

Submitted via Email: MainePackagingEPR@maine.gov

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

RE: Request to Amend Maine Regulation “Stewardship Program for Packaging Law”

The undersigned organizations are providing comments and requesting an amendment to §2146, a measure “[Stewardship program for packaging](#)”, to exempt infant formula, medical foods,¹ and foods for special dietary use (FSDU). As these products are often medically necessary and thus prescribed by a healthcare provider, may provide sole-source nutrition for vulnerable populations, and may be paid for by government programs such as Medicare and Medicaid, including them in this legislation would negatively impact patients and potentially limit their access to these important and at times lifesaving products. Specialized packaging is often used for these products to protect their quality and safety as well as ensuring nutrient delivery through product shelf life.

§2146 aims to reduce packaging waste by requiring packaging producers to pay into a “packaging stewardship fund” based on the amount of packaging material used in its goods. To meet the criteria as a covered producer, a company must generate at least \$2,000,000 in total gross revenue during the prior calendar year, package its goods using at least one ton of packaging materials in total, or distribute perishable food using at least 15 tons of packaging material in total. Infant formula, medical foods, and FSDUs are often medically indicated and used with healthcare provider recommendation or supervision. These specialized nutrition products are often more expensive than other food and beverage products because they are specifically formulated to meet individual needs. Requiring that companies pay additional fees on these products places undue burden on manufacturers that may pass the cost to consumers or the government through a markup in the sales price.

We are requesting to exempt infant formula, medical foods, and FSDUs to protect consumers and government programs that offer these products from possibly higher costs. These products are regulated differently than other foods and beverages and are often prescribed by a healthcare provider to serve a specific purpose when nutrition needs cannot be met through breastmilk or other foods. Our goal is to help ensure patients and families continue to have access to affordable nutrition products that are life-sustaining and, ultimately, will possibly help them prevent malnutrition. Exempting infant formula, medical foods, and FSDUs from this bill will help contain cost and help ensure continued availability of these products to consumers who use them. Fees on these products could consequently create health inequalities if manufacturers raise costs to accommodate the fee and consumers are no longer able to afford these products. Additionally, these products are

¹ A **medical food** as defined in section 5(b)(3) of the Orphan Drug Act, 21 USC 360ee(b)(3): “a food which is formulated to be consumed or administered **enterally** under the **supervision of a physician** and which is intended for the specific **dietary management of a disease or condition** for which **distinctive nutritional requirements**, based on recognized scientific principles, are established by **medical evaluation**.”

available through programs like the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and higher costs could negatively strain government resources in these programs.

Our proposed amendment is noted in **bold language** below:

*13.D.(1). Material that is used for the containment, protection, delivery, presentation or distribution of a drug, as that term is defined under Section 321 of the federal Food, Drug, and Cosmetic Act, as regulated by the United States Food and Drug Administration under the federal Food, Drug, and Cosmetic Act or as collected under a stewardship program in the State that has been approved for operation by the department and has been established to collect and dispose of such drugs, including, but not limited to, prescription and nonprescription drugs, drugs in medical devices and combination products, branded and generic drugs and drugs for veterinary use, **infant formula, medical foods, or foods for special dietary use...***

Colorado did make this exemption for “infant formula, medical foods, and fortified nutritional supplements” in their recent [House Bill 1355](#) section 25-17-703 Definitions (13)(b)(XIV). Thank you for considering the above amendment to exempt infant formula, medical foods, and FSDU manufacturers from §2146 and ensuring patients and families can have continued access to affordable specialized nutrition products. If you have any questions, please contact Berit Dockter MPP, RD, LD, Healthcare Nutrition Council, at bdockter@healthcarenutrition.org or 202-207-1112.

Respectfully,

American Partnership for Eosinophilic Disorders
FPIES Foundation
HCU Network America
Healthcare Nutrition Council
National Organization for Rare Disorders
National PKU Alliance
National PKU News
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)