Challenges in the Supply, Market Competition and Regulation of Infant Formula in the United States – NASEM Consensus Study

Patricia A. Hansen, Ph.D.
Deputy Director, Office of Nutrition and Food Labeling
Project Advisory Group Members
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Presented to the Study Committee- September 28, 2023

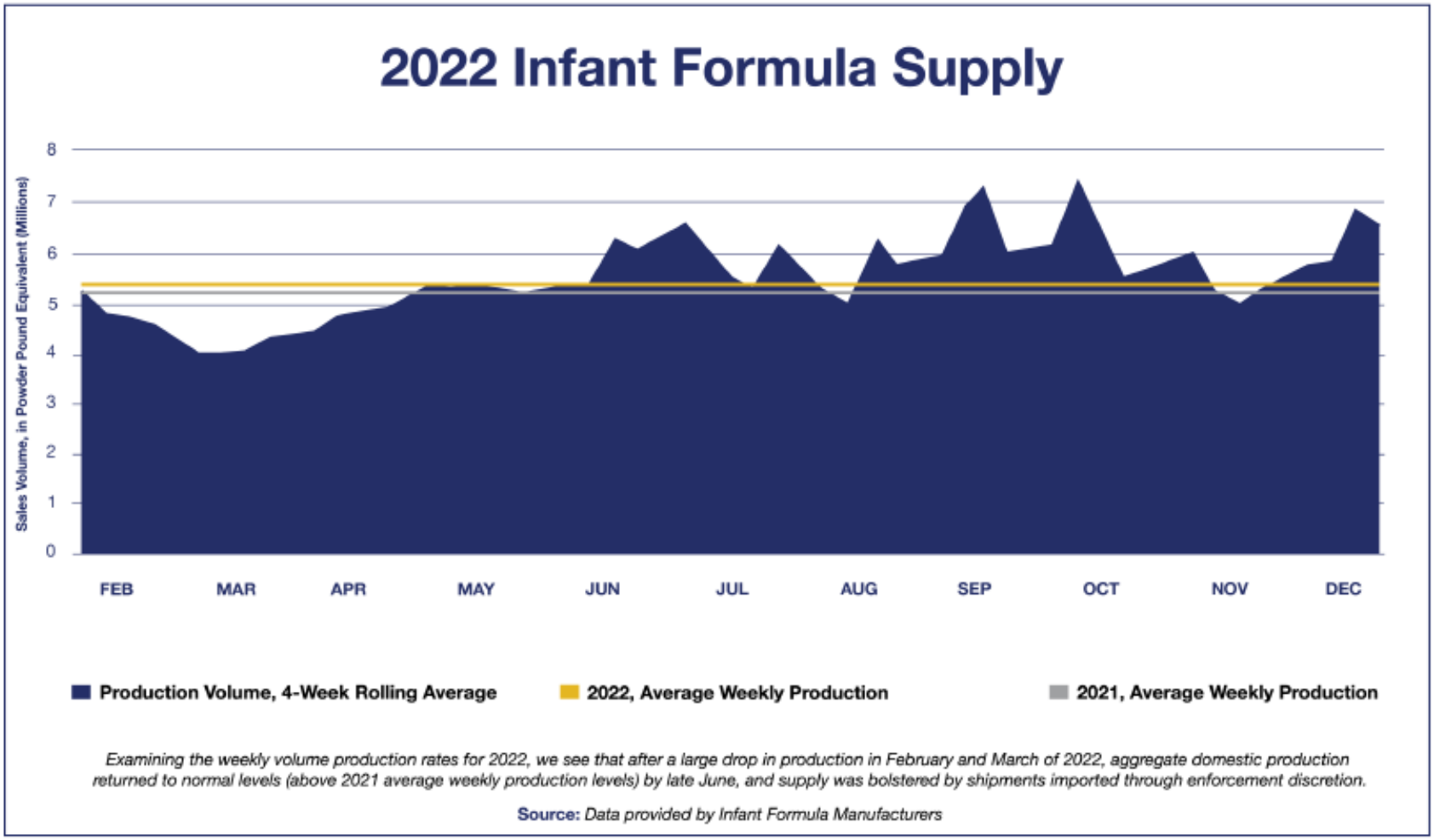
Overview

- Background
- Goal and intended use of the study report
- Overview of scope, focus of the study/report
- Statement of Task
  - Deeper dive on certain points
- Summary/Key Takeaways
- Q&A

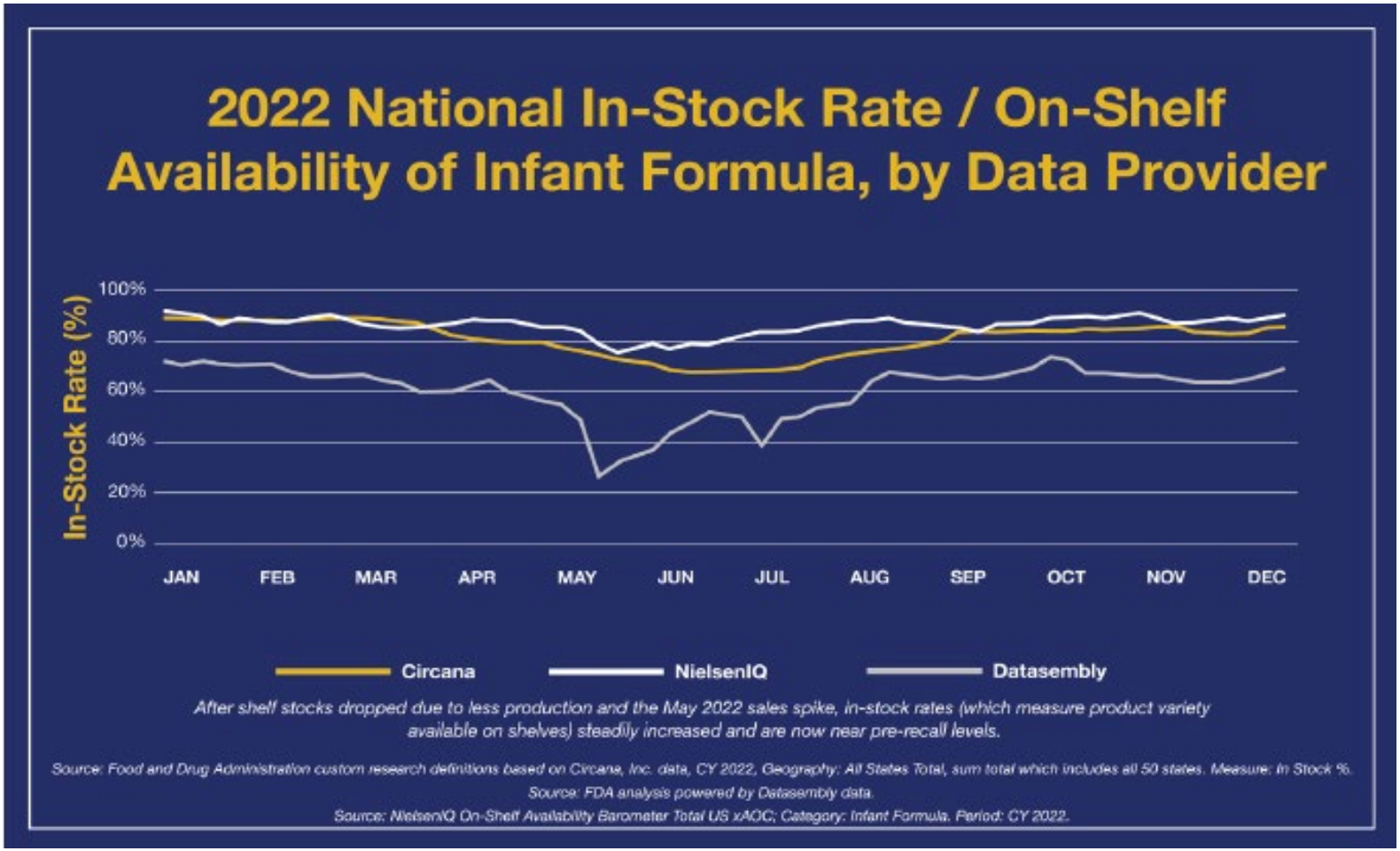
General Background

- A highly concentrated market for infant formula in the U.S.
- Pre-existing challenges in the overall food supply chain associated with aspects of the COVID-19 pandemic
- Severe challenges in the U.S. infant formula supply beginning in spring 2022 in the wake of a major recall and facility shut-down by Abbott
- Many actions to address the challenges taken by FDA and other Federal partners in a “whole of government” effort, the infant formula industry and other stakeholders
- Congressional direction for further actions, including this Consensus Study, provided in the Food and Drug Omnibus Reform Act of 2022

Further Background



Further Background



Congressional Direction – NASEM Consensus Study

‘…the Secretary shall seek to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to in this paragraph as the ‘‘National Academies’’) to examine and report on challenges in supply, market competition, and regulation of infant formula in the United States.’

Congressional Direction – NASEM Consensus Study

The report is to …

- Assess and evaluate—
  - (I) infant formula marketed in the United States;
  - (II) any challenges in supply, or market competition with respect to such infant formula; and
  - (III) any differences between infant formula marketed in the United States and infant formula marketed in the European Union, including with respect to nutritional content and applicable labeling and other regulatory requirements; and
- Include recommendations, including for infant formula manufacturers, on measures to address supply and market competition in the United States.

FDA's Intended Use of the Study Report

- The study report will be used by FDA, along with other data and information, to inform the development of the long-term National Strategy on Infant Formula described in the Food and Drug Omnibus Reform Act of 2022
- Specifically, the report will be used, along with other data and information, to update and expand the March 2023 Immediate National Strategy on Infant Formula into a long-term national strategy
- The report will also be used to otherwise inform FDA's overall efforts to enhance its systems, tools, and processes to support a robust and resilient supply of safe and nutritionally adequate infant formula

National Strategy on Infant Formula - Congressional Direction

"The Secretary, in consultation with the Secretary of Agriculture and other heads of relevant departments and agencies, shall develop and issue…a national strategy on infant formula to increase the resiliency of the infant formula supply chain, protect against future contamination and other potential causes of supply disruptions and shortages, and ensure parents and caregivers have access to infant formula and information they need."

Immediate National Strategy on Infant Formula

Increase resiliency in short term by:

- Assessing causes of current shortage and potential causes of future disruption
- Assessing and addressing immediate supply needs associated with the shortage
- Development of a plan to increase supply including through increased competition
- Development and updating of educational materials for parents/caregivers

https://www.fda.gov/media/166520/download

Long Term National Strategy on Infant Formula

Will update the Immediate National Strategy to include efforts to improve preparedness against infant formula shortages in the long-term by:

- Outlining methods to improve info-sharing among levels of government
- Recommending measures to protect IF integrity and prevent contamination
- Outlining methods to incentivize new infant formula manufacturers
- Recommending any new authorities needed to gain insight into the supply chain, understand risks of shortages, and incentivize new infant formula manufacturers to enter the market

Report Recommendations – FDA Suggestions

Key Stakeholders for Receiving Recommendations

- FDA
- Other relevant Federal departments and agencies (e.g., USDA, FTC, Commerce, other)
- Consider State and local governments in areas where they may be particularly relevant
- Infant formula manufacturers and distributors
- Other entities in the overall infant formula supply chain, as appropriate

Report Recommendations – FDA Suggestions

Directing and Prioritizing Recommendations

- FDA is interested in receiving both recommendations that could be implemented with current authorities and recommendations that may require additional authorities
- For areas where FDA lacks authority, consider whether FDA should seek the authority or whether the recommendation might be better directed toward other Federal departments/agencies, or other stakeholders
- Please prioritize recommendations or groups of recommendations and provide insight into the principles or criteria used for prioritization

Area in the Statement of Task

Infant Formula Marketed in the U.S.

A number of different aspects of the U.S. infant formula supply and market are identified for exploration

- Characterization of the current U.S. infant formula market 2018/2019 (pre-COVID-19 pandemic), 2020/2021 (before the Abbott recall), and current (2023)
- Number, market share, and other characteristics of firms manufacturing in the U.S. and similar for firms manufacturing infant formula for the U.S. market (including contract manufacturers), including firms marketing infant formulas under FDA's policy for continued exercise of enforcement discretion (see May 2022 and September 2022 guidances)
- Manufacturing sites for infant formula marketed in the U.S. (domestic and foreign). To the extent possible, indicate specific formulas and types manufactured at a given site
- Amount of formula produced domestically for the U.S. market and amount imported.
- Firms supplying formulas distributed through WIC. Break out by state.

Area in the Statement of Task
Infant Formula Marketed in the U.S.

A number of different aspects of infant formulas marketed in the U.S., their production, and the marketplace are identified for exploration

- We recognize that some of the areas delineated on the previous slide will be more tractable than others
- Wherever possible, please break out information regarding formulas for healthy, full-term infants (“non-exempt,” sometimes referred to as “routine”) from information regarding formulas for infants that are premature, of low birth weight, have an inborn error of metabolism, or have other medical conditions (“exempt,” sometimes referred to as “medical specialty” or “specialty” formulas)
- Distinguishing domestic and foreign manufacture and domestically produced and imported formulas is helpful. Characterizing firms as domestic and foreign less so, because a fair number have both domestic and foreign sites

Area in the Statement of Task

Challenges in Supply or Market Competition*

A number of different topics are identified for exploration

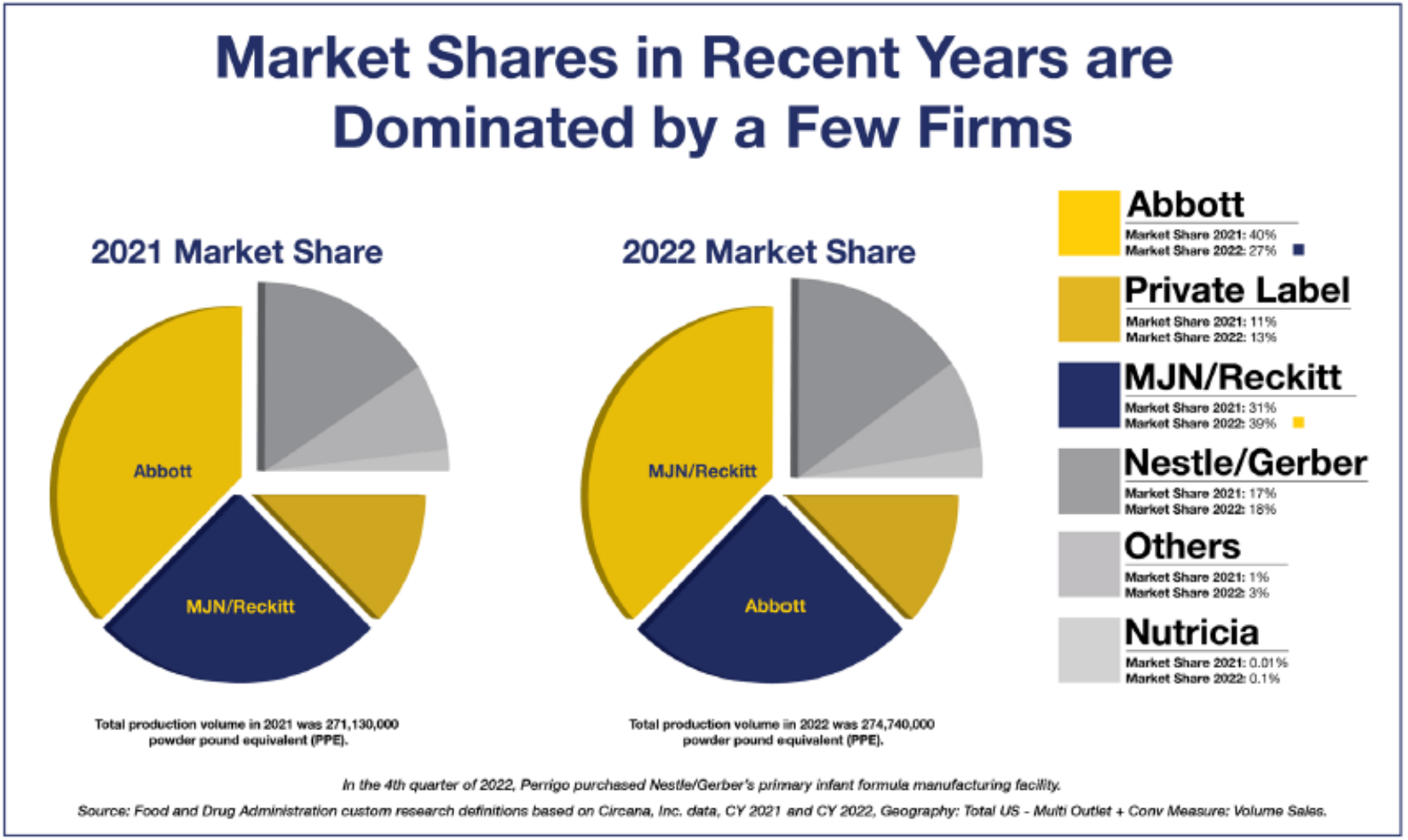
- Necessary investments and resources for firms to enter into and remain in the U.S. market
- Tariffs and taxes
- Structure and implementation by states of the USDA WIC program
- Securing stable sourcing for key ingredients** for infant formula formulas
- Other marketplace barriers, incentives, and disincentives

* Consider also in terms of “market concentration”

** Include also packaging components

Area in the Statement of Task

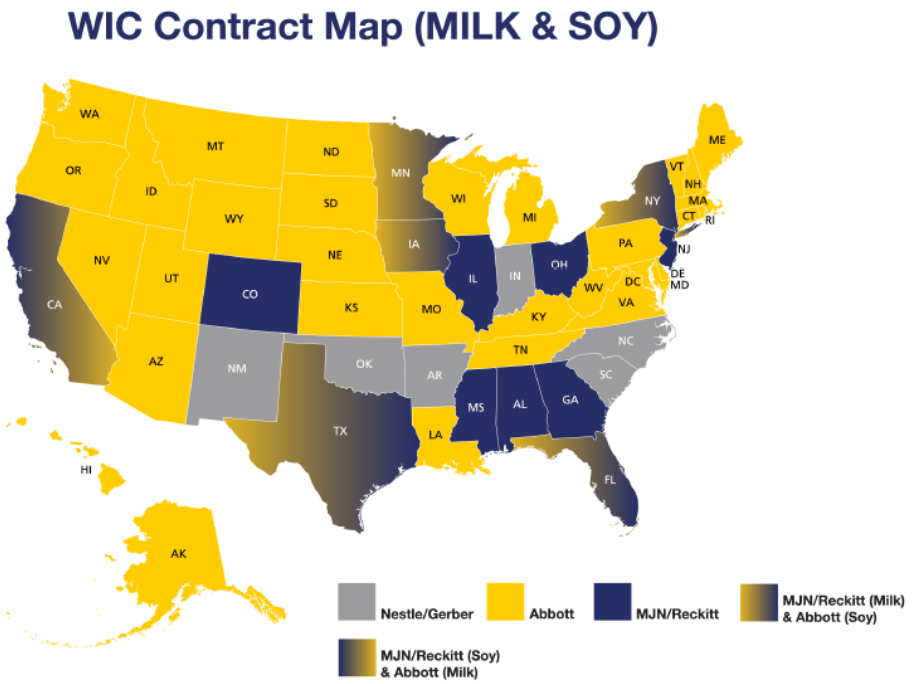
Challenges in Supply or Market Competition*



Area in the Statement of Task

Challenges in Supply or Market Competition*

- The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) serves nearly 7 million people, including nearly 2 million infants. Over half of the infant formula sold in the U.S. is purchased through WIC.
- Contracts are awarded to the manufacturer offering the highest discount on wholesale prices. This can pose challenges for non-contract manufacturers to gain market share in any given state.



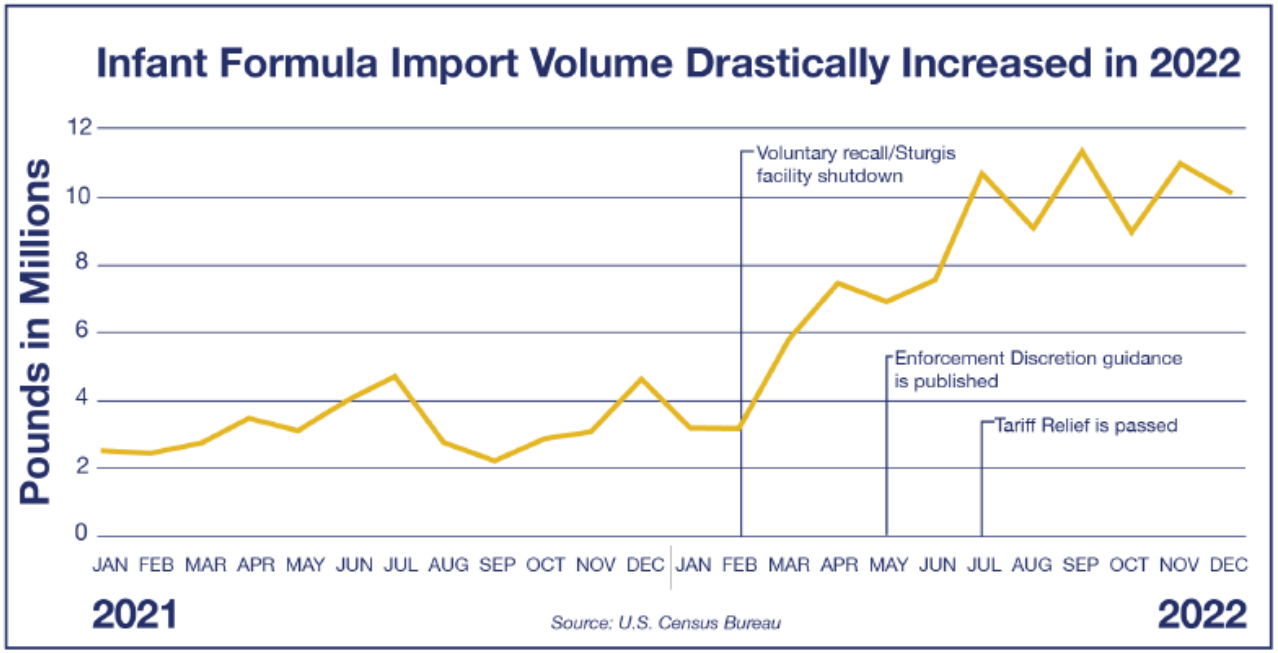
In the 4th quarter of 2022, Perrigo purchased Nestle/Gerber's primary infant formula manufacturing facility.

Source: *U.S. Department of Agriculture, 2022*

Area in the Statement of Task

Challenges in Supply or Market Competition*

- The U.S. has historically produced more infant formula than it consumes; imports prior to 2022 represented less than 1% of the total volume of infant formula sold in the U.S.
- Infant formula products are subject to a base tariff rate of nearly 15 percent, and an effective rate of about 25 percent.



Area in the Statement of Task

Challenges in Supply or Market Competition*

New statutory requirements not explicitly mentioned in the SOT that relate to infant formula supply challenges and tools to manage them

- New statutory requirement for manufacturers to notify FDA in the event of a "meaningful disruption" in the supply of a "critical food"*
- New statutory requirement for manufacturers of a critical food to establish and maintain redundancy risk management plans
- New statutory requirement regarding infant formula manufacturer's notification responsibilities in the event of a recall
- New statutory requirement for FDA to notify Congress of the information supplied by an infant formula manufacturer in the event of a recall and also to provide information on the current state of the infant formula supply

* Defined as any infant formula or medical food (as defined in the statute)

Area in the Statement of Task

Differences in Regulatory Requirements for Infant Formula in the U.S. and in Other Regions

Several specific regions are identified for exploration

- European Union
- United Kingdom
- Australia and New Zealand
- Mexico and Canada

Several areas for consideration are noted

- Nutritional content
- Labeling
- Other regulatory requirements and oversight (e.g., finished product testing, ingredients, inspections) – Note that this list of examples is not all-inclusive

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Statutory and Regulatory Requirements for Infant Formula

A Quick Overview

History – Need for Legislation

- 1978: Addition of sodium chloride to infant formula discontinued by one manufacturer
- 1978–1979: More than 130 infants developed hypochloremic metabolic alkalosis
  - Serious alterations in acid-base balance
  - Presented as vomiting, nausea, and poor growth
  - Many required hospitalization

Infant Formula Act

- Enacted 1980
- Amended 1986
- Section 412 of the Food, Drug, and Cosmetic Act (21 U.S.C. 350a)
  - Safe production
  - Nutritional sufficiency
  - Premarket notification and registration
  - Records
  - Adulteration
  - Mandatory recall authority

Infant Formula Regulations

- Title 21 Code of Federal Regulations (CFR)
  - Part 106 : Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula
  - Part 107 : Infant Formula
- Infant Formula Final Rule (2014)

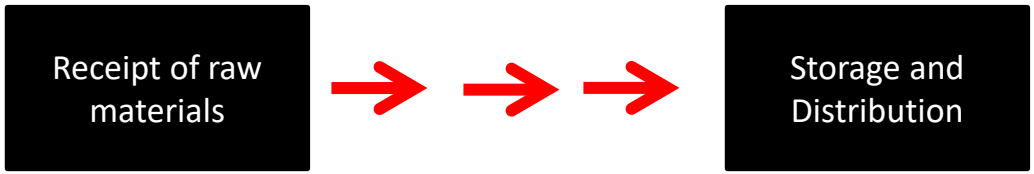
21 CFR 106

INFANT FORMULA REQUIREMENTS PERTAINING TO GOOD MANUFACTURING PRACTICE, QUALITY CONTROL PROCEDURES, QUALITY FACTORS, RECORDS AND REPORTS, AND NOTIFICATIONS

Subpart	Title
A	General Provisions
B	Current Good Manufacturing Practice
C	Quality Control Procedures
D	Conduct of Audits
E	Quality Factors for Infant Formulas
F	Records and Reports
G	Registration, Submission, and Notification Requirements

Subpart B – Current Good Manufacturing Practices (cGMP)

- Minimum cGMP requirements
  - Manufacture, processing, packaging, holding
  - Failure to comply = adulterated infant formula
- Production and in-process control system covering all stages of processing
  - Written plan or set of procedures
  - Designed to ensure infant formula is manufactured in a manner to prevent adulteration



cGMP

- Controls to prevent adulteration:
  - Workers
  - Facilities
  - Equipment or utensils
  - Automatic (mechanical or electronic) equipment
  - Ingredients, containers, and closures
  - Manufacturing
  - Microorganisms
  - Packaging and labeling
- Controls on the release of finished infant formula
- Traceability

Ingredients

- Ingredients must be safe and suitable ***for use in infant formula*** per applicable food safety provisions of FD&C Act
  - Used in accordance with FDA's food additive regulations
  - Generally Recognized as Safe (GRAS) for use in infant formula
  - Authorized by prior sanction
- Information must be included in premarket infant formula submission

21 CFR 106.40(a)

Microorganism Testing

- Powdered infant formula
  - Test each production aggregate at final product stage
  - *Cronobacter* spp. and *Salmonella* spp.
  - Above M value (none detected) = adulterated

Microorganism	Number of Samples	Sample Size	M value
Cronobacter spp.	30	10 g	0
Salmonella spp.	60	25 g	0

- Liquid – Must comply, as appropriate, with procedures in:
  - 21 CFR 113 Thermally processed low-acid foods packaged in hermetically sealed containers (LACF)
  - 21 CFR 114 Acidified foods

21 CFR 106.55

Subpart C – Quality Control Procedures

- Nutrient testing requirements – each production aggregate
  - Nutrient premixes and indicator nutrient
  - All required nutrients prior to release
    - Vitamins A, C, E and thiamin – at final product stage
    - Others during production and/or final product stage
- Shelf-life testing
  - First production aggregate: all nutrients (except minerals) every 4 months
  - All production aggregates: all nutrients (except minerals) at end of shelf life

21 CFR 106.91

Nutrient Content Requirements

- Currently 30 required nutrients
  - Minimum levels for all 30 nutrients
  - Maximum levels for 10 nutrients*

- Protein*
- Fat*
- Linoleic acid
- Vitamin A*
- Vitamin D*
- Vitamin E
- Vitamin K
- Thiamin (Vitamin B_1)
- Riboflavin (Vitamin B_2)
- Vitamin B_6
- Vitamin B_{12}
- Niacin
- Folic acid
- Pantothenic acid
- Biotin
- Vitamin C (Ascorbic acid)
- Choline
- Inositol
- Calcium
- Phosphorus
- Magnesium
- Iron*
- Zinc
- Manganese
- Copper
- Iodine*
- Selenium*
- Sodium*
- Potassium*
- Chloride*

21 CFR 107.100

Subpart G – Registration, Submission, and Notification

- Infant formula registration (§ 106.110)
- Premarket submission types

1) New infant formula submission (90 days premarket) (§ 106.120)
    - New product from new manufacturer
    - New product from existing manufacturer
    - Major change in formulation, processing, or packaging of existing product
2) Before first processing submission (§ 106.140)
3) Export only submission (§ 106.120(c))

New Infant Formula Submission

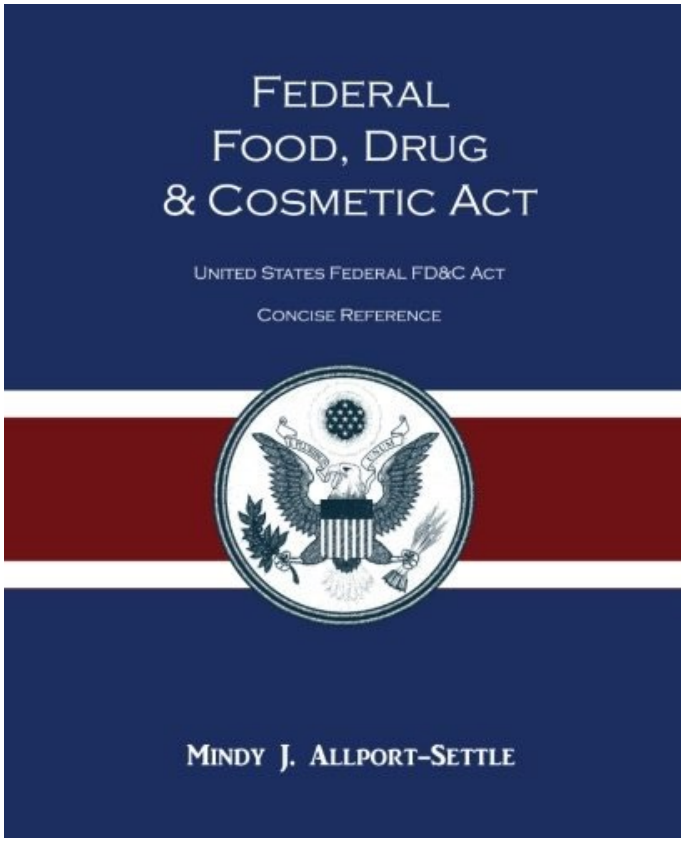
(90 days premarket)

- Name and description of infant formula
- Quantitative formulation (recipe)
  - Including discussion of effects of changed ingredients on the nutrient levels
- Processing and packaging information
- Assurances (data and information)
  - Quality factor requirements
  - Compliance with nutrient content requirements
  - Basis for each ingredient meeting safety and suitability requirements of 21 CFR 106.40(a)
- Exemption requests, if applicable

21 CFR 106.120 and 106.121

21 CFR 106.3
Quality Factors

"those factors necessary to demonstrate the **safety** of the infant formula and the **bioavailability** of its nutrients, as prepared for market and when fed as the **sole source of nutrition**, to ensure the healthy growth of infants."



Quality Factors*

Sufficient biological quality of protein

Normal physical growth

*Apply to non-exempt infant formula designed for healthy, term infants.

Infant Formula Label

- Nutrient Information
  - Number of fluid ounces supplying 100 kilocalories (kcal)
  - Amount of each nutrient supplied by 100 kilocalories of formula
    - 30 required nutrients plus carbohydrate and water
  - Iron Statement
    - "Infant Formula with Iron" if ≥ 1 mg iron per 100 kcal
    - "Additional Iron May Be Necessary" if < 1 mg iron per 100 kcal
- Directions for Use
  - In addition to applicable labeling requirements in 21 CFR 101 and 105
  - Pictograms
- 'Use by' date
- Claims must be truthful and not misleading

Summary Points

This Committee's report will be an important resource for FDA in developing the Congressionally-mandated long-term national strategy to increase the resiliency of the U.S. infant formula supply chain and market. Other resources will also be important in developing this strategy.

Summary Points

- Fundamental structural features of the market contributed to the widespread infant formula supply shortage in 2022, along with other factors more situation-specific or “acute.” From this study, FDA is hoping to gain a better understanding of contributing fundamental marketplace factors influencing the U.S. infant formula supply chain and market competition/concentration, and changes that may be helpful to increase resiliency long-term and prevent future shortages.

- Valuable insights may be gained through an examination of the infant formula regulatory frameworks and requirements in other global regions. FDA is hoping to obtain insights that could be applied domestically to increase supply chain resilience while maintaining the safety and nutritional adequacy of the U.S. infant formula supply.

Summary Points

Mitigation of the infant formula shortage of 2022 required an "all of government" approach and the engagement of the infant formula industry. The long-term national strategy has as its goal the development of a more resilient infant formula supply and the prevention of future shortages. It will also require an "all of government" approach and engagement on the part of industry. We encourage the Committee to address its recommendations to a broad array of government stakeholders, as well as the infant formula industry.


FDA
U.S. FOOD & DRUG
ADMINISTRATION