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IN FOCUS

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An Overview of Federal Regulation of Infant Formula

Approximately two-thirds of all infants in the United States receive formula (or other nutritional supplementation) by six months of age. Infant formula may supplement breastfeeding or serve as the sole source of nutrition for an infant. The use of infant formula can stem from a variety of factors, including breast milk availability, feeding preferences, or nutritional and other medical needs. Infant formula is typically available as a dehydrated powder that is reconstituted with water, a ready-to-eat formula, and a concentrated liquid that must be diluted.

Some policymakers, researchers, and other stakeholders have shown interest in infant formula regulation, particularly following the 2022 infant formula shortage. More recent developments include outbreaks and product recalls, ongoing federal efforts to reexamine the safety and nutritional adequacy of U.S.-based infant formula manufacturing, and litigation related to infants developing a life-threatening gastrointestinal condition. This In Focus provides an overview of federal regulation of infant formula by the U.S. Food and Drug Administration (FDA) and summarizes select recent FDA actions related to infant formula.

Definitions

Infant formula is classified as a food under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§301 et seq.), which sets out various requirements for all foods and outlines requirements specific to infant formula (e.g., §350a and §350a-1). The FFDCA defines *infant formula* as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk." FDA regulations define *infant* as a person not more than 12 months old.

The FFDCA exempts certain infant formulas from specific requirements pertaining to infant formula, such as requirements related to nutritional content and registration requirements for new infant formulas, discussed below. Manufacturers of these *exempt* infant formulas are permitted to deviate from certain requirements to tailor their infant formulas for use by infants with "an inborn error of metabolism or a low birth weight, or ... who otherwise ha[ve] an unusual medical or dietary problem." Special requirements for these exempt infant formulas are set out in regulation and require manufacturers to submit to FDA the product's label, the product's formulation, and "a detailed description of the medical conditions for which the infant formula is represented." FDA maintains a list of exempt infant formulas on its website.

The FFDCA also imposes additional requirements on a subset of foods called "critical foods," which includes infant formula. Manufacturers of all critical foods are required to report to FDA certain interruptions and discontinuances in the manufacture of a critical food and to maintain a risk management plan to mitigate the impacts of a supply disruption.

Nutrient Requirements

Unless a product qualifies as an exempt infant formula, the FFDCA requires infant formulas to meet specific nutrient requirements. Every four years, FDA is to consider whether a revision to its nutrient requirement regulations is appropriate in light of new scientific data or international standards. To date, the most recent update to the nutrient requirements involved the addition of the mineral selenium in 2015. The current list specifies 30 nutrients and their accompanying units of measure and maximum and minimum levels that must be present in infant formula.

Labeling Requirements

Labels for infant formula products must adhere to FFDCA provisions and FDA regulations that set out requirements applicable to all food labels, as well as those specifically pertaining to infant formula. Like all food labels, infant formula labels must bear the common or usual name of the food on the principal display panel. Infant formulas must also include on the information panel the list of ingredients and the name and place of business of the manufacturer, packer, or distributor. Infant formulas also must include

- nutrient information in the order, units, and tabular format specified in 21 C.F.R. §107.10;
- written and pictorial directions for preparation and use, including how to store, sterilize, and dilute the infant formula;
- a "use by" date, reflecting the month and year through which the formula will contain sufficient nutrients and be of acceptable quality; and
- statements (1) regarding the use or disuse of water, (2) cautioning that improper preparation may affect infant health, and (3) indicating that parents should consult their physicians about the use of infant formula.

Additionally, the FFDCA regulates the use of certain claims that food manufacturers may seek to make on infant formula labels. An infant formula manufacturer may not make a nutrient content claim—a claim that characterizes the level or absence of a nutrient—unless there is a regulation specifically allowing its use on the labeling of products intended for use by infants. For example, FDA regulations allow the use of factual statements that an infant formula is unsweetened.

An infant formula manufacturer may not use health claims, which are claims that characterize the relationship between a nutrient and a disease or health-related condition, absent

FDA's approval of the use of the claim. FDA permits the use of only one health claim on infant formula labels. Specifically, infant formula labels may describe the relationship between the consumption of 100% Whey-Protein Partially Hydrolyzed infant formula and a reduced risk of atopic dermatitis, provided the claim includes an appropriately worded disclaimer and a warning not to feed the product to infants with certain allergies or symptoms.

Manufacturing Requirements

At least 90 days prior to marketing a new infant formula, a manufacturer must register with FDA and submit descriptions of the product type (e.g., powder, ready-to-eat, or concentrate), an explanation for why the infant formula is a new infant formula, any product reformulation or modification in processing, and the quantitative formulation of the product. This registration requirement pertains to new infant formulas, which include new manufacturers of infant formula and current manufacturers of infant formula that are marketing a new formulation.

The submission must also contain assurances that the product will not be marketed unless it meets nutrient requirements (unless the infant formula is exempt), meets all quality factor requirements, and is manufactured in accordance with quality control procedures and good manufacturing practices. Quality factors require the manufacturer to provide assessments that the infant formula contains sufficient protein quality and supports an infant's normal physical growth. Quality control procedures refer to nutrient testing to ensure the quality of the infant formula; the applicable regulations also require the maintenance of quality control records and regular audits of the quality control procedures. Good manufacturing practices require manufacturers to maintain controls to prevent adulteration by workers, facilities, equipment, and by other means.

Infant formula manufacturing facilities are required to be inspected annually. FDA sets out inspection guidance in its infant formula compliance program.

Recalls

FDA or a manufacturer may decide to initiate an infant formula recall if the infant formula poses a risk to human health or otherwise violates the FFDCA or FDA regulations. If a manufacturer initiates a recall, it must notify FDA within 24 hours. The manufacturer must evaluate the identified health hazards in writing and identify and address the root cause of the problem that made the recall necessary. The manufacturer must also report the actions taken to implement the recall to the Secretary of the U.S. Department of Health and Human Services (HHS) every 14 days until the recall is terminated.

Manufacturers must also notify FDA if they discover that an infant formula may not provide the nutrients required by law or may be otherwise adulterated or misbranded, so that FDA may evaluate whether or not a recall is appropriate. If FDA determines that an adulterated or misbranded infant formula "presents a risk to human health," the FFDCA requires the manufacturer to "immediately take all actions necessary" to recall the affected product and request affected retail establishments to post a notice of such recall at the point of purchase (for both manufacturer- and FDA-initiated recalls). Following the initiation of a recall, FDA is to notify the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce. This notification is to include certain information, including the reason for the recall, when FDA was made aware of the circumstances of the recall, and an initial estimate of the disruption in domestic production that might result. Until September 30, 2026 (when this requirement sunsets), FDA must also submit a report to Congress for each recall, containing information on the current domestic supply. If the recall affects more than 10% of the domestic production of infant formula, it also must include additional information on FDA's plan to increase production, along with the specification of any additional authorities or supplemental funding deemed necessary to address the shortage.

If a manufacturer voluntarily withdraws an infant formula that does not violate the FFDCA or FDA regulations such that it would not be subject to legal action by FDA, the withdrawal is not considered a recall, and the manufacturer need not adhere to the requirements for voluntary recalls. Nonetheless, due to infant formula's status as a "critical food," the FFDCA requires a manufacturer to notify FDA of "a permanent discontinuance" or an "interruption" in the manufacturing "as soon as practicable, but not later than 5 business days after such discontinuance or such interruption."

Select Recent FDA Actions

In January 2025, FDA released the "Long-Term Strategy to Increase the Resiliency of the U.S. Infant Formula Market," which seeks to "ensure a safe, stable, nutritious infant formula supply" and includes five objectives: (1) ensure proper oversight; (2) strengthen resiliency; (3) collaborate with government partners; (4) communicate with industry, consumers, and other stakeholders; and (5) evaluate authorities, regulations, and guidance. The document also addresses actions taken since the previous "Immediate National Strategy" was published in March 2023.

In March 2025, HHS and FDA jointly announced "Operation Stork Speed," a set of actions and initiatives focused on infant formula. As part of this initiative, FDA issued a Request for Information in May 2025 and held an expert roundtable in June 2025 to begin a comprehensive update and review of the required infant formula nutrients. Despite periodic updates (e.g., the addition of selenium, as discussed above), FDA had not comprehensively reviewed the nutrient requirements since 1998. Operation Stork Speed also seeks to increase testing for heavy metals and other contaminants in infant formula and to improve interagency and industry collaboration and communication.

FDA's FY2026 Congressional Budget Justification includes proposals aimed at reducing infant formula contamination and shortages, modernizing infant formula surveillance systems, and monitoring adverse events.

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