Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States

Infant formula is the primary or sole source of nutrition for many infants in the United States. Because of this, disruptions to the supply or safety of infant formula can have a severe impact on infants’ health. In late 2021 and early 2022, reports of infant illness and death were linked to the consumption of contaminated powdered infant formula produced by Abbott Nutrition. The U.S. Food and Drug Administration (FDA) initiated an investigation at the facility and warned consumers not to use certain products manufactured there. Abbott then implemented a voluntary recall of certain products and a temporary shutdown of the affected plant, which was one of the nation’s largest infant formula production sites; flooding at the plant extended this shutdown. The widespread infant formula shortage that resulted was unprecedented in scope and duration and created hardships for families that used infant formula. Families that receive infant formula through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) were particularly adversely impacted. This incident demonstrated that additional risk management planning is needed to protect U.S. infants from the consequences of potential future disruptions in the infant formula supply chain.

As directed by the 2023 Consolidated Appropriations Act, FDA contracted with the National Academies of Sciences, Engineering, and Medicine (the National Academies) to examine and report on the challenges in supply, market competition, and regulation of infant formula. The National Academies convened the Committee on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States, which comprised experts in public health safety and policy; public health nutrition and policy; infant health and nutrition; equity in access to formula supply; business and economics, including supply chain dynamics; and regulatory standards and oversight.
The resulting consensus study report, *Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States*, explains the policy and marketplace vulnerabilities that were exposed during the shortage, describes the extent to which actions taken by relevant stakeholders following the shortage addressed these vulnerabilities, identifies remaining gaps, and recommends actions to address them.

**INFANT FORMULA REGULATION AND MARKETPLACE BEFORE, DURING, AND AFTER THE 2022 INFANT FORMULA SHORTAGE**

The regulatory environment for the production and marketing of infant formula is complex and involves numerous federal departments, including FDA, the U.S. Department of Agriculture (USDA), Centers for Disease Control and Prevention, Centers for Medicare & Medicaid, and the Federal Trade Commission, which collectively have authority over product ingredients, nutritional quality, manufacturing safety, product packaging and labeling, and importation. While the U.S. regulatory framework for infant formula is consistent with international standards, differences between U.S. and other countries’ regulations serve as barriers to importation.

The infant formula supply chain consists of upstream (production of ingredients and packaging materials), manufacturing, downstream (distribution from manufacturer to vendor), and consumer segments. The supply side of the infant formula market is highly concentrated at multiple levels, including production capacity and sales.

About half of the infant formula purchased in the United States is consumed by infants enrolled in WIC. The infant formula brand issued by each state’s WIC agency is determined through a competitive bidding process, which results in significant price discounts for WIC in the form of rebates. The winning bidder also has marketing advantages in the non-WIC market.

**Response to the Shortage**

In response to the 2022 infant formula shortage, the federal government enacted and implemented policies focused on education, enforcement discretion, and new requirements related to disruptions, recalls, shortages, and reporting (see Figure S-4 in the report). FDA enforcement discretion, temporary suspension of tariffs, and Operation “Fly Formula” supported the importation of international infant formula into the United States. The Access to Baby Formula Act of 2022 created authority to waive WIC rules during supply disruptions, facilitate communication and coordination between USDA and the U.S. Department of Health and Human Services (HHS) regarding supply chain disruptions, and required state WIC agency infant formula contracts to include remedies in the event of a recall. The Food and Drug Omnibus Reform Act of 2022 (FDORA) established a new category of foods called “critical foods” which includes infant formula and medical foods and took further actions related to recalls, inspections, national strategies, personal importation, labeling, and more.

With limited consumer guidance available on appropriate substitution strategies, consumers often switched brands and stockpiled available infant formula, exacerbating the shortage. WIC participants faced unique challenges, as their benefits could only be used for certain brands and product types without a temporary waiver. U.S.-based manufacturers made frequent and substantial changes to production, but their ability to increase supply was limited by production capacity and availability of inputs.

**VULNERABILITIES AND CORRESPONDING RECOMMENDATIONS**

The committee used a framework to assess the vulnerability of the infant formula supply chain before, during, and in response to the 2022 shortage (Figure 1). As such, vulnerabilities were identified in the following five areas:

- **Risk Management Planning:** Development and implementation of redundancy risk management plans (RRMPs) by the federal government and infant formula companies are key elements of a preparedness strategy for potential supply disruptions. FDORA required that infant formula facilities develop RRMPs. Currently, there is limited guidance on development of RRMPs, how they will be reviewed, or if implementation will be monitored to ensure the plans have the desired effect. Report recommendations address:
sector–wide risk management planning by HHS and FDA (see Recommendation 1 in the report),

developing, reviewing, and monitoring implementation of evidence–based RRMP regulatory standards (see Recommendation 2 in the report), and

meeting the evidence–based standards to be considered a responsive WIC bidder (see Recommendation 3 in the report).

**Market Concentration:** Sales shares of infant formula in the United States are concentrated, with the top three firms accounting for more than 80 percent of the market in 2021 and 2022. Production of infant formula may also be concentrated in a few large facilities due to economies of scale. Concentration of production, in particular, creates vulnerability to supply disruptions. Production disruptions at a single facility can create significant supply disruptions relative to the size of the market. Report recommendations address:

- meeting the evidence–based RRMP standards, including measures to prevent the spread of contaminants within manufacturing facilities (see Recommendation 4 in the report);
- extending required infant formula contract remedies to emergencies or disruptions not caused by a recall (see Recommendation 5 in the report); and

- facilitating infant formula distribution to WIC–authorized vendors during disruptions (see Recommendation 5 in the report).

**Speedy Supply Recovery:** The restoration of production was slowed by gaps in FDA authority in oversight of manufacturing and regulatory requirements that inhibited rapid importation of infant formula. FDORA requires FDA to review the list of nutrients and data related to international infant formula standards and consider needed revisions. FDORA also requires formula manufacturers to notify FDA in advance of a supply disruption so it can respond more quickly; however, FDORA improperly grouped permanent discontinuation with interruption for purposes of notifying FDA. Report recommendations address:

- requirements for manufacturers to give advanced notice before removing a critical food from the market temporarily or permanently (see Recommendation 6 in the report),
- granting FDA remote access of records for critical foods (see Recommendation 7 in the report),
- creating a database of nutrition and labeling requirements used by other countries to facilitate the importation of infant formula in case of a shortage (see Recommendation 8 in the report),
- establishing a trigger rule to suspend tariffs and tariff–rate quotas on imported infant formula and ingredients in the event of a market...
disruption (see Recommendation 9 in the report), and

- working with wholesalers and distributors to develop risk management and disaster plans (see Recommendation 10 in the report).

- **Management of Adverse Consumer Effects:**
  Adverse effects were heightened by inadequate communication with the public, unique constraints faced by WIC participants and users of formulas for infants with special medical needs, and a lack of coordination between government and industry. Report recommendations address:

  - developing consistent guidance on infant formula substitutions and how to feed infants when breast milk or safe infant formula are not available (see Recommendation 11 in the report),
  
  - maintaining a public list of all infant formulas marketed in the United States (see Recommendation 12 in the report),
  
  - designing a governance structure for crisis response and a dashboard to track critical data on supply and shortages at the state or national level (see Recommendation 13 in the report), and
  
  - planning for disruption of nutrition support for hospitalized infants (see Recommendation 14 in the report).

- **Breastfeeding Promotion and Support:** Lack of access to qualified breastfeeding protection and support contributes to the dependence on infant formula.

  See report for further details on the committee’s recommendations.

**GOING FORWARD**

The infant formula shortage in 2022 revealed the inadequacy of risk management planning by both the infant formula industry and the federal government, creating challenges for families that use infant formula and WIC customers in particular. The committee’s conclusions and recommendations are intended to ensure that the United States is better positioned to respond to any future shortage.

Access the full report at www.nationalacademies.org/infant-formula-supply-study.
FOR MORE INFORMATION
This Consensus Study Report Highlights was prepared by National Academies’ staff based on the Consensus Study Report Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States (2024).

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