ANIMAL HEALTH INSTITUTE
Representing manufacturers of animal health products

October 31, 2023

Commissioner Melanie Loyzim
Department of Environmental Protection
17 State House Station
Augusta, Maine 04333-0017

RE: Exemptions, Definitions, Readily Recyclable and Producer Fees

The Animal Health Institute (AHI) appreciates the opportunity to submit comments to the Maine Department of Environmental Protection (DEP) during its development of rules to implement the Maine Stewardship Program for Packaging law, 38 M.R.S. Section 2146. AHI represents companies that make medicines for animals. These medicines are important contributors to public health.

As further detailed in our letter to you dated January 18, 2023, it would be appropriate for DEP to exempt animal health products from the EPR law. We reference and reincorporate those points because many of the considerations DEP is proposing in the concept draft rule would disproportionately affect animal health products if they are not exempt, and, in turn, the humans and animals who rely on them.

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. AHI members make a variety of products including pharmaceuticals, biologics, flea and tick treatments, medical devices and diagnostics. These products are essential tools used by veterinarians, food producers and pet owners to protect the health and welfare of animals.

The concept draft rule's fee schedule and proposed definitions are unworkable for animal health products. The proposed fee structure is meant to incentivize switching to readily recyclable material. Setting goals and fee structures to incentivize reformulating packaging will not be effective if there are no collection/ sorting and recycling streams established for all materials. For many materials it is technically not possible or reasonable to recycle them. Recyclable materials are usually mono materials, which are composed of a single type of material. Use of mono materials reduces the shelf life for many products which results in loss/ waste of finished product.

In addition, packaging material that was in contact with the drug product is not desired in the recycling streams as the active pharmaceutical ingredient (API) is contaminating the recycled material and equipment. Washing the shredded plastic flakes in the process often cannot eliminate the API residues in the plastic.

The high fees for non-recyclable packaging material will have socio-economic impact, as prices for the products will increase. Changing the primary packaging material from non-recyclable to a recyclable alternative needs time for stability and extractable and leachable studies as well as for approval from federal regulators. Currently there is not enough available alternative and recyclable material to the classic aluminum blister, for example.

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The draft proposes that base material must contain a minimum of 10% post-consumer recycled material by 2030. Currently, PCR is not allowed as a contact material with the drug product or component in a film/foil composition without a functional barrier. Each batch of recycled packaging material might contain a different source for contamination, unless the recycled material was made of ethylene.

Currently, no other state EPR laws encompass animal health products. However, regulators should be mindful that in the future, the definition of packaging material type and labelling might differ from state to state and should be aligned throughout all US states. State specific labelling is not feasible for producers.

It is not clear if the definition of throughput at1% by weight refers to a United States or Maine average. It will be difficult to differentiate between products sold in Maine or somewhere else in the US. This same concern applies to the initial registration and reporting requirement—producers will need to somehow figure out how much of their packaging enters the waste stream in one state.

Finally, approved recycling plants need to be in Maine or at least in the US to avoid recyclers getting paid for recycling waste, while the non-recyclable fractions or even more are declared to be raw materials for sorting / recycling plants in Africa or Asia, resulting in waste in the environment of the receiving countries.

AHI and its members support efforts to increase the circularity of used packaging and are making progress in our operations. The veterinary medical products we produce, however, carry special handling requirements. The existing federal requirements and the complexity of appropriately recycling packaging that has been used to protect veterinary medical products make full compliance with the Maine law unworkable. We recommend Maine follow the example other states have taken and exempt packaging used to contain these federally regulated veterinary medical products from the state's stewardship program for packaging.

Sincerely,

Mandy Hagan
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