Neha D. Shah, MPH, RD, CNSC, CHES, Series Editor
Elizabeth Wall, MS, RDN-AP, CNSC, Series Editor

The Infant Formula Shortage: Reasons, Responses, and Resources for Clinicians

Tegan Medico

In the United States, regulatory and trade barriers contributed to an infant formula market dominated by a few domestic companies, such that a major recall in 2022 swiftly and profoundly reduced access nationally. Limited data points to an adverse impact broadly on households with formula-dependent infants, particularly those reliant on specialized formulas. To remedy the crisis, several federal actions aimed to augment the domestic formula supply and increase flexibility in formula purchasing by participants of the Supplemental Nutrition Program for Women, Infants, and Children. Clinicians in inpatient and outpatient pediatric care settings will benefit from an understanding of the systems that influence infant formula use and access to help provide families with safe recommendations and resources.

INTRODUCTION

In 2022, a widespread shortage of infant formula in the United States sent parents and clinicians into a panic. An unprecedented crisis, the shortage aroused scrutiny of the conditions that set its stage, elicited emergency guidance from governmental and professional organizations, and sparked discussion about ways to mitigate the risk of future shortages. This review provides both inpatient and outpatient clinicians in pediatric care settings with the necessary context for understanding and navigating the crisis. Included are an historical discussion of the infant formula industry in the United States, an explanation of features which make infant formula an indispensable commodity, the sociopolitical background for the recent infant formula shortage, a review of known and theoretical safety concerns, the federal response, and practical tips for clinicians.

Tegan Medico, MS, MPH, RDN, CNSC
University of Virginia, Children's Division of Pediatric Gastroenterology, Hepatology and Nutrition, Charlottesville, VA

History of Infant Formula

Commercialization

Commercial alternatives to human milk emerged following advances in science and technology of the Industrial Revolution.[1,2] Early infant formulas were expensive, and many were complicated to prepare.[3] Energy density ranged widely.[1] Some products were accompanied by recipe books containing numerous preparation permutations based on a perceived clinical indication, variations were known as the "percentage method".[1,4] The percentage method largely was implemented in hospitals and specialized commercial laboratories.[1] Hence, many physicians more simply recommended

recipes amenable to home preparation that consisted of boiled milk or diluted evaporated milk and corn syrup or table sugar, a practice that persisted widely into the mid-20th century.[1,3]

Infant formulas with more straightforward preparation methods and improved nutritional compositions, achieved by the addition of cod liver or vegetable oils and vitamins, emerged in the 1920s and peaked in popularity in the early 1970s.[1] Breastfeeding rates reached a low with the increased usage of formulas: 25% initiation during the first week of life.[5] Homemade formula preparation was a dwindling practice as well.[1,6]

Regulation

Regulation of infant formula was an evolving endeavor beginning in 1938 with the Federal Food, Drug, and Cosmetic Act (FFDCA). The FFDCA established standards for food product identity, quality, and volume that were applicable to infant formulas, and it authorized oversight by the United States Food and Drug Administration (FDA).[7] A 1941 amendment to the Act included infant formula labeling requirements[1] and a 1966 amendment included minimums for 11 vitamin levels following cases of vitamin B6 deficiency associated with a production change to a liquid concentrate.[1,8] By the time these latter changes were implemented in 1971, minimum concentrations (per 100 kilocalories of formula) for protein, fat, linoleic acid and 17 vitamins and minerals also were established.[1] A later reformulation oversight that resulted in 141 cases of hypochloremic metabolic alkalosis[9,10] gave way to the most comprehensive amendment to the FFDCA, the Infant Formula Act of 1980 and its 1986 amendment.

To date, the Infant Formula Act remains the most significant legislation concerning infant formula production and composition, and it is the most rigorous legislation for any food sold in the United States. Notable provisions include:[11,12]

- infants defined as less than 12 months of age
- mandated alerts to the FDA prior to first manufacture and with any formulation changes
- mandated scientific evidence of safety and efficacy across product shelf-life
- standards for good manufacturing practices and quality control procedures
- expanded nutrient minimums and maximums
- standards for certain nutrient forms and ratios
- updated product labeling requirements

The *International Code of Marketing of Breast-milk Substitutes* is a set of policy-aimed recommendations adopted by the World Health Organization to limit the marketing reach of infant formula manufacturers. The *Code* has not been adopted by the United States, nor has the United States produced any legislation pertaining to one or more of the *Code's* specific articles.[13]

Nutritional Features of Infant Formula

All infant formulas marketed and sold in the United States must meet nutrient composition requirements set by the FDA, unless designated exempt. Nutrient composition requirements for non-exempt formulas are detailed in Title 21, Chapter 1B, Part 107, of the Code of Federal Regulations and are publicly available online.[12] Exempt formulas are intended to address specific medical and/or nutritional problems, such as low birth weight, cow milk protein-induced allergic proctocolitis, malabsorption, and inborn errors of metabolism.[12,14] Nutrient compositions of exempt formulas vary widely depending upon their unique indications. Some exempt formulas are medically compulsory, such that unavailability could pose a significant health risk, and they often require a prescription from a medical provider. The FDA status (exempt/non-exempt) is shown in Table 1, along with primary indications for use, major nutritional features, and contemporary brand examples.

Nutrients that are not required by the FDA, but nevertheless widespread in modern options domestically and abroad, include docosahexaenoic acid (DHA) and arachidonic acid (ARA) (long-chain fatty acids); oligosaccharides (prebiotics); taurine (amino acid); lutein (carotenoid); and carnitine (amino acid derivative). These components are targets of growing research interest related to infant nutrition.[15,16]

Precursors to the Infant Formula Shortage

Domestic Monopolies

Despite its comprehensiveness, the Infant Formula Act does not abide mutual recognition of foreign regulatory approval of infant formulas, though such

(continued on page 31)

(continued from page 23)

provisions apply to pharmaceuticals.[17] Without recognition of foreign regulatory approval, infant formulas produced in other countries must undergo FDA approval prior to legal sale in the United States. According to a report from the Congressional Research Service, few foreign companies have pursued and obtained FDA approval historically, ostensibly due to significant trade barriers—high tariffs, quota tariffs, and export caps—that threaten profitability in the United States market.[18]

These regulatory and trade barriers contribute to a domestic infant formula market dominated by a few companies: Abbott Nutrition (of Abbott Laboratories), Mead Johnson (of Reckitt Benckiser Group), Gerber Products Company (of Nestlé), and Perrigo. The latter is the major white label manufacturer of store-brand and boutique formulas. Although exact figures are unavailable, common estimation is that Abbott Nutrition held approximately 40% of the total infant formula market share [19] and 75% of the amino acid formula market share.[20]

Supplemental Nutrition Assistance Program for Women, Infants, and Children

Domestic monopolies are reinforced by contracts between infant formula manufacturers and state-level WIC (Women, Infants, and Children Program) agencies. Federally funded via the United States Department of Agriculture (USDA) Food and Nutrition Service (FNS), WIC is a nutrition assistance program that provides supplemental foods, including infant formula, to infants from low-income families. It covers all 50 states, the District of Columbia, 33 Indian Tribal Organizations, American Samoa, Guam, the Commonwealth Islands of the Northern Marianas, Puerto Rico, and the U.S. Virgin Islands. The greatest program expense, the cost of infant formula, is contained via contracts between individual state programs or state consortia and a single infant formula company. Contracts are determined via a competitive bidding process. The winning company provides WIC with rebates for approximately 85% of retail price and in turn enjoys priority shelf space in WIC-participating retailers, thus recouping money in the non-WIC market via a "spillover effect".[21-23]

In 2022, 43% of infants in the United States participated in WIC.[24] An estimated 85-90% of participating infants receive formula as a program benefit.[25] Thirty-four states and the District of Columbia contracted with Abbott Nutrition,[23] thus directing a majority of total domestic infant formula sales toward Abbott products.

Abbott Nutrition Recall and Plant Closure

On February 17, 2022, Abbott Nutrition issued a largescale recall of its Similac® and Elecare® product lines. The recall followed troubling findings during an FDA inspection of one of Abbott's primary plants in Sturgis, MI. The inspection was prompted by four reports of infant illness, including two deaths, from *Cronobacter sakazakii* infection. Additionally, a whistleblower report to the FDA in October 2021 detailed safety concerns at the Sturgis plant.[26] Although evidence was insufficient to determine a direct link between the Sturgis plant and the infected infants, the plant closed production shortly after issuing the recall. Under a consent decree with the FDA, it remained closed until June 2022 but closed again soon thereafter due to storm flooding. It resumed operations in July 2022.

Consequences of the Infant Formula Shortage

Medical & Nutritional Risk

Availability of infant formulas following the Abbott Nutrition recall was largely gauged via retail data. Information Resources, Inc. (IRI) Worldwide and Datasembly reported out-of-stock figures of approximately 30-40% during the shortage peak.[27,28] However, out-of-stock rates ranged widely store-by-store and state-by-state providing a limited interpretation of the crisis.

There are two big limitations of out-of-stock rates in evaluating the full extent of the infant formula shortage. Foremost, the out-of-stock rate is more a measure of product variety on the shelves rather than overall quantity. Considering the uneven demand across formula brands because of WIC participants' restrictions to specific products, overall quantities of the most in-demand formulas is important. A major WIC-approved formula out-of-stock represents lack of access for a significant portion of infants. Furthermore, retail data does not capture formulas obtained through durable medical equipment companies (DMEs), WIC-contracted special formula distribution centers, medical

Table 1. Infant Formula Types *(continued on page 33)*

Type (FDA Exemption Status)	Indications	Macronutrients	Micronutrients	United States Brands (not inclusive of store-based brands)
Preterm (exempt)	Catch-up growth for infants <34 weeks gestation and <1800 grams	**Protein** ↑ concentration bovine-based polymers (80% whey, 20% casein) **Carbohydrate** lactose + corn syrup solids **Fat** 40% as MCT[1] DHA[2]/ARA[3]	↑ vitamin D ↑ calcium ↑ phosphorus ↑ iron ↑ zinc	**Abbott Nutrition** Similac® Special Care® 20 Similac® Special Care® 24 Similac® Special Care® 24 High Protein Similac® Special Care® 30 **Mead Johnson** Enfamil® Premature 20 Cal Enfamil® Premature 24 Cal Enfamil® Premature 24 High Protein Enfamil® Premature 30 Cal
Preterm Post-Discharge (exempt)	Continued catch-up growth for preterm infants discharged from neonatal intensive care units	**Protein** ↑ concentration bovine-based polymers (60-80% whey, 20-40% casein) **Carbohydrate** lactose + corn syrup solids **Fat** 25% as MCT DHA/ARA	↑ vitamin D ↑ calcium ↑ phosphorus ↑ iron	**Abbott Nutrition** Similac® Neosure® **Mead Johnson** Enfamil® Enfacare® Enfamil® NeuroPro™ Enfacare®
Routine Term (non-exempt)	Normal needs of healthy term infants	**Protein** bovine-based polymers **Carbohydrate** lactose oligosaccharides **Fat** ↑ LCT[4], ↓ MCT DHA/ARA	Standard	**Abbott Nutrition** Similac® Advance® Similac® Pro-Advance® Similac® 360 Total Care® Similac® Organic Similac® Organic with A2 Milk Pure Bliss™ by Similac® **Mead Johnson** Enfamil Premium™ Newborn Enfamil Premium® Infant Enfamil® Infant Enfamil NeuroPro™ Infant Enfamil® Enspire® Enfamil Premium™ A2 Enfamil Simply™ Organic **Nestlé** Gerber® Good Start® Gentle Gerber® Good Start® GentlePro **Bobbie™** Organic Infant Formula **Earth's Best Organic®** Organic Dairy Infant Formula
Soy (non-exempt)	Galactosemia or cow milk protein allergy without concurrent soy allergy	**Protein** soy protein isolate + methionine **Carbohydrate** corn syrup solids sucrose **Fat** ↑ LCT, ↓ MCT DHA/ARA	Standard	**Abbott Nutrition** Similac® Soy Isomil® **Mead Johnson** Enfamil® Prosobee® **Nestlé** Gerber® Good Start® Gentle Soy **Earth's Best Organic®** Non-GMO Plant-Based

1. medium-chain triglyceride 2. docosahexaenoic acid 3. arachidonic acid 4. long-chain triglyceride

Table 1. Infant Formula Types *(continued from page 32)*

Type (FDA Exemption Status)	Indications	Macronutrients	Micronutrients	United States Brands (not inclusive of store-based brands)
Added Rice (non-exempt)	Spit-up	**Protein** bovine-based polymers **Carbohydrate** lactose or corn syrup rice starch **Fat** ↑ LCT, ↓ MCT DHA/ARA	Standard	**Abbott Nutrition** Similac® for Spit-Up® **Mead Johnson** Enfamil A.R.™
Sensitive/Comfort (non-exempt)	Acute gastroenteropathy or chronic fussiness and gas	**Protein** whey or mixture of bovine-based polymers and peptides **Carbohydrate** ↓ lactose corn syrup solids maltodextrin oligosaccharides **Fat** ↑ LCT, ↓ MCT DHA/ARA	Standard	**Abbott Nutrition** Similac Sensitive® Similac Pro-Sensitive® Similac Pro-Total Comfort® **Mead Johnson** Enfamil Premium® Gentlease® Enfamil NeuroPro™ Gentlease® Enfamil® Enspire™ Gentlease® Enfamil NeuroPro™ Sensitive Enfamil® Reguline® **Nestlé** Gerber® Good Start® SoothePro Earth's Best Organic® Organic Gentle® Organic Sensitivity®
Extensively Hydrolyzed (exempt)	Cow milk protein allergy or fat malabsorption (↑ MCT options)	**Protein** bovine-based peptides **Carbohydrate** may include corn syrup solids, maltodextrin, or potato starch **Fat** variable MCT content DHA/ARA	Standard	**Abbott Nutrition** Similac® Alimentum® **Mead Johnson** Nutramigen® with Probiotic LGG® Pregestimil® **Nestlé** Gerber® Good Start® Extensive HA®
Amino Acid	Severe cow milk protein allergy not responsive to extensively hydrolyzed formula	**Protein** amino acids **Carbohydrate** corn syrup solids **Fat** variable MCT content DHA/ARA	Standard	**Abbott Nutrition** Elecare® **Mead Johnson** PurAmino™ **Nestlé** Alfamino® Infant **Nutricia** Neocate® Infant DHA/ARA Neocate® Syneo® Infant
Renal (Exempt)	↓ potassium and/or phosphorus needs	**Protein** bovine-based polymers (60% whey, 40% casein) **Carbohydrate** lactose **Fat** variable MCT content DHA/ARA	↓ potassium ↓ phosphorus ↓ iron	**Abbott Nutrition** Similac® PM 60/40
Metabolic (exempt)	Inborn errors of metabolism	variable (per product)	variable (per product)	many

1. medium-chain triglyceride 2. docosahexaenoic acid 3. arachidonic acid 4. long-chain triglyceride

clinics, and hospitals. Specialized formulas, such as those for inborn errors of metabolism, renal disease, and severe allergies, are not typically available or obtained via retail channels. At this time, there is no quantitative data to confirm the many anecdotes from families and clinicians who were challenged in accessing specialized formulas, nor is there data of medical emergencies directly related to the shortage or of the impact on specific patient populations.

There is, however, data supporting adverse impact broadly. The United States Census Bureau's Household Pulse Survey was developed to assess socioeconomic impacts of the SARS-CoV-2 (COVID-19) pandemic rapidly and continually. In 2022, questions specific to the infant formula shortage were included. First results for these questions from September 2022[29] revealed the following:

- Of households with infants, 50.2% reported being affected by the infant formula shortage.
- Of households with infants who used formula, 31.8% reported difficulty obtaining formula over the last 7 days, including 32.9% using routine infant formula, 32.6% using extensively hydrolyzed infant formula, 65.1% using amino acid formula, and 65.9% using metabolic formula.
- Of households with infants who used formula, 6.2% reported having no formula on hand, and 18% reported having less than a week's supply on hand.
- Of households affected by the infant formula shortage, irrespective of income level, 8.1% reported watering down formula or making a homemade version. The household income categories with the highest rates of watering down or using homemade formula: <$25,000 (25.5%), $35,000-$49,999 (17.8%) and ≥ $200,000 (13.9%).

Federal Response

The impacts assessed by the Household Pulse Survey were likely mitigated by several federal actions in response to the shortage. These initiatives aimed to increase the domestic supply of infant formula and to increase flexibility in formula purchasing by WIC participants. Major actions are listed below.

Defense Production Act

On May 18, 2022, President Joseph Biden delegated authority to the Secretary of the HHS to invoke the Defense Production Act (DPA). By invoking the DPA, HHS was able to prioritize procurement of raw materials for infant formula production by Abbott Nutrition and Mead Johnson.[30]

Operation Fly Formula

Along with the DPA, President Biden announced Operation Fly Formula. A coordinated effort of the USDA, HHS, and Department of Defense, Operation Fly Formula was a series of air shipments of formulas sourced from other countries. As of October 5, 2022, 26 missions were completed.[31]

FDA Enforcement Discretion to Manufacturers

Most formulas imported via Operation Fly Formula were products previously not approved by the FDA for domestic sale. Announced on May 16, 2022, the FDA's Enforcement Discretion to Manufacturers was essentially an accelerated and temporary approval of foreign formulas for sale in the United States on a case-by-case basis. Among the FDA

Table 2. Infant Formula Shortage Emergency Guidelines

Organization	Web Resource
American Academy of Pediatrics (AAP)	publications.aap.org/DocumentLibrary/Solutions/PPE/BabyFormulaShortages_ppe_document263_en.pdf
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)	naspghan.org/recent-news/naspghan-tools-for-hcps-affected-by-formula-recall/
United States Centers for Disease Control and Prevention (CDC)	cdc.gov/nutrition/infantandtoddlernutrition/formula-feeding/infant-formula-shortage.html
United States Department of Agriculture (USDA) Food and Nutrition Service (FNS)	fns.usda.gov/infant-formula
United States Department of Health and Human Services (HHS)	hhs.gov/formula/index.html

criteria for review were nutritional composition, ingredients, product label and packaging, current or anticipated inventory, microbiological testing, and facility inspection history. A stop-gap approach, the FDA Enforcement Discretion to Manufacturers expired November 14, 2022, though some products approved before that date may remain in the United States market.[32]

Access to Baby Formula Act

The Access to Baby Formula Act (ABFA) was passed on May 21, 2022. This amendment to the Child Nutrition Act of 1966 has two broad objectives. The first is to require state WIC agencies to include language in their infant formula rebate contracts regarding manufacturers' plans to prevent supply disruption for WIC participants in the event of a recall. For example, the FNS recommends that "manufacturers be required to pay rebates on both contract brand and non-contract brand formula in any available unit size, type, or form".[33]

The second main objective of the ABFA is to give the USDA permanent authority to issue waivers for WIC program rules during emergencies, disasters, and supply chain disruptions.[33] Prior to the ABFA, state WIC agencies submitted individual requests to implement emergency waivers. Some states had done so with the COVID-19 pandemic, and they were able to invoke their existing emergency waiver to allow participants to access non-contract formula substitutes during the infant formula shortage. The ABFA allows for a more streamlined waiver process.

Tips for Clinicians

Formula Substitutions

- See Table 2 for emergency guidance from governmental and professional organizations.
- See Table 3 for a formula substitution matrix.
- Formulas marketed for sensitivity/comfort have varying degrees of lactose reduction. There is no evidence supporting lactose reduction in infants apart from rare circumstances: galactosemia, an inborn error of metabolism that requires total lactose elimination; congenital disaccharidase deficiency; and transient lactose intolerance from acute gastroenteropathy.[34] Thus, the lactose contents of these formulas should not be used as a criterion for determining appropriate substitutions in most cases.
- Toddler formulas are not regulated like infant formulas. They have varying calorie concentrations and may not be nutritionally complete. The nutritional composition of toddler

Table 3. Formula Substitution Matrix

Formula Unavailable	Substitute Options								
	Preterm Discharge	Routine Term	Soy	Added Rice	Sensitive/ Comfort	Extensively Hydrolyzed	Amino Acid	Renal	Metabolic
Preterm Discharge	-	Yes	Avoid*	Avoid*	Yes	Avoid*	Avoid*	No	No
Routine Term	Avoid*	-	Yes	Yes	Yes	Avoid*	Avoid*	No	No
Soy	Avoid*	No	-	No	No	Yes+	Avoid*	No	No
Added Rice	Avoid*	Yes	Yes	-	Yes	Avoid*	Avoid*	No	No
Sensitive/ Comfort	Avoid*	Yes	Yes	Yes	-	Avoid*	Avoid*	No	No
Extensively Hydrolyzed	No	No	Caution±	No	No	-	Avoid*	No	No
Amino Acid	No	No	Caution±	No	No	No∨	-	No	No
Renal	No	No	No	No	No	No	No	-	No
Metabolic	No	No	No	No	No	No	No	No	-

*Option may be used safely but is not recommended, either due to nutrient composition or because it is a specialty formula needed by high-risk populations.
+Extensively hydrolyzed (EH) formula may be used for infants on soy formula due to cow milk protein allergy. Most EH formulas are lactose-free and may be used with galactosemia. Imported EH formulas may contain lactose, however.
±Infants with cow milk protein allergic conditions may also react to soy. Use cautiously.
∨Infants with severe cow milk protein allergic conditions requiring amino acid formula may eventually be able to tolerate EH formula. Use cautiously.

Table 4. Foreign Formulas Approved via FDA Enforcement Discretion to Manufacturers

Routine Term Formulas	Specialty Formulas
a2 Platinum® Infant Formula Stage 1	Nutricia Pepticate™
a2 Platinum® Follow-On Formula Stage 2	Nutricia Pepticate Syneo®
Aptamil® First Infant Milk Stage 1	Vitaflo PKU Start™
Bellamy's Organic Infant Formula Step 1	SMA Nutrition Althéra®
Bellamy's Organic Infant Formula Step 2	
Bubs® Organic Grass Fed Infant Formula Stage 1	
Bubs® Organic Grass Fed Follow-On Formula Stage 2	
Bubs® Supreme A2 Beta Casein Protein Infant Formula Stage 1	
Bubs® Supreme A2 Beta Casein Protein Infant Formula Stage 2	
Bubs® Easy-Digest Goat Milk Infant Formula Stage 1	
Bubs® Easy-Digest Goat Milk Follow-On Formula Stage 2	
Care A2+™ 0-12 months	
Gerber® Good Start® Gentle	
Kendamil® Classic First Infant Milk Stage 1	
Kendamil® Organic First Infant Milk Stage 2	
Kendamil® Goat First Infant Milk Stage 1	
Kendamil® First Infant Formula with Iron	
Nestlé NAN® Supreme Pro 1	
Nestlé NAN® Supreme Pro 2	
Nestlé NAN® Expert Pro Sensi Pro	

formulas should be thoroughly evaluated prior to use, and use should be temporary (<1 week).

Foreign Formulas

- Foreign formulas sold within the FDA Enforcement Discretion to Manufacturers may be used with confidence.
- Safety, quality, and identity cannot be guaranteed for foreign formulas imported outside the FDA Enforcement Discretion.
- See Table 4 for an updated list of FDA-approved foreign formulas.
- Some foreign formulas are "staged". "Stage 1" or "first milk" is for infants up to 6 months of age. Stage 2, "second", or "follow-on" milk is for infants 6-12 months of age. Stages vary in nutritional composition, particularly iron. Guide caregivers to use the correct stage for their infant's age.

Accurate and Safe Formula Preparation

- Never dilute infant formula.
- Scoop sizes are formula-specific and may not be interchanged. The mixing instructions for specialty formulas and imported formulas may differ.
- Imported formulas may express water measurements as milliliters instead of ounces. Ensure caregivers understand how to convert between units (one fluid ounce contains 30 milliliters).
- Families who were instructed to mix formula to a non-standard calorie concentration using a hospital- or clinic-provided recipe should receive updated mixing instructions with every formula change.
- If non-standard mixing instructions are not immediately available, instruct families to prepare formula per can instructions until the specialized recipes can be conveyed.
- Reinforce safe formula mixing methods to minimize the growth of harmful pathogens. See Infant Formula Preparation and Storage on the Centers for Disease Control and Prevention website (cdc.gov) for guidance.

Homemade Formulas and Milks

- Ask caregivers whether they are making homemade formulas, as this practice has been reported by a significant percentage of households.[29]
- Discourage use of homemade formula.

Although once a common practice, it was not without documented health consequences, including hypertonic dehydration, rickets, scurvy, and iron deficiency.[1,6] Contemporary variations of homemade formulas available on social media have been noted to contain unsafe ingredients,[35,36] and some have been implicated in cases of malnutrition, electrolyte disarray, acidosis, rickets, seizure, and cardiac arrest.[37-39]

- Emergency guidance from the American Academy of Pediatrics states that pasteurized whole cow milk or fortified soy milk may be used for infants older than 6 months and for no longer than one week.[40]
- Plant-based alternative milks, other than temporary use of soy milk described above, should not be used.
- Raw milk from cows, goats, or other mammals, should never be given.

Human Milk

Select recommendations from the Academy of Breastfeeding Medicine include:[41]

- Support those wishing to increase milk production by referring to a qualified lactation expert.
- If accessible, consider pasteurized donor milk from milk banks certified by the Human Milk Banking Association of North America (visit hmbana.org for a map of milk bank locations).
- Exercise caution with informal milk sharing. Consider the health of the donor, along with flash pasteurization methods.
- Discourage online purchasing of human milk, especially from unknown donors.

Collaboration

- As applicable, be familiar with state WIC program formularies and approved substitutions.
- Be aware of current limitations in how WIC participants may access formula. For example, formulas may only be purchased at WIC-approved retailers; online purchases are not currently a feature of the program. Some states offer ship-to-home services for specialty formulas.
- As applicable, be familiar with DME company formularies and communicate with DME personnel to stay abreast of inventory changes.
- Give input to hospital stakeholders involved in facility formula contract negotiations to optimize formula access.
- Utilize registered dietitian/nutritionists (RDNs) with expertise in infant nutrition for guidance on the features and indications of various formulas, as well as for specialized mixing instructions.

CONCLUSION

The evolution of the infant formula industry has shaped, and has been shaped, by scientific advances, infant feeding trends, and regulatory constraints and liberties, both. The 2022 shortage experienced in the United States may reshape the domestic market and industry at large. Notwithstanding, at the time of this writing, the major trade and regulatory structures underpinning formula access in the United States remain intact. Time will tell whether the market diversity and resiliency will improve. Clinicians in inpatient and outpatient pediatric care settings will benefit from an understanding of the systems that influence infant formula use and access to help provide families with safe recommendations and resources. ■

References

1. Fomon SJ. Infant feeding in the 20th century: Formula and beikost. *J Nutr*. 2001;131(2).
2. Wargo WF. The history of infant formula: quality, safety, and standard methods. *J AOAC Int*. 2016;99(1):7-11.
3. Schuman A. A concise history of infant formula (twists and turns included). *Contemp Pediatr*. 2003; 2:91.
4. *The Mellin's Food Method of Percentage Feeding*. Press of Mellin's Food Company; 1908.
5. Martinez GA, Krieger FW. 1984 milk-feeding patterns in the United States. *Pediatrics*. 1985;76(6).
6. Bertmann F, Dunn CG, Racine EF, Fleischhacker S. The risk of homemade infant formulas: Historical and contemporary considerations. *J Acad Nutr Diet*. 2022;122(4):697-708.
7. U.S. Federal Food, Drug, and Cosmetic Act. 21 U.S.C. §§301-392, 52 Stat. 1040 (1938).
8. Nelson EM. Association of vitamin B6 deficiency with convulsions in infants. *Public Health Rep*. 1956;71(5).
9. Laskin CR, Pilot LJ. Defective infant formula: The Neo–Mull–Soy/Cho–Free incident. *Prev Hum Serv*. 1982;1(4).
10. Malloy MH, Willoughby A, Berendes H, et al. Hypochloremic metabolic alkalosis from ingestion of a chloride-deficient infant formula: Outcome 9 and 10 years later. *Pediatrics*. 1991;87(6).
11. Infant Formula Act of 1980. 21 U.S.C. 106 §350a (2014). Accessed November 11, 2022. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106.
12. Infant Formula Act of 1980. 21 U.S.C. 106 §350a (1985). Accessed November 11, 2022. https://www.ecfr.gov/current/

title-21/chapter-I/subchapter-B/part-107.
13. Soldavini J, Taillie LS. Recommendations for adopting the International Code of Marketing of Breast-milk Substitutes into U.S. policy. *J Hum Lact*. 2017;33(3).
14. U.S. Food and Drug Administration. *Exempt Infant Formulas Marketed in the United States by Manufacturer and Category*. Updated December 3, 2019. Accessed November 11, 2022. https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/exempt-infant-formulas-marketed-united-states-manufacturer-and-category.
15. Koletzko B, Baker S, Cleghorn G, et al. Global standard for the composition of infant formula: Recommendations of an ESPGHAN coordinated international expert group. *J Pediatr Gastroenterol Nutr*. 2005;41(5).
16. Alles MS, Scholtens PAMJ, Bindels JG. Current trends in the composition of infant milk formulas. *Current Paediatrics*. 2004;14(1).
17. U.S. Food & Drug Administration. Mutual Recognition Agreement (MRA). Updated November 8, 2021. Accessed November 11, 2022. https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra.
18. Casey, C. Congressional Research Service. Published May 23, 2022. Accessed October 29, 2022. Tariffs and the infant formula shortage. https://crsreports.congress.gov/product/pdf/IN/IN11932.
19. Leo L, Khandekar A. Abbott aims to recapture baby formula market share. *Reuters*. July 20, 2022. Accessed November 11, 2022. https://www.reuters.com/business/healthcare-pharmaceuticals/abbott-raises-2022-profit-forecast-2022-07-20.
20. Bottemiller Evich H. "I don't know how my son will survive": Inside the dangerous shortage of specialty formulas. Politico. May 7, 2022. Accessed November 11, 2022. https://www.politico.com/news/2022/05/07/i-dont-know-how-my-son-will-survive-inside-the-dangerous-shortage-of-specialty-formulas-00030787.
21. Choi YY, Ludwig A, Andreyeva T, Harris JL. Effects of United States WIC infant formula contracts on brand sales of infant formula and toddler milks. J Public Health Pol. 2020;41(3):303-320.
22. Rojas CA, Wei H. Spillover mechanisms in the WIC infant formula rebate program. J Agric Food Ind Organ. 2019;17(2).
23. Neuberger Z, Bergh K, Hall L. Center on Budget and Policy Priorities. Infant formula shortage highlights WIC's critical role in feeding babies. June 22, 2022. Accessed October 29, 2022. https://www.cbpp.org/research/food-assistance/infant-formula-shortage-highlights-wics-critical-role-in-feeding-babies.
24. USDA Economic Research Service. WIC Program. Updated August 10, 2022. Accessed November 6, 2022. https://www.ers.usda.gov/topics/food-nutrition-assistance/wic-program.
25. USDA Food and Nutrition Service. Fiscal Year 2020 WIC Breastfeeding Data Local Agency Report. Published June 2021. Accessed October 29, 2022. https://fns-prod.azureedge.us/sites/default/files/resource-files/FY2020-BFDLA-Report.pdf.
26. Bottemiller Evich H. Whistleblower warned FDA about formula plant months before baby deaths. Politico. April 28, 2022. Accessed November 11, 2022. https://www.politico.com/news/2022/04/28/whistleblower-fda-baby-formula-00028569.
27. Snider M. Baby formula shortage continues: nearly 30% of popular brands sold out, stores ration sales. USA Today. April 9, 2022. Accessed October 29, 2022. https://www.usatoday.com/story/money/shopping/2022/04/09/baby-formula-shortage-2022-worsens/9525498002.
28. Datasembly releases latest numbers on baby formula. Datasembly. May 10, 2022. Accessed October 29, 2022. https://datasembly.com/news/datasembly-releases-latest-numbers-on-baby-formula.
29. U.S. Census Bureau. Week 49 Household Pulse Survey: September 14 - September 26. Published October 5, 2022. Accessed November 5, 2022. https://www.census.gov/programs-surveys/household-pulse-survey/data.html.
30. U.S. Department of Health and Human Services. HHS Secretary Becerra Invokes Defense Production Act for Third Time to Further Increase Production of Infant Formula for American Families. Published May 27, 2022. Accessed October 29, 2022. https://www.hhs.gov/about/news/index.html.
31. The White House. President Biden Announces Twenty-Sixth Operation Fly Formula Mission. Published October 5, 2022. Accessed November 11, 2022. https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/05/president-biden-announces-twenty-sixth-operation-fly-formula-mission.
32. U.S. Food and Drug Administration. Enforcement Discretion to Manufacturers to Increase Infant Formula Supplies. Updated November 2, 2022. Accessed November 12, 2022. https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies.
33. U.S. Department of Agriculture Food and Nutrition Service. WIC Policy Memorandum #2022-6: Implementation of the Access to Baby Formula Act of 2022 - PL 117-129. Published June 6, 2022. Accessed November 11, 2022. https://fns-prod.azureedge.us/sites/default/files/resource-files/WPM-2022-6-Access-Baby-Formula-Act-2022.pdf.
34. Heine RG, Alrefaee F, Bachina P, et al. Lactose intolerance and gastrointestinal cow's milk allergy in infants and children - Common misconceptions revisited. World Allergy Organization Journal. 2017;10(1).
35. Davis SA, Knol LL, Crowe-White KM, Turner LW, McKinley E. Homemade infant formula recipes may contain harmful ingredients: A quantitative content analysis of blogs. Public Health Nutr. 2020;23(8).
36. Aiken S, Knol L, Crowe-White K, Turner LW. A Content Analysis of Blogs Featuring Homemade Infant Formula Recipes. J Acad Nutr Diet. 2017;117(10).
37. Vieira MA, Kube PK, van Helmond JL, et al. Recipe for disaster: Homemade formula leading to severe complications in 2 infants. Pediatrics. 2021;148(3).
38. Calello DP, Jefri M, Yu M, Zarraga J, Bergamo D, Hamilton R. Vitamin D-deficient rickets and severe hypocalcemia in infants fed homemade alkaline diet formula — three states. August 2020-February 2021. MMWR Recomm Rep. 2021;70(33). doi:10.15585/mmwr.mm7033a4.
39. Davydov D, Martin A, Bauerfeld C. Detrimental effects of internet-promoted "healthy" homemade formula in two infants. Pediatrics. 2021;147(3_Meeting Abstract).
40. Abrams S. With the baby formula shortage, what should I do if I can't find any? American Academy of Pediatrics. Updated June 28, 2022. Accessed November 11, 2022. https://www.healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/Are-there-shortages-of-infant-formula-due-to-COVID-19.aspx.
41. Kellams A. Academy of Breastfeeding Medicine Recommendations during shortage of artificial breast milk substitutes. Breastfeed Med. 2022;17(6):469-471.