U.S. FOOD & DRUG ADMINISTRATION

The U.S. Food and Drug Administration's Long-Term National Strategy to Increase the Resiliency of the U.S. Infant Formula Market

January 2025

Introduction

In March 2023, the Food and Drug Administration (FDA), in conjunction with the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), and other federal partners, released an *Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market* (Immediate National Strategy), which collected observations, described immediate actions, and detailed short-term plans to improve the resilience of the infant formula supply. The Immediate National Strategy was a direct response to the unprecedented infant formula recall in February 2022 and subsequent shortage of infant formula products on store shelves across the U.S. The Immediate National Strategy detailed the multifaceted approach the FDA and other government stakeholders were taking to improve the supply of infant formula. It also illustrated that what happened in early 2022 was the result of a unique set of circumstances, which compounded on one another and resulted in disruption of a highly concentrated U.S. infant formula marketplace.

Since the implementation of actions described in the Immediate National Strategy, the U.S. market has experienced relatively minor supply chain disruptions resulting from product recalls, natural disasters, or regulatory actions due to failures to meet the FDA requirements for infant formula; however, those minor disruptions have not led to meaningful shortages in the supply of infant formula due largely to the planning and actions outlined within the Immediate National Strategy.

In July 2024, the National Academy of Science, Engineering and Medicine (NASEM), with funding received from the FDA, produced a report titled *Challenges in Supply, Market Competition, and Regulation of Infant Formula in*

the United States, which further emphasizes the need for a multifaceted approach to building resilience into this important industry.

Internal analyses, lessons learned from the development and implementation of the Immediate National Strategy, recommendations from NASEM, and valuable insights gathered from industry, healthcare professionals, consumer groups, regulatory partners, and other engagements on this issue for the past two and a half years have culminated in the development of this *Long-Term National Strategy to Increase the Resilience of the U.S. Infant Formula Market*. This Long-Term National Strategy identifies the actions the FDA has taken since the issuance of the Immediate Strategy and details our long-term goals in achieving a more robust and nimble U.S. infant formula supply. In the Long-Term Strategy, we outline methods to improve information-sharing across all stakeholder groups, recommend measures for protecting the integrity of the infant formula supply chain and preventing contamination, outline methods to incentivize new infant formula manufacturers to enter the U.S. market, and recommend other necessary authorities to enhance our insight into the supply chain and ability to identify risk for shortages earlier. No single agency can resolve the vulnerabilities in the infant formula market, but together with our U.S. Government partners, we are working to improve the resilience of the U.S. infant formula market for all consumers.

Although we are in a more stable situation in 2024 than we were one year ago, we are committed to continued engagement and increased oversight of the U.S. infant formula market, especially considering the critical need for a steady supply of specialty infant formulas. Through this strategy, we aim to focus efforts on the areas where we have seen the largest impact.

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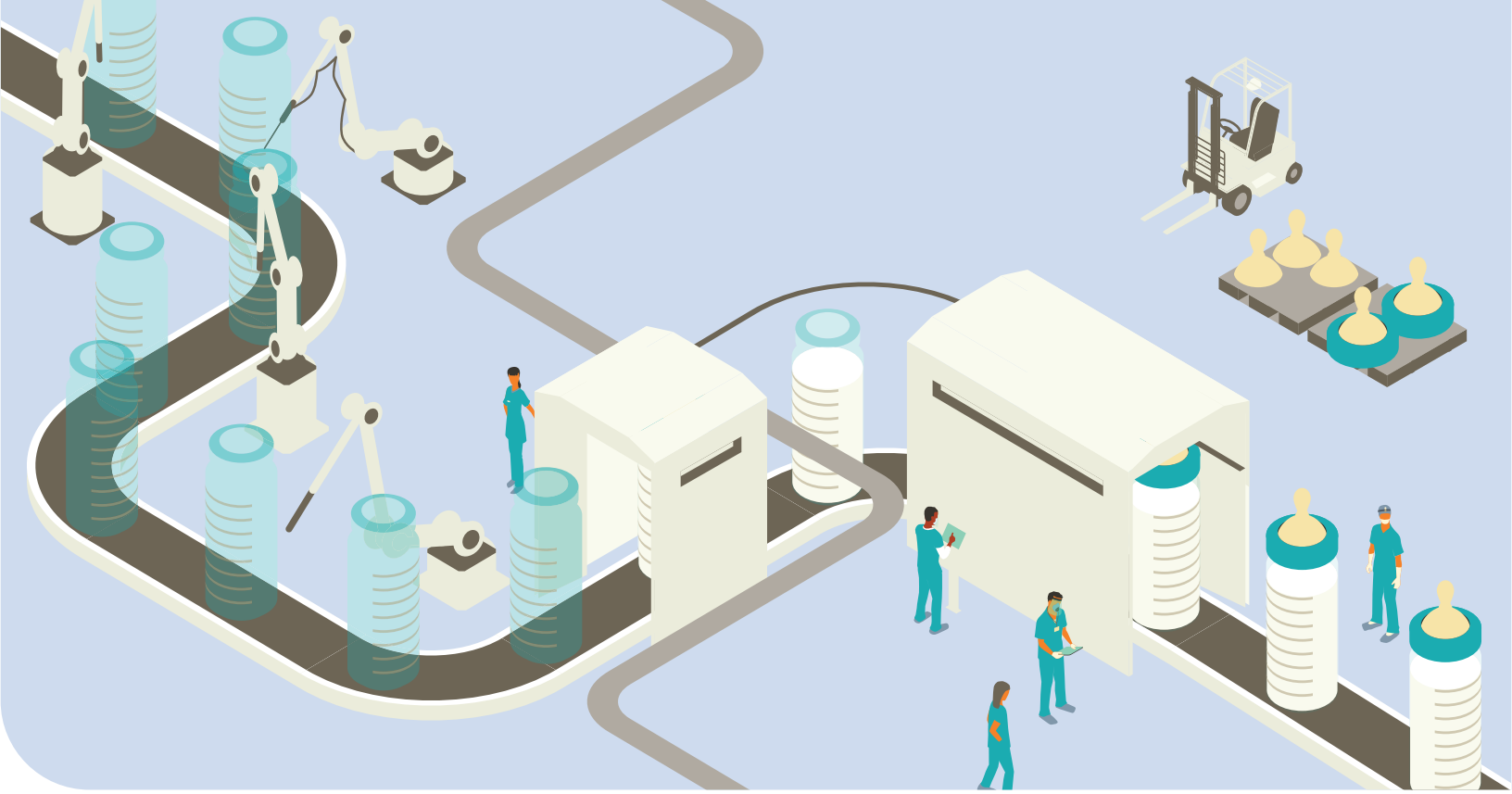
Long-Term Strategy to Increase the Resiliency of the Infant Formula Supply

Since issuing the immediate national strategy in March 2023, the U.S. government has made significant strides toward improving the safety and security of the U.S. infant formula supply chain. This long-term strategy advances a prevention-oriented approach to help ensure a safe, strong, and nutritious infant formula supply, building upon the work of the Immediate National Strategy. Numerous federal agencies are involved in assuring the quality, safety, availability, and affordability of infant formula including but not limited to the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), and the U.S. Department of Agriculture (USDA). Strong collaboration between federal agencies is and has been essential to improving the resiliency of the infant formula supply.

The FDA is prioritizing actions to enhance oversight of infant formula and prevent contamination, protect the integrity of the infant formula supply chain and incentivize new entrants to the U.S. market, support collaboration to strengthen the infant formula supply chain, ensure stakeholders have the most up-to-date information on infant formula and improve information sharing, and gain additional tools and authorities to further enhance the FDA's oversight of infant formula.

The FDA aims to focus efforts on the areas where we have seen the largest impact on the supply of infant formula and highlight where more efforts are needed to further improve the safety and resilience of the supply of infant formula. The FDA will continue using its authorities, both long standing and newly granted, to help increase the resilience of the U.S. infant formula market by continuing to inspect all manufacturers of U.S. infant formula on a regular basis, working with manufacturers as the science around *Cronobacter* prevalence and effective mitigation continues to advance and best practices in the industry evolve, supporting entry and competition in the domestic infant formula market, monitoring supply metrics and identifying potential signs of disruption, sustaining regular communication with infant formula manufacturers and retailers to share information and data, building upon collaboration with U.S. Government partners to reduce the number of disruptions in the future and mitigate any impacts, and communicating often with consumers and other industry stakeholders as significant developments occur. The combined effect of the objectives laid out in this strategy will continue to enhance the safety and resiliency of the U.S. infant formula supply into the foreseeable future.

The USDA's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) program provides supplemental nutrition support for income-eligible, pregnant, and postpartum participants, and infants and children under age 5, which includes providing infant formula. WIC participants use their benefits to purchase about half of the infant formula sold in the United States. The USDA's administration of the WIC program, including steps to prevent infant formula supply chain issues and respond flexibly when they do occur, plays an important role in ensuring the resilience of the infant formula supply.



Objective 1: Ensure the Proper Oversight of Safe Infant Formula Production

As a part of the FDA's mission to protect public health by ensuring the safety of our nation's food supply, the FDA plays a critical role in overseeing the safe production of infant formula. In addition to regularly inspecting all infant formula facilities and maintaining regular communications with infant formula manufacturers, we must be actively engaging to improve the science upon which our oversight of safe production practices is based. Safe production is essential for a steady supply of infant formula to U.S. consumers.

To enhance our oversight of infant formula production and assist industry with contamination prevention efforts, the FDA will take the following actions:

- Conduct surveillance food safety inspections, including sampling as appropriate, of all infant formula manufacturers at least annually and make additional use of voluntary remote regulatory assessments, as appropriate.
- Set annual targets to collect samples of infant formula for both microbiological and nutritional analysis per foreign manufacturer each year, in addition to the FDA's annual surveillance inspection.
- Continue evaluating and improving infant formula training for investigators and other appropriate staff to ensure every infant formula inspection is robust, thorough, and focused on the most critical aspects of the infant formula manufacturing process.
    - Continue holding interactive in-person infant formula inspection workshops, based on continued lessons learned from previous inspections, for staff who conduct, support, or evaluate inspections of powdered infant formula manufacturers.

- Improve knowledge to better prevent contamination of infant formula, including through the continued implementation of the FDA's *Strategy to Help Prevent Cronobacter sakazakii Illnesses Associated with Consumption of Powdered Infant Formula* by
    - Receive new scientific data from the charge advanced through the 2023–25 National Advisory Committee on Microbiological Criteria in Foods (NACMCF) on industry and public health interventions to address *Cronobacter* infections associated with powdered infant formula and standing ready to implement and operationalize any new insights that may be used to improve the food safety, detection methods, or resiliency of the infant formula supply chain.
    - Discuss best practices with industry, especially as new scientific data emerges related to sampling, corrective actions, or root cause analysis.
- Continue improving upon structural changes and process improvements, including enhanced processes for handling consumer and whistleblower complaints throughout the Agency, based on the recommendations from the Office of the Inspector General's (OIG) report in an effort to fully close out the recommendations as complete.

Objective 2: Strengthen the Resiliency of the Infant Formula Supply Chain

Although the FDA's Human Foods Program has minimal supply chain monitoring authorities, it is critical that the FDA has visibility into the infant formula supply to forecast and mitigate any potential disruptions. This visibility is even more important when considering specialty infant formulas, which are intended for use by an infant who has allergies, low birth weight, rare genetic disorders, such as an inborn error of metabolism, or who otherwise has an unusual medical or dietary problem. In these cases, specialty infant formula may be the infant's sole source of nutrition. By working closely with the industry, leveraging multiple data sources, and considering issues from a holistic perspective, the FDA has gained significant visibility into the infant formula supply chain, particularly since 2022, and the FDA will continue to gather and analyze critical information from both producers and consumers of infant formula on the state of the U.S. infant formula market. In addition, these activities will allow us to identify and mitigate vulnerabilities in the infant formula supply chain by working with current manufacturers and those seeking to enter the U.S. market to enhance production and diversity of supply.

To protect the integrity of the infant formula supply chain and incentivize diversification of and new entrants to the U.S. market, the FDA will take the following actions:

- Continue to implement and improve upon our process to assess the infant formula supply, including general market health, potential signs of production challenges, manufacturer inventory, and other leading indicators.
    - Continue tracking production information provided voluntarily by major manufacturers, as appropriate given authority and resources, for early signals of potential supply chain disruptions.

- Monitor in-stock rates to track proxy measures for product volume and variety, as well as sales data to track whether sales volumes are commensurate with estimated demand for infant formula.
- Develop additional models and metrics to monitor and assess ongoing infant formula market health and resilience, including a forecasting model as part of a predictive analysis for near future events and supply chain disruptions, as resources allow.
- Monitor state-level data (as data permits) to assess any state-level problems with infant formula supplies and distribution.
- Collaborate with industry and other parties to examine supply chains, as resources permit, to identify and assess manufacturer concentration risks (including production facility concentration risks), supplier concentration and other sourcing risks (e.g., raw materials constraints), and other critical points of failure.

- Complete pre-market review of new infant formula submissions, including those from transition plan participants who received a letter of enforcement discretion from the FDA, in a timely manner.
  - Prioritize review of premarket submissions for new infant formula products to mitigate or prevent shortages.
  - Support infant formula manufacturers interested in and taking steps toward lawful marketing of these products in the U.S. market by providing information to assist them in meeting the applicable regulatory requirements, including through the issuance of guidance on the protein efficiency ratio (PER) rat bioassay studies, to help ensure the submissions are accurate and complete, thereby enabling a shorter review timeline.

- Enhance assistance to those considering entering the U.S. infant formula market, in particular smaller businesses.

- Continue to reinforce, especially with the specialty infant formula industry, the new requirement to have Redundancy Risk Management Plans (RRMPs), which identify and evaluate the risks to the infant formula supply for each establishment in which it is manufactured, and the critical importance of identifying and/or creating redundancies in their supply chains. As a part of developing RRMPs, industry may consider the following:
    - Over-reliance on a single facility or a single production line. especially in the case of specialty formula production.*
    - Inventory management, stockpiling, and surge capacity in mitigating supply shocks.*
    - Over reliance on a single supplier, domestic or foreign.*
    - The development of an industry-led supply chain resilience assessment program, designed to measure and communicate insights on supply chain risks on an ongoing basis.
    - The added value, over and above what manufacturers will cover in their RRMPs, of wholesalers and distributors of infant formula developing RRMPs to prepare for supply disruptions that could lead to a shortage of infant formula.*
- Analyze methods and approaches for potential international harmonization of regulatory requirements for infant formula to determine whether doing so could increase resilience in supply and provide flexibility in situations of potential shortage.
    - Continue participating in The Codex Committee on Nutrition and Foods for Special Dietary Uses to facilitate harmonization of international standards for infant formula, for example, nutrient requirements, labeling, and microbiological testing.
    - Explore the utility of collecting information on nutrient and labeling requirements used by other countries to facilitate the further use of enforcement discretion in case of a shortage.*

* Consistent with a recommendation from NASEM's 2024 study on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.

Objective 3: Continue to Work with U.S. Government Partners at the Federal, State, Local, Territorial, and Tribal Levels Involved in the Production, Distribution, or Sale of Infant Formula

The FDA continues to undertake numerous activities to support the resilience and safety of the infant formula supply chain, but we are very cognizant that no one agency alone can resolve the vulnerabilities in the infant formula market. Together with our Government partners across multiple levels, we are working to communicate efficiently and effectively on all manner of topics that affect the infant formula supply.

To support collaboration to strengthen the infant formula supply chain, the FDA will take the following actions:

- Engage with U.S. Government partners to address long-term infant formula needs, in particular, where those partners are able to influence the infant formula supply chain outside of the FDA's control and build long-term resilience into the infant formula supply chains.
    - Continue to work with the Department of Health and Human Services (HHS) to conduct sector-wide risk management planning.*
    - Work with CDC, infant nutrition experts, and infant formula manufacturers to explore jointly developing information on how caregivers can safely substitute infant formula.*
    - Support CMS in ensuring hospitals have a plan for a meaningful disruption of nutrition support for hospitalized infants.*

* Consistent with a recommendation from NASEM's 2024 study on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.

- Engage with the USDA to support resilience and adequate reserve planning. For example:
    - Collaborate with the USDA/WIC to ensure infant formula manufacturers meet the expectations with regard to evidence-based RRMPs standards to be considered a "responsive" bidder.*
    - Discuss the feasibility of strengthening infant formula contract flexibilities authorized by WIC during disruptions.*
- Coordinate with the USDA's WIC program to distribute our consumer education materials on safe preparation, handling and feeding practices for infant formula.
- Continue to communicate and collaborate with Council of State and Territorial Epidemiologists (CSTE) as *Cronobacter* has recently become a nationally notifiable disease.

The FDA continues to support the USDA as they work on:

- The USDA is in the process of updating the Guide to Coordinating WIC Service During Disasters ensuring that information and lessons learned from the 2022 infant formula recall and subsequent shortage are reflected where possible and appropriate.
- In FY 2025, the USDA will initiate research to inform recommendations about the needed iron levels in infant formula requirements in WIC to ensure the formula plays its role in the supplementation of diets to address anemia in WIC-participating infants.
    - The USDA will monitor the impact of these and other actions taken since 2022 and solicit feedback from WIC stakeholders to inform additional efforts to assist WIC State agencies and better serve WIC participants.
- The USDA will explore developing a WIC governance structure framework for crisis response that describes how the response could be coordinated at the State-agency level and could be adapted to meet the needs of individual State agencies.*

Objective 4: Ensure Timely Communication with Industry, Consumers, and Other Stakeholders on Infant Formula Issues of Public Health Significance

Public health is a shared responsibility. As a regulatory agency, the FDA, in close coordination with HHS, including CDC, and other U.S. Government partners, will continue working to ensure the best and latest scientific information is incorporated in all aspects of our work to protect public health. However, this information must be shared widely to have a measurable impact on the numerous and diverse parties involved in the infant formula market. Working with producers of infant formula, the FDA is improving efforts to communicate best compliance, manufacturing, and risk management practices for the infant formula industry. In addition, we aim to communicate more effectively with consumers and medical professionals, through a variety of

* Consistent with a recommendation from NASEM's 2024 study on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.

platforms, and ensure that all affected groups are receiving the most up-to-date information, including consumers of specialty infant formulas given the unique nature and vital importance of those products.

To ensure stakeholders have the most up-to-date information on infant formula and to improve information sharing, the FDA will take the following actions:

- Collaborate with major infant formula producers and retailers, including:
    - Host a webinar to provide detailed information about infant formula processing and critical control points to assist both firms participating in the transition plan and firms making submissions through the FDA's normal notification process.
    - Continue regular communication with infant formula manufacturers to support information sharing on production levels, raw materials, and distribution.
    - Continue to support major infant formula producers by providing information on mandatory reporting under FDORA of potential shortages of product, raw materials, and ingredients, and the critical importance of specialty infant formula supply chains.
- Continue further developing educational materials, in close coordination with HHS, including CDC, and other U.S. Government partners, for consumers, medical professionals, and industry:

- Consolidate, reorganize, and translate our educational materials on FDA.gov to improve accessibility for all families.
- Continue enhancing and leveraging the FDA's partnerships with health care providers and professionals, particularly infant care professionals, to further build our consumer education program.
    - Continue to work with the American Academy of Pediatrics and other medical groups and societies, including the Metabolic Dietitians Practice Group and support groups for individuals with metabolic disorders, while also exploring new opportunities to partner with other healthcare providers and facilities to enhance and promote our consumer education regarding the safe use of infant formula.
    - Establish a joint memorandum of understanding (MOU) with the USDA's Food and Nutrition Service (which handles the WIC program) and the American Academy of Pediatrics to collaborate on developing and disseminating education and outreach initiatives for health care providers who support parents and caregivers of infants and children to help increase awareness and understanding of the safe handling of infant formula.

- Continue work, in close coordination with U.S. Government, industry, expert, and other partners, to develop communication materials to be used in event that infant formula is unavailable, including during any future recall or supply disruption.
    - Continue work with HHS, including CDC, and other partners to develop materials on how caregivers can substitute infant formula when breast milk or preferred infant formula type is unavailable, including during any future recall or supply disruption.
    - Work with the industry to create and maintain a public list of all infant formulas currently marketed and registered in the U.S.*
    - Continue work with HHS, including CDC, and other partners to refine communications materials and plans for use during any future recall or disruption, in order to provide caregivers and industry with the latest information on infant formula availability and alternatives.
- Promote policies and information, including from U.S. Government partners, that support breastfeeding as well as infant and maternal health.

* Consistent with a recommendation from NASEM's 2024 study on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.

Objective 5: Continually Evaluate Authorities for Infant Formula, While Ensuring Necessary Regulations and Guidances are Clear and Science-Based

While Congress has recently granted the FDA additional authorities related to infant formula, we know that more is needed to help ensure the FDA can effectively oversee the continued safe production and availability of infant formula. Simultaneously, there is more the FDA can do with guidance documents and rulemaking to ensure that producers and potential entrants into the infant formula market have the information they need.

To enhance the FDA's oversight of infant formula, the FDA will take the following actions:

- Continue to evaluate all new scientific, production, and regulatory information to determine if an update is needed to existing regulations.*
    - Incorporate the results of the NASEM study on the state of the science pertaining to possible alternatives to the Protein Efficiency Ratio (PER) and growth monitoring studies to help assess where the science is sufficiently robust to support changes to our regulations and/or guidance documents to provide for additional flexibility regarding these important requirements.
    - Evaluate current testing requirements for pathogens in finished infant formula product, as part of a review of regulatory requirements of infant formula led by the Office of Critical Foods.
- Publish several guidance documents for industry, including:
    - Notifying the FDA of a Permanent Discontinuance in the Manufacture or an Interruption of the Manufacture of an Infant Formula: Draft Guidance for Industry*
    - PER Rat Bioassay Studies to Demonstrate that a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein: Guidance for Industry
    - Establishing Sanitation Programs for Low-Moisture Ready-to-Eat Human Foods and Taking Corrective Actions Following a Pathogen Contamination Event: Draft Guidance for Industry
- Promote infant formula market health and diversification, especially for specialty formulas, by exploring the development of regulatory standards or guidance for RRMPs, a process for reviewing RRMPs, and a mechanism for monitoring implementation of the RRMPs.*
- Help ensure the availability of a safe and steady supply of infant formula to all U.S. consumers, by continuing to work with Congress, where appropriate, to:
    - Encourage all infant formula manufacturers, including specialty formula manufacturers, to implement the RRMPs and modernize manufacturing plants and equipment.*

* Consistent with a recommendation from NASEM's 2024 study on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.

- Require manufacturers of critical foods to give sufficient advanced notice 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. *
- Grant the FDA mandatory authority for remote access of records for all critical food manufacturers.*
- Provide technical assistance to Congress, where appropriate and within the FDA's purview, should Congress consider suspending tariffs on imported infant formula or inputs used in the domestic production of infant formula in the event of a meaningful disruption to the market.*

- Continue to advance legislative proposals to strengthen the FDA's regulatory oversight and enforcement tools for infant formula safety and supply chain resilience.

The FDA appreciates the resources provided for infant formula oversight in the wake of the 2022 shortage, which have gone a long way in securing additional oversight of this important commodity. However, additional resources as requested in the 2024 Budget would allow us to hire additional staff and experts to increase pre-market notification review capacity, which would further diversify the market and allow for the hiring of additional inspectors to focus on issues such as ensuring that fraudulent products, both domestic and imported, are not available to U.S. consumers.

* Consistent with a recommendation from NASEM's 2024 study on Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States.

Appendix: Progress Since the Release of the Immediate National Strategy

To address the supply chain crisis following the 2022 recall of infant formula from Abbott's Sturgis, MI, facility and the subsequent temporary shutdown of that facility, the FDA immediately engaged our United States Government partners and external parties. For example, the FDA worked closely with infant formula manufacturers to mitigate supply disruption by anticipating potential disruption issues, forecasting production needs, encouraging the advancement and adjustment of production schedules for particular types of infant formula, and encouraging the release of safety stocks on hand. However, at the time, the FDA lacked authority, resources, and staff specifically dedicated to predicting, detecting, and responding to supply chain issues for infant formula, although we had requested authority to do so since 2020.

The FDA's actions over the past year to improve the safety and availability of infant formula are described in the sections below.

Oversight of Safe Production

To enhance its oversight of safe infant formula production, the FDA:

- Negotiated a consent decree with Abbott Nutrition at its Sturgis, MI facility, which was entered by the U.S. District Court for the Western District of Michigan on May 16, 2022. This consent decree requires Abbott to take steps necessary to safely produce infant formula in close coordination with the FDA and under our oversight of its manufacturing and food safety processes.
- Conducted 45 routine annual inspections of domestic and foreign facilities that produce infant formula (including some that also produce medical foods), meeting the FDA's inspection targets for FY 2023.
- Conducted 40 routine annual inspections of domestic and foreign facilities that produce infant formula (including some that also produce medical foods), meeting the FDA's inspection targets for FY 2024.
- Issued warning letters to three infant formula manufacturers, on August 30, 2023, related to their failure to establish adequate process controls to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the process environment. These actions form part of the Agency's ongoing commitment to enhance regulatory oversight to help ensure that the industry is producing infant formula that meets the FDA's safety standards.
- Increased surveillance sampling of imported infant formula and conducted targeted Foreign Supplier Verification Program (FSVP) inspections of FSVP importers importing infant formula to determine their compliance with FSVP requirements.

- Continued to implement the FDA's strategy to prevent ***Cronobacter sakazakii*** illnesses associated with the consumption of powdered infant formula. The FDA:
    - Collaborated with industry, coalitions, academia, and consumer groups, through a series of meetings, to better understand and explore ways to enhance the safety of powdered infant formula.
    - Issued a letter to the powdered infant formula industry to share current safety information and to call on to industry to take prompt action to improve processes related to the safe production of powdered infant formula.
    - Initiated hiring of six additional investigators to build the dedicated cadre to conduct infant formula inspections.
    - Initiated hiring of staff to support the new Office of Critical Foods within the new HFP.
    - Released an update to chapter 29 of the Bacteriological Analytical Manual (BAM) with an updated method for testing powered infant formula samples for ***Cronobacter***, to be used by the FDA and other federal partners, as well as state and local laboratories.
    - Expanded the FDA laboratory capacity for testing of powdered infant formula and environmental samples. Over 200 regulatory samples have been analyzed for the Infant Formula Program since October 2022.
    - Advanced a charge through the NACMCF, in November 2022, to gain scientific insight on possible industry and public health interventions to address ***Cronobacter*** infections associated with powdered infant formula.
- Updated the compliance program for infant formula, which serves as a field guide to FDA investigators of infant formula production facilities.
    - Hosted a webinar to brief field investigators, compliance officers, and managers on significant updates to the compliance program.
    - Significantly expanded and improved a required infant formula online training course for investigators and other appropriate staff to ensure every infant formula inspection is robust, thorough, and focused on the most critical aspects of the infant formula manufacturing process.
    - Developed and delivered two interactive in-person powdered infant formula inspection workshops, which provided critically relevant and timely inspectional information for investigators and other appropriate staff, including updates from lessons learned during previous inspections, for staff who conduct or support inspections of powdered infant formula manufacturers.

- Participated in numerous reviews, including an evaluation of the agency's infant formula response and the Reagan-Udall Foundation's evaluation of the FDA's Human Foods Program (conducted at the FDA's request) to identify areas for improvement within the Agency, as well as the Office of the Inspector General's (OIG) report on the FDA's Infant Formula Inspection and Recall Process.
    - The FDA is implementing changes in response to these reviews, including establishing an internal process for triaging, evaluating, and consistently notifying leadership of consumer complaints, adverse events, or whistleblower complaints involving infant formula.
    - As part of the restructuring, which includes modernization of the FDA's HFP and Office of Inspections & Investigations (OII), the FDA created new organizations, such as the Office of Critical Foods in the HFP and a Critical Foods Investigation Branch within the Office of Global and Specialty Human Food Inspectorate in OII, which are responsible for oversight, coordination, and activities related to critical foods, including infant formula.

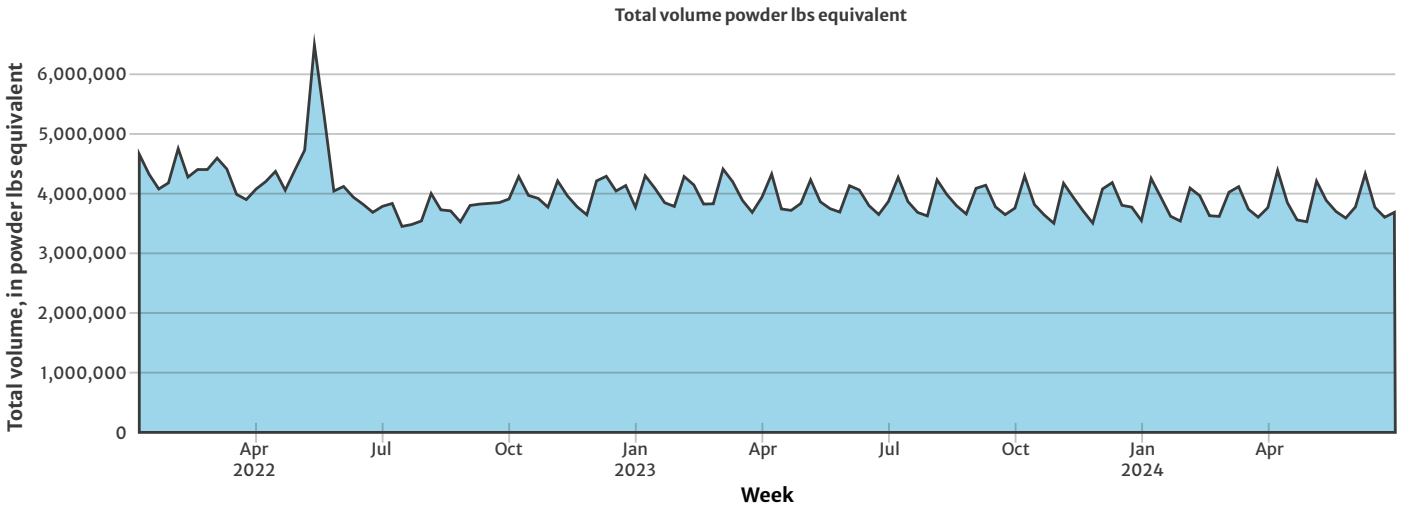
Resilience of the Supply Chain

To protect the integrity of the infant formula supply chain and incentivize new entrants to the U.S. market, the FDA:

- Continued to work with major domestic infant formula producers to increase infant formula production, frequently communicated and shared data with manufacturers on production levels and potential supply chain issues, and emphasized the critical importance of redundancies in infant formula supply chains, especially for specialty products.
    - As the Agency noted in the Immediate National Strategy, the US infant formula supply is highly concentrated in a small number of manufacturers. In 2022, four companies controlled 99 percent of the infant formula market; in 2024, the number of major manufacturers was down to three, highlighting the importance of RRMPs.

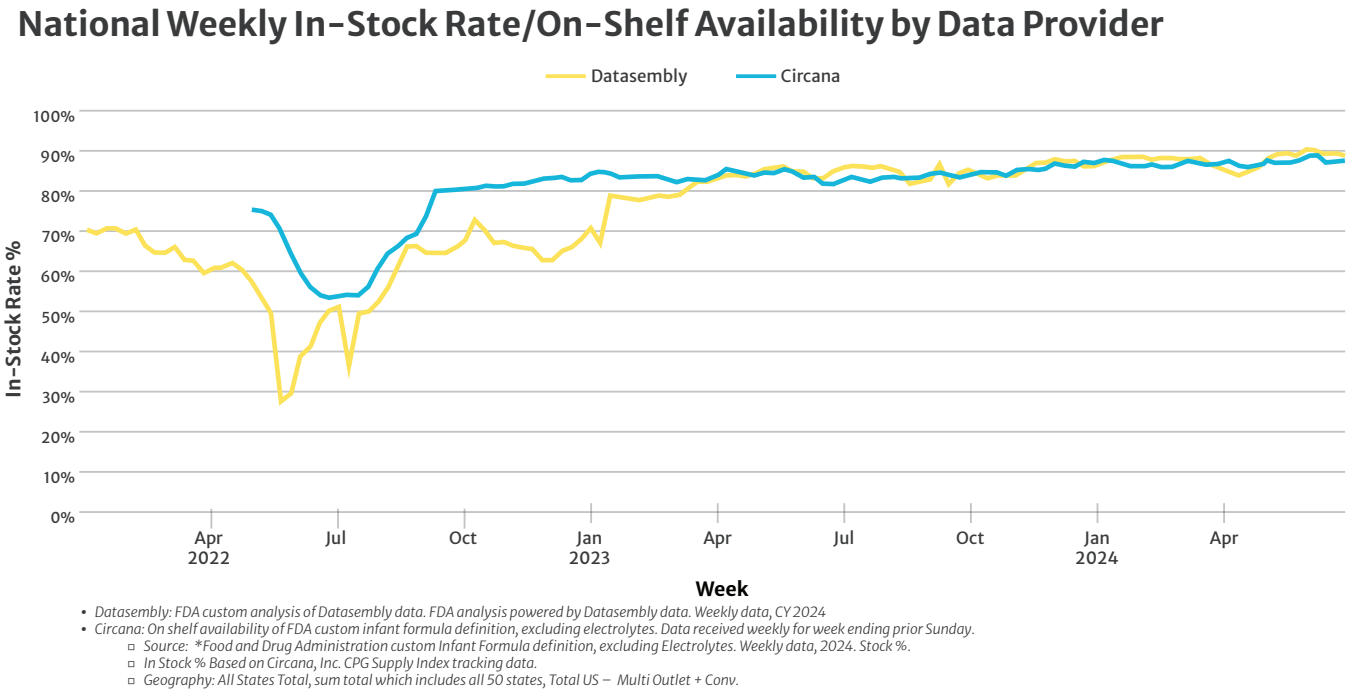
- Successfully transitioned, in September 2023, to an in-house platform to track and analyze production data and supply chain information, using data provided to the Agency voluntarily by infant formula manufacturers to track production projections/goals to give the Agency early signals of potential issues. (Figure 1.)

Total Weekly Volume Sales for All Brands



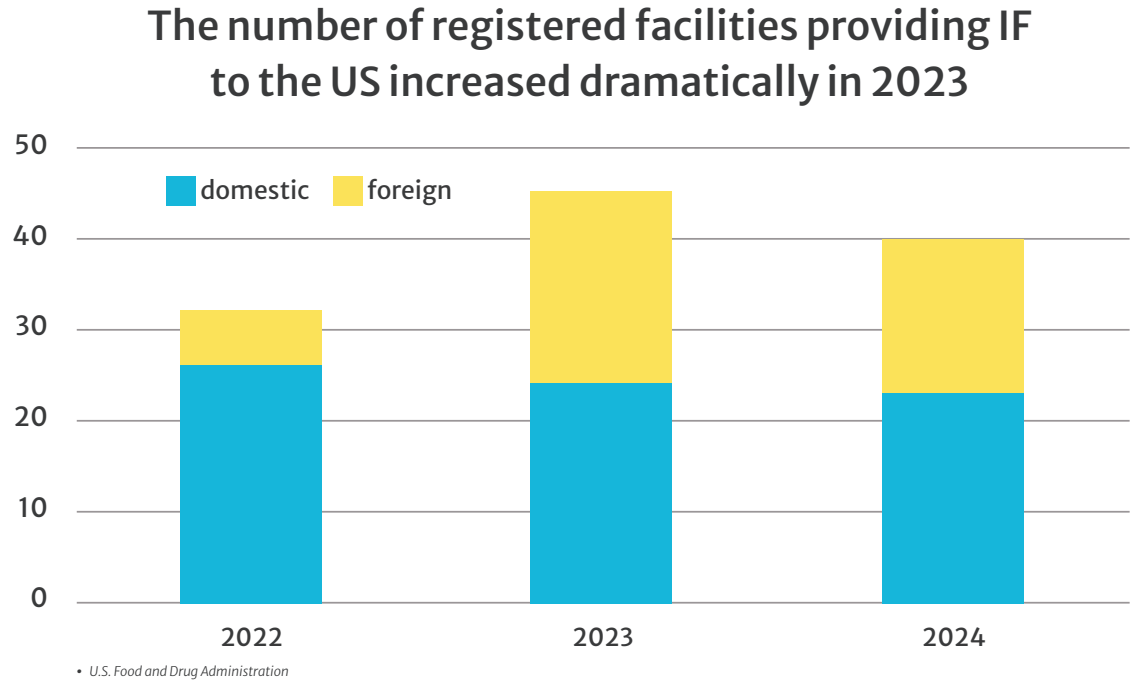
- *Circana Sales Data 2024*
  - *Food and Drug Administration custom Infant Formula definition, excluding Electrolytes, based on Circana, Inc. data.*
  - *Weekly data, CY 2024.*
  - *Geography: All States Total, sum total which includes all 50 states, Total US – Multi Outlet + Conv.*

- Continued to monitor in-stock rates to track proxy measures for the recovery of product volume and variety on store shelves. (Figure 2.)



- *Datasembly: FDA custom analysis of Datasembly data. FDA analysis powered by Datasembly data. Weekly data, CY 2024*
- *Circana: On shelf availability of FDA custom infant formula definition, excluding electrolytes. Data received weekly for week ending prior Sunday.*
  - *Source: *Food and Drug Administration custom Infant Formula definition, excluding Electrolytes. Weekly data, 2024. Stock %.*
  - *In Stock % Based on Circana, Inc. CPG Supply Index tracking data.*
  - *Geography: All States Total, sum total which includes all 50 states, Total US – Multi Outlet + Conv.*

- Issued the Infant Formula Transition Plan for Exercise of Enforcement Discretion guidance, in September 2022, that outlines a path for interested firms temporarily marketing products in the U.S. under the FDA's exercise of enforcement discretion to bring those products into full compliance with U.S. requirements to facilitate longer-term supply resilience in the U.S. market. (Figure 3.)



- *U.S. Food and Drug Administration*

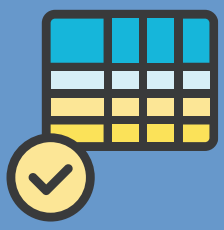
- Six firms that manufacture infant formula are currently participating in the transition plan to bring 16 infant formula products into compliance with all U.S. requirements for infant formula after having previously received a letter of enforcement discretion from the FDA.
- The FDA completed its review of two new infant formula submissions for products from firms participating in the transition plan, which are now available long-term in the US, having met all of the FDA's requirements. The FDA continues to diligently monitor the firms' progress with the remaining 16 products.

- Contracted with the NASEM, in early 2023, to conduct two independent studies:
  - On the Challenges in Supply, Market Competition, and Regulation of Infant Formula in the United States to better understand where different levers may be applied to aid in the continued safe and steady supply of infant formula.
    - Report was a requirement of the Food and Drug Omnibus Reform Act of 2022 and was completed and delivered publicly by NASEM on July 25, 2024.
  - On the state of the science pertaining to possible alternatives to the protein efficiency ratio and growth monitoring studies that are prescribed in the FDA's current regulations to satisfy quality factor requirements, which is still ongoing.

The FDA continues to support the USDA as they work on:

- Since the release of the Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market in March 2023, the USDA has taken multiple actions to bolster resilience in the infant formula market, including publishing a final rule to codify provisions of the Access to Baby Formula Act of 2022 (ABFA, PL 117-129) and implement changes to:
  - Make permanent the expanded waiver authority to ensure continuity of WIC services during emergency periods and supply chain disruptions.
  - Require WIC infant formula cost containment contracts to contain remedies in the event of an infant formula recall, including how an infant formula manufacturer would protect against disruption to supplemental food access by WIC participants.
  - Require WIC state agencies to include as a part of their state plan a "plan of alternate operating procedures" in the event of an emergency period, supplemental food recall,† or other supply chain disruption.
- In 2024, the Secretary of Agriculture exercised the new authority provided by ABFA to declare two separate supply chain disruptions – one related to a limited supply of Gerber's WIC contract brand formulas and a second related to the impact of a tornado that hit a Mead Johnson distribution center. This enabled the USDA to provide regulatory flexibilities during temporary shortages unrelated to a recall to ensure WIC participants had access to infant formula.

† Under the USDA's WIC program, a "supplemental food recall" is a recall of a WIC provided food, such as infant formula.



Work with U.S. Government Partners at the Federal, State, Local, Territorial, and Tribal Levels

To support collaboration to strengthen the infant formula supply chain, the FDA:

- Supported the Council of State and Territorial Epidemiologists (CSTE) position on elevating ***Cronobacter*** to a nationally notifiable disease, which was successfully adopted by the CSTE on June 29, 2023, and went into effect as of January 1, 2024.
    - Met regularly with the CSTE and the CDC to support implementation of this newly authorized notification process.
    - In June 2024, CSTE released additional materials addressing Clinical Specimen, Isolate Submission, and Communications and Product Testing Recommendations, related to ***Cronobacter*** illnesses in infants, in close consultation with the FDA and the CDC.
- Held regular meetings with international partners in Canada to discuss the potential for harmonizing regulatory requirements for infant formula, including inspections, labeling, and nutritional requirements.
- Collaborated with the U.S. Customs and Border Protection (CBP) to expedite entries granted enforcement discretion.

The FDA has also continued to work closely with the USDA on Infant Formula supply chain resilience:

- The FDA and the USDA senior leadership met regularly to discuss infant formula issues and the FDA and the USDA staff in the WIC program met to ensure that the FDA and the USDA were informed of relevant infant formula activities, including any issues that might affect supply.
    - Meetings included regular communication on potential recalls, ongoing actions by each agency to provide support to the supply of infant formula, and the general supply of infant formula.
- The USDA continues to collaborate with federal partners to monitor and strengthen the supply of infant formula.
    - In FY 2024, the USDA Food and Nutrition Service (FNS) and Economic Research Service executed an interagency agreement to establish a direct source for infant formula in-stock rate data. The USDA is currently taking action to develop data dashboards to track and anticipate changes in market availability of infant formula to inform, as needed, proactive actions to ensure WIC participants have consistent access to the formula they need.
    - Also in FY 2024, the USDA FNS and the FDA executed an interagency agreement to develop a continuing medical education program for healthcare providers inclusive of information related to infant formula safety.

Communication with Industry, Consumers, and Other Stakeholders

To ensure stakeholders have the most up-to-date information on infant formula and to improve information sharing, the FDA took the following actions:

- Engaged with stakeholders from a wide variety of perspectives on infant formula safety, including, but not limited to, the American Hospital Association, Children's Hospital Association, the National Rural Health Association, the Safe Food Coalition, Center for Science in the Public Interest, and the Infant Formula Nutrition Council of America.
- Updated and reorganized infant formula related materials on the FDA.gov website to provide consumers, health care professionals, and industry with more accessible information, including:
    - Infant Formula
    - *Cronobacter sakazakii*
- Published new resources for industry, including an informational one-pager on the new requirement for manufacturers of critical foods to develop a redundancy risk management plan (RRMP).
- Hosted an initial four-part webinar series to provide detailed information about the transition plan for infant formulas marketed under the exercise of enforcement discretion as well as the established process for new infant formula submissions, and to address questions.
    - Hosted two supplemental webinars to provide additional detailed information about safety evaluation of infant formula ingredients and infant formula packaging.
- Worked with industry to establish a system for voluntary reporting to the FDA of product samples that test positive for *Cronobacter* or *Salmonella* even if the products are still within the firm's control (which is posted under the Information for Infant Formula Manufacturers portion of our Infant Formula webpage).
    - Received, processed, and appropriately followed-up on voluntary notifications from infant formula manufacturers for ***Cronobacter spp.*** findings in finished product or in-process product.
- Issued notification to the import industry on how to properly transmit infant formula entries subject to enforcement discretion.
- Released new and updated infant formula materials, including two new consumer infographics (for high-risk babies and tips for preparing powdered infant formula), a guide for health care professionals, and an updated ***Food Facts for Consumers*** resource on handling infant formula.

- Handling Infant Formula Safely: What You Need to Know (Additionally translated into Spanish, Arabic, Dari, Nepali, Somali, and Burmese)
- Safe Feeding of Babies at Higher Risk of Foodborne Illness (Consumer Infographic) (Additionally translated into Spanish, Arabic, Dari, Nepali, Somali, and Burmese)
- Tips for Safely Preparing Powdered Infant Formula (Consumer Infographic) (Additionally translated into Spanish, Arabic, Dari, Nepali, Somali, and Burmese)
- Information for Health Care Professionals on Safe Handling of Infant Formula (Additionally translated into Spanish)
- Conducted multiple outreach and promotional efforts including: ongoing FDA social media outreach (Facebook, X, Instagram); CFSAN News For Educators newsletter; cross-promotion from other FDA and federal newsletters (OWH, OMHHE, HHS Digital Digest, Friends of NICHD, and WIC); PR Newswire; and a Google AdWords Campaign.

The FDA continues to support the USDA as they work on:

- The USDA also provided the following information and technical assistance to State agencies:
  - Implementing ABFA Requirements in WIC State Plans
  - Requirements and Best Practices for Oversight of the Infant Formula Suppliers List
  - Oversight of Infant Formula Purchase Requirements in WIC
  - Infant Formula Flexibilities for Food Package III
  - In addition, the USDA has increased transparency about infant formula bids by making public information about which manufacturers currently hold the WIC infant formula contract for each State agency, open solicitations, and a checklist that WIC State agencies can use to inform their infant formula rebate contract solicitations.

New Authorities, Regulations, and Guidances

To enhance the FDA's oversight of infant formula, the FDA:

- Developed legislative proposals, as noted in the FY 2024 and FY 2025 FDA budgets, seeking new authorities to modernize the regulation of critical foods and other foods marketed for consumption by infants and young children. These new authorities would help the FDA better understand levels of contaminants in foods, allow the FDA to monitor industry progress in reducing levels of contaminants over time, and help identify where the FDA should devote more time and resources. Specifically, the FDA requested new authority to:
    - Allow the FDA to establish binding contamination limits in foods, including those consumed by infants and young children, via an administrative order process to provide a faster way to set and update binding limits as new scientific information becomes available.
    - Require industry to conduct testing of final products, including those marketed for consumption by infants and young children, for contaminants and maintain such records of these testing results for the FDA inspection.
    - Require industry to report all product positive test results for relevant pathogens in infant formula.
    - Require industry to conduct more effective environmental monitoring in their facilities to identify the presence of relevant pathogens on surfaces from which the risk of critical food contamination is the greatest and maintain the results of such testing for the FDA inspection, either in person or remotely.
    - Permit the FDA to remotely access records of these test results, so the Agency can request and review test results whenever necessary and in a more streamlined fashion.
    - Require a mandatory recall when the FDA determines through any means that there is a reasonable probability that an article of infant or toddler food (other than infant formula)[+] bears or contains a contaminant that renders the product adulterated.
- Requested in the FY 2025 FDA budget that Congress clarify that the FDA can impose additional conditions on notifications submitted by manufacturers of critical foods when there is a permanent discontinuance or interruption in manufacture that is likely to lead to a meaningful disruption in the U.S. supply, including requirements to submit specific information as part of the notification.
- The combination of these new authorities would empower the FDA to work with firms in real time to resolve issues around product positive findings and better ensure the safety of critical foods entering the market.

+ There is already specific mandatory recall authority for infant formula in section 412 of the FD&C Act, and we are not proposing to change that authority. For this reason, infant formula is carved out of the existing mandatory recall authority in section 423 and should also be excluded from this proposed expansion of the mandatory recall authority in section 423.

The U.S. Food and Drug Administration's Long-Term National Strategy to Increase the Resiliency of the U.S. Infant Formula Market