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

Guide for Infant Formula Trade Related Analyses

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 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.

As was recognized during the shortage, tariff and non-tariff barriers have kept the U.S. market relatively closed to the import of formula, such that even during a period of shortage it is difficult to obtain large quantities of infant formula produced overseas. Agencies that inform on trade policy, such as the U.S. Trade Representative (USTR) and the U.S. International Trade Commission (USITC) can play a role in assessing the concentration of infant formula manufacture in the U.S. domestic market.

In the United States, national sales shares of infant formula companies are concentrated, with the top three firms accounting for more than 80 percent of the market in 2021 and 2022. By contrast, imported infant formula accounts for less than 1 percent of sales in the United States. While several U.S. producers have FDA–registered manufacturing facilities in other countries as well as in the United States, they do not use these facilities to diversify their capacity to supply the U.S. market.

Importing infant formula could make the U.S. supply chain more robust in the event of a disruption that affects domestic manufacturers, but it is unclear what actions would most effectively encourage such imports. High tariffs on infant formula and ingredients may be discouraging imports, but more research is needed to determine what effects lowering or eliminating tariffs might have.
AREAS FOR FUTURE RESEARCH
To address concentration in production and enable key actors to make evidence-informed decisions aimed at averting or limiting future shortages of infant formula, USTR could commission USITC to perform several analyses on the effects of changes to infant formula tariffs as described below:

- Assess the effects on firms, consumers, and food security of lowering or eliminating tariffs on U.S. manufacturers that already diversify their capacity.

- Assess whether lowering or eliminating tariffs on infant formula for U.S. manufacturers will lead them to diversify their capacity to supply the U.S. market using imports from their facilities in other countries.

- Existing foreign infrastructure of compatible U.S. manufacturer owned sites as well as capacity to increase diversification without heightening geopolitical risk should also be considered.

- Assess whether tariffs on infant formula ingredients discourage production within the United States by small or mid-size producers.

- Assess the possible effects of lowering or eliminating tariffs for U.S. manufacturers on U.S. firms, employment, customers, and food security.

- Assess the possible effects on U.S. firms, workers, farmers, and consumers of granting permanent tariff exclusions for importers of infant formula and inputs used in domestic production, as well as for producers with FDA-regulated facilities outside the United States.

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