Packaging Material Exemption Request for Packaging Stewardship Program

Submitted by The Infant Nutrition Council of American https://infantnutrition.org

Specialized nutrition products provide supplemental or sole-source nutrition for infants and young children and often are life sustaining products without viable alternatives. The US Food and Drug Administration (FDA) regulations delineate distinctive nutrition categories for these products, including infant formula, medical food, and food for special dietary use. Not exempting such products from the Maine *Stewardship Program for Packaging* could disrupt product supply and impact product safety and access for vulnerable populations. Infant formula products are packaged in a manner to protect nutritional requirements, meet manufacturing standards and regulatory compliance, and they provide significant WIC support. As a federally regulated sole-source of nutrition its packaging is based on efficacy and safety.

1. **Which federal laws or regulations preclude or significantly diminish a producer's ability to increase the recyclability or reduce the volume of packaging material? Please provide specific citations and language.**

   Infant formula, medical food, and food for special dietary use are explicitly defined in federal food regulations:

   Infant Formula: 21 U.S.C. 321(z)
   Medical food: 21 U.S.C. 360ee(b)(3)
   Food for special dietary use: 21 USC 350(c)(3).

   For these specialized nutrition products, there are additional statutory and regulatory requirements beyond those that apply to conventional foods. For example, FDA has established specific compositional and labeling requirements for infant formula as well as specific infant formula good manufacturing practices.

   Such requirements along with important manufacturing and packaging considerations for specialized nutrition products can make both the selection of and any changes in packaging components more difficult, including changes that that are intended to increase recyclability or reduce the volume of packaging material.

   Specifically:

   1) Packaging for specialized products must be "food grade." The Food and Drug Administration (FDA) has established guidelines for safe, direct contact of packaging materials to be considered food grade. An important consideration for specialized nutrition products is that some food contact substances may potentially negatively affect sensitive individuals at an increased rate (compared

to the general population) because of the individuals' age, size, metabolism, or health conditions.

2) Packaging materials must further meet the specific safety requirements of the types of food with which they come into contact, while at the same time meet manufacturers' individual production specifications. This includes for example, the ability to withstand high temperature and/or pressure during manufacturing of infant formula, medical food, or food for special dietary use. Packaging must also successfully keep these products safe and of high quality and protect against any potential chemical compound or bacterial migration for the entire life of the product--throughout the supply chain and delivery until the product is finally consumed. All of these requirements along with the need to maintain product nutrient levels to support the nutrition of vulnerable populations place very high demands as well as expectations on the packaging for specialized products and limit flexibilities in the type and volume of packaging used.

2. If content or construction standards are not directly specified in the citations referenced in response to Question 1, please explain how the cited federal laws or regulations indirectly specify content or construction standards.

FDA regulations require pre-market notification of any new or updated infant formula as well as any changes in manufacturing, including in packaging materials. This premarket review is defined in statute as 90 days, but in practice is often much longer so that the actual length of time for pre-market review cannot be accurately predicted. Practically speaking this means that every individual infant formula product with any packaging change must be submitted for a separate FDA pre-market review, with no known date of when that review may be completed or the potential impact on product supply chains.

Further, FDA has recently established the Office of Critical Foods, as directed by the 2023 Consolidated Appropriations Act. Both infant formula and medical food are defined in the statute as critical foods. However, FDA is still developing the regulatory framework for critical foods, meaning there may be additional requirements promulgated that could impact manufacturing and packaging processes and pre-market reviews.

3. To which product or group of products do the federal laws or regulations referenced in response to Question 1 and any circumstances specified in response to Question 2 apply?

The federal laws/regulations referenced and circumstances specified apply to the specialized nutrition products defined as infant formula, medical food, and food for special dietary use. These specialized nutrition products support health equity when they are provided free of charge through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) or purchased with Supplemental Nutrition Assistance Program (SNAP)

benefits. Specialized nutrition products provide supplemental or sole-source nutrition, helping meet nutritional needs through all stages of life (infants through older adults) and supporting the nutritional needs of individuals with health conditions (such as illness, disease, injury, malnutrition).

It is for these reasons as well as the requirements and concerns described in responses to questions 1 and 2 that several states (Oregon, Colorado, and California) have already exempted specialized nutrition products from packaging sustainability legislation. Further, a recent peer-reviewed paper on the role and importance of functional food packaging in specialized products for vulnerable populations has described these unique product categories and the role of packaging. In addition, the paper has reviewed considerations for emerging legislative/regulatory policies in addressing the functional packaging requirements for these specialized products.

4. **Do the federal laws or regulations referenced in response to Question 1 and any circumstances specified in response to Question 2 apply to some or all packaging material associated with the product or group of products identified in response to Question 3? If some, identify the packaging material that is affected.**

   The federal laws/regulations referenced and circumstances specified apply to all packaging materials used with the specialized nutrition products defined as infant formula, medical food, and food for special dietary use.

5. **Who should the Department contact with questions regarding this exemption request?**

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