, 2022, correspondence that LD 1503 will result in duplicate reporting of PFAS and fail to provide DEP with an accurate assessment of the amount of PFAS entering the state. 38 MRS § 1614(2)(A) requires manufacturers to notify the state of products they sell in Maine that contain PFAS where "product" means an item sold or distributed to customers for personal, residential, commercial, or industrial use, "including for use in making other products." This definition indicates that both manufacturers of bulk ingredients and finished product manufacturers will be required to report sales of products containing PFAS to the state, resulting in inaccurate and overreporting.

Finally, we strongly urge DEP to provide a blanket extension allowing all products subject to the reporting requirement additional time to comply for three reasons. First, until there is clarity on interpretation of 38 MRS § 1614(4)(A) and the arguments presented above, companies are unsure of the applicable regulatory requirements under LD 1503. This lack of clarity undermines sound regulatory decision-making. Second, reporting should not be required until the DEP has provided both clear reporting guidance as well as an established technical reporting mechanism. Without such a viable system in place, the state will receive a flood of data in different or competing formats and reporting schemes that will only place company information at risk while providing no immediate benefit to the state. A third and related reason is the concern about the protection of confidential business information (CBI), including the levels of PFAS in products. One vitally important aspect of a reporting mechanism is a function that protects CBI. While we recognize the state has asked specific companies to request an extension, these concerns are common to all potential reporters, and the DEP, as a matter of equal treatment, should delay all reporting until these mechanisms are in place. This request for a delay should in no way be interpreted as an admission or recognition that animal health products are or should be subject to these requirements. Rather, it is a request to give all parties sufficient time for DEP to adequately consider the issues outlined here and issue revised and corrected rulemaking.

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AHI appreciates the regulatory challenges that come with implementing LD 1503, especially given the broad definition of PFAS, and seeks confirmation from DEP that animal health products are exempt from this law under 38 MRS § 1614(4)(A). We are committed to working with the state. For example, we welcome continued dialogue with DEP, including an opportunity to explain in more detail how federal oversight and regulatory frameworks govern the safety of animal health products and to highlight the essential function and low levels of PFAS in our members' products. We look forward to DEP's consideration of these comments in its ongoing rulemaking processes and would be happy to schedule a meeting or discussion should any clarification or further information be needed.

Sincerely,

Ronald B. Phillips
Senior Vice President, Policy

cc: Blazka Zgec, Environmental Specialist