FDA Guidance – RTE Etc.

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Ready-to-Eat Food

- Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

21 CFR 117.3

Considerations in the Hazard Analysis for RTE Food

- A facility's hazard analysis must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

21 CFR 117.130(c)(1)(ii)

Considerations in the Hazard Analysis for RTE Food

- A facility's hazard evaluation must also consider the effect of intended or reasonably foreseeable use on the safety of the finished food for the intended consumer.

21 CFR 117.130(c)(2)(viii)

Other Considerations for RTE Foods

- Sanitation controls are used to significantly minimize or prevent hazards such as environmental pathogens. (21 CFR 117.135(c)(3))
- Facilities must conduct environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control. (21 CFR 117.165(a)(3))
- Facilities must take corrective actions for detection of a pathogen or appropriate indicator organism in an RTE product or when detected through environmental monitoring. (21 CFR 117.150(a)(1)(i) and (ii))

FDA Guidance on RTE Foods

- FDA is drafting guidance on Classifying Food as Ready-to- Eat or Not Ready-to-Eat
- This guidance will be Chapter 17 in Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry.

FSMA Guidance Process

- Drafted by SMEs and reg writers, in consultation with legal counsel as needed
- Formal clearance process, which, depending on the specific guidance, involves clearance by multiple offices in FDA, legal counsel, upper management, and, for some documents, HHS.
- Draft guidance made “508 compliant” (made accessible to people with disabilities) prior to posting on web

FSMA Guidance Process (cont.)

- Notice of Availability (NOA) for *Federal Register* drafted and cleared
- NOA published and guidance posted as draft for comments
- Comments analyzed
- Revisions made to guidance
- Clearance of final guidance (generally same clearance process as for draft guidance)
- NOA for *Federal Register* drafted and cleared
- NOA published and final 508-compliant guidance posted

FDA Food Safety Modernization Act (FSMA)

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Sign-Up for FSMA Email Updates

About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

The FDA Food Safety Modernization Act (FSMA) is transforming the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system.

FDA has finalized seven major rules to implement FSMA, recognizing that ensuring the safety of the food supply is a shared responsibility among many different points in the global supply chain for both human and animal food. The FSMA rules are designed to make clear specific actions that must be taken at each of these points to prevent contamination.

Spotlight

- FDA Takes Important New Steps to Strengthen Oversight of Food Imports
  January 2018
- FDA Issues Guidance Documents to help Importers and Food Producers meet FSMA Requirements
  January 2018

Rules and Related Programs

Guidance Documents

Training and Technical Assistance

Compliance and Implementation Tools

FSMA Background

Food

Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA)

- **Food Safety Modernization Act (FSMA)**
- The Law, Rules & Guidance
- Frequently Asked Questions on FSMA
- FDA Actions and Meetings
- FSMA Rules & Guidance for Industry
- FSMA Training
- FSMA Technical Assistance Network (TAN)

FSMA Final Rule for Preventive Controls for Human Food

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Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Preventive Standards under the FSMA Main Page

Generally, domestic and foreign food facilities that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA) as well as the modernized Current Good Manufacturing Practices (CGMPs) of this rule (unless an exemption applies). It is important to note that applicability of the CGMPs is not dependent upon whether a facility is required to register.

This rule, which became final in September 2015, requires food facilities to have a food safety plan in place that includes an analysis of hazards and risk-based preventive controls to minimize or prevent the identified hazards.

Compliance dates are staggered, based on the size of the business, with separate dates for the requirements of the supply chain program. Training, education, and technical

Final Rule

- Federal Register Notice
- Docket Folder FDA-2011-N-0920
- Questions & Answers
- Clarification of Compliance Date for Certain Food Establishments
- Fact Sheet (PDF: 138KB)

Public Meetings & Webinars

- Preventive Controls for Human and Animal Food Final Rules Public Meeting [ARCHIVED]
- Webinar: Preventive Controls Hazard Analysis and Risk-Based Draft Guidance
- Webinar Series [ARCHIVED]

Related Guidance

FDA

Food

Home > Food > Guidance & Regulation > Guidance Documents & Regulatory Information by Topic

Guidance Documents & Regulatory Information by Topic

- Acidified and Low-Acid Canned Foods
- Allergens
- Biotechnology
- Bottled Water & Carbonated Soft Drinks
- Chemical Contaminants, Metals, Natural Toxins & Pesticides
- Dietary Supplements
- Eggs
- Emergency Response
- Food Defense
- Imports & Exports
- Infant Formula
- Ingredients, Additives, GRAS & Packaging
- Juice

Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food

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Contains Nonbinding Recommendations
Draft — Not for Implementation

January 2018

Please Note: This guidance is being distributed for comment purposes only.

In 21 Code of Federal Regulations (CFR) part 117 (part 117), we have established our regulation entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food." We published the final rule establishing part 117 in the Federal Register of September 17, 2015 (80 FR 55908). Part 117 establishes requirements for current good manufacturing practice for human food (CGMPs), for hazard analysis and risk-based preventive controls for human food (PCHF), and related requirements.

The PCHF requirements implement the provisions of the FDA Food Safety Modernization Act (FSMA), established in section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g). Part 117 includes several complete or partial exemptions from the PCHF requirements. See 21 CFR 117.5 for a list and description of these exemptions.

Resources

- Download the Guidance (PDF: 4MB)
- Federal Register Notice for this Guidance (Chapters 1-5)
- Federal Register Notice for this Guidance (Chapter 6)
- Federal Register Notice for this Guidance (Chapter 15)
- Constituent Update: FDA Issues Guidance Documents to help Importers and Food Producers meet FSMA Requirements
- Constituent Update: FDA Extends Certain FSMA Compliance Dates; Issues Draft Guidance
- FSMA Final Rule for Preventive Controls for Human Food

Appendix 1: Potential Hazards for Foods and Processes

- Food-related and process-related potential hazard information for 17 food (including ingredients and raw materials) categories – includes spices
- Series of tables for (1) food-related biological hazards, (2) food-related chemical hazards, and (3) process-related biological, chemical and physical hazards
- Potential hazards that a facility should consider for each food subcategory are indicated by an "X" in the column for the hazard being assessed.

Appendix 1: Potential Hazards for Foods and Processes

- Appendix 1 is being revised to address comments received, inconsistencies, and errors.
- Investigators will ask about hazards indicated by an “X” in the tables.
- Facilities should be able to explain the potential hazards they identified in their food safety plan and their conclusions as to whether or not the potential hazard requires a PC.
- Investigators can confer with SMEs at CFSAN when they have concerns about a facility’s hazard analysis.

Contract (Toll) Processing

- Spices are often sent to a processor (another business) for treatment to reduce pathogens (e.g., *Salmonella*)
  - Ethylene oxide (ETO)
  - Steam
  - Irradiation
- Treatment is the preventive control for the hazard

Contract (Toll) Processing

- Toll processors may be an independent business or may be a spice manufacturer that also does toll processing; toll processor generally does not own the spices processed.
  - Who determines the process delivery parameters?
  - Who validates the process preventive control?
  - Who maintains the validation data?
  - Where does the processed product go? (e.g., back to spice manufacturer? To the spice manufacturer's customers?)
- If the toll processor validates the process, how will FDA access the validation data when conducting a PC inspection at the spice manufacturer?

Circumstances in Which a Manufacturer is Not Required to Implement a PC

- Relies on another entity to implement the PC
  - Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and
  - Obtains written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard

21 CFR 117.136

Concerns about Written Assurances

- FDA received feedback from industry expressing concern that certain product distribution chains would require vastly more written assurances (and consequently resources to comply with the requirement) than anticipated by FDA during the rulemaking process.
- FDA believes that the requirement for written assurance in the "customer provisions" of part 117 significantly exceeds the current practices of even the largest facilities.

Enforcement Discretion for Written Assurances

- Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs (January 2018)
- FDA intends to initiate a rulemaking that takes into consideration the complex supply chain relationships and resource requirements. To provide sufficient time for us to pursue that rulemaking, we are exercising enforcement discretion with regard to the written assurance requirements of part 117, part 507, part 112, and the FSVP regulation until completion of that rulemaking process.

Rulemaking Process (Simplified)

- Regulation drafted by SMEs and reg writers, in consultation with legal counsel as needed
- Formal clearance process, which, depending on the specific guidance, involves clearance by multiple offices in FDA, legal counsel, upper management, HHS and, in many cases, OMB.

Rulemaking Process (Simplified)

- Draft regulation published in *Federal Register* for comments (e.g., through www.regulations.gov)
- Comments analyzed after close of comment period
- Revisions made to regulation
- Clearance of final regulation (generally same clearance process as for draft regulation)
- Final regulation - with preamble addressing comments - published in *Federal Register*, with implementation/compliance dates

FDA U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION