Foods Program Guidance Documents Under Development

(Expected to publish as drafts or finals by the end of December 2023.)

Introduction

The following list of guidance topics includes possible new topics for guidance documents or revisions to existing guidance documents that the FDA Foods Program is considering.[1] We currently intend to develop guidance on each topic; however, the FDA Foods Program is neither bound by this list of topics, nor required to issue every guidance document on this list. Several factors may impact FDA's ability to issue the listed guidances, including, for example, new Administration priorities, emerging public health issues, or other extenuating circumstances. We are not precluded from issuing guidance documents on topics not on this list.

You may submit comments on the guidance topics at www.regulations.gov at Docket FDA- 2022-D-2088.

[1] Veterinary Medicine also has published a list of Guidances Under Development for 2023.

Guidance for Industry

Title of Guidance	Category
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5); Guidance for Industry	Allergens
Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act; Guidance for FDA Staff and Stakeholders	Allergens
New Dietary Ingredient (NDI) Notifications and Related Issues: NDI Notification Procedures and Timeframes; Guidance for Industry	Dietary Supplements
Dietary Supplement Master Files: Draft Guidance for Industry	Dietary Supplements
Preparation of Premarket Submission for Food Contact Substances (Chemistry Recommendations): Draft Guidance for Industry	Food Additives
Premarket Consultation on Cultured Animal Cell Foods: Draft Guidance for Industry	Food Additives
Foods Derived from Plants Produced Using Genome Editing; Draft Guidance for Industry	Food Safety
Detention Without Physical Examination (DWPE) of Fish and Fishery Products Due to the Appearance of Adulteration by Bacterial Pathogens, Unlawful Animal Drugs, Scombrotoxin (Histamine), or Decomposition – Evidence Recommended for Release of Goods Subject to DWPE and Removal of a Foreign Manufacturer's Goods from DWPE; Draft Guidance for Industry	Food Safety
Compliance Policy Guide Sec. 555.320 Listeria monocytogenes in Human Food; Draft Guidance for FDA Staff	Food Safety
Evaluation and Establishment of Safety of Low-Moisture Ready-to-Eat Foods Following Equipment Microbiological Contamination Event: Guidance for Industry	Food Safety
Action Levels for Arsenic in Food Intended for Babies and Young Children: Draft Guidance for Industry	Food Safety
Action Levels for Cadmium in Food Intended for Babies and Young Children: Draft Guidance for Industry	Food Safety
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Appendix 1: Potential Hazards for Foods and Processes; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 11: Food Allergen Controls; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 9: Validation of Process Controls; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 17: Classifying Food as Ready-To-Eat or Not Ready- to-Eat; Draft Guidance for Industry	FSMA
Hazard Analysis and Risk-Based Preventive Controls for Human Food; Chapter 16: Acidified Foods; Draft Guidance for Industry	FSMA
Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations: Guidance for Industry	FSMA
Labeling of Plant-Based Alternatives to Animal-Derived Foods; Draft Guidance for Industry	Labeling
Use of Nutrient Content Claims for Added Sugars in the Labeling of Human Food Products: Draft Guidance for Industry	Labeling
Amendment to Guidance for Industry: Menu Labeling Supplemental Guidance	Labeling
Protein Efficiency Ratio (PER) Rat Bioassay Studies to Demonstrate that a New Infant Formula Supports the Quality Factor of Sufficient Biological Quality of Protein: Guidance for Industry	Nutrition