

Consumer Federation of America

Kids In Danger

Public Citizen

January 28, 2020

The Honorable Frank Pallone
United States House of Representatives
Washington, DC 20515

The Honorable Greg Walden
United States House of Representatives
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden,

As organizations dedicated to working to improve child product safety, we write to express our support for H.R. 2267, the Infant Formula Protection Act of 2019.

H.R. 2267 would protect infants by prohibiting the sale of infant formula past its expiration date. Currently, any retailer that sells infant formula, including pharmacies, supermarkets, and convenience stores, can sell expired infant formula.

According to the Food and Drug Administration (FDA), “While breastfeeding is strongly recommended and many mothers hope to breastfeed their infants, most infants in the U.S. rely on infant formula for some portion of their nutrition. An estimated 1 million infants in the United States are fed formula from birth, and by the time they are three months old, about 2.7 million rely on formula for at least part of their nutrition.”¹

Unlike other foods, infant formula must meet certain nutrient specifications, which are prescribed by federal regulations.² The FDA also requires a “use by date” on infant formula. “The ‘use by’ date on infant formulas is a date, selected by the manufacturer based on tests and other information, to inform retailers and consumers about the quality of the infant formula. Until that declared date, the infant formula will contain no less than the amount of each nutrient declared on the product label and will otherwise be of acceptable quality. The ‘use by’ date is required by FDA regulations on each container of infant formula.”³ The FDA does not prohibit the sale of infant formula after the “use by date.”

For infant formula, the “use by date” is significant for safety because, according to the FDA, “Consumption by this date ensures the formula contains not less than the quantity of each nutrient as described on the label. Formula must maintain an acceptable quality to pass through

¹ <https://www.fda.gov/consumers/consumer-updates/fda-takes-final-step-infant-formula-protections>.

² “FDA has requirements for nutrients in infant formulas, which are located in section 412(i) of the FFDCFA and 21 CFR 107.100. These nutrient specifications include minimum amounts for 29 nutrients and maximum amounts for 9 of those nutrients. If an infant formula does not contain these nutrients at or above the minimum level or within the specified range, it is an adulterated product.” <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-frequently-asked-questions-about-fdas-regulation-infant-formula>

³ <https://www.fda.gov/food/people-risk-foodborne-illness/questions-answers-consumers-concerning-infant-formula>
(Source: FDA/CFSAN Office of Nutritional Products, Labeling and Dietary Supplements July 2002.)

an ordinary bottle nipple.”⁴ In other words, after the “use by” date has passed, consumers cannot have confidence that the infant formula for sale contains the nutrients required under federal law. Nevertheless, despite requiring the ‘use by’ date on each container of infant formula, FDA does not prohibit the sale of infant formula after that date has passed.

Clearly, no caregiver should feed an infant expired formula. For example, a publication about infant formula feeding by WIC Works, a resource system that provides education and training for the staff of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC),⁵ explicitly encourages caregivers to “[c]heck the infant formula’s expiration date on the label, lid, or bottom of the can. If the expiration date has passed, then the infant formula has expired and should not be used.”⁶

We support H.R. 2267 since it will protect infants from potential harms caused by expired infant formula and is consistent with recommendations urged by government agencies and professionals with expertise in infant nutrition.

We urge support for H.R. 2267 and support its passage.

Thank you for your consideration.

Sincerely,

Rachel Weintraub
Legislative Director and General Counsel
Consumer Federation of America

Thomas Gremillion
Director of Food Policy
Consumer Federation of America

Nancy Cowles
Executive Director
Kids In Danger

Remington A. Gregg
Counsel for Civil Justice and
Consumer Rights
Public Citizen

Cc: Representative Meng

⁴ <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/food-product-dating/food-product-dating>, (under the header, “What are the Requirements for Dating Infant Formula?”)

⁵ See <https://wicworks.fns.usda.gov/>.

⁶ https://wicworks.fns.usda.gov/wicworks/Topics/FG/Chapter4_InfantFormulaFeeding.pdf at 89.