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March 29, 2023

The Honorable Kumar P. Barve
Chair, House Environment and
Transportation Committee
251 House Office Building
6 Bladen Street
Annapolis, Maryland 21401

Re: SB 222 – Environment – Reducing Packaging Materials – Producer Responsibility
Favorable with Amendments

Dear Chair Barve:

On behalf of our client, Abbott Laboratories, I am writing to respectfully request consideration of language exempting specialized nutrition products from Senate Bill 222.

States that have included similar language as part of their Extended Producer Liability (EPR) laws include California (2022), Colorado (2022), Oregon (2021), Washington (2022), and New Jersey (2020).

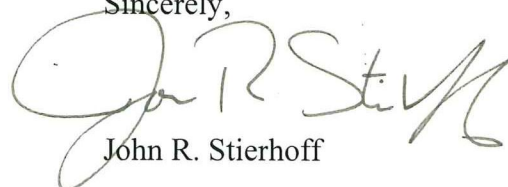
In order to better ensure the nutrition of individuals requiring specialized nutritional products, and to maintain a regimen critical to their health and survival, Abbott Laboratories proposes the following amendments:

On page 11, in line 27, strike “OR”; after line 27, insert “**3. “INFANT FORMULA” AS DEFINED IN 21 U.S.C. 321(Z), “MEDICAL FOOD” AS DEFINED IN 21 U.S.C. 360EE(B)(3), AND “FOOD FOR SPECIAL DIETARY USE” AS DEFINED IN 21 U.S.C. 350(C)(3); OR**”; and in line 28, strike “3.” And insert “**4.**”.

On page 12, in line 8, after “DEVICE” insert “**, INFANT FORMULA, MEDICAL FOOD, OR FOOD FOR SPECIAL DIETARY USE**”.

I have attached additional information with respect to EPR exemptions of specialized nutrition products. Thank you, in advance, for your consideration of these critical amendments.

Sincerely,



John R. Stierhoff

cc: Members, Environment and Transportation Committee
Members, Economic Matters Committee

Why Exempt Specialized Nutrition Products from Extended Producer Responsibility (EPR) Legislation

- Specialized nutrition products provide supplemental or sole-source nutrition for vulnerable populations
- US Food and Drug Administration (FDA) regulations delineate distinctive nutrition categories, including medical food, food for special dietary use (such as oral nutrition supplements), and infant formula
- Not exempting such products from an EPR bill could disrupt product access for vulnerable populations

Specialized Nutrition Products Help Meet Nutrition Requirements of Vulnerable Populations



SUPPORT FOR HEALTH EQUITY

Specialized nutrition products support health equity when:

- Provided free of charge through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)
- Purchased with Supplemental Nutrition Assistance Program (SNAP) benefits



NUTRITION FOR VULNERABLE POPULATIONS

Specialized nutrition products provide supplemental or sole-source nutrition, helping:

- Meet nutritional needs through all stages of life (infants through older adults)
- Support the nutritional needs of individuals with health conditions (such as illness, disease, injury, malnutrition)



IMPORTANT PACKAGING CONSIDERATIONS

Selection of packaging materials is an important consideration for specialized nutrition products:

- The multilayer containers used today must withstand processing and heat treatment conditions while maintaining product integrity and nutrient levels throughout product shelf life
- Further research is needed on functional and sustainable packaging options, but may be slower to develop because of the many important packaging considerations for specialized nutrition products



EXEMPTION LANGUAGE

- “*Infant formula*” as defined in 21 U.S.C. 321(z)
- “*medical food*” as defined in 21 U.S.C. 360ee(b)(3)
- “*food for special dietary use*” as defined in 21 USC 350(c)(3)

STATE EPR BILLS WITH EXEMPTIONS

Oregon SB582 (signed into law in 2021)

Colorado HB22-1355 (signed into law in 2022)

California SB54 (signed into law in 2022)

Reference: Pascall MA et al. Role and Importance of Functional Food Packaging in Specialized Products for Vulnerable Populations: Implications for Innovation and Policy Development for Sustainability. *Foods* 2022, 11, 3043. <https://doi.org/10.3390/foods11193043>

Expanded Producer Responsibility (EPR)

Oregon EPR language. Definition section under what a “covered product” does NOT include:

(O) Packaging and paper products sold or supplied in connection with: (i) Infant formula as defined in 21 U.S.C. 321(z); (ii) Medical food as defined in 21 U.S.C. 360ee(b)(3); or (iii) Fortified oral nutritional supplements used for individuals who require supplemental or sole source nutrition to meet nutritional needs due to special dietary needs directly related to cancer, chronic kidney disease, diabetes, malnutrition, or failure to thrive, as those terms are defined as by the International Classification of Diseases, Tenth Revision, or other medical conditions as determined by the commission.

Colorado EPR language. Packaging material does NOT include:

(XIV) PACKAGING MATERIAL USED TO CONTAIN A PRODUCT THAT IS REGULATED AS INFANT FORMULA, AS DEFINED IN 21 U.S.C. SEC. 321 (z), AS A MEDICAL FOOD, AS DEFINED IN 21 U.S.C. SEC. 360ee (b)(3), OR AS FORTIFIED NUTRITIONAL SUPPLEMENTS USED FOR INDIVIDUALS WHO REQUIRE SUPPLEMENTAL OR SOLE SOURCE NUTRITION TO MEET NUTRITIONAL NEEDS DUE TO SPECIAL DIETARY NEEDS DIRECTLY RELATED TO CANCER, CHRONIC KIDNEY DISEASE, DIABETES, MALNUTRITION, OR FAILURE TO THRIVE, AS THOSE TERMS ARE DEFINED BY THE WORLD HEALTH ORGANIZATION'S "INTERNATIONAL CLASSIFICATION OF DISEASES" (TENTH REVISION), AS AMENDED OR REVISED, OR ANY OTHER MEDICAL CONDITIONS AS DETERMINED BY THE COMMISSION BY RULE; AND

California EPR language. Covered material does NOT include:

(iv) Infant formula, as defined in Section 321(z) of Title 21 of the United States Code.

(v) Medical food, as defined in Section 360ee(b)(3) of Title 21 of the United States Code.

(vi) Fortified oral nutritional supplements used for persons who require supplemental or sole source nutrition to meet nutritional needs due to special dietary needs directly related to cancer, chronic kidney disease, diabetes, malnutrition, or failure to thrive, as those terms are defined as by the International Classification of Diseases, Tenth Revision, or other medical conditions as determined by the department.