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. The U.S. Department of Agriculture (USDA) can play an important role in addressing three major vulnerabilities in the infant formula supply chain: risk management planning, market concentration, and management of adverse effects on consumers.

**RISK MANAGEMENT PLANNING**

Sector-wide resiliency planning is needed to reduce the likelihood that a supply chain disruption is triggered and to adequately buffer such a disruption. Because WIC provides more than half of the infant formula consumed in the United States, companies holding a WIC contract have a heightened responsibility to adequately prevent supply disruptions and speedily mitigate the effect of disruptions that do occur. Likewise, the federal government has a heightened role to play in overseeing and incentivizing WIC contract holders’ planning and implementation of resiliency measures. Under the Food and Drug Omnibus Reform Act of 2022, critical foods facilities, including infant formula facilities, must develop redundancy risk management plans (RRMPs), subject to inspection by FDA under its authority to inspect production facilities. The committee recommended that FDA develop evidence based RRMP standards and a mechanism for monitoring implementation. **USDA should promulgate regulations requiring an infant formula manufacturer to meet FDA’s expectations with regard to evidence-based redundancy risk management plan standards to be**
considered a “responsive” bidder under 7 C.F.R. § 246.16a(c)(5).

Because implementing a more robust RRMP may have additional costs for the manufacturers, bidders could reduce the discounts they offer (in the form of rebates) to WIC. To avoid this outcome, the committee noted that it would be important to pair a requirement for WIC bidders to have RRMPs that comply with regulatory standards with tax credits or other financial incentives for companies that invest in resiliency measures to strengthen their RRMPs.

MARKET CONCENTRATION

WIC’s competitive bidding process, which awards a single contract for infant formula production to the lowest bidder in each state, influences formula sales throughout each state to become more concentrated, thus increasing the potential harm of a supply chain disruption. The committee did conclude that WIC’s competitive bidding process is not a driver of industry concentration at the national level. However, changing or eliminating the competitive bidding process could lead to unintended consequences such as increases in the price of formula. Currently, the best way to protect consumers from the effects of a disruption to the dominant state brand is through expanding the WIC contract remedies required under the Access to Baby Formula Act. The specific remedies that USDA now requires WIC infant formula contracts to include would not help during shortages precipitated by factors other than a recall. USDA should extend some of the required infant formula contract remedies to emergency periods or supply chain disruptions precipitated by factors other than a recall and facilitate infant formula distribution to vendors authorized by WIC during disruptions to protect consumers from the effects of a disruption to the WIC contract holder’s supply.

- USDA should revise 7 C.F.R. § 246.16a(n) to require that during all emergency periods and supply chain disruptions:
  
  i. contracts permit the issuance, without medical documentation, of infant formula in container sizes, physical forms, and brands that are not usually permitted; and
  
  ii. the contract holder provides the state WIC agency with action plans that include supply data.

- USDA should provide states with template contract language and guidance to facilitate implementation of all the contract remedies in 7 C.F.R. § 246.16a(n).

- USDA should revise 7 C.F.R. § 246.16a(n) to require WIC infant formula contracts to specify that the contract holder will:
  
  i. distribute infant formula based proportionally on past allocations during an emergency period or supply chain disruption; and
  
  ii. modify its distribution contracts based proportionally on past allocations during an emergency period or supply chain disruption.

- USDA should update 7 C.F.R. § 246.12(g)(9) and § 246.12(h)(3)(xvi) to require WIC–authorized vendors to provide a list of infant formula wholesalers and distributors that they use, upon authorization and upon subsequent request by USDA or the state WIC agency.

ADVERSE CONSUMER IMPACT

The committee found WIC played a critical role in allowing participants to obtain infant formula during the shortage, but participants were more constrained than other customers in purchasing infant formula. Steps USDA and state WIC agencies took to buffer the 2022 shortage for participants were viewed by a variety of groups as effective, but not timely, and were hampered by a lack of emergency preparedness. In particular, USDA’s 2021 Guide to Coordinating Special Supplemental Nutrition Program for Women, Infants, and Children Services When Regular Operations Are Disrupted and requirements regarding state alternate operating procedure plans lacked key components. USDA should update the 2021 USDA Guide and requirements regarding state alternate
operating procedure plans in 7 C.F.R. § 246.4(a)(30) to include a design of a governance structure for crisis response that articulates all stakeholders that should be involved, how they should work together, what is expected of them, and how the overall response should be coordinated at the state level. USDA should also develop a dashboard to track critical data on the supply and shortages of infant formula at the state or national level.

AREAS FOR ADDITIONAL RESEARCH

As a component of sector-wide preparedness efforts, USDA, in consultation with FDA and the National Institute of Standards and Technology, could conduct additional research to address vulnerabilities in the infant formula supply chain for WIC participants as described below:

- Develop proposals for ways to help infant formula companies that are almost within reach qualify as “responsive bidders” on WIC infant formula contracts.
- Identify changes to WIC’s competitive bidding process to allow bids by a company that does not sell all three physical forms of infant formula (i.e., powder, liquid concentrate, and ready-to-feed).
- Model scenarios other than a recall that could lead to an infant formula shortage, their effect on the availability of infant formula to WIC participants and others, and the cost of providing infant formula to WIC participants.

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