November 10, 2022

Commissioner Melanie Loyzim
Maine Department of Environmental Protection
State of Maine
17 State House Station
Augusta, Maine 04333

Subject: Comments on Second Concept Draft - Scope of Applicability of 38 MRS § 1614

Boehringer Ingelheim
Animal Health USA Inc.

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Dear Commissioner Loyzim:

I write today on behalf of Boehringer Ingelheim Animal Health USA Inc. (BI Animal Health).

BI Animal Health manufactures animal drugs, biologics, veterinary medical devices and other products regulated by the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, and the U.S. Department of Agriculture under federal laws including the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., the Virus-Serum-Toxin Act, 21 U.S.C. § 151 et seq., the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 201 et seq., and their respective implementing regulations. Under 38 MRS § 1614(4)(a), the following are exempt from all requirements of 38 MRS § 1614: "product[s] for which federal law governs the presence of PFAS in the product in a manner that preempts state authority." Under this section of the Maine law, as well as general principles of federal preemption, drugs, biologics, and devices – for humans and animals – regulated by the federal government are out of scope of 38 MRS § 1614, as is their packaging. This includes an exemption from Maine's reporting requirement with a current statutory deadline of January 1, 2023.

During an October 27, 2022 webinar, Department of Environmental Protection ("Department") officials invited the public to engage with the Department on whether it has thus far correctly interpreted the scope of its legal authority and obligations under 38 MRS § 1614. A Department official stated that "at this time" the Department believes drugs, medical devices, and packaging are in scope of the reporting requirement. We disagree with this interpretation of the Department's authority. Rather, we urge the state of Maine to undertake a more nuanced look at the doctrine of federal

preemption, which bars states from regulating products that have already been evaluated and approved for sale in commerce by the FDA and the USDA. Further, Maine should exercise enforcement discretion for FIFRA-registered animal health parasiticides because these products provide important health benefits to animals in accordance with a federal regulatory program similar to FDA and USDA. We therefore respectfully request further review and engagement of BI Animal Health and other animal health stakeholders in scoping exemptions to 38 MRS § 1614.

BI Animal Health appreciates the opportunity to engage with the Department and looks forward to your response.

Best Regards,

Wendi Godwin

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