



Maria Cahill
Senior Director, Government Affairs
67 Collier Road
Scituate, MA 02066

M: 617-872-1259
Maria.cahill@abbott.com

October 26, 2023

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

RE: Request to Amend "Part 2: Conceptual draft rules for Stewardship Program for Packaging"
Submitted via Email: MainePackagingEPR@maine.gov

Dear Members of the Maine Board of Environmental Protection:

This letter provides comments regarding the recently released *Part 2: Conceptual Draft Rules for the Stewardship Program for Packaging*. In submitting our comments, Abbott asks the Board to exempt from the Maine Stewardship Program for Packaging products that are infant formulas, medical foods, or foods for special dietary use (FSDUs). Such products play an important role in helping meet special nutrition and medical needs and are specifically defined in federal regulations:

Infant Formula as defined in [21 Code of Federal Regulations 321\(z\)](#) means a:

- "food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk."

Medical Foods as defined in section [5\(b\) of the Orphan Drug Act \(21 U.S.C. 360ee \(b\) \(3\)\)](#) are 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."

FSDUs as defined in the [Code of Federal Regulations \[21 Code of Federal Regulations 105.3 \(c\) \(3\)\]](#), can be used:

- "for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight
- for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood."

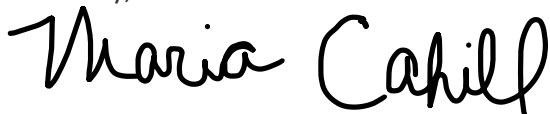
Nutrition is an important social determinant of health. These categories of special products help support health equity and nutrition when provided free of charge through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and also when covered by Supplemental Nutrition Assistance Program (SNAP) benefits, as both of these programs serve low-income populations in the state.

The special products also include those that provide supplemental or sole source nutrition for other vulnerable populations as well, such as older adults and individuals with chronic diseases like cancer and diabetes. Indeed, no other type of food product on the store shelves today can fulfill the role of infant formulas and some medical foods and FSDUs which provide a full complement of macro and micronutrients to meet supplemental or sole source nutrition needs.

Selection of packaging materials is an important consideration for specialized products. The multilayer containers used today must withstand processing and heat treatment conditions while maintaining product integrity and nutrition levels throughout product shelf life. Multilayer containers are not part of the closed-loop recycling processes and are limited in ability to use post-consumer recycle (PCR) content because of material instability, contaminant migration risk, and lack of approval for safe food contact use. For these reasons and because the products all serve vulnerable populations who depend on the products delivering very specific levels of needed nutrients that other states including California, Colorado, and Oregon have already explicitly exempted infant formulas, medical foods, and FSDUs from their EPR policies.

Abbott is a science-based company that has been developing innovative products like infant formulas, medical foods, and FSDUs since our founding. Our goal has remained unchanged: to help people live their best lives at every stage, from infancy through adulthood. We are asking that you exempt infant formulas, medical foods, and FSDUs from Maine's Stewardship Program for Packaging to help ensure continued access for the vulnerable populations who need these important products and rely on them to meet daily nutrition and health requirements.

Sincerely,

A handwritten signature in black ink that reads "Maria Cahill". The signature is written in a cursive, flowing style.

Maria Cahill
Senior Director, Abbott State Government Affairs