U.S. FOOD & DRUG ADMINISTRATION

Update from FDA

National Association of Dairy Regulatory Officials

Annual Meeting

Beth Briczinski, PhD

Senior Science Advisor for Milk Safety

FDA Center for Food Safety & Applied Nutrition

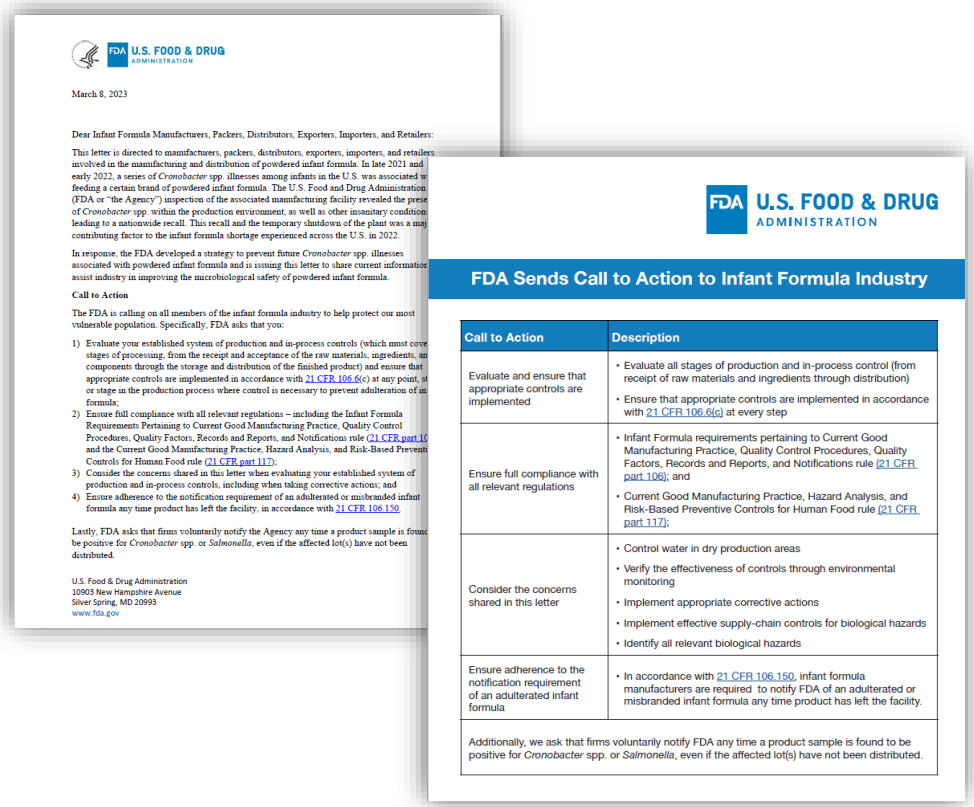
July 11, 2023

Discussion

- Food Safety
  - Powdered Infant Formula
  - Prevention Strategy - Queso Fresco
- Nutrition & Labeling
  - Yogurt Standard of Identity
  - Plant-Based Milk Alternative (PBMA) Guidance

Powdered Infant Formula

- March 2023:
  FDA issued a letter to the powdered infant formula industry and a Call to Action



U.S. FOOD & DRUG ADMINISTRATION

March 8, 2023

Dear Infant Formula Manufacturers, Packers, Distributors, Exporters, Importers, and Retailers:

This letter is directed to manufacturers, packers, distributors, exporters, importers, and retailers involved in the manufacturing and distribution of powdered infant formula. In late 2021 and early 2022, a series of *Cronobacter* spp. illnesses among infants in the U.S. was associated w feeding a certain brand of powdered infant formula. The U.S. Food and Drug Administration (FDA or "the Agency") inspection of the associated manufacturing facility revealed the prese of *Cronobacter* spp. within the production environment, as well as other insanitary condition leading to a nationwide recall. This recall and the temporary shutdown of the plant was a maj contributing factor to the infant formula shortage experienced across the U.S. in 2022.

In response, the FDA developed a strategy to prevent future *Cronobacter* spp. illnesses associated with powdered infant formula and is issuing this letter to share current information assist industry in improving the microbiological safety of powdered infant formula.

Call to Action

The FDA is calling on all members of the infant formula industry to help protect our most vulnerable population. Specifically, FDA asks that you:

1) Evaluate your established system of production and in-process controls (which must cove stages of processing, from the receipt and acceptance of the raw materials, ingredients, an components through the storage and distribution of the finished product) and ensure that appropriate controls are implemented in accordance with 21 CFR 106.6(c) at any point, st or stage in the production process where control is necessary to prevent adulteration of in formula;
2) Ensure full compliance with all relevant regulations – including the Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications rule (21 CFR part 10 and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventi Controls for Human Food rule (21 CFR part 117);
3) Consider the concerns shared in this letter when evaluating your established system of production and in-process controls, including when taking corrective actions; and
4) Ensure adherence to the notification requirement of an adulterated or misbranded infant formula any time product has left the facility, in accordance with 21 CFR 106.150.

Lastly, FDA asks that firms voluntarily notify the Agency any time a product sample is found be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

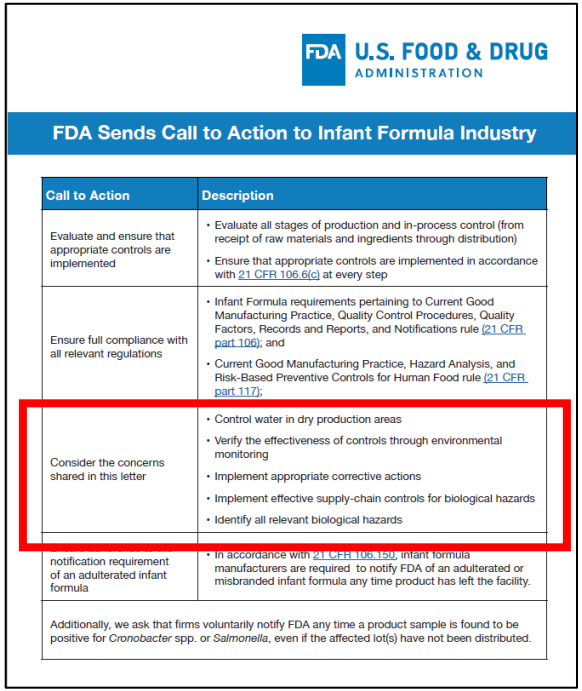
U.S. FOOD & DRUG ADMINISTRATION

FDA Sends Call to Action to Infant Formula Industry

Call to Action	Description
Evaluate and ensure that appropriate controls are implemented	• Evaluate all stages of production and in-process control (from receipt of raw materials and ingredients through distribution) • Ensure that appropriate controls are implemented in accordance with 21 CFR 106.6(c) at every step
Ensure full compliance with all relevant regulations	• Infant Formula requirements pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications rule (21 CFR part 106); and • Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117);
Consider the concerns shared in this letter	• Control water in dry production areas • Verify the effectiveness of controls through environmental monitoring • Implement appropriate corrective actions • Implement effective supply-chain controls for biological hazards • Identify all relevant biological hazards
Ensure adherence to the notification requirement of an adulterated infant formula	• In accordance with 21 CFR 106.150, infant formula manufacturers are required to notify FDA of an adulterated or misbranded infant formula any time product has left the facility.
Additionally, we ask that firms voluntarily notify FDA any time a product sample is found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed.	

FDA's Call to Action

- Controlling water in dry production areas
- Verifying effectiveness of controls through environmental monitoring
- Implementing appropriate corrective actions when pathogen is found
- Implementing effective supply chain controls
- Identifying all relevant biological hazards



U.S. FOOD & DRUG ADMINISTRATION

FDA Sends Call to Action to Infant Formula Industry

Call to Action	Description
Evaluate and ensure that appropriate controls are implemented	• Evaluate all stages of production and in-process control (from receipt of raw materials and ingredients through distribution) • Ensure that appropriate controls are implemented in accordance with 21 CFR 106.6(c) at every step
Ensure full compliance with all relevant regulations	• Infant Formula requirements pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications rule (21 CFR part 106); and • Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117);
Consider the concerns shared in this letter	• Control water in dry production areas • Verify the effectiveness of controls through environmental monitoring • Implement appropriate corrective actions • Implement effective supply-chain controls for biological hazards • Identify all relevant biological hazards
notification requirement of an adulterated infant formula	• In accordance with 21 CFR 106.150, infant formula manufacturers are required to notify FDA of an adulterated or misbranded infant formula any time product has left the facility.
Additionally, we ask that firms voluntarily notify FDA any time a product sample is found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed.	

Powdered Infant Formula

- FDA will continue to implement Infant Formula Prevention Strategy*.
- We need your help to protect this most vulnerable population.

* Outline of FDA's Strategy to Help Prevent Cronobacter sakazakii Illnesses Associated with Consumption of Powdered Infant Formula | FDA

FDA Prevention Strategies

Prevention Strategies to Enhance Food Safety | FDA

Queso Fresco Prevention Strategy

- Enhancing awareness of and compliance with regulatory requirements for industry
- Increase education and training materials
- Increase consumer messaging and education

Summary of FDA's Strategy to Help Prevent Listeriosis Outbreaks Associated with Soft Fresh Queso Fresco-Type Cheeses

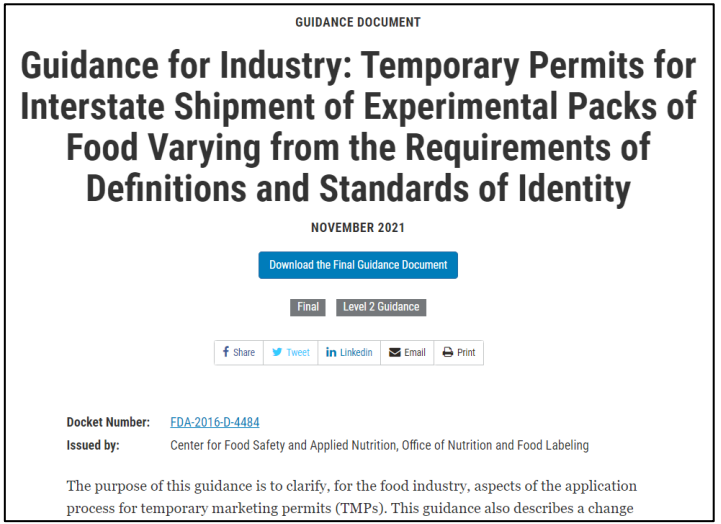
Update: Yogurt Standard of Identity

- June 2021: Final rule for yogurt SOI published
- December 2022: *Federal Register* response to 5 of 6 objections; sent a proposed order about changes to pH/TA requirements
- April 2023: Final order published codifying changes to pH/TA

Note: More information can be found in the docket folder and on the FDA website. Docket FDA–2000–P–0126, FDA Constituent Update Page

Update: Yogurt Standard of Identity

- Compliance date: January 1, 2024
- FDA received requests for compliance date extensions for provisions related to “lowfat yogurt”.
  - FDA is offering enforcement discretion on a case-by-case basis (see FDA response in the Docket)
- There may be interest in applications for TMPs



GUIDANCE DOCUMENT

Guidance for Industry: Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity

NOVEMBER 2021

Download the Final Guidance Document

Final | Level 2 Guidance

Share | Tweet | Linkedin | Email | Print

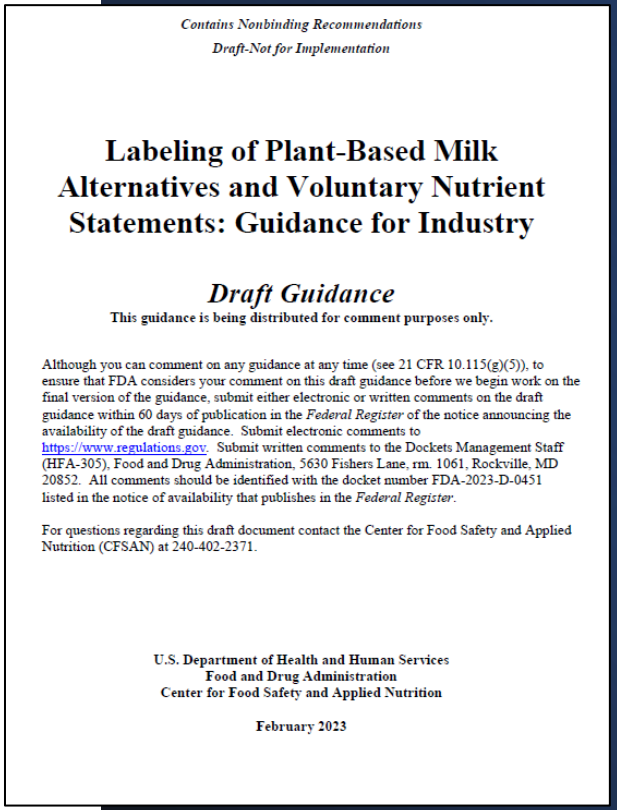
Docket Number: FDA-2016-D-4484

Issued by: Center for Food Safety and Applied Nutrition, Office of Nutrition and Food Labeling

The purpose of this guidance is to clarify, for the food industry, aspects of the application process for temporary marketing permits (TMPs). This guidance also describes a change

Draft Guidance: Labeling of Plant-Based Milk Alternatives (PBMA) and Voluntary Nutrient Statements

- Issued February 22, 2023 with a 60-day comment period
- Comment period reopened on May 1st for 90 days until July 31st
- Informed by FDA's 2018 Request for Information on the labeling of plant-based alternatives with names that include the names of dairy foods and consumer research



Contains Nonbinding Recommendations
Draft-Not for Implementation

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry

Draft Guidance
This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2023-D-0451 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

February 2023

Overview: Consumer Research, Information from Comments, FDA Work, Selected Public Sources

In general, research appears to show or suggest that

- A large majority of consumers refer to PBMA by names such as “soy milk” and “almond milk” and understand that PBMA do not contain milk.
- There is low knowledge level about the nutrients in PBMA.

Potential Public Health Concern

- *The Dietary Guidelines for Americans* identifies the Dairy Group as a key contributor of 12 nutrients, including nutrients of public health concern for all age groups (calcium, vitamin D, potassium).
- Potential public health concern related to the substitution of milk with PBMA that are not nutritionally similar to milk, particularly in children.
- Ensuring PMBA labels are clear will help consumers make informed dietary choices.

Draft Guidance: Voluntary Nutrient Statement Recommendations

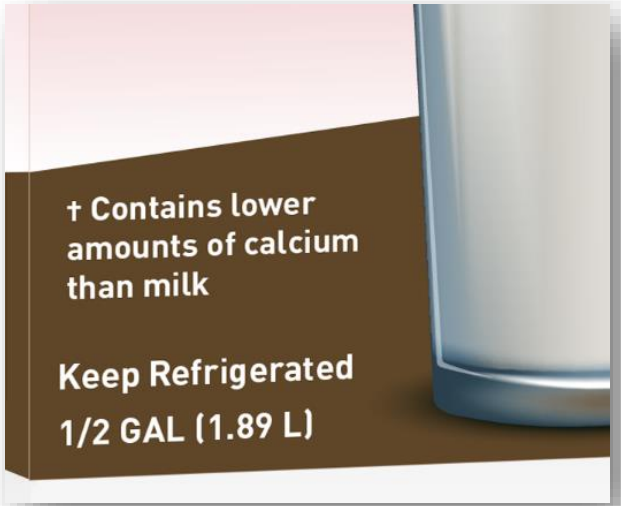
- PBMA should bear a voluntary nutrient statement if:
  - it includes the term “milk” in the name or statement of identity (e.g., “almond milk,” etc.); and
  - has a nutrient composition that is different than milk

USDA FNS Fluid Milk Substitutes Nutrient Criteria

Nutrient	Per cup (8 fluid ounces) (minimums)
Calcium	276 milligrams (mg)
Protein	8 grams
Vitamin A	500 International Units (IU)*
Vitamin D	100 IU*
Magnesium	24 mg
Phosphorus	222 mg
Potassium	349 mg
Riboflavin	0.44 mg
Vitamin B12	1.1 micrograms

Example of Voluntary Nutrient Statement

Close-up of a possible voluntary nutrient statement



Draft Guidance: Labeling of PBMA and Voluntary Nutrient Statements

- Comments, information, research, and data are critical to inform decisions for the final guidance.
- In the Notice of Availability, we requested comment specifically on the nutrient criteria, if USDA criteria are most appropriate.
- Docket FDA-2023-D-0451 open until July 31, 2023.


FDA
U.S. FOOD & DRUG
ADMINISTRATION