



## Insight

# 2022 Access to Baby Formula Act: Final Rule Misses the Mark

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## Executive Summary

- On December 14, 2023, the Food and Nutrition Service (FNS) released a final rule to implement the Access to Baby Formula Act of 2022, a law that requires contracted manufacturers to continue to pay rebates on their formulas in the event of a product recall potentially increasing manufacturer costs and decreasing rebate offerings.
- The current state infant formula contract model provides the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) with approximately \$1.5 billion in manufacturer rebates in 2022, and only a few domestic baby formula manufacturers operate to supply about 98 percent of all formula; therefore, increased regulatory liability during a potential formula recall could create additional risk for a single manufacturer.
- Policymakers should consider if the FNS final rule will further limit manufacturer competition within an already consolidated market with a poor food safety record without expanding beneficiary choice in WIC.

## Introduction

On December 14, 2023, the Food and Nutrition Service (FNS) released a [final rule](#) to implement the Access to Baby Formula Act of 2022 (ABFA), a law that requires contracted manufacturers to continue to pay rebates on their formulas in the event of a product recall potentially increasing manufacturer costs and decreasing rebate offerings. Passed in the wake of a nationwide baby formula shortage in 2022, ABFA implements two key provisions: first, establishing the secretary of the Department of Agriculture's permanent waiver authority to address infant formula disruptions during emergencies or supply chain failures and second, requiring that state Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) infant formula cost containment contracts include remedies to prevent beneficiary disruptions in the event of a formula recall. The final rule uses the Food and Drug Administration's (FDA) [definition](#) of a recall to exclude voluntary manufacturer withdrawals, stock recoveries, or recalls in which the FDA would not initiate legal action. The final rule requests comments to be submitted by February 12, 2024.

The current state infant formula contract model provides WIC with approximately [\\$1.5 billion](#) in manufacturer rebates in 2022. Only a few domestic baby formula manufacturers (Abbott, Mead-Johnson, and Nestlé) operate to supply about [98 percent](#) of all formula. Increased regulatory liability during a potential formula recall could create additional risk for a single manufacturer, with FNS estimating in the final rule that a 5 percent decrease in rebates offered would equate to approximately \$80 million less per year to federal WIC food spending.

Policymakers should consider if the FNS final rule will further limit manufacturer competition within an already consolidated market with a poor food safety record without expanding beneficiary choice in WIC.

See AAF's work for a deeper dive on the infant formula market and WIC: [Baby Formula in the United States: Health and Economic Policy Issues](#),

## **Brief Program Background and Abbott 2022 Recall**

Of the 3.5 million births in the United States in 2020, approximately half (1.8 million) were eligible for formula through the Department of Agriculture WIC program. The WIC program is generally recognized as a cost-effective, federally funded, state-administered nutrition program for low-income families. Notably, only 50 percent of WIC-eligible Supplemental Nutrition Assistance Program (SNAP) and Medicaid recipients participated in WIC in 2021. After awarding a contract to a single baby formula manufacturer to obtain sizable rebates (known as a sole-source contract), each WIC state agency requires eligible beneficiaries to purchase a specific baby formula (including the size and type). The rebates generated from baby formula sales are then reinvested into the WIC program. State agencies are permitted to engage in alternative contracts if savings are equal to or greater than the sole-source contracting model. Currently, none of the 89 WIC agencies have engaged in an alternative contracting model.

Following a 2022 widely reported recall of baby formula by Abbott – after reports of poor manufacturing practices following complaints of fatal bacterial infections in infants – the United States experienced a significant shortage of baby formula. In June 2023, the specific bacteria (*Cronobacter sakazakii*) was adopted as a nationally notifiable disease by the Council of State and Territorial Epidemiologists for infants under a year old. Doctors will now be required to report any *Cronobacter sakazakii* cases to state health departments. With baby formula recalls due to bacterial contamination continuing into 2024, it seems that increased disease surveillance alone is not enough to prevent continued cases of contamination. Congressional requests for information continue into these recalls, as should congressional oversight of the FDA’s actions and activities to improve baby formula manufacturer inspections.

## **FDA Recall Limitations and Manufacturer Rebate Liability**

The FNS final rule follows the FDA’s definition of a recall, which only applies to products that are voluntarily recalled and for which the FDA would take legal action (e.g., in the case of seizure) against the manufacturer. In this framework, recall does not include a market withdrawal or stock recovery. At what point could a market withdrawal become a recall? For baby formula manufacturers, it may be in their best interest to engage in a market withdrawal rather than a prolonged recall as the FNS final rule places increased rebate liability on manufacturers that experience a significant or prolonged recall.

During the Abbott 2022 recall, for certain state WIC agencies, the manufacturer continued to pay rebates on “competitive non-contract brand infant formula” even though their product was off the market. As not all WIC state agencies had this provision within their contract, the FNS final rule requires all state agencies to adopt this provision. FNS acknowledges that this provision “requires all infant formula manufacturers to pay these rebates in the future when their product is the subject of a recall, which in turn could pose an added cost to the manufacturer subject to the recall[.]” If, however, a national supply chain disruption occurred and the state received a waiver to allow the issuance of non-contracted formula, the sole-source baby formula manufacturer would not be subject to this requirement, as their product did not experience a recall.

FNS notes that this regulatory change may impact manufacturer behavior during the competitive bidding process, which could see the rebate amounts offered increase or decrease to state agencies. With only three large manufacturers, it is unlikely that rebate offerings would increase, as these manufacturers were required to continue providing rebates on products not sold during a recall. FNS could not give a full cost impact of the

final rule but acknowledged that a 5 percent decrease in rebate offerings would equate to approximately \$80 million.

## **Conclusion**

The U.S. baby formula market remains highly concentrated with only a few manufacturers able to bid for contracts with WIC state agencies. Following the Abbott 2022 recall, increased disease surveillance is likely to help track and identify instances of new *Cronobacter sakazakii* cases, but it would not stop continued recalls due to product contamination.

The FNS final rule may create a perverse incentive for manufactures by requiring them to pay rebates for off-the-market products during a recall. Congress should consider policies that encourage market competition to expand the number of formula products WIC beneficiaries could purchase, rather than increasing WIC state agency reliance on a smaller number of manufacturers.