

*Submitted via Email*

April 15, 2022

The Honorable Ronald D. Kouchi  
President  
Hawaii State Senate  
Hawaii State Capitol, Room 409  
415 South Beretania Street  
Honolulu, HI 96813

The Honorable Scott Saiki  
Speaker  
Hawaii State House of Representatives  
Hawaii State Capitol, Room 431  
415 South Beretania Street  
Honolulu, HI 96813

Re: Request to Amend Hawaii House Bill 2399/HD 1/SD 1 to Exempt Infant Formula, Medical Foods, and Foods for Special Dietary Use

Dear President Kouchi and Speaker Saiki,

The undersigned organizations are providing comments and requesting an amendment to House Bill 2399/HD 1/SD 1, a measure “Related to Waste Management”, to exempt infant formula, medical foods,<sup>1</sup> 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.

HB 2399 aims to reduce packaging waste by adding a fee to manufacturers and producers of “fast-moving consumer goods” which includes food and beverage manufacturers (the bill exempts drugs, medical devices, and dietary supplements). To meet the criteria as a covered producer, a company must produce a packaging volume of more than 10,000 metric tons internationally and have international gross sales of fast-moving consumer goods of more than \$500,000,000. In short, at a baseline of 10,000 metric tons of packaging, a covered producer would pay a minimum of \$1.5 million per year for 5 years. 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 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.

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<sup>1</sup> 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.”

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

*SECTION II. Applicability. This Act shall not apply to any material that is used in the packaging of a product that is regulated as a drug, medical device, **infant formula, medical food, food for special dietary use**, or dietary supplement by...*

Thank you for considering the above amendment to exempt infant formula, medical foods, and FSDU manufacturers from HB 2399 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](mailto:bdockter@healthcarenutrition.org) or 202-207-1112.

Respectfully,

American Partnership for Eosinophilic Disorders  
The FPIES Foundation  
Global Liver Institute  
HCU Network America  
Healthcare Nutrition Council  
Infant Nutrition Council of America  
National Organization for Rare Disorders  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

CC: Representative Nicole Lowen