

# EAS Consulting Group

A Certified Group Company

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

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# 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 (~~HARPC~~) for FDA-regulated foods

## 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, etc., matter
  - (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 – Very Important!**

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

# 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 (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

## Food Recalls by Agency

- **USDA FSIS**: More than 90% 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
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

# Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis



**Food Processor**



**Food Processor**

# Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis



**Food Processor**



**Food MANUFACTURER**

# 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:
  - 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 current Good Manufacturing Practices (cGMPs) and Statutory Basis

- Current Good Manufacturing Practices (CGMPs) and Statutory Basis
- 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)

# Overview of current Good Manufacturing Practices (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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# **Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority**

- Food and Drug Administration:
  - 21 CFR 108: Emergency Permit Control
  - 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



# Bon Vivant Voluntarily Recalls All Vichyssoise From Dealers

By PAUL L. MONTGOMERY

Bon Vivant, Inc., disclosed yesterday that it was voluntarily recalling from dealers all the vichyssoise it produces under 22 brand names. But it emphasized that so far Federal authorities had singled out only one 6,444-can lot of its Bon Vivant brand as a suspected carrier of deadly botulinum toxin.

The company, speaking through the National Canners Association in Washington, said it had "no reason to suspect anything wrong" with the other products but was recalling them as a matter of "prudence."

It did not say how many cans might be involved in the recall.

The company came under suspicion after the death of a Westchester County banker Wednesday night from botulism was traced to a can of vichyssoise from lot V-141 of the Bon Vivant brand.

A spokesman for the Federal Food and Drug Administration in Washington said yesterday that that lot—which appears as V-141-USA-71 on the Bon Vivant label—was the one the agency was concentrating on.

## 'One Can, One Death'

"We are doing analytical work on all the company's products and procedures, but we have no reason at this time to warn the public against anything but lot V-141," the spokesman said. "We want to keep this problem in total perspective and the perspective we have at this time is one can of soup and one death."

Dr. Hollis S. Ingraham, New York State Commissioner of Health, continued a warning against all Bon Vivant products. He explained that since the company's factory was in Newark, out of his jurisdiction, he had no direct information about conditions there.

"Until the F.D.A. and the New Jersey Health Department assure us, we think it's wise for all the company's products to be regarded with suspicion," Dr. Ingraham said.

The National Canners Association spokesman declined yesterday to give the names of Bon Vivant's 22 vichyssoise brands. However, a state health official said they were the following:



The New York Times  
An F.D.A. biologist fills hypodermic with solution of vichyssoise, to be injected into lab animals.

Columbia Presbyterian Medical Center.

Blood from the couple, and the remaining contents of the soup can were tested at the state health laboratory in Albany. A mouse injected with the soup died within 24 hours. Further tests indicated that the toxin was botulinum type A, which causes death in 70 per cent of the cases in which it is ingested.

One concern of authorities is that botulinum antitoxin, the only treatment for the poison, will be administered unnecessarily to people who have eaten vichyssoise soup and then become panicky upon hearing about the Bon Vivant case. An F.D.A. spokesman said that administration of the antitoxin is a "serious matter" and can



GE COURTESY OF FDA. PHOTO BY BILL MINDAK.

# July 4, 1971

Bon Vivant, Inc...voluntarily recalling vichyssoise...but authorities had singled out only one 6,444-can lot of its Bon Vivant brand as a suspected carrier of deadly botulinum toxin

The company came under suspicion after the death of a Westchester County banker Wednesday night from **botulism**...traced to a can of vichyssoise from...Bon Vivant brand

# Special Training to Manufacturers of LACF and Acidified Foods

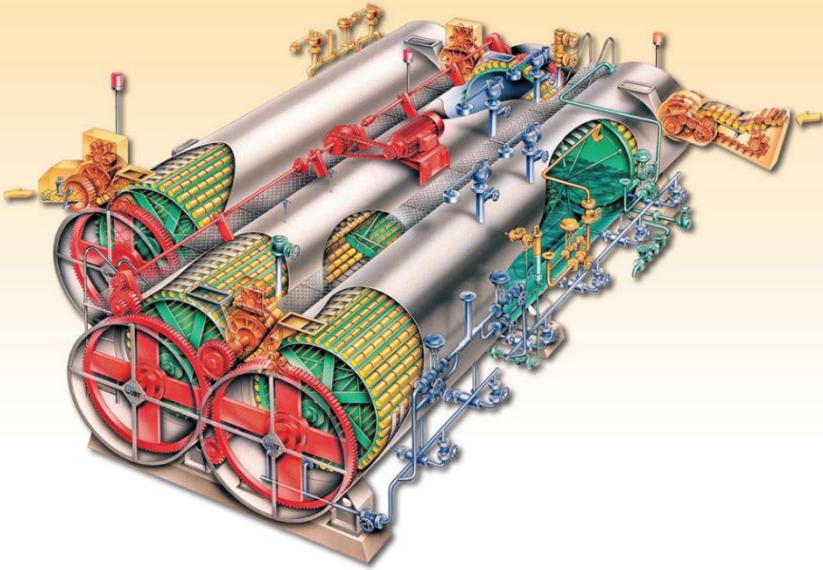
The Better Process Control School and a textbook, the Canned Foods Manual (since 1973) to help processors understand:

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

Ninth Edition

# CANNED FOODS

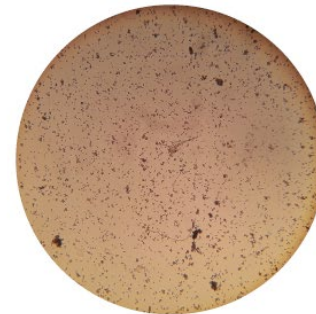
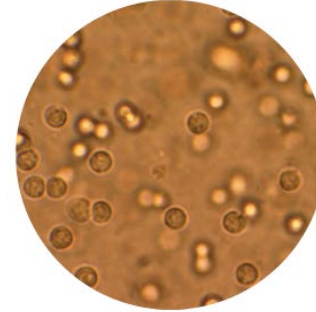
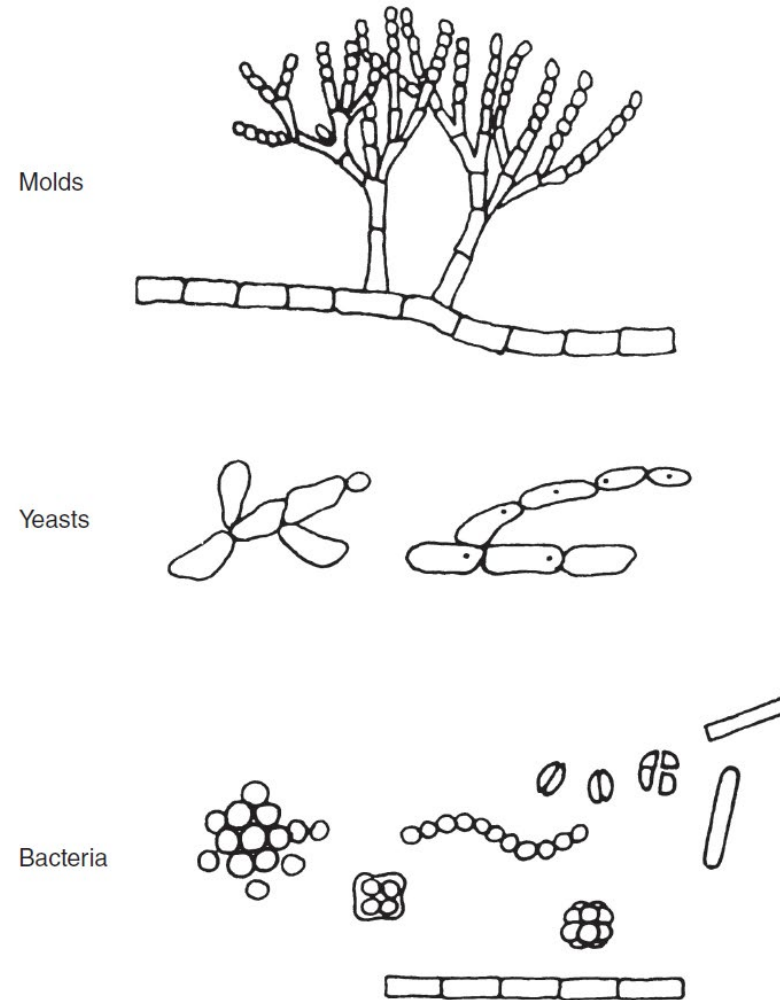
Principles of Thermal Process Control, Acidification  
and Container Closure Evaluation



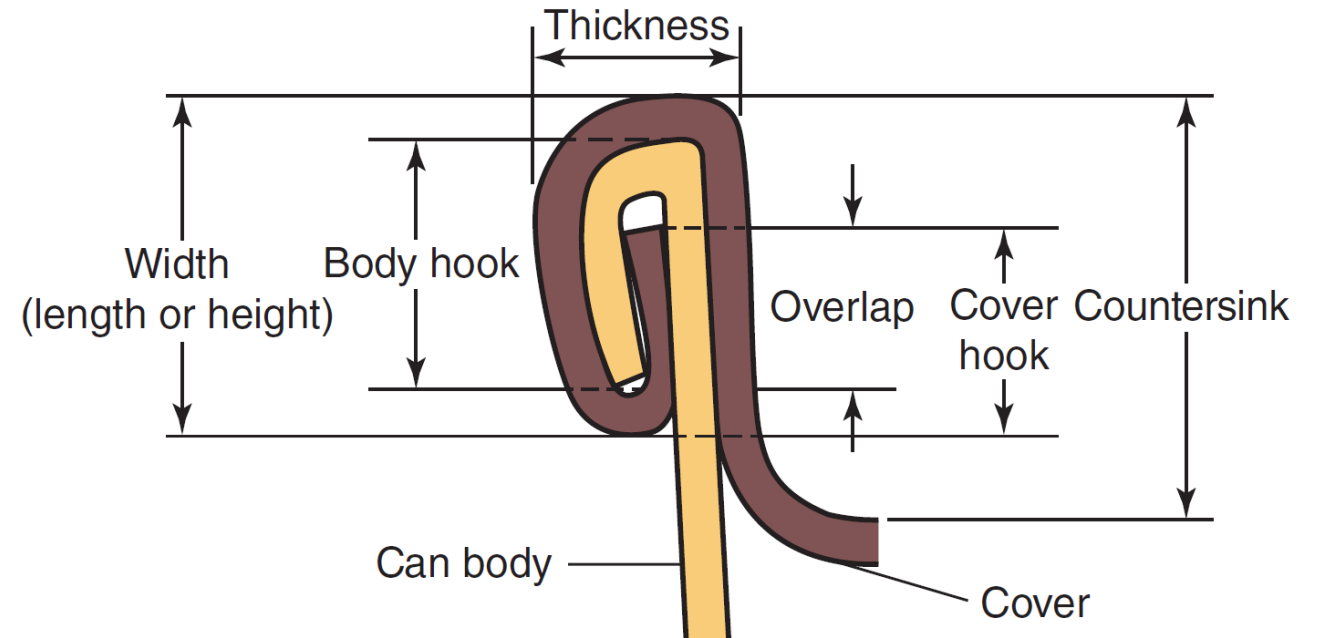
## Canned Foods: Principles of Thermal Process Control, Acidification and Container Closure Evaluation (9th Ed.)



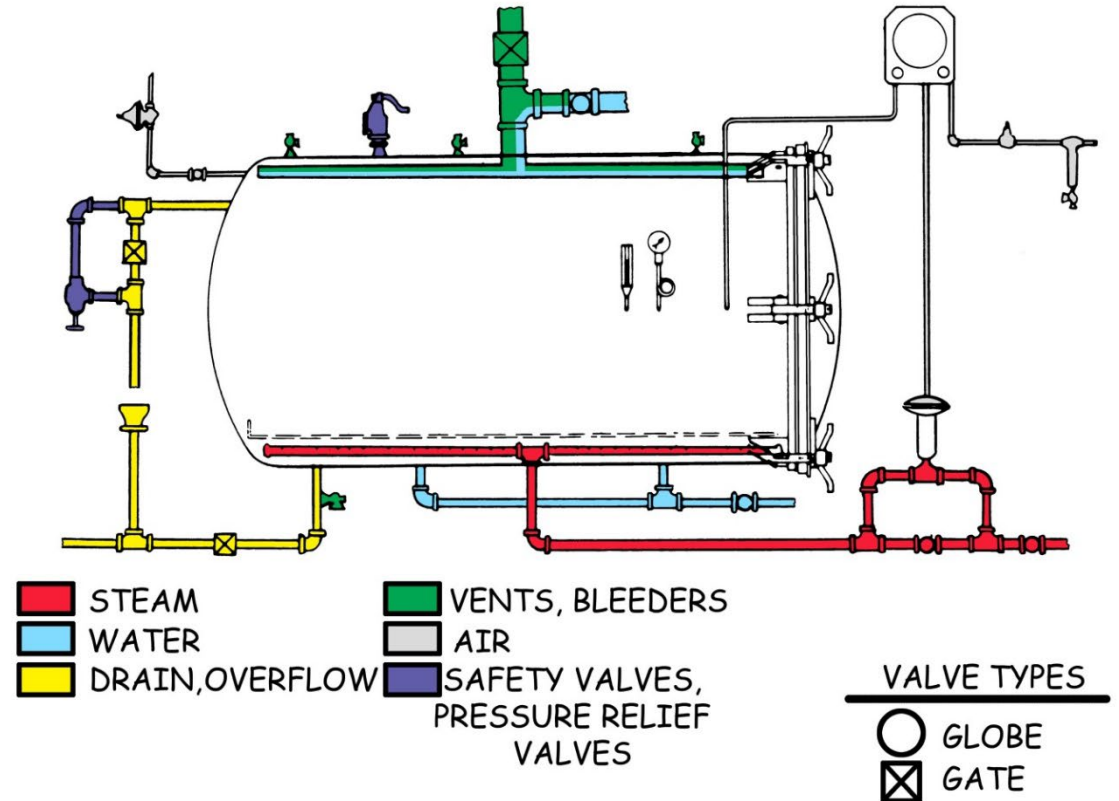
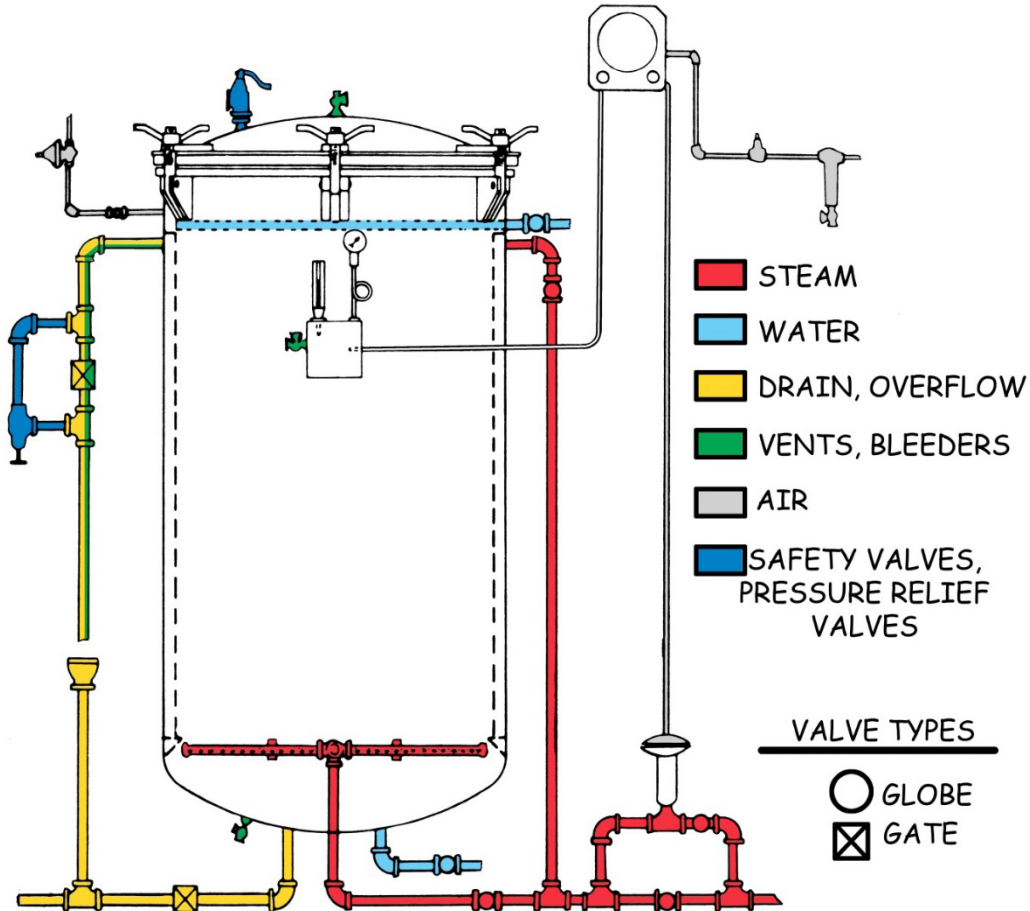
# Topic Covered



# Topic Covered



# Topic Covered





FORM APPROVED: OMB No. 0910-0037  
EXPIRATION DATE: 8-31-2011

TYPE OF SUBMISSION

- ☐ Initial Registration  
☐ Relocation (*new registration required*)  
☐ Change of Registration Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**FOOD CANNING ESTABLISHMENT REGISTRATION**

Specify Type of Change

Enter Current FCE: (If applicable)

## FOOD PROCESSING PLANT LOCATION

Establishment  
Name

Number and  
Street \_\_\_\_\_

City and State

or Province

(or other Subdivision)

Zip (or other Country (if other

Postal Code) \_\_\_\_\_ Country (if other than U.S.) \_\_\_\_\_

Telephone No.

Telefax No.

**LOW ACID AND/OR ACIDIFIED FOODS PROCESSED AT THIS LOCATION**

Food Product name, form or Style, and packing Medium

(Do not list meat and poultry foods under the jurisdiction of the Food Safety and Inspection Service of the U.S. Department of Agriculture)

(Check One)

Low-Acid	Acidified
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□ □

□ □

□      □

10/10

[illegible]





PLEASE NOTE THE FOLLOWING:
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- The form 2541 is only accepted through the postal system. Please do not e-mail or fax this form.
- After successfully registering the Food Canning Establishment with this form and the address validation is completed you will be mailed instructions on how to file your processes using our online system.
- Forms, Instructions, regulations, and information can also be secured online at <http://www.cfsan.fda.gov/~comm/lacf-toc>
- For more information contact the LACF Registration Coordinator at (301) 436-2411 or by e-mail at [lacf@fda.hhs.gov](mailto:lacf@fda.hhs.gov)

See "Instructions for Establishment Registration and Process Filing for Acidified and Low-Acid Canned Foods" for guidance in completing this form. Forward completed form to:

**Food and Drug Administration  
LACF Registration Coordinator (HFS-303)  
Center for Food Safety & Applied Nutrition  
5100 Paint Branch Parkway  
College Park, Maryland 20740-3835**

## FACILITY CONTACT PERSON (must be located at a plant location)

Name, Business Address and Position Held at Plant Location:

Phone Number:

Email Address:

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**NOTE:** No commercial processor shall engage in the processing of low-acid or acidified foods unless completed Forms FDA 2541 and FDA 2541a or FDA 2541c have been filed with the Food and Drug Administration, 21 CFR 108.25(c)(1) and (2) and 108.35(c)(1) and (2).

FORM FDA 2541 (12/10)

PREVIOUS EDITION IS OBSOLETE

PSC Graphics: (301) 443-6740 EF

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

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# 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 the 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
- 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

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## FDA Food Code

[Food Code 2017](#)

[Food Code 2013](#)

[Food Code 2009](#)

[Food Code 2005](#)

[Food Code 2001](#)

[Food Code 1999](#)

[Food Code 1997](#)

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

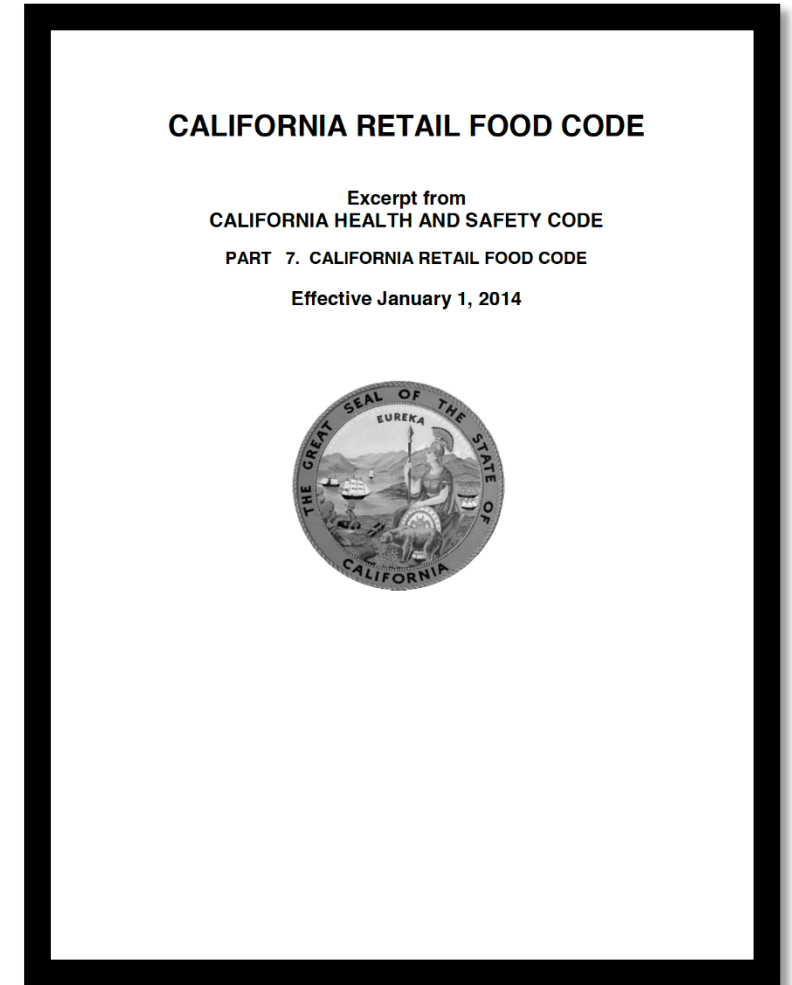
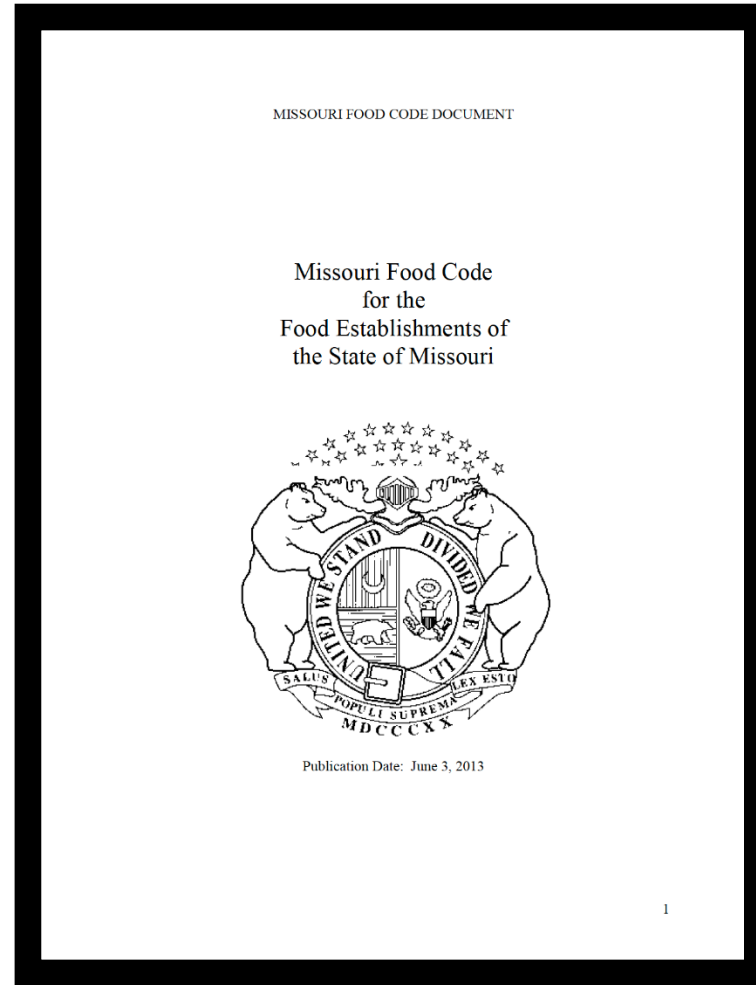
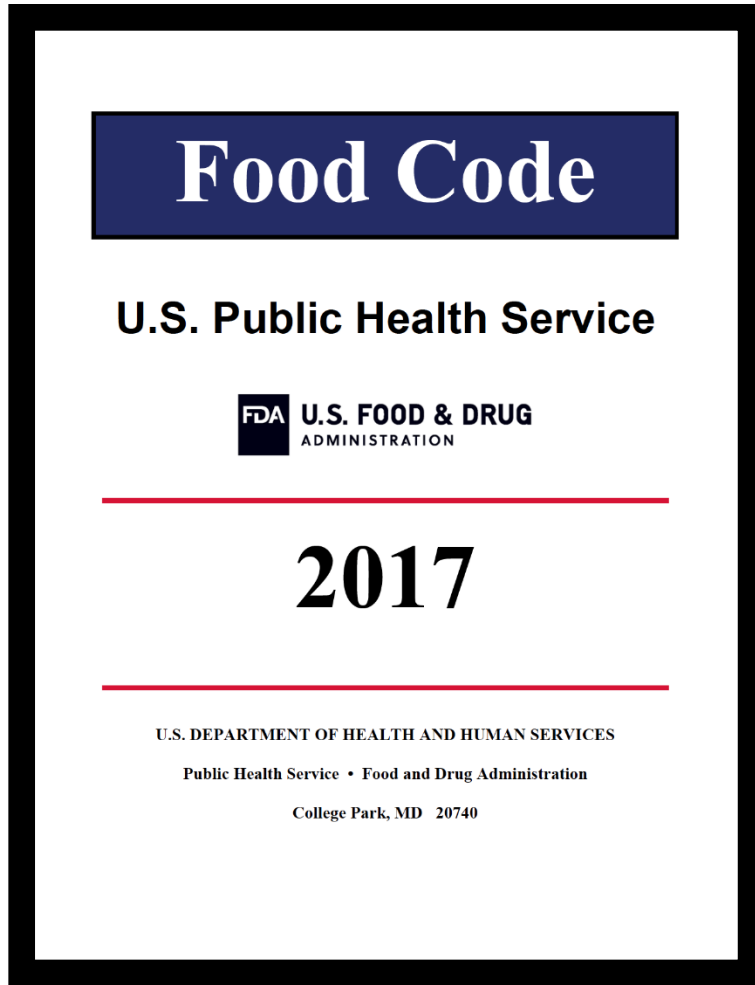
**Regulated Product(s)**  
Food & Beverages

**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



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# 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

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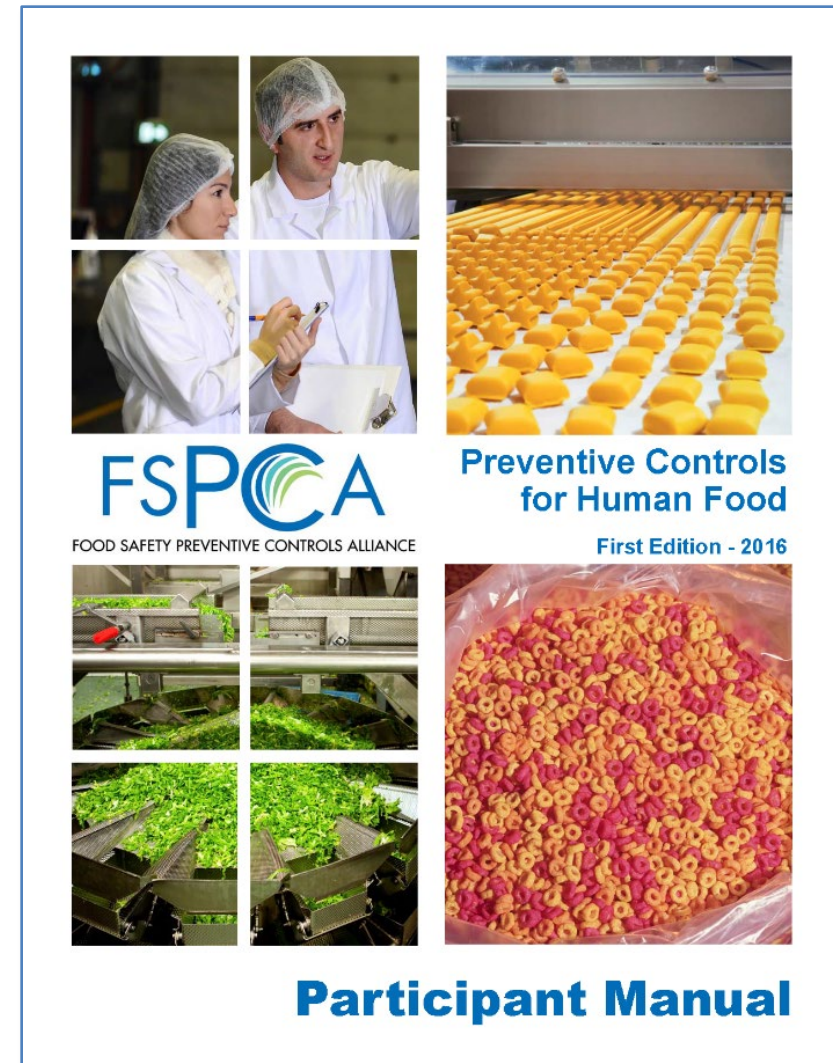
## **Subpart C – Hazard Analysis and Risk-based Preventive Controls**

- |   |   |
|---|---|
| § 117.126 Food safety plan  | § 117.150 Corrective actions and corrections  |
| § 117.130 Hazard analysis   | § 117.155 Verification  |
| § 117.135 Preventive controls   | § 117.160 Validation  |
| § 117.136 ... when a facility is not required to implement a preventive control | § 117.165 Verification of implementation and effectiveness  |
| § 117.137 Provisions of assurances required under § 117.136...                  | § 117.170 Reanalysis  |
| § 117.139 Recall plan   | § 117.180 Requirements applicable to a preventive controls qualified individual and qualified auditor |
| § 117.140 Preventive control management components                              | § 117.190 Implementation records required for this subpart  |
| § 117.145 Monitoring  |   |

# 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	ISSUE DATE	PAGE 1 of 16
PLANT NAME: Example	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

## **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

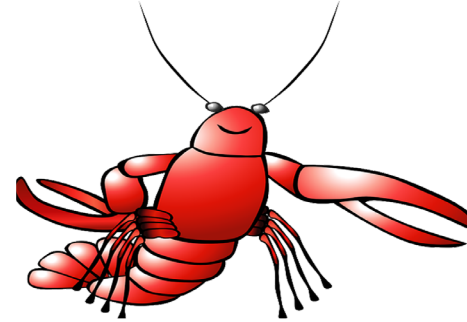
# Risk-based Food Safety Programs



**US Space  
program**



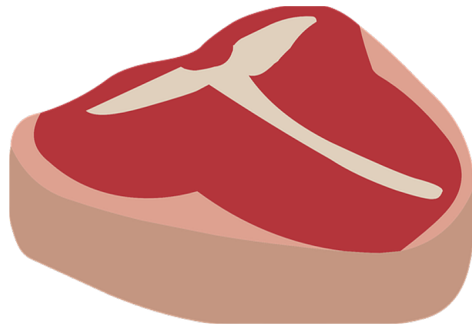
**Low-acid  
canned food regs**



**FDA Seafood  
HACCP regs**



**FDA Juice  
HACCP regs**



**USDA HACCP regs**



**Codex HACCP  
Annex**



**NCIMS Dairy  
HACCP**



## **B. Manufacturing**

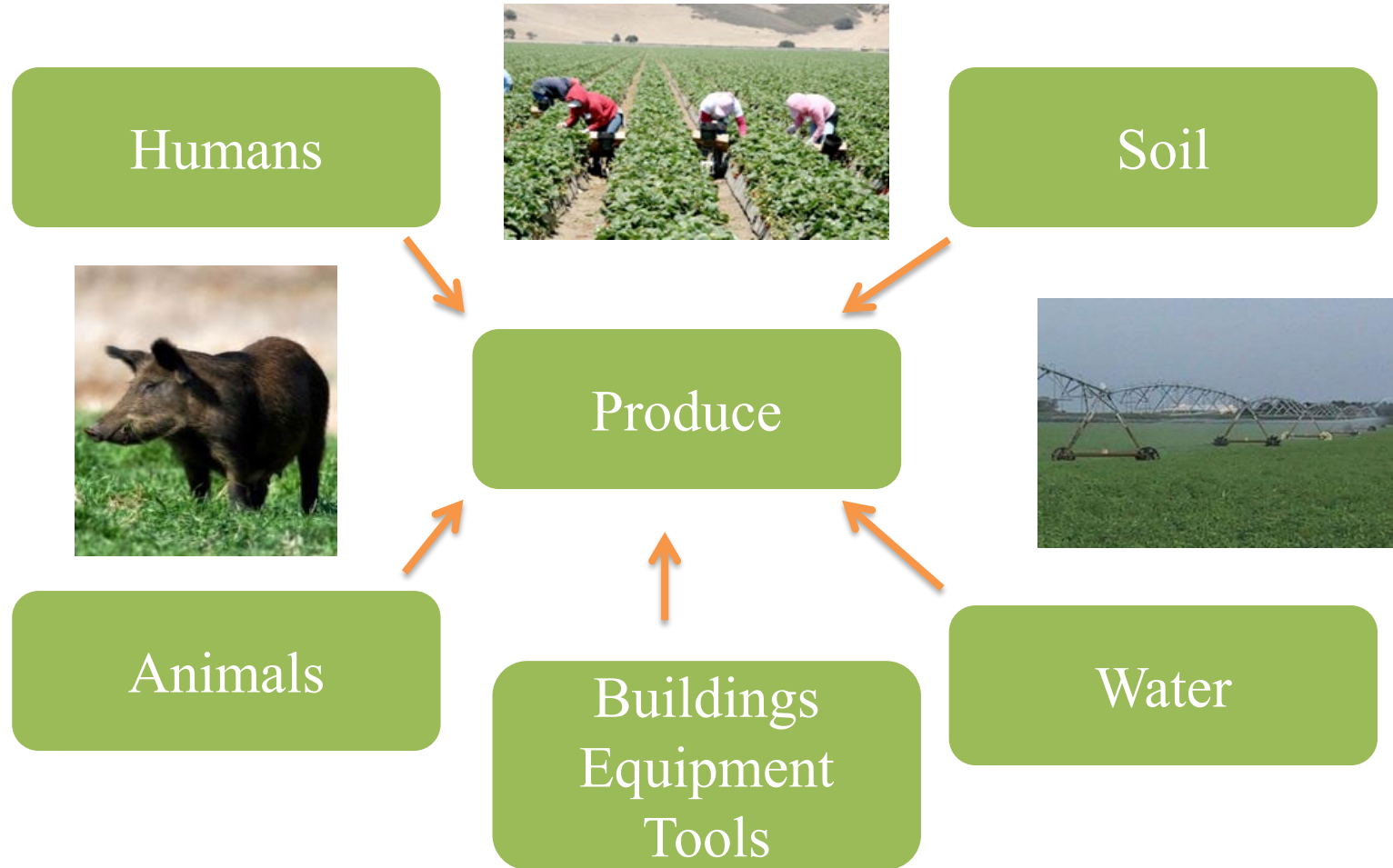
1. Overview of current Good Manufacturing Practices (cGMPs) and Statutory Basis
2. Low Acid Canned Foods (LACF) and Acidified Foods: Emergency Permit Authority
3. Model Food Code (MFC) and Adulteration (FDA/States)
4. Hazard Analysis Critical Control Points (HACCP)/Hazard Analysis, and Risk Based Preventative 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

# Prevention of Contamination



# C. Reportable Food Registry and Recalls



The screenshot shows the FDA's "Reportable Food Registry for Industry" page. The header includes the FDA logo and navigation links. The main heading is "Reportable Food Registry for Industry". Below it are social media sharing buttons. The main text explains that the Registry is an electronic portal for reporting food safety issues. It also mentions the Food and Drug Administration Amendments Act of 2007. Two buttons are provided: "For Industry/Regulators Submit a Report" and "For Consumers Contact FDA". Below these are four links: "Who Should Use the Reportable Food Registry?", "Reportable Food Registry Policy Information Video", "RFR At A Glance", and "Policy Information". On the right side, there is a sidebar with "Content current as of: 02/22/2022" and "Regulated Product(s): Food & Beverages".

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Search Menu

Home / Food / Compliance & Enforcement (Food) / Reportable Food Registry for Industry

## 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.

[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](#)

Content current as of:  
02/22/2022

Regulated Product(s)  
Food & Beverages

## 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 plan 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

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## 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



**i** ALERT: Frickenschmidt Foods LLC Recalls Ready... See more details

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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.