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# II. Food Safety: Current Good Manufacturing Practices and Related Requirements; Unintended Components/Contaminants of Food

**Omar A. Oyarzabal, PhD**
**EAS Consulting Group, LLC**
ooyarzabal@easconsultinggroup.com
www.easconsultinggroup.com

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# Presenter

**Omar Oyarzabal, D.V.M., M.S, Ph.D.**

**Senior Consultant for Food Services**

- Omar develops food safety plans and systems for USDA FSIS and FDA regulated facilities, and provides client training programs
- Ex-Member of the National Advisory Committee on Microbiological Criteria for Food
- Founder and Ex-Editor in Chief of Microbial Risk Analysis., published by Elsevier
- FDA recognized Processing Authority
- Lead instructor for:
  - ✓ Acidified and low acid canned food
  - ✓ Meat and poultry HACCP
  - ✓ Seafood HACCP
  - ✓ Preventive Controls for Human food (FSM)
  - ✓ Foreign Supplier Verification Program (FSMA)

# Learning Objectives

- Learn the definition and applications of “adulteration”
- Discuss current Good Manufacturing Practices (cGMPs) and its relation to food
- Examine the use of:
  - Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and
  - Risk-Based Preventative Controls for FDA-regulated foods

# A. Adulteration

1. FD&C Act – Prohibited Acts: Producing/Distributing Adulterated
2. When is a Food Adulterated?
    a. Adulterated Food: Failure to Conform with Safety Standards of FD&C Act or Use of Unapproved Food Additive, Color Additive or Pesticide. USDA: Statutory Framework for Adulteration
    b. Economic Adulteration

# A. Adulteration

- The definition of adulteration is extensive, but in general it can be summarized as a condition when the food fails to meet legal standards
  - The food is not longer considered "**wholesome**"
- Adulteration includes (**21 U.S. Code § 342 - Adulterated food**):

  (a) Poisonous, insanitary, etc., ingredients

  (b) Absence, substitution, or addition of constituents (valuable constituent or ingredient missing)

  (c) Color additives (unsafe)

# A. Adulteration

- Adulteration includes (21 U.S. Code § 342 - Adulterated food)

  (d) Confectionery containing alcohol or nonnutritive substance

  (e) Oleomargarine containing filthy, putrid matter, etc.

  (f) Dietary supplement or ingredient: safety (risk of illness or injury)

  (g) Dietary supplement: manufacturing practices

  (h) Reoffer of food previously denied admission (imported foods)

  (i) Noncompliance with sanitary transportation practices

# A. Adulteration

It can be:

- Unintentional
  - Presence of pathogen because the manufacturer did not know how to implement good manufacturing practices
- Intentional
  - Economic adulteration

# A. Adulteration

FD&CA – Food is adulterated within the meaning of:

- Section 402 (a)(3) – Manufactured under such conditions that it is unfit for consumption
- Section 402 (a)(4) – Prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health

# A. Adulteration – Very Important!

The term ‘adulteration” is linked to:

- Manufacturing practices
- Insanitary conditions
- Preparation, packing and holding practices
- Any other case where the food may get contaminated

# Misbranding

- Also an extensive definition
- Misbranding includes (**21 U.S. Code § 343 - Misbranded food**):
    a) False or misleading label
    b) Offer for sale under another name
    c) Imitation of another food
    d) Misleading container
    e) Package form

# Misbranding

- Misbranding includes (**21 U.S. Code § 343 - Misbranded food**)

  (f) Prominence of information on label

  (g) Representation as to definition and standard of identity

  (h) Representation as to standards of quality and fill of container

  i) Label where no representation as to definition and standard of identity

  (j) Representation for special dietary use

# Misbranding

- Misbranding includes (**21 U.S. Code § 343 - Misbranded food**)

  (k) Artificial flavoring, artificial coloring, or chemical preservatives

  (l) Pesticide chemicals on raw agricultural commodities (without labels)

  (m) Color additives (labels)

  (q) Nutrition information

  (r) Nutrition levels and health-related claims

  (t) Catfish (different species from *Ictaluridae* family)

# Misbranding

- Misbranding includes (**21 U.S. Code § 343 - Misbranded food**)

  (u) Ginseng (different species from genus *Panax*)

  (v) Failure to label; health threat

  **(w) Major food allergen labeling requirements (chemical hazards)**

  (x) Nonmajor food allergen labeling requirements

# Adulteration and Misbranding - Summary

- **Adulterated Food**
  - Food unfit for human consumption
  - Mainly related to the potential presence of a hazard
- **Misbranded food**
  - Dishonest presentation of the food
  - Mainly related to "presentation," no safety except for allergens (chemical hazards)

# Food Recalls by Agency

- **USDA FSIS**: More than 60% of the products recalled because of potential, or actual presence, of bacterial foodborne pathogens
  - Biological hazards: Adulteration
- **FDA** (about 80% of the food sold in the USA): More than 40% of the products recalled because of potential, or actual presences of undeclared allergens
  - Undeclared chemical hazards: Misbranding

# B. Manufacturing

1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
    a. Conventional Foods/Medical Foods
    b. cGMPs for Dietary Supplements
    c. Infant Formulas
    d. Shell Eggs
    e. Antimicrobial Controls Guidance on *Listeria* and *Salmonella*

# B. Manufacturing

1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
2. Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority
3. Model Food Code (MFC) and Adulteration (FDA/States)
4. Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and Risk Based Preventative Controls (~~HARPC~~) FDA-regulated Foods
5. Controlling Microbial Hazards Presented by Fresh Produce

# cGMP

- They apply to food (human and animal) drugs (human and animal), biologics, medical devices, and dietary supplements
- Minimum manufacturing and control practices that focus on what specifically to do in a facility
  - Two facilities manufacturing a similar product may have different cGMP
- Failure in the implementation of these practices may result in adulterated product
  - Product is now subject to regulatory action

# List of Major cGMP from FDA by Publication Year

- § 117 Subpart B (Archived version: § 110: Manufacturing, Packing, or Holding Human Food, 1986)
- § 210: Manufacturing, Processing, Packing, or Holding of Drugs. General (1963; 1978)
- § 211: Finished Pharmaceuticals (1963; revamped 1978)
- § 226: Type A Medicated Articles (1975)
- § 606: Blood and Blood Components (1975)
- § 225: Medicated Feeds (1976)
- § 820: Quality System Regulation (1996)
- § 216: Pharmacy Compounding (1999)
- § 1271.145-320: Current Good Tissue Practice [for HCT/Ps] (2001)
- § 111: Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (2007)

# Example of Other Food Regulations with CGPM

- § 113 Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers. § 113.5 Current good manufacturing practice.
- § 114 Acidified Foods. § 114.5 Current good manufacturing practice.
- § 120 Hazard Analysis And Critical Control Point (HACCP) Systems. § 120.5 Current good manufacturing practice.
- § 123 Fish and Fishery Products. § 123.5 Current good manufacturing practice.
- § 106 Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications
- 9 CFR 416. Sanitation. § 416.1 General rules:
  - Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

# CGMPs

- Practices that provide the basic environmental and operating conditions necessary to manufacture wholesome foods
- These practices provide the “baseline” and support the preparation of risk-based food safety systems, such as:
    - HACCP plans
    - Food Safety Plans

# Food Safety and Modernization Act
# 21 CFR § 117.3 Definitions

- Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients…
- Examples: Baking, boiling…canning, cooking, cooling, cutting…. distilling…homogenizing… labeling…packaging…trimming… waxing…
  - …manufacturing, processing, packing, or holding food
  - …manufacturing/processing, packing, or holding food

# cGMPS – Prevent Adulteration!

- Food is adulterated within the meaning of:
  - Section 402 (a)(3) -- specifies that food has been manufactured under such conditions that it is unfit for consumption
  - Section 402 (a)(4) -- prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health
- Ensure the manufacturing of WHOLESOME foods
  - Non-adulterated, not misbranded

# Overview of cGMPs and Statutory Basis

- Current Good Manufacturing Practices (CGMPs)
- Conventional Foods/Medical Foods
  - 21 CFR 117, Subpart B – CGMPs for human food
- cGMPs for Dietary Supplements
  - 21 CFR 111 – CGMPs dietary supplements
- Infant Formulas
  - cGMPs for food

# 21 CFR 117, Subpart B

- 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food
- Sections:
  - Subpart A – General Provisions
  - **Subpart B – Current Good Manufacturing Practice**
  - 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 That Must be Established and Maintained
  - Subpart G – Supply-chain Program

# 21 CFR Part 117— Subpart B

§117.10 Personnel
§117.20 Plant and grounds
§117.35 Sanitary operations*
§117.37 Sanitary facilities and controls
§117.40 Equipment and utensils
§117.80 Processes and controls*
§117.93 Warehousing and distribution
§117.95 Holding and distribution of human food by-products for use as animal food
§117.110 Defect action levels

* Some could be preventive controls (Subpart C)

# Cleaning and Sanitation within GMP

- Cleaning and Sanitation are part of GMP
  - §117.35 Sanitary operations*
  - §117.37 Sanitary facilities and controls
  - §117.40 Equipment and utensils
- Seafood HACCP and Juice HACCP
  - Sanitation included within the actual regulations
  - §120.6 Sanitation standard operating procedures
  - § 123.11 Sanitation control procedures.
- USDA FSIS
  - 9 CFR 416 Sanitation

# Overview of cGMPs and Statutory Basis

- Shell Eggs
  - 21 CFR Parts 16 and 118 - Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation; Final Rule
- Antimicrobial Controls: Guidance on Listeria and Salmonella?
  - Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods – 21 CFR 117, manufacturing RTE products

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3. Model Food Code (MFC) and Adulteration (FDA/States)
4. Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and Risk Based Preventative Controls (~~HARPC~~) FDA-regulated Foods
5. Controlling Microbial Hazards Presented by Fresh Produce

# Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority

- Food and Drug Administration:
  - 21 CFR 113: Thermally processed Low-Acid Foods Packed in Hermetically Sealed Containers
  - 21 CFR 114: Acidified Foods

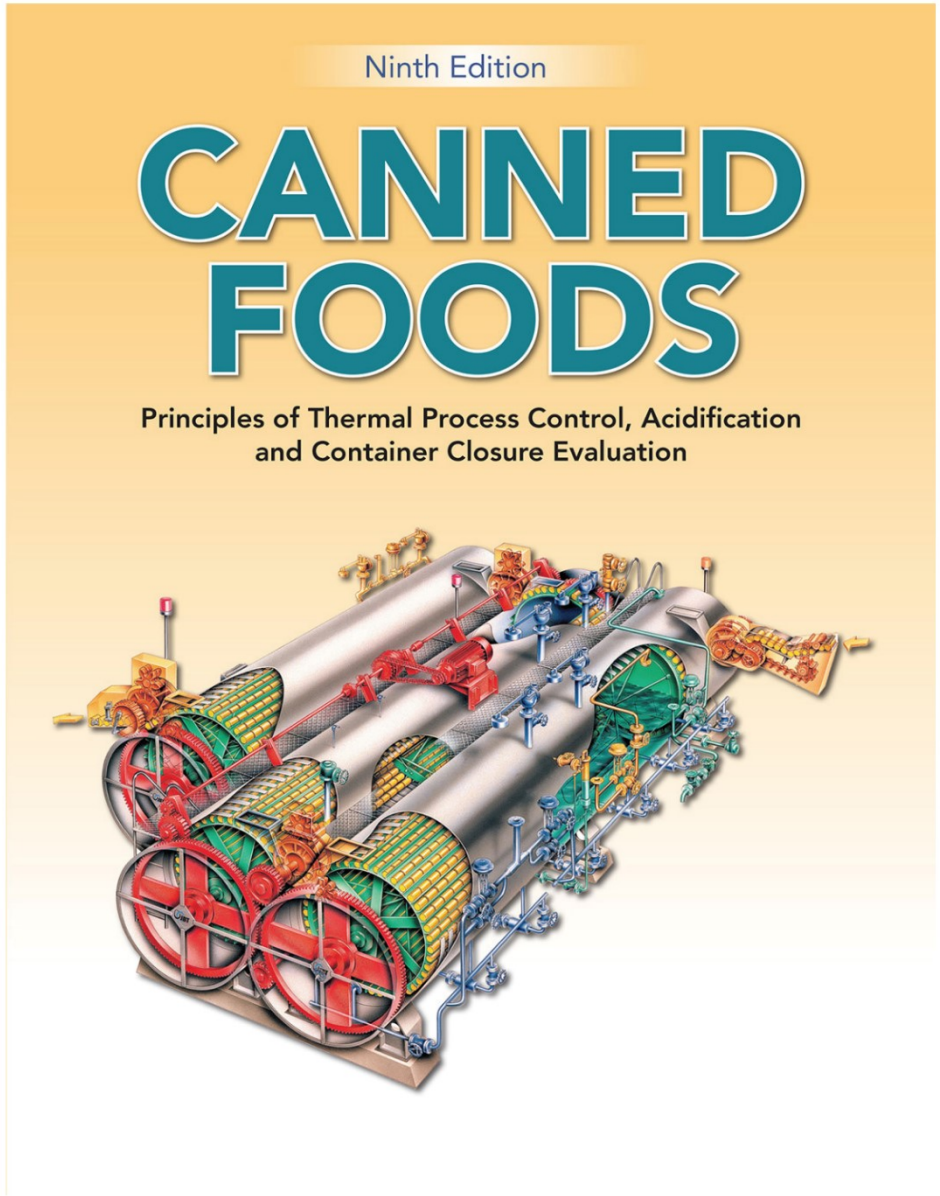
# Main Hazard to Control in LACF and Acidified Foods

- Food process safety depends on carefully and accurately performed technical operations
- The main public health concern with shelf-stable, hermetically sealed foods is the formation of toxin from *Clostridium botulinum*
  - The illness that results from this toxin is **botulism**, a muscle-paralyzing disease that can be fatal

# Special Training to Manufacturers of LACF and Acidified Foods

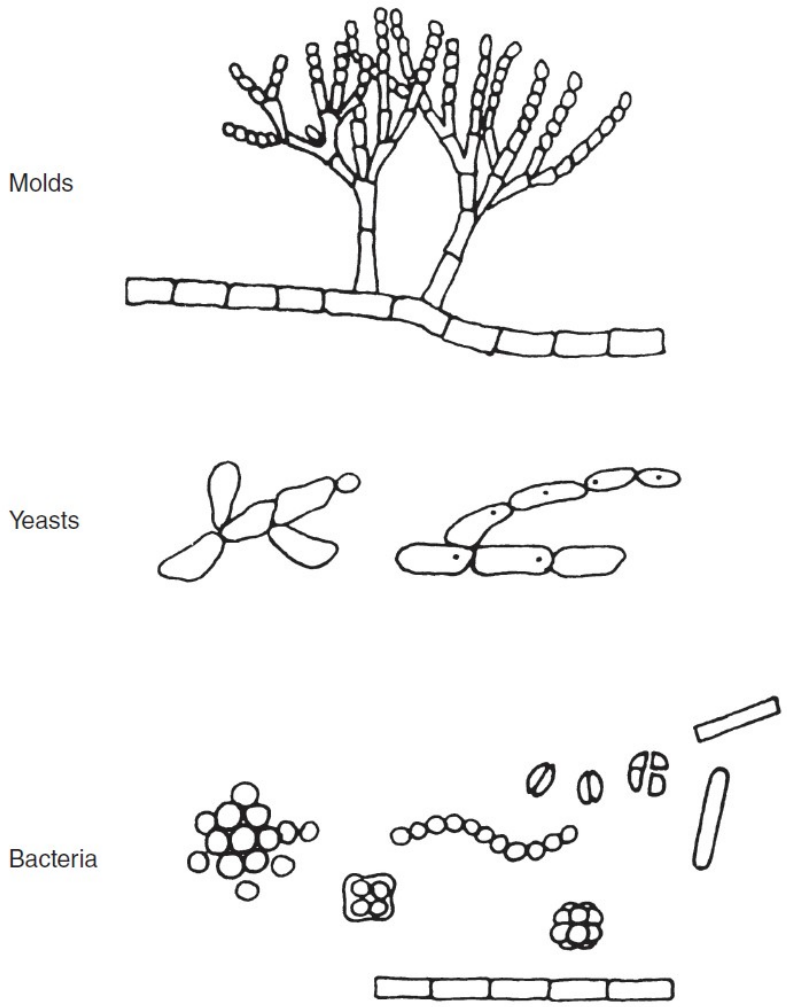
The Better Process Control School and a textbook, the Canned Foods Manual (since 1973) to help processors understand:

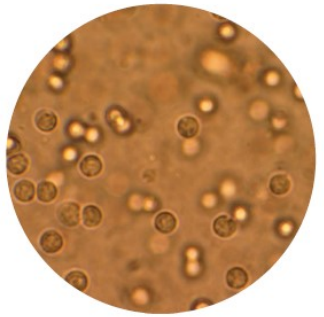
- Food safety principles
- Thermal process development
- Supervisor training
- Proper equipment usage
- Container handling
- Good recordkeeping
- Regulatory compliance

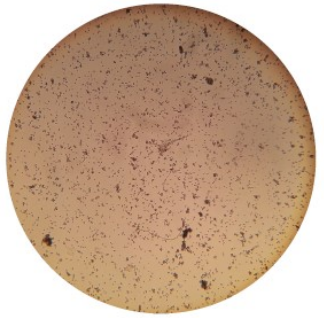



# Canned Foods: Principles of Thermal Process Control, Acidification and Container Closure Evaluation (9th Ed.)

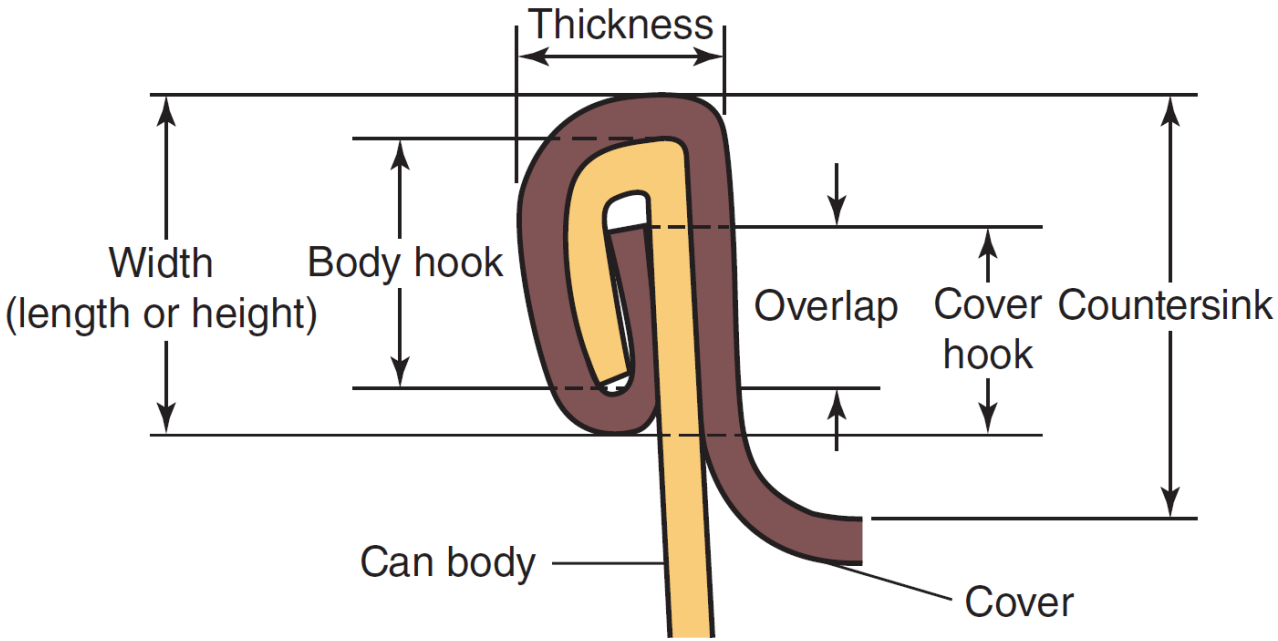
# Topic Covered



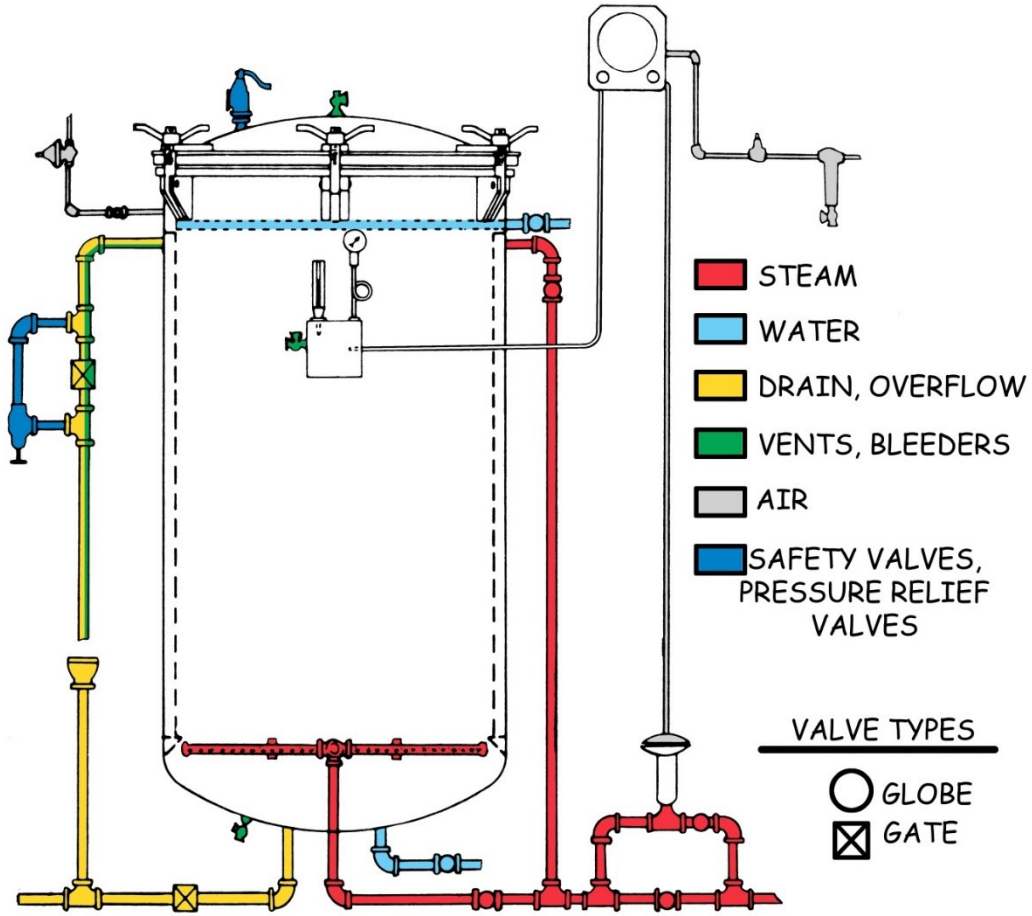



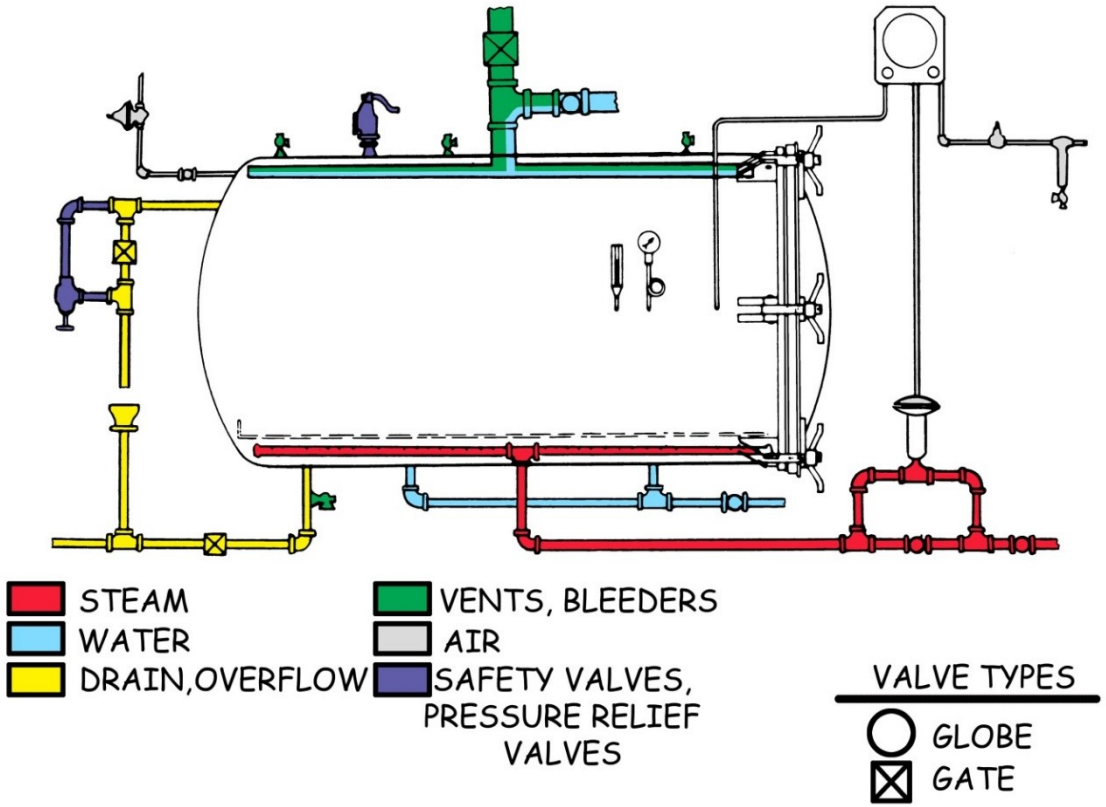


# Topic Covered



# Topic Covered



Form Approved: OMB NO. 0910-0037; Expiration Date 10/31/2020 *(See PRA Statement on last page)*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d)

**Note:** There are separate process filing forms for each of the following: Food Process Filing for Low-Acid Retorted Method (Form FDA 2541d); Food Process Filing for Acidified Method (Form FDA 2541e); Food Process Filing for Water Activity/Formulation Control Method (Form FDA 2541f); and Food Process Filing for Low-Acid Aseptic Systems (Form FDA 2541g).

**USE FDA INSTRUCTIONS ENTITLED "Instructions for Paper Submission of Form FDA 2541d (Food Process Filing for Low-Acid Retorted Method)"**

**FDA USE ONLY** **Date Received by FDA:** __ / __ / ____ *(MM/DD/YYYY)*

| Food Canning Establishment (FCE) Number *(Enter number assigned by FDA)* | Submission Identifier (SID) *(YYYY-MM-DD/SSS)* |
|---|---|
| _____ | 20__ - __ - __ / ___ |

## A. Product Information

***Note: Section A.1 (Food Product Group) requests optional information.***

**1. (Optional) Select one Food Product Group. If there is no single best Food Product Group that applies, select Other.**

- ☐ Aquaculture Seafood (e.g., farming of aquatic organisms including fish, mollusks, crustaceans, etc.)
- ☐ Baby Food (infant/junior foods including infant formula)
- ☐ Bakery Products (canned brown bread, bakery glazes)

**Beans, Corn, or Peas**

- ☐ Beans or Peas - Dry or Mature Soaked ☐ Beans, Corn, Peas - Fresh Succulent

**Berry/Citrus/Core Fruit**

- ☐ Berry/Citrus/Core Fruit
- ☐ Berry/Citrus/Core Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

- ☐ Beverage Base ☐ Breakfast Foods (liquid form – ready-to-eat, such as porridge, gruel)
- ☐ Cheese (does not include soy cheese or imitation dairy)
- ☐ Cocoa ☐ Coffee/Teas (excluding herbal and botanical teas)
- ☐ Crustacean (e.g., crab, shrimp, lobster, etc.) ☐ Dairy (milk-based)
- ☐ Dietary Supplement and/or herbal and botanical teas
- ☐ Dressings/Condiments (e.g., salad dressing, chutney, salsa, pepper sauce, etc.)
- ☐ Engineered Seafood (e.g., shelf-stable imitation crab, surimi, etc.) ☐ Fishery (finfish)
- ☐ Fishery (other aquatic (e.g., alligator, cuttlefish, frog legs, squid, etc.)

**Fruit as a Vegetable**

- ☐ Fruit as a Vegetable (e.g., eggplant, pumpkin, etc.)
- ☐ Fruit as a Vegetable Juice or Drink (e.g., eggplant juice, pumpkin juice, etc.)

***A.1 (Food Product Group)*** *(Continued)*

- ☐ Fungi (e.g., mushrooms, pleurotus, truffles, etc.)
- ☐ Gelatin, Pudding Filling for Pies, Pie Filling (liquid form ready-to-eat such as apple pie filling, etc.)
- ☐ Gravies/Sauces (spaghetti sauce, mushroom gravy)
- ☐ Imitation Dairy (includes soy-based products)

**Imitation/Pit/Mixed/Subtropical Fruit**

- ☐ Imitation/Pit/Mixed/Subtropical Fruit
- ☐ Imitation/Pit/Mixed/Subtropical Fruit as a Jam, Jelly, Preserve, Drink, Syrup, Topping

**Leafy/Stem Vegetables**

- ☐ Leafy/Stem Vegetable
- ☐ Leafy/Stem Vegetable as a Juice or Drink (e.g., spinach juice, etc.)

- ☐ Meal Replacement/Medical Foods (e.g., supplemental liquid nutrition, etc.)
- ☐ Meat Products (Exotic Meat (emu, elk, etc.)) ☐ Mixed Fishery (e.g., seafood salad, etc.)

**Mixed Vegetables**

- ☐ Mixed Vegetables (e.g., carrots and peas, etc.)
- ☐ Mixed Vegetables as a Juice or Drink (e.g., carrot and green bean juice, etc.)

- ☐ Multiple Food (one container with a separate compartment for each product item (e.g., lasagna dinner, chop suey dinner, etc.)
- ☐ Noodle/Pasta ☐ Nut Spread and Nut Topping ☐ Other Vegetables
- ☐ Pet Food (e.g., dog/cat food, etc.)
- ☐ Rice, Wheat, Oat or Grain (liquid form – ready-to-eat such as grits)

# FDA Forms 2541

- Food Canning Registration
  Form FDA 2541 (Food Canning Establishment Registration)
- Food Process Filing for Low-Acid Retorted Method
  Form FDA 2541d
- Food Process Filing for Acidified Method
  Form FDA 2541e
- Food Process Filing for Water Activity/Formulation Control Method
  Form FDA 2541f
- Food Process Filing for Low-Acid Aseptic Systems
  Form FDA 2541g

# B. Manufacturing

1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
2. Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority
3. Model Food Code (MFC) and Adulteration (FDA/States)
    a. Legal Status
    b. Scope of Application
    c. Current Issues

# The Food Code

- FDA publishes the Food Code to assist food control jurisdictions at all levels of government (local, state, tribal, and federal ) with “scientifically sound technical and legal basis” for regulating:
  - Retail and food service industry (restaurants, grocery stores and institutions such as nursing homes)
- Food control jurisdictions can use the FDA Food Code as a model to develop or update their own food safety rules

# The Food Code

- Consistency with national food regulations
- The Conference for Food Protection (CFP) helps FDA, every four-year interval, to update the Food Code and release the new edition

# FDA Food Code





The U. S. Food and Drug Administration (FDA) publishes the Food Code, a model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes). Local, state, tribal, and federal regulators use the *FDA Food Code* as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy.

Between 1993 and 2001, the Food Code was issued in its current format, every two years. With the support of the Conference for Food Protection (CFP), FDA decided to move to a four-year interval between complete Food Code editions. During the interim period between full editions, FDA may publish a Food Code Supplement that updates, modifies, or clarifies certain provisions. The 2005 Food Code was the first full edition published on the new four-year interval, and it was followed by the Supplement to the 2005 Food Code, which was published in 2007. The 2017 Food Code is the most recent full edition published by FDA.

**Content current as of:**
03/07/2022

**Regulated Product(s)**
Food & Beverages

**Topic(s)**
Retail Food Protection
Food & Beverage Safety

## Food Code Adoptions

- Benefits Associated with Complete Adoption and Implementation of the FDA Food Code

# The Food Code

## Food Code

### U.S. Public Health Service

FDA U.S. FOOD & DRUG ADMINISTRATION

**2017**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

College Park, MD 20740

MISSOURI FOOD CODE DOCUMENT

Missouri Food Code
for the
Food Establishments of
the State of Missouri

Publication Date: June 3, 2013

1

## CALIFORNIA RETAIL FOOD CODE

Excerpt from
CALIFORNIA HEALTH AND SAFETY CODE

PART 7. CALIFORNIA RETAIL FOOD CODE

Effective January 1, 2014

# B. Manufacturing

1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
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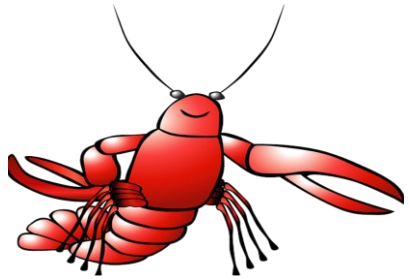
# Risk-based Food Safety Programs

US Space program


Low-acid canned food regs



FDA Seafood HACCP regs

FDA Juice HACCP regs

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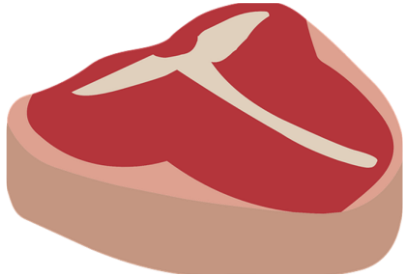


USDA HACCP regs


Codex HACCP Annex


NCIMS Dairy HACCP

# HACCP Regulations

- FSIS USDA
  - 9 CFR 417 Meat and poultry products. Effective Jan. 1998-2000
- FDA
  - 21 CFR 123 Fish and fishery products. Effective Dec. 1997
  - 21 CFR 120 Juice and juice products. Effective Jan 2002-2004
- Other commodities now under Preventive Control for Human Food (21 CFR 117, Subpart C)

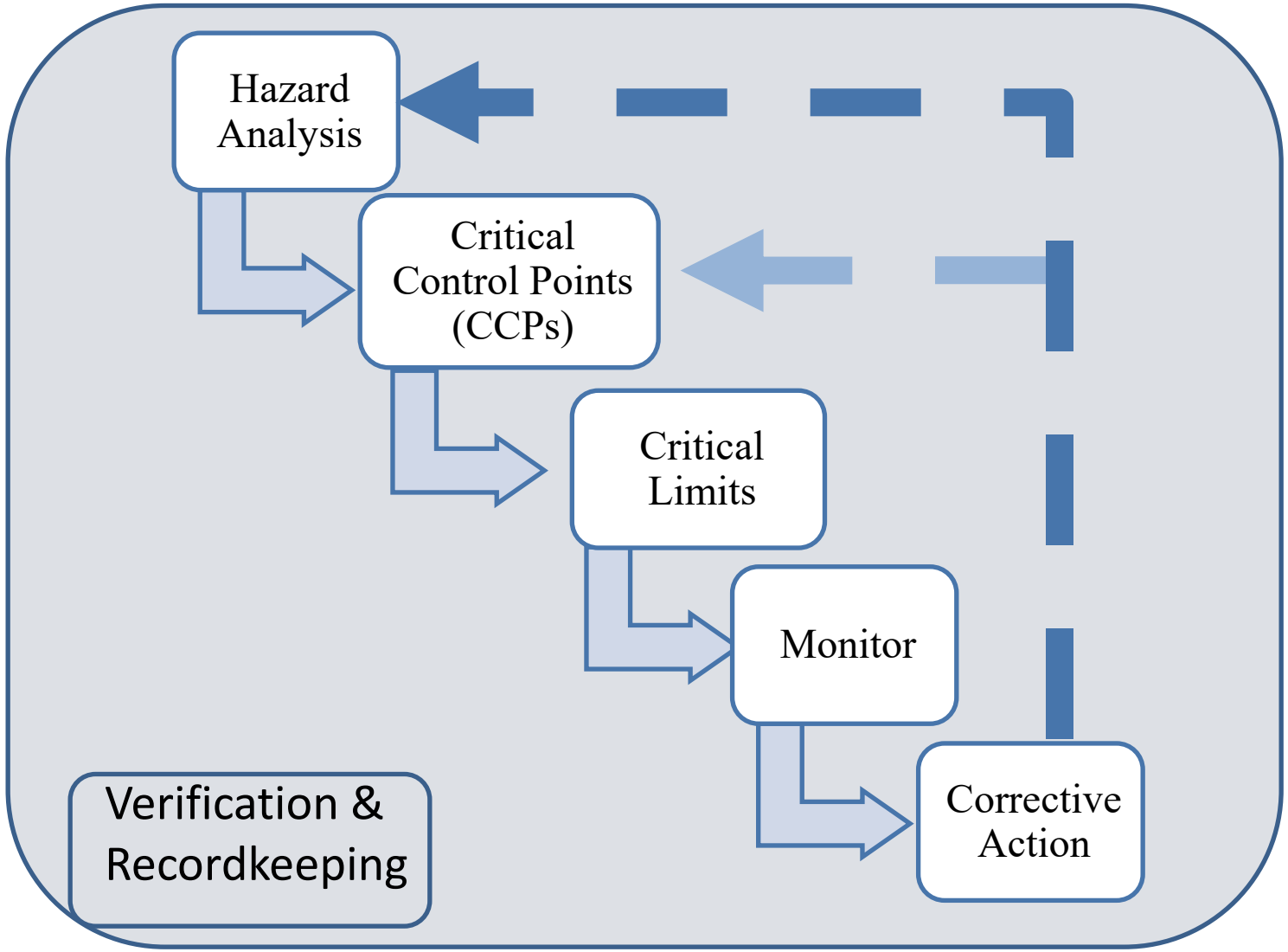
# HACCP

- A management system that focuses on the prevention of problems that could lead to foodborne illness or injury
- Establish control over the process, raw materials, the environment and people, instead of conducting extensive tests of product and ingredients
- HACCP Plan: A written document delineating the procedures after following the HACCP principles developed by the National Advisory Committee on Microbiological Criteria for Foods

# The Seven HACCP Principles

- Conduct a hazard analysis
- Determine the CCPs
- Establish critical limits
- Establish monitoring procedures
- Establish corrective actions
- Establish verification procedures
- Establish record keeping and documentation

# HACCP Focuses on the Process



# Food Safety Modernization Act

- **Preventive Controls for Human Food (21 CFR 117)**
- **Standards for Produce Safety (21 CFR 112)**
- Preventive Controls for Food for Animals (21 CFR 507)
- Foreign Supplier Verification Programs (21 CFR 1, Subpart L)
- Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR 121 [11])
- Accredited Third-Party Certification (21 CFR 1, 11, 16)
- Sanitary Transportation of Human and Animal Food (21 CFR 1, Subpart O [11])

# Preventive Controls for Human Food (21 CFR 117)

- 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food
- Sections:
  - Subpart A – General Provisions
  - Subpart B – Current Good Manufacturing Practice
  - **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 That Must be Established and Maintained
  - Subpart G – Supply-chain Program

# Subpart C – Hazard Analysis and Risk-based Preventive Controls

§ 117.126 Food safety plan

§ 117.130 Hazard analysis

§ 117.135 Preventive controls

§ 117.136 … when a facility is not required to implement a preventive control

§ 117.137 Provisions of assurances required under § 117.136…

§ 117.139 Recall plan

§ 117.140 Preventive control management components

§ 117.145 Monitoring

§ 117.150 Corrective actions and corrections

§ 117.155 Verification

§ 117.160 Validation

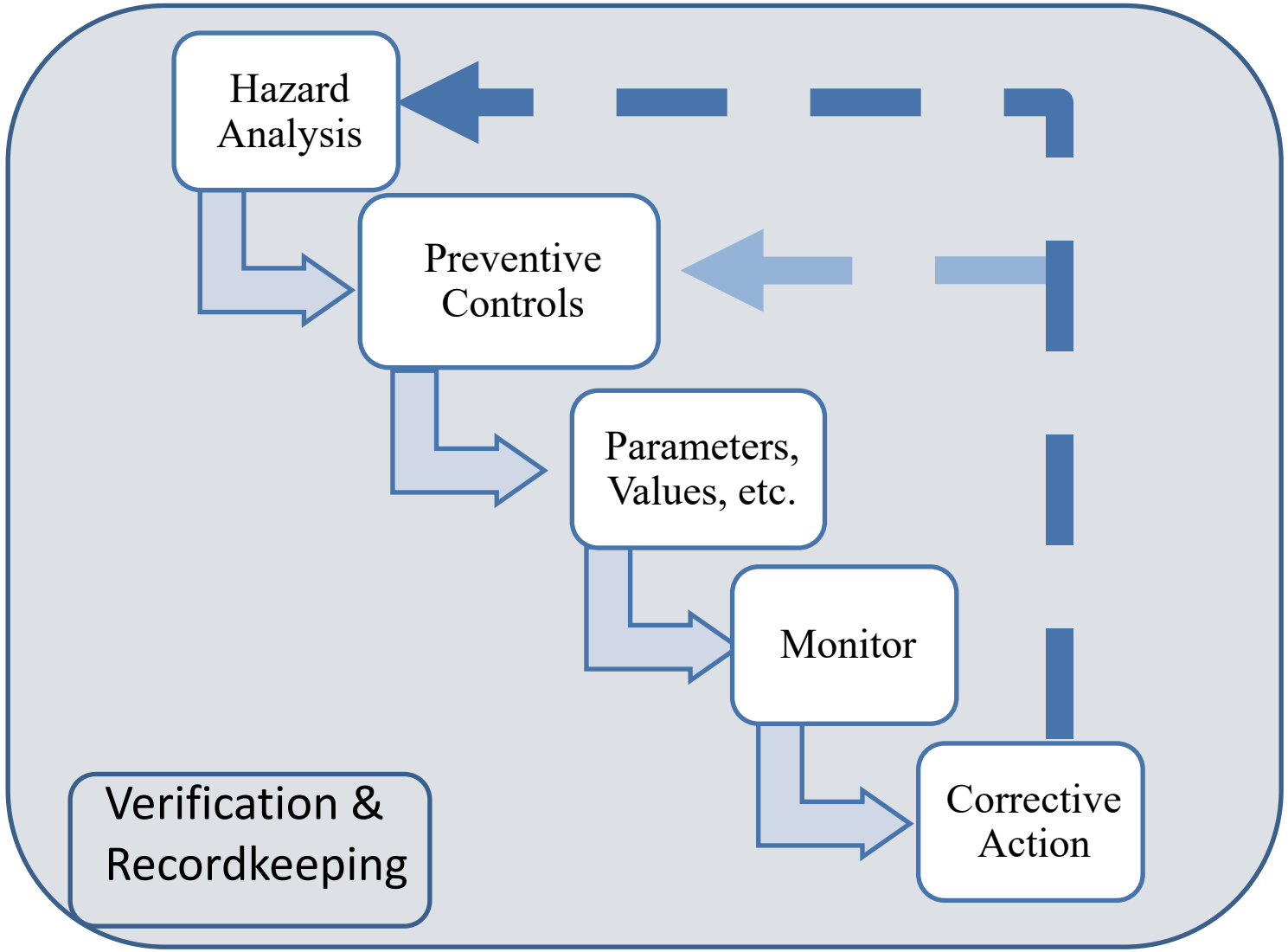
§ 117.165 Verification of implementation and effectiveness

§ 117.170 Reanalysis

§ 117.180 Requirements applicable to a preventive controls qualified individual and qualified auditor

§ 117.190 Implementation records required for this subpart

# Preventive Controls for Human Food

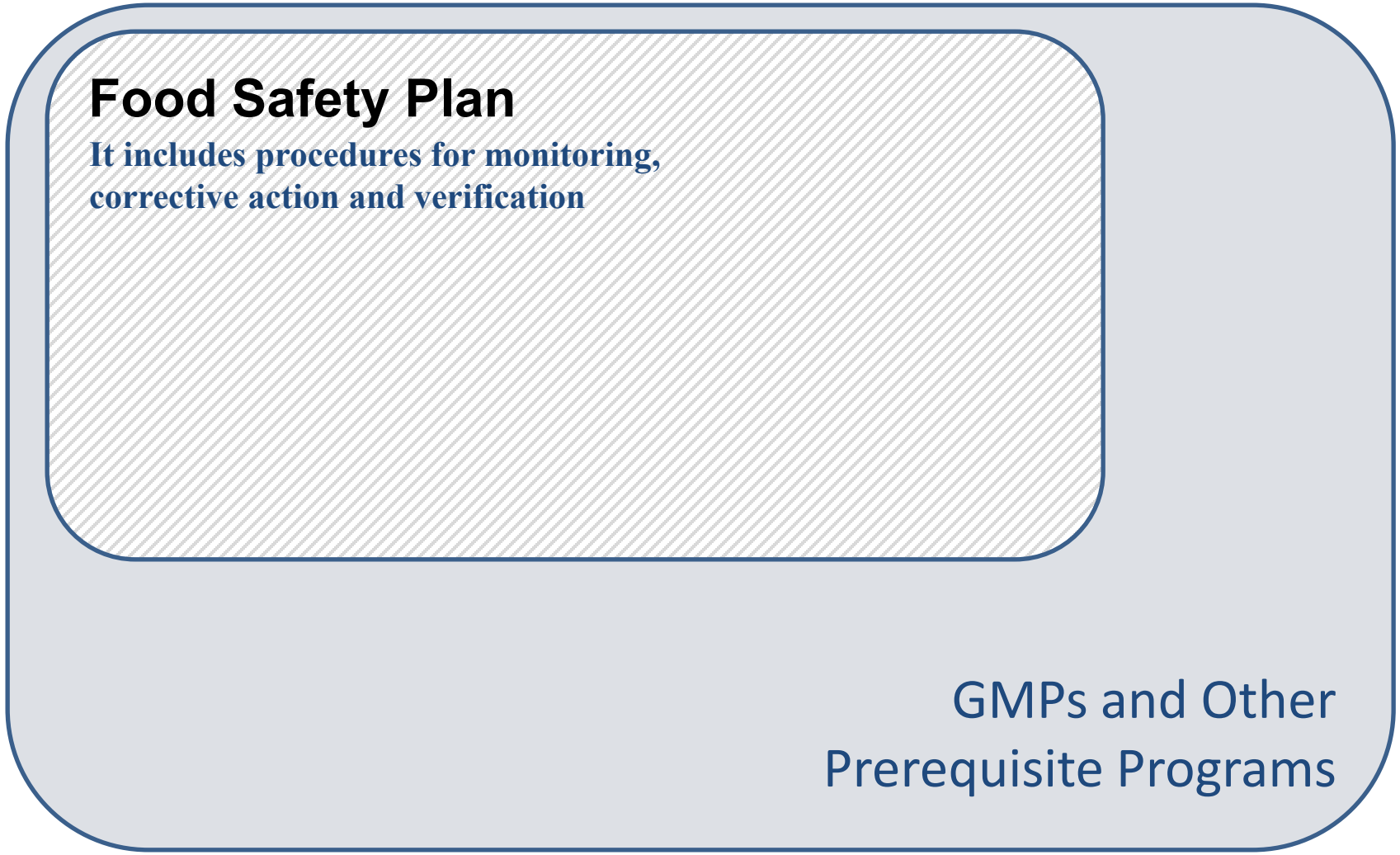


# Food Safety Systems - Preventive Controls

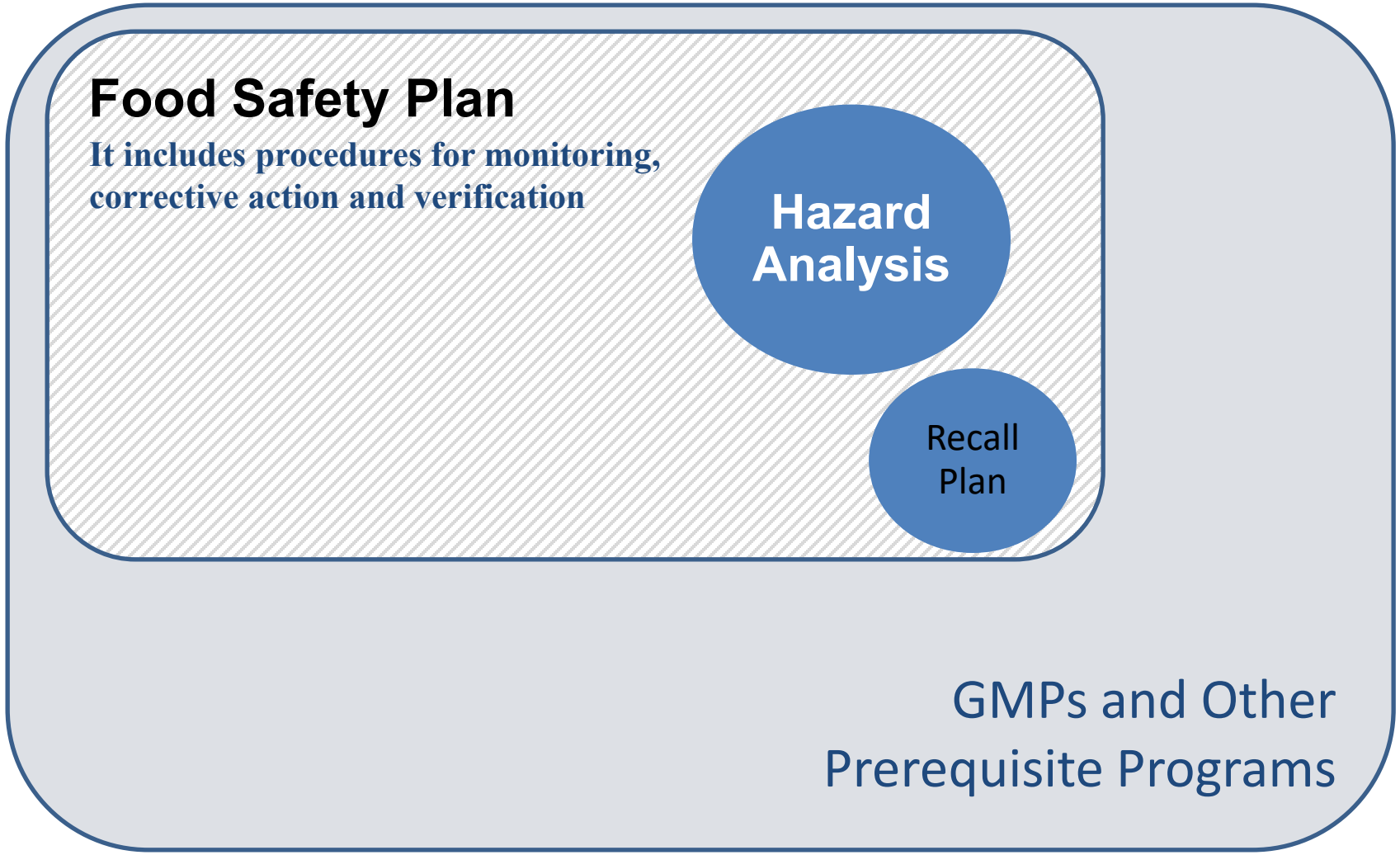
## Food Safety Plan

**It includes procedures for monitoring, corrective action and verification**

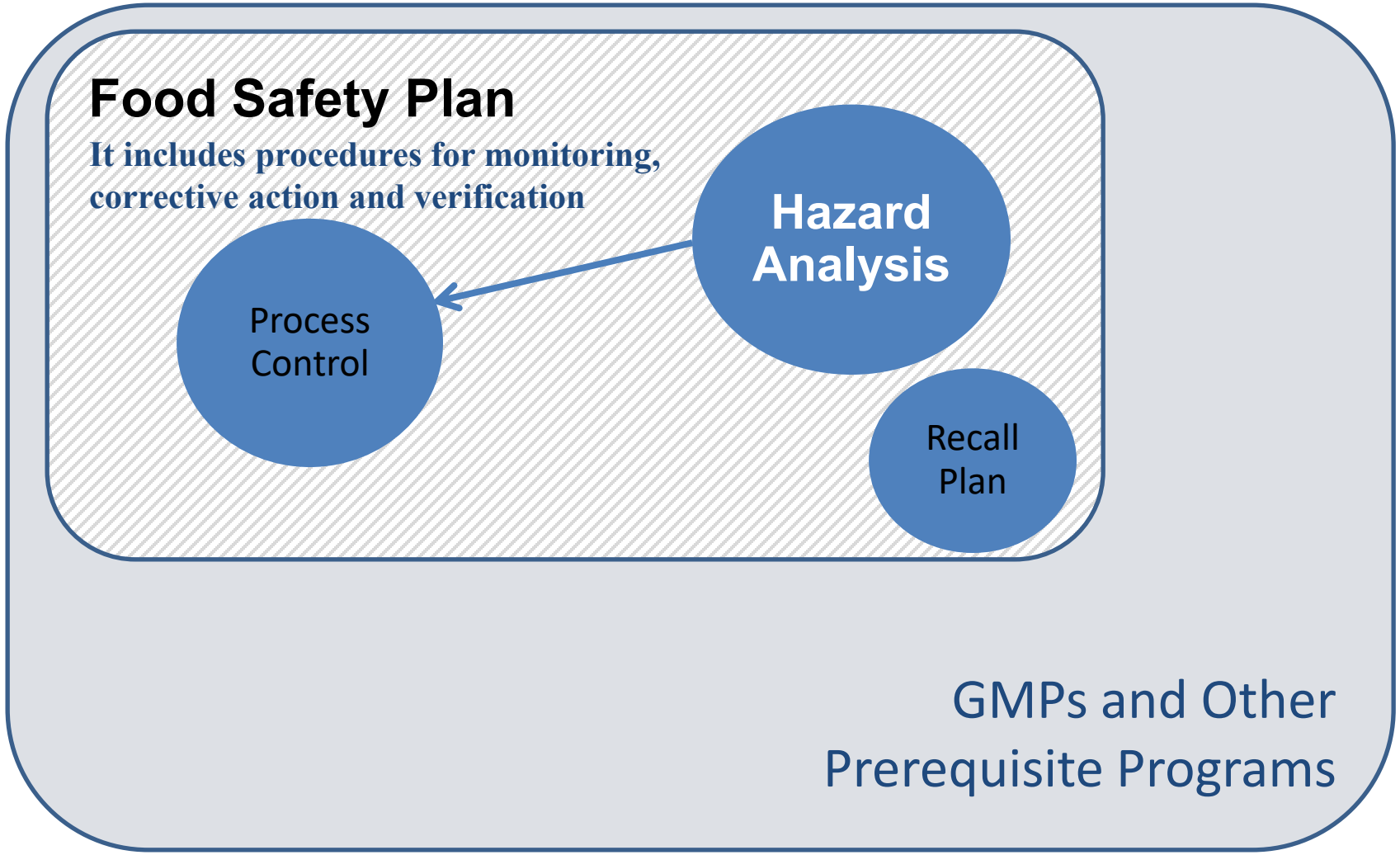
# Food Safety Systems - Preventive Controls



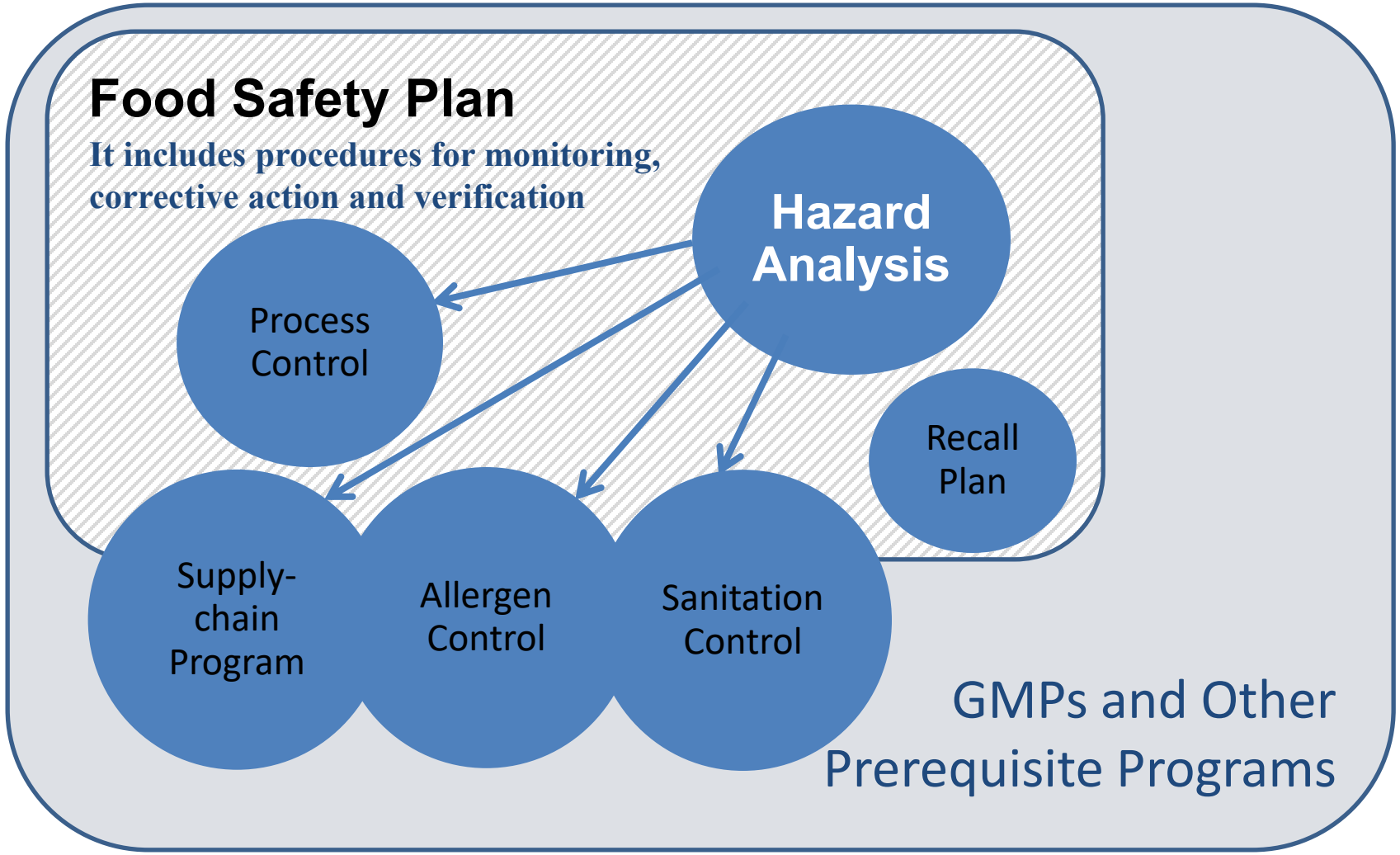
# Food Safety Systems - Preventive Controls



# Food Safety Systems - Preventive Controls



# Food Safety Systems - Preventive Controls



# Avoid Using the Acronym HARPC

- Before 2015 many providers were offering training using the term "HARPC"
- The official course name is "FSPCA Preventive Controls for Human Food"
- Training delivered prior to the publication of the final regulations may not include all provisions in the final regulation

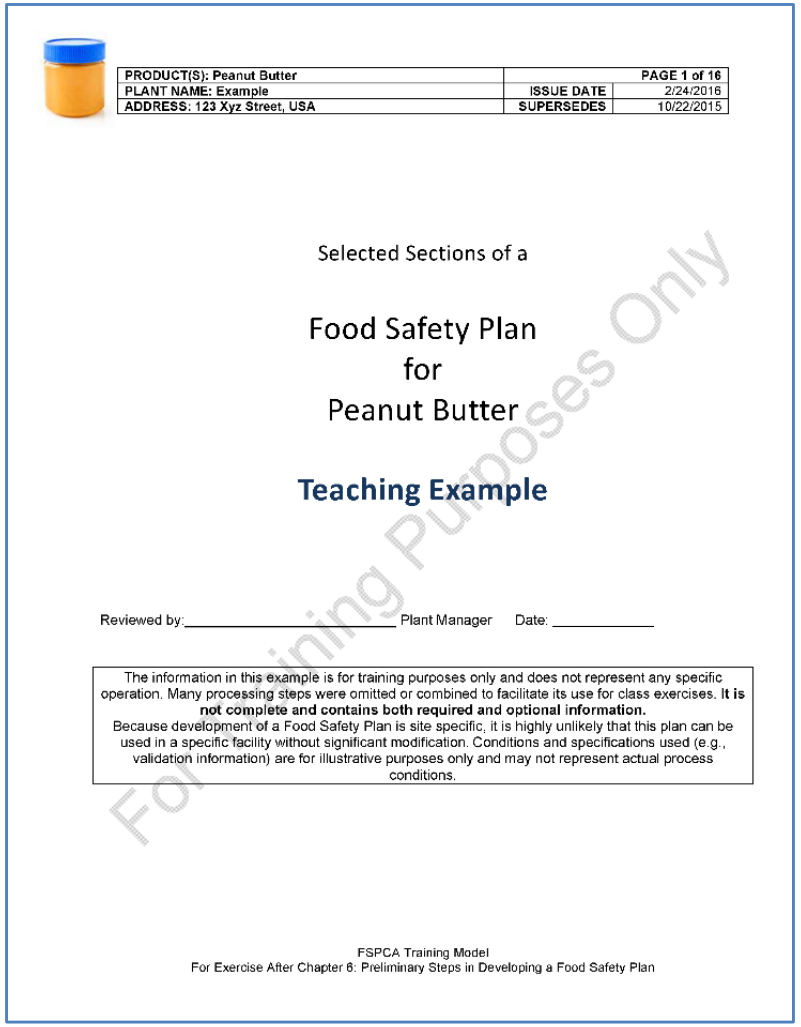
# Training for Food Manufacturers

- Course
  - Includes comprehensive information about each subject
- References
  - The end of each chapter has references for the content as additional resources
- Appendices

  Regulation, food safety plan worksheets, and other useful information

# Model Food Safety Plans

- Course
  - These model food safety plan exercises are used to discuss the organization of a food safety plan for selected food commodities



| PRODUCT(S): Peanut Butter | | PAGE 1 of 16 |
|---|---|---|
| PLANT NAME: Example | ISSUE DATE | 2/24/2016 |
| ADDRESS: 123 Xyz Street, USA | SUPERSEDES | 10/22/2015 |

Selected Sections of a

Food Safety Plan
for
Peanut Butter

**Teaching Example**

Reviewed by:_____ Plant Manager Date: _____

The information in this example is for training purposes only and does not represent any specific operation. Many processing steps were omitted or combined to facilitate its use for class exercises. **It is not complete and contains both required and optional information.**
Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.



FSPCA Training Model
For Exercise After Chapter 6: Preliminary Steps in Developing a Food Safety Plan

# B. Manufacturing

1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
2. Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority
3. Model Food Code (MFC) and Adulteration (FDA/States)
4. Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and Risk Based Preventative Controls (~~HARPC~~) FDA-regulated Foods
5. Controlling Microbial Hazards Presented by Fresh Produce

# Prevention of Contamination

Unique Features of Produce:

- Fresh produce is often consumed raw
- Contamination is generally sporadic
- Microbial contamination is extremely difficult to remove once present
  - Natural openings, stem scars, bruises, cuts
  - Rough surfaces, folds, netting
- Bacteria can multiply on produce surfaces and in fruit wounds, provided the right conditions are present

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# Prevention of Contamination

Humans

Soil

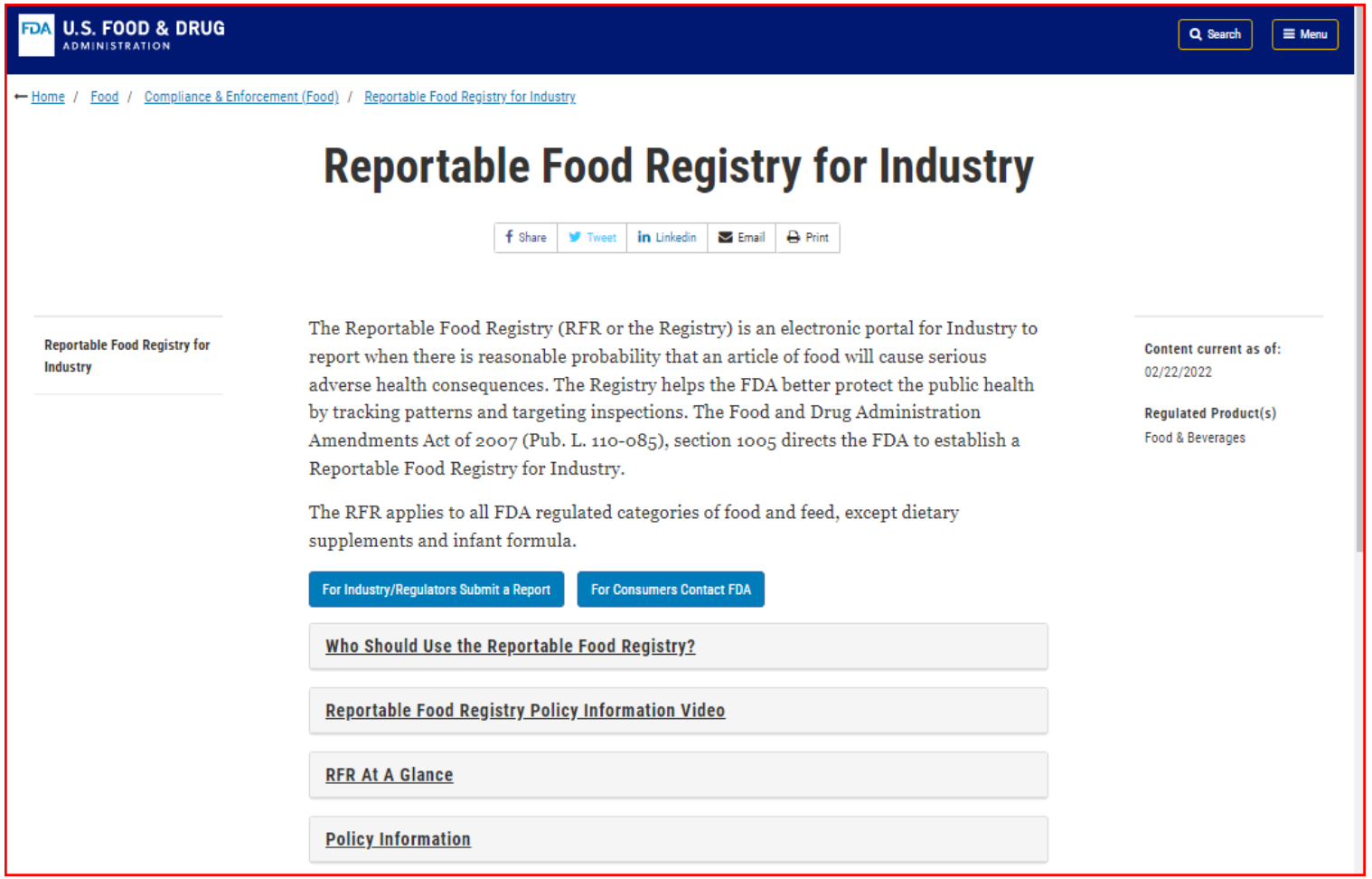
Produce

Animals

Buildings
Equipment
Tools

Water

# C. Reportable Food Registry and Recalls



FDA U.S. FOOD & DRUG ADMINISTRATION

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## Reportable Food Registry for Industry

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Reportable Food Registry for Industry

The Reportable Food Registry (RFR or the Registry) is an electronic portal for Industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Registry helps the FDA better protect the public health by tracking patterns and targeting inspections. The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-085), section 1005 directs the FDA to establish a Reportable Food Registry for Industry.

The RFR applies to all FDA regulated categories of food and feed, except dietary supplements and infant formula.

Content current as of: 02/22/2022

Regulated Product(s) Food & Beverages

For Industry/Regulators Submit a Report | For Consumers Contact FDA

Who Should Use the Reportable Food Registry?

Reportable Food Registry Policy Information Video

RFR At A Glance

Policy Information

# D. Food Defense

- Mitigation Strategies to Prevent Food Against Intentional Adulteration regulation (21 CFR Part 121)
- Know as the “IA rule”
- A Food Defense Plan describes the “the practices implemented to protect food from intentional acts of adulteration where there is an intent to cause wide scale public health harm.”
- The difference with Food Safety plan are?

# D. Food Defense

- Components of a Food Defense Plan:
  - A written vulnerability assessment
  - Written mitigation strategies
  - Written procedures describing the monitoring of the implementation of the mitigation strategies
  - Written procedures for food defense corrective actions
  - Written procedures for food defense verification
  - Maintenance of all appropriate records

# D. Food Defense

- Resources:
  - FDA have quite a bit of information about food defense and a food defense plant builder: https://www.fda.gov/food/food-defense-tools/food-defense-plan-builder.
  - USDA FSIS has the functional food defense plans website: https://www.fsis.usda.gov/food-safety/food-defense-and-emergency-response/food-defense/functional-food-defense-plans

# Food Defense Plan Builder



**Food Defense Tools**

Food Defense Plan Builder

Mitigation Strategies Database

Food Related Emergency Exercise Bundle (FREE-B)

The Food Defense Plan Builder (FDPB) version 2.0 is a user-friendly tool designed to help owners and operators of a food facility in the development of a food defense plan that is specific to their facility and may assist them with meeting the requirements of the Mitigation Strategies to Prevent Food Against Intentional Adulteration regulation (21 CFR Part 121) (IA rule).


This user-friendly tool harnesses existing FDA tools, guidance, and resources for food defense into one single application. Use of this tool is not required by law (see legal disclaimer) and is not required to comply with the IA rule. FDA expects this tool to supplement and not replace other education, training, and experience needed to understand and implement the requirements of the IA rule.

The Food Defense Plan Builder guides the user through the following sections:

**Content current as of:**
10/07/2020

**Regulated Product(s)**
Food & Beverages

USDA Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

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ALERT: Frickenschmidt Foods LLC Recalls Ready… See more details

- Food Safety
  - Recalls & Public Health Alerts
  - Food Safety Stats
  - Foodborne Illness and Disease
  - Safe Food Handling and Preparation
  - Food Defense and Emergency Response
    - Emergency Response
    - Continuity of Operations (COOP)
    - Food Defense

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# Functional Food Defense Plans

A functional food defense plan is an important tool an establishment can use to prevent, protect against, mitigate, respond to, and recover from an intentional contamination incident.

## What makes a food defense plan functional?

A food defense plan is functional when it meets ***all*** four of the following conditions:

1. **Developed** – the plan is documented and signed
2. **Implemented** – food defense practices are implemented
3. **Tested** – food defense measures are monitored and validated
4. **Reviewed and maintained** – the plan is reviewed at least annually and revised as needed

## Step 1: Develop your food defense plan

The food defense plan should be written or documented to identify mitigation strategies and protective measures that will be implemented within the facility. Vulnerability assessments help to inform where mitigation strategies are needed.

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*Thank you*