FDA Foods Jurisdiction and Preventive Controls

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What Does FDA Regulate (Foods)

Foods regulated by the Food and Drug Administration (FDA) generally include:

• Food products (other than meat, poultry, egg products, some species of catfish as regulated by the United States Department of Agriculture), such as:
  • Dairy, produce, spices, nuts, cereals, flour, legumes, fruit & vegetable juices, vegetarian entrees, etc.

• Dietary supplements
• Bottled water
• Food additives
• Infant formulas
Numerous Food Safety Regulations

There are numerous FDA food safety regulations, among them are (not exhaustive):

- Seafood HACCP (Hazard Analysis Critical Control Point – borrowed from NASA!!) 21 CFR 123
- Juice HACCP 21 CFR 120
- Low-Acid Canned Food (LACF) Processor – 21 CFR 117 (with some caveats later), 21 CFR 108.35, 21 CFR 113
- Growing, Harvesting, Packing, and Holding of Produce For Human Consumption 21 CFR 112
Numerous Food Safety Regulations

• Alcoholic Beverages 21 CFR 117 (some caveats later)
• Interstate Travel Facilities – somewhat complicated
  – Registered facility, commissaries (warehousing food for conveyances) and caterers (making food such as airline meals for conveyances) – storage of exposed or unexposed, does it require refrigeration for safety (Amanda will go into this later)
• Dietary Supplements 21 CFR 117 (some caveats), 21 CFR 111
• Eggs – complicated 21 CFR 118
• Retail establishments (that do not have to register) – generally Food Code (guidance provided by the Agency) – adopted into regulation by the States
• Other – food additive regulations, and MORE...
21 CFR Part 117

Preventive Controls for Human Foods
Structure of the Regulation

• Subpart A: General Provision
• Subpart B: CGMPs
• Subpart C: Hazard analysis and risk-based preventive controls
• Subpart D: Modified requirements
• Subpart E: Withdrawal of a qualified facility exemption
• Subpart F: Requirements applying to records
• Subpart G: Supply-chain program
Subpart A: General Provisions

• Definitions
• Exemptions – certain foods, activities, and facilities
• Applicability
• Qualified Individual requirements
Definition of Facility

• Facility
  – Must register per Food Facility Registration (Bioterrorism Act)
  – Manufactures, processes, packs, holds human foods for consumption in the United States
  – Domestic and Foreign
• Subject to Part 117 unless an exemption applies
Food Facility Registration Exemptions

• Exempt from food facility registration
  – Farms
  – Retail food establishments
  – Restaurants
  – Transporters
  – Nonprofit food facilities
  – Private residences

• Resource: **Guidance for Industry: Questions and Answers Regarding Food Facility Registration**
Preventive Controls
Exemptions (117.5)

• (a) Qualified facilities
• (b) 123: Fish and Fishery
• (c) 120: Juice
• (d) 113: LACF for micro hazards only
• (e) 111: Dietary Supplements
• (g) and (h): small and very small farm mixed-type facilities conducting certain low-risk activity/food combinations
• (i) Alcoholic beverages
• (j) Facilities solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution
Preventive Controls Exemptions

- Facilities making acidified foods are **not** exempt from the preventive controls requirements of Part 117
- FSMA did not grant an exemption for acidified food facilities
- Acidified food facilities can incorporate their scheduled/filed processes into their food safety plan
Facilities solely engaged in the storage of unexposed packaged food that does not require refrigeration for safety

- Exempt from subparts C and G (117.7)
Farm mixed-type facilities: Exemptions

- Exempt from C and G if it is a *small* or very small *business* and does:
  - Low-risk packing or holding activity/food combinations listed in 117.5(g)(3)
  - Low-risk manufacturing/processing activity and food combinations listed in 117.5(h)(3)
  - 117.5(g)(2) describes the foods associated with the activity/food combinations
Subpart B: Good Manufacturing Practices (GMPs)

• Applies to all facilities subject to regulation unless exempt under 117.5(k)
• Added “allergen cross-contact”
• Added section 117.95 for human food by-products intended for use as animal food
  – Held and distributed to protect against contamination
  – Accurately labeled and identified
Subpart C: Hazard Analysis and Risk-Based Preventive Controls

117.126(a)(1): Food Safety Plan

- Written
- Implemented
Outline of Food Safety Plan

Hazard Analysis

Preventive Controls

- Process
  - Sanitation
  - Allergen
  - Supply-chain
  - Recall Plan

- Monitoring (parameters/critical limits)
  - Corrective Action
  - Verification (includes validation)

- Monitoring
  - Corrective Action
  - Verification
  - Verification
  - Corrective Action
Hazard Analysis

- **117.130(a)(1): Hazard Analysis**
  - For each type of food manufactured, processed, packed or held at the facility
  - Identify known or reasonably foreseeable hazards (potential hazards)
  - Determine if any hazards require a preventive control (are significant)

- **117.130(a)(2): Hazard Analysis** – written, even if the conclusion is that there are no significant hazards
Preventive Controls

• **117.135(a)(1): Preventive controls**
  – Identified and implemented
  – Provide assurance that hazards are significantly minimized or prevented and the food is not adulterated or misbranded under the Federal Food, Drug, and Cosmetic Act

• **117.135(b): Preventive controls**
  – Written procedures
Types of Preventive Controls

- Process controls
- Allergen controls
- Sanitation controls
- Supply-chain controls
- Recall plan
- Other
Recall Plan

• 117.139(a): Recall plan - written
• 117.139(b): Recall plan contents and procedures
  – Assigns responsibility for:
    • Notifying direct consignees how to return or dispose of affected food
    • Notifying public
    • Conducting recall effectiveness checks
    • Appropriately disposing of recalled food
  – Only required when there is at least one hazard requiring a preventive control
Management Components

• 117.140: Preventive Control Management Components
  – Process, allergen, and sanitation preventive controls must have, as appropriate:
    • Monitoring
    • Corrective actions and corrections
    • Verification
Subpart D: Modified Requirements

• Qualified facility:
  – A very small business; or
  – A business where:
    (1) Average annual value of food sold directly to qualified end-users exceeded sales to all other purchasers during the 3-year period; and
    (2) Sales of food sold during the same 3-year period was less than $500,000, adjusted for inflation
Subpart D: Modified Requirements

• **117.201:** Modified requirements that apply to a qualified facility:
  – Must submit attestation to FDA stating it:
    • Averages <$1 million annual sales of human food over a three-year period, adjusted for inflation, and;
    • Identified potential hazards for food and implements and monitors preventive controls; or
    • Is a facility in compliance with state, local, etc. law

• Qualified facilities are exempt from subparts C and G *regardless of whether they attest*
  – Still subject to GMPs unless another exemption applies
Modified Requirements

• 117.206: A facility solely engaged in the storage of unexposed packaged food refrigerated for safety:
  – Exempt from subparts C and G
  – Must:
    • Establish and implement temperature controls
    • Monitor temperature at adequate frequency
    • Take corrective actions
    • Verify temperature controls
    • Establish and maintain records
  – Subject to GMPs
Subpart E: Withdrawal of a Qualified Facility Exemption

- 117.251: Circumstances that may lead FDA to withdraw a qualified facility exemption
  - Foodborne illness outbreak directly linked to qualified facility
  - FDA determines it is necessary to protect public health or prevent foodborne illness outbreak
Subpart F: Requirements Applying to Records That Must Be Established and Maintained:

- **117.305: Preventive controls records - general requirements**
  - Original records, true copies, or electronic records
  - Actual values and observations
  - Accurate, indelible and legible
  - Created concurrently with performance of activity
  - Detailed as necessary
Subpart F: Records

• 117.305: Preventive controls records
  – general requirements (cont.)
    – Information adequate to identify facility
    – Date and, when appropriate, the time of activity documented
    – Signature or initials of the person performing activity
    – Identity of product and lot code, where appropriate
Subpart G: Overview of Supply-Chain Program

- 117.410(a):

  Use approved suppliers

  Determine supplier verification activities

  Conduct supplier verification activities

  Document supplier verification activities

  When applicable, verify a supply-chain-applied control applied by an entity other than your supplier
Food Safety Regulations and Standards

Publicly available via internet

- U.S. Food and Drug Administration (fda.gov)
- Food Safety Modernization Act (FSMA) | FDA
- CFR - Code of Federal Regulations Title 21 (fda.gov)
Industry Resources

• FDA Industry System - to conduct Registration, LACF/AF Registration, etc: **FDA Industry Systems**

• FDA Assistance: 1-888-723-3366 (1-888-SAFEFOOD)

• FDA Technical Assistance Network **FSMA Technical Assistance Network (TAN) | FDA**