



**U.S. FOOD & DRUG**  
ADMINISTRATION



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

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March 2023



# Introduction

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Between September 2021 and January 2022, the U.S. Food and Drug Administration received information about four cases of illness or death in infants who consumed powdered infant formula. After learning that each of these infants consumed powdered infant formula products manufactured by Abbott Nutrition in Sturgis, Michigan, and initiating an investigation at the facility that revealed insanitary conditions, the FDA warned consumers not to use certain products manufactured at this facility. On February 17, 2022, Abbott Nutrition issued a voluntary recall of certain infant formula products manufactured in Sturgis, Michigan, and temporarily ceased production. The recall was voluntarily expanded on February 28, 2022, by Abbott Nutrition to cover additional products. While necessary to safeguard public health, the recall and pause in production further stressed a supply chain already strained by the COVID-19 pandemic and preceding market concentration issues. A shortage of these products created hardships for parents and caregivers who rely on infant and specialty formulas to feed their babies, as well as loved ones with certain metabolic disorders.

FDA had concerns about the resiliency of the supply chains for infant formula and medical foods beginning in the first days of the COVID-19 pandemic, given that the pandemic stressed ingredient and packaging supply chains used in infant formula as well as the labor and manufacturing sectors. The concentration of production in the industry, lack of robust risk management plans by major manufacturers, and lack of statutory authority to ensure FDA insight into production challenges left the infant formula market in the United States vulnerable to issues that could stress or disrupt the supply chain – be it a major recall, natural disaster, or labor shortage.

There are numerous factors that led to the shortages encountered with infant formula in 2022. This Immediate National Strategy collects what we have observed, describes immediate actions taken to address the situation, and details what we plan to do to further help improve the resiliency of the infant formula market, while noting additional issues that need to be addressed beyond the purview of FDA. This initial strategy represents a first step toward issuing, with input from the National Academy of Science, Engineering and Medicine (NASEM), a long term national strategy to improve preparedness against infant formula shortages by outlining methods to improve information-sharing, recommending measures for protecting the integrity of the infant formula supply chain and preventing contamination, outlining methods to incentivize new infant formula manufacturers to increase supply, and recommending other necessary authorities to gain insight into the supply chain and risk for shortages.



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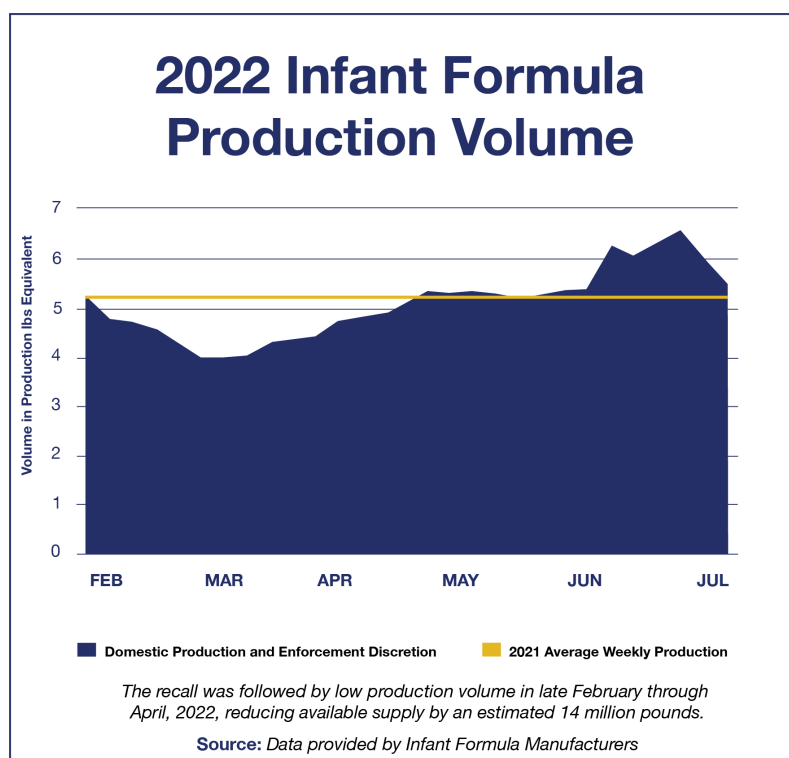




## Assessing Contributing Factors to the Shortage

The infant formula shortage in 2022 was caused by multiple factors and influenced by others. The immediate factors leading to the shortage were in part a result of long-standing circumstances that had shaped the production of infant formula over the years. At a time when the COVID-19 pandemic had already strained supply chains for many consumer products, the infant formula industry was particularly vulnerable to disruption.

Most acutely, the combination of insanitary conditions in the Abbott Nutrition Sturgis, Michigan facility, the significant reliance on this single facility for both routine and critical specialty formulas, the firm's lack of capacity for back-up production of specialty formulas, and inadequacy of redundancy plans for production of powdered formula, created a “perfect storm” resulting in the supply chain disruption in 2022 that affected the entire U.S. market.



### Acute Contributing Factors

- On February 17, 2022, Abbott Nutrition voluntarily recalled over 7 million pounds of powdered infant formula products from retail shelves manufactured in Sturgis, Michigan, and temporarily ceased production at the facility. The recall was voluntarily expanded on February 28, 2022, to cover additional products. (Figure 1.)

Figure 1.



- Lower volume and less variety on the shelves contributed to abnormal purchasing behavior that has been called “panic buying” or “pantry loading” in the [business literature](#), which can be [driven](#) by [media exposure](#). Specifically, with regard to the infant formula shortage this phenomenon peaked in May 2022 and contributed to increased draw down of formula inventories. (Figure 2.)

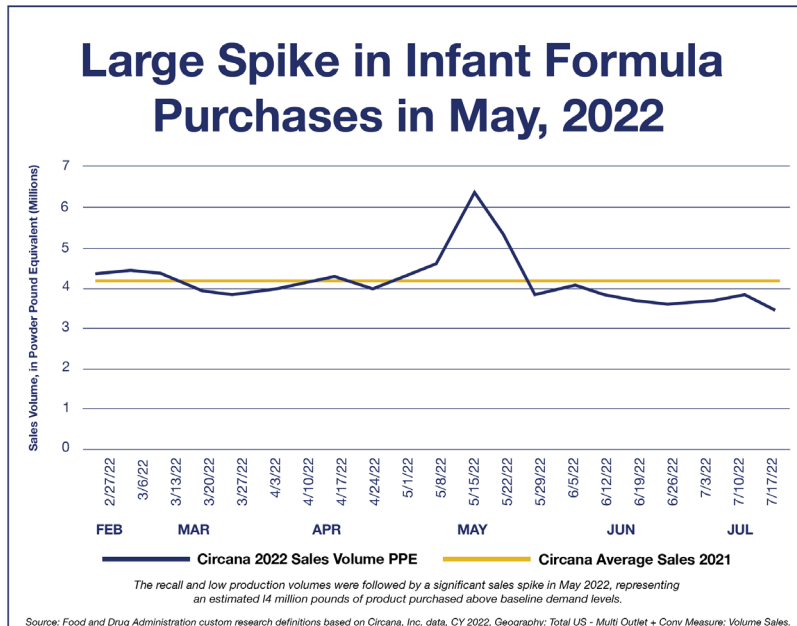


Figure 2.

- Although Abbott Nutrition was able to resume production initially on June 4, 2022, under a consent decree entered on May 16, 2022, their operations were shut down again due to flooding on June 13, 2022; operations did not resume again until July 1, 2022. Abbott Nutrition did not announce it was resuming routine formula production until August 26, 2022 – following some “[stops and starts](#)” in production.
- The COVID-19 pandemic and the Ukraine/Russia conflict exposed and amplified the fragility of supply chains in general, straining raw materials/ ingredients, labor, packaging, transportation, and other resources across all supply chains.



## Market Contributing Factors

- Infant formula supply is highly concentrated in a small number of manufacturers, which means that if there is a problem in production in one company, the overall supply can be significantly affected. In 2022, four companies controlled 99 percent of the infant formula market. (Figure 3.)
- In addition, the dominant manufacturers rely on relatively few manufacturing facilities that account for a significant amount of their production. For example, prior to the February 2022 recall, the Sturgis facility produced 40 percent of Abbott's powdered infant formula for the domestic market.
- Lack of competition means there is less incentive for investment in excess or improved manufacturing infrastructure or innovation in the marketplace.

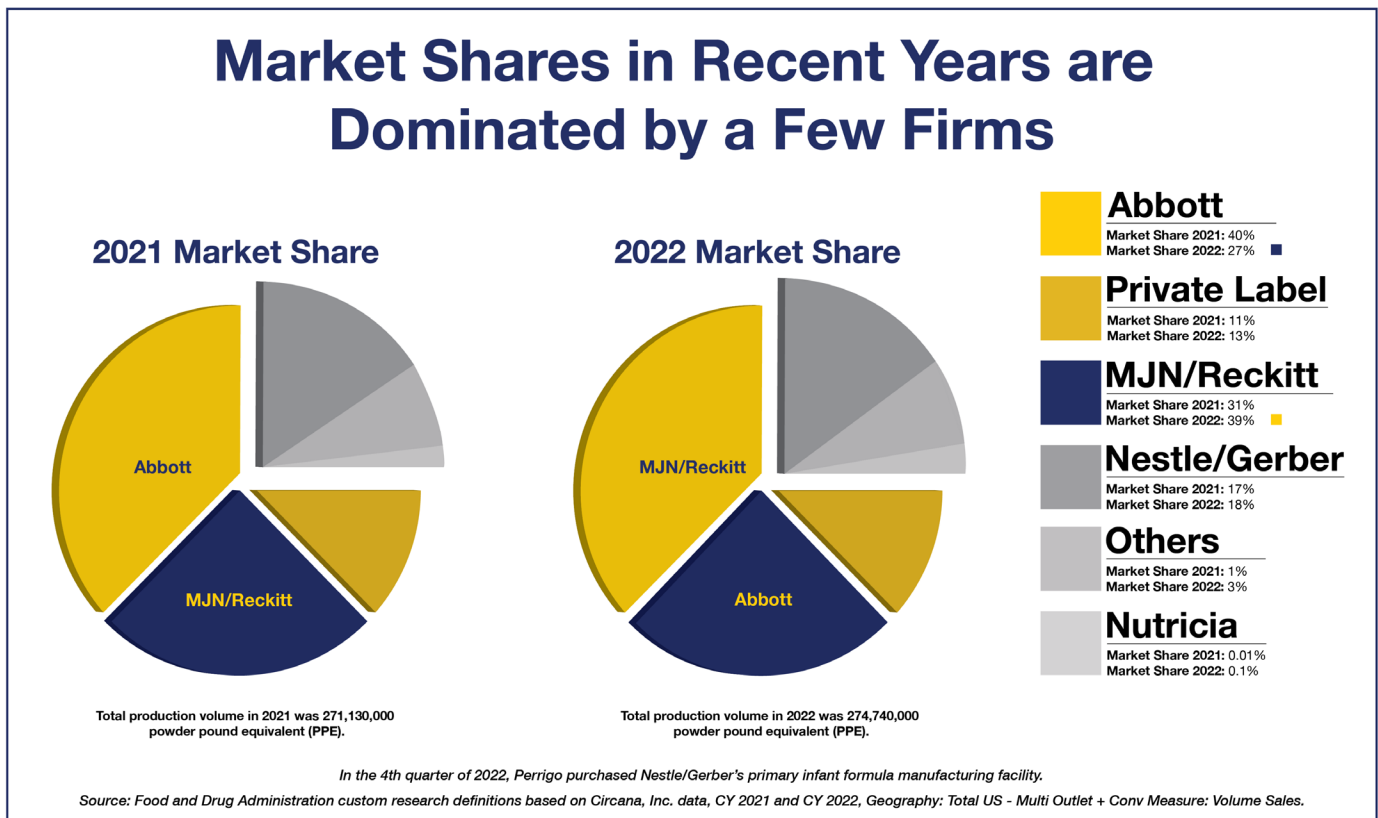


Figure 3.

- The U.S. market has never experienced a triple shock like it did with the COVID-19 pandemic, a large-scale voluntary recall, and the shutdown of a major manufacturing facility due to insanitary conditions of the Sturgis plant. This situation was subsequently further exacerbated by an additional closure following a major flood. As a result of these events affecting one of the largest producers of infant formula in the U.S., the industry was not prepared with appropriate risk management strategies to cope with shifting market conditions.
- With the reliance on “just in time” production methodology, there is insufficient excess capacity built into finished product, ingredient, labor, or packaging supply chains and only a modest inventory of finished product is maintained (e.g., 4-8 weeks of safety stocks). Although finished product is shelf stable (with nutrients eroding over 18-24 months after production), the costs associated with storing ingredients or finished product are considerable, and the recent shortage exhausted any safety stocks that manufacturers had on hand.



- Due to the specialized nature of different infant formula recipes (e.g., unique ingredients such as amino acids or allergen concerns), production is not quickly or easily shifted to a new location or even a different process flow within the same facility. Instead, ingredients, packaging, and labor decisions are planned well in advance of final production, with limited ability to shift those resources. Additionally, some manufacturers utilize the same facility for multiple products or brands, which adds complexity to the overall supply chain.

- These issues are all magnified when looking at specialty infant formulas, which include medically necessary amino acid-based, extensively hydrolyzed, and specially formulated metabolic infant formula products for infants and individuals with medical conditions, who often rely on these formulas as their sole source of nutrition. There is a smaller number of manufacturers, facilities, and facility lines (which often need to be dedicated to avoid cross-contamination with other ingredients) that produce specialty infant formulas. Since the number of infants needing these products is lower, these specialty products are typically produced less often and in lower volumes. Because some specialty formula also does not provide higher profit margins, firms have even fewer incentives to make large capital investments.









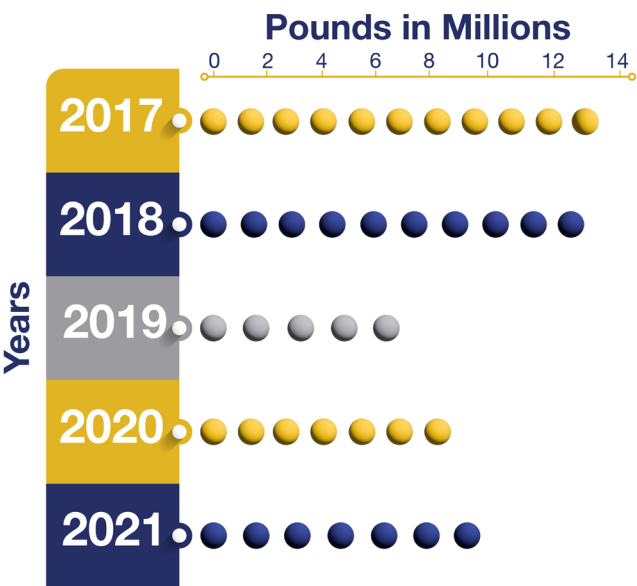
## Factors that Led to Market Concentration

The structure of the current U.S. market for infant formula was not radically different in 2022 than it had been in recent years. Rather, multiple factors, which have been in place for decades, have shaped the infant formula market into the one we have today. As we evaluate each of the contributing factors to the shortage, it is helpful to take a step back to understand the underlying forces that consolidated the infant formula market and any levers, within the government or otherwise, that may be able to ease that concentration. There are a variety of factors that keep new firms from easily entering or gaining a meaningful share of the market:

- The production of infant formula is a highly specialized process with substantial up-front capital investments needed to enter the market. Because of the large capital investments needed, a large volume of product and substantial market share are necessary to recover these costs and remain viable. Thus, potential entrants may be deterred because of high start-up costs, fixed retail prices, and difficulty gaining a substantial market share.
- To ensure formulas are safe and nutritionally adequate for our most vulnerable consumers, all manufacturers must produce infant formula in accordance with the Federal [Food, Drug, and Cosmetic Act](#), including [Current Good Manufacturing Practices \(CGMP\) for Human Food](#) and [CGMPs for Infant Formula](#); however, it can be challenging for a new firm to meet the relevant pre-market and post-market requirements for producing infant formula, especially if they do not have access to the same level of legal, food safety, or nutritional resources as their more established counterparts.

• According to a recent [analysis](#), the U.S. has historically produced more infant formula than it traditionally consumes, thereby reducing the need for imported formula. Indeed imports prior to 2022 represented less than one percent of the total volume of infant formula sold in the U.S. Infant formula products are subject to a base tariff rate of nearly 15 percent, and an effective rate of about 25 percent. Tariff rates are dependent on country-by-country agreements and established tariff rate quotas (TRQs), meaning the tariff rate will increase once an agreed upon volume of product is shipped into the U.S. These TRQs are designed to prevent a sudden surge in imports from disrupting U.S. domestic infant formula production, but they can also increase the cost of imported infant formula in the event of unexpected need and might have contributed to the decision of foreign manufacturers not to enter the U.S. market.

Import Volume of Powdered Infant Formula  
has Remained Consistently Low



Source: U.S. Census Bureau

Figure 5.







## Work Over the Past Year in Response to the Infant Formula Shortage

To address the supply chain crisis following the recall of infant formula product from Abbott's Sturgis facility and the subsequent shutdown of the facility, FDA engaged our United States Government partners and external stakeholders when it became clear FDA would recommend a recall of products produced at Sturgis. FDA also worked closely with all major infant formula manufacturers to mitigate supply disruption. However, at the time 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.<sup>1</sup>

### Specifically, FDA:

- Negotiated a consent decree with Abbott Nutrition, 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 FDA and under our oversight of its manufacturing and food safety processes.
- Ensured that Abbott, in consultation with FDA, held, and did not discard, any specialty and metabolic products not released into commerce, reviewed batch records and developed enhanced sampling schemes, and worked to make these products available on a case-by-case basis to consumers in need.
- Worked with major domestic infant formula producers to increase formula production to compensate for decreased Abbott Nutrition output, frequently communicated and shared data with manufacturers on production levels and potential supply chain issues, prioritized reviews related to before first processing changes to help maintain infant formula supply, and emphasized the critical importance of redundancies in infant formula supply chains, especially for specialty products.

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<sup>1</sup>For a more complete update of all activities related to infant formula, not just improving the resiliency of the supply chain, see Appendix: FDA Fact Sheet.

- Worked with suppliers of raw and packaging materials, including through the Defense Production Act (DPA), to prioritize the needs of infant formula manufacturers. To date, the FDA and U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) DPA- Emergency Response Authorities (ERA) Office have helped to resolve over 62 raw material related constraints and leveraged priority rating authorities in three instances when required to ensure prioritization and timely delivery of purchase orders to infant formula manufacturers.
- Leveraged the [21 Forward system](#) built during the COVID-19 pandemic to better understand supply chain issues and enhanced its functionality by populating it with infant formula data voluntarily provided by infant formula manufacturers. FDA then enhanced 21 Forward using external data to analyze production levels, in-stock rates, and sales of infant formula to understand the rapidly evolving market for infant formula.
  - Received and analyzed production data from top manufacturers for early signals of supply chain issues, to track production projections/goals and progress towards production level recovery. (Figure 6.)

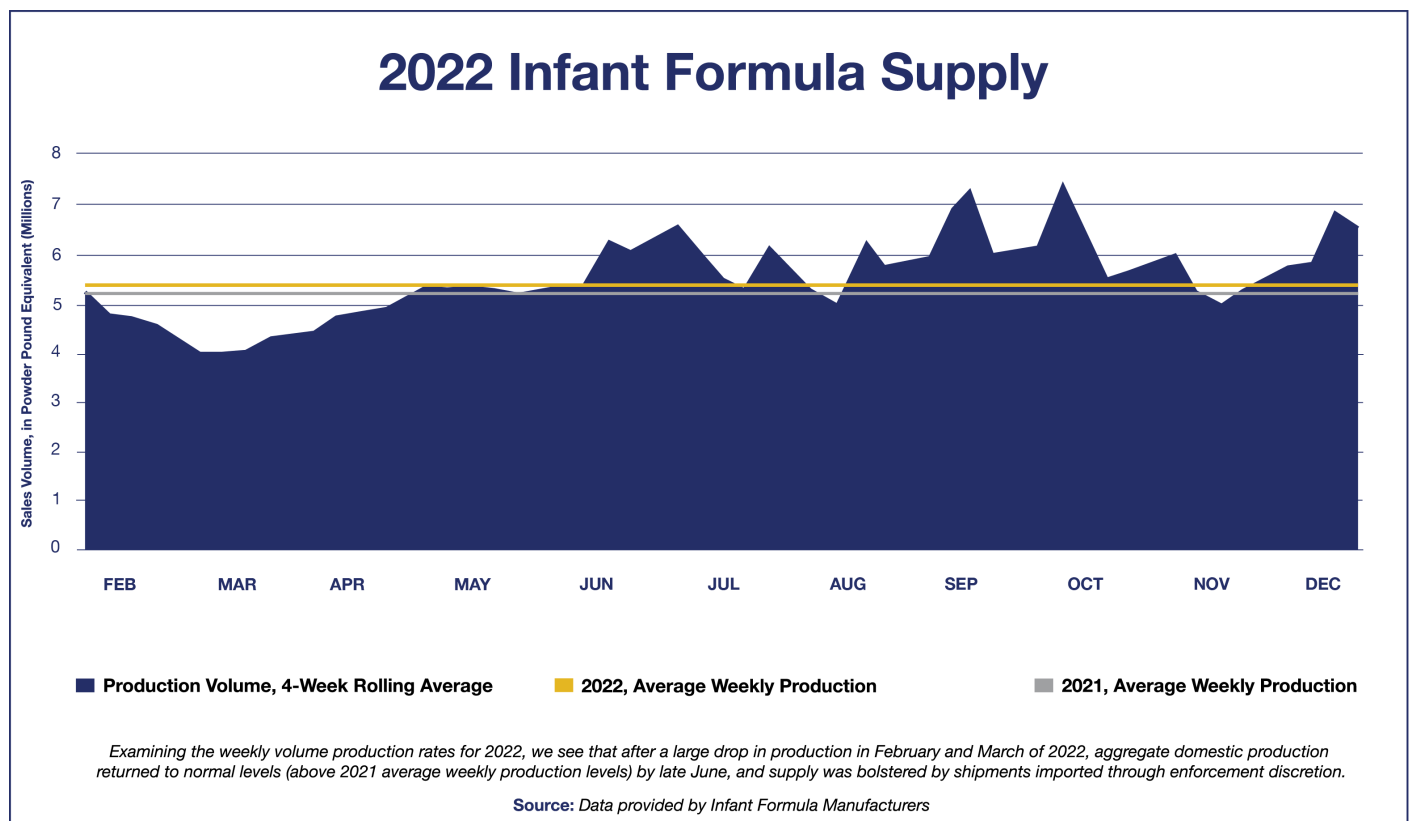


Figure 6.



- Monitored sales data to assess whether sales volumes track recovery of demand and sales of infant formula after the recall. (Figure 7.)

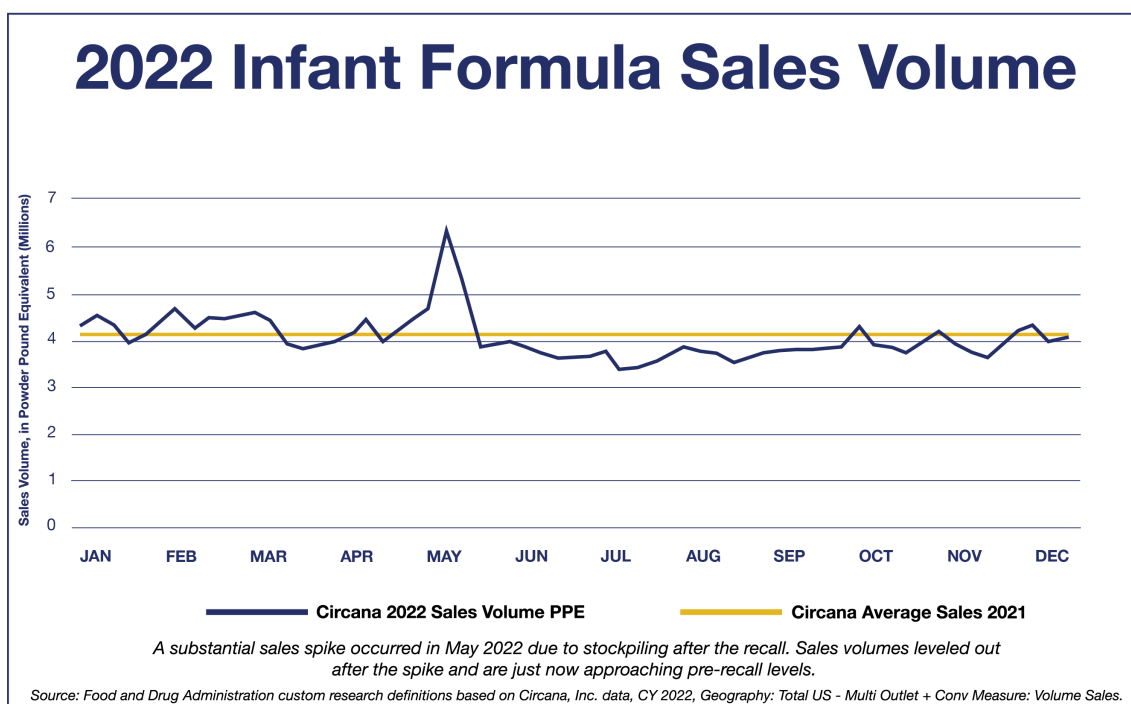


Figure 7.

- Monitored in-stock rates to track proxy measures for the recovery of product volume and variety on store shelves.<sup>2</sup> (Figure 8.)

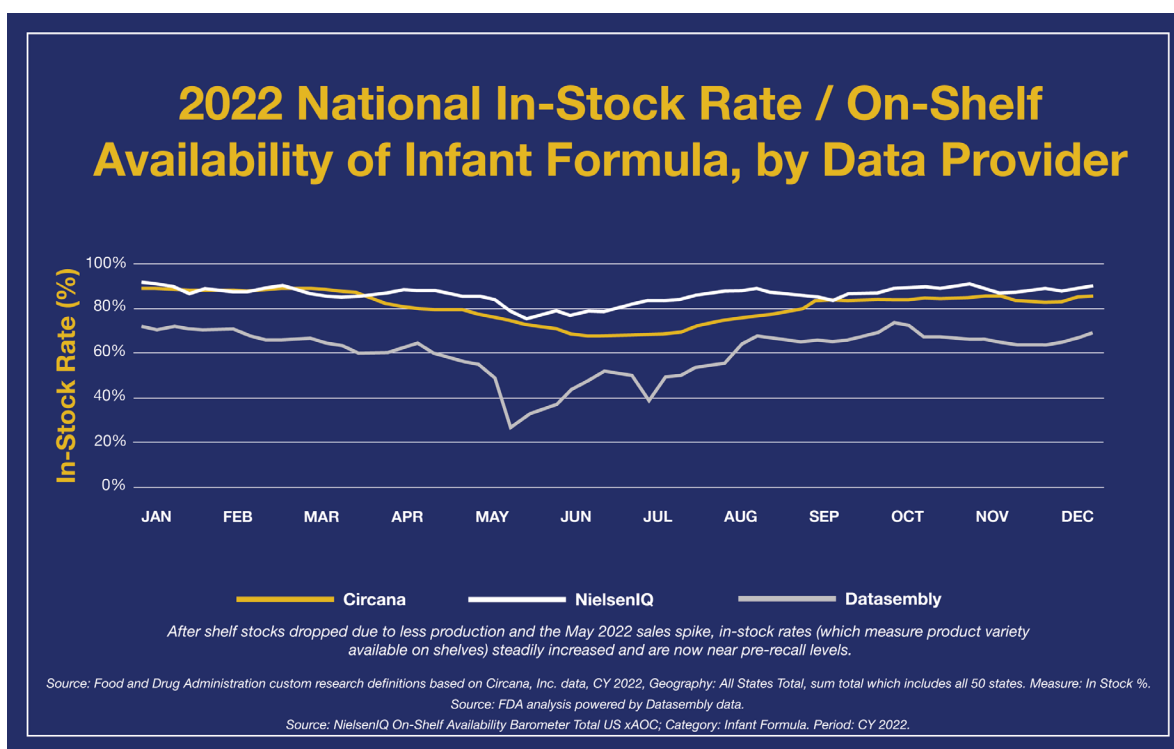


Figure 8.

<sup>2</sup>In-stock rates measure the availability of product variety usually found on store shelves, but do not capture volume available. The data for in-stock rates, when coupled with the production and sales volume data, show that both the variety of products on store shelves and volume available improved in the second half of 2022.

- Developed these data into a proof-of-concept model to forecast near-future events and possible supply disruptions, allowing us to anticipate and preemptively respond to potential supply chain challenges.
- Met regularly with USDA to share information and analyses on the supply of infant formula. In addition to these meetings and information sharing, USDA performed the following actions:
  - Following Abbott Nutrition's voluntary infant formula recall due to insanitary conditions at its Sturgis, Michigan manufacturing plant, USDA [worked](#) to ensure that safe and nutritious infant formula was available to every WIC family that needed it. In the immediate wake of the recall, USDA Food and Nutrition Service (FNS) provided guidance to WIC state agencies and, within days, offered flexibilities including waivers to help them respond to the impacts of the recall.
  - USDA helped ensure that WIC participants could continue to access formula during times of crisis. USDA has taken action to require WIC state agencies to include a provision in future infant formula rebate contracts to include remedies in the event of an infant formula recall, including how an infant formula manufacturer would protect against disruption to program participants in the state.
  - USDA ensured WIC state agencies were prepared for future supply chain disruptions. USDA worked with WIC state agencies to have disaster plans in place, including identifying methods to provide infant formula during a supply chain disruption, disaster, or emergency period.
  - USDA increased transparency with the goal of promoting competition in WIC infant formula bids. To procure infant formula rebate contracts, WIC state agencies solicit bids from infant formula manufacturers to provide a rebate for infant formula. To ensure all manufacturers have the information they need to compete for state contracts and to support





any new qualified companies in the market, USDA established a dedicated webpage for state bid solicitations for infant formula, similar to actions called for on a bipartisan basis in Congress.

- FDA also engaged with multiple other U.S. Government partners that have the specialized supply chain authorities, expertise, and influence to build immediate flexibility and relief into the infant formula supply chain, and we supported temporary policies designed to alleviate the shortage. This included (Figure 9.):

- Supporting HHS to mobilize Operation Fly Formula to arrange for emergency transport of large volumes of formula from outside the U.S. at the peak of the crisis. Between May and September 2022, HHS helped facilitate over 70 Operation Fly Formula shipments from Europe, Asia, and North America that imported over 6 million pounds of infant formula (equivalent to nearly 100 million 8-oz bottle equivalents) into the United States.
- Collaborating and communicating regularly with USDA, U.S. Digital Service, and the HHS Supply Chain Control Tower on analyses and tracking of infant formula products in different parts of the supply chain, including production, distribution, and retail.

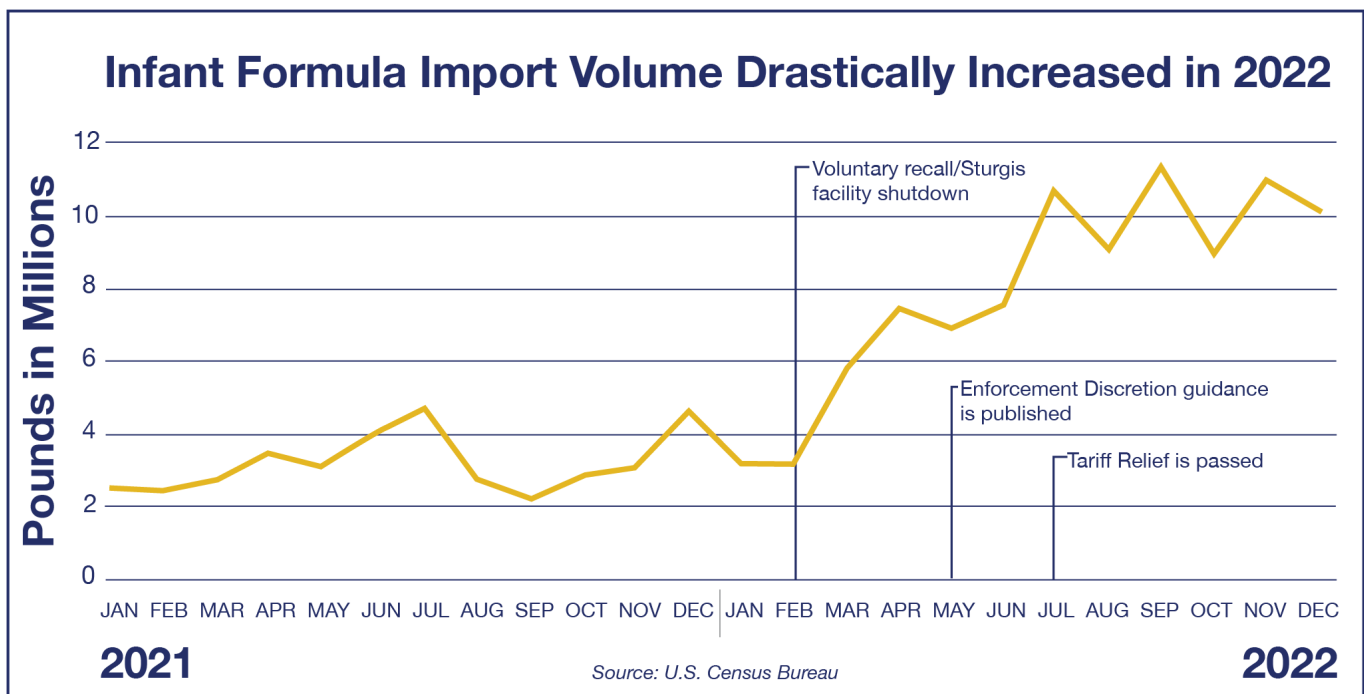


Figure 9.

- Working with HHS ASPR to help ensure the timely availability of raw materials, when applicable, and participating in FDA-led weekly calls with manufacturers.

- Successfully worked with Congress, leading to new requirements for firms to notify FDA of a permanent discontinuance or interruption in the supply of infant formula and to write and implement redundancy risk management plans, including mechanisms to mitigate impacts of supply disruption through alternative production sites, alternative suppliers, stockpiling of inventories, and other means.

- Worked with the U.S. Department of State and USDA to identify foreign manufacturers of infant formula with immediate capacity to export regular and specialty formulas to the U.S. under FDA's exercise of enforcement discretion and followed up with the manufacturers to provide additional

information regarding enforcement discretion, and to better understand their manufacturing processes, capacity, and formulations.

- Issued the [Infant Formula Enforcement Discretion Policy: Guidance for Industry](#) to describe considerations for firms and formulas entering the market temporarily under FDA's exercise of enforcement discretion, then subsequently issuing the [Guidance for Industry: Infant Formula Transition Plan for Exercise of Enforcement Discretion](#) to outline a path for interested firms marketing products in the U.S. under the exercise of enforcement discretion to bring those products into compliance with U.S. requirements to facilitate longer-term availability in the market. (Figure 10.)

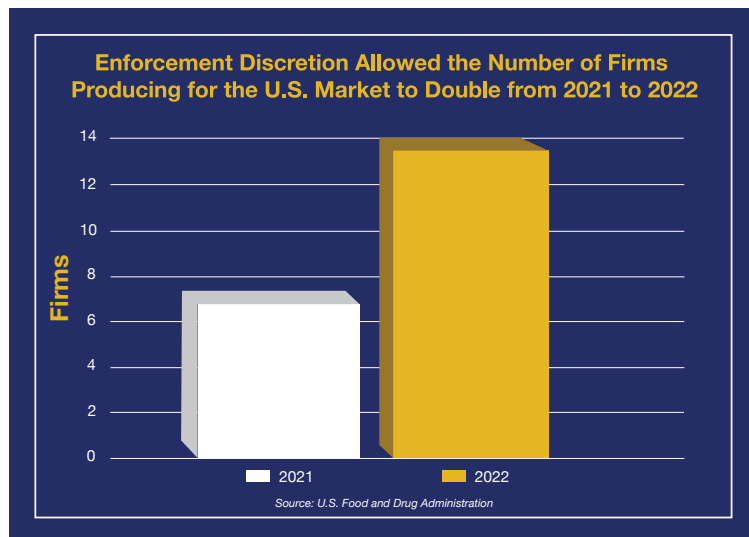


Figure 10.

- Issued [Draft Guidance for Industry: Protein Efficiency Ratio \(PER\) Rat Bioassay Studies to Demonstrate that a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein](#), relating to a key component of a new infant formula submission.
- Hosted multiple webinars in autumn 2022 to support infant formula firms interested in marketing their products in the U.S., including those marketing as part of the transition plan and new market entrants more generally. Topics of the webinars included: the Infant Formula Transition Plan guidance, FDA's requirements and recommendations for new infant formula submissions, PER studies, and Growth Monitoring Studies (GMS).
- Developed webpages about the [new, imported formulas](#) that were entering the market under FDA's exercise of enforcement discretion, with information about how to safely switch to those formulas, if needed.
- Published an [Outline of FDA's Strategy to Help Prevent Cronobacter sakazakii Illnesses Associated with Consumption of Powdered Infant Formula](#) to explore options for strengthening food safety throughout the product's lifecycle. This prevention strategy is intended to help limit or prevent future illnesses associated with adulterated powdered infant formula. FDA has met with numerous infant formula producers to actively engage on the development and refinement of this strategy moving forward.
- Advanced a charge through the USDA, Food Safety and Inspection Service's [National Advisory Committee on Microbiological Criteria for Foods \(NACMCF\)](#) to gain scientific insight on the prevalence, pathogenesis, possible industry and public health interventions, and food safety messaging to address Cronobacter infections associated with powdered infant formula (PIF). NACMCF will convene in FY2023 through its current authorized 2-year tenure to review current science, define research gaps, and make recommendations to advance PIF safety.



- Engaged with the Council of State & Territorial Epidemiologists (CSTE) and Centers for Disease Control and Prevention (CDC) about elevating reporting for *Cronobacter* infection in infants less than 1 year of age to a nationally notifiable disease.
- Engaged with NASEM to examine and issue a report (expected in 2024) on challenges in the supply, market competition, and regulation of infant formula in the U.S.
- In March 2023, as part of the prevention strategy work, the FDA sent a [letter](#) to the powdered infant formula industry to share current safety information and [call](#) on the industry to take prompt action to improve processes and programs for the protection of our most vulnerable population.

## Resources for Parents and Caregivers on Imported Infant Formula

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The FDA has created resources for parents and caregivers to help explain some of the processes associated with, and results of, the agency's efforts to help facilitate importing infant formula.

On May 16, 2022, [FDA announced](#) increased flexibilities for the importation of infant formula products, which have resulted in more than 520 million bottles worth of infant formula coming to the U.S.

Many of the imported products are, or will be soon, available through regular places to shop for infant formula, like major retailers, grocery stores and their online counterparts, as well as through company-specific websites.

### Infant Formula Names to Know

Learn to recognize the labels of imported formula products you may see available at U.S. retailers now or coming soon. Click [here](#) for a few examples of imported infant formula you may be seeing.



[Tips for Preparing Imported Infant Formula](#)



### Tips on Where to Find Products and Comparable Formulas

Although the supply of infant formula is steadily increasing, you may follow these [tips to help find safe substitutes](#) in the interim, including trying a new brand of formula ([see list](#)).

Figure 11.

• Conducted health fraud investigations related to domestic and foreign infant formula manufacturers who had not provided the required premarket notification to FDA before introducing or delivering for introduction into interstate commerce any new infant formula.

• Worked in collaboration with HHS to develop and distribute [education and communication materials](#) for consumers to ensure they had the latest information to manage during the shortage, such as how to locate safe alternative formulas. (Figure 11.)

• Created content to highlight the [importance of safe handling practices](#) and the mechanisms for reducing the risk of *Cronobacter sakazakii* infection during infant formula preparation. (Figure 12.)

## Help Prevent Cronobacter Illness:

### Prepare and Store Powdered Infant Formula Safely

In most cases, it is safe to mix powdered infant formula following manufacturer's instructions. But if your baby is less than 2 months old, was born prematurely, or has a weakened immune system, you may want to take the following extra steps to prepare your formula with hot water (at least 158°F/70°C) to help protect against *Cronobacter*:

<p><b>1</b> Clean work surfaces, such as countertops and sinks with soap and water, or use a disinfectant wipe or paper towel sprayed with cleaning product. Do not place feeding items directly in the sink, because germs in sinks or drains could contaminate these items.</p>	<p><b>5</b> Add the exact amount of formula listed on the container.</p>
<p><b>2</b> Wash hands with soap and water before preparing infant formula.</p>	<p><b>6</b> Carefully shake the capped bottle rather than stirring the mixture.</p>
<p><b>3</b> Boil water and let it cool for about 5 minutes.</p>	<p><b>7</b> If you plan to use the prepared formula right away, cool the formula to body temperature to ensure it is not too hot before feeding your baby. Run the prepared, capped bottle under cool water or place it into an ice bath. Do not let the cooling water get into the bottle or on the nipple.</p>
<p><b>4</b> Pour the water into a clean bottle or feeding cup.</p>	<p><b>8</b> Before feeding the baby, test the formula's temperature by putting a few drops on the inside of your wrist. It should feel warm, not hot.</p>

Use prepared infant formula within 1 hour from start of feeding and within 2 hours of preparing it. If your baby does not finish the entire bottle of formula, throw away leftover formula.

If you do not plan to start feeding your baby with the prepared formula right away, refrigerate it immediately. Use refrigerated formula within 24 hours. If you can't remember how long you have kept formula in the refrigerator, it is safer to throw it out than to feed it to your baby. For more information visit [www.cdc.gov/cronobacter](http://www.cdc.gov/cronobacter).

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Figure 12.



## Strategy to Increase the Resiliency of the U.S. Infant Formula Market

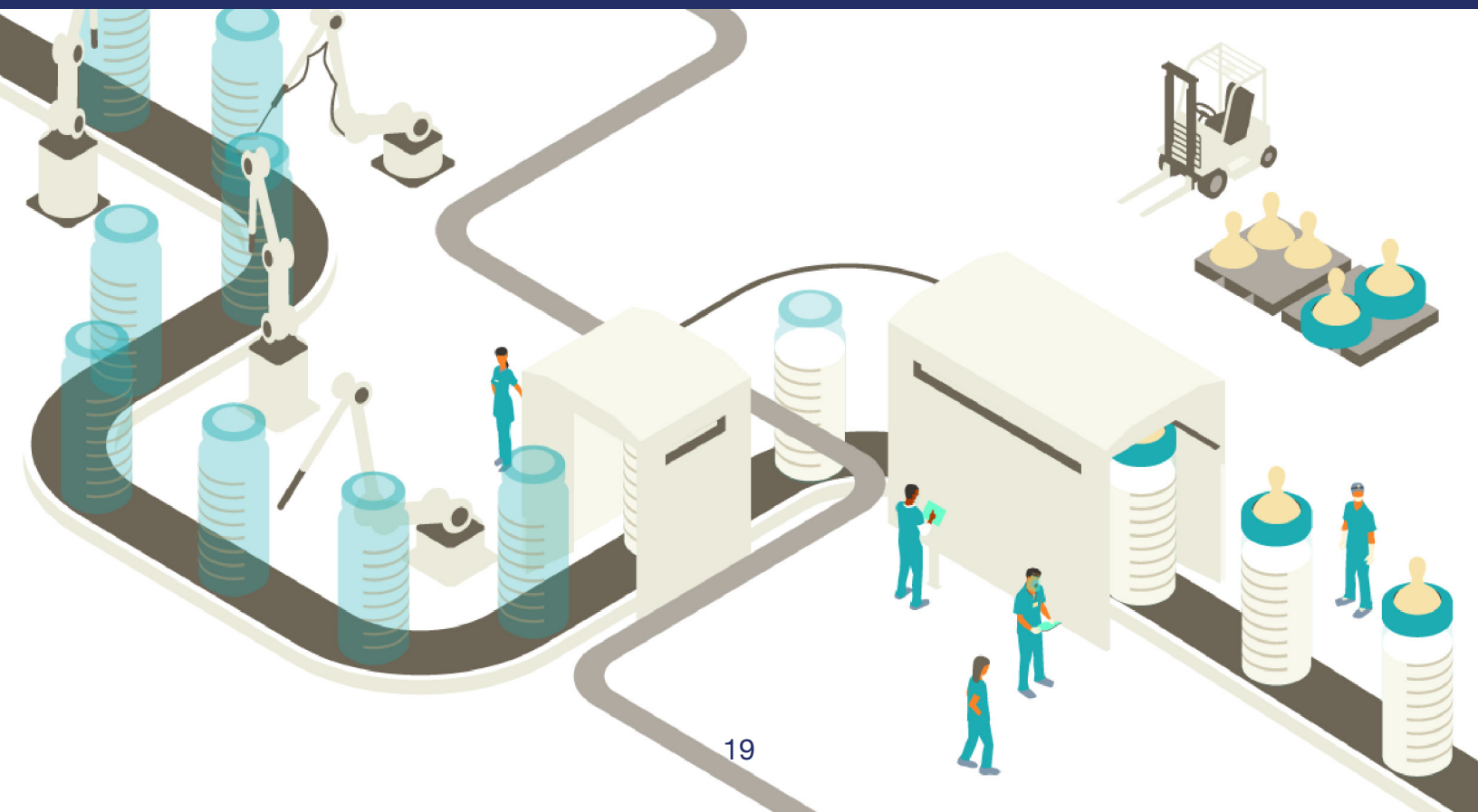
FDA will continue using its authorities to help increase the resiliency of the U.S. infant formula market by working with manufacturers to ensure that they implement robust redundancy and risk-monitoring plans; supporting entry and competition in the domestic infant formula market; monitoring supply metrics and identifying potential signs of production issues; sustaining regular communication with infant formula manufacturers and retailers to share information and data; and building upon collaboration with U.S. Government partners to reduce the number of disruptions in the future and mitigate any impacts.

### Specifically, FDA is working to:

- Conduct surveillance food safety inspections of all infant formula manufacturers at least annually and use remote regulatory assessments, as needed.
- Significantly expand and improve 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 collaborating with major infant formula producers and retailers, including:
  - Communicating with manufacturers and continuing to receive information about production levels, raw materials, and distribution.
  - Issuing the Infant Formula Transition Plan guidance, which outlines a path for interested firms marketing products in the U.S. under the exercise of enforcement discretion to bring these products into compliance with U.S. requirements to facilitate longer-term availability of these products in the U.S.



- Supporting infant formula manufacturers trying to access the U.S. market through the provision of information (such as on the PER rat bioassay studies and the infant GMS) to help them make new infant formula submissions and ensure the submissions are complete and meet our requirements, enabling a shorter review timeline.
- Sharing, especially with the specialty infant formula industry, the new requirement to have redundancy risk management plans and the critical importance of identifying and/or creating redundancies in their supply chains, including mechanisms to mitigate impacts of supply disruption through alternative production sites, alternative suppliers, stockpiling of inventories, and other means.
- Communicating with major infant formula producers on mandatory reporting of potential shortages of product, raw materials, and ingredients, and the critical importance of specialty infant formula supply chains.
- Enhancing technical assistance to those considering entering the U.S. infant formula market, in particular smaller businesses.
- Monitor the infant formula supply and supply chain to assess general market health and current and future demand and identify potential signs of production challenges by:
  - Continuing to receive and analyze production data from current major manufacturers, as made available on a continuing basis to FDA, for early signals of supply chain disruptions, tracking whether production projections and goals will meet estimated demand, and tracking progress towards production goals.
  - Monitoring 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.

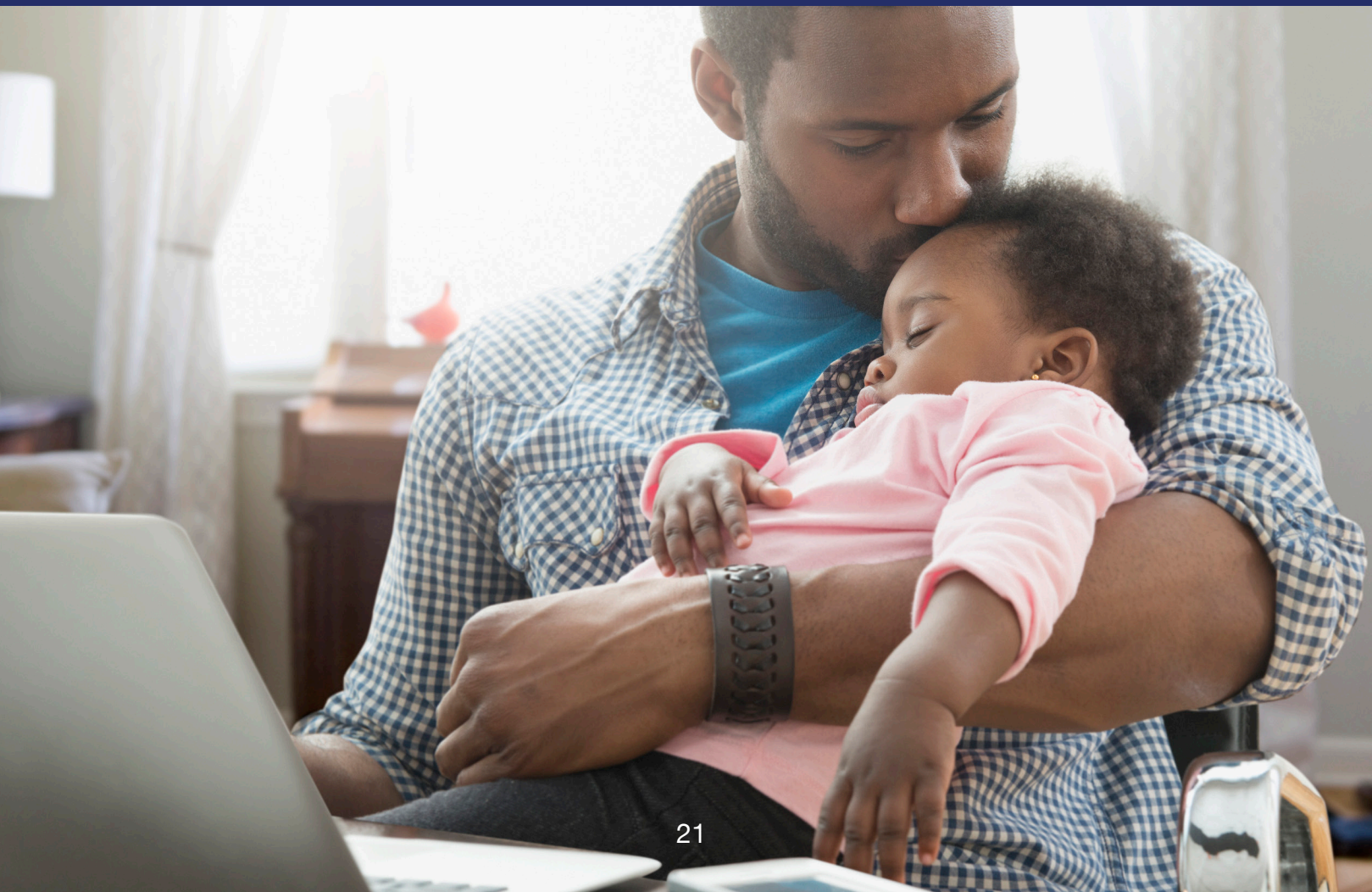


- Developing additional models and metrics to monitor and assess ongoing infant formula market health and resilience, including a forecasting model as a part of predictive analysis for near future events and supply disruptions.
- Monitoring state-level data (as data permit) to assess any state-level problems with infant formula supplies.
- Examining supply chains to assess critical points (e.g., raw materials constraints).
- Engage with U.S. Government partners to address immediate infant formula needs, in particular, where those partners are able to influence the infant formula supply chain outside of FDA's control and build long-term resiliency into the infant formula supply chains. For example, considering whether tariffs play a role in market diversification, and evaluating support for the construction of new and updated facilities for manufacturing infant formula.
- Engage with USDA to support resiliency and adequate reserve planning through the administration of the WIC program. For example, USDA is:
  - Taking additional steps to ensure that the families who rely on the WIC program have safe and reliable infant formula options even in an emergency, in light of the crisis and new authority provided through the bipartisan Access to Baby Formula Act, in July 2022.
  - Supporting WIC state agencies in prioritizing resources and developing a separate disaster plan for the distribution of specialty formula for infants with health conditions. Disaster plan actions might include how WIC agencies will coordinate with health care centers to manage the supply of specialty formula or an integrated plan for WIC retailers to share information about infant formula stock with WIC to support a formula locator.



- Testing and launching online shopping for infant formula for WIC participants. WIC participants may not currently use their benefits to purchase infant formula or other food items online. This can make it more challenging for families to find formula if their local stores are not carrying it. As part of the White House's National Strategy on Hunger, Nutrition and Health USDA will use funds from the American Rescue Plan to expand online shopping in WIC. In FY 2022, FNS awarded approximately \$10 million in grants to improve the WIC shopping experience, including planning efforts for online shopping, and subsequent rounds of funding are planned for FYs 2023 and 2024. USDA also has proposed rulemaking to address regulatory barriers to online shopping and to expand the types of stores eligible to participate in the program.

- Complete reviews of pending infant formula submissions from firms seeking access to the U.S. market (those marketing as part of the transition plan as well as new market entrants more generally).
- Develop policies to promote infant formula market health and diversification, including measures to support redundancy planning and promote entry and competition.
- Design and promote policies from U.S. Government partners that support breastfeeding as well as infant and maternal health.
- Refine, in consultation with industry and other stakeholders, the [Strategy to Help Prevent Cronobacter sakazakii Illnesses Associated with Consumption of Powdered Infant Formula](#) to improve the overall safety of infant formula and minimize the potential for disruptions in the supply chain.





- Receive new scientific data from the [NACMCF charge](#), and stand 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.
- Work with the NASEM to understand their analysis on challenges in the supply of infant formula in the U.S. and incorporate their findings into an updated, long-term national strategy to increase the resiliency of the U.S. infant formula market.
- Analyze methods and approaches for potential international harmonization of regulatory requirements for infant formula to determine whether doing so could increase resiliency in supply and market competition.
- Use expanded hiring authorities under the 21st Century Cures Act to support infant formula work and work to implement new infant formula authorities provided for in the Food and Drug Omnibus Reform Act of 2022.
- Create a new Office of Critical Foods responsible for oversight, coordination, and activities related to critical foods, which is defined to include infant formula and medical foods.
- Expedite review of premarket submissions for new infant formula products to mitigate or prevent shortages.

## **Providing Education and Communication Materials for Parents, Caregivers, and Medical Providers**

There's nothing as important to families as the health and safety of their babies. As the country faced the powdered infant formula recall in February 2022 and the subsequent formula shortage, we understood that families had many questions regarding access, availability, and safety. Throughout the infant formula shortage, FDA and HHS have worked together to develop and distribute materials for consumers. However, even with FDA's recent efforts to improve consumer education related to infant formula, more can be done.



### Specifically, FDA is working to:

- Consolidate, reorganize, and translate our educational materials on FDA.gov in the coming months to improve accessibility for all families. As part of this effort, we will also be evaluating how we can incorporate related consumer information for safely feeding infants, such as the information found on CDC's [infant and toddler nutrition pages](#) and [breastfeeding webpage](#).
- Coordinate with USDA's WIC program to distribute our consumer education materials.
- Enhance and leverage our partnerships with health care providers and professionals, particularly infant care professionals, to further build our consumer education program. For example, during the infant formula shortage, the FDA partnered with the American Academy of Pediatrics and built relationships with other medical groups and societies including the metabolic dietitians practice group and support groups for individuals with metabolic disorders. The FDA will continue to work with these groups, 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.



# Appendix: FDA Fact Sheet

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Status Update | March 2023

## FDA's Infant Formula Response Activities

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Since the Abbott infant formula [recall](#) in February 2022, the U.S. Food and Drug Administration (FDA or the Agency) and U.S. Government partners have been working to expand consumer access to infant formula products, while also ensuring that these products meet the agency's safety, nutrition, and quality standards. As we emerged from the acute crisis, the agency conducted 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 FDA's request) to identify areas for improvement within the Agency. While work continues on all fronts, the FDA is committed to transparency. Below is an update on actions the FDA has taken, and those underway, to strengthen the safety and resiliency in the supply of nutritious infant formula.

### ***Safety of Infant Formula***

- In 2022, FDA conducted 34 inspections of foreign and domestic facilities that produce infant formula (including some that also produce medical foods), meeting FDA's inspection targets for FY22. Appropriate follow up actions were taken as warranted. Importantly, FDA had set targets to inspect facilities that produce infant formula annually, even prior to a requirement to do so established in the Food and Drug Omnibus Reform Act of 2022.
- In November 2022, FDA released a draft outline of a [strategy](#) to prevent *Cronobacter sakazakii* illnesses associated with the consumption of powdered infant formula. This outline was intended to guide discussions with stakeholders over the next several months as FDA further developed the strategy.
  - FDA conducted meetings with infant formula manufacturers throughout January and February 2023 to discuss the strategy, learn more about what industry is doing to enhance safety, and hear their ideas for prevention.
  - In March 2023, as part of the prevention strategy work, FDA sent a [letter](#) to the powdered infant formula industry to share current safety information and [call](#) on the industry to take prompt action to improve processes and programs for the protection of our most vulnerable population.
- In November 2022, the FDA advanced a charge through the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service's [National Advisory Committee on Microbiological Criteria for Foods \(NACMCF\)](#) to gain scientific insight on possible industry and public health interventions to address *Cronobacter* infections associated with powdered infant formula.
- Initiated engagement with the Council of State & Territorial Epidemiologists (CSTE) and Centers for Disease Control and Prevention (CDC) about elevating reporting for *Cronobacter* infection in infants less than 1 year of age to a nationally notifiable disease.
- FDA has expanded the availability of education materials to help [consumers better understand Cronobacter risks](#) associated with powdered infant formula and the steps they can take at home to help minimize any potential contamination.
- FDA continues to work with Abbott Nutrition under the consent decree entered by the U.S. District Court for the Western District of Michigan on May 16, 2022. This consent decree requires Abbott to take the steps necessary to safely produce infant formula in close coordination with FDA and under our oversight of its manufacturing and food safety processes.



## ***Resiliency in the Supply of Nutritious Infant Formula***

- At the height of the supply challenges, FDA staff worked daily with clinicians and hospitals to address crucial issues of specialty and medically necessary formula supply for infants with serious metabolic diseases who were dependent on highly specialized formulas.
- FDA supported our colleagues at HHS to mobilize Operation Fly Formula to arrange for emergency air transport of large volumes of formula at the peak of the crisis.
- FDA worked with Customs and Border Protection (CBP) to implement legislation that provided temporary relief for infant formula importers from tariffs during the latter half of 2022.
- FDA has helped to expand access to infant formula by temporarily exercising enforcement discretion, on a case-by-case basis, for certain infant formula requirements. Twelve manufacturers have brought various infant formula products into the U.S. market under FDA's exercise of enforcement discretion, doubling the number of firms supplying product to the U.S. market from 2021 to 2022.
  - FDA conducted an expedited review of certain food safety and nutrition records associated with the firms and products prior to issuing letters of enforcement discretion.
  - FDA also adjusted import screening criteria to help facilitate the immediate importation of millions of pounds of infant formula and infant formula base powder (an ingredient used in producing infant formula products).
- FDA also issued the [Infant Formula Transition Plan for Exercise of Enforcement Discretion guidance](#) that outlines a path for interested firms marketing products in the U.S. under the exercise of enforcement discretion to bring those products into compliance with U.S. requirements to facilitate longer-term supply resiliency in the U.S. market.
  - During October and November 2022, FDA [hosted](#) a four-part webinar series to provide detailed information about the transition plan for infant formulas marketed under the exercise of enforcement discretion and to address questions.
- FDA has leveraged [21 Forward](#), a tool that was built to help track supply chain shortages during the COVID-19 pandemic, to now inform ongoing work to track and anticipate supply disruptions across the infant formula supply chain. The platform uses data provided to the agency voluntarily by infant formula manufacturers.
  - FDA staff continue to meet regularly with infant formula manufacturers to discuss current and forecasted production and to identify potential distribution issues.
- The Agency coordinated with colleagues in the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) Defense Production Act (DPA) Office to leverage their capabilities and authority to identify and provide appropriate support to resolve raw material constraints on ingredients needed to manufacture formula – including through technical assistance and DPA authorities when needed.

## ***Operational Improvements***

- FDA has revised its internal [consumer complaint procedure](#) to strengthen the escalation process to better define when certain consumer complaints need to be escalated to senior officials. This change involves rapid escalation of reports of serious illness or death to the highest levels of the agency and specifically addresses triggers for any hospitalization or death involving an infant.
- FDA has 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.
- The Office of Regulatory Affairs (ORA) has significantly expanded the agency's capacity to analyze samples of infant formula by adding two laboratories with the capacity to test for Cronobacter, partnering with state laboratories with existing capabilities, and enhancing its system for prioritizing sample analysis.
- FDA staff who conduct or support inspections of powdered infant formula manufacturers attended an interactive in-person powdered infant formula inspection workshop with specific training on conducting infant formula inspections in January 2023. The workshop provided critically relevant and timely inspectional information for investigators and other

appropriate staff, including updates from lessons learned during previous inspections.

- In February 2023, CFSAN issued a schedule with instructions for improved routine surveillance inspections and sampling to be conducted at domestic and foreign infant formula and medical food facilities in fiscal year (FY) 2023. These instructions, issued to FDA investigators, included numerous modifications that incorporate lessons learned during inspections conducted in FY22 and address feedback from internal and external stakeholders.

- In 2022, prior to FDA's evaluation of the infant formula response, CFSAN began amending its instructions to ORA related to inspections of infant formula and medical food facilities. The changes provided additional considerations for environmental sampling, a renewed focus on the supply chain requirements under the Preventive Controls for Human Food Rule, and scheduling adjustments to minimize potential supply chain disruptions.

- CFSAN's Office of Nutrition and Food Labeling has increased its staff by 66 percent to better facilitate infant formula reviews.

### ***New Authorities***

While FDA has taken actions to improve access to safe and nutritious infant formula, there also has been widespread recognition that new authorities, provided by Congress, could help to build a lasting foundation for a more resilient infant formula supply in the U.S. The FDA is currently designing implementation plans for new authorities received in the Food and Drug Omnibus Reform Act of 2022, including:

- Creating a new Office of Critical Foods responsible for oversight, coordination, and activities related to critical foods, which is defined as infant formula and medical foods.

- Expediting review of premarket infant formula submissions if an infant formula shortage has been identified.

- Mandating critical foods manufacturers to notify FDA of a permanent discontinuance or interruption that is likely to lead to a meaningful disruption in infant formula supply.

- Requiring critical foods manufacturers to develop, maintain and implement, as appropriate, redundancy risk management plans to identify and evaluate risks to the supply of the critical food, such as infant formula, and ways to mitigate such risks.

- Issuing guidance to support new infant formula submissions.

- Exploring pathways to harmonize international regulatory requirements for infant formula.

- Notifying Congress of infant formula recalls.

- Working with relevant federal agencies to work together to develop a National Strategy on Infant Formula to address infant formula supply chain resiliency and provide education and communication for parents and caregivers.

- Engaging with the National Academy of Science, Engineering and Medicine to examine and report on challenges in the supply, market competition, and regulation of infant formula in the U.S.

FDA also received expanded hiring authorities under the [21st Century Cures Act](#) to recruit additional staff to, among other things, support the infant formula work underway and implement new infant formula authorities provided for in the Food and Drug Omnibus Reform Act of 2022.

FDA is also seeking additional authority through the [FY24 budget request](#) to require that, among other things, manufacturers report to FDA final product positive test results for relevant pathogens, conduct more frequent environmental monitoring in their facilities to identify relevant pathogens, and maintain the results of such testing for FDA inspection, either in person or remotely. 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 assure the safety of product entering the market.

***The FDA appreciates the continued collaboration with the infant formula industry, retailers, educators, and federal partners to strengthen the resiliency and safety of infant formula in the United States.***

