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

Role of the U.S. Congress

Infant formula is the primary or sole source of nutrition for many infants in the United States. Consequently, disruptions to the supply or safety of infant formula can have a severe impact on infants’ health and well-being. In late 2021 and early 2022, a recall and pause in production of specific infant formula products resulted in a widespread, national shortage that created hardships for many families. Those receiving infant formula through the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) were particularly adversely impacted. This incident demonstrated that more action is needed to protect U.S. infants from the consequences of potential future supply chain disruptions.

With funding provided by the 2023 Consolidated Appropriations Act, the U.S. Food and Drug Administration (FDA) contracted with the National Academies of Sciences, Engineering, and Medicine to convene an expert committee to examine and report on the challenges in supply, market competition, and regulation of infant formula. The resulting consensus study report explains policy and marketplace vulnerabilities that were exposed by examining the infant formula landscape before, during, and after the 2022 shortage. The report also describes the extent to which actions taken by relevant groups addressed these vulnerabilities, identifies remaining gaps in the system, and recommends actions to address the gaps. Congress played an important role in responding to the 2022 shortage and can take further action to address two major vulnerabilities: market concentration and the ability to support speedy supply recovery.

RESPONSE TO THE SHORTAGE

The government took various actions in response to the closure of the Abbott plant and the infant formula shortage in 2022. This includes enacting the Access to Baby Formula Act of 2022 (ABFA), temporarily suspending tariffs on infant formula and its ingredients, and enacting the Food and Drug Omnibus Reform Act of 2022 (FDORA) as part of the Consolidated Appropriations Act of 2023. ABFA and FDORA laid the groundwork for permanently addressing vulnerabilities by making critical changes to the regulatory framework and clarifying responsibilities of infant formula companies.

More specifically, FDORA defined a new category of food, “critical foods” (21 U.S. Code § 350a–1), which includes infant formula and medical foods and provided new requirements for critical foods. FDORA also includes provisions relating to the “meaningful disruption” of the infant formula supply, which considers both “interruptions” and “permanent discontinuations” to be meaningful disruptions.

MARKET CONCENTRATION

Concentrating production capacity in a small number of facilities increases the risk and potential harm of
a shortage. If production for a given form of infant formula (e.g., milk-based powder or ready-to-feed) is concentrated in specific facilities, a disruption to those facilities significantly affects the supply, as the United States experienced during the 2022 shortage. The relevant concentration measure for supply chain reliability is concentration of production capacity, not the number of companies marketing products or the sales concentration of those companies. Despite duplicate facilities among dominant companies, infant formula production capacity in the United States is likely concentrated, meaning the relative share of product volume coming from a specific facility or even line may be large relative to the U.S. market for that product. In addition, domestic plants may have multiple production lines, but technical constraints mean that some facilities or individual lines within facilities are not able or flexible enough to switch production between different products. Modern design and safety protocols may allow some lines to continue operating if adulteration is identified within the facility, but this is challenging in older facilities. The social benefits to a reliable infant formula supply chain exceed private benefits, requiring government intervention to close the gap.

FDORA requires each manufacturer of a critical food to “develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which such food is manufactured” (21 U.S. Code § 350m [b]). The law suggests that the risk management plan “may identify and evaluate risks to the supply of more than one critical food, or critical food category, manufactured at the same establishment” and “may identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means” (21 U.S. Code § 350m [b]). The committee provided a recommendation to FDA to develop evidence-based redundancy risk management plan (RRMP) regulatory standards, a process for reviewing RRMPs, and a mechanism for monitoring the implementation of RRMPs.

The committee recommends that Congress should provide suitable incentives (e.g., offering tax credits, accelerated depreciation) to encourage all FDA-registered infant formula manufacturers that have met FDA expectations with regard to evidence-based RRMP standards to implement the RRMP and modernize manufacturing plants and equipment located in the United States. This modernization should include measures to prevent the spread of possible contaminants from one area of a facility to another, thereby ensuring product safety and minimizing the size and scope of a plant shutdown following the identification of contamination.

SPEEDY SUPPLY RECOVERY
Advance notice about an interruption or discontinuation of infant formula production could help FDA prevent or mitigate shortages. Producers of critical foods, including formula, are legally required to notify FDA about a potential meaningful disruption in supply, but the reporting requirements may leave FDA with insufficient warning before a permanent discontinuation. Some WIC contracts require manufacturers to provide 120 days’ notice to the state for discontinuation of a contract brand infant formula, but such clauses are not standard across all state contracts, which may result in disparities across states in their response to potential disruptions caused by discontinuation.

The committee recommends that Congress should amend the Federal Food, Drug, and Cosmetic Act (FDCA) to require manufacturers of critical foods to give sufficient advanced notice to FDA when they decide to discontinue a critical food that is likely to lead to a meaningful disruption prior to removing the product from the market temporarily or permanently. FDA will need to determine the minimum amount of time before discontinuance that it will need to be notified to mitigate the possible adverse effects of a resulting disruption on access to infant formula and provide this information to Congress to inform its amendment to the FDCA.

FDA did not have remote access to records during the COVID-19 public health emergency when physical access to manufacturing facilities was limited. To maintain
adequate oversight of these critical foods and speed resolution of problems during a shock, FDA should have remote access to records in addition to the physical inspections that are already required. **Congress should grant FDA the authority for remote access of records for critical foods.**

Tariffs on the import of the final infant formula product from most countries are high and rise even higher once their total volume reaches a certain level (i.e., a quota). Although Congress’s suspension of tariffs on infant formula in late July 2022 and on a key input into infant formula in October 2022 were helpful in mitigating the effects of the shortage, these policy changes took time, and widespread shortages had already begun by May. **Congress should establish a trigger rule to suspend tariffs and tariff-rate quotas automatically on imported infant formula and imported inputs used in the domestic production of infant formula in the event of a meaningful disruption to the market, as defined by the U.S. Department of Health and Human Services.**

To access the full report and other supporting materials, visit www.nationalacademies.org/infant-formula-supply-study.