The United States produces about 98% of its infant formula. Abbott Nutrition alone manufactures about 48% of the domestic baby formula supply. Over the past year, the Food and Drug Administration (FDA) received complaints of a potential contamination at Abbott’s Sturgis, Michigan facility linked to a rare bacterial infection and organ damage in four infants, which led to two fatalities. The manufacturer voluntarily ceased production following the complaints.

As a result, American families are struggling to obtain baby formula. Compounding this crisis, the average cost of the most popular baby formula products – already costing some families up to $1,500 per year – increased by 18% over the past year, during a time when Americans were emerging from the pandemic and experiencing crushing inflation. Meanwhile, the Biden Administration was caught flat-footed at every turn.

A brief timeline of the Biden Administration’s mismanagement is as follows:

- **February 2021:** A whistleblower files an Occupational Safety and Health Administration (OSHA) complaint about conditions at Abbott Nutrition’s Sturgis facility. The Labor Department notifies the FDA and Abbott of the OSHA complaint that same month.
- **October 19-20, 2021:** A whistleblower warned the FDA of negligent cleaning and safety practices at Abbott’s Sturgis facility in a 34-page report in October 2021. The whistleblower mailed the report by FedEx to seven senior FDA officials, including then-Acting FDA Commissioner Woodcock.
- **October 21, 2022:** Three of the seven senior FDA officials are notified of the report via email. FDA officials confirmed receipt “in a detailed email” the same day.
- **December 7, 2021:** The FDA claims this as the first date the agency reached out to the whistleblower to schedule an interview. Due to scheduling issues, the whistleblower is unable to interview until December 22, 2021.
- **January 31, 2022:** FDA inspects Abbott Nutrition’s facility in Sturgis, Michigan.
- **February 2022:** FDA Commissioner Califf testified to Congress that the whistleblower report got lost in FDA’s mailroom and did not reach senior officials until mid-February 2022. Commissioner Califf is confirmed by the Senate on February 15. Abbott voluntarily shuts down the Sturgis facility and recalls certain powdered formulas on February 17. The FDA and CDC announce a joint investigation into the facility. Abbott expands its recall on February 28.
- **April 2022:** President Biden claims he “became aware” of the formula shortage in April 2022. At least six states report over half of their formula stockpiles are exhausted, and 26 states report 40-50% out of stock rates.
- **May 2022:** 43% of infant formula was reported out of stock across the U.S. as of May 9. FDA Commissioner Califf appoints Dr. Woodcock to lead the agency’s internal review of food operations during this month.
• **June 2022:** Abbott reopens the Sturgis plant under FDA oversight in June but is forced to close the facility again on June 15 due to rain and flooding.14

**Big Government Drives Mass Shortage**

The **WIC program creates a national duopoly of manufacturers.** The federal Women, Infants, and Children (WIC) nutrition program is the largest purchaser of formula in the U.S. About half of all babies in the U.S. qualify for WIC, and the program accounts for more than half of domestically-produced formula. Currently, only two companies – Abbott Nutrition and Mead Johnson – serve about 90% of the infants in the program, due in part to WIC’s contract award practices.15 States are required by federal law to award a sole-source contract to a manufacturer in exchange for rebates to lower costs. These rebates represent one-quarter of funding for the WIC program, or about $1-$2 billion annually in revenues.16 Accordingly, Abbott Nutrition is the sole source WIC provider in 23 states and Washington, D.C. and is the only supplier of specialty formulas.17 Allowing more free market competition may help prevent a shortage crisis of this scale in the future, if a facility were to close.

The **U.S. restricts access to foreign infant formula manufacturers.** FDA regulations are the most extensive in the world. Domestic and foreign manufacturers must meet high bars for nutritional ingredient requirements, as well as comply with specific labeling guidelines.18 Once FDA-approved for import, these products are subject to high tariffs (up to 17.5%) and tariff-rate quotas (TRQs). TRQs are additional duties that increase the tariff rate, and can be placed on goods once total imports pass a certain level.19 Newly-approved retailers and those who have modified their product must also then wait 90 days before marketing the baby formula product.20

Many European countries are substantial producers and exporters of infant formula. Further, many European formulas meet or exceed FDA nutritional requirements21 but are unable to comply with FDA’s labeling guidelines and are, therefore, barred from exporting products to the U.S.22 In April 2021, for example, Customs and Border Protection (CBP) seized $30,000 worth of European baby formula for not meeting FDA labeling guidelines and regulatory requirements.23

In 2021, U.S. imports of infant formula represented about 1.5% (or $28.8 million) of the estimated domestic demand of $1.8 billion, according to the Congressional Research Service, as shown below.24

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<tr>
<th>Table 1. Sources of Imports of Infant Formula in 2021</th>
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**Source:** U.S. Census Bureau.

**Notes:** Infant formula only. See shaded box for HTSUS codes.

**Federal regulations prevent domestic startups from competing.** In 2022, ByHeart, located in Pennsylvania, became the first new domestic formula manufacturer in the U.S. since 2007.25 It reportedly took ByHeart over $190 million in premarket funding and five years to start production. ByHeart’s CEO attributed the lack of new market entry to spending “years trying to study and understand FDA regulations. We also heard a lot of ‘you guys are nuts.’”26
Congress enacted the Access to Baby Formula Act in May 2022. The law increased flexibility for WIC participants to purchase other formula products other than sole-source contractors. In addition, Congress should conduct oversight of WIC’s contracting practices and assess other options to promote competition among formula manufacturers supplying the program.

The House of Representatives passed H.R. 8351, the Formula Act, sponsored by Rep. Blumenauer (D-CT) on July 15, 2022. The Formula Act would temporarily suspend tariffs on infant formula products. Congress may consider other long-term reforms to lower tariff rates to ease import restrictions and regulations.

The 2020 United States-Mexico-Canada Agreement (USMCA) imposed new restrictions on Canadian global exports of formula due to preexisting U.S. concerns that Canada was “‘dumping’ powdered milk products, including baby formula.” The U.S. did not import any formula from Canada in 2021. Ironically, the Department of Agriculture reported that U.S.-manufactured formula accounted for the largest amount (22%) of dairy exports to Canada that same year. Congress may consider other trade reforms to ease import restrictions.

Publ. July 21, 2022

1 Abbott Nutrition, Mead Johnson, and Nestle account for 98% of domestic manufacturers. Perrigo supplies the remainder, as a domestic producer of store brands for several retailers, such as Walmart, CVS, and Target, and a very small amount is imported.


25 CRS distinguishes between infant formula (babies 12 months and younger) and child formula (children at least 12 months old, but not older than 12 years old). CRS, IN11932, Tariffs and the Infant Formula Shortage, May 23, 2022, at https://crsreports.congress.gov/product/pdf/IN/IN11932.


29 CRS IN11932, supra, at 24.