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US infant formula industry: a qualitative analysis of a major food safety recall and its implications

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Abstract

A major food safety recall of infant formula in February 2022 in the United States caused significant disruptions in the supply chain that was already fragile, causing a severe shortage in the marketplace. This study examines its implications using data gathered from qualitative interviews with experts in the industry. Key findings provide a detailed map of the US infant formula supply chain, highlight its vulnerabilities during crises, analyze communication dynamics, and summarize coping strategies from stakeholders during this major food safety recall. We highlight key issues at the manufacturing, retail, and consumer level, and provide policy recommendations to strengthen the resiliency of the infant formula industry in the United States, while protecting the consumer.

Keywords: infant formula; food safety recall; supply chain; shortage; qualitative interviews.

JEL codes: D18, D43, I18

1. Introduction

In 2022, a food safety recall of infant formula in the United States disrupted the market's already fragile supply chain and exacerbated the shortage of this vital product (Christensen 2022). Infant formula is a specialized food product designed to closely replicate the composition and functionality of breast milk, providing essential nutrition for infants up to one year of age, when breastfeeding needs to be fully or partially replaced (Happe and Gambelli 2015). Abbott Nutrition, the leading manufacturer of infant formula, initiated a voluntary recall of several products under the Similac®, Alimentum®, and EleCare® brands due to the potential contamination with *Cronobacter sakazakii*, a pathogenic bacterium that presents a severe risk to infants, including the potential for illness and mortality (Jaffe 2022). Due to the food safety recall, infant formula out-of-stock rates increased to 74 percent by May of that year, leading to extreme hardships for consumers, challenges for the industry, and emergency short-term policy response (Yenerall et al. 2024).

This recall was not an isolated incident; over the past three years, there have been twelve recalls of infant formula products from various brands, with seven of these recalls attributed

to potential bacterial contamination [Food and Drug Administration (FDA) 2023b]. These incidents have led to substantial supply chain disruptions, severely impacting infants and their families. The oligopolistic structure of the infant formula market, stringent import restrictions and the FDA regulations have further compounded the impact of these disruptions (Vakil 2022).

Infant formula is the sole recommended source of nutrition for infants six months and younger who are not breastfed (Kalaitzandonakes, Ellison, and Coppess 2023). The American Academy of Pediatrics (AAP) and the Dietary Guidelines for Americans advocate exclusive breastfeeding for the initial six months and, if breast milk is not available, infant formula feeding. Following this, breastfeeding alongside complementary foods is recommended until the child reaches two years old. If breast milk is not available, infant formula feeding is recommended until the age of one, alongside complementary foods (Meek and Noble 2022; AAP 2023). Moreover, for some infants with specific health conditions that prevent them from consuming breast milk, specialty formulas are the sole source of nutrition and finding an alternative to specialty formulas is particularly challenging (Jung, Olynk Widmar, and Ellison 2023). On average, infants consume about 32 ounces[1] of breast milk and/or infant formula per day (AAP 2022a). Nationwide, this amounts to an estimated 2.3 billion ounces of powdered formula consumed annually. The heavy reliance on infant formula highlights the critical need to address ongoing safety and supply chain concerns. In addition to addressing these issues, it is crucial to explore the coping strategies of parents and caregivers during periods of shortage and offer clear, practical guidance on this matter. A crisis involving this essential product can impose significant hardships on families, and misinformation could result in serious, potentially life-threatening consequences.

The infant formula market, especially within agriculture and food economics literature, remains critically underexplored. Emerging studies by Muhammad et al. (2023) and Yenerall et al. (2024) use publicly available secondary data to investigate the infant formula market concentration and supply chain disruptions by discussing the regulatory framework, specifically focusing on policy changes. Literature on other related fields, including health marketing and public health, focuses primarily on the regulatory aspect, market concentration, and marketing claims and strategies of infant formula (Cutler and Wright 2002; Kent 2006; Belamarich, Bochner, and Racine 2016; Hughes, Landa, and Sharfstein 2017; Choi et al. 2020; Hastings et al. 2020). Public health studies such as Jung, Olynk Widmar, and Ellison (2023) and Samuel, Goodstein, and Basch (2022, 2024) investigate the coverage and responsiveness of online media toward infant formula recalls and shortages. Studies in medical literature focus on the impact of infant formula crisis on consumers and their feeding practices (Doig 2010; Sylvetsky et al. 2022; Cernioglo and Smilowitz 2023; Kalaitzandonakes, Ellison, and Coppess 2023). Meanwhile, Imboden, Sobczak, and Kurilla (2023) examine the breastfeeding rates during the shortage period. Abrams (2023) and Abrams and Duggan (2022), also in the medical literature, propose several policies to prevent similar infant formula supply disruptions. However, the infant formula industry structure with its vulnerabilities and dynamics, as well as the major recall's implications, are not well understood. Further studies are needed to bridge the gap in understanding, particularly in the context of supply chain dynamics during and post-crises.

Previous research in the economics of food safety domain has examined diverse aspects of recalls for products such as spinach, lettuce, eggs, and meat in the United States, including impacts on consumers (such as Brady, Peace, and Brown 2009; Arnade, Kuchler, and Calvin 2011; Shang and Tonsor 2017), and industry (such as Houser, Dorfman, and Rejesus 2019; Spalding et al. 2023). While this literature is vast, in general studies find that consumer demand is affected, but generally short-lived (Piggott and Marsh 2004; Moghadam, Schmidt, and Grier 2013). Consumers typically respond by switching to other brands of the same product (in differentiated markets) (Law and Cornelsen 2022), or to product substitutes (Arnade, Calvin, Kuchler 2009; Fahs, Mittelhammer, and McCluskey 2009). Literature also

finds that food safety recalls often generate substantial losses to the industry (Hussain and Dawson 2013; Pozo and Schroeder 2016).

Aside from food safety recalls and related shortages, literature on pharmaceutical shortages, such as Nonzee and Luu (2019) and Gu et al. (2011), is relevant to our study due to the unique nature of the product, and they address how regulatory barriers contribute to shortages. Gray and Manasse (2012) examine shortages of crucial medicines, mentioning limited number of suppliers and manufacturing facilities as one of the driving factors of prevalent shortages. Our research study expands on these insights and contributes to the economic literature by investigating US infant formula supply chain disruptions, short-term policy changes, communication strategies, and coping mechanisms among stakeholders, following the 2022 food safety recall of infant formula. We conducted semi-structured qualitative interviews with fourteen industry experts, including one of the four top manufacturers, five retailers, three food safety specialists, three coordinators of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and two pediatricians, and performed a thematic analysis. To enhance the analysis of the supply chain structure and supplement the information provided by the interviewees in the study, we also incorporated information from publicly-available webinars featuring focus groups of industry experts conducted by the National Academies of Sciences, Engineering, and Medicine (NASEM). These discussions were part of a study, sponsored by the US Department of Health and Human Services (HHS) and the FDA, aimed at addressing challenges in the US infant formula market and evaluating market entry requirements to develop a long-term FDA strategy [United States Department of Agriculture Food and Nutrition Service (USDA FNS) 2023b].

This study offers three main contributions to literature. First, to the authors' knowledge, it is the first study in economic literature to utilize primary data, specifically interviews with stakeholders, to investigate the impact of the 2022 US infant formula food safety recall. We conducted an inductive thematic analysis using ATLAS.ti, a qualitative data analysis software. A second contribution of this study is that it provides a map of the infant formula supply chain in the United States, shedding light on its structure and vulnerabilities during shocks, such as food safety recalls. A third contribution of the study is that it provides insight into communication dynamics and coping strategies employed by the industry and consumers during the recall, revealing the lack of information and standards that exist within the industry. Given consumers' reliability on infant formula, the complexities of public policies and programs related to this product, and the oligopolistic nature of the industry, the information collected and analyzed as part of this study is of interest to academics, policymakers, industry leaders, and the general public.

The remainder of the article is organized as follows. Section 2 provides a background to the US infant formula market. Section 3 explains the methods and materials used, followed by Section 4 presenting the results. Section 5 provides a discussion and concludes the paper.

2. The US infant formula market: a background

In the United States, the infant formula industry generates about $2 billion in revenues, supplying about 524,000 metric tons of product (Casey 2022; IBISWorld 2023). This market is dominated by four leading manufacturers controlling 99 percent of the market (FDA 2023c). As of 2021, Abbott Nutrition held a 40 percent market share (FDA 2023c). Mead Johnson/Reckitt, Nestle/Gerber, and Perrigo held 31, 17, and 11 percent of the market share in 2021, respectively. In 2022, these market shares shifted to 39, 18, and 13 percent, respectively, with Abbott Nutrition holding 27 percent (FDA 2023c). This oligopolistic structure can be attributed to various factors that create barriers to market entry. These factors include high initial production costs, fixed retail pricing, regulations outlined by the FDA, high tariffs, and the WIC's rebate system (FDA 2023b).

Infant formula imports to the United States are subject to tariffs ranging from 14.9 to 17.5 percent, with additional fees applied once specific thresholds are exceeded (Casey 2022). While free trade agreements allow for duty-free imports, only 19.4 percent of infant formula imports qualified for this exemption between 2012 and 2021 (Casey 2022). For the remaining imports, the average duty rate was calculated to be 25.1 percent (Casey 2022). Due to substantial tariffs, infant formula imports have historically remained low, averaging under $4 million annually between 2000 and 2009 (Yenerall 2024). However, imports surged to $80.2 million in 2021 and further increased to $322 million in 2022 (Yenerall 2024). The increase in 2021 was largely driven by an exceptional increase in imports from Mexico, whereas the spike in 2022 was a direct response to the nationwide infant formula shortage and resulting short-term policy changes (Yenerall 2024). On average, US domestic production amounts to 524,000 metric tons annually, whereas imports in 2022 reached 42,500 metric tons, accounting for approximately 8 percent of total production (Yenerall 2024).

2.1 The impact of the WIC program on the US infant formula market

The WIC program, a federally funded initiative by the United States Department of Agriculture (USDA), aims to assist low-income women, infants, and children in maintaining a healthy diet. This program plays a significant role in the infant formula market, as more than 50 percent of all infant formula consumed in the United States is by infants enrolled in WIC[2] [United States Department of Agriculture Economic Research Service (USDA ERS) 2022; USDA 2023]. Since 1989, Congress has mandated that WIC state agencies use competitive bidding to award contracts for infant formula based on the lowest wholesale price bidder, thereby providing discounts to WIC participants (USDA FNS 2023d). The contract price is the manufacturers' lowest national wholesale price of infant formula minus the rebate offered to WIC (Oliveira and Davis 2006; An et al. 2023). Manufacturers who win WIC contracts often see their market share increase by 74 percent, thanks to direct sales from WIC and indirect benefits such as increased brand visibility through prominent shelf placement, physician recommendations, word-of-mouth among parents, and improved brand loyalty (Oliveira, Frazao, and Smallwood 2011). Rebates provide significant funding for WIC, totaling $1.6 billion in fiscal year 2021, about one-third of the overall cost (Oliveira, Frazao, and Smallwood 2011; USDA FNS 2023c). Since the mid-1990s, three manufacturers—Abbott Nutrition, Mead Johnson, and Nestle Gerber—have consistently secured most WIC infant formula contracts (Oliveira, Frazao, and Smallwood 2011). As the leading supplier, Abbott Nutrition holds most state contracts to supply WIC participants, further strengthening its market dominance[3] (USDA FNS 2023d). This regulatory and market framework creates significant barriers for smaller, noncontracted manufacturers, further contributing to the oligopolistic structure of the industry (An et al. 2023; FDA 2023c).

2.2 The major infant formula recall and government response

On 17 February 2022, Abbott Nutrition, the leading manufacturer of infant formula in the United States, recalled its powdered formulas that were produced in its Sturgis, MI, facility due to potential *C. sakazakii* contamination (FDA 2023a). This decision was made because of reports received by the FDA regarding four infants getting infected after consuming Abbott Nutrition's formulas, two of whom tragically died (Jaffe 2022). Abbott Nutrition took the voluntary step of shutting down the Sturgis, MI, facility on the same day (FDA 2023a). After the incident, the FDA investigated the Sturgis plant and pointed out noncompliance with sanitation protocols, revealing the presence of *C. sakazakii* bacterium, as well as water leaks, and equipment cracks at the plant (Califf 2022). The infant formula supply was reduced by roughly 14 million pounds between late February and April 2022 (Miranda 2022; FDA 2023c). This reduction was largely attributed to the shutdown of Abbott Nutrition's

largest factory in Sturgis, MI, which accounted for 20 percent of the US infant formula production (Berfield and Edney 2022).

Amid the infant formula recall, the US federal government took several steps to mitigate the severe shortage.

On 16 May 2022, the FDA issued the *Infant Formula Enforcement Discretion Policy*, permitting the temporary introduction of safe infant formula products, whether domestic or imported, into US commerce, even if they did not fully meet regulatory requirements (FDA 2022a). For example, formulas meeting safety and nutritional standards but lacking full labeling compliance were allowed (FDA 2022a). This policy aimed to expand the formula supply to address shortages caused by recalls and supply chain disruptions (FDA 2022a). This policy remained in effect until 14 November 2022 (FDA 2022a). On 29 September 2022, the FDA issued the *Infant Formula Transition Plan for Exercise of Enforcement Discretion*, extending enforcement discretion beyond 14 November 2022, for companies committed to meeting regulatory standards (FDA 2022b). This plan, effective until 18 October 2025, provides guidance to manufacturers working toward compliance while ensuring consistent product availability (FDA 2022b). As part of this effort, eleven companies have received letters of enforcement discretion for regular formulas, with five participating in the transition plan; for specialty formulas, six companies received letters, and four committed to compliance (FDA 2024). To further address the crisis, the government launched *Operation Fly Formula* on 18 May 2022 (White House 2022). This initiative involved agencies such as the USDA, HHS, and DOD (Department of Defense) to import formula from overseas. By 29 September 2022, the operation had conducted 74 flights, importing over 97.9 million 8-ounce bottle equivalents of infant formula (HHS 2022). However, operations only covered a few days' worth of average sales, underscoring the need for long-term solutions (McPhillips 2022). As part of the efforts to address the infant formula shortage, the *Formula Act* was signed into law on 21 July 2022, temporarily suspending tariffs on imported infant formula (US Congress 2022c). This measure aimed to encourage importers to increase supply and ease the crisis. However, the tariff suspension was only in effect until 21 December 2022 (US Congress 2022c).

On 18 May 2022, Congress passed the *Infant Formula Supplemental Appropriations Act, 2022*, allocating $28 million to the FDA to address formula shortages (Jaffe 2022). This funding aimed to hire additional staff for facility inspections, review applications for imported formulas to prevent fraudulent products, and enhance supply monitoring and market data collection (Jaffe 2022; US Congress 2022a).

On the same day, President Biden invoked the *Defense Production Act* to prioritize essential raw materials and consumables for formula manufacturers. Under this directive, Abbott Nutrition increased production by 25 percent, and Reckitt, another major producer, projected a 40 percent boost in production capacity (White House 2022).

On 23 May 2022, President Biden signed the *Access to Formula Act of 2022*, granting the USDA permanent authority to issue waivers during emergencies. These waivers allowed greater flexibility in relaxing certain WIC program requirements to ensure participants could access formula (US Congress 2022b). The Act also required manufacturers to include disaster plans in WIC contracts, preparing for future crises (US Congress 2022b).

On 29 December 2022, President Biden signed the *Food and Drug Omnibus Reform Act of 2022 (FDORA)* into law as part of the Consolidated Appropriations Act, 2023. FDORA, addressing regulatory gaps that contributed to shortages, includes measures to enhance supply chain resilience and prevent contamination incidents (FDA 2023c). The Act mandates annual FDA reports to Congress on formula supply, requires manufacturers to outline plans for increasing supply, and tasks the FDA with developing a national strategy to prevent future shortages. FDORA also established the Office of Critical Foods within the FDA, mandated risk management plans for manufacturers, and required the FDA to release a national strategy by March 2023 to support long-term industry stability (FDA 2023c).

Table 1. Interviewee profiles.

Interviewee alias	Job title
Manufacturer 1	Director, supply chain, infant formula
Retailer 1	Business analyst, infant formula
Retailer 2	Buyer, infant formula
Retailer 3	Director, infant formula
Retailer 4	Category manager, infant formula
Retailer 5	Assistant category manager, infant formula
Food Safety Specialists 1 and 2	University extension food safety educator
Food Safety Specialist 3	Professor of food science and food safety
WIC Coordinators 1, 2, and 3	WIC coordinator and registered dietitian
Pediatrician 1	Professor in pediatrics, physician
Pediatrician 2	Primary care pediatrician

These policies were primarily short-term measures aimed at mitigating the immediate impacts of the severe formula shortage by accelerating infant formula imports and production to boost the supply in the United States. However, to ensure the industry's resilience against future disruptions, the implementation of robust long-term policies is essential. The full impact of these policies remains to be studied.

3. Methods and materials

To better understand the infant formula industry and supply chain disruptions following the 2022 infant formula recall in the United States, we conducted semi-structured interviews with professionals in the field. Given the limited primary and secondary data available on this specific event and the unique challenges with collecting such data, in-depth interviews with stakeholders provide nuanced and in-depth insights into the industry structure and the impact of the recall. Other studies that also use interviews with stakeholders to study key food policy issues include Alsukait et al. (2020), Choi et al. (2019), Meyerding et al. (2019), Monticone et al. (2023), Moya, Parker, and Sakrabani (2019), and Walls et al. (2016).

We conducted fourteen interviews via Zoom, and an overview of the participants and their roles in the infant formula supply chain is reported in Table 1 (see Supplementary Table A1 for more details). The data collection period started on 13 February 2024, and ended on 29 March 2024. Interviews lasted from 35 to 90 min, with an average of 50 min. Except for the last two interviews involving retailers, all interviews were conducted individually. In the case of the last two interviews, Retailers 1 and 2 were interviewed together, and Retailers 3, 4, and 5 participated in the final interview to provide more precise information, since they are positioned in various departments related to the formula category of a retail company.

During the interview, participants were asked various questions, which were grouped into the following themes: (1) structure of the supply chain, (2) coping mechanisms, (3) communication dynamics, and (4) policy changes. The core interview questions were tailored for each group of professionals, keeping the same themes. Each expert was asked 10–17 tailored core questions, as well as follow-up questions to explore topics in more depth. Table 2 presents examples of core questions from the interviews, categorized by theme. The themes of the questions were designed based on areas identified by the authors as underexplored from the analysis of the literature and background on the US infant formula sector, with a specific focus on the major infant formula recall. The "Structure of the Supply Chain" theme aimed to uncover the production and distribution stages of infant formula in the United States, providing insights into the overall process while identifying stages that are more vulnerable to crises. The "Coping Mechanisms" theme sought to explore how various

Table 2. Thematic areas and examples of core questions in the qualitative interviews.

Thematic areas	Core question examples
The structure of the supply chain	• What is the process of getting the infant formula products from manufacturing facilities to the end consumers? • Where do you perceive the most significant vulnerabilities within the supply chain?
Communication dynamics	• With whom and what information do manufacturers/retailers/WIC coordinators communicate in the event of a food safety recall? • What are the communication and coordination gaps, and how could these be improved?
Coping mechanisms with the recall	• What protocols do you have in place to handle and respond to food safety concerns or recalls? • How did consumers cope with the resulting shortage?
Policy changes	• Based on your experience, which policies and programs were the most effective and why? • Moving forward, what should government regulatory agencies and/or infant formula producers and retailers do to mitigate/prevent similar food safety recalls and product shortages in general?

actors within the supply chain managed the impact of the major recall and how they were affected by it. The "Communication Dynamics" theme focused on understanding which supply chain actors communicated with one another during the crisis, highlighting potential weaknesses in information transfer that could be critical during a recall or similar emergencies. The "Policy Changes" theme aimed to examine the government's response to the major recall, focusing on the policies implemented to address the ongoing infant formula shortage. It also sought to capture how these policy changes were perceived and experienced by different actors in the supply chain. In summary, these themes were developed to provide both an overview of the US infant formula sector and insights into the major recall's implications for the industry and its stakeholders. Prior to conducting the interviews, approval was obtained from the Institutional Review Board of our higher education institution.

The qualitative data from the interviews were analyzed using an inductive thematic analysis using ATLAS.ti, a qualitative data analysis software (see Supplementary Fig. A1 for the identified themes and the contribution of interviewees to each theme). The coding methodology outlined by Miles, Michael Huberman, and Saldana (2014) was followed in this study. ATLAS.ti facilitated the coding process by enabling data to be tagged with concise labels, such as words or short phrases, at various levels—including specific phrases, sentences, or entire sections—and condensed into manageable parts for further analysis. The software also allowed for further adjustments to the codes and the creation of networks between them, facilitating the identification of patterns and themes across interviews. The analysis included pattern identification, interpretation, and drawing conclusions to address the study's research questions (Miles, Michael Huberman, and Saldana 2014).

To supplement the findings and provide a more comprehensive analysis, this study also incorporated focus group discussions conducted by the NASEM regarding the infant formula industry. The webinar videos were transcribed, and sections related to the supply chain structure were incorporated into this study's interview data during analysis. The data from the NASEM interviews were primarily used to detail the supply chain map of the infant formula industry.

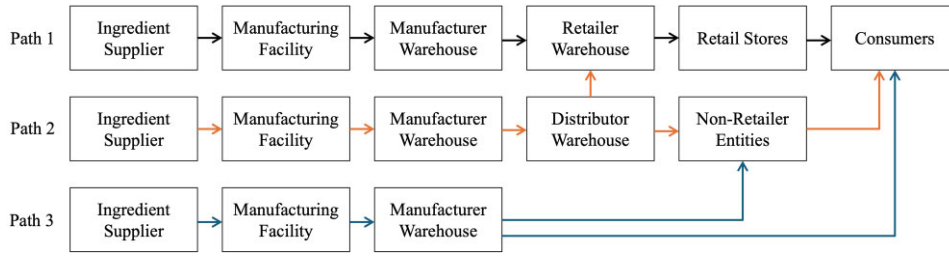

Figure 1. Infant formula supply chain and information flow. Path 1 (Direct upstream route): most common supply chain route; Path 2 (Intermediate route): distribution through intermediary distributors; Path 3 (Direct downstream route): direct distribution to downstream.

4. Results

The infant formula supply chain in the United States consists of several routes, as depicted in Fig. 1 using different colored arrows to present different pathways. The most common route is the direct distribution from manufacturers to retailers (path 1). Other routes involve intermediary distributors who deliver to both retailers and nonretail entities such as hospitals, institutes, and doctors' offices (path 2), or have manufacturers distribute to consumers or nonretail entites (path 3), which are less common (NASEM 2023a, 2024).

The most common supply chain route where manufacturers distribute directly to retailers indicates that the infant formula supply chain is short and utilizes the just-in-time production and distribution approach in the industry (FDA 2023c; Manufacturer 1). However, this makes the industry vulnerable to supply chain disruptions, as manufacturers and retailers do not keep a large supply in stock (Manufacturer 1; NASEM 2023a). Therefore, delays in the ingredient allocation stage or the manufacturing stage may quickly lead to shortages in the marketplace. The infant formula supply chain implies a range of factors and challenges at the upstream, midstream, and downstream stages, which have been discussed in the following subsections.

4.1 Upstream: ingredient allocation and manufacturing

The discussions with manufacturers highlighted several challenges that upstream operators face. The first challenge relates to the way the infant formula ingredients are procured. According to Manufacturer 1, *infant formula's primary ingredients, such as milk protein concentrates, lactose, and caseinates, are sourced both domestically and internationally*, with New Zealand being a major international supplier. Other inputs such as carbohydrates, oils, vitamins, and minerals are mostly sourced regionally for cost reasons, while special ingredients such as human milk oligosaccharides are obtained from specific locations in Europe (Manufacturer 1). Additionally, since some main and special ingredients are sourced internationally, challenges such as transportation issues, piracy in the Red Sea, and the lingering effect of the COVID-19 pandemic, among others, further pose challenges for the manufacturer (Manufacturer 1). When combined with the just-in-time approach and nonrobust safety stocks, the challenges lead to significant costs for manufacturers and a vulnerable supply chain (FDA 2023c). For example, during the COVID-19 pandemic, the manufacturer chartered their own planes to obtain ingredients abroad, bought new warehouses to improve their safety stocks, and stated a required amount of safety stock of ingredients in supplier contracts to sustain the supply of formula in the marketplace (Manufacturer 1).

Moreover, the main ingredient of infant formula, dairy products, faces another challenge: *seasonal changes*. Dairy products may have variabilities in their mineral and vitamin contents due to cows' diet that is related to seasonal changes, which is potentially exacerbated

by global climate change (Manufacturer 1). The diversification of sourcing regions may be one approach to ensure the consistency of quality ingredients; however, this strategy may increase costs of production and lead to inefficiencies.

The ingredients of infant formula are highly specialized; hence, there are few suppliers who meet the level of specification dictated by policy, which falls between food and pharmaceutical grade (Manufacturer 1; NASEM 2023b). This implies high concentration in the infant formula ingredient market, thus increasing vulnerabilities in the supply chain, and the potential for ingredient shortages. In addition, *infant formula manufacturers represent just a small share of ingredient suppliers' business*; hence, the business interests between these two segments of the industry may not be fully aligned. To address this, during the 2022 infant formula food safety recall, the government invoked the Defense Production Act, which mandated the ingredient suppliers in the United States to prioritize infant formula manufacturers in obtaining essential ingredients.

> The goal was to say we have higher priority because of what we're making. Some [ingredient] suppliers didn't like that, because we would cut off other customers and that would upset them, to be honest. But at the same time, I think those customers would understand like, okay, there's only so much in the world that's being produced. […] It [the policy] was pretty short-lived, actually. I thought that they would keep it rolling. —Manufacturer 1

This policy temporarily benefited US infant formula manufacturers by facilitating the obtaining of ingredients from domestic suppliers; however, it did not address the challenges of sourcing ingredients from abroad.

To boost the supply of infant formula during the shortage period, infant formula manufacturers implemented various coping mechanisms. Manufacturer 1 mentioned that they moved production to their manufacturing facilities abroad to keep certain capacities and meet government regulations. They also cut off the volume of production for other products, to free up capacity for infant formula production during this period (Manufacturer 1). To improve productivity, manufacturers maximized their production capacity and optimized their product lines by reducing the number of sizes and varieties (known as stock-keeping units) of infant formula they produced (Retailer 2). As the market approached normalcy, manufacturers found it necessary to reduce their production capacities to address FDA safety concerns and improve resilience against similar crises (Manufacturer 1; NASEM 2024). This provides them with idle capacity that can be utilized to increase production when needed.

In addition to supply chain challenges, the infant formula market faces other obstacles that create barriers to entry and sustain a presence in the market; these are addressed by Manufacturer 1. In the infant formula industry, *the increased frequency of regulatory changes* leads to confusion and difficulty in meeting standards. Manufacturer 1 claimed that government agencies may not fully understand the time needed to implement changes, creating a mismatch between regulatory timelines and the industry's adaptability.

> I would say that the regulatory changes are probably the most difficult to adapt, because it takes time to make these changes. And I don't think government agencies understand the amount of time it takes. […] And so, you're looking at something that will take three to four years, but the regulation will be in place within one or two years. […] And then sometimes [ingredient] suppliers don't want to do it. Because again, we're a small fraction of their sales. […] So, you know, we have a good relationship with them. We build additional business on different things that are not, as, I'll say, commoditized. And so that helps us with the overall portfolio of what we purchase. —Manufacturer 1

Another challenge for infant formula manufacturers is that advertising infant formula on TV is prohibited in the United States, prompting manufacturers to develop alternative promotion strategies. One such approach is *medical detailing*, also known as the gratis model,

where pharmaceutical companies distribute free formula samples to nonretailer entities such as doctor's offices and hospitals (United States General Accounting Office Human Resource Division 1990). Providing samples assists pediatricians in assessing product suitability for infants and supports families, particularly those facing financial constraints or seeking a supplement while breastfeeding (Pediatrician 2). Pediatrician 2 observed that companies not contracted with the WIC state agency tend to distribute free samples more often. This suggests that WIC-contracted manufacturers already promote through WIC, while others resort to the gratis model to capture market share in states where they do not hold WIC contracts. Medical detailing is performed by manufacturers who have existing networks with these nonretailer entities (hospitals, doctors' offices), as these manufacturers are medical companies (Yenerall 2024). Other manufacturers, which are not medical companies and therefore lack these networks, struggle in establishing a robust supply chain network in the United States, which further limits their ability to hold a foot in the market (Manufacturer 1; NASEM 2024). This is one of the contributing factors of the high concentration in the infant formula manufacturing industry.

4.2 Midstream: retailing operations

The impact of the *WIC program* is significant in retail operations regarding infant formula. Retailers determine inventory and shelf placement of infant formula products based on WIC requirements and demand forecasts (Retailers 2 and 3). WIC-contracted brands and product sizes are prioritized on shelves, with other products of the same manufacturer arranged around them (Retailer 2). Specialty formulas, and expensive formulas with lower expected sales have minimal facing on the shelves (Retailer 2).

During the shortage period, especially after WIC flexibilities were provided to WIC participants and the media began paying more attention to the major recall, a *panic-buying environment emerged in the marketplace* (Asiodu 2022). As a result, retailers started imposing limits on infant formula product purchases to ensure that more customers had access to the available options (Wile 2022).

However, the stockpiling behavior of consumers and imported formulas were not the only challenges retailers faced as a result of the major recall. Retailers explained that changes in manufacturing practices due to the efforts to improve safety have been causing supply chain challenges since the 2022 food safety recall occurred. One such challenge involves *manufacturers having longer quality hold times* for further testing and discarding all bad batches that were produced after the last cleaning, which leads to stricter cleaning practices but slows down the production process (Retailers 2, 4, and 5). Retailers also explained that *manufacturers are transitioning from dry cleaning to wet cleaning*, which makes the process even slower and riskier, as water may increase the risk of contamination. Retailers elaborated on these challenges and their implications:

> The FDA has changed a lot of requirements of the suppliers since the recall. And so, some of that is prolonging the shortage. I'm not saying it's a bad thing; it's prolonging the shortage because they've asked for longer quality hold times. […] So normally … if they found something wrong with a batch, either the nutrition was off or they found a bacteria or something in one, they throw away that batch and the batch before and the batch after. […] And then one of the things that the FDA changed was, now if you find a bad batch, you have to throw out everything from the last, between the whole cleanings. […] So, they tend to clean more often, which just slows down the process a little bit more. —Retailer 2

> And you got to also remember, first of the month … when they [the WIC participants] do get the WIC dollars … we have to be ready for when they're ready to come shop. And if all of a sudden, a cleaning issue or quality hold or something pushes you back, that definitely creates challenges. —Retailer 3

4.3 Downstream: marketing claims and emerging consumer preferences

Insights on parents' preferences for infant formula were gathered from pediatricians, WIC coordinators, and retailers, revealing various opinions. Pediatrician 1 highlights the significant impact of advertisements, marketing efforts, and function claims made by formula companies on parental decision-making. These *marketing strategies and the wide array of available formulas can be confusing*, making it difficult for parents to make informed choices (Pediatrician 1). Marketing claims, such as "gentle on the stomach" or "lactose-free," may not have a scientific basis or be necessary for healthy infants (Belamarich, Bochner, and Racine 2016; Pediatrician 1). Pediatrician 1 suggests that this confusion may be intentional on the part of formula manufacturers, allowing manufacturers to have a greater influence on consumers' formula choices, as well as increase market share and profitability.

Several factors influence formula choice, with pediatricians and healthcare providers playing a significant role in recommending formulas based on the infant's individual needs, availability, and cost (Pediatrician 2). Marketing and parental beliefs can also impact decision-making, occasionally leading to the excessive consumption of specialty formulas (Polack, Khan, and Jeffrey Maisels 1999). Pediatrician 2 discussed several factors that influence formula selection, such as WIC coverage and hospital recommendations, noting that store brand formulas provide a more budget-friendly alternative for families while not compromising quality. Furthermore, Pediatrician 2 highlighted the impact of various information sources on formula selection, including online resources, advice from other parents, and marketing efforts by formula companies.

Parents often develop brand loyalty to infant formula that works well for their babies, especially if it is provided as a free hospital sample or covered by WIC, according to Pediatricians 1 and 2. Pediatrician 1 mentioned that if parents transitioned to a non-Abbott product during the recall and the baby was doing fine, they were less likely to switch back.

> I think once if they're reassured by their provider, they probably lean heavily on them. […] I think that the concern for the rare issues that led to the recall should not engender an overall concern about formulas in the United States … it's important to, you know, place this in the context of the actual scale … which is extraordinarily low. —Pediatrician 1

Infant formula has a short lifecycle, as infants are only in this stage for a year. This means that the infant formula market's consumer base changes frequently, and most interviewees noted that new parents may not have experienced the shortage or be aware of previous recalls (Pediatrician 2 and Retailers 3 and 4). While Retailer 1 observed a mistrust toward Abbott Nutrition's infant formula products, Retailers 3 and 4 observed that consumers were ready to switch back to Similac as soon as the products were available.

Media reports about the recall led to panic buying, which accelerated the shortage (FDA 2023c). *Parents faced limited access to infant formula during the shortage and resorted to various coping strategies*. According to the interviewees, while some strategies were beneficial, others were harmful practices that could lead to adverse health outcomes for babies. The strategies identified as suggested or beneficial included increasing breastfeeding, purchasing alternative products, ordering formula online, and relying on friends or relatives to locate formula in various stores. Food Safety Specialist 1 addressed that seeking information or purchasing infant formula from regulated and trustworthy sources is important. Many parents coped with the recall by ordering FDA-regulated formula online from reputable sources when they could not obtain it on store shelves (WIC Coordinator 1). Though often more expensive, options such as direct-to-consumer channels and imported formulas were available (Retailer 5; NASEM 2024). However, these were not an option for parents relying on WIC benefits to purchase formula (Retailer 1). Harmful practices were prevalent on social media and other unreliable sources (Food Safety Specialists 1, 2, and 3; Pediatrician 2). Interviewees identified stockpiling, homemade formulas, and diluting formula as very harmful practices. Homemade formulas lack proper nutritional value and pose

contamination risks, while diluting formula compromises its nutritional content (Pediatrician 2). Therefore, in future crises, it is crucial to provide clear, user-friendly guidance and prevent the spread of misinformation that could lead to adverse health outcomes for infants (Pediatrician 2 and Food Safety Specialist 1).

During the shortage, the AAP advised consumers to feed cow's milk to healthy babies after six months of age if there are no other options available[4] (AAP 2022b). However, there is limited or contradicting information regarding the standard amount of cow's milk for infants aged 6–12 months (AAP 2022c). *The lack of specific guidelines by the AAP* trickles down to professionals in the field. In our interviews, Pediatrician 1 and WIC Coordinator 1 offered differing advice on when to transition infants to cow's milk. Pediatrician 1 mentioned that transitioning to cow's milk can be an option for healthy infants who are older than six months, even younger, with providing additional iron as the primary issue with cow's milk is inadequate amount of bioavailable iron, which can lead to iron deficiency in infants. On the other hand, WIC Coordinator 1 mentioned the same strategy for babies at least nine months old.

Another coping strategy that emerged from the data was *breastfeeding*, considered the best way to feed healthy infants by pediatricians (Meek and Noble 2022). As expected, the percentage of fully or partially breastfed infants in the WIC program increased during the shortage period, while the percentage of fully or partially formula-fed infants decreased (USDA ERS 2024). Interviewees, particularly WIC coordinators, noted that initiation alone is not sufficient without sustained breastfeeding. WIC Coordinator 3 highlighted the challenge of accurately assessing breastfeeding rates, as many mothers start breastfeeding in the hospital but may not report when they stop and fail to adjust their WIC food packages from fully breastfeeding to one that reflects their current practices. Breastfeeding initiation does not necessarily lead to continued duration due to various challenges mothers face, such as the need to return to work, which limits the time available for breastfeeding or storing breast milk (Pediatrician 2; WIC Coordinators 1 and 3). WIC Coordinators and Pediatrician 2 stressed the importance of supporting postpartum women and addressing existing challenges, emphasizing the need to improve parent education on breastfeeding benefits, create more breastfeeding-friendly environments, and focus on extending breastfeeding duration.

WIC flexibilities was the most addressed policy response to the infant formula shortage by the interviewees. WIC allowed more flexibility in the type, size, and brand of formula, helping parents access safe options available on store shelves (USDA FNS 2024). Despite the increased flexibility granted to WIC participants, it was insufficient when shelves were nearly empty (WIC Coordinator 1). Retailer 2 and WIC Coordinator 1 mentioned that some states, especially those not contracted with Abbott, were slow to provide WIC flexibility or were only offering limited flexibility. This was problematic as the recall led to a shortage in all infant formula brands, as non-WIC consumers also switched from the recalled to the nonrecalled brands (WIC Coordinator 1).

To highlight *differences between WIC agencies*, WIC Coordinators 1 and 3 noted that WIC participants in their state can now purchase any approved standard formula available without needing to change their benefits from one type of formula to another. This flexibility was introduced to participants after the recall and continues to be in effect. However, WIC Coordinator 2 indicated that this flexibility is not provided to WIC participants in their state.

Operational differences among WIC agencies led to varying challenges. For example, WIC Coordinator 3 addressed a communication issue their local agency faced during the recall period: the lack of immediate communication between WIC state agencies and local agencies. This situation underscores the critical need for improved interagency communication and the development of a robust emergency response plan to handle such crises effectively.

> So, on February 17, the phone was ringing off the hook with calls about the recall. We first heard about the recall at the local agency level through our clients. We had many people

calling us, and we didn't know anything about it. So, we were Googling, trying to figure it out. There wasn't a coordinated response at the state level, so we were overwhelmed with clients calling us. We didn't receive any communication from the state that day, and it was a Friday. We had to scramble and figure it out ourselves. Additionally, it was a holiday weekend; the following Monday was Presidents' Day, and we were closed. Clients were panicking, asking what they were going to do. Our agency, like many local agencies, was left hanging to figure it out on our own. To give the state credit, I'm sure they were trying to develop a coordinated response. At the same time, we didn't have the answers. —WIC Coordinator 3

5. Discussion and conclusion

This study examines the US infant formula industry, along with the 2022 infant formula food safety recall, which interviewees described as a "nightmare," "disaster," or "the biggest impacting recall that I've seen in my career." It contributes to the literature by analyzing a market for an important product with no available market substitutes and a highly concentrated market structure. Supplementary Figure A2 provides a summary of the findings, listing the challenges and coping mechanisms across the upstream, midstream, and downstream segments of the infant formula supply chain. The study presents results derived from qualitative interviews with stakeholders, a method particularly valuable for addressing topics of national interest that are underresearched and lack sufficient quantitative data. Such interviews provide researchers with critical insights into key issues and policy implications (Walls et al. 2016; Choi et al. 2019; Meyerding et al. 2019; Alsukait et al. 2020). This paper has limitations due to the relatively low acceptance rate for interviews, at only 8 percent (see Supplementary Table A1). Those experts who declined to be interviewed mentioned that they were either not comfortable discussing the topic or were not allowed to do so due to the sensitivity of the topic. Hence, we supplemented the findings from the interviews, with publicly available interviews with stakeholders conducted by the NASEM.

The findings of the research shed light on the infant formula supply chain structure, as well as the challenges that contribute to shortages in the marketplace, supplementing findings by Muhammad et al. (2023) and Yenerall et al. (2024). The findings regarding the upstream of the supply chain reveal that the infant formula market has many layers of concentration: ingredient supplier concentration and manufacturer concentration combined with a just-in-time approach present many challenges. Future research should explore the just-in-time approach, its advantages, and drawbacks in highly concentrated food markets. Moreover, it is crucial to investigate the market for highly specialized infant formula ingredients, with a particular focus on identifying strategies for manufacturers to diversify their ingredient sources while maintaining quality control and abiding by regulatory requirements. Future research may also delve deeper into comparisons between the infant formula industry structure in the United States and other large countries or regions. For example, the European formula market, as the largest supplier and net exporter, benefits from having many smaller manufacturers, which mitigates the impact of recalls despite the concentrated market structure (Chen 2018; Speed 2023). Exploring the policy framework and the industry changes needed to make such a model possible in the United States may be the topic of future research. It is also important to note that the findings of this study are specific to the infant formula market in the United States, a developed country. Examining infant formula markets in developing countries could provide valuable insights from a different perspective and represent an important direction for future research.

The midstream supply chain findings indicate that retailers face challenges related to stockpiling and changes in manufacturers' practices. These changes create difficulties for retailers in obtaining products from manufacturers, leading to intermittent shortages that

in some cases still persist. Understanding the specifics of these changes, particularly those related to quality holds, cleaning practices, and formula disposal, is an important area for researchers to explore. This includes identifying the primary reasons behind these changes, their connection to FDA policies, their prevalence, and their impact on the marketplace. In addition, quantitative analysis is needed to understand the discrepancy between the decrease in total production capacity due to the closure of the Sturgis plant in Michigan for part of the year (responsible for approximately 20 percent of the total production), and the extremely high out-of-stock rates observed, reaching well above 90 percent in many large cities.

The findings regarding the downstream supply chain present a confusing marketplace with many infant formula product varieties and differing marketing claims. Future research should focus on understanding the marketing claims, their scientific bases, and their impact on consumer decision-making. Additionally, findings show that during the major recall, parents found alternative ways to feed their babies, including increasing breastfeeding (USDA ERS 2024). Therefore, the coping strategies of parents require further attention, particularly in understanding how breastfeeding rates have increased, how to sustain them, and how to improve guidelines for parents in situations where they cannot obtain infant formula. In this context, it is important to draw comparisons between breastfeeding rates and infant formula industry structure in the United States, compared to other regions in the world. For example, based on World Health Organization data, the European region has the lowest exclusive breastfeeding rate at the age of six months, at below 25 percent (Theurich et al. 2019). Yet, maternity leave in Europe is generally longer than in the United States and is supported by national policies (Goralczyk 2023). Therefore, the relationship between maternity leave, breastfeeding rates, and the consumption of infant formula warrants further exploration, particularly by conducting a comparative analysis of different regions. Finally, as consumer food purchase data from that period become available, future studies should conduct quantitative analysis to explore consumer behavior, including stockpiling, brand substitution, brand loyalty, and the duration of the impact.

Future research is needed to understand the impact of policies and regulations regarding infant formula production, distribution, marketing, consumption (including WIC), and trade. For example, it is important to assess the role of current trade barriers for infant formula and its ingredients, and evaluate the impact of easing such barriers on supply chains and safety standards. Another avenue for future research includes exploring the impact of policy changes on the WIC program. Interviewees highlighted WIC flexibilities as one of the most effective policies enacted during the shortage. While crucial in providing alternatives and alleviating the shortage faced by consumers, WIC flexibilities were short-term policies, and their sustainability remains a question. As a long-term policy, it may eliminate incentives for companies to offer rebates, potentially leading to additional costs for the WIC program and limiting participant numbers (Yenerall et al. 2024). WIC Coordinators interviewed for this study have proposed two options to provide more choices for WIC participants: setting a fixed dollar amount for participants to purchase their preferred product (WIC Coordinators 2 and 3) or establishing a standardized rebate agreed upon by all manufacturers, which would allow multiple manufacturer contracts (WIC Coordinator 1). The potential effects of changes to the WIC rebate system on manufacturers, the WIC program, and its participants require further investigation.

There are a few key policy recommendations that emerge from our study. This study highlights the need for comprehensive regulations to address major challenges in the US infant formula industry. These include providing clear guidelines and establishing crisis management plans across all stages of the supply chain and at the governmental level to ensure a proactive response to crises. Moreover, it is essential to improve communication channels and transparency for better supply chain management. The current market structure significantly restricts consumer choice, creating vulnerability tied to the performance of a limited number of manufacturers. Interviewees expressed a desire for more market players and manufacturing facilities in the United States. Furthermore, Manufacturer 1 emphasized

the importance of educating the government and regulatory bodies about the infant formula supply chain to prevent challenges associated with regulatory changes. Regulatory changes in the infant formula market have significant economic implications, influencing resource allocation, market dynamics, trade relations, and consumer confidence. Ultimately, these strategies impact the industry and its long-term resilience. It is important for government interventions not to disrupt the market and create economic uncertainty, but to enhance market stability and increase consumer confidence. At the consumer level, improving the WIC program to provide flexibility to consumers is crucial. Our study also emphasized the need for clear and concise, even if nuanced, guidelines on infant feeding, including breast milk, infant formula, cow's milk, and solid foods. The development of these guidelines should be science-based, and effectively communicated to all those responsible for the well-being of infants, including parents, pediatricians, and WIC coordinators, as well as manufacturers and retailers. Addressing the challenges with infant formula production, distribution, policies, and safety standards is a costly and complex task, but it is a must, to keep the most vulnerable among us, babies, safe and well-nourished.

Supplementary data

Supplementary data is available at *Q Open* online.

Conflict of interest

None declared.

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Data availability

Sample interview quotes by themes are available.

End Notes

1 Assuming that half of this consumption is infant formula—16 ounces—which requires eight scoops of formula, with each scoop being approximately one-third of an ounce, the total amount of formula needed is approximately 2.34 ounces per day (Jana and Shu 2022). Each year in the United States, 75 percent of the 3.7 million infants born receive formula, either exclusively or as a supplement, during their initial six months of life (Centers for Disease Control and Prevention 2023).

2 Prospective participants should be either pregnant or postpartum women (up to six months for a non-breastfeeding woman or one year after childbirth for a breastfeeding woman), infants up to one year old, or children up to five years old. Additionally, their household income should be at or below 185 per cent of the federal poverty guidelines (Oliveira, Frazao, and Smallwood 2011; USDA FNS 2023a).

3 Currently, Abbott holds thirty-seven contracts, Mead Johnson has thirteen, and Nestle Gerber has six, excluding Indian tribal organizations (USDA FNS 2023d).

4 Typically, the AAP does not recommend the consumption of cow's milk for infants who are younger than one year (AAP 2022c).

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