

Requirements for a **food hub** that is fully covered under the Preventive Controls Rule

USDA NIFA Food Safety Outreach Program : Jan 2019

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Who is covered?


By the Preventive Controls Rule for Human Food

- Facilities that manufacture, process, pack, or hold human food
- Fully covered:
 - Not food hubs on farms (meeting the primary or secondary farm definition) or retail food establishments
 - Have >\$1,000,000 in annual sales

What if my food hub is fully covered under the Preventive Controls for Human Food Rule?

- Subject to full requirements under 21 CFR Part 117
- Implement cGMPs and other prerequisite programs (SSOPs)
- Conduct a Hazard Analysis
- Develop a Food Safety Plan
 - See specific requirements for the FSP
- FSP development and certain other activities must be conducted by Preventive Controls Qualified Individual (PCQI)
- Register with FDA
- FDA inspection

Illinois Institute of Technology



FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Menu ▾

[FSPCA Home](#)

The Food Safety Preventive Controls Alliance (FSPCA) is a broad-based public private alliance consisting of key industry, academic and government stakeholders whose mission is to support safe food production by developing a nationwide core curriculum, training and outreach programs to assist companies producing human and animal food in complying with the preventive controls regulations that will be part of the Food Safety Modernization Act (FSMA).

<https://www.ifsh.iit.edu/fspca>

Types of Foodborne Illness

- Chemical
 - Allergens
- Physical
- Biological
 - Bacteria
 - Viruses
 - Parasites

Foodborne Illness Acquired in the United States—Major Pathogens

Elaine Scallan,¹ Robert M. Hoekstra, Frederick J. Angulo, Robert V. Tauxe, Marc-Alain Widdowson, Sharon L. Roy, Jeffery L. Jones, and Patricia M. Griffin

January 2011, CDC, Emerging Infectious Diseases

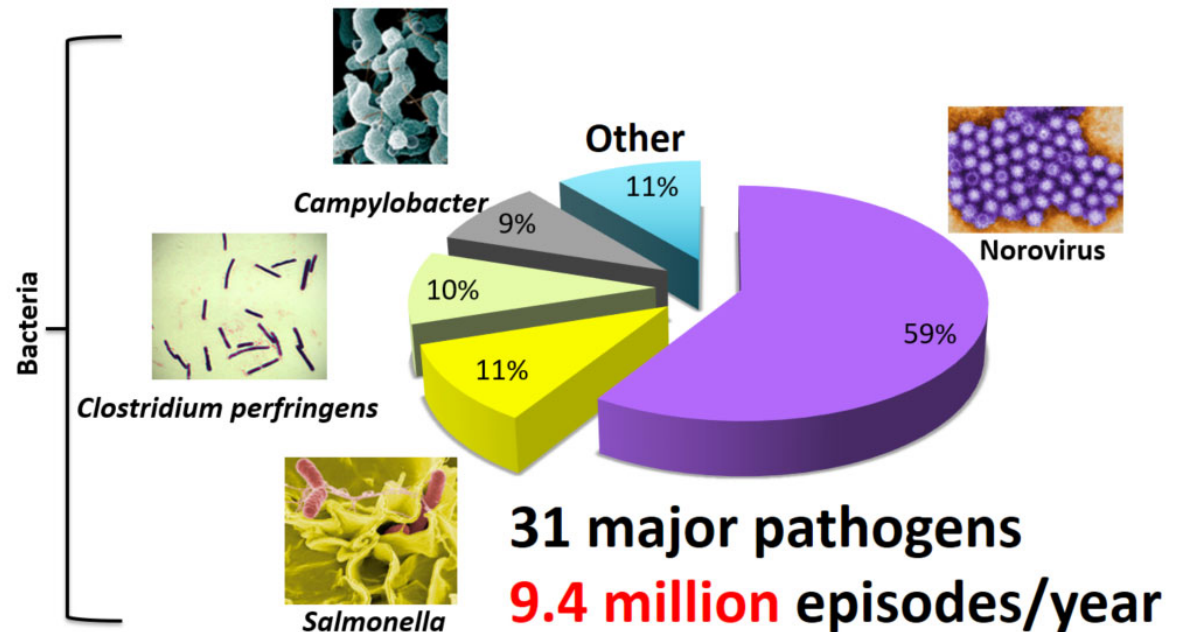
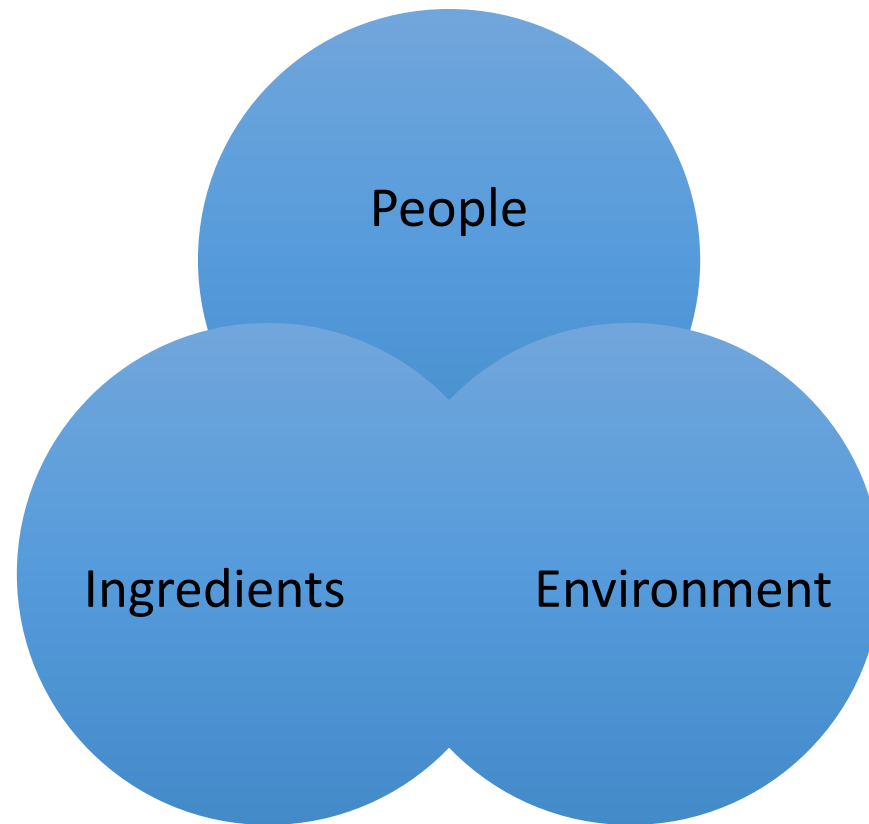


Photo credits: www.foodsafety.gov

Potential sources of hazards



Don't Let This Happen to You!

Examples of Outbreaks and Recalls

Outbreak and/or Recall	Preventive Controls Lacking
<p>Salmonella in peanut products for commercial use 2008-09 U.S.</p> <ul style="list-style-type: none">• ~3900 products recalled by 200+ companies• 714 ill, 9 dead in 46 states	<p><u>Primary Processor</u> –</p> <ul style="list-style-type: none">Process – Roaster validationSanitation – cross-contamination prevention and environmental pathogen control <p><u>Customers</u> – Supply-chain program</p>
<p>Botulism from hazelnut yogurt 1989 England</p> <ul style="list-style-type: none">• 27 cases, 1 death	<p><u>Primary Processor</u> –</p> <ul style="list-style-type: none">Process – validation or refrigeration of hazelnut conserve <p><u>Customers</u> – Supply-chain program</p>
<p>Allergen recalls</p> <ul style="list-style-type: none">• Undeclared allergens account for over 1/3 of FDA food recalls• Most common root cause – wrong package or label	<p>Allergen controls – accurate labeling and prevention of allergen cross-contact</p>

Selected multistate outbreaks in fresh produce reported by the U.S. Centers for Disease Control and Prevention, 2006-2018

Commodity	Pathogen	Year	Case Count/Deaths
Romaine lettuce	<i>Escherichia coli</i> O157:H7	2018	210/5
Leafy greens	<i>Escherichia coli</i> O157:H7	2017	25/1
Alfalfa Sprouts	<i>Escherichia coli</i> O157	2016	11/0
Clover Sprouts	<i>Escherichia coli</i> O121	2014	19/0
Ready to eat Salads	<i>Escherichia coli</i> O157:H7	2013	33/0
Organic spinach and spring mix	<i>Escherichia coli</i> O157:H7	2012	33/0
Clover sprouts	<i>Escherichia coli</i> O122	2012	29/0
Romaine lettuce	<i>Escherichia coli</i> O157:H7	2011	58/0
Shredded Romaine lettuce	<i>Escherichia coli</i> O145	2010	26/0
Spinach	<i>Escherichia coli</i> O157:H7	2006	199/3

Commodity	Pathogen	Year	Case Count/Deaths
Packaged salad	<i>Listeria monocytogenes</i>	2016	19/1
Caramel apples	<i>Listeria monocytogenes</i>	2015	35/7
Bean sprouts	<i>Listeria monocytogenes</i>	2014	5/2
Cantaloupes	<i>Listeria monocytogenes</i>	2011	147/33



Commodity	Pathogen	Year	Case Count/Deaths
Pre-cut melon	<i>Salmonella</i> Adelaide	2018	77/0
Sprouts	<i>Salmonella</i> Montevideo	2018	10/0
Maradol papayas	<i>Salmonella</i> (multiple)	2017	220/1
Alfalfa sprouts	<i>Salmonella</i> Reading, <i>Salmonella</i> Albony	2016	36/0
Alfalfa sprouts	<i>Salmonella</i> Muenchen, <i>Salmonella</i> Kentucky	2016	26/0
Cucumbers	<i>Salmonella</i> Poona	2015	907/6
Cucumbers	<i>Salmonella</i> Newport	2014	275/1
Bean sprouts	<i>Salmonella</i> Enteritidis	2014	115/0
Cucumbers	<i>Salmonella</i> Saintpaul	2013	84/0
Mangoes	<i>Salmonella</i> Braenderup	2012	127/0
Cantaloupe	<i>Salmonella</i> Typhimurium, <i>Salmonella</i> Newport	2012	261/3
Papayas	<i>Salmonella</i> Agona	2011	106/0
Cantaloupe	<i>Salmonella</i> Panama	2011	20/0
Alfalfa sprouts	<i>Salmonella</i> I 4	2011	140/0
Alfalfa sprouts	<i>Salmonella</i> Newport	2010	44/0
Alfalfa sprouts	<i>Salmonella</i> Saintpaul	2009	234/0
Raw produce	<i>Salmonella</i> Saintpaul	2008	1414/2
Cantaloupes	<i>Salmonella</i> Litchfield	2008	51/0
Tomatoes	<i>Salmonella</i> Typhimurium	2006	183/0

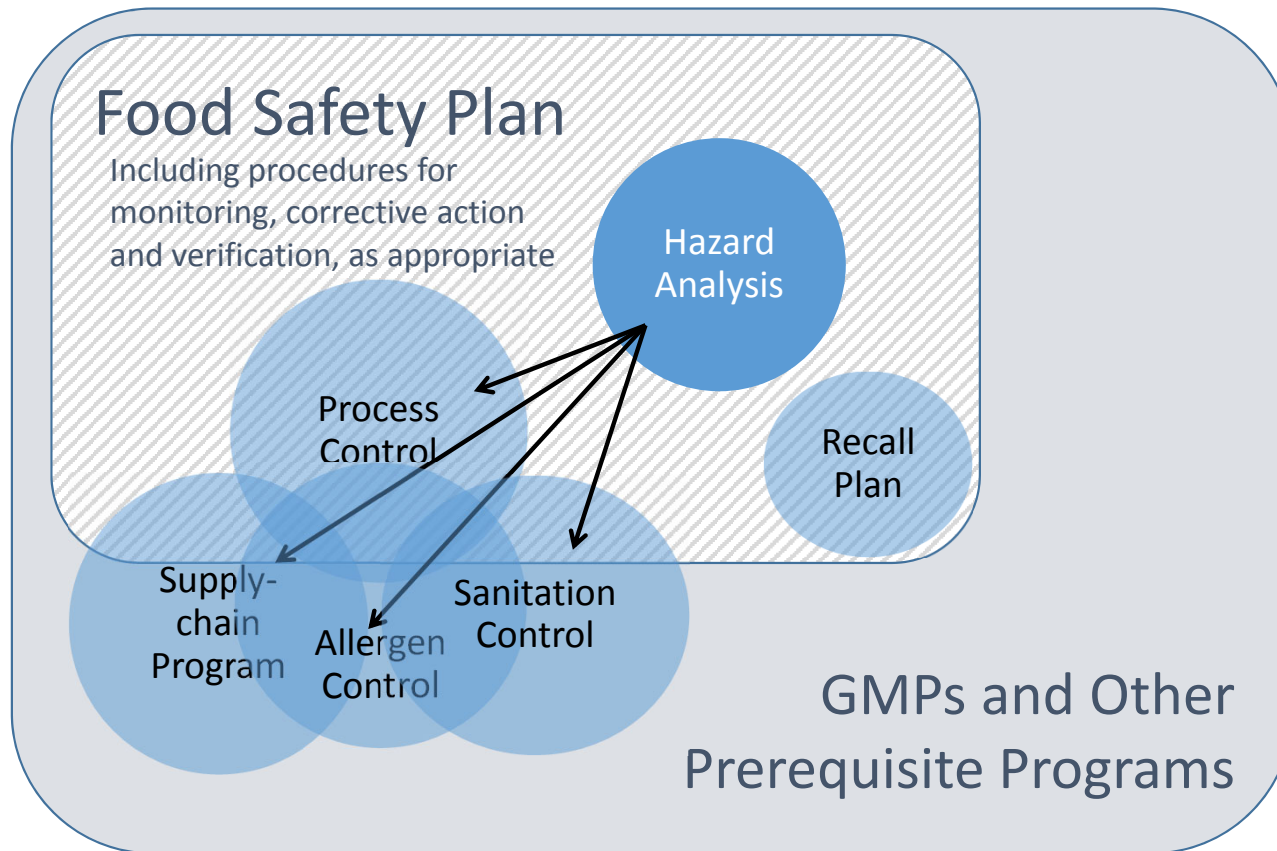
Commodity	Pathogen	Year	Case Count/Deaths
Salad mix	<i>Cyclospora cayetanensis</i>	2018	511/0
Vegetable tray	<i>Cyclospora cayetanensis</i>	2018	250/0
Cilantro	<i>Cyclospora cayetanensis</i>	2014	117/0
Fresh produce	<i>Cyclospora cayetanensis</i>	2013	631/0
Frozen strawberries	Hepatitis A virus	2016	143/0
Pomegranate seeds	Hepatitis A virus	2013	165/0



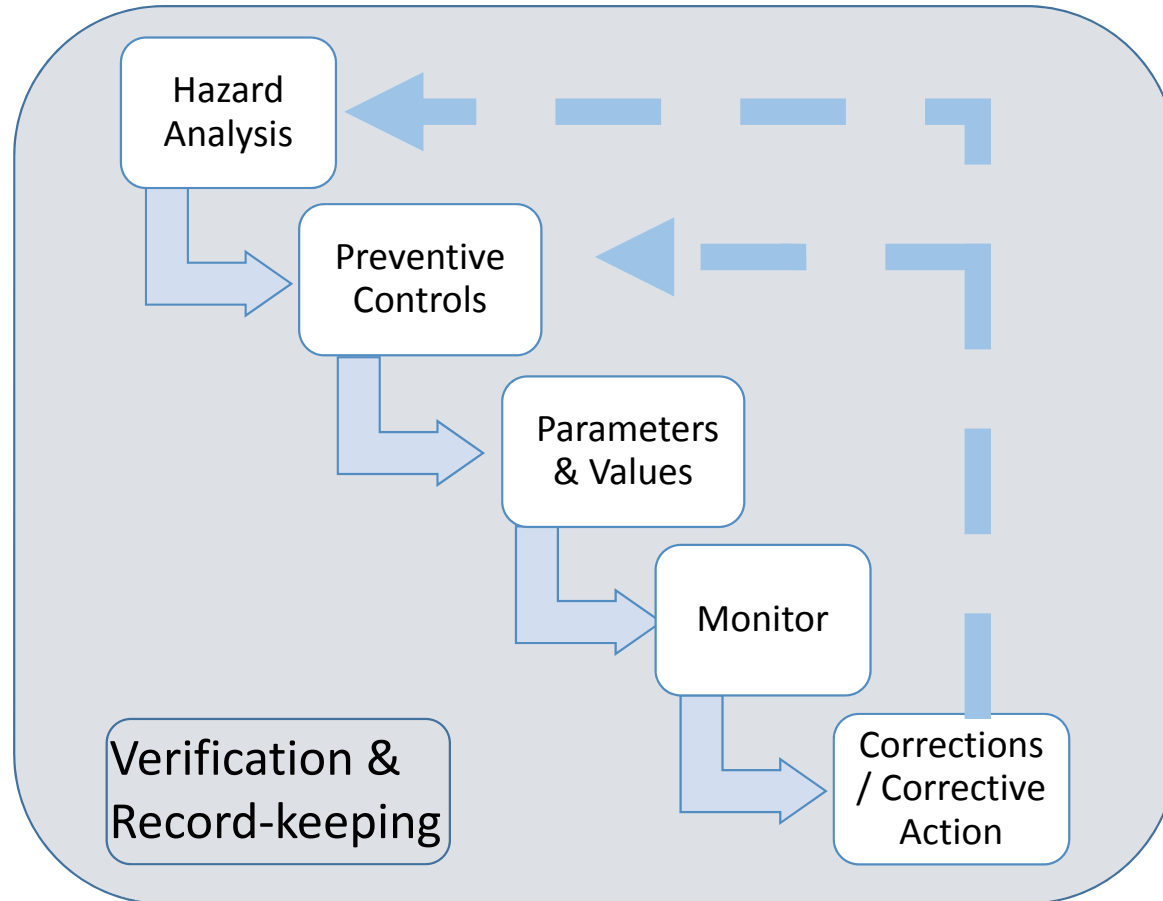
Risk-based Preventive Controls

- Focus on what matters most for food safety
- Preventive, not reactive
- Work in conjunction with and supported by other programs like Good Manufacturing Practices
- Designed to minimize the risk of food safety hazards

Preventive food safety systems



Determining Preventive Controls is systematic



Contents of a food safety plan

Required

- Hazard analysis
- Preventive controls*
 - Process, food allergen, sanitation, supply-chain and other
 - Recall plan*
- Procedures for monitoring, corrective action and verification*

Useful

- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when a hazard requiring a preventive control is identified

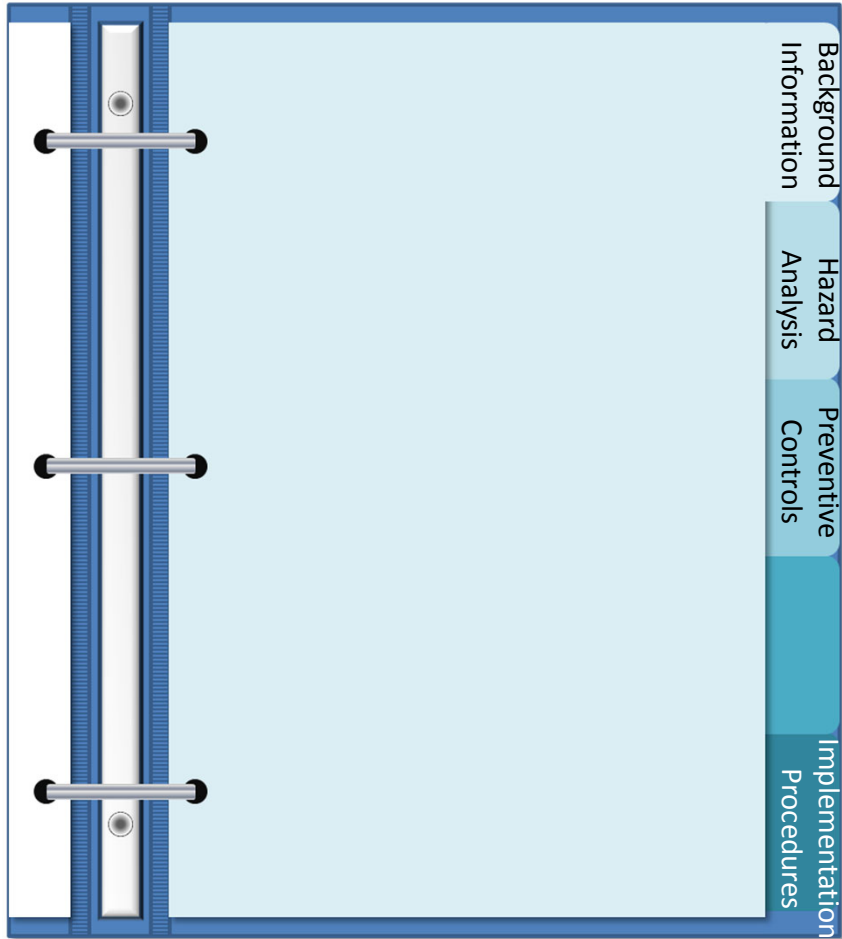
Scope of the food safety plan

- Specific to a facility
 - Preventive controls specific to a product and process
- Products may be grouped if hazards and controls are managed generally the same
- Define and address:
 - Specific product(s) and process(es)
 - Part of the food chain to be studied
 - Biological, chemical, and physical hazards

Food safety plan format is flexible

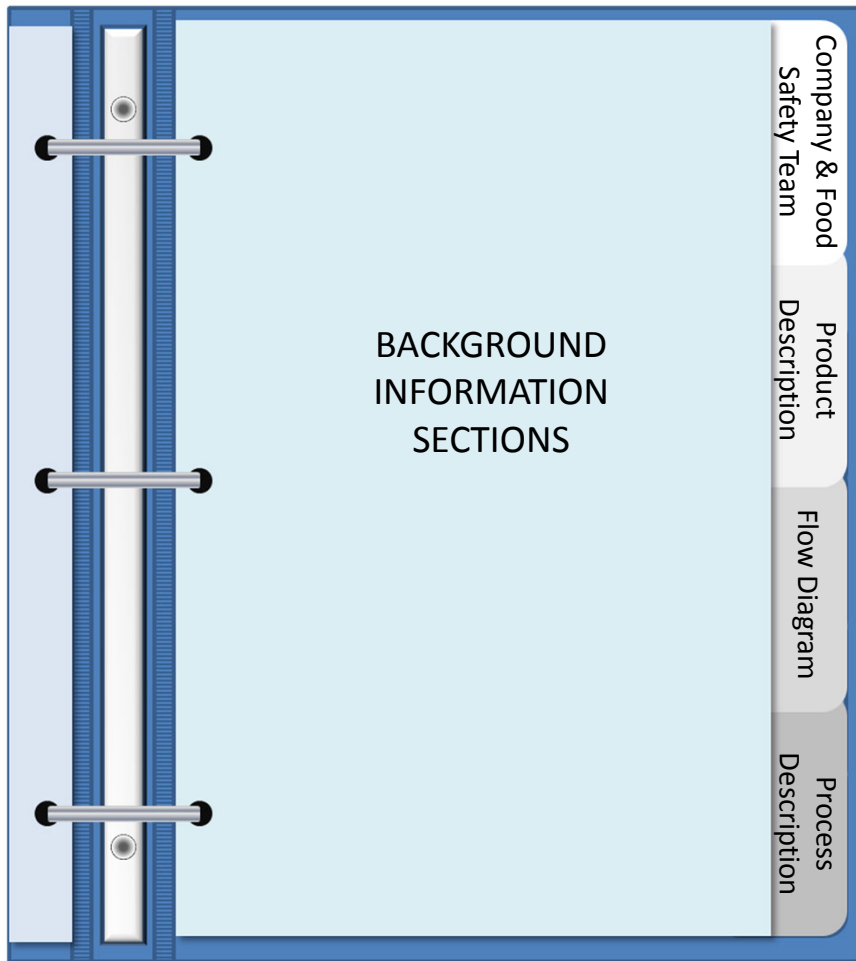


Main organizational sections



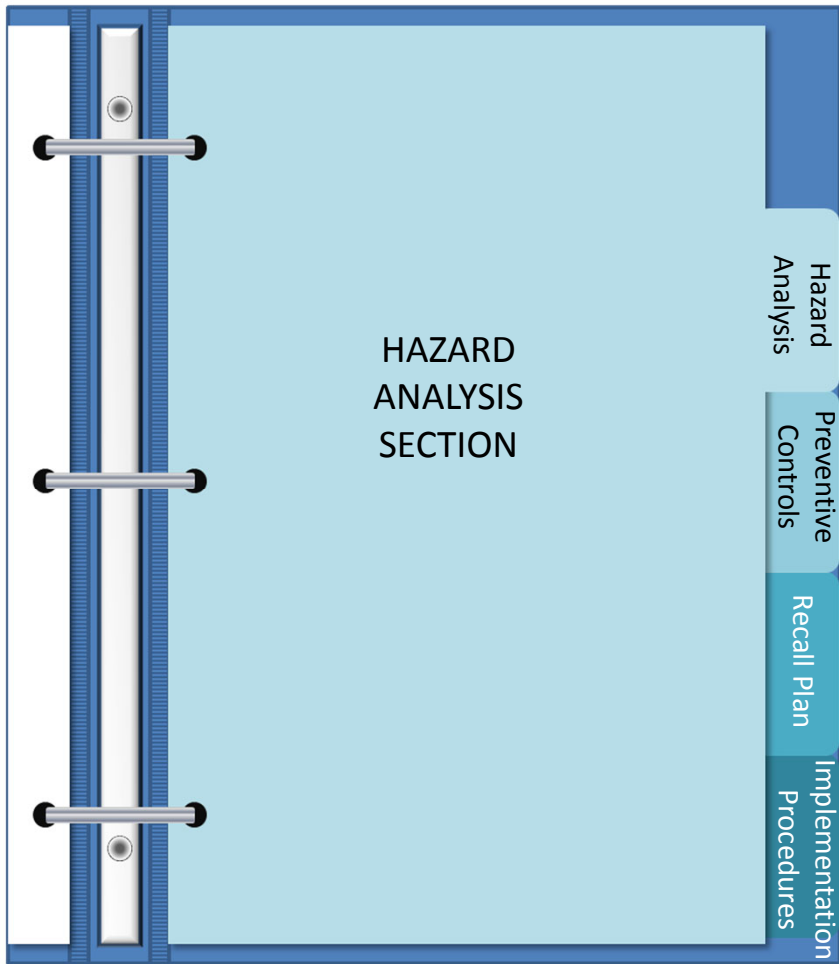
1. Background information - optional
2. Hazard analysis
3. Preventive controls
4. Recall plan
5. Implementation procedures

Background information



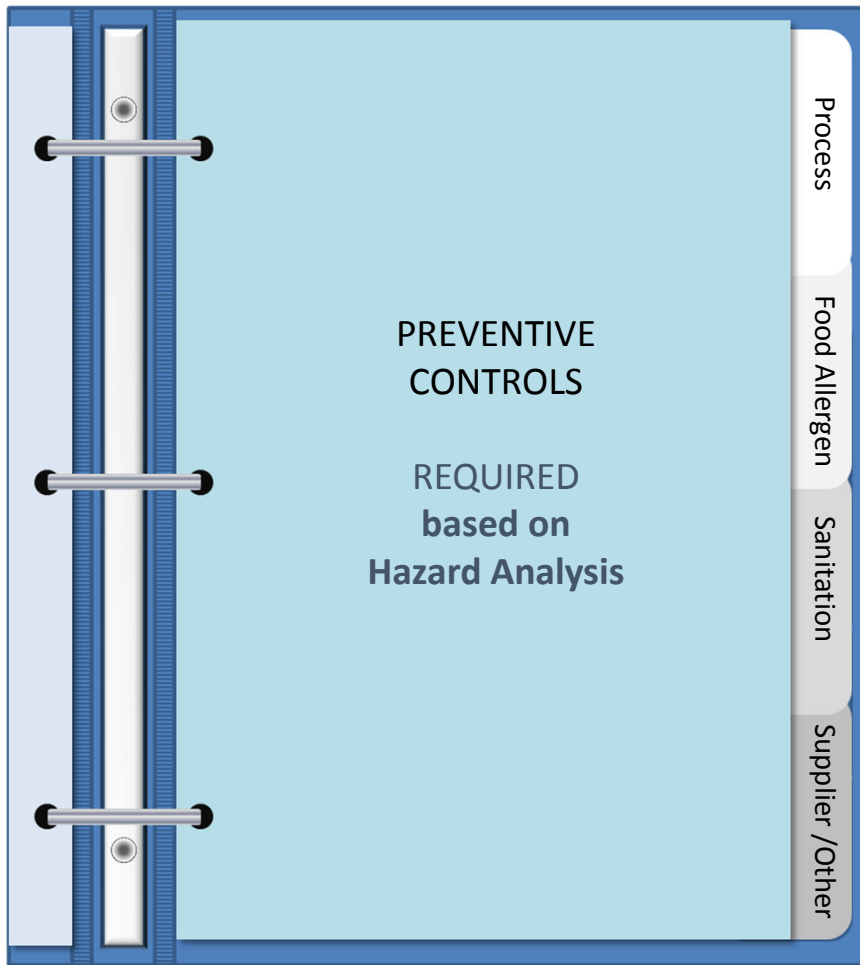
- Useful information to organize the plan:
 - Facility overview and Food Safety Team
 - Product description
 - Flow diagram
 - Process description

Hazard Analysis – Required



- Drives decision making for the controls that must be included in the Food Safety Plan

Preventive and Other Controls May Include:



Process preventive controls

- Critical control points (CCPs)

Food allergen preventive controls

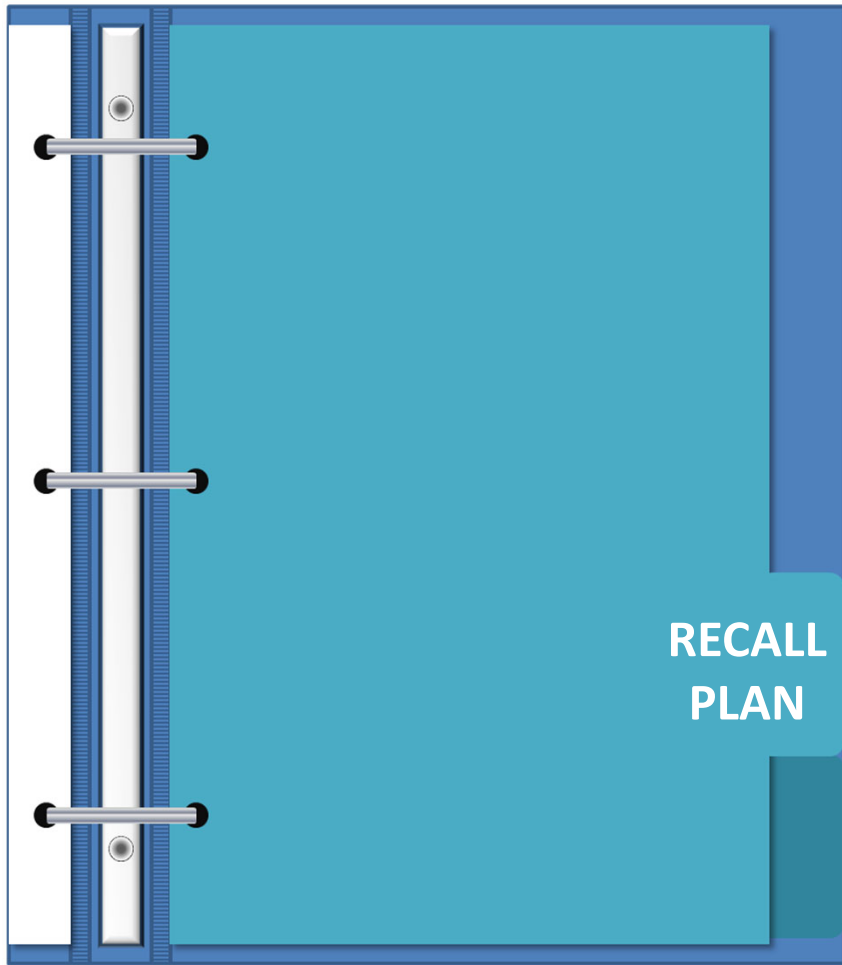
- Accurate labeling
- Cross-contact prevention

Sanitation preventive controls

- Environmental pathogens
- Cross-contamination, cross-contact

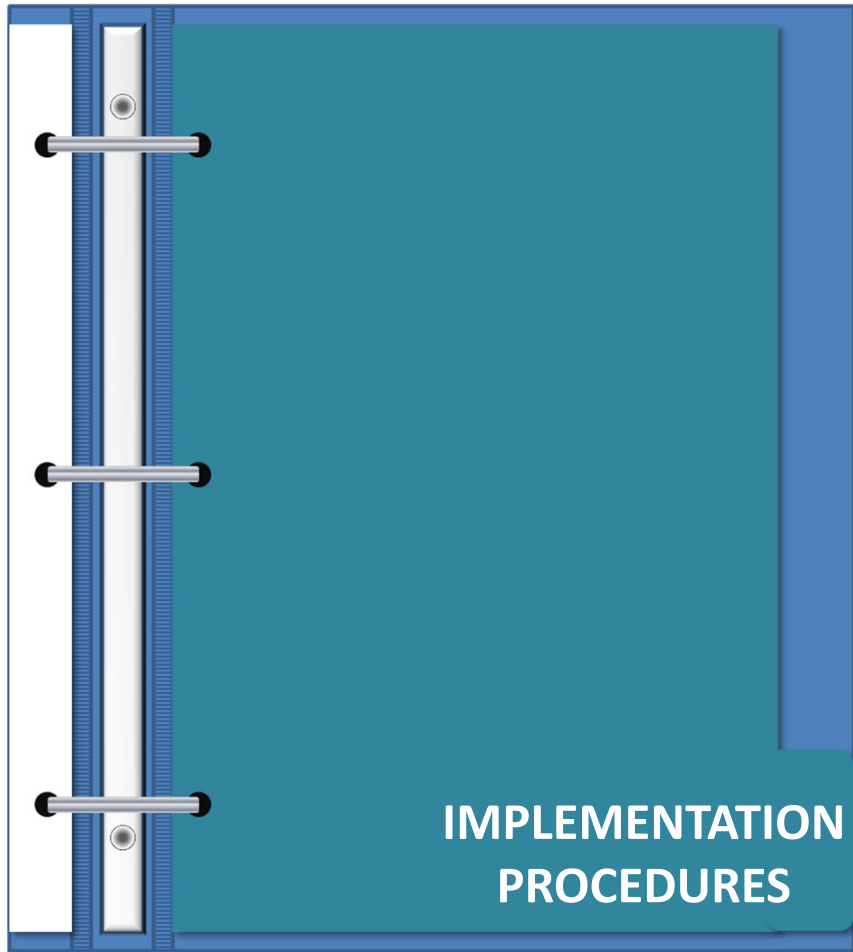
Supply-chain preventive controls

Recall Plan



- Required when a hazard requiring a preventive control is identified
- What to do when something goes wrong

Implementation Procedures



- Examples that may be required include:
 - Validation studies
 - Procedures for monitoring, verification and corrective action

Who can prepare the Food Safety Plan?

- Prepared or preparation overseen by ***Preventive Controls Qualified Individual***
- Someone who knows your operation well
- Preventive Controls Qualified Individual:
An individual who has successfully completed training in the development and application of risk-based preventative controls at least equivalent to that received under the standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Activities that must be performed by a Preventive Controls Qualified Individual

1. Preparation of the Food Safety Plan
2. Validation of the preventive control
3. Records review
4. Reanalysis of the Food Safety Plan

FDA registration

- Fully covered facilities must register with FDA
- Facilities can register online on FDA's website
 - <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006832.htm>
- Registration renewal required biennially (every even year)

The screenshot shows the FDA website's navigation bar with categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The 'Food' category is selected. Below the navigation bar, the breadcrumb trail reads: Home > Food > Guidance & Regulation > Food Facility Registration. A sidebar on the left lists various registration options, with 'Online Registration of Food Facilities' highlighted. The main content area is titled 'Online Registration of Food Facilities' and includes social sharing icons for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print. The text explains that the FDA Industry Systems (FIS) was created to facilitate submissions to the FDA, including registrations, listings, and other notifications, and has been available since October 16, 2003. It also provides a list of guides to assist with using FIS for online registration of food facilities.

Home > Food > Guidance & Regulation > Food Facility Registration

Food Facility Registration

- ▶ Online Registration of Food Facilities
- Acidified & Low-Acid Canned Foods (LACF) Registration
- Infant Formula Notification
- New Dietary Ingredient Notification Instructions
- Qualified Facility Attestation
- Shell Egg Producer Registration
- Structure/Function Claims Process

Online Registration of Food Facilities

f SHARE | t TWEET | in LINKEDIN | p PIN IT | e EMAIL | p PRINT

[FDA Industry Systems \(FIS\)](#) was created to facilitate making submissions to FDA, including registrations, listings, and other notifications. FIS has been available 24 hours a day, seven days a week, since October 16, 2003.

The following are guides to assist with using FIS for the online registration of food facilities.

- [Account Management](#)
- [Registration of Food Facilities Step-by-Step Instructions](#)
- [Update Facility Registration](#)
- [Biennial Registration Renewal](#)
- [Retrieve Registration PIN](#)
- [Additional Capabilities in FFRM](#)

Information need for FDA facility registration

- Type of Registration
- Facility Name / Address Information
- Optional: Preferred Mailing Address Information
- Parent Company Name / Address Information
- Facility Emergency Contact Information
- Trade Names
- United States Agent
- Seasonal Facility Dates of Operation
- General Product Categories – human/Animal/Both
- General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility
- General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility
- Owner, Operator, or Agent in Charge Information
- Inspection Statement
- Certification Statement

Frequency of inspection

- FSMA directs FDA to inspect domestic facilities at a rate determined by the risk its products pose to public health
- High-risk facilities are to be inspected every three years, while low-risk facilities are to be inspected every five years

Commonly occurring inspection violations

- **Lack of effective pest exclusion / screening** – FDA cites a facility for not taking effective preventative measures against pest presence in food processing areas or not implementing controls to protect food from contamination due to pests
- **Sanitation monitoring** – FDA cites a facility for failing to effectively monitor sanitation practices and conditions consistently
- **Floors, walls, and ceilings** – FDA cites a facility for being constructed in a way that inhibits proper sanitation and repair of the floors, walls, and ceilings
- **Importer Verification** – FDA cites a seafood importer for failing to document verification of a supplier's compliance with Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations.
- **Food Safety Plan Implementation** – FDA cites a facility for failing to implement procedures established in its written Food Safety Plan

FDA inspection

- When a food facility registers with FDA, it grants FDA permission to inspect the facility at any given time
- Initial FDA food facility inspections are of no cost to the facility
 - Occur due to routine reasons, a facility's level of potential risk to public health, or as a response to a problem or complaint
- If FDA discovers certain food safety violations during an initial inspection, the Agency may decide it needs to return at a later date to evaluate whether the facility implemented appropriate corrective actions.
- The second evaluation is considered a reinspection (also sometimes referred to as a “compliance follow-up inspection”)
- Cost of reinspection for 2018 is \$248/hour