



**Infant Nutrition Council of America
Testimony on H.R. 2267 – Infant Formula Protection Act of 2019**

The Infant Nutrition Council of America (INCA) appreciates the opportunity to testify on H.R. 2267, the Infant Formula Protection Act of 2019. INCA is an association representing manufacturers¹ of infant formula, and our member companies manufacture over 95% of the infant formula fed in the United States. INCA member companies are centers of excellence for scientific research and education in the area of global infant nutrition with a strong emphasis on infant growth, development, and positive health outcomes. The primary focus of INCA and its member companies is and will always remain the health and welfare of infants and young children. That is why we share Congresswoman Meng’s goal of preventing the purchase of infant formula that is past its “use by” date and support the intent of H.R. 2267.

Most babies in the United States receive infant formula – which is the only safe and medically-recommended alternative to human breast milk – at some point during their first year of life. Most new mothers initiate exclusive breastfeeding when their baby is born; however, many also use combination feeding (feeding both breast milk and formula) or switch to infant formula during the first year. For this reason, assuring the quality of infant formula is important to millions of parents, caregivers, and infants.

Infant formula is one of the most highly regulated foods in the world because it may be fed as the sole source of nutrition at a time of critical infant growth and development, making quality a key factor for regulatory oversight. U.S. infant formula products are manufactured with high-quality ingredients and with strict adherence to the U.S. Infant Formula Act and the U.S. Food & Drug Administration’s (FDA) Good Manufacturing Practices for Infant Formula Manufacturers. All infant formulas are required by law to include a “use by” date on the container, which ensures that throughout the product’s shelf life, the infant formula provides the 30 essential nutrients listed on the infant formula label. Adhering to the “use by” date assures that a baby who is fed the formula receives the federally-regulated and required level of nutrients listed on the product label. Infant formula fed past the “use by” date may not deliver all nutrients at the exact levels listed on the label due to degradation over time. Thus, the “use by” date is primarily an indicator of product quality, not safety. By contrast, the term “adulterated,” as defined by FDA, and as set forth in Section 342 of the Federal Food, Drug, and Cosmetic Act generally means a product is harmful or injurious to human health because it contains a poisonous or deleterious substance. And although Section 350a of the Act expands the definition of “adulterated” for infant formula to also include...

- (1) an infant formula that does not provide the Federally mandated nutrients, (2) an infant formula that does not meet the quality factor requirements prescribed by FDA, or (3) an infant formula that was not manufactured in conformance with FDA’s good manufacturing practices and quality control procedures.

...those are in specific reference to manufacturer activities rather than more general retailers and distributors. Accordingly, calling an infant formula that is past its “use by” date adulterated would be inconsistent with Section 342, and also ill-fitting with Section 350a.

¹ INCA members are Abbott Nutrition, Gerber Products Company, Perrigo Nutritionals, and Reckitt Benckiser.



In this light, INCA suggests alternative language that would instead more succinctly prohibit the retail sales of infant formula past its “use by” date. Indeed, Congress took a similar approach in 2011, with the passage of the Food Safety Modernization Act (FSMA), when it implemented the hazard analysis and risk-based preventive controls at Section 350g. Instead of those violations rendering a food product “adulterated,” Congress simply cut to the chase and made it a new “Prohibited Act” in Section 331. We suggest that the Infant Formula Protection Act of 2019 be implemented in a likewise manner.

For background information, in 1985, FDA amended its regulations with respect to infant formula to require that a “use by” date be placed prominently on every infant formula product. In codifying this requirement, FDA reasoned that: “Retail store employees can easily determine when to remove stock from store shelves based on a “use by” date.² FDA also underscored in this rulemaking the necessity for manufacturers to conduct stability testing to determine the appropriate “use by” date. As a result, infant formula manufacturers must be able to document that any infant formula consumed before its “use by” date will provide at the required levels all the nutrients specified by Section 412 of the Federal Food, Drug, and Cosmetic Act.

INCA and its member companies consistently work with stakeholders to ensure infant formula is safe and nutritious. INCA meets regularly with FDA’s Office of Nutrition and Food Labeling to share information on infant feeding issues and seek alignment as needed. INCA is working with the retail industry to develop a joint resource guide outlining best practices for handling infant formula returns and ensuring returned or expired product is never re-shelved. INCA has also engaged with the U.S. Department of Agriculture regarding strengthening recommendations that state WIC agencies do not accept expired or returned infant formula or allow it to be given to area food banks or distributed through any other channels, due to potential safety and quality concerns.

Today we have the opportunity to establish statutory measures to ensure expired infant formula is not sold at retail. Indeed, while infant formula manufacturers have been required for nearly 35 years to provide “use by” date information on product labeling and to have data on hand supporting the propriety and accuracy of such dating, there has been no commensurate legal obligation to ensure that infant formula that is past its “use by” date is removed from store shelves and not sold to consumers.

In summary, INCA supports the intent of the Infant Formula Protection Act of 2019, but believes the best way to accomplish the goal of legislatively precluding the retail sale of expired infant formula is to amend Section 301 of the Federal Food, Drug, and Cosmetic Act, so that it would unequivocally prohibit retailers from the sale of infant formula products beyond their “use by” date. Failure to abide by this restriction would constitute a prohibited act. We believe this would be the most effective method of supporting the collective goal of establishing statutory measures that ensure formula fed infants receive safe, nutritious products, while continuing to reassure parents and caregivers about the high quality of that formula. INCA and its members look forward to working with the bill sponsor, Committee, and all interested stakeholders to determine a workable solution to this issue.

² Federal Register, Vol. 50, No. 9, Page 1838. January 14, 1985.