

October 23, 2025

Documents Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2025-N-1793, Ultra-Processed Foods; Request for Information

To Whom It May Concern,

Consumer Reports¹ appreciates the opportunity to comment on the Food and Drug Administration's (FDA) request for information about ultra-processed foods. While we agree with the comments submitted by the Center for Science in the Public Interest (CSPI), we are submitting short comments urging FDA not to exempt either infant formula or medical foods from the definition of ultra-processed foods. We believe both infant formula and medical foods should be included in consideration of being ultra-processed foods, since some of their ingredients have been associated with adverse health effects. In infant formula, the presence of added sugars, particularly non-lactose sugars, has been linked to a number of adverse health effects, particularly risk of childhood obesity and later Type 2 diabetes.

The Infant Formula Act of 1980 set up nutrient requirements for infant formula, which haven't been updated since 1986. For carbohydrate levels in infant formula, the FDA indicates that total carbohydrates should range from 7.0 to 15.7 grams per serving (100 ml).² In addition, human breast milk contains about 6 - 8 grams per serving, of which about 80% is lactose.³ Lactose is the sole carbohydrate source for infants in human milk since roughly 20% of carbohydrates in human milk are composed of around 200 oligosaccharides, which are non-digestible carbohydrates that act as prebiotics for gut bacteria. Although the FDA indicated a range for total carbohydrates in infant formula, they didn't specify what those carbohydrates could be used, only specifying that those carbohydrates should be considered GRAS (generally recognized as safe). Thus, infant formula frequently contains non-lactose sugars, such as glucose-based polymers (corn syrup solids, maltodextrins) and sucrose, which are considered added sugars when present in other foods.

¹ Founded in 1936, [Consumer Reports](#) (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

² <https://www.sciencedirect.com/science/article/pii/S0889157525001838>

³ <https://www.preprints.org/manuscript/202508.0225>

Human milk contains around 7.8 grams of lactose per serving.⁴ Yet FDA recommendations for carbohydrate levels in infant formula can be as high as 15.7 grams per serving. Thus, infant formula could contain a lot of added sugar. A 2022 study of powdered infant formula sold in the U.S. found that 59% of powdered formula contained a glucose-based polymer.⁵ A study published in 2025, using data from 2022, found that most infant formulas contained added sugars, with from 60% to 90% of the sugar in infant formula being from refined added sugars.⁶ For the standard formula, which primarily contains lactose, some 60% of that lactose was refined and added in, not naturally-occurring lactose. For gentle formulas, some 85% of the sugars were added sugars, while that figure was 90% for the lactose-free formula.

Other studies have linked consumption of non-lactose sugars in infant formula with adverse health outcomes. A study of over 15,000 infants in California's Special Supplemental Nutrition Program for Women, Infants and Children (WIC) published in 2022 found that infants fed glucose-based lactose-reduced infant formula made with corn syrup solids (CSSF) had a higher risk of obesity at ages 2 and 4 compared to infants fed lactose-based formula.⁷ As the study concluded, "CSSF issuance is associated with increased obesity risk in the first 5 y life in a dose dependent manner, in a dose dependent manner". Indeed, the obesity risk was 16% higher at age 2 for children fed CSSF for 12 months compared to infants fed lactose-based formula.

The 2015 U.S. Dietary Guidelines Advisory Committee concluded that "Strong and consistent evidence shows that intake of added sugars from food and/or sugar-sweetened beverages are associated with excess body weight in children and adults."⁸ The 2020-2025 Dietary Guidelines for Americans concluded that added sugars are contraindicated for infants less than 2 years of age.⁹

Given these findings from the 2015 and 2020 Dietary Guidelines for Americans, it is clear that refined added sugars can no longer be generally recognized as safe (GRAS). Thus, FDA's 1998 affirmation that these refined sugars (corn sugar, corn syrup, invert sugar, and sucrose) are GRAS is no longer applicable. Given this, these refined sugars should not really be allowed in infant formula, since one of the requirements for carbohydrates added to infant formula is that they must be determined to be GRAS. FDA seems to recognize that infant formula may contain too much added sugars and recently did a request for information on how to update the nutritional requirements for infant formula.¹⁰ The FDA Expert Panel on Infant Formula "Operation Stork Speed" even stated that a "growing body of evidence showing adverse effects

⁴ <https://www.sciencedirect.com/science/article/abs/pii/S0002822308018853>

⁵ <https://onlinelibrary.wiley.com/doi/10.1111/cea.14232>

⁶ <https://www.sciencedirect.com/science/article/pii/S0889157525001838>

⁷ <https://pmc.ncbi.nlm.nih.gov/articles/PMC10157812/pdf/main.pdf>

⁸ Pg. 460 in https://ods.od.nih.gov/pubs/2015_dgac_scientific_report.pdf

⁹ https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf

¹⁰ <https://www.govinfo.gov/content/pkg/FR-2025-05-14/pdf/2025-08419.pdf>

of lactose-reduced and corn syrup-based formulas justifies the need to revisit the rationale and recommendations for replacing lactose with other sugars like corn syrup solids (glucose polymers) and/or sucrose.”¹¹

Thus, given the potential adverse health effects associated with added sugars to infant formula, infant formula should definitely be considered to fall under the definition of ultra-processed foods, and should not be excluded from the definition of ultra-processed foods.

If we look at medical foods, we can see that some of them should be considered as ultra-processed foods as well. For example, Ensure drinks, which are considered to be medical foods, often contain ingredients that would fall under the ultra-processed label. Although specific ingredients may differ by specific flavor and formula, most Ensure drinks contain corn maltodextrin or other refined sugars, milk protein concentrate or soy protein concentrate, natural or artificial flavors to enhance taste, and may contain nonnutritive sweeteners, and stabilizers such as cellulose gum or gel, soy lecithin, monoglycerides and carrageenan. Given this, we think that at minimum, the Ensure drinks should not be considered to fall under the definition of ultra-processed food. Consequently, medical foods should not be given an exemption from consideration as ultra-processed foods.

Sincerely yours,

Michael Hansen
Senior Scientist

Brian Ronholm
Director Food Policy

¹¹ <https://www.preprints.org/manuscript/202508.0225>