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
- Acidified Food Processor 21 CFR 117, 21 CFR 108.25, 21 CFR 114
- Bottled Water 21 CFR 117, 21 CFR 129, 21 CFR 165.110
- Growing, Harvesting, Packing, and Holding of Produce For Human Consumption 21 CFR 112

Numerous Food Safety Regulations

- Infant Formula 21 CFR 117, 21 CFR 106, 21 CFR 107
- 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

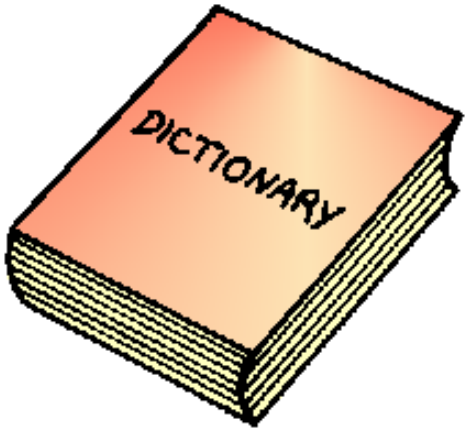
Preventive Controls for Human Foods

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

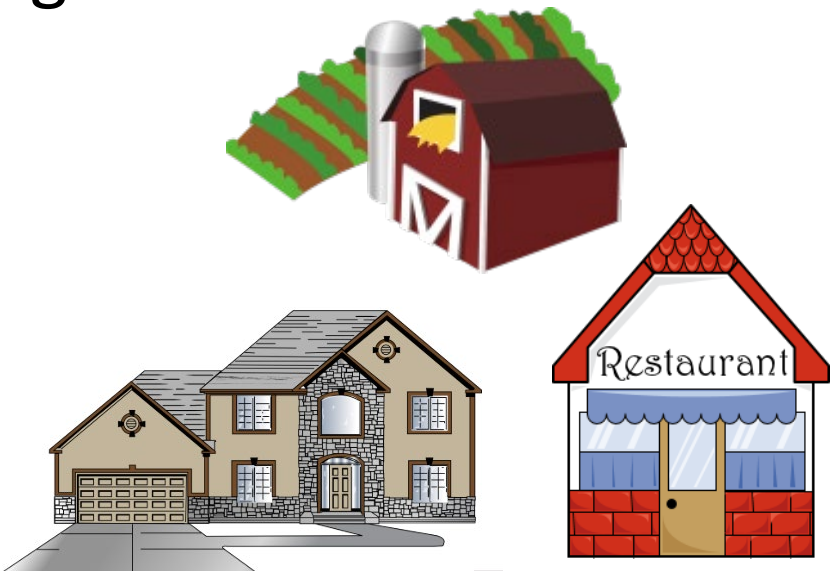


Definition of Facility

- 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

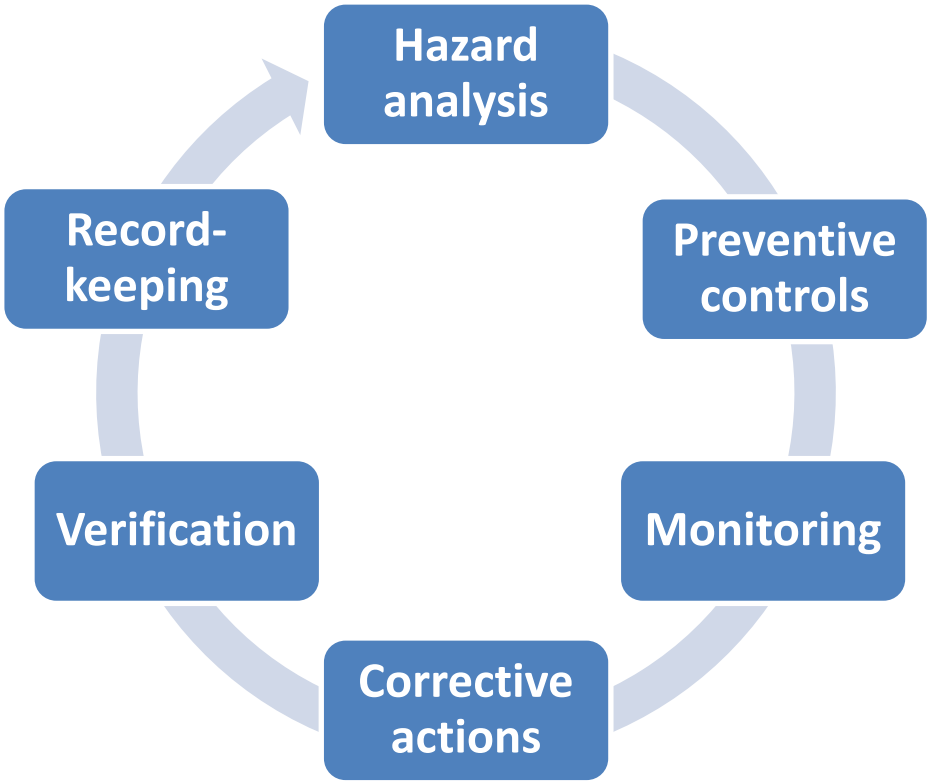
Subpart B: Good Manufacturing Practices (GMPs)

- 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

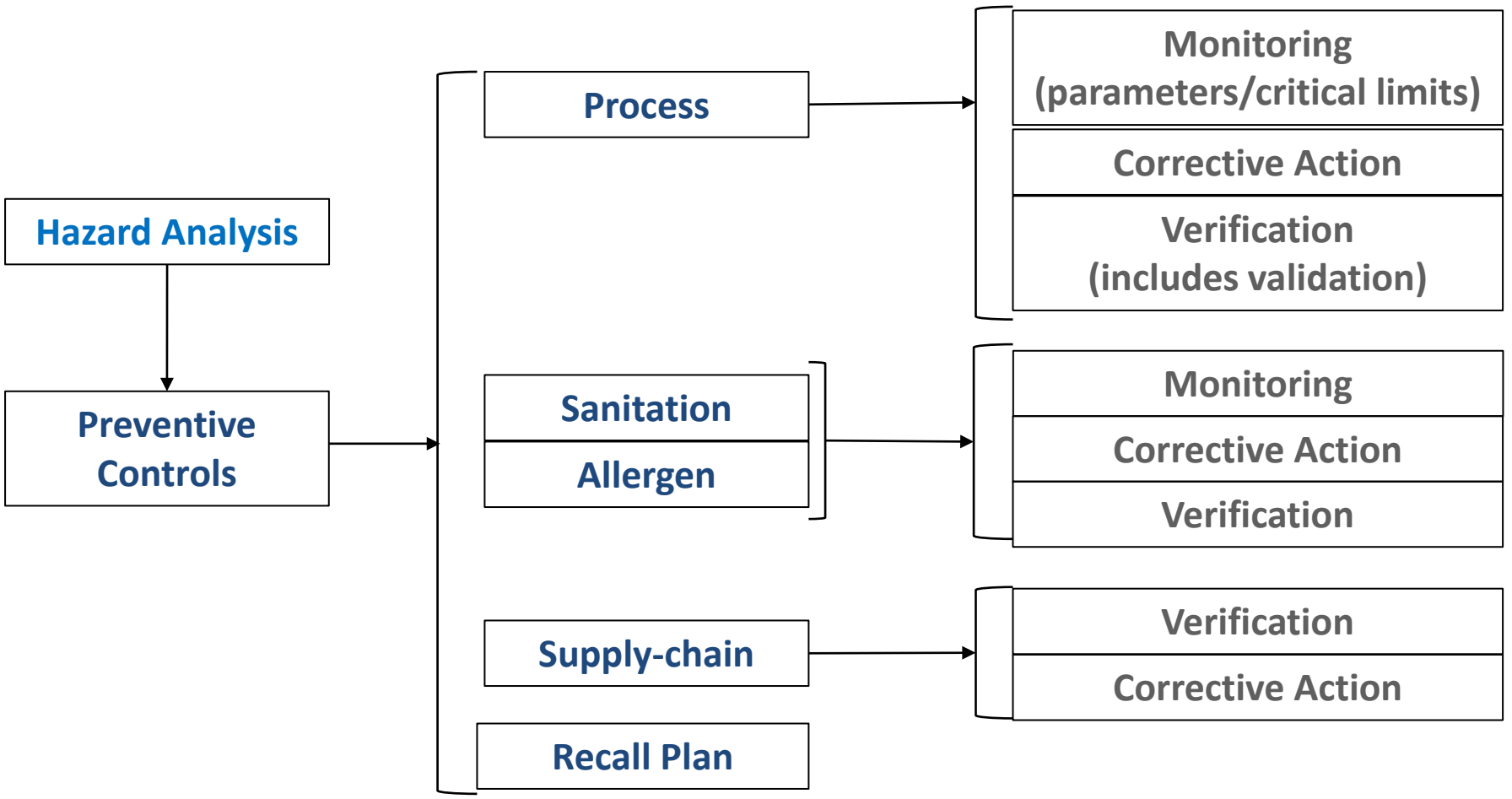
Subpart C: Hazard Analysis and Risk-Based Preventive Controls

117.126(a)(1): Food Safety Plan

- Written
- Implemented



Outline of Food Safety Plan



Hazard Analysis

- **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

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):**

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