

Extended Producer Responsibility and Medical Foods and Foods for Special Dietary Use

Who We Are

The Healthcare Nutrition Council (HNC) is an association representing manufacturers¹ of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods², foods for special dietary use (FSDU)³, and parenteral nutrition (PN). These formulas and supplements are frequently used by individuals who require supplemental or sole source nutrition to meet nutritional needs due to special dietary requirements directly related to cancer, chronic kidney disease, diabetes, malnutrition, or failure to thrive (as defined by the International Classification of Diseases, Tenth Revision), or other medical conditions as determined by a health authority. HNC's mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access to essential nutrition support therapies across the continuum of care.

The Role of Specialized Nutrition Products

The aim of EPR legislation is to accelerate the move toward a circular economy, this is an admirable pursuit that is widely supported by industry. However, the important and unique contributions FSDU and medical foods make to the health and wellness of some at risk populations necessitate unique considerations in EPR program design. Medical foods and FSDU are often medically necessary and used under healthcare provider recommendation or supervision. These specialized nutrition products may provide sole-source nutrition for vulnerable populations, serving a specific purpose when nutrition needs cannot be met through other foods. Government programs such as Medicare and Medicaid often provide medical foods and FSDU for patients needing these products, and HNC is committed to ensuring continued patient access. While packaging for products designed for general consumption may effectively address function as well as recyclability without sacrificing product safety or quality, the specificity of application and material sensitivity of many FSDU, medical foods, and infant formulas require that packaging be designed for safety, efficacy, and application before anything else. In consideration of the important role these products play in our health system, HNC requests an exemption for medical foods and FSDU in legislation that includes provisions for Extended Producer Responsibility (EPR).

Recommended Proposed Exemption Language for EPR Legislation

HNC recommends exemption of medical foods, FSDU, and infant formula from EPR legislation, using legislative language such as: "Foods defined under 21 USC 360ee(b)(3) and 21 CFR Part 105 and Part 107.3 are not subject to these requirements." This language ensures that patients will continue to have access to these medically necessary and recommended products.

States Including Medical Foods, FSDU, and Infant Formula Exemptions in EPR Legislation

The Colorado legislature made this exemption for "medical foods, and fortified nutritional supplements" in their recent [House Bill 1355](#) section 25-17-703 Definitions (13)(b)(XIV). Exemptions were also included in [Oregon SB 582](#) and [California SB 54](#). HNC encourages all state legislatures to include similar language in future legislation.

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¹ HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

² 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**."

³ 21 CFR Part 105