



Foods Program Guidance Documents Under Development

(Expected to publish as drafts or finals by the end of June 2022.)

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.ⁱ 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-2021-N-0553.

Guidance for Industry

Title of Guidance	Category
Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Defined in the Federal Food, Drug, and Cosmetic Act; Draft Guidance for FDA Staff and Stakeholders	Allergens
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5); Draft Guidance for Industry	Allergens
Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market Notifications; Draft Guidance for Industry	Dietary Supplements
Best Practices for Convening a GRAS Panel: Guidance for Industry	Food Additives
Action Levels for Lead in Juice; Draft Guidance for Industry	Food Safety
Inorganic Arsenic in Apple Juice: Action Level; Guidance for Industry	Food Safety



Title of Guidance	Category
Lead action levels for categories of foods consumed by babies and young children: Draft Guidance for Industry	Food Safety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, Scombrototoxin (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– Evidence Recommended for Release of Goods Subject to DWPE and Removal of a Foreign Manufacturer's Goods from DWPE; Draft Guidance for Industry	Food Safety
Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Access to Areas Outside the Poultry House): Questions and Answers Regarding the Final Rule; Guidance for Industry	Food Safety
Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting; Guidance for Industry	Food Safety
Scombrototoxin (Histamine)-Forming Fish and Fishery Products-- Decomposition and Histamine; Draft Guidance for FDA Staff	Food Safety
Compliance Policy Guide Sec. 555.320 <i>Listeria monocytogenes</i> in Human Food: Draft Guidance for FDA Staff	Food Safety
Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and/or Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions; Guidance for Industry	FSMA
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 16: Validation of Process Controls; Draft Guidance for Industry	FSMA



Title of Guidance	Category
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 18: Acidified Foods; Draft Guidance for Industry	FSMA
Questions and Answers Regarding the Accredited Third-Party Certification Program: Draft Guidance for Industry	FSMA
Refusal of Inspection by a Foreign Food Establishment or Foreign Government; Guidance for Industry	FSMA
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals; Guidance for Industry	FSMA
Labeling of Plant-based Milk Alternatives; Draft Guidance for Industry	Labeling
Questions and Answers About Dietary Guidance Statements in Food Labeling; Draft Guidance for Industry	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; Draft Guidance for Industry	Nutrition
Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Guidance for Industry	Nutrition

ⁱ FDA's Center for Veterinary Medicine also has published a list of [Guidances Under Development for 2021](#).