Dechra
Veterinary Products

May 20, 2024

VIA ELECTRONIC MAIL
(MainePackagingEPR@maine.gov)

Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0017

Re: Packaging Material Exemption Request

To Whom It May Concern:

Dechra Veterinary Products, LLC, on behalf of itself and its affiliates (collectively, "Dechra"), hereby submits the following Packaging Material Exemption Request for the Maine Department of Environmental Protection's (DEP's) consideration as part of its review of packaging material associated with federal laws and regulations pursuant to Section 13(D) of 38 M.R.S. § 2146.

Dechra is a multinational veterinary pharmaceutical company engaged in the development, distribution, and sale of animal health products, including pharmaceuticals, nutritional supplements, feeds, and wellness products. Dechra's global range of animal health products are essential tools used by veterinarians, food producers, and pet owners to protect the health and welfare of animals, and therefore, also serve as important contributors to public health. Protecting the health and welfare of food animals contributes to the safety and wholesomeness of the food supply. Advancing the health and welfare of companion animals enables owners to live with their treasured companions without fear of zoonotic disease.

Dechra, which has an office in Portland, Maine, recognizes the value of our unique environment and has already adopted and implemented a global sustainability program in line with science-based targets (SBT). Our near-term SBTs were recently approved by the Science Based Targets initiative (SBTi). As part of our public commitment to building a sustainable future, Dechra is currently making progress to reduce scope one, two, and three GHG emissions, achieve net zero by 2050, eliminate suppliers who are not FSC approved, and achieve zero waste to landfill by 2025. You can read more about Dechra's sustainability efforts at https://www.dechra.com/sustainability.

Notwithstanding Dechra's extensive sustainability efforts, our products are highly regulated products with packaging that must meet specific requirements. As a result, Dechra strongly urges the DEP to exempt Dechra's animal health products from Chapter 428's standards to conform to the DEP's mandate under Maine's Extended Producer Responsibility law, 38 M.R.S. § 2146, and to exempt certain packaging if it is already required to meet stringent standards under federal regulation.

Under 38 M.R.S. § 2146(13)(D), the DEP must review packaging for certain federally regulated products to determine if that packaging should be excluded from the definition of "packaging material." At a minimum, the DEP is statutorily required to review packaging for drugs, medical devices, biological products, and substances requiring special packaging under the Poison Prevention Packaging Act, although the DEP has discretion to review packaging for other products as well. In determining whether to exempt packaging, the DEP must decide whether federal regulations are so stringent as to diminish the recyclability of the packaging or the ability of a producer to reduce the volume of packaging material it uses.

Packaging is an integral part of delivering safe and effective products. Safety and quality factors must be considered in packaging decisions, including protecting the efficacy of a product for the intended shelf life; protecting the product from migration of contamination in packaging components; ensuring uniformity of the product through all production lots; and controlling potential degradation of products from moisture, heat, light, and other factors.

These considerations are a significant barrier to Dechra using completely recyclable packaging. Most, if not all, recycled materials are downcycled, meaning they contain some amount of contamination and raise the risk of migration of these contaminants into or onto our products. Another barrier is the availability of packaging materials which are suitable to be recycled. Finally, the technical performance of recycled or recyclable materials often causes issues with the filling and packing lines in pharmaceutical manufacturing.

In addition to these considerations, there are other variables affecting the recyclability of packaging components which also form a barrier to Dechra's adoption of greater recyclability in packaging. The collection and sorting process of used material remains uneven. Furthermore, there is a lack of recycling technologies operating at commercial scale, often leaving incineration as the only available option. Some packaging should be treated as medical waste, material composition remains an issue, and multilayer packaging materials that are necessary to protect product integrity are difficult to separate.

For these reasons, Dechra's products are exactly the types of products that the legislature envisioned should be exempted; they are highly regulated products with packaging that must meet specific requirements to protect the integrity of the product. As a result, Dechra strongly urges the DEP to exempt Dechra's products from Chapter 428's standards.

Dechra develops, manufactures, and distributes veterinary pharmaceuticals, feeds, and medical devices to veterinarians, pet owners, and food animal producers. Each of these animal health products and their packaging are highly regulated by federal agencies for many of the reasons stated above, leaving Dechra little discretion to change its packaging.

For example, under the Food, Drug and Cosmetic Act (FDCA), the U.S. Food and Drug Agency (FDA) regulates drugs and medical devices. As part of FDA approval, each drug or device has its own unique approved packaging, which is designed to help maintain the sterility, purity, and stability of the drug or device over the course of its shelf-life. In its Guidance for Industry on Container Closure Systems for Packaging Human Drugs and Biologics, the FDA goes so far as to advise that "Postconsumer recycled plastic should not be used in the manufacture of a primary packaging component[1]." This guidance is also followed in the animal health industry.

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-systems-packaging-human-drugs-and-biologics

Recognizing the impossibility of requiring compliance with extended producer responsibility requirements, other states have exempted animal health pharmaceutical, feed, and device products from such requirements[2]. We respectfully request that the DEP do the same in Maine.

However, not all of Dechra's products are pharmaceutical products. As previously mentioned, Dechra also manufactures and sells nutritional supplements and animal wellness products. While Dechra's nutritional products are not subject to the same pre-approval requirements of the FDA's Center for Veterinary Medicine (CVM) as our pharmaceutical products prior to entering the marketplace, they are subject to similar safety and manufacturing requirements. Further, Dechra's animal wellness products are regulated by the Consumer Products Safety Commission and the DEP has discretion to review and exempt these products from Chapter 428's standards to conform to the DEP's mandate under Maine's Extended Producer Responsibility law. Although not regulated under the FDCA, Dechra's animal wellness products have the same safety and efficacy concerns as our pharmaceutical products. Like our pharmaceutical products, these products have their own unique packaging, which is designed to help maintain the purity and stability of the products. For example, these products are tested for contaminants and stability according to their product specifications to ensure product integrity over its shelf-life, which is largely dependent on the packaging components.

Accordingly, due to the risks and for the reasons stated above, Dechra's products are designed to meet stringent federal requirements and any mandate to change packaging components could impact the integrity of our products, thus adversely impacting the health and wellbeing of animals that consume or use these products, as well as the public health in the State of Maine.

For the reasons provided herein, Dechra respectfully requests that the DEP exempt Dechra's animal health products from Chapter 428's standards to conform to the DEP's mandate under Maine's Extended Producer Responsibility law, 38 M.R.S. § 2146, since they are already required to meet stringent standards under federal regulation to protect the integrity of the products, the health and wellbeing of animals, and the public health.

Please do not hesitate to contact me if you have any questions.

Sincerely,

Nate Arends
Assistant General Counsel
Dechra Veterinary Products, LLC

[2] See e.g., Ca. Pub. Res. Code § 42070 "Plastic Pollution Prevention and Packaging and Producer Responsibility Act;" 22 C.R.S. 17-701 "Producer Responsibility Program for Statewide Recycling," and ORS 459A.860 "Plastic Pollution and Recycling Modernization Act."