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IN FOCUS

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Infant Formula Shortage: FDA Regulation and Federal Response

Some media sources report that as of May 8, 43% of infant formula was out of stock nationwide. This garnered widespread concern and significant congressional attention. This shortage may pose severe health risks for some infants. This In Focus provides an overview of initial federal response actions to the infant formula shortage.

On February 17, 2022, the Food and Drug Administration (FDA), in collaboration with the Centers for Disease Control and Prevention (CDC), announced it was investigating consumer complaints received from September 2021 to January 2022 of infant illness attributed to powdered infant formula. FDA's initial findings identified, among other concerns, positive results for bacterial contamination in a manufacturing facility owned by Abbott Nutrition (Abbott). FDA advised consumers to cease using certain infant formula products from Abbott. Subsequently, the manufacturer initiated a voluntary recall of select powdered infant formula products. As FDA's investigation continued, the recall was expanded to include additional specialty powdered infant formula products. On March 22, 2022, FDA released its initial inspectional observations of the conditions found in the facility and determined that the manufacturer had not yet minimized the threat to public health. These initial observations did not constitute final FDA determination on whether the conditions in the facility were in violation of the Federal Food, Drug, and Cosmetics Act (FFDCA). As of April 29, 2022, Abbott had committed to completing enhanced testing of stored product batches before deciding whether to release those products.

Abbott's voluntary recall of infant formula product, coupled with other factors such as ongoing supply-chain issues, contributed to a widespread shortage of infant formula products.

Infant Formula Manufacturer Overview

Infant formula is typically available in one of three forms: a dehydrated powder that is added to water before serving; a ready-to-feed formula that can be given directly to an infant; or a concentrated liquid that must be diluted. In recent years, manufacturers reduced infant formula manufacturing to increase production of products meant to supplement breastfeeding and formula derived from nondairy sources. Some industry experts have attributed this shift to broader U.S. trends showing a general increase in breastfeeding.

According to a 2020 IBISWorld industry report on the infant formula industry in the United States, the industry is dominated by four major manufacturers (see **Table 1**). Disruptions in the infant formula supply chain were noted as early as August 2020. The report notes that the COVID-19 pandemic caused both a surge in demand and a disruption in global supply chains for infant formula products.

Table 1. U.S. Infant Formula Manufactures and Market Share, August 2020

Manufacturer	Market Share (%)
Abbott Laboratories	48.1
Mead Johnson	20.0
Perrigo	11.6
Nestle	7.7
Other[a]	12.6

Source: Jack Curran, *Infant Formula Manufacturing*, IBISWorld, August 2020.

a. The report states that in 2020, no manufacturer in the "other" category accounted for more than 1% of total revenue. These manufacturers are individually characterized as small, independent operators.

Infant Formula Imports

According to FDA, the United States normally produces 98% of the infant formula it consumes, with the primary source of imports coming from trading partners in Ireland and the Netherlands. FDA infant formula regulations apply equally to infant formula manufactured domestically or abroad. Manufacturers whose infant formula products are imported into the United States may have to contend with higher costs of manufacturing to meet FDA specifications. Additionally, those products face compound duties that have averaged approximately 25% on imports over the past decade for a small market share of American consumers. These factors may make the United States a relatively unattractive market for foreign manufacturers.

FDA Regulation of Infant Formula Products and Response to Shortage

FDA Regulation of Infant Formula Products

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" (FFDCA §201(z)). FDA regulations define an "infant" as an individual aged not more than 12 months old (21 C.F.R. §105.3(e)). As a food product, infant formula must comply with the laws and regulations governing food

products as well as additional statutory and regulatory requirements specific to infant formula products. All infant formula products must meet specific nutrient requirements unless considered "exempt." "Exempt" infant formulas are used for infants who have an inborn error of metabolism, low birth weight, or who otherwise have an unusual medical or dietary problem (FFDCA §412(h)(1)). Labels for infant formula products must also adhere to all applicable provisions of the FFDCA and accompanying regulations. In some instances, children over the age of 12 months may still be directed to use infant formula products by their health care providers.

The FFDCA does not require infant formula to be approved before it is marketed. Instead, infant formula manufacturers are required to register with FDA and submit certain information about a new infant formula at least 90 days before marketing the new infant formula (FFDCA §412(c) and (d)). This submission requires various information and assurances that the product adheres to applicable statutory and regulatory requirements. FDA inspects infant formula manufacturing facilities to confirm that they adhere to applicable FDA regulations; FDA collects infant formula samples for analysis. FDA also inspects foreign manufacturing facilities intending to import infant formula into the United States and samples those products intended for the U.S. market. Once infant formula manufacturers begin production, they are subject to certain requirements regarding quality factors, current good manufacturing practices, quality control, and testing. Manufacturers must notify FDA if they obtain knowledge that an infant formula may not provide the required nutrients or otherwise may be adulterated or misbranded. Consumers, health care providers, and industry members are encouraged to report complaints or concerns to FDA through one of several voluntary mechanisms.

An infant formula product may be recalled by FDA when it determines that the product poses a risk to human health (21 C.F.R. §107.200). A manufacturer may also voluntarily determine that a recall of its product is necessary (21 C.F.R. §§107.210, 107.220). Among other requirements, the recalling entity is required to evaluate the hazard to human health associated with using its product and to produce a recall strategy outlining how the entity will remove the product from the supply chain. In addition, FDA conducts its own health evaluation and shares the results with the recalling entity. The recalling entity is responsible for carrying out the recall strategy effectively in collaboration with FDA and for identifying and addressing the root cause of the deviation that made the recall necessary.

FDA Response to Acute Infant Formula Shortage

Throughout this incident, FDA has committed to a number of actions to ensure that the supply chain for infant formula is restored. For example, FDA is coordinating emergency response actions through its Incident Management Group, compiling data on trends for in-stock rates, working with retailer stakeholder groups to discuss purchase limits, collaborating with other infant formula manufacturers to increase and monitor supply, and allowing Abbott to release select products on a case-by-case basis.

On May 16, 2022, Abbott and FDA entered into a consent decree that outlines (1) the steps Abbott must take to resume operations, and (2) the controls the manufacturer must implement to ensure continued compliance going forward. Abbott has stated that once FDA allows operations to resume at the facility, production can begin in two weeks but that it may take up to 10 weeks for the affected infant formula products to make their way to the public. Additionally, on May 16, 2022, FDA issued guidance describing the agency's intention to temporarily exercise enforcement discretion, on a case-by-case basis, for certain requirements that apply to infant formula. This action will potentially increase imports of infant formula from foreign manufacturers and is to be in effect until at least November 14, 2022.

Use of the Defense Production Act (DPA)

On May 18, 2022, the President determined that the national infant formula supply chain is a component of U.S. critical infrastructure for the purposes of the DPA, and that the ingredients used to manufacture infant formula are "scarce and critical materials." Accordingly, the President delegated authority under Title I of the DPA to the HHS Secretary, directing him to use such authority as appropriate for health resources, including ingredients for infant formula, to respond to the formula shortage.

For more information on the use of the DPA in the infant formula shortage, see CRS Insight IN11935, *Use of Defense Production Act Authorities to Respond to the U.S. Infant Formula Shortage*.

USDA Institutes Flexibilities for WIC

Based on 2018 estimates, over half of the infant formula in the United States is consumed by infants in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), a nutrition program serving low-income mothers and their young children. For cost containment reasons and according to federal law, WIC state agencies typically exclusively provide one manufacturer's formula. In response to the Abbott recall, using Stafford Act authorities available due to COVID-19, in February and March 2022, USDA offered state agencies flexibility to expand the brands and sizes of formula available through WIC. In response to states that had not accepted this flexibility, on May 13, 2022, USDA urged state agencies to use these options. P.L. 117-129, enacted on May 21, 2022, expands WIC's authority to respond to supply chain disruptions.

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