U.S. INFANT FORMULA INDUSTRY: A QUALITATIVE ANALYSIS OF A MAJOR FOOD SAFETY RECALL AND ITS IMPLICATIONS

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A THESIS

Submitted to
Michigan State University
in partial fulfillment of the requirements
for the degree of

Agricultural, Food, and Resource Economics – Master of Science

2024

ABSTRACT

A major food safety recall of infant formula in February 2022 caused significant disruptions in the supply chain that was already fragile, causing a severe shortage in the marketplace. The highly concentrated market structure, strict policies and regulations that characterize infant formula production further contributed to the shortage. Infant formula is a unique product with no close market substitutes available, especially for specialty formulas which are designed for babies with medical conditions. Therefore, shortages in the marketplace may threaten the lives and well-being of infants who do not have alternative sources of nutrition, particularly in the first few months of life. Given the substantial reliance on infant formula, maintaining a sufficient supply of this product in the marketplace is crucial. This makes the major recall an important case study and a policy-relevant issue. This study presents a unique contribution to the literature by investigating the infant formula industry, including the 2022 infant formula food safety recall, utilizing data and information obtained from qualitative interviews with experts in the industry. A key finding is a comprehensive map of the infant formula supply chain, shedding light on its dynamics and vulnerabilities. Additionally, the research details communication dynamics and coping strategies employed by the industry and consumers during the recall, revealing the lack of information and standards in this industry. Our study contributes to the limited literature on the infant formula industry, with the goal of developing effective strategies to enhance its resilience and affecting government policy and industry practices.

To my loved ones. Thank you.

ACKNOWLEDGEMENTS

First, I would like to thank Dr. Jeta Rudi Polloshka for her unwavering support and invaluable assistance throughout my thesis journey. Her proactive mentorship and guidance were crucial to the completion of this thesis. I would also like to express my gratitude to Dr. Vincenzina Caputo, whose support and inspiration have been a source of motivation throughout my master's degree program. My thanks also go to Dr. R. Brent Ross for his support and guidance. Additionally, I would like to express my appreciation to Dr. Kimberly Chung; the knowledge I gained from her class on qualitative methods has been invaluable in enabling me to conduct and analyze qualitative interviews for this thesis.

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CHAPTER 1: INTRODUCTION

In 2022, a food safety-related recall of infant formula caused a significant disruption in the market's already fragile supply chain. This, in turn, exacerbated the shortage of this vital product (Christensen, 2022) and emphasized the urgent need to address safety and supply chain concerns. This topic is particularly significant, considering the recommendations of the American Academy of Pediatrics (AAP) and the Dietary Guidelines for Americans, which advocate exclusive breastfeeding for the initial six months and, if breast milk is not available, infant formula feeding[1] (Meek & Noble, 2022; USDA & HHS, 2020). Data from the Centers for Disease Control and Prevention (CDC) indicates that approximately 3.7 million babies are born each year in the U.S. (CDC, 2023c), and about 75% of infants receive formula, either exclusively or as a supplement, during their initial six months of life (CDC, 2023b). Given the substantial reliance on infant formula, maintaining a sufficient supply of this product in the marketplace is crucial. However, given the regulations governing its production and distribution, it presents a formidable challenge.

In February 2022, Abbott Nutrition, the top manufacturer of infant formula, issued a food safety recall for several products under Similac, Alimentum, and EleCare brands (FDA, 2023a). The recall was initiated due to the potential contamination with *Cronobacter sakazakii*, a bacteria that presents a severe risk to infants, including the potential for illness and mortality (Jaffe, 2022). The mortality rate among infected newborns and young infants can reach 80% (Patrick et al., 2014).

[1] 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 1, alongside complementary foods; thereafter, whole cow's milk is suggested (AAP, 2023; Meek & Noble, 2022). On June 27, 2022, the American Academy of Pediatrics (AAP) released a new policy statement in which the breastfeeding period suggestion was extended from one year to two years, aligning with WHO guidelines (Meek & Noble, 2022).

The shortage began due to supply chain disruptions related to the COVID-19 pandemic and lasted throughout the food safety recall period (Samuel et al., 2022). Additionally, the crisis's impact was exacerbated by the oligopolistic structure of the infant formula market, import restrictions, and the FDA regulations concerning safety, nutrition, labeling, and packaging (Vakil, 2022). A shortage of infant formula is particularly concerning given that this product is the only substitute for breast milk during a baby's first six months of life, significantly impacting the health and development of infants (Kalaitzandonakes et al., 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 et al., 2023) The significance of infant formula and the challenges many families face in obtaining an adequate supply make this shortage an important case study and a policy-relevant issue.

This study investigates U.S. infant formula supply chain disruptions, policy changes, communication strategies, and coping mechanisms among stakeholders, due to a major food safety recall of a major brand in this product category.

This study contributes both to the literature on food safety recalls and to the literature on food industries with high levels of regulation and high market concentration. Previous research has examined diverse economic aspects of food safety recalls for products such as spinach lettuce, and meat, including impacts on consumers (Arnade et al., 2011; Brady et al., 2009; Fahs et al., 2009; Shang & Tonsor, 2017), industry (Houser & Dorfman, 2019; Spalding et al., 2023). However, while infant formula is a food product, the implications of a food safety recall for this product are potentially much more severe compared to other food items. This is because infant

formula does not have other close market substitutes and is the sole recommended source of nutrition for a fragile portion of the population: infants.

Related literature on pharmaceutical shortages, such as Nonzee & Luu (2019) and Gu et al., (2011) are relevant to our study due to the unique nature of the product, and they also address how regulatory barriers contribute to shortages. Gray & Manasse Jr (2012) examine shortages of crucial medicines, mentioning the limited number of suppliers and manufacturing facilities as one of the driving factors of prevalent shortages. Shifting the focus to market concentration literature, Sexton (2000) and Hendrickson et al. (2020) explore consolidation and concentration in the U.S. food systems and their impact on the industry.

In the context of infant formula recalls in the U.S., Muhammad et al. (2023) and Yenerall et al. (2024) use publicly available secondary data to investigate the infant formula crisis by discussing the regulatory framework, specifically focusing on policy changes. Jung et al., (2023) and Samuel et al. (2022, 2023) investigate the coverage and responsiveness of online media towards infant formula recalls and shortages. A few studies in medical literature focused on the impact of infant formula crisis on consumers and their feeding practices (Cernioglo & Smilowitz, 2023; Doig, 2024; Kalaitzandonakes et al., 2023; Sylvetsky et al., 2022). Meanwhile, Imboden et al. (2023) examine the breastfeeding rates during the shortage period. Abrams (2023) and Abrams & Duggan (2022) propose several policies to prevent similar infant formula supply disruptions.

This study presents a unique contribution to the literature by investigating the infant formula industry, including the 2022 infant formula food safety recall by conducting qualitative interviews with experts in the industry. A key finding is a comprehensive map of the infant formula supply chain, shedding light on its structure, and vulnerabilities during economic

shocks, such as food safety recalls. Additionally, the research provides an in-depth analysis of communication dynamics and coping strategies employed by the industry and consumers during the recall, revealing the lack of information and standards that exist in the industry. The findings will be of interest to academics, policymakers, as well as industry and consumer representatives.

This thesis utilizes qualitative interviews as the primary data collection method, conducting interviews with key stakeholders, including infant formula manufacturers, retailers, food safety specialists, WIC coordinators, and pediatricians. The interviews provide insights into the infant formula market, supply chains, regulatory framework, consumers, and food safety and quality assurance processes. Thematic analysis was performed using ATLAS.ti, a qualitative data analysis software.

The thesis proceeds as follows: Chapter 2 provides information about the infant formula industry and its structure, as well as market dynamics. Chapter 3 details the significant infant formula recall of 2022, including the regulatory framework, policy response, and consumer response to the recall. Chapter 4 explains the methods, data collection, and data analysis. Chapter 5 reports the interview results. Chapter 6 provides a discussion and Chapter 7 presents a conclusion.

CHAPTER 2: U.S. INFANT FORMULA INDUSTRY STRUCTURE AND MARKET DYNAMICS

The infant formula market in the United States is dominated by four leading manufacturers, whose respective brands and market shares are outlined in Table 1. The four leading manufacturers control 99% of the market[2], and Abbott Nutrition held a 40% market share in 2021. In 2022, Abbott's market dominance declined due to a food safety recall, allowing MJN/Reckitt to capture a larger portion of the market (FDA, 2023c). The oligopolistic structure can be attributed to various factors that lead to barriers to entering the market, such as high initial production costs, fixed retail pricing, regulations outlined by the FDA, high tariffs[3], and the WIC program's rebate system (see section 3.3.) (FDA, 2023g).

[2] The Herfindahl-Hirschman Index (HHI) is a calculation of market concentration done by summation of squared market shares of all market players. HHI below 1500 represents unconcentrated markets, HHIs between 1500 and 2500 represent moderately concentrated markets, and HHI above 2500 represents highly concentrated markets (DOJ & FTC, 2010). The infant formula market is highly concentrated with a HHI that is higher than 2971.

[3] Infant formula imports face tariffs ranging from 14.9% to 17.5%, with additional duties beyond certain thresholds (Casey, 2022). Some lower-priced formulas encounter extra tariffs upon reaching another threshold. Duty-free entry is granted under free trade agreements, but only 19.4% of imports qualified during the period from 2012 to 2021 (Casey, 2022). The average calculated duty rate for the remaining imports is 25.1% (Casey, 2022).

Table 1: Infant Formula Industry Structure in the United States

Leading Manufacturers	2021 Market Shares	2022 Market Shares	Leading Infant Formula Brands
Abbot Nutrition	0.40	0.27	Similac EleCare
MJN/Reckitt	0.31	0.39	Enfamil Nurtamigen
Nestle/Gerber[4]	0.17	0.18	Gerber
Perrigo	0.11	0.13	Private Labels: Parents' Choice at Walmart CVC Health at CVS Well Beginnings at Walgreens Love & Care at Amazon Meijer Baby at Meijer Up & Up at Target Comforts For Baby at Kroger Member's Mark at Sam's Club Kirkland Signature ProCare at Costco

Source: Abbott Nutrition (2023), FDA (2023g), Nestle USA (2023), Perrigo Pediatrics (2023), Reckitt (2023)

Infant formula feeding guidelines reflect different feeding frequencies and amounts based on the age of the infant (see Figure 1).

[4] Gerber, originally the infant formula brand of Nestle, had its rights purchased by Perrigo in November 2022, along with the production facility in Wisconsin where the potentially contaminated products were manufactured (FDA, 2023d).

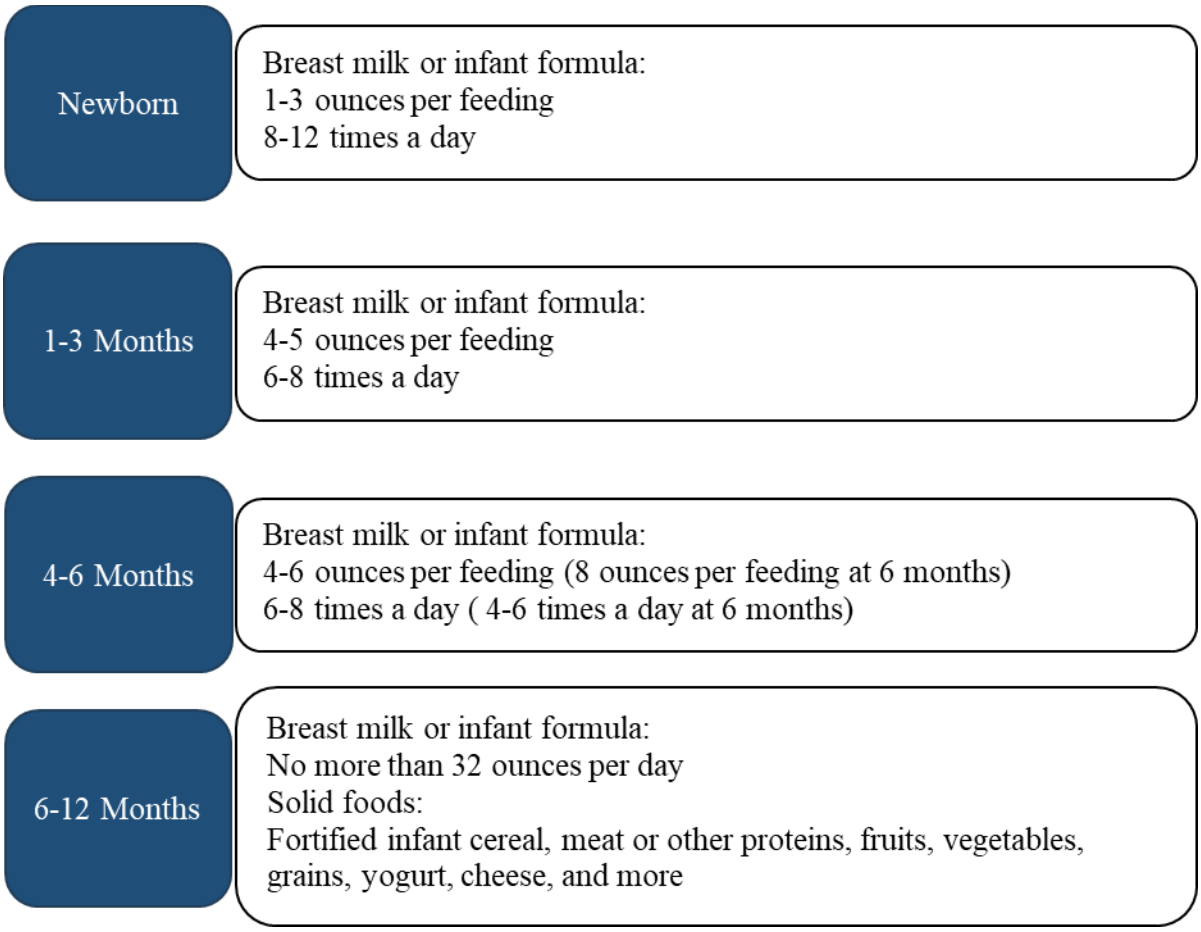

Figure 1: Infant Feeding Guide for the First Year
Source: AAP (2022a), CDC (2023a)

As mentioned before, out of the approximately 3.7 million babies born in the U.S. each year, 75% receive formula, either exclusively or as a supplement, during their first six months of life (CDC, 2023b, 2023c). Table 2 demonstrates the estimates of infant formula consumption each year.

Table 2: Estimates of Infant Formula Consumption Based on Births in the U.S.

Year	All Births in USA	Infants Born Received Formula, Either Exclusively or as a Supplement, by Three Months of Life		Infants Born Received Formula, Either Exclusively or as a Supplement, by Six Months of Life	
		Percentage	Estimated Total	Percentage	Estimated Total
2013	3,578,321	55.60%	1,989,546	77.70%	2,780,355
2014	3,848,486	53.40%	2,055,092	75.10%	2,890,213
2015	3,978,497	53.10%	2,112,582	75.10%	2,987,851
2016	3,945,875	52.50%	2,071,584	74.60%	2,943,623
2017	3,855,500	53.10%	2,047,271	74.40%	2,868,492
2018	3,791,712	53.70%	2,036,149	74.20%	2,813,450
2019	3,747,540	54.70%	2,049,904	75.10%	2,814,403
2020	3,613,647	54.70%	1,976,665	74.60%	2,695,781
2021	3,664,292	53.85%*	1,973,221	75.10%*	2,751,883
2022	3,667,758	53.85%*	1,975,088	75.10%*	2,754,486

Source: Authors' calculations based on data from the Center for Disease Control and Prevention (CDC, 2023b, 2023c)
*For the years 2021 and 2022, the percentage of formula is unavailable, so the mean from previous years is used to estimate the reported totals.

In 2022, an estimated 2.7 million infants in the USA (75% of births) received formula (see Table 2), consuming approximately 2.3 billion ounces of powdered formula throughout the year[5].

Infant formulas are available in three different forms: powder, liquid, and ready-to-feed (Martin et al., 2016). The primary type of infant formulas found in the market is in powdered form, accounting for 83% of total sales in 2008 (Oliveira et al., 2010). This prevalence can be attributed to the cost-effectiveness of powdered formulas when compared to liquid formulas (Oliveira et al., 2011).

There are several types of infant formula, with the most common being standard cow's milk-based formula (Rossen et al., 2016). There are specialized formulas for fussiness, colic, and

[5] On average, these infants consumed approximately 32 ounces of breast milk and/or infant formula per day (see Figure 1). Assuming that half of the milk is infant formula that is 16 ounces, which requires 8 scoops of formula, each scoop being approximately one-third of an ounce, the final amount of formula needed is approximately 2.34 ounces (Jana & Shu, 2022).

metabolic issues, as well as specialty formulas for infants with particular medical conditions (Green Corkins & Shurley, 2016). Physicians may recommend different types of formula based on the specific health conditions and needs of infants.

CHAPTER 3: INFANT FORMULA RECALL: REGULATORY FRAMEWORK AND RESPONSES

3.1. Infant Formula Recall in the U.S.

In February 2022, a food safety recall of infant formula occurred due to potential *Cronobacter sakazakii* contamination in Abbott Nutrition's powdered formulas, which are sold under Similac, Alimentum, and EleCare brands (FDA, 2023a). The FDA received four reports of infected infants after consuming Abbott Nutrition's formulas, two of whom tragically died (Jaffe, 2022). These formulas were produced at Abbott Nutrition's largest facility in Sturgis, Michigan, prior to the recall in February (Jaffe, 2022).

Abbott Nutrition took the voluntary step of shutting down the Sturgis, MI plant and recalled its powdered infant formula products from the market on February 17, 2022 (FDA, 2023a). This recall was further expanded on February 28 to include a specific lot of Similac infant formula, produced in Sturgis, MI (Abbott, 2022b).

After the incident, the FDA investigated the Sturgis plant and issued Form 483 (Notice of Inspectional Observations) to Abbott on March 18, pointing out non-compliance with sanitation protocols (FDA, 2022a) The inspection report revealed the presence of *Cronobacter sakazakii* bacteria, 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 February and April 2022 (FDA, 2023g; Miranda, 2022). This reduction was largely attributed to the shutdown of Abbott Nutrition's largest factory in Sturgis, MI, which accounts for 20% of the U.S.

infant formula production (Berfield & Edney, 2022). This disrupted the already fragile supply chain, which had been impacted by the COVID-19 pandemic[6] (Samuel et al., 2022).

Figure 2 provides a timeline of events that occurred during the recall period.

[6] The 2022 infant formula food safety recall was the most significant, but it was not an isolated incident. Over the past three years, there have been ten recalls of infant formula products, with seven of these recalls attributed to potential bacterial contamination (FDA, 2023e). See Table A1 for food safety recalls occurred in 2023.

Figure 2: Timeline of the 2022 Infant Formula Recall
Source: Califf (2022), FDA (2023e), Lincicome et al. (2023)

3.2. Regulatory Framework

The FDA oversees the regulatory framework for infant formula within the United States. The regulations enforced by the FDA cover safety and nutrition standards[7]. The FDA does not hold a formal approval (FDA, 2023c). However, manufacturers must notify the FDA before introducing their formula, and non-compliance can lead to FDA enforcement measures, including mandatory recalls for adulterated or misbranded products (FDA, 2023c). Infant formula's specific nutrient requirements ensure that all ingredients must meet safety standards. Final product testing is required for *Salmonella* and *Cronobacter*, and water used must meet U.S. Environmental Protection Agency (EPA) standards (FDA, 2023c). Additionally, labeling standards ensure clear instructions for safe use (FDA, 2023c).

3.3. The Special Supplemental Nutrition Program for Women, Infants, and Children

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is a federally funded initiative by the USDA, aiming to assist low-income women, infants, and children in maintaining a healthy diet (USDA, 2023). The WIC program plays a significant role in the infant formula market since infants enrolled in the WIC program accounted for 56% of all infant formula consumption in the United States in 2018 (USDA ERS, 2022). WIC provides food instruments such as vouchers or electronic benefits transfer cards, allowing its participants[8] to purchase a predetermined amount of specified products, including infant formula, from authorized retailers (Tiehen & Frazão, 2016).

[7] Specified in the FD&C Act's Section 412 and in 21 CFR parts 106 and 107.

[8] Prospective participants should be either pregnant or non-breastfeeding women (up to 6 months or 1 year after childbirth), infants up to 1 year old, or children up to 5 years old. Additionally, their household income should be at or below 185 percent of the federal poverty guideline. Furthermore, individuals or their family members should not already be participants in SNAP, Medicaid, or the Temporary Assistance Program for Needy Families (TANF) (Oliveira et al., 2011; USDA FNS, 2023a).

Data from U.S. Department of Agriculture Food and Nutrition Service (USDA FNS) demonstrates that the overall count of WIC participants reached approximately 6.2 million in 2022, with calculations showing that 22% were infants (USDA FNS, 2023c). The author's calculations show that, among infant participants, 64.1% were exclusively formula-fed in February 2022, and this percentage gradually decreased to 59.2% by September 2022 (USDA FNS, 2023c). As of August 2023, this percentage was calculated as 58.4% (USDA FNS, 2023c).

Since 1989, Congress has required WIC state agencies to use competitive bidding to award infant formula contracts to the lowest wholesale price bidder, providing discounts to infant formula purchases made by WIC participants (USDA FNS, 2023d). The contract price is determined by subtracting the rebate provided to WIC from the manufacturers' lowest national wholesale price of infant formula (An et al., 2023; Oliveira & Davis, 2006). The amount of rebate can vary for different types of products and a manufacturer can offer smaller rebates for some products such as liquid formulas (Oliveira & Davis, 2006). However, this manufacturer can still win the contract by providing a large rebate on a product that has more weight in the market, such as powdered formula (Oliveira & Davis, 2006). Contract renewals occur approximately every four years (Oliveira et al., 2011). Rebates provide significant funding for WIC, totaling $1.6 billion in fiscal year 2021, about one-third of the overall cost (Oliveira et al., 2011; USDA FNS, 2023c). This approach can be challenging for non-contract manufacturers, especially the smallest ones (An et al., 2023; FDA, 2023g).

Since the mid-1990s, three major manufacturers – Abbott, Mead Johnson, and Nestle Gerber – have secured most WIC infant formula contracts[9] (Oliveira et al., 2011). The leading manufacturer in the infant formula market, Abbott Nutrition, holds most of the exclusive state

[9] Currently, Abbott holds 37 contracts, Mead Johnson has 13, and Nestle Gerber has 6, excluding Indian tribal organizations (USDA FNS, 2023d)

contracts for supplying WIC participants (USDA FNS, 2023d). This is a factor that strengthens the dominance of Abbott Nutrition in the marketplace. Companies with WIC contracts typically see a substantial 74% increase in market share due to direct sales from WIC and indirect effects, such as increased brand visibility through prominent shelf placement, physician recommendations, word-of-mouth among parents, and enhanced brand loyalty (Oliveira et al., 2011).

3.4. Response to the Recall

3.4.1. Policy Response

During the infant formula recall, the U.S. federal government acknowledged the severe shortage in the U.S. market and took action to address this crisis. Table 3 demonstrates the policy response of the U.S. government during 2022, in the light of the food safety recall.

Table 3: Governmental Response to the Recall

Policy Response	Definition
Infant Formula Enforcement Discretion Policy (16 May 2022)	The act permits the FDA to allow safe and nutritious infant formula products to be introduced into interstate commerce, even if they don't fully comply with all regulations.
Infant Formula Supplemental Appropriations Act (18 May 2022)	This act allocates $28 million in emergency funds to the FDA with a purpose of recruiting additional staff for conducting more thorough inspections of facilities that manufacture infant formula.
Invocation of Defense Production Act (18 May 2022)	It expedites infant formula production, ensuring manufacturers obtain essential raw materials and consumables.
Operation Fly Formula (18 May 2022)	This operation conducted flights to bring safe infant formulas from overseas.
The Access to Formula Act of 2022 (21 May 2022)	This Act granted the USDA permanent authority to issue waivers during emergencies, allowing greater flexibility in relaxing certain WIC program requirements to ensure participants access infant formula. Moreover, it requires the USDA to include provisions in formula contracts to ensure manufacturers create a disaster plan.
Infant Formula Transition Plan for Exercise of Enforcement Discretion (29 Sep 2022)	It enabled an extension for enforcement discretion that is specifically applied to companies that showcased their commitment to aligning with all U.S. requirements.
The Food and Drug Omnibus Reform Act of 2022 (29 Dec 2022)	The act aims to fix regulatory issues causing infant formula shortages by requiring annual FDA reports, supply enhancement plans by manufacturers, and a national strategy to improve the supply chain and prevent contamination. It also mandates the creation of an "Office of Critical Foods" within the Center for Food Safety and Applied Nutrition (CFSAN) and requires risk management plans for manufacturers.

Source: FDA (2022b, 2022c, 2023b, 2023g), H.R. 7791. (117th Congress) (n.d.), Jaffe (2022), USDA FNS (2023b), HHS (2022a), White House (2022)

As a response to the major recall, USDA initially provided some waivers that offered brand, type, and size flexibility (maximum monthly allowance waivers), vendor exchange waivers, and medical documentation waivers for noncontracted formulas via a collaboration with the White House, United States Department of Health and Human Services (HHS), and FDA (USDA FNS, 2024). The Access to Formula Act of 2022 granted the USDA permanent authority to issue waivers during emergencies, allowing greater flexibility in relaxing certain WIC program requirements to ensure participants have access to infant formula (USDA FNS, 2023b).

Other than the responses mentioned in Table 3, President Biden urged the Federal Trade Commission (FTC) and state attorneys to combat price gouging and unfair market practices, leading to an FTC investigation and the Department of Justice's encouragement for state attorneys to oversee and address instances of price gouging (HHS, 2022a, 2022b). Additionally, on May 19, 2023, the FDA announced that the National Academies of Sciences, Engineering, and Medicine (NASEM) would conduct a study, sponsored by the HHS and the FDA, to identify challenges in the supply of infant formula, market competition, regulations, and requirements for entering the market in the EU and the USA. The FDA will use insights from this study to develop a long-term national strategy (FDA, 2023g).

3.4.2. Consumer Response

Infant formula has a crucial impact on the lives of millions of babies. For some, infant formula serves as the sole source of nutrition, while for others, it is a significant supplement. Therefore, the impact of the 2022 infant formula safety recall is substantial, as many families face challenges in providing and sustaining an adequate supply of breast milk, the only other recommended alternative for infants six months and younger.

While the impacts of the 2022 food safety infant formula recall on consumers are yet to be completely understood, early studies found that the shortage had a disproportionate impact on non-white and Hispanic/Latino consumers, as well as participants in nutrition assistance programs (Kalaitzandonakes et al., 2023). Mothers reported allocating more financial resources to formula due to rising costs, stockpiling, increasing the time spent searching for formula at multiple stores, and traveling longer distances to allocate formula (Marino et al., 2023). This situation took a toll on the mental and emotional well-being of mothers, resulting in increased anxiety (Sylvetsky et al., 2022).

According to Datasembly, out-of-stock rates rose from 45% to 70% by the end of May. States like California, Missouri, Minnesota, Nevada, Montana, Louisiana, Arizona, and Utah saw out-of-stock rates exceeding 80% (Paris, 2022b). By early July, in-stock items improved to about 70%. Alaska, Utah, Wyoming, Kansas, and Colorado had the lowest availability, with in-stock rates below 60% (Paris, 2022a).

Parents sought alternatives to infant formula when the product was not readily available. Some parents turned to donor milk banks (Cernioglo & Smilowitz, 2023), while others attempted to find formula from multiple stores and online retailers, relying on others to help them locate it (Kalaitzandonakes et al., 2023). Some parents switched to a different brand or type of formula (Fisher et al., 2023; Sylvetsky et al., 2022), some continued breastfeeding or introduced solid foods earlier than anticipated, and yet others even diluted formula so that it could last longer (Marino et al., 2023).

However, some of these alternative solutions can be harmful, leading to adverse effects on the child's health. For instance, diluting the formula may lead to risks of hyponatremia, growth failure, and anemia (Abrams & Daniels, 2019). Other feeding practices, such as switching the type or brand of formula, or replacing formula with cow's milk or juice, can result in nutrient deficiencies, allergic reactions, and choking hazards due to feeding infants inappropriately for their age (Marino et al., 2023).

CHAPTER 4: MATERIALS AND METHODS

4.1. Qualitative Interviews: Sample Selection and Procedures

To gain an in-depth understanding of the infant formula industry and supply chain disruptions in the United States, semi-structured interviews were conducted with professionals in the field. Qualitative methods, such as interviews, are particularly useful when little or no information is known about a topic, when main questions remain unanswered despite extensive literature using quantitative methods, when the topic has a complex structure that needs to be unfolded, or when interviewees' subjective thoughts are required (Starr, 2014). Interviews are a widely used qualitative data collection method in social sciences, including economic studies on topics for which quantitative data is not readily available or feasible to collect (Starr, 2014). Given the limited research on the infant formula industry and recalls, as well as the scarcity of secondary data on infant formula purchases during and after the recall period, conducting interviews with key stakeholders in the industry is essential for understanding the structure of the infant formula industry and the impact of the 2022 food safety recall.

Sample sizes for studies employing interviews can vary depending on the research objectives. In qualitative interviews, interviewees are generally chosen purposively instead of via a randomized sample. This sampling strategy is called purposive or purposeful sampling (Patton, 2015). The reason behind it is to reach research objectives more effectively, thus interviewing individuals who are information-rich is the key (Patton, 2015). Even though a larger sample size is seen as the criteria for having more comprehensive and generalizable results, it should not be seen as a crucial issue. The most important aim of a qualitative interview is to clarify the concepts and increase the understanding of the topic and achieve the goals of the research, rather than yielding empirical generalizations (Patton, 2015; Starr, 2014).

To examine various aspects of the infant formula industry, a diverse set of interviewees was selected. Potential interviewees were contacted via email or LinkedIn and invited to participate in the study (see Table A2 and Appendix C for more detail). In total, interviews were conducted with 14 participants. Several individuals declined the invitation, stating they were unable to discuss the topic because of its sensitive nature.

Interviewees included representatives from the infant formula manufacturing industry, food retail industry, food safety specialists, WIC coordinators, and physicians (see Table A3 for more detail). The interview with a large manufacturer focused on the infant formula manufacturing industry, covering topics such as supply chain structure, market challenges, and infant formula recalls. Retailers provided insights into the infant formula market structure, supply chain disruptions, and recall procedures. Additionally, food safety specialists were consulted to understand food safety and quality assurance throughout various supply chain stages, along with the challenges leading to supply chain disruptions. WIC coordinators were interviewed to gain insights into the WIC program, and coping strategies utilized by WIC and its participants during the 2022 recall period. Furthermore, pediatricians were interviewed to enhance our understanding of infant formula products, and the coping mechanisms employed by both pediatricians and their patients during the recall period. The interview questions tailored for each group of professionals are presented in Appendix D.

Before conducting the interviews, approval was obtained from the MSU Institutional Review Board. The study's consent form can be found in Appendix B.

4.2. Data Collection

The interviews were conducted through Zoom and recorded for transcription purposes. All interviewees were informed about the interview process, including confidentiality measures

and their consent was obtained to record the meeting. The data collection period started on February 13, 2024, and ended on March 29, 2024. Each interview lasted approximately 35 to 90 minutes. 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. These interviewees worked in various departments related to the formula category of a retail company and thus preferred to be interviewed together to provide the most precise information. The interviews were semi-structured to allow probe and follow-up questions to clarify or obtain more information from the interviewee (Patton, 2002).

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 referenced in the “3.4.1. Policy Response" section. The data gathered from NASEM was mainly used to detail the supply chain map.

4.3. Data Analysis

Thematic analysis was conducted on the interview data using ATLAS.ti, a qualitative data analysis software. ATLAS.ti was selected for its advantages, such as enhancing research credibility and replicability, saving time, and simplifying the data management process (Hwang, 2008). The coding process, which is the first stage of thematic analysis, involves tagging data with words or short phrases to condense it into manageable chunks for further analysis, pattern identification, interpretation, and drawing conclusions to address the study's research questions (Miles et al., 2014). The coding methodology outlined by (Miles et al., 2014) was followed in this study.

Initially, the interviews were transcribed verbatim. Then, First Cycle coding was conducted iteratively, allowing for inductive analysis of the data to let concepts and themes emerge naturally. Subsequently, codes were refined and categorized to begin constructing the codebook (see Appendix G1 for defined theme categories). Simultaneously, definitions for the codes were developed. As the coding process progressed, the definitions and rules for applying the codes were refined and improved. This was done to establish clear, essential codes that all researchers involved in the study could easily agree upon and use to code the data effectively. The Second Cycle coding method was then applied to group the data chunks identified in the First Cycle coding into smaller categories or themes, providing a more meaningful unit of analysis (see Appendix G2 for themes and quote examples). This method, also known as Pattern Coding, reflects its goal of identifying patterns based on concepts/themes, theories, relationships among individuals, and causes/explanations (Miles et al., 2014).

Rubin & Rubin (2012) suggest that a quality interview study yields results that are "fresh and real", "balanced and thorough", "accurate and credible", and "rich and detailed". To obtain fresh and real results, unknown or less-explored information surrounding the infant formula industry and the 2022 infant formula safety recall were identified, and individuals who have information on the topic were contacted. To create a balanced and thorough study, interviewees with different professions from various institutions were selected to gather a range of perspectives. To achieve accurate and credible results, interviews were carefully transcribed verbatim and double-checked; furthermore, special emphasis was placed on consistency and transparency. Follow-up questions and probes were used to obtain information in greater detail and gather richer data to identify additional themes. Conclusions were drawn by clearly

referencing the interviews. While aiming to sustain consistency in themes and individuals, the goal was not to eliminate inconsistencies but to identify the reasons behind them.

CHAPTER 5: RESULTS

5.1. The Infant Formula Supply Chain: Structure and Information Flow

The infant formula supply chain, illustrated in Figure 3, begins with ingredient allocation from suppliers.

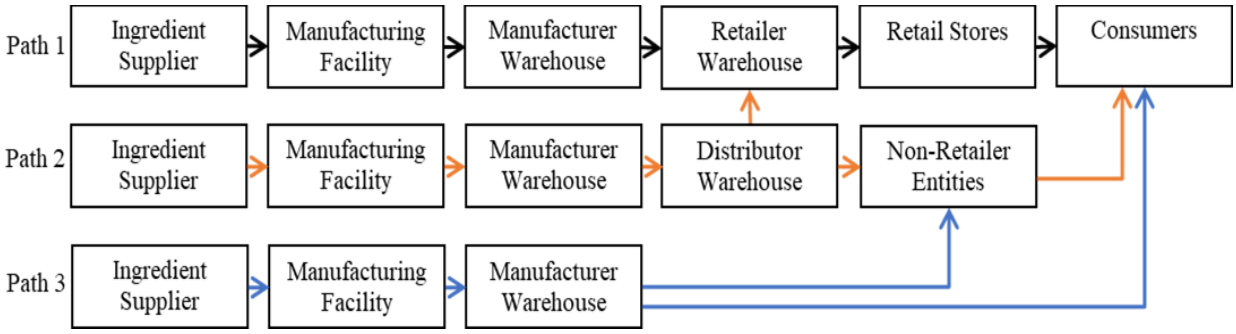

Figure 3: Infant Formula Supply Chain and Information Flow

Note: 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

The primary ingredients, such as Milk Protein Concentrates (MPCs), lactose, and caseinates, are sourced both domestically and internationally, with New Zealand being a major international supplier (Manufacturer1). Other inputs such as carbohydrates, oils, vitamins, and minerals are mostly sourced regionally for cost reasons, while special ingredients such as Human Milk Oligosaccharides (HMO) are obtained from specific locations in Europe, as mentioned by Manufacturer 1.

After production, infant formula is stored in the manufacturer's warehouse for quality assurance and safety stock. Once approved, the product is primarily distributed to retailer warehouses, and then to retail stores where consumers purchase it (Manufacturer 1, NASEM, 2023a). Less commonly, manufacturers distribute to distributor warehouses, which then supply retailers or non-retailer entities (hospitals, institutions, medical offices) before reaching consumers (NASEM, 2023a). Some manufacturers directly distribute to non-retailer entities or

consumers, such as Bobbie's consumer subscription service (NASEM, 2024). Internationally manufactured products are shipped to the US manufacturers' warehouse by sea or air freight, then follow the same distribution process as domestic products (NASEM, 2023a).

Retailers determine storage and shelf placement of infant formula based on WIC requirements and demand forecasts (Retailers 2 and 3). WIC-contracted brands and sizes are prioritized on shelves, with other products arranged around them (Retailer 2). Specialty formulas and expensive formulas with lower expected sales have minimal facing (Retailer 2). Retail pricing is influenced by competitors' prices, manufacturers' minimum advertised prices, and costs associated with the product, transportation, and handling (Retailer 2). Pricing strategies vary among retailers, with drug stores offering higher prices but more discounts, and box retailers carrying bulk sizes at lower prices with less variety (Retailer 2). Despite these differences, price discrepancies are not substantial. Retailers occasionally run promotions funded by vendors, but some invest this fund in themselves instead, as promoting infant formula has been challenging (Retailer 2).

In the US, advertising infant formula on TV is prohibited, prompting manufacturers to develop alternative promotion strategies (Manufacturer 1). One such approach is medical detailing, also known as the gratis model, where pharmaceutical companies distribute free formula samples to non-retailer entities such as doctor's offices and hospitals (U.S. GAO, 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). Moreover, Pediatrician 2 noted that companies without WIC contracts tend to distribute more free samples. 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 lack WIC contracts.

The infant formula supply chain faces its challenges at different stages. The challenges in the ingredient allocation stage, their impact, their reasons, and coping strategies are indicated in Table 4 as they were noted by Manufacturer 1. These challenges include variable mineral and vitamin contents in dairy products, the high specialization of infant formula ingredients, and geopolitical disruptions in transportation.

Table 4: Supply Chain Challenges and Coping Measures at Ingredient Allocation Stage

Supply Chain Stage	Challenges	Impact	Reasons (R) Coping Measures (C)
Ingredient Allocation: Region Identification	Variability in mineral and vitamin contents of dairy products.	Inconsistent quality of ingredients.	R: Seasonal effect, and cow diet. The seasonal effect is exacerbated by climate change. C: Diversifying sourcing regions
Ingredient Allocation: Supplier Identification	The infant formula market is highly specialized.	Limited supplier options, potential ingredient shortages, and increased complexity of ingredient procurement.	R: Infant formula manufacturers are a small fraction of the market for suppliers. Specialized ingredients quickly shrink the number of suppliers, as not every supplier can meet certain levels that have a specification between food and pharmaceutical grade. C: Diversifying supplier partnerships.
Ingredient Allocation: Transportation	Geopolitical challenges causing transportation issues.	Disruptions in supply chain flow, leading to delays and potential shortages.	R: Supplying ingredients internationally brings challenges within transportation such as piracy in the Red Sea. C: Exploring alternative transportation routes and duplicating supply sources.
Ingredient Allocation: Transportation	Interruptions in transportation during the Covid-19 pandemic.	Disrupted supply chain flow and increase in out-of-stock rates.	R: Just-in-time approach, non-robust safety stocks, non-available commercial flights. C: Chartering their own planes to obtain ingredients, increasing safety stocks, buying more warehouses, and stating a required amount of safety stock in contracts with ingredient suppliers.

In addition to supply chain challenges, the infant formula market faces other challenges that create barriers to entry and stay in the market. The following challenges were addressed by Manufacturer 1. In the infant formula industry, regulatory challenges have increased significantly

over the years. Frequent regulatory changes create confusion and difficulty in meeting realistic standards. There are instances of a lack of clear guidance on the regulatory process. Moreover, government agencies may not fully understand the time needed to implement changes, creating a mismatch between regulatory timelines and the industry's adaptability. Suppliers may hesitate to invest, as infant formula represents a small portion of their business. Companies can navigate these challenges and ensure compliance by maintaining strong supplier relationships and diversifying with non-commoditized products.

Another challenge that new entrants face is limited production capacities due to the time-consuming and costly process of constructing specialized manufacturing facilities, ensuring compliance with regulations[10], and expanding or adding new manufacturing lines. Moreover, struggles in establishing a robust supply chain network in the U.S. further exacerbate their challenges in holding a foot in the market.

5.2. Safety of Infant Formula: Risk and Assurance

Cronobacter sakazakii is a bacterium that can be found in the normal environment and poses a high risk for infants, especially premature and young infants, whose immune systems are underdeveloped and not always able to tackle potential bacterial exposure or other food safety-related issues (Food Safety Specialist 3).

The Council of State and Territorial Epidemiologists designated *Cronobacter sakazakii* as a nationally notifiable disease in June 2023, with the notification process beginning in 2024 (FDA, 2023f). *Cronobacter sakazakii* has the highest rate of invasive infection among infants, with approximately 18 cases per year (Haston et al., 2023; Patrick et al., 2014). However, due to

[10] Clinical growth studies and protein quality testing (Rat PER bioassay) were addressed as some of the biggest challenges for manufacturers since they require significant financial investment and time commitment (NASEM, 2023b).

its lack of national notifiability, there exists a significant gap in the available data. Pediatrician 1 and Food Safety Specialist 3 suggest that increased surveillance and detection will lead to earlier problem identification, timely industry notification, and improved resilience. However, Pediatrician 1 noted that the lack of national notifiability was due to limited public awareness about the bacteria, and moreover, making a disease nationally notifiable has reporting implications that can be burdensome.

Contamination of infant formula products with this bacteria can occur at different stages of the product's processing. In the production stage, Food Safety Specialist 3 mentioned that in dry processing facilities like powdered infant formula facilities, water usage should be very limited, and after wet cleaning, the water should be kept out. Therefore, roof leaks, as observed in the Sturgis facility, or any event involving water, can cause these organisms to grow and multiply, potentially leading to contamination. Not only water but also air movement or circulation could cause contamination (Food Safety Specialist 3). Moving to the formula preparation stage before consumption, these bacteria can infect infants if safety recommendations are not followed (Food Safety Specialists 1, 2, and 3).

To prevent contamination, stakeholders must adhere to strict food safety practices throughout the supply chain. Figure 4 outlines these practices for each stage, based on information provided by Food Safety Specialists 1, 2, and 3.

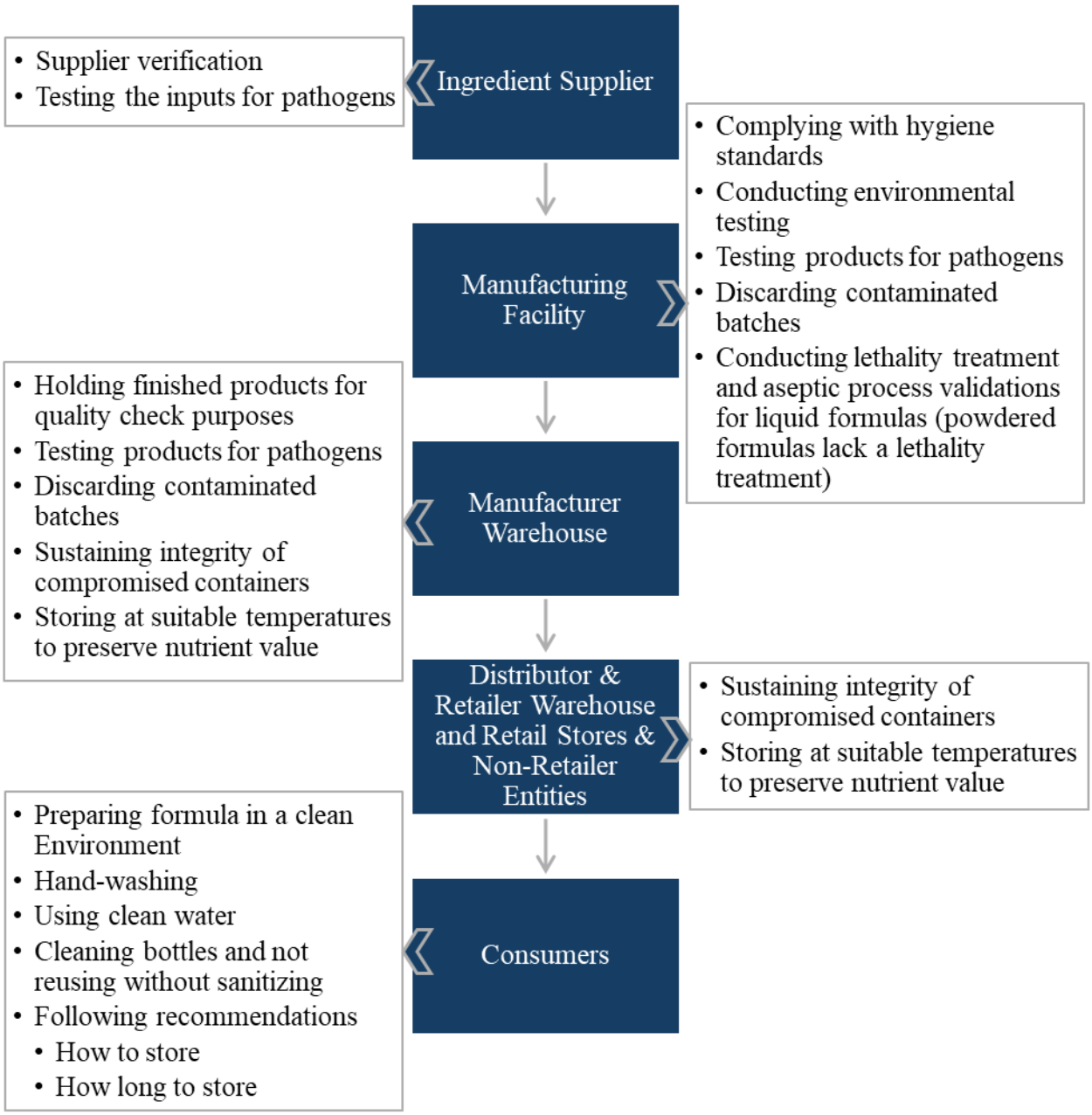

Figure 4: Ensuring Safety and Quality of Infant Formula Across the Supply Chain

However, non-compliance with recommendations remains a significant issue, despite education and advice. Food Safety Specialists 1 & 2 emphasize that individuals often fail to follow best practices, even with simple tasks such as handwashing. While many consumers express interest in recall information, they often fail to act upon it and check the status of recalled items (Food Safety Specialist 1).

5.3. The After Recall: New Prospects and Challenges for Policy Makers, Industry Operators and Consumers

Among all the policies implied and actions taken by the government, interviewees of this study mentioned WIC flexibilities, Operation Fly Formula, and the Defense Production Act as effective policies, or the ones that they are more aware of. After the recall, due to the severe shortage, the government put some relaxation on the restrictive import regulations. This includes Operation Fly Formula and Enforcement Discretion (see 3.4.1. Policy Response). The imported formulas reached consumers through retailers, WIC agencies, or online platforms. Retailer 2 mentioned that some of the imported formulas had higher retail prices, so even though it was helpful to have options, it was not a realistic option for some customers due to lack of affordability. Pediatrician 3 addressed that even though these formulas had to follow FDA requirements, their production plants were not getting inspected by the FDA, which could create further issues. Moreover, WIC Coordinator 3 mentioned that there were issues with imported formula cans getting damaged during transportation.

Another government policy was to use the Defense Production Act to prioritize manufacturer access to infant formula ingredients. This was seen as an effective policy by Manufacturer 1, even though it may have negatively affected input suppliers.

As mentioned in the "3.4.1. Policy Response" section, the Food and Drug Omnibus Reform Act of 2022 added requirements for critical food manufacturers, including infant formula manufacturers, to create risk redundancy plans and notify the FDA about production disruptions that may lead to shortages. New Acts, such as the Safeguarding Kids and Families from Critical Food Disruptions Act of 2023 and The Protect Infants from Formula Shortages Act of 2022, have also been introduced in Congress, proposing stricter notification requirements. However,

Manufacturer 1 indicated that the requirements outlined, particularly those related to risk redundancy plans and disruption notifications, remain unclear and are currently undergoing further refinement[11].

The infant formula crisis has led to increased FDA involvement and government-mandated weekly stock-level reporting by manufacturers. While new regulations and inspections aim to improve safety, they can cause supply chain disruptions and delays. Moreover, Retailer 1 addressed that if the FDA goes to an infant formula facility, it creates panic for the stakeholders and causes them to increase inventories in distribution centers and retail stores by ordering more formula.

Changes in practices due to FDA regulations and efforts to improve safety cause supply chain challenges for retailers, as demonstrated in Table 5. Transitioning to a wet cleaning process and longer quality hold times were identified as the most significant supply chain challenges for retailers (see Appendix F for insights provided by Retailers)

[11] *"So, we've been working diligently, trying to understand exactly what the FDA wants. They don't know what they want. And so, I think it's just educating them as well as working together, trying to figure out exactly what we should do if there is a production issue. So that the law mandates that we're supposed to notify the FDA if there is a shortage. So, we have a process that we're putting in place. [...] I think we're working with them trying to really define it. It's a little bit gray right now." -Manufacturer 1*

Table 5: Challenges Caused by Changes in Manufacturing Practices

Challenges	Impact	Reasons (R) Coping Measures (C)
Transition from dry cleaning to wet cleaning.	Slower manufacturing process, reduced production efficiency, delays in supply chain flow, and intermittent out-of-stocks.	R: Increased FDA cleaning requirements. Optimizing cleaning procedures. C: Increasing safety stocks, and communicating with retailers, or other customers.
Longer quality hold times.	Delays in supply chain flow.	R: Increased FDA quality requirements. Enhancing quality control products and implementing robust testing procedures. C: Increasing safety stocks, and communicating with retailers, or other customers.
Throwing all bad batches away that were produced after the last cleaning.	Delays in supply chain flow.	R: Increased FDA safety requirements. C: Increasing the frequency of cleaning practices.

After the major recall, a significant portion of the business shifted to Reckitt, but the company could not meet the increased demand[12]. Retailer 1 indicated that until May 2022, Reckitt managed to catch up with demand. However, after May, the industry encountered inventory shortages and couldn't produce at the demanded rate (Retailers 1 & 2). In February 2023, a year later, both Abbott and Reckitt continued to struggle, with inventory levels remaining critically low for both manufacturers, as mentioned by Retailer 1. However, the supply chain disruptions did not start with the major recall; rather, the recall substantially compounded the already fragile supply chain due to Covid 19 pandemic. Retailers indicated that they aim to return to the inventory levels before the pandemic.

[12] The sales peaked in May due to panic buying (FDA, 2023g)

5.3.1. Policy Changes: WIC flexibilities

WIC formula flexibilities was the most addressed response to the infant formula shortage by the interviewees. The WIC Program typically has many restrictions on the brand, type, and size of formula, including specialty formulas, which require a pediatrician's prescription (USDA, 2023). A specific brand and/or type of formula suggestion from a pediatrician for an infant who does not have a medical condition and a relevant prescription is not sufficient for WIC agencies to provide that formula (WIC Coordinator 1 & 2). If a pediatrician prescribes a formula not included on the WIC list, it is not provided by the WIC Program (WIC Coordinator 2). However, during the shortage, WIC allowed more flexibility in the type, size, and brand of formula, helping parents access safe options available on store shelves (USDA FNS, 2024). WIC-related responses to the recall are outlined in Table 6.

Table 6: WIC Response to the Recall and Shortage: Federal, State, and Local Strategies

Response of USDA[1]	Response of WIC State Agencies	Response of WIC Local Agencies
Providing brand, type, and size flexibility (maximum monthly allowance waivers)	Deciding to provide the flexibilities	Checking various stores to locate formula and informing participants
Providing vendor exchange waivers	Determining products that can be substitutes for the contracted brand's products	Providing assistance beyond working hours in switching participants' benefits to a formula the parent can obtain[3]
Providing medical documentation waivers for noncontracted formulas	Supplying formula for those in emergency situations[2]	Communicating with retailers and sharing inventory information with participants[4]
		Purchasing infant formula with external funding and providing it to participants

[1]Source: USDA FNS (2024)
[2]Some of the WIC State agencies were able to order formulas directly from manufacturers and distribute them among participants in need, however, this solution was not sustainable (WIC Coordinator 2).
[3] This meant that WIC officers had to manually update participants' benefits in the system to enable them to purchase a different type of formula than what their benefits originally allowed.
[4]Inventory data were not up to date, diminishing their effectiveness.

Despite the increased flexibility granted to WIC participants, it was insufficient when shelves were nearly empty. WIC officers employed various strategies to help participants access infant formula (see Table 6). 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 (WIC Coordinator 1).

Transitioning back to contracted brands was challenging, with some states requiring deadline extensions due to ongoing issues with formula availability (WIC Coordinator 3). Specific to some WIC agencies, WIC participants are now able to purchase any approved standard formula that is available without the need 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 (WIC Coordinators 1 and 3). However, WIC agencies have variations in practices, meaning this flexibility is not provided to all participants (WIC Coordinator 2).

5.3.2. 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 can be confusing, making it difficult for parents to make informed choices (Pediatrician 1). The wide array of available formulas and the subtle nuances in marketing claims further complicate the decision-making process for both parents and pediatricians (Pediatrician 1). Pediatrician 1 suggests that this confusion may be intentional on the part of formula manufacturers, allowing them to have a greater influence on formula choices, as well as increase market share and profitability.

Marketing claims, such as "gentle on the stomach" or "lactose-free," may not always have a scientific basis or be necessary for healthy infants (Pediatrician 1; Belamarich et al., 2016). 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 et al., 1999). Pediatrician 2 discussed several factors that influence formula selection, noting that store-brand formulas, which are considered comparable to major brands by experts, provide a more budget-friendly alternative for families. Pediatrician 2 also mentioned that WIC coverage and hospital recommendations play a role in shaping parents' choices. Furthermore, the pediatrician highlighted the impact of various information sources on formula selection, including online resources, advice from other parents, and marketing efforts by formula companies. Throughout this complex landscape, pediatricians and healthcare providers aim to provide evidence-based, unbiased advice on formula choice, considering factors such as the infant's medical needs, nutritional requirements, and family circumstances (Pediatrician 2).

Parents often develop brand loyalty to infant formula that works well for their babies, especially if it's provided as a free hospital sample or covered by WIC, according to Pediatricians 1 and 2. Furthermore, Pediatrician 1 noted anecdotally that many individuals develop brand loyalty, especially as manufacturers co-brand toddler drinks with infant formula, aiming to cultivate brand loyalty.

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. However, the interviewee also noted that in recent years, parents faced a lot of recalls (see Table A1). Except

for a subgroup of parents who are extraordinarily concerned, most parents are reassured about the safety of infant formula products (Pediatrician 1).

WIC coordinators discussed shifts in preferences, focusing on WIC flexibilities and the transition back to normal procedures. WIC Coordinator 1 emphasized the challenges of reverting to the contracted brand and reassuring parents about formula safety, particularly for those who had to switch halfway through. WIC Coordinator 2 explained that some parents believed non-contracted brands were superior, while others resisted switching back and opted to pay for imported products.

Infant formula has a short lifecycle, as babies are only infants for a year. This means that the infant formula market's consumer base changes frequently. Most interviewees noted that new parents may not have experienced the shortage or be aware of previous recalls (Pediatrician 2, Retailers 3 & 4).

Retailers had different perspectives on the matter of changes in consumer preferences after the recall. Retailer 1 explained that Abbott and Reckitt have nearly equal market shares, with Abbott slightly leading in their state, which has a WIC contract with Abbott. They carry only Similac WIC items in WIC stores and all assortments of Enfamil in all stores, adjusting the assortment to meet local customer preferences. Retailers 3 and 4 observed that consumers were ready to switch back to Similac as soon as the products were available. Both Enfamil and Similac sell well in their stores, but Retailer 3 specifically noted that business quickly returned to Similac.

Some interviewees also highlighted that mistrust extends beyond just manufacturers to include the government and medical system. While avoiding delving into politics, they noted the existing lack of trust in the medical system and pointed out the public perception of government

negligence in allowing the shortage to occur (Food Safety Specialist 1, Pediatrician 2, WIC Coordinator 3).

5.4. Coping Mechanisms with the Recall

To boost the supply of infant formula during the shortage period, infant formula manufacturers took action regarding their production practices. Manufacturer 1 mentioned that some manufacturers moved production to their manufacturing facilities abroad to keep certain capacities and meet government regulations. Some manufacturers cut off the volume of production for other products, to free up capacity for infant formula production during this period (Manufacturer 1). To increase the efficiency of production, manufacturers maximized their production capacity and optimized their product lines by reducing the number of sizes and varieties (known as stock-keeping units or SKUs) they offered (Retailer 2). As the market approached normalcy, manufacturers found it necessary to reduce their capacities to address FDA safety concerns (Manufacturer 1).

Additionally, Abbott Nutrition initiated the construction of a new plant in Bowling Green, Ohio, to increase capacity for producing specialty infant formulas. Expected to commence production in 2027, this endeavor reflects a long-term commitment to meet evolving regulatory standards and consumer needs (Abbott, 2022a).

To increase the number of infant formula products on shelves, Retailers stated that they were able to place some formulas imported from overseas on their shelves. They were not importers of record; instead, they purchased them domestically from manufacturers (Retailer 2). During that time, the formulas were brought to the U.S. by Operation Fly Formula (White House, 2022). Retailers were constantly updating planograms, which are visual representations of store shelves, to better reflect changes in the availability of each product (Retailer 2).

Moreover, they were communicating with each store to inform them of any related updates on the recall (Retailer 2).

After some point, retailers started putting limits on infant formula product purchases to ensure that more customers have access to available options.

"Putting the limits on really has to do with making sure more customers have a chance to get some, and that a handful of customers who were there first thing in the morning don't buy at all. You know, it's really a customer-friendly move to make sure that, you know, we spread a limited supply among as many customers as we could." -Retailer 2

Despite improvements in supply, certain retailers maintain the practice of sharing inventory data with select WIC state and local agencies based on needs (Retailer 1). They do so to ensure that participants in the program have continued access to formula. While not all retailers adopted this strategy during the most severe shortage periods or during recent times of relative stability, ongoing collaboration with WIC agencies remains a valuable approach for supporting participants' needs. Retailer 1 mentioned that they are sending inventory information to two states where Mead Johnson/Reckitt holds the WIC contract. This is because Reckitt's product availability has not yet fully recovered from the shortage.

Parents faced limited access to infant formula during the shortage and resorted to various coping strategies, as demonstrated in Figure 5. According to the interviewees, while some strategies were beneficial, others were harmful practices that could lead to adverse health outcomes for babies. Harmful practices were prevalent on social media and other unreliable sources (Pediatrician 2, Food Safety Specialists 1, 2, and 3).

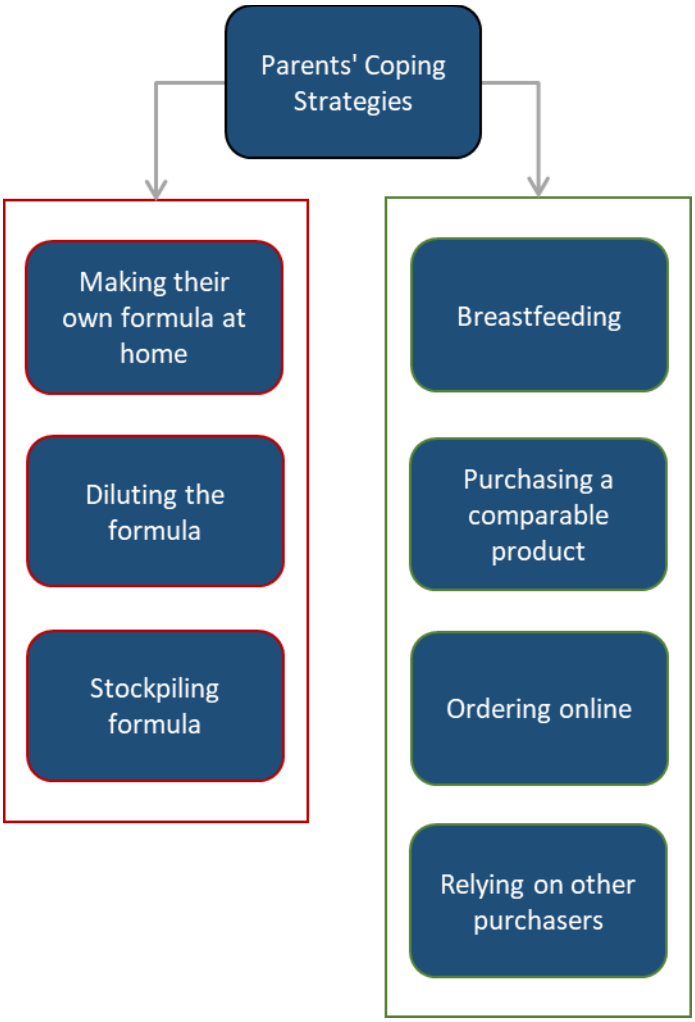

Figure 5: Coping Strategies Used by Parents/Caregivers
Note: The red box lists harmful practices, and the green box lists safer practices.

Interviewees identified stockpiling, homemade formulas, and diluting formula as very harmful practices. Media reports about the recall led to panic buying, which accelerated the shortage (FDA, 2023c). Additionally, homemade formulas lacked proper nutritional value and posed contamination risks, while diluting formula compromised its nutritional content (Pediatrician 2).

During the shortage, AAP advised giving cow's milk to healthy babies after 6 months of age if there are no other options available (AAP, 2022b). However, there is limited or contradictory information regarding the standard amount of cow's milk for infants aged 6-12

months (AAP, 2022c). The lack of specific guidelines by AAP trickles down to professionals in the field. Pediatrician 1 and WIC Coordinator 1 offered differing advice on when to transition infants to milk in the interviews, highlighting the lack of standards and clear guidelines.

Buying comparable products, checking different stores, and relying on relatives and friends to purchase formula from a different store were safer strategies (Food Safety Specialist 1 & 2, Pediatrician 1& 2). Food Safety Specialist 1 addressed that seeking information or purchasing infant formula from non-regulated sources should be avoided. Many parents coped by ordering FDA-regulated formula online from reputable sources when they couldn't find it on store shelves (WIC Coordinator 1). Though often more expensive, options like direct-to-consumer channels and imported formulas were available (Retailer 5; NASEM, 2024). However, this wasn't an option for parents relying on WIC benefits to purchase formula (Retailer 1).

Pediatrician 1 mentioned purchasing toddler drinks with required nutrients for babies, as recommended in an AAP newsletter, but not as a formal recommendation. Another coping strategy that emerged from the data was breastfeeding, considered the best way to feed healthy infants by pediatricians (Meek & 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, reported an increase in breastfeeding initiation rates among WIC participants but noted that initiation alone isn't 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. Furthermore, stress is another factor that can negatively impact breast milk supply (WIC Coordinator 1). WIC coordinators stated that the program supports breastfeeding more than promoting infant formula by offering education and increased food in breastfeeding mothers' packages. WIC Coordinators and Pediatrician 2 stressed the importance of supporting postpartum women and addressing existing challenges. Pediatrician 2 and WIC Coordinator 3 emphasized the need to improve parent education on breastfeeding benefits, create more breastfeeding-friendly environments, and focus on extending breastfeeding duration.

5.5. Communication: Challenges and Opportunities

Communication dynamics play an important role in effectively coordinating and sustaining the resiliency of a market. By examining these dynamics, we gain insight into stakeholders' coordination efforts and better understand the economic implications of supply chain disruptions.

Figure 6 demonstrates the communication and information flows between various entities involved in the infant formula industry.

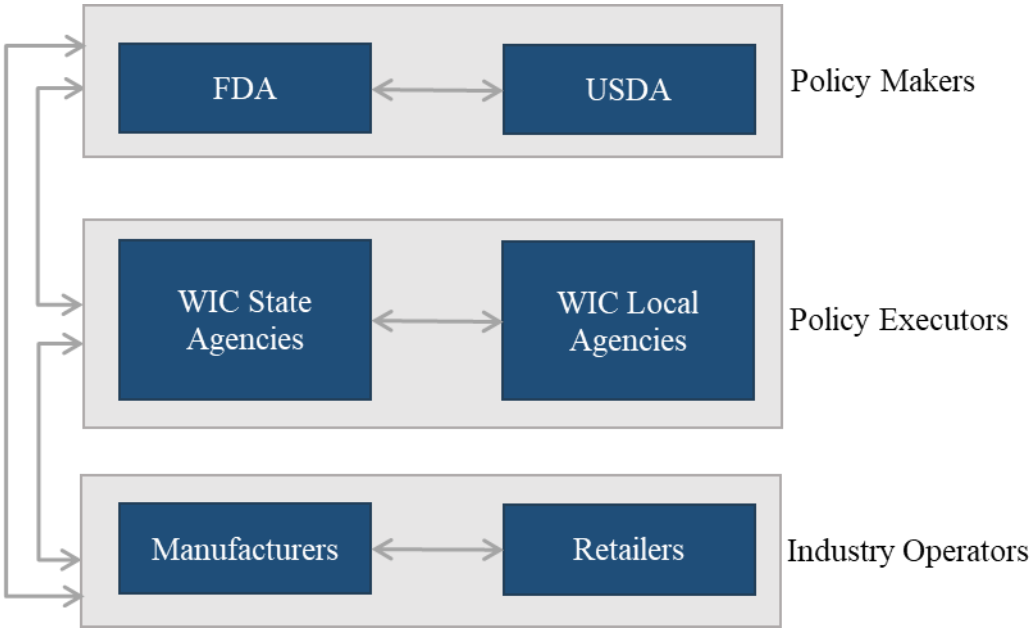

Figure 6: Communication Dynamics: Upstream & Midstream Supply Chain

Figure 6 shows communication dynamics in the upstream supply chain. The source of information was categorized as policy makers, policy executors, and industry operators. All parties are interconnected, and bidirectional communication occurs both between each group and within the groups themselves. Policy makers were defined as FDA and USDA. The information provided by policy makers includes recall information and updates, policy implications, and industry, and consumer guidelines. Policy executors were defined as WIC state and local agencies. Policy executors communicate within themselves to provide information regarding guidance and support to local agencies and WIC participants. Moreover, policy executors inform policy makers and industry operators with updates regarding policies executed. Industry operators were classified as manufacturers and retailers. Industry operators share information regarding inventory, production, demand forecasts, recall notifications, and supply updates.

There have been several communication challenges during the recall, such as the lack of immediate communication between WIC State Agencies and WIC Local Agencies[13] (WIC Coordinator 3), and the incomplete or delayed information from manufacturers to WIC Agencies and retailers (Retailer 2). This situation underscores the critical need for improved inter-agency communication and the development of a robust emergency response plan to handle such crises effectively. Moreover, retailers regularly communicate with infant formula producers to get information regarding the supply of the product. However, Retailer 1 mentioned that manufacturers did not communicate transparently about production issues, as they have been cautious about disclosing information to avoid creating a panic environment and to present a better picture. Moreover, Retailer 2 addressed that there have been discrepancies regarding the supply information provided to different parties, leading to further confusion. Despite initial challenges, retailers noted that producers have improved their communication approach since the beginning of the recall.

Interviewees in the retail industry mentioned that they have an effective recall process and communication system throughout their entire operations for all products, including infant formula as shown in Figure 7.

[13] In detail, WIC Coordinator 3 highlighted a significant issue regarding their WIC State agency's handling of the recall, indicating a lack of cohesive response at the state level: *"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*

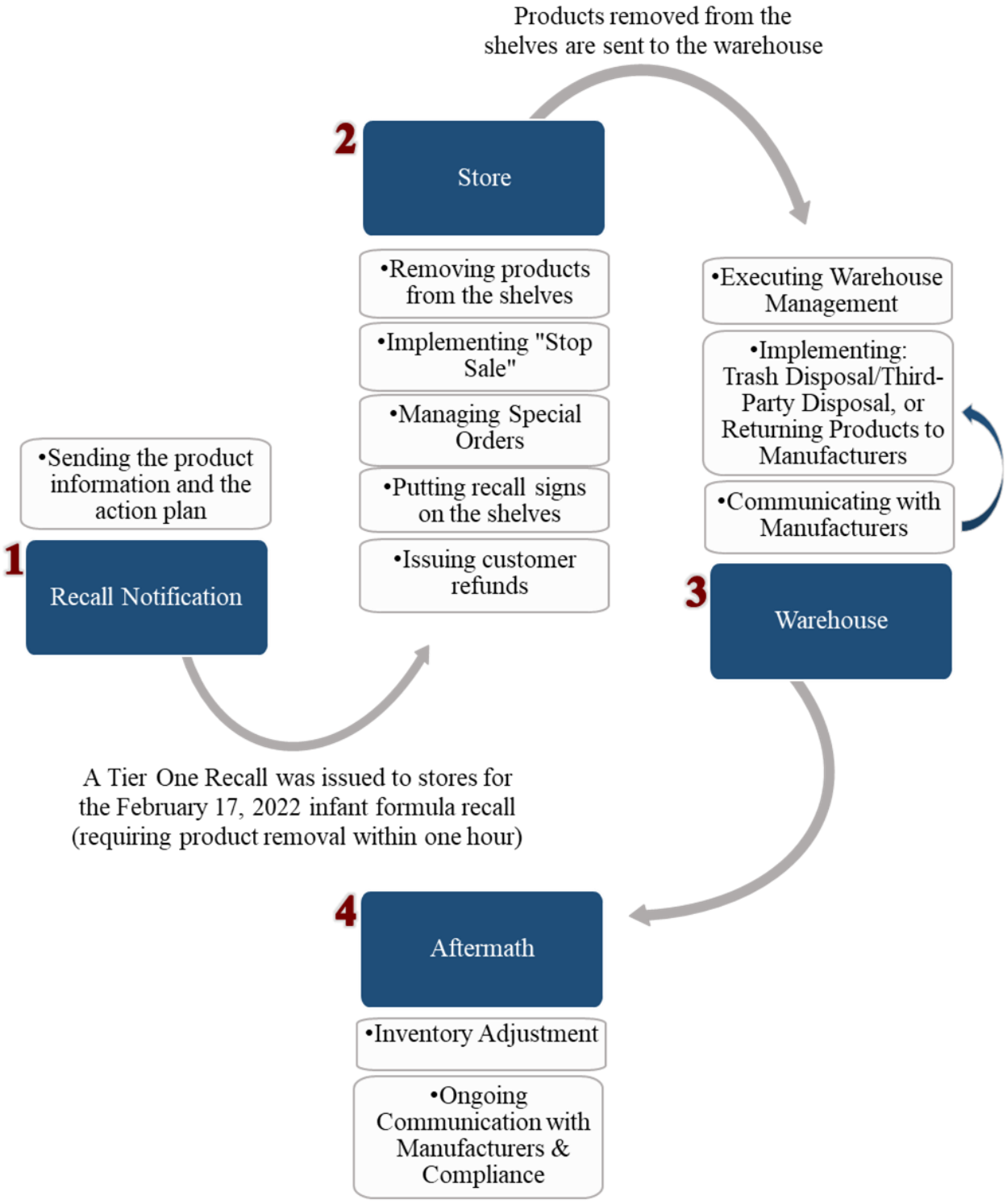

Figure 7: Retailer's Infant Formula Recall Process Flowchart

The process begins with initial notification, where stores are informed about an urgent recall and instructed to remove the affected products from shelves within one hour for tier-one recalls, such as the 2022 infant formula food safety recall (Retailer 2).

At the store level, the recalled products are removed, a "Stop Sale" function is implemented to prevent the sale of affected items at the register, customer-related actions, and specialty formulas that require prescriptions and provided through the pharmacy section are managed (Retailer 2). Recalled products are held in the back room until the disposal method is approved (Retailer 2).

The removed products are then returned to the warehouse for management and disposal. Disposal methods include trash disposal, third-party disposal, or returning products to the manufacturer for further testing (Retailer 2). Discussions with the manufacturer of the recalled products take place to determine the handling method of the recalled products (Retailer 2). Retailers expect the company to cover the costs associated with the recalled products (Retailer 2). Products in the warehouse are also checked and recalled products are ensured to be disposed of properly (Retailer 2). After all this process, inventory adjustment processes begin, and alternative methods for restocking empty shelf spaces, such as pushing other brands' products, are devised (Retailer 2).

During the major recall period, continuous communication occurred with manufacturers, especially Abbott, to ensure adherence to safety protocols, and regulatory compliance teams were involved in these communications (Retailer 2). Throughout the shortage, some local agencies and retailers collaborated to provide participants, parents, daycare providers, and doctor's offices with information about the availability and inventory of infant formula products (WIC Coordinator 3).

In response to severe shortages, an unusual communication occurred involving the White House, which convened meetings with retailers, the FDA, and other stakeholders (Retailers 2 & 3). These information-sharing sessions focused on retailers' forecasts and import processes to better understand the situation and facilitate a more effective resolution (Retailer 2). The involvement of governmental bodies highlights the significance of infant formula availability and the importance of maintaining market stability.

Effective communication with parents and caregivers is of utmost importance, however, reaching out to consumers presents challenges (Food Safety Specialist 1). Based on interviews, various modes of communication were determined, including product labels, QR codes, healthcare providers, WIC clinics, social media, traditional media, university extension, email/text, and government websites. Pediatricians and WIC clinics are trusted sources, but social media has the biggest impact due to its wide reach (Food Safety Specialist 1). However, information on social media can be confusing and misleading, so it's 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 recall, stakeholders communicated with consumers to provide information and support, as demonstrated in Figure 7.

Table 7: Information Flow: Downstream Supply Chain

Stakeholders	Information Shared with Consumers
AAP, USDA, FDA, etc.	Sharing recommendations about infant feeding practices, and guidelines online
Pediatricians	Disseminating information from trustable sources such as AAP, and providing assistance and guidelines regarding infant feeding
WIC State Agency	Notifying consumers regarding the recall via text, developing reference sheets for formula substitutes, and sharing them online
WIC Local Agency	Sharing reference sheets by text, email, social media, or via the WIC app, sharing recommendations from various sources such as AAP and USDA, and sharing information regarding retailer inventory information if available
Manufacturers	Sharing public notices and statements online, engaging in direct communication via consumer service channels
Retailers	Putting notices on the shelf, and sending notifications via text

During the severe shortage period, parents desperately sought help locating formulas or alternative feeding solutions, which was emotionally challenging for those trying to assist them due to limited options. Interviewees shared personal experiences of the toll this took on them:

"And, you know, people would call us and say, 'I can't find the formula. Where do I find it?' And we had no crystal ball." -WIC Coordinator 2

"One, it's a personal thing. I think, like I said, we had to answer calls from all the different consumers. And so probably my worst day at [company name] ever was that one dealing with the supply chain. So, working a 14-hour day trying to get everything moved, and what are the plans, and then jumping on the phone that evening. Listening to moms call you and say, 'How do I get formula for my baby?' That was probably the hardest thing." -Manufacturer 1

CHAPTER 6: DISCUSSION

The major infant formula recall had far-reaching consequences for all manufacturers. The manufacturer at the center of the recall suffered substantial losses, as it had to stop producing in its largest manufacturing plant for months, provide rebates for their competitors' products in its WIC contracted states, compensate retailers for their losses resulting from the recall, and face severe damage to its brand reputation (Manufacturer 1). All of this created a huge impact that will take years for the manufacturer to recover from, and for researchers to estimate.

While other manufacturers increased their market share, their idle capacity was insufficient to meet the country's demand. This crisis reinforced the importance for manufacturers to improve their safety stocks, move away from the just-in-time approach in ingredient allocation and production stages, and diversify ingredient sources.

The major recall has also led to increased attention to and concern for the safety of infant formula products. This has initiated a more proactive search for safety vulnerabilities, as well as the implementation of precautions to prevent potential similar crises. Food Safety Specialist 3 attributed the recent increase in the number of recalls to this heightened awareness. Additionally, retailers mentioned some challenges due to these increased precautions, such as longer quality hold times or increased wet cleaning practices, which lead to delays in the supply chain. All these factors highlight the major recall's significant impact on the entire infant formula industry.

Interviewees emphasized the importance of having well-prepared emergency plans for infant formula manufacturers, retailers, and the government. Such plans would enable quick responses and guidance during crises, particularly given the lack of knowledge across the supply chain and the unexpected impact of the recall. Also, it is essential to formalize clear guidelines

on various infant feeding practices to be followed during a crisis, with appropriate substitutes and precise consumption measures.

Education emerged as a key theme, focusing on addressing knowledge gaps and correcting harmful misinformation. Interviewees were concerned about parents' lack of understanding of safe formula preparation and the risk of misinformation from unreliable sources. Additionally, Food Safety Specialist 1 pointed out that many states do not require food safety training for daycares, revealing insufficient standards[14].

Given the high-risk nature of infants and young children, it is crucial to ensure that parents and caregivers are well-informed about proper food safety practices. While reputable sources like government websites provide valuable information, interviewees noted that parents are less likely to consult them. Therefore, effective strategies for disseminating accurate information to parents and caregivers are essential.

Improving communication dynamics and transparency was another important theme highlighted in the interviews. Interviewees stressed the significance of teamwork throughout the supply chain. Effective communication facilitates timely responses to supply chain disruptions, minimizing economic losses and maximizing access to vital products such as infant formula.

Interviewees highlighted WIC flexibilities as one of the most effective policies enacted during the shortage. While crucial in providing alternatives and sustaining consumer spending, WIC flexibilities were short-term policies, and their sustainability remains a question. As a long-term policy, it eliminates incentives for companies to offer rebates, potentially leading to additional costs for WIC and limiting participant numbers (Yenerall et al., 2024). Therefore, diversification of sources has become a hot topic in the industry. WIC Coordinators of the study

[14] Paez & Alcorn (2018) indicate that 24 states have food safety regulations on their website and only 16 of those states have these regulations specific to childcare facilities.

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 study's interviewees pointed out the market concentration and described the system as somewhat flawed, identifying WIC as part of the problem. However, WIC contracts are not the sole reason for the market concentration, as the market was more concentrated prior to the introduction of the competitive bidding system[15] (Hodges et al., 2024). Nevertheless, the current market structure significantly restricts consumer choice, creating vulnerability tied to the performance of a limited number of companies. The limited number of production facilities capable of producing infant formula in the US also greatly contributes to supply chain challenges.

Interviewees expressed a desire for more market players and production facilities in the U.S. Retailers noted that some top U.S. players operate facilities in countries such as Mexico. Permanently approving these facilities by the FDA could increase the number of production facilities more quickly, considering that the emergent authorization ends in 2025.

During the major shortage, Manufacturer 1 found the government's response slow, attributing it in part to a lack of timely information about the extent of the problem. The interviewee highlighted that measures such as importing formula from outside the country should have been implemented earlier. Pediatrician 1 discussed the potential risks associated with relaxing requirements during shortages, by emphasizing that doing so could compromise safety and quality.

[15] In 1987, the top three manufacturers accounted for the 99% of the market sales (Hodges et al., 2024).

Instead, Food Safety Specialist 3 suggested that funding research to better understand the specific problems that have emerged in the industry over time could help prevent future crises. 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.

Pediatricians indicated that despite the recent crises in the infant formula market, infant formula is a safe product, with the scale of risk being in single digits. However, given infants' vulnerability, any contamination is unacceptable, they stated, as even a single case can have severe consequences. While an increase in the intensity of manufacturer facility inspections is suggested by many interviewees, Manufacturer 1 addressed that the FDA is chronically underfunded, and increasing the intensity of inspections would require additional resources. Despite these challenges, the industry must uphold the highest safety standards and aim for a zero-tolerance policy towards potential risks.

6.1. Comparing Other Major Infant Formula Markets: Europe and China

Europe is the largest infant formula supplier, producing approximately one-third of global supply, and the biggest exporter by exporting around 60% of its production (Chen, 2018).

China is the second largest infant formula supplier, after Europe (Chen, 2018). However, almost all formulas produced in China are consumed in the country (Chen, 2018). Approximately

half of Europe's exports are made to China (Chen, 2018), indicating the significance of imported products in the Chinese infant formula market.

The European formula market is concentrated, with leading manufacturers holding substantial market share[16]. Moreover, infant formula recalls also take place in the European market. In the last four years, five infant formula recalls that were determined to pose serious risks occurred in Europe, three of which were related to *Cronobacter sakazakii* contamination of the products (Rapid Alert System for Food and Feed, 2024). However, these recalls do not pose as substantial risks to the supply of formula as they do in the U.S. This is because, despite the concentration, the European infant formula market has many smaller players (Speed, 2023). In China, on the other hand, the infant formula market is more competitive (Koe, 2024).

Therefore, the U.S. infant formula market is different from these two largest infant formula markets, as it presents a highly concentrated market in which formula recalls lead to major crises in the marketplace. Stringent non-tariff regulations are limiting imports from other infant formula markets, which further exacerbates the impact of supply chain disruptions. Differences in nutrient requirements are one of the most challenging factors that limit European formula imports to the U.S. (DiMaggio et al., 2019) However, it is a fact that European Food Safety Authority (EFSA) infant formula regulations are updated based on new scientific evidence, while FDA regulations are more outdated, with few updates since 1980 (DiMaggio et al., 2019). This opens a new avenue for researchers to explore the European policy framework and examine the FDA regulations to facilitate the process of importing European formulas to the U.S. and improve the resiliency of the market.

[16] For example, two leading manufacturers are holding around 85 per cent market share in the UK (Speed, 2023).

CHAPTER 7: CONCLUSION

This thesis examines the U.S. infant formula industry, along with the 2022 infant formula food safety recall. It contributes to the literature by analyzing a market for an important product with no available market substitutes and a highly concentrated market structure. The study presents results that are obtained through qualitative interviews with key stakeholders.

The findings of the research shed light on the infant formula supply chain structure, as well as the challenges and vulnerabilities that contribute to shortages in the marketplace. The research also examines the safety of infant formula by pointing out risks and safety assurance practices. Furthermore, it explores changes in the industry after the major recall, painting an aftermath picture. Lastly, it investigates the coping mechanisms and communication dynamics within the industry in response to the recall.

The results indicate that the infant formula market presents many challenges to manufacturers due to the regulatory framework and unclear regulatory guidelines. Furthermore, the oligopolistic structure observed in both ingredient suppliers and infant formula manufacturers, with only four major manufacturers and a limited number of FDA-approved manufacturing facilities, poses significant risks to the supply of infant formula in the marketplace. The lack of knowledge, transparency and clear standards regarding regulations, communication, and crisis management plans across all stages of the supply chain and at the governmental level prevents a proactive response to crises that occur in the infant formula market. Therefore, this research presents the need for regulatory reforms to address major challenges in the infant formula market; however, providing clear guidelines and realistic standards plays an important role. The competitive bidding system of WIC not only contributes to the fragile structure of the infant formula market but also presents significant challenges to

WIC participants. To eliminate its vulnerabilities and provide more security to the industry, policymakers may need to reassess the bidding system. The policies implemented to increase the supply of infant formula in the U.S. during the shortage were short-term measures that relaxed some requirements. If policymakers consider modifying the requirements in the future, it is crucial to ensure that such changes do not compromise the safety and quality of the formula.

Using qualitative interviews as the primary method of data collection has its limitations. First, due to the sensitive nature of the topic, this study has a limited number of participants. As a result, it does not claim to provide all the key information regarding the U.S. infant formula industry. However, it contributes to the existing knowledge. Second, qualitative methods raise concerns about gathering untruthful information from interviewees (Starr, 2014). To mitigate this, knowledgeable individuals were invited to participate in the interviews. Moreover, information that was vague or for which the interviewee acknowledged a lack of sufficient knowledge was excluded from the study. Additionally, the confidentiality of interviewees was strictly maintained. Third, there is a heightened risk in qualitative data analysis of researchers imposing their own perspectives (Starr, 2014). To minimize this risk, priority was given to properly referencing the interviewees when needed and writing all the results based solely on the interview data and literature.

Future research is required to understand the impact of the regulatory changes implemented after the major recall, both as a response to the recall and to improve the resilience of the infant formula market. Also, the impacts of potential changes to the WIC rebate system on manufacturers, the WIC program, and its participants warrant further investigation. Moreover, given the discrepancies between interviewees' observations regarding consumer preferences and confidence as discussed in the section “5.3.2. Marketing Claims and Emerging Consumer

Preferences", conducting research on consumer behaviors and infant formula market shares is crucial for gaining valuable insights and a clearer understanding of the market dynamics. Additionally, a study investigating parents' adherence to infant formula safety and feeding recommendations, as well as their awareness of post-recall updates and developments, could provide valuable insights into understanding compliance with the recommendations and identifying ways to improve parents' utilization of important safety information. Moreover, investigating consumer confidence in the U.S. medical system and government is essential, as it emerged as an issue in the interviews.

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APPENDIX A: FOOD SAFETY RECALLS

Table A1: Food Safety Recalls of Infant Formula in the U.S. in 2023

Company	Product	Date	Reason
Reckitt/Mead Johnson Nutrition	Enfamil Nutramigen Powder Infant Formula	December 31, 2023	Potential *Cronobacter sakazakii* Contamination
Associated Wholesale Grovers, Inc.	Gerber Good Start	May 14, 2023	Potential *Cronobacter sakazakii* Contamination
Perrigo Company	Gerber Good Start SoothePro Powdered Infant Formula in the U.S.	March 17, 2023	Potential *Cronobacter sakazakii* Contamination
Reckitt	Enfamil ProSobee	February 20, 2023	Potential *Cronobacter sakazakii* Contamination

Source: FDA (2023e)

APPENDIX B: CONSENT FORM

Research Participant Information and Consent Form

1. EXPLANATION OF THE RESEARCH and WHAT YOU WILL DO:

Purpose: This study aims to understand the infant formula product and the US market, particularly focusing on the 2022 infant formula recall and shortage, and its impact on consumers. It also includes an overview of the industry structure, supply chains, and unique characteristics of the product, as well as an examination of related government actions, policies, and industry initiatives.

Procedure: If you agree to participate in the study by signing the consent form, an interview will be conducted via Zoom. The information gathered through the interview will serve as qualitative data to understand the infant formula industry, its challenges, and opportunities. Additionally, the data will contribute to the master's thesis of Sevval Buse Sariman, a graduate student in Agricultural, Food, and Resource Economics at Michigan State University. You must be at least 18 years old to participate in this research.

Confidentiality: The interview will be recorded for transcription and analysis purposes and will not be shared. Participants have the right to have access to their recording. Participants' personal information that would reveal their identity or the identity of people they talk about will not be included in the study.

2. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW:

Participation in this research project is completely voluntary. You have the right to decline participation. If you decide to participate, you may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time.

3. COSTS AND COMPENSATION FOR BEING IN THE STUDY

There will be no costs to participate in this project, and you will not receive any compensation other than the authors' appreciation for your contribution.

4. CONTACT INFORMATION FOR QUESTIONS AND CONCERNS:

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researchers.

Researchers: Sevval Buse Sariman, Graduate Student, College of Agriculture and Natural Resources, Department of Agricultural, Food, and Resource Economics. E-mail: sarimans@msu.edu, Phone number: [number].

Dr. Jeta Rudi Polloshka, Assistant Professor, College of Agriculture and Natural Resources, Department of Agricultural, Food, and Resource Economics. E-mail: rudipoll@msu.edu.

Dr. Vincenzina Caputo, Associate Professor, College of Agriculture and Natural Resources, Department of Agricultural, Food, and Resource Economics. E-mail: vcaputo@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

5. DOCUMENTATION OF INFORMED CONSENT.

You indicate your voluntary agreement to participate by beginning this Zoom interview.

APPENDIX C: INTERVIEW INVITATION FORMAT

Dear [last name],

I hope this message finds you well. I am Sevval Buse Sariman, a second-year master's student in the Agricultural, Food, and Resource Economics Department at Michigan State University. I am conducting thesis research on the supply chains, food safety, and quality assurance of infant formula in the US, under the guidance of Dr. Jeta Rudi Polloshka and Dr. Vincenzina Caputo. Currently, I am conducting interviews with [profession], and would greatly appreciate the opportunity to interview you, in your role as [job title].

Interviews are conducted via Zoom and last 30-45 minutes. If you are interested and available, please use the following link to schedule a time that works for you, preferably in the months of February and March 2024. Click here for the link. If none of the dates suit your schedule, please inform us of your availability.

This study aims to examine infant formula production, distribution, and marketing, as well as challenges faced by the industry (such as notable food safety recalls), and consumers. The qualitative data gathered will contribute to my master's thesis and any resulting academic publications. In line with requirements from the Institutional Review Board of MSU, the names and any other identifiable information about the interviewees will not be disclosed in the thesis or any resulting publications.

If you are interested, we are happy to provide the full list of questions ahead of the interview. For further questions, please contact Dr. Jeta Rudi Polloshka at rudipoll@msu.edu or graduate student Sevval Buse Sariman at sarimans@msu.edu. Your prompt response would be greatly appreciated!

Thank you for considering this invitation! We look forward to the possibility of your valuable contribution.

Best Regards,
Sevval Buse Sariman
Dr. Jeta Rudi Polloshka
Dr. Vincenzina Caputo

APPENDIX D: INTERVIEW QUESTIONS

Questions to Manufacturers:

Section 1: Understanding the Infant Formula Manufacturing Industry

[1] Can you please provide a brief overview of your company's current production setup? This could include your approximate annual production, geographic location(s) of manufacturing facilities, and type of infant formula products, etc. (Any information that you can share, that is not sensitive)

[2] What are the main ingredients of infant formula and where are they sourced from?
How does the geographical location of your company's manufacturing facilities relate to the locations of input providers, in your experience? What other factors determine the location of manufacturing facilities?

[3] Could you please describe the process of getting the infant formula products from your manufacturing facilities to the end consumers? In other words, what is the supply chain for this product?

[4] Based on the description of the infant formula supply chain you provided, where do you perceive the most significant vulnerabilities within the chain?
What measures can be implemented to mitigate these vulnerabilities and enhance the resilience of the infant formula supply chain?

[5] What are the barriers to entry for a new manufacturer in infant formula industry?
What initiatives, if any, exist to encourage entry for new manufacturers in this industry, whether from government entities or others?

[6] Which of the following developments are perceived as challenges or threats by the manufacturing industry, and in what ways do they pose concerns?

i. Increase in breastfeeding initiation rates among low-income women
ii. AAP recommendation changes of breastfeeding for 2 years; instead of 1
iii. Decreasing birth rates
iv. Potential increase in imports of infant formula
v. Increase in food safety recall occurrences
vi. WIC rebates
vii. Market competition
viii. Other challenges not included on this list that you may want to address

[7] Which of the following developments are perceived as opportunities by the manufacturing industry, and in what ways are they regarded as such?

i. Expanding to new markets
ii. Industry consolidation
iii. Specialty formulas
iv. Brand differentiation
v. Other opportunities you may want to address

Section 2: Understanding the Impact of Food Safety Recalls & Market Withdrawal

[8] As you know, a major food safety recall of Abbott Nutrition's selected brands occurred in February 2022. This was a major recall involving one of the top producers of infant formula. However, other food safety recalls and market withdrawals have also occurred in recent years, involving other manufacturers.
In your view, how does a food safety recall affect the company involved?
Are the impacts different for companies not directly involved, if so, how are they different?

[9] What marketing strategies does the company that has experienced a recall use to gain or maintain consumer confidence, for this product specifically?
What marketing strategies do their competitors use to gain or maintain consumer confidence when not directly involved in a food safety recall?
[10] In your knowledge, to what extent have recent food safety recalls led to changes in industry competitiveness, consumer confidence, consumer choice, and/or market shares?
What are the main lessons learned from recent food safety recalls for all parties involved?
[11] In recent years, consumers have often experienced shortages of infant formula products. Such shortages have in extreme cases been manifested with a complete lack of availability (i.e. empty store shelves), and in other cases with limitations on buying (i.e. being limited to buying 2 cases at a time). According to the Household Pulse Survey, around 30% of parents still had difficulty obtaining infant formula in October 2023.
What factor(s) have contributed to these shortages, and are such shortages likely to occur again in coming years?
[12] During the food safety infant formula recall of February 2022, the federal government instituted a series of short-term policy changes as well as programs to alleviate the infant formula shortage in the marketplace.
Which policies and programs are you aware of, and based on your experience, which initiatives were the most effective and why?
[13] Moving forward, what should government regulatory agencies and/or infant formula producers do to mitigate and/ or prevent similar food safety recalls and product shortages in general?

Questions to Retailers:
Section 1: Understanding the Infant Formula Supply Chain
[1] Within the baby formula category, what products does your company sell? (e.g. Regular infant formula, specialty formula, toddler formula etc. / brands)
[2] Could you please describe the process of getting the infant formula products from manufacturing facilities to retail stores? In other words, what is the supply chain for this product? Where is your company in this supply chain?
How much formula should be stored in a store, and what determines shelf space and placement?
[3] Based on the description of the infant formula supply chain you provided, where do you perceive the most significant vulnerabilities/challenges, both generally, as well as specifically at the distribution and retail levels?
What measures can be implemented to mitigate these vulnerabilities and enhance the resilience of the infant formula supply chain?
[4] How is retail price for infant formula determined?
What is the reason behind the price discrepancy of same brand/package size infant formula in different retail markets?
Section 2: Understanding the Impact of Food Safety Recalls & Market Withdrawal
[5] As you know, a major food safety recall of Abbott Nutrition's selected brands occurred in February 2022. This was a major recall involving one of the top producers of infant formula. However, other food safety recalls and market withdrawals have also occurred in recent years, involving other manufacturers.
What was the impact of this major food safety recall on retailers?

[6] What protocols do you have in place to handle and respond to food safety concerns or recalls, particularly in infant formula products?
How do retailers decide to limit quantities for purchase for consumers?
[7] With whom do retailers communicate in the event of a food safety recall, and what information do they need to communicate?
In your knowledge, how was communication handled by retailers for the specific recall of infant formula?
What are the communication and coordination gaps that retailers face, and how could these be improved?
[8] In your knowledge, to what extent have recent food safety recalls led to changes in industry, consumer confidence, consumer choice?
What are the main lessons learned from recent food safety recalls for all parties involved?
[9] In recent years, consumers have often experienced shortages of infant formula products. Such shortages have in extreme cases been manifested with a complete lack of availability (i.e. empty store shelves), and in other cases with limitations on buying (i.e. being limited to buying 2 cases at a time). According to the Household Pulse Survey, around 30% of parents still had difficulty obtaining infant formula in October 2023.
What factors have contributed to these shortages, what general issues do they create at the retailer level?
[10] During the food safety infant formula recall of February 2022, the federal government instituted a series of short-term policy changes as well as programs to alleviate the infant formula shortage in the marketplace.
Which policies and programs are you aware of, and based on your experience, which initiatives were the most effective and why?
[11] Moving forward, what should government regulatory agencies and/or infant formula producers do to mitigate and/ or prevent similar food safety recalls and product shortages in general? What can be done to mitigate challenges faced by retailers?
Do retailers have preparedness plans in case of a similar crisis, or what measures can be taken to improve the market situation for a potential crisis?

Questions to Food Safety Specialists:
Section 1: Understanding Safety of Infant Formula
[1] Let's begin with an exploration of the importance of ensuring food safety in infant formula products. Could you kindly share your insights on this matter?
[2] Using language understood by non-experts, could you describe what measures are taken to ensure that products such as infant formula remain uncontaminated throughout the input allocation and production process?
If there is an indication of contamination with a harmful bacteria or virus while the product is still in the processing facility, generally what are the steps taken?
[3] After leaving the production facility, what are the critical points in the supply chain (from production to retail) and in consumers' homes (up to consumption) where vulnerabilities in food safety might occur? Could you describe those vulnerabilities?
In your opinion, how should these vulnerabilities be addressed, and who is responsible for addressing them?
[4] In your view, who is responsible for educating others across the supply chain (distributors, retailers) as well as consumers about those vulnerabilities?

Section 2: Understanding Recent Food Safety Recalls & Market Withdrawal

[5] As you may know, a major food safety recall of Abbott Nutrition's selected brands occurred in February 2022. This was a major recall involving one of the top producers of infant formula. However, other food safety recalls and market withdrawals have also occurred in recent years, involving other manufacturers. In the last three years, there have been ten recalls of infant formula. Seven of these recalls were due to potential bacterial contamination of products.

In your view, what contributes to the infant formula market experiencing frequent food safety recalls recently?

[6] In your view, how may product contamination with the *Cronobacter sakazakii* bacteria occur?

How do different types of products, such as liquid formula and powdered formula, differ in their vulnerability to bacterial contamination?

[7] What other bacteria or viruses may contaminate infant formula in manufacturing facilities? How about at any other stages of the supply chain or in consumers' homes?

What is the significance of these bacteria or viruses in terms of posing a threat to food safety?

[9] In your view, what is the role of government regulatory agencies in ensuring food safety in the infant formula industry?

How can the government agencies improve their support for the infant formula industry to jointly ensure a safe product?

[10] What are the main lessons learned from this recall for all parties involved?

Questions to Food Safety Educators:

Section 1: Understanding Infant Formula Consumers

[1] There are several types and brands of infant formula products, each with different health claims such as brain nourishment, easy digestion, immune support, or marketing claims such as being #1 recommended by pediatricians or #1 fed in hospitals.

In your experience and observation, how do consumers (parents and caregivers) decide which formula to purchase? What influences and contributes to these choices?

Based on your observation, how do parents perceive and understand the distinctions among diverse types of formulas, including their labels and ingredients?

[2] How loyal are consumers to certain brands when choosing formula products, based on what you've noticed?

[3] How do you foresee the following developments influencing consumer choices or the demand for infant formula? Please provide your insights and perspectives.

i. Increase in breastfeeding initiation rates among low-income women

ii. AAP recommendation changes of breastfeeding for 2 years; instead of 1

What other developments are you aware of that may impact infant formula demand?

[4] What concerns have consumers raised regarding infant formula products and preparation?

[5] What are the vulnerabilities in food safety during preparation of infant formula and feeding? How can food safety be assured in consumers' homes during preparation and feeding?

Section 2: Understanding Recent Food Safety Recalls & Market Withdrawal

[6] As you know, a major food safety recall of Abbott Nutrition's selected brands occurred in February 2022. This was a major recall involving one of the top producers of infant formula. However, other food safety recalls and market withdrawals have also occurred in recent years, involving other manufacturers. In the last three years, there have been ten recalls of infant formula. Seven of these recalls were due to potential bacterial contamination of products.

How did the 2022 Abbott Nutrition recall impact consumer preferences and consumer trust in infant formula products?
How did consumers cope with the shortage? What strategies did consumers employ to feed their babies?
[7] What alternatives do parents have if the infant formula they use for their child is recalled due to food safety concerns? What actions should be taken, and what actions should be avoided in such a situation?
[8] The Council of State and Territorial Epidemiologists made *Cronobacter sakazakii* a nationally notifiable disease on June 29, 2023.
Could you explain this change and help us understand its potential impact on future incidents of infant formula contamination?
[9] After the recall, efforts have been made to alleviate the difficulties consumers face when feeding their babies. For instance, organizations such as the FDA, AAP, USDA, and others have provided guidelines to parents to reduce misinformation. Additionally, WIC participants have been granted increased flexibility, enabling them to purchase from a broader range of options rather than solely purchasing the specified WIC brand by the state contract.
Could you share your perspective on how these efforts assisted parents in increasing their knowledge on the matter and addressing difficulties they face?
Could you share any additional efforts you are aware of that aimed to alleviate the impact of the recall on consumers?
[10] What measures can be taken to enhance communication with consumers and proactively address potential shortages of infant formula and challenges in infant feeding? Who should take these measures?
[11] What are the main lessons learned from this recall for all parties involved?
[12] Considering the occurrence of smaller food safety recalls since then, to what extent are consumers still concerned about food safety and potential shortages in the marketplace?

Questions to WIC Coordinators:
Section 1: Understanding the WIC Program
[1] Could you provide insights into WIC food packages and their inclusion of infant formula? Additionally, how restrictive is the WIC allowance for infant formula?
[2] "Under the sole-source competitive system, a WIC State agency uses competitive bidding to award a contract to a manufacturer of infant formula in exchange for a rebate for each can of infant formula issued to WIC participants." (USDA, ERS)
Could you provide us with information regarding the WIC rebate system, mentioning its advantages? What are the disadvantages? (to producers, WIC, and consumers)
How can the WIC rebate system be improved, and how would this change affect producers, the WIC program, and consumers?
[3] According to USDA (US Department of Agriculture), the breastfeeding initiation rate increased among low-income households during 2009-2017. Is this trend observed in Minnesota as well?
What do you foresee as the impact of this trend?
Additionally, how might WIC contribute to this change?
Section 2: Understanding the Impact of Food Safety Recalls & Market Withdrawal
[4] As you know, a major food safety recall of Abbott Nutrition's selected brands occurred in February 2022. This was a major recall involving one of the top producers of infant formula.

However, other food safety recalls and market withdrawals have also occurred in recent years, involving other manufacturers. In the last three years, there have been ten recalls of infant formula. Seven of these recalls were due to potential bacterial contamination of products.
At the time of Abbott Nutrition's initial recall, on February 17, 2022, could you walk us through what happened those first few days after the recall? How did WIC in [state name] react? What were the first steps taken?
What difficulties did WIC agencies face during this period in their role of supporting infants and their parents? Could you tell us about your experiences?
[5] How does the communication process with WIC agencies work in the case of a food safety recall? Who communicates with WIC agencies and who does WIC agencies communicate with? What information is communicated?
[6] WIC participants have been granted increased flexibility, enabling them to purchase from a broader range of options rather than solely purchasing the specified WIC brand by the state contract.
How did WIC flexibilities come into effect?
In [state name], what other brands became WIC eligible during this policy change? What constraints still persist?
Are you aware of any states that did not provide this flexibility?
[7] How was the end date of these WIC flexibilities decided? Who decides, states or the government?
Once the flexibilities ended, how challenging was it to revert back to the original brands?
[8] What can be done to provide more flexibility to WIC participants moving forward? How would these changes affect the WIC budget and the infant formula industry?
[9] What other efforts were made by WIC to ensure that its participants had access to formula, apart from offering flexibility in brand choice?
[10] What kind of feedback or recommendations did you receive from parents regarding the recall, shortage, and formula choice flexibility?

Questions to Pediatricians:

Section 1: Understanding Consumers

[1] There are several types and brands of infant formula products, each with different health claims such as brain nourishment, easy digestion, immune support, or marketing claims such as being #1 recommended by pediatricians or #1 fed in hospitals.
In your experience and observation, how do consumers (parents and caregivers) decide which formula to purchase? What influences and contributes to these choices?
Based on your observation, how do parents perceive and understand the distinctions among diverse types of formulas, including their labels and ingredients?
[2] How loyal are consumers to certain brands when choosing formula products, based on what you've noticed?
[3] As a physician, what are the considerations that influence your recommendations for infant formula?
For healthy infants, do you recommend a particular brand/type of formula?
[4] "Medical detailing is a practice in which manufacturers market directly to hospitals and medical professionals. This practice can include providing free infant formula samples in hospital discharge packets given to new mothers." (Yenerall et al, 2024).

Is it common practice for most pediatricians' offices to provide free samples? If so, do manufacturers offer the samples, or do pediatrician practices purchase them?
If companies provide free samples, to what extent is the brand the same as the one covered by WIC?
Typically, are there financial incentives for pediatricians to recommend a particular brand?
If parents are offered brand X, either in the hospital or at the pediatrician's office, to what extent do parents stick with that brand, in your knowledge?
[5] What are the factors that determine a parent's decision to feed the baby formula?
[6] How are specialty formulas different from regular ones? Could you explain this difference from both the aspect of ingredients and the impact on health, mentioning why some infants may require specialty formulas?
[7] What are the vulnerabilities in food safety during preparation of infant formula and feeding? How can food safety be assured in consumers' homes during preparation and feeding?
[8] Is infant formula a safe alternative to breastmilk?
Section 2: Understanding the Impact of Food Safety Recalls & Market Withdrawal
[9] As you know, a major food safety recall of Abbott Nutrition's selected brands occurred in February 2022. This was a major recall involving one of the top producers of infant formula. However, other food safety recalls and market withdrawals have also occurred in recent years, involving other manufacturers. In the last three years, there have been ten recalls of infant formula. Seven of these recalls were due to potential bacterial contamination of products.
What difficulties did physicians face during this period in their role of supporting infants and their parents? Could you tell us about your experiences?
[9] How significant is the threat from *Cronobacter sakazakii*, especially for infants?
What are the other foodborne illnesses that pose a threat to infants, both more generally as well as specifically related to infant formula consumption? How? How significant?
[11] In your view, how did the 2022 Abbott Nutrition recall impact consumer preferences and consumer trust in infant formula products?
How did consumers cope with the resulting shortage? What strategies did consumers employ to feed their babies?
[12] What alternatives do parents have if the infant formula they use for their child is recalled due to food safety concerns? What actions should be taken, and what actions should be avoided in such a situation?
[13] The Council of State and Territorial Epidemiologists made *Cronobacter sakazakii* a nationally notifiable disease on June 29, 2023.
Could you explain this change and help us understand its potential impact on future incidents of infant formula contamination?
[14] After the recall, efforts have been made to alleviate the difficulties consumers face when feeding their babies. For instance, organizations such as the FDA, AAP, USDA, and others have provided guidelines to parents to reduce misinformation. Additionally, WIC participants have been granted increased flexibility, enabling them to purchase from a broader range of options rather than solely purchasing the specified WIC brand by the state contract.
Could you share your perspective on how these efforts assisted parents in increasing their knowledge on the matter and addressing difficulties they face?
Could you share any additional efforts you are aware of that aimed to alleviate the impact of the recall on consumers?

[15] What measures can be taken to mitigate challenges physicians face, enhance communication with consumers, and proactively address potential shortages of infant formula and challenges in infant feeding? Who should take these measures?
[16] Considering the occurrence of smaller food safety recalls since then, to what extent are consumers still concerned about food safety and potential shortages in the marketplace?
[17] What are the main lessons learned from this recall for all parties involved?

APPENDIX E: INTERVIEWEE INFORMATION

Table A2: Participation Invitation Counts by Profession

Profession	Number of Individuals Reached	Number of Individuals Interviewed
Manufacturer (Supply Chain Specialist)	21	1
Retailer	38	5
Food Safety Specialist	28	3
WIC Coordinator/ Director	60	3
Pediatrician	22	2

Table A3: 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 Specialist 1	University Extension Food Safety Educator
Food Safety Specialist 2	University Extension Food Safety Educator
Food Safety Specialist 3	Professor of Food Science and Food Safety
WIC Coordinator 1	WIC Coordinator & Registered Dietitian
WIC Coordinator 2	WIC Coordinator & Registered Dietitian
WIC Coordinator 3	WIC Coordinator & Registered Dietitian
Pediatrician 1	Professor in Pediatrics, Physician
Pediatrician 2	Primary Care Pediatrician

APPENDIX F: INTERVIEW QUOTES

Insights of Retailers Regarding Table 6

"And just I guess to add into that, so 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. I think most retail or most manufacturers before were in that 14 to 20 days that they'd hold it now, they're holding it 30-40-45 days. So that's just even if they're producing the same amount, it's longer that it's they're holding, that they're holding on, they're holding it I don't know the specific rule behind that." -Retailer 2

"Another thing that would cause delays is they're due to the FDA; they're switching to a wet cleaning versus a dry cleaning. So, we just experienced that very recently with one of the brands. And so that took longer than they anticipated, which resulted in out of stocks for us."- Retailer 5

*"And you got to also remember, first of the month, so when you k*now *when they do have get the WIC dollars, and things like that, that you as a retailer, 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*

"Yeah, [throwing batches] happens a lot, they don't always tell us that it happens. I just find out by being told that x product is not going to be available, or these couple of products aren't going to be available, or sometimes it's not told, and then we just don't get the product. And then I have to reach out and they told me." -Retailer 1

APPENDIX G: THEME CATEGORIES

Category: Infant Feeding Practices	IFP
IFP: Breastfeeding	IFP-B
IFP: Infant Formula	IFP-IF
Confusion	IFP-IF-C
Safety	IFP-IF-S
Category: Education	EDU
EDU: Education to Parents/Caregivers	EDU-P
EDU: Education to Others	EDU-O
Category: Communication	COM
COM: Communication with Parents	COM-P
COM: Communication within Governmental Agencies	COM-G
COM: Communication within Stakeholders	COM-S
Category: Food Safety of Infant Formula	FOS
FOS: Sustaining Food Safety at Consumer Level	FOS-P
Noncompliance with Safety Recommendations	FOS-P-N
FOS: Sustaining Food Safety at Supply Chain Level	FOS-S
FOS: Food Safety Significance	FOS-F
FOS: *Cronobacter sakazakii*	FOS-C
FOS: Other Risks	FOS-O
FOS: Heightened Food Safety Awareness	FOS-A
Category: Coping Strategies During the Shortage	COP
COP: Coping Strategies of Parents	COP-P
COP: Coping Strategies of Stakeholders	COP-S
COP: Coping Strategies of Governmental Agencies	COP-G
WIC Flexibilities	COP-G-W
Category: Industry Gaps and Recommendations	IGR
IGR: Lack of Standards/Plans	IGR-S
IGR: Recommendations for Governmental Agencies	IGR-G
Recommendations for WIC	IGR-G-W
IGR: Recommendations for Producers	IGR-P
Category: Infant Formula Recalls	IFR
IFR: Food Safety Recall of 2022	IFR-R
IFR: Other Food Safety Recalls	IFR-O

Category: Infant Formula Market	IFM
IFM: Market Concentration	IFM-C
IFM: Market Challenges	IFM-M
IFM: Production Decisions	IFM-P
IFM: Marketing Practices	IFM-K
IFM: Supply Chain	IFM-S

Category: Consumer Preferences	CPR
CPR: Brand Loyalty	CPR-B
CPR: Changes in Preferences	CPR-P
CPR: Mistrust	CPR-M

Category: WIC Program	WIC
WIC: WIC Coverage and Restrictions	WIC-R
WIC: WIC Operations	WIC-O
WIC: WIC Rebate Contract System	WIC-C

APPENDIX H: THEMES AND QUOTE EXAMPLES FROM THE INTERVIEWS

Infant Feeding Practices:

IFP-B (Breastfeeding)

"Unfortunately, particularly when it comes to low-income households, I don't necessarily see the trend changing a whole lot. Not from maybe initiation, but more from a long-lasting perspective. Like, how many babies are still being breastfed at six months? We have so many low-income families that are having to go back to work." -WIC Coordinator 1

"It's a multifactorial time commitment. Most parents and moms want what's best for their baby, but breastfeeding is a commitment. A lot of factors are socioeconomic. Some parents need to go back to work, some moms need to go back to work. And, whether we like it or not, we need to admit that not all places are still breastfeeding-friendly. Some parents go through hoops and are very dedicated, and it doesn't mean they're bad parents if they can't continue. They're very good, but when they see so many barriers, and they're already stressed from raising kids, they just can't afford to fight with this anymore. Sometimes it's a medical reason. I think there is always room for improvement and continuing work for us in pediatrics, explaining why breast milk is a better choice than even the best formulas, especially in the first six months of life and even beyond that. It's also our responsibility to advocate at different levels to make more and more places breastfeeding friendly." -Pediatrician 2

IFP-IF (Infant formula):

"Well, it's generally the macronutrients that are the issue [why some infants require specialty formulas]. So, protein, fat, and carbohydrates. The most common genuine reason to use specialty formula is the infant that has a suspected adverse reaction to the protein, usually an allergy. There are a variety of specialty formulas that have different protein sources. The composition can be an intact protein or anything with intact amino acids, and anything in between. There are also those few infants that have issues with carbohydrates. That's actually a fairly rare situation. But, you know, the way they are marketed [specialty formulas], and pediatricians and parents are inundated with marketing, you would think this is a terrible combination. So, you know, again, it's usually the macronutrients; it's not usually the micronutrients that are an issue.." -Pediatrician 1

"To be honest, I feel personally that a lot of these formulas are comparable, but it all depends on what we use them for. Premature neonates might need more premature formulas. Some babies do not tolerate regular formula; they need better-digested formulas, including what we call elemental formulas. A few babies, not too many, need what we call amino acid-based formulas. There are other formulas for babies and toddlers, depending on the medical issues, including if they have serious kidney problems or something like that, but it's a minority." -Pediatrician 2

IFP-IF-C (Confusion):

"I can tell you anecdotally what I feel. I think they're bombarded with advertisements. You know, the marketing of infant formulas, as you know, is a function of claims, and it gets into some really significant nuances about what they can and cannot claim. That subtlety is lost on just about everybody. So, I don't think it really does very much in terms of encouraging good behavior by manufacturers of these formulas. When I was in training, there were maybe three formula companies, and there were maybe a total of six or seven different formulas available. Now, it's impossible for pediatricians and parents to make heads or tails out of all these different types of formulas and the claims made by each company. I think that's intentional, to confuse them, so that it leaves the marketing in a more powerful position of determining what parents consider. I think it's confused the heck out of everybody, and I think that's intentional." - Pediatrician 1

"I think pediatricians are also confused. There are varying degrees of education among pediatricians; some will take the time, and others do not. You know, these claims of, 'gentle,' 'lactose-free,' because it's gentle on the stomach. That's allowable, but they can't say for other companies, 'lactose-free for your child is best for lactose intolerance.' I can't say that, again, put a disease. I think it confuses the heck out of everybody. So, I think more and more, pediatricians will lean on dieticians to help them sort through some of this stuff. Some will educate themselves about certain formulas if they find themselves needing to prescribe frequently, for example, for allergic conditions. But that gets into a whole other can of worms or different kinds of allergies. It's really a complex landscape." -Pediatrician 1

IFP-IF-S (Safety):

"But otherwise, I think formula is a balanced, pretty safe product. Even with the Cronobacter cases, we're usually talking single digits in terms of the number of children who died from it. Any child dying is one too many, but having said that, it's not on the scale of some other things for sure." -Pediatrician 1

"Yeah, I mean, it's safe. Even with breastfeeding, you need to follow certain rules. I would say, yes, using appropriate products is relatively safe for a reason. It's not something new that in 2022, some formulas were contaminated. It happens once in a while. Breast milk might get contaminated for some reason. But overall, I would say, yes, it's safe." -Pediatrician 2

Education:

EDU-P (Parents/Caregivers)

"I think pediatricians are also confused. There are varying degrees of education among pediatricians; some will take the time, and others do not. You know, these claims of 'gentle,' 'lactose-free,' because it's gentle on the stomach. That's allowable, but they can't say for other companies, 'lactose-free for your child is best for lactose intolerance.' I can't say that, again, put a disease. I think it confuses the heck out of everybody. So, I think more and more, pediatricians will lean on dieticians to help them sort through some of this stuff. Some will educate themselves

about certain formulas if they find themselves needing to prescribe frequently, for example, for allergic conditions. But that gets into a whole other can of worms or different kinds of allergies. It's really a complex landscape." -Pediatrician 1

"Also, I would focus on other things despite shortages of formulas and more difficulties in getting formula. It's important to strongly encourage and recommend not deviating from standards. Don't dilute formula more than it should be because some families try to save. We try to explain and educate families that it might not be safe for their baby to dilute a lot more than it should be or unsafely keep formulas not in the fridge or something like that. I think it's even more important than ever to work on these things." -Pediatrician 2

EDU-O (Others)

"Again, I think the government doesn't understand the total supply chain a lot of times. I think that's where education needs to come into play." -Manufacturer 1

"Yeah, so I think it's kind of a shared responsibility between the industry as well as the government. Academia should probably be included in this mix of people who share responsibility for educating. The distributors and retailers should already have some sort of best practices for handling these types of products. That training then needs to be provided to the folks on the front lines, the people who are stocking the infant formula, or those types of things." -Food Safety Specialist 1

Communication:

COM-P (Communication with Parents)

"So, you know, even when you're in the hospital, there's an opportunity for education. I mean, new moms have a lot going on. You're sleep-deprived, you just gave birth, and there's lots of information coming in. But that might also be a really good time to provide education to people. I looked at the government's information posted online, but I don't think most people would think, 'Oh, I'm going to Google FDA and infant formula and find out how I should prepare it properly.' So, the FDA probably needs to develop materials and information and then use doctors and nurses as an avenue to disseminate the information." -Food Safety Specialist 3

"They were pretty irate at times, saying, 'What am I supposed to do? You're starving my baby.' I didn't have more information than they did about where the formula was. I would tell people, 'Your guess is as good as mine.' It was really difficult. I'd like to be able to help them, but it was like looking online for where it was available, and by the time they got there, it would be sold out. I didn't have a crystal ball to tell people where the formula was, so there were some angry words exchanged." -WIC Coordinator 2

COM-G (Communication within Governmental Agencies)

"[…] the recall process, I'm pretty sure the State agency had, like, got information from the USDA, which then obviously gets communicated down, you know, to us." WIC Coordinator 1

"Well, we get our information from the state office who gets their information from USDA. Sometimes there's direct communications from USDA as well, or like the National WIC Association, and WA, puts out communications as well. So, our state agency would give us the final word about what procedures would be in [state name]. And then, you know, we communicate that information to our participants, to our local staff, of course, and then that is communicated to the participants. So, the participants obviously didn't get all the background about exactly what was going on. But they were given the state developed reference sheets that we could share with participants by text or email to show them what some of the options were for them. I think it was on the app as well." WIC Coordinator 2

COM-S (Communication within Stakeholders)

"And then from, like, a local agency standpoint, we would obviously talk with our state office, as well as, you know, communicate through email. But then also trying to communicate with stores. Even like, you know, conversations about, when do your trucks come in? Or do they come in on Tuesdays? Because I'll tell my client to come on a Tuesday morning, or whatever. You know, in any case, we're trying to kind of communicate with all different parties." -WIC Coordinator 1

"So, the supplier reaches out to myself or our suppliers. Now they need to reach out to recall teams along with notification to us. That team goes into action to get the information for your supplier. They have a form that gets filled out, and then they do research with them, you know, based on the information they get from the supplier to see what warehouses and what divisions stores are affected because sometimes it's not nationwide. Sometimes it's very specific to a batch that was delivered to two or three distribution centers. So, they do all that research, and then they communicate. They send out alerts via email to the divisions and within divisions, vice presidents, merchandising, and everything that's involved. Warehousing, the entire network, will get this stuff to stores to react and give them the process of how the return is to be done." -Retailer 4

Food Safety of Infant Formula:

FOS-P (Sustaining Food Safety at Consumer Level)

"Once it reaches the consumer's home, if it was safe when it left the facility, and if the container was intact, then really it boils down to the consumer's practices in the home, right? Are they using water that is safe? Are they preparing that product in a kitchen or space that is also, you know, free of foodborne pathogens? So, are they, you know, washing their hands? Are they clean? Are they efficiently cleaning the containers that they're using to make the infant formula? And so, there's a lot of potential, I think, for contamination to occur under those particular in-home situations. In the events that, you know, maybe the container that the infant formula is in gets contaminated, you know, then the person making subsequent infant formula could-those next bottles could be contaminated as well. And then, if the consumer makes the infant formula and it's contaminated, and then they, you know, it sits out at room temperature for too long, there's some sort of abuse that goes on with it. If present, those microorganisms could

grow to higher concentrations and be, you know, more detrimental to infants." -Food Safety Specialist 3

"I think, to stay with common rules in most pediatric offices, you know, we usually help... we even have some kind of flyers or handouts on how to prepare formula, how to safely store formula. You know, if there is something in the bottle, you know, how to put it in the fridge or just dump the rest… There are a few sites, but there is one site called Healthy Children, healthychildren.org, which is the American Academy of Pediatrics site. It is for pediatricians as well as for parents. They have information from essential neonates until we stop seeing kids, around 20-21, something like that. There is general information for particular ages, but there is also specific information. And actually, there is very good information from experts in this area on formulas as well as how to store them. I usually don't memorize necessarily everything. I know the common rules, but, you know, sometimes, especially if parents want more and more information, I usually refer them to reliable sources." -Pediatrician 2

FOS-P-N (Noncompliance with Safety Recommendations)

"You know, everybody thinks they know how to wash hands; you do some education on simple things like hand washing, people like, 'Yeah, yeah.' But then USDA, for example, uses observational studies. And when they do those studies, during food preparation, only 3% of the people are washing their hands when they should and doing it appropriately. So, it's like, we can, we can keep talking and talking. But that doesn't mean people are following through." -Food Safety Specialist 1

"Yeah, so the struggle of food safety, which hits the infant formula recall, is that many people just don't think it's gonna happen to them. You know, so we have a lot of studies that show that people are interested in recall information … But when it comes down to how many people are following through and checking their food supply to see if they have a recalled item, it's much smaller than that... So, we say we're interested, but then we don't actually act on that." -Food Safety Specialist 1

FOS-S (Sustaining Food Safety at Supply Chain Level)

"Yeah, they should hold and not release the product [in case of an indication of contamination]. Yeah. And that's something these folks can do. I mean, the infant formula industry, like there's at least a shelf life on their product. I know this isn't dealing with leafy greens, but there are some products, such as leafy greens or a lot of produce, that have such a short shelf life on them that, you know, holding product is a challenge for them. Because, you know, it could take a couple of days. And, you know, when you only have a week or two of shelf life, that can be problematic. But the infant formula folks should be able to hold product under their control and not release it until the test results come back." -Food Safety Specialist 3

"The other thing, and this is what most of the manufacturers right now are upset about and are lobbying Congress for, is they've always done dry cleaning, and the FDA is mandating wet cleaning. It's slower, but it's also more dangerous in terms of these machines processing dry powder. If you get water in them, you have to make sure they're super dry before you start

processing dry powder again, or it's more likely that bacteria will grow in a machine that has had water in it. So, they used to never put water in there and did dry cleaning with sterilization and all these things. Now the FDA is saying it requires wet cleaning, and instead of taking a day for cleaning, it takes four or five days for cleaning. It just slows down production even more, which is why all the manufacturers claim they can't catch back up and why there's still not massive shortages, but there are still intermittent out-of-stocks and shortages on the shelf." - Retailer 2

FOS-F (Food Safety Significance)

"I think food safety is important for everyone and all of our food products. But infants are considered a higher-risk population. And because of that, typically, food safety matters are handled or elevated, considered more serious. You know, of course, infants, since they're young, their immune systems oftentimes are underdeveloped and don't necessarily have the immune system to be able to tackle or manage potential exposure to, you know, whether it be bacterial issues or other food safety-related matters. And so, yeah, because of this, infant formula or any product that is sold to such a high-risk population typically undergoes more testing, or they may have more stringent requirements that are associated with them." -Food Safety Specialist 3

FOS-C (*Cronobacter sakazakii*)

"You know, it's zero credit if you get infected, right? If you're an infant, and it's not a threat otherwise. So, the absolute numbers are very small in terms of threat. But, you know, infants are relatively immune compromised compared to older children and adults, so that's why they're more prone to having adverse reactions to Cronobacter infection. So, of course, it's meningitis. An older child or adult that's exposed to Cronobacter doesn't get meningitis. It's very rare. It's rare in infants, but it's very rare in non-infants. So, I think the threat in terms of numbers is extraordinarily low. But in our country, we have an intolerance to any risk, and so, you know, in a situation like the most recent instance, it's certainly less than 20, and probably less than that, less than 15 infants. I'm not sure about that, but I think that's kind of the ballpark figures we're talking about. […] So, the absolute risk is extraordinarily low, as is the threat." - Pediatrician 1

"Well, I think if you have increased surveillance [Cronobacter sakazakii was made nationally notifiable], you'll have increased identification, right? You know, you know, Cronobacter. So, if you had increased detection, you'd be able to identify the problem earlier." - Pediatrician 1

FOS-O (Other Risks)

"Well, from an infection standpoint, Salmonella is probably a big one. But it's generally not from a contaminated formula. However, I think that is an infection to which infants are especially vulnerable." -Food Safety Specialist 3

"I think it's regulated here, as well as in general. It's not that we don't see GI pathogens in the food or water, but it's much less than in developing countries, so I think the threat is less.

[…] But, you know, right now, in a lot of areas, water is pretty safe. Some contamination might be not just for formula but also for the water. But it is definitely not zero, and as always, you know, low-income populations, with lower socioeconomic status and fewer resources, could be more at risk of contamination." -Pediatrician 2

FOS-A (Heightened Food Safety Awareness)

"So, I think there are a couple of things. I mean, certainly, anytime there's a recall, regardless of the product, there's typically a kind of heightened awareness among those involved with that product. Whether it be peanut butter, almonds, or chocolate, the industry, and I think the FDA, kind of go like, 'Oh, no, this could happen to us.' And they start, you know, there's this real push to maybe reevaluate their sanitation protocols, their testing protocols, all those types of things. So, one, I think, when a big event happens, people, like everybody, become more aware of the potential situation. And because of that, because they're on this heightened awareness, they either increase testing and environmental monitoring, and they find stuff, and they're like, 'Oh, no, we need to do something about this. And we're going to recall products out of caution.' Maybe they were doing that all along, but now they look at the results a little bit differently and say, 'We don't want to take a risk.'" -Food Safety Specialist 1

"I'm not gonna say when there's a bad batch with, you know, bacteria in the batch, but they find one instance in another country that maybe was affected. And I mean, everybody's being extra cautious right now." -Retailer 2

Coping Strategies:

COP-P (Coping Strategies of Parents)

"But also, I think social media, and I don't blame social media, but I think it was at least some information or there was contributing to kind of confusion and even more stress for families. Some information on homemade formulas and something like that also was there. That's why the American Academy of Pediatrics responded right here, you know, pretty quickly saying, be careful. And as a pediatrician, you need to be aware of this and, you know, provide the best information to parents." -Pediatrician 2

"So, as far as creating more access, you know, one of the things that you, you could do potentially, like with, like food stamps, I know, some people did, this was like ordering formula off, like Amazon, or like ordering it online." -WIC Coordinator 1

COP-S (Coping Strategies of Stakeholders)

"So, with infant formula, we had to cut off some adult formulation supplies. So now you're cutting off some folks that might need something for their own health factors. So, if you look at our products, I can ensure, you know, we cut off some of that supply because, in reality, elderly people have different means of supply. Eating [adult formula] is not their sole source of nutrition like it is with infant formula. So, you know, we ended up cutting those sales and cutting

back capacity to free up capacity to make infant formula during some of the tougher times." - Manufacturer 1

"We are still in place today on that, just understanding how fragile this ecosystem is. And so, I would say our preparedness plans. Yeah, it's you can't over-order this stuff, right? It's all got dates on it, and it's needed everywhere. We can't be the only retailer that hoards things. So, we're going to try to order our needs. We're going to make sure our pipeline and our flow of product is as good as possible. Any other brands that are doing well, like the imported brands, like the Aussie Bubs or the Kendamil, they did find a demand, and so we kept them. We kept what we could on the shelf. The biggest preparedness plan we've got is, I think, our ability to communicate now with the vendors. We know people in the FDA now, we know people in the White House now that, you know, before that recall, we didn't have that communication. So, I do think the entire communication process is much better because of this." -Retailer 3

COP-G (Coping Strategies of Governmental Agencies)

"I think, you know, relaxation of the import of non-states produced formulas, there was some relaxation. You know, imported formulas are supposed to be subject to the same requirements of the FDA that the FDA requires, but they're obviously not inspecting their plants, right? You know, there are a lot of imported formulas that don't meet the FDA requirements that are, you can find them periodically pushed on Amazon or eBay or something. And there have been some adverse effects of those." -Pediatrician 1

"I know some [imported infant formula], how it was funneling into everybody's system. So, I think we were all kind of tapping into what they brought in. It was a very quick fix. It wasn't enough. I mean, yeah, it didn't make a lasting impression, but it got a little bit of product out there." -Retailer 3

COP-G-W (WIC Flexibilities)

"Because the state gave us a list of different size packages, or from liquid to a powder or the other way around kind of situation. So, you know, we could have the ability to then switch it to their benefit so they could purchase that item, which is unusual. You know, we don't usually have the ability to switch things up when that is what they see in the store. So that was a good thing. And it was a challenging thing at the same time because there were so many participants that were getting desperate, you know, to find formula. And to some extent, we were able to order some formula directly from the company through the state office and have some here for participants to pick up, but that didn't always work either. It was a mess. It was a mess." -WIC Coordinator 2

"Some of the states that were Enfamil states were a little slower because they're like, well, Enfamil has not been recalled, we're fine. But then when there were shortages and families who were buying bigger tubs started buying the smaller tubs because the bigger tubs weren't available, they were like, 'Oh, no, what do we do now?'. And they were a little slower to maybe recognize the severity of what was happening." -Retailer 2

Industry Gaps and Recommendations:

IGR-S (Lack of Standards/Plans)

"One of the vulnerabilities, I would say, is that manufacturers only manufacture their product in one location versus having four in multiple plants that can manufacture. Because if something happens at one, then as we experienced, everything goes out. So that is, you know, should be mandatory that they manufacture in more than one place." -Retailer 4

"But having more than one facility is absolutely critical to the process. I mean, by far, that's what we need. You don't want all your ducks in one basket, you know, all your eggs in one basket. You want options where they can produce it in other parts. I think by far, the biggest thing we can do to mitigate challenges that we faced is to have more than one facility to produce the product." -Retailer 3

IGR-G (Recommendations for Governmental Agencies)

"I also think that it's important for our governing bodies, and not just the US government, but also manufacturers to have an emergency action plan in place for similar occurrences. Having resources readily available is crucial. There was a bit of a scramble this last time in providing some of the guidance from some of these bigger entities down to the parents. So, having those readily available with guidance is essential." -Food Safety Specialist 1

"I think some of what we talked about, you know, additional facilities, sort of really approved facilities outside of the country, that are like, sort of permanently preserved, permanently approved, sort of as a backup. So, if this were to happen, let's just say, they shut this factory in Sturgis down again, we still aren't to the point where we can keep up with everything else. And, you know, can we start regularly using the facility that Enfamil has in Mexico? Or, you know, that Similac has in Spain, and so forth? Can we use those facilities? And can those be partly permanently approved?" -Retailer 2

IGR-G-W (Recommendations for WIC)

"Can we agree that all these companies can just get on board for $6 a can? You know, I don't know if that is an option or not. If it is, it'd be awesome. I think the more options that are available to clients, the better. I also, you know, certainly don't want to have-or really, what I guess I want to know is-how are we planning for or making sure that this doesn't happen again? Because, like, I don't know that you can guarantee that this won't happen again, like that some massive recall is not going to happen again. -WIC Coordinator 1

"But I've always advocated for giving them a dollar amount, and they can buy whatever formula they choose. We spend a lot of time discussing formula and why it's the contract formula, what's wrong with the other one, because we go back and forth between Similac for a few years, and then it's Enfamil for a few years, and it goes back and forth." -WIC Coordinator 2

IGR-P (Recommendations for Producers)

"I feel like they didn't want to tell us necessarily the whole story. They didn't want to scare us or give us too much information. I often get messages from vendors about products not being available, and I just feel like they could have told me a little bit sooner. There's still a little transparency that could be happening." -Retailer 1

"So, honestly, I'm like, please build another facility specifically for Reckitt. I'm like, please do that because I think that would help in getting more facilities that can produce infant formula up to FDA regulations. The need outweighs the production at the moment. But who knows, they may actually catch up in the next year or so. We'll see." -Retailer 1

Infant Formula Recalls:

IFR-R (Food Safety Recall of 2022)

"So, you can't just turn off your competition and then suck up all that capacity. There's not that much idle capacity. [...] So, you have to think about how everything is balanced through. Like, what can you do?... There's limited capacity; they can't just snap their fingers and build an infant formula plant. You know, just the construction alone will take you three years, and you have to do a whole year of testing to make sure it meets the compliance of the FDA, and then you do more testing. So, you're looking at a five- to six-year program if you're going to get a manufacturing plant up right now. If you do third-party manufacturing, maybe you can do it quicker, but that's still like a two-year endeavor." -Manufacturer 1

"I think all safety recalls have an impact on the retailer. I will tell you, the Abbott one was probably the biggest impacting recall that I've seen in my career, and I've been in the business for over 30 years … I mean, there's only so many baby food manufacturers in the United States. [...] And then anything that hit the shelf was gone. There was really no pipeline, there was no pipeline fill, you know. Typically, as you alluded to, not only do we carry so many days of supply in the store, but we also carry inventory in our warehouse to make sure we can keep that pipeline being filled. [...]It took a lot of 2023 to kind of get the process and the pipeline filled back up." -Retailer 3

IFR-O (Other Food Safety Recalls)

"Particularly in this landscape where all of a sudden, we have shortages. You know, prior to the recall, we didn't experience supply chain issues. And these issues are persisting today, you know, a year plus since the Abbott manufacturing plant has been reopened, we are still experiencing shortages. I don't understand them." -WIC Coordinator 3

"But you've seen a couple of minor recalls lately. There was one for Nutramigen … Gerber had a recall last fall, but minor recalls compared to the big Similac recall, where Similac had to recall everything that was produced in their factory." -Retailer 2

Infant Formula Market:

IFM-C (Market Concentration)

"But given that there are still shortages and tightness in the market, I think it's important that we have alternative sourcing and alternative supply in the country besides just Similac and Enfamil." -Retailer 2

"So, yeah, I mean, that's sort of the problem. All the facilities in the U.S. are running pretty much at capacity, and it takes a long time to get a facility approved. It's a long time to get a new formula approved. So, when one goes down, the weakness in the supply chain was that 20% of the formula in the country was made at that Coldwater Sturgis Similac facility. None of the facilities had 20% excess capacity." -Retailer 2

IFM-M (Market Challenges)

"Yeah, I think, you know, it's expensive to build manufacturing facilities for us. So, you're talking, you know, plus a billion dollars nowadays to build a new facility. So, a lot of things we do, depending on what product we're going to make, we'll either make it if we have the capacity for it and we have to put in new lines, which are also not cheap, or we'll look at third-party manufacturers to help us if they have the capabilities or line time already available. So, it's kind of a balance between, you know, what we can do and what we want to pay for when we enter a market. So, what's the risk profile? If we think the sales will be there, do we want to invest? If we feel like it's okay, kind of a trial and error, we'll look at a shorter-term agreement with a third-party manufacturer." -Manufacturer 1

"I would say that the regulatory changes are probably the most difficult to adapt to because it takes time to make these changes. And I don't think government agencies understand the amount of time it takes." -Manufacturer 1

IFM-P (Production Decisions)

"Now you have different things that hit you. So sometimes, like, there are spikes in sales and such, and so why is WIC important to plan that out? If you want a WIC state, that means you're giving up a lot of capacity. So, you have to make sure you have the backfill for that capacity. We try to build up more and more safety stock, but you have to look at shelf life and such as well. For liquid products, it's one year; for powder products, it's two years. So, we change that because we have to report what our levels are to the government on a weekly basis now. So, there are targets that we try to hit, and they're greater than they were before." -Manufacturer 1

"We have multiple plants inside the U.S. that manufacture different types of infant formulas. So, you break it down by powder and liquid in the U.S., which is different from the international. The international community typically uses powder. And we do have some plants that do support the U.S., not particularly by design, but with the recalls and such, we did have to move different production out of the U.S. to a European location in [country name]. So that's

ramping down at this point. But in order to keep certain capacities and to meet government regulations, we are still manufacturing out of [country name].” -Manufacturer 1

IFM-K (Marketing Practices)

“And so that's where we introduce things to the hospital to make sure that the baby gets whatever their needs are. So, we'll give gratis product. But the goal is to get the baby sustained on some type of formula that they can grow and mature on. So, it's kind of a gratis model. And, you know, our competitors do the same thing. But the basis is to make sure that moms are comfortable with whatever they leave the hospital with.” -Manufacturer 1

"I think, from my experience, and I might be wrong, usually it's kind of the opposite. For example, right now, if it's Similac, Abbott, I see more free samples provided to offices from Enfamil. You know, that one company who has an agreement will be saying, 'Oh, we already have an agreement. Why do we need to do more?' I don't want to speculate." -Pediatrician 2

IFM-S (Supply Chain)

“Yeah, some of the ingredients are very specialized. There are certain plants, like one or two, that manufacture those. So, it's not like there's an abundance of different suppliers out there. It depends on what you're buying. If you're looking at just vegetable oils, there are a lot of suppliers out there, but you have to make sure that they can meet certain fatty acid profiles we need, certain micro levels that we would require. So, when you think about it, you start with a big pool of different suppliers, and you start doing investigations, RFIs (request for information), RFPs (request for proposal), and figure out exactly what we need based on our specifications. And it shrinks really quickly. As far as controls and their process for microbiology, risk, and such, Cronobacter and Salmonella are the two things that are very hot in the industry right now. Not everyone can meet those levels because they're not necessarily pharmaceutical levels, but they're very close to it. So, they're right in between a food and a pharma kind of specification.” -Manufacturer 1

“The other thing, and this is what most of the manufacturers right now are upset about and are lobbying Congress for, is they've always done dry cleaning. And the FDA is mandating wet cleaning. And they're like, it's slower, but it's also more dangerous in terms of these machines that are processing dry powder. If you get water in them, you have to make sure they're super dry before you start processing dry powder again, or it's more likely that bacteria will grow in a machine that has had water in it. So, they used to never put water in there and do this dry cleaning with sterilization and all these things. Now the FDA is saying it’s going to take wet cleaning, and then instead of taking a day for cleaning, it takes four or five days for cleaning. And it just slows down production even more, which is why all of the manufacturers claim that they can't catch back up and why there are still intermittent out-of-stocks and shortages on the shelf.” -Retailer 2

Consumer Preferences:

CPR-B (Brand Loyalty)

"I think a lot of people develop brand loyalty. And, you know, once they do, it influences quite significantly. My more recent and direct involvement in this topic was with the toddler formulas, where they co-brand toddler drinks to infant formulas with the goal of attaining brand loyalty. So, brand loyalty is a definite phenomenon." -Pediatrician 1

"From my experience, if, you know, the hospital already gives a formula and the baby responds well, and WIC covers it or parents buy it out-of-pocket and it's reasonable, they stay with it, I think. And I personally encourage them to stay with this brand or this formula. But if they give, for example, Enfamil in the hospital and more Similac at home-I don't remember exactly right now-but, you know, if WIC covers different products or they find a cheaper option, like store brands, which I usually recommend, I advise them not to buy too much right away. Buy maybe one or two cans to try, and if it works well, then continue with it." -Pediatrician 2

CPR-P (Changes in Preferences)

"So, it's a very unique market. So new moms don't know, really, they probably don't know anything about recall." Manufacturer 1

"I have families who recover and, kind of, right now are already forgetting because I remember, you know, some families came a year or 18 months ago very stressed, and now they are more relaxed. You know, a lot of babies at that time are not babies anymore. But, you know, I had families who had babies at that point in time, and now they have older children." Pediatrician 2

CPR-M (Mistrust)

"So, due to the Abbott recall, a lot of business went to Enfamil, which is owned by Reckitt Benckiser. There are still customers who don't necessarily trust Similac and the Abbott name because of the recall and their experience." -Retailer 1

"They [WIC participants] recommended that we have a different contract. There was a lot of push and feedback, you know, 'Why are we keeping this contract with Similac?', 'Why can't we go back to Enfamil?', 'They broke their contract by breaking these regulations and having this contamination and shutting down. They broke the contract, so why can't we change?' I heard from a lot of clients that we should have a contract with a different formula. It's hard to understand, and I'm sure it was just a big financial burden, but it's hard to understand that we were able to do that." -WIC Coordinator 3

WIC Program:

WIC-R (WIC Coverage and Restrictions)

"As far as infant formula goes, we are a supplemental program. So, we're not designed to cover 100% of an infant's needs when it comes to formula. A lot of times, I tell families that we are covering maybe 80 to 85% of what they may need in a month. But even with those, like even if they're on a specialty formula because of a medical condition, it's still a supplemental nature. We're still only providing that 80-85% of what they need." -WIC Coordinator 1

"In [state name], clients have access to those four formulas, those four standard formulas. Before, like pre-COVID, pre-formula shortage, it was only like, they would only have access to one specific formula unless they called the office and switched to that formula. So, like, they could be on Similac Advance, and that would be the only formula they had access to unless they called us and said, 'I want to switch to a different formula,' or 'My baby is having problems.' Whereas now, they technically have the option to just switch on their own, as long as it's within those four formulas." -WIC Coordinator 1

WIC-O (WIC Operations)

"So, WIC is throughout all 50 states, but every state operates a little bit differently." -WIC Coordinator 1

"There is a nice app for [state name] WIC participants to use with their debit card. Thank God we had switched to a debit card before the pandemic, or we would have been printing and mailing these paper checks. It was hard enough to mail a card out when we were supposed to be closed. So, it's really kind of nice. It gives them their benefits, and then it will adjust every time they make a purchase, showing the actual balance. I think other states have different apps as well. It's really helpful. And now our app has a way that they can send more secure text messages through the app." -WIC Coordinator 2

WIC-C (WIC Rebate Contract System)

"Well, I think a lot depends on how the WIC contracts are given and obtained, which is state by state. They will dictate a certain manufacturer for infant formula, and that will usually determine what formula is recommended." -Pediatrician 1

"Which, in a way, is a signal to the customer that this is the preferred formula. It's the preferred WIC formula, and that's why the vendors try to get that WIC contract because it gives them that sort of halo of being a perfect formula." -Retailer 2