



Artisan Dairy Food Safety Plan Session

September 2, 2021



UtahStateUniversity



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Course Materials

- Agenda
- Agenda Overview
- Manual Content and Materials
- Digital Materials

ARTISAN DAIRY FOOD SAFETY: FSMA & FOOD SAFETY PLAN BASICS

THURSDAY, SEPTEMBER 02, 2021

10:45 am	FSMA and Food Safety Plan Overview
11:15 am	Hazards and Hazard Analysis – Overview and Preliminary Documents
11:45 am	Hazards and Hazard Analysis – Types and Process
12:15 am	Q&A: Discussing the Hazard Analysis with Food Safety Experts
12:30 pm	Lunch
1:30 pm	Preventive Controls: Process Control
2:05 pm	Preventive Controls: Sanitation Controls
2:40 pm	Preventive Controls: Allergens
3:15 pm	Overview of Environmental Monitoring
3:50 pm	Preventive Controls: Supplier Controls
4:25 pm	Q&A with Food Safety Experts and Dairy Producer(s)
5:00pm	Adjourn

Responsibility Statement



This workshop does not replace the PCQI training content, it assumes participants are already familiar with that training and basic HACCP concepts.


The goal of this workshop is to facilitate the development of food safety plans by the course participants themselves.

The participants are responsible for the validation and implementation of this plan.

Ultimately, the participants are responsible for the production of safe food in their facility.



FSMA Food Safety Plan Overview



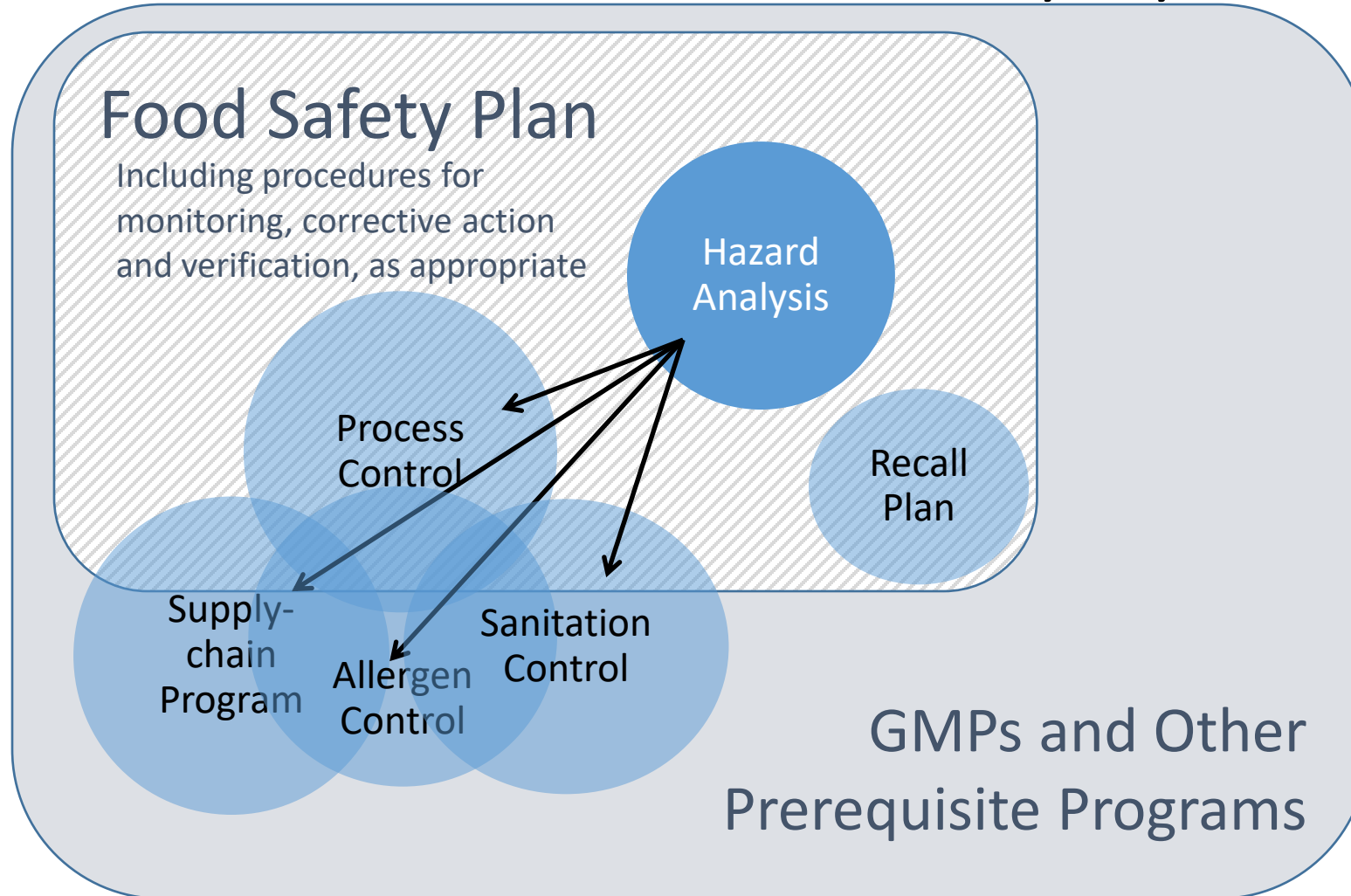
Risk-based Preventive Controls

- 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

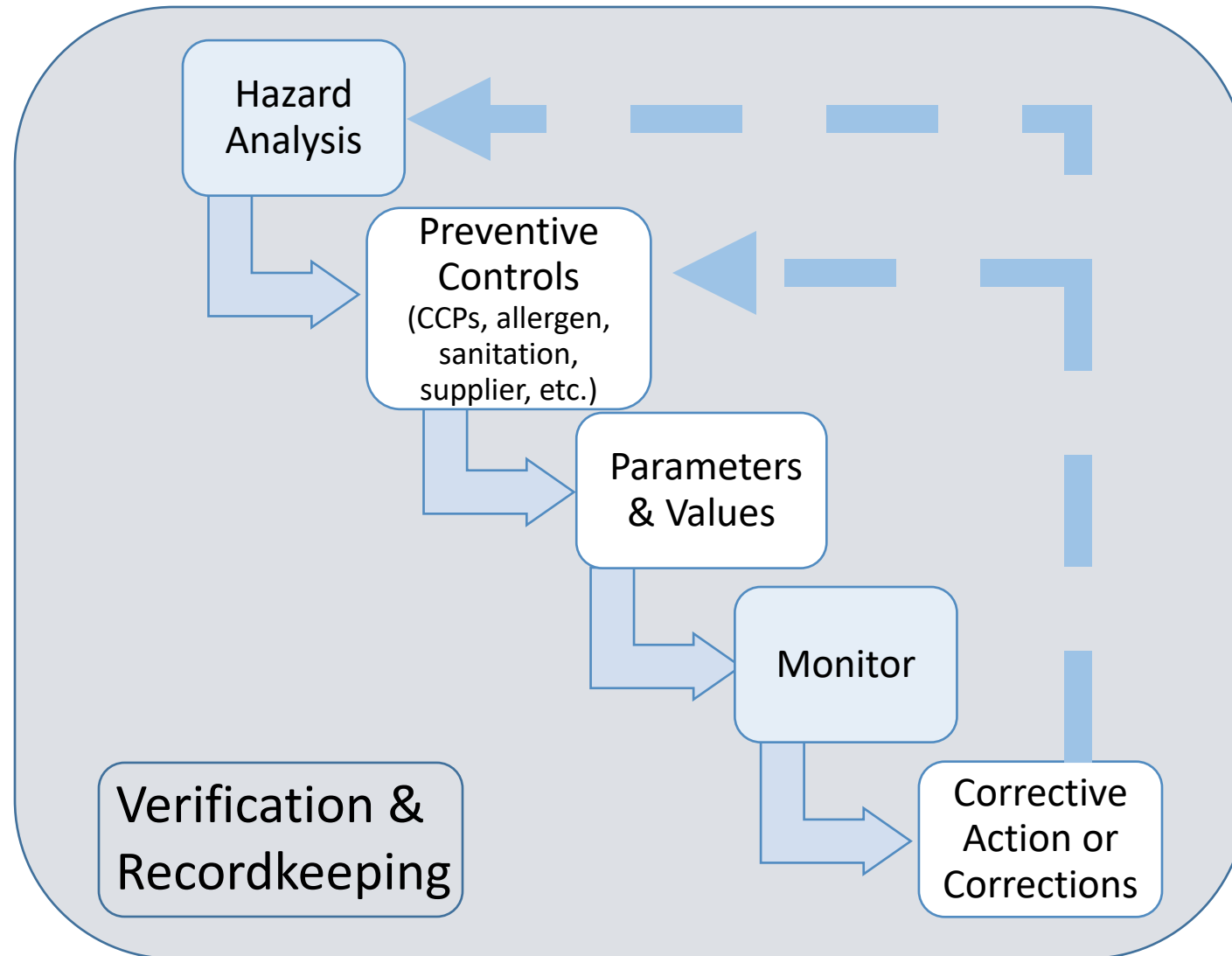
Food Safety Modernization Act



Update View of the Food Safety Systems

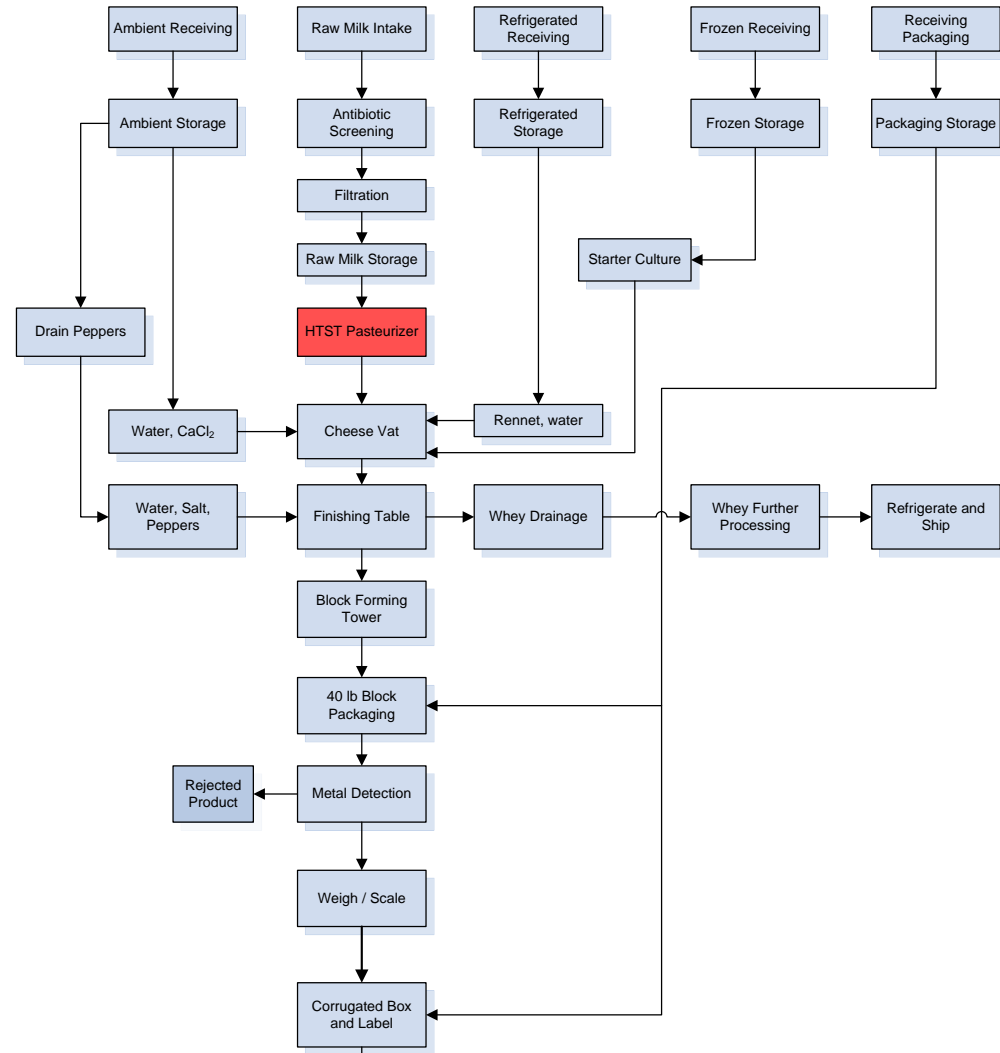


Creating an Systematic Risk-based Approach



Think About Potential Sources of Hazards





Identifying Controls for Hazards

Preventive Controls Qualified Individual Definition

- A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
 - 21 CFR 117.3 Definitions

Definitions

- Food Safety Plan
 - A set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, supply-chain programs and a recall plan; and delineates the procedures to be followed for monitoring, corrective actions and verification.
 - Adapted from 21 CFR 117.126
- Food safety system
 - The outcome of implementing the Food Safety Plan and its supporting elements

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*

Very Useful

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

* Required when a hazard requiring a preventive control is identified

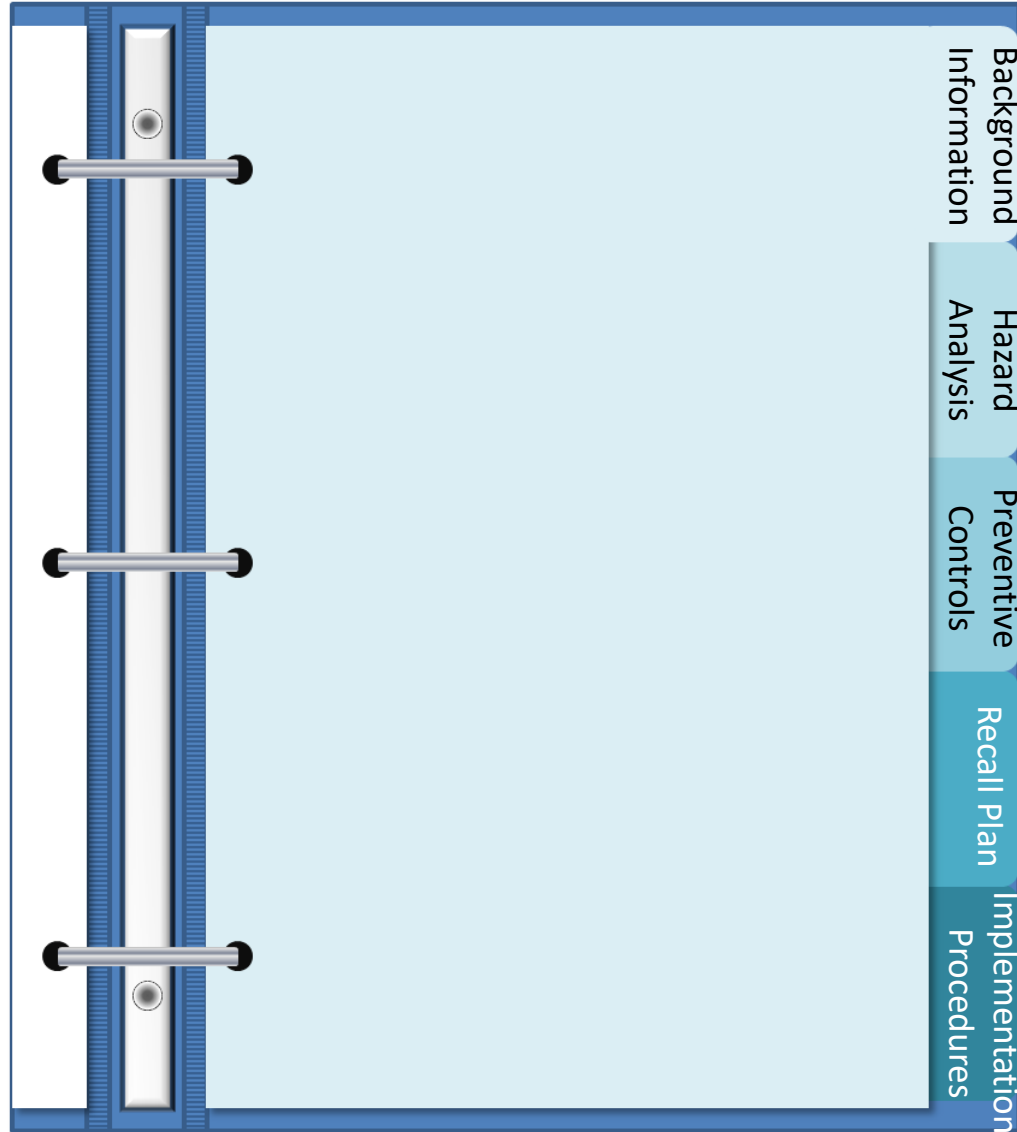
Scope of the Food Safety Plan

- 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 (including radiological) and physical hazards

Food Safety Plan Format is Flexible

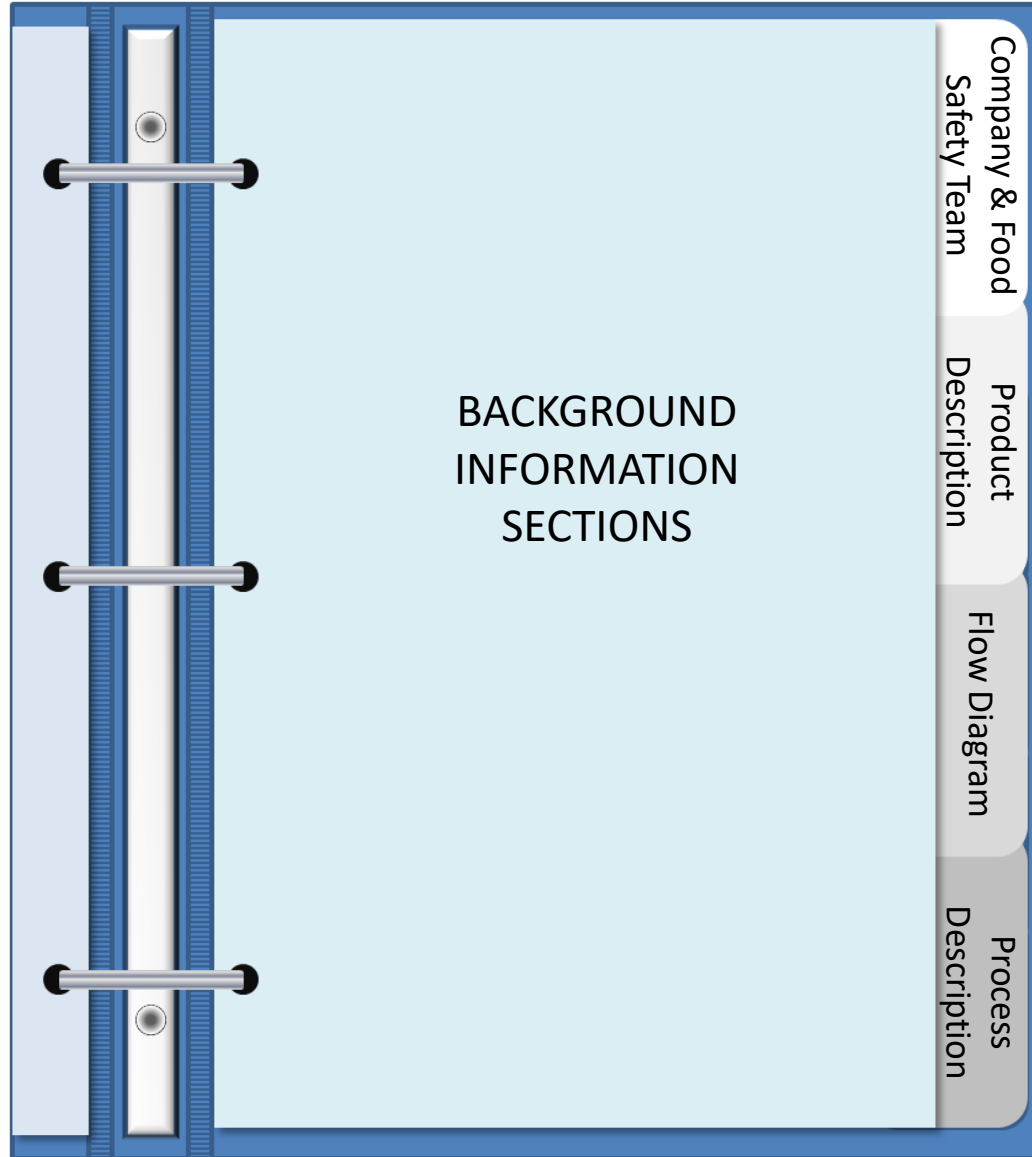


Main Organizational Sections



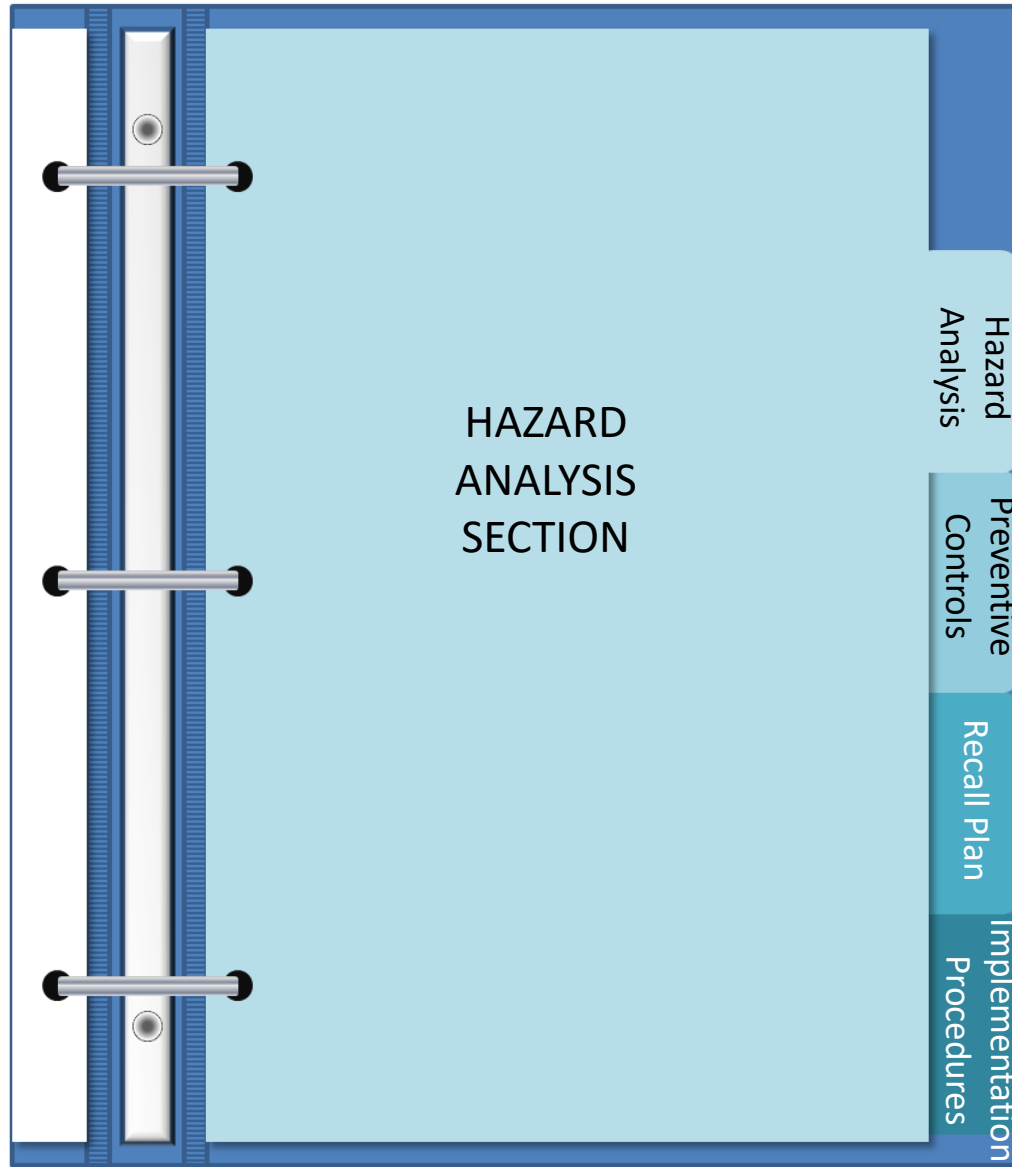
1. Background information - optional
2. Hazard analysis
3. Preventive controls
4. Recall plan
5. Implementation procedures

Background Information



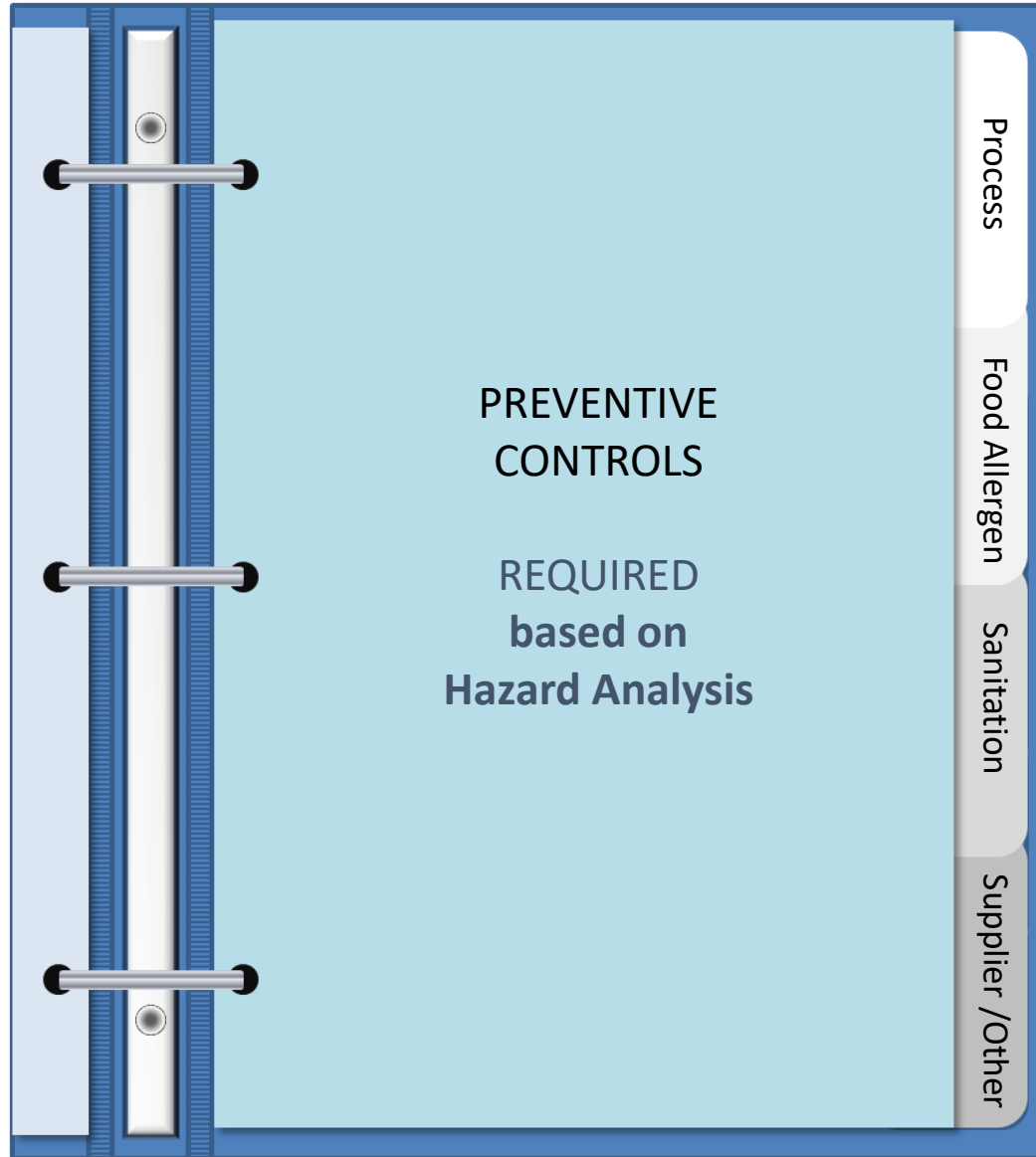
- Useful information to organize the plan:
 - Facility overview and Food Safety Team
 - Product description
 - Flow diagram
 - Process description

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

- Process specific controls discussed in Chapter 9

Food allergen preventive controls

- Accurate labeling
- Cross-contact prevention

Sanitation preventive controls

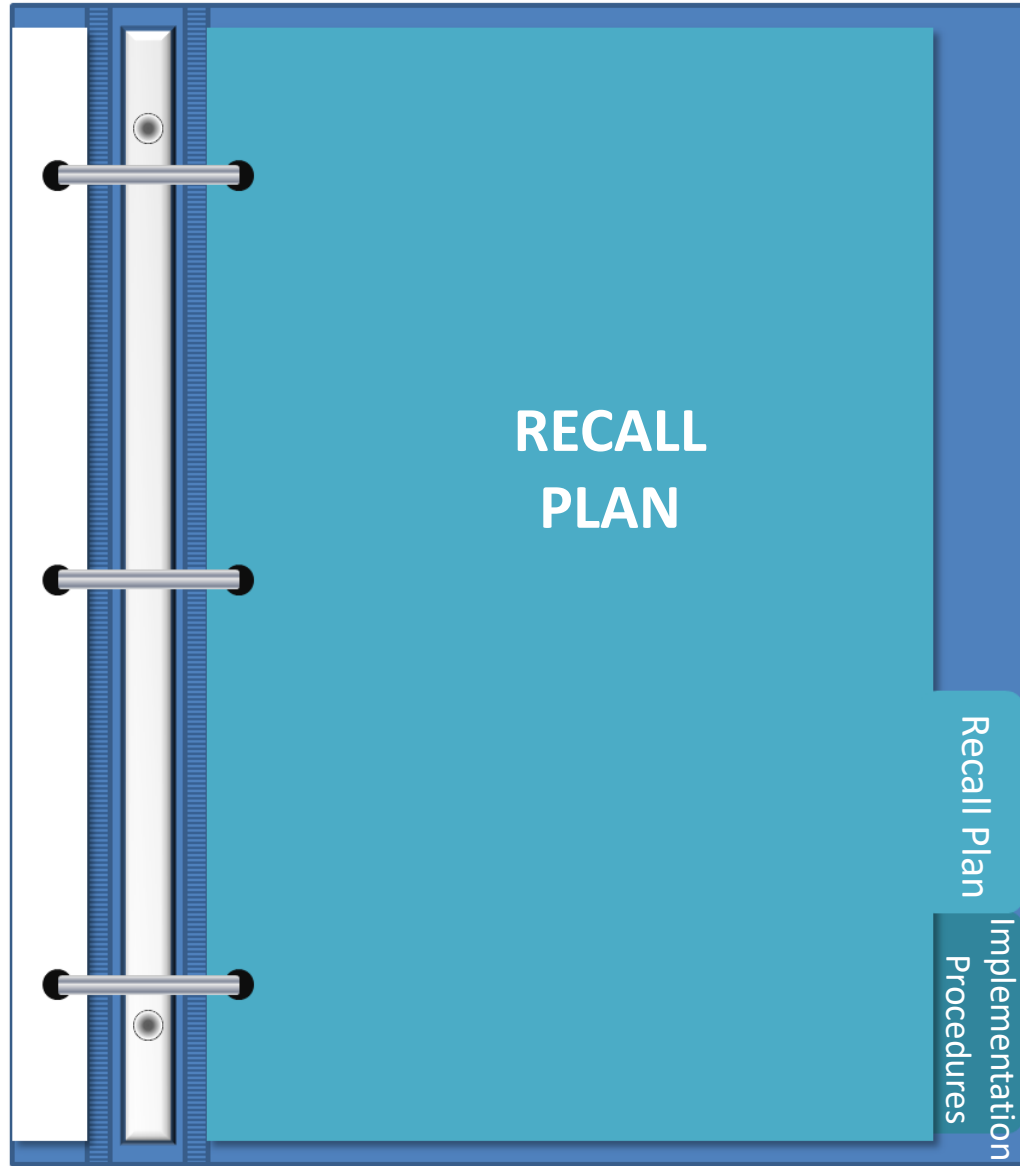
- Environmental pathogens
- Cross-contamination, cross-contact

Other preventive controls

- If needed

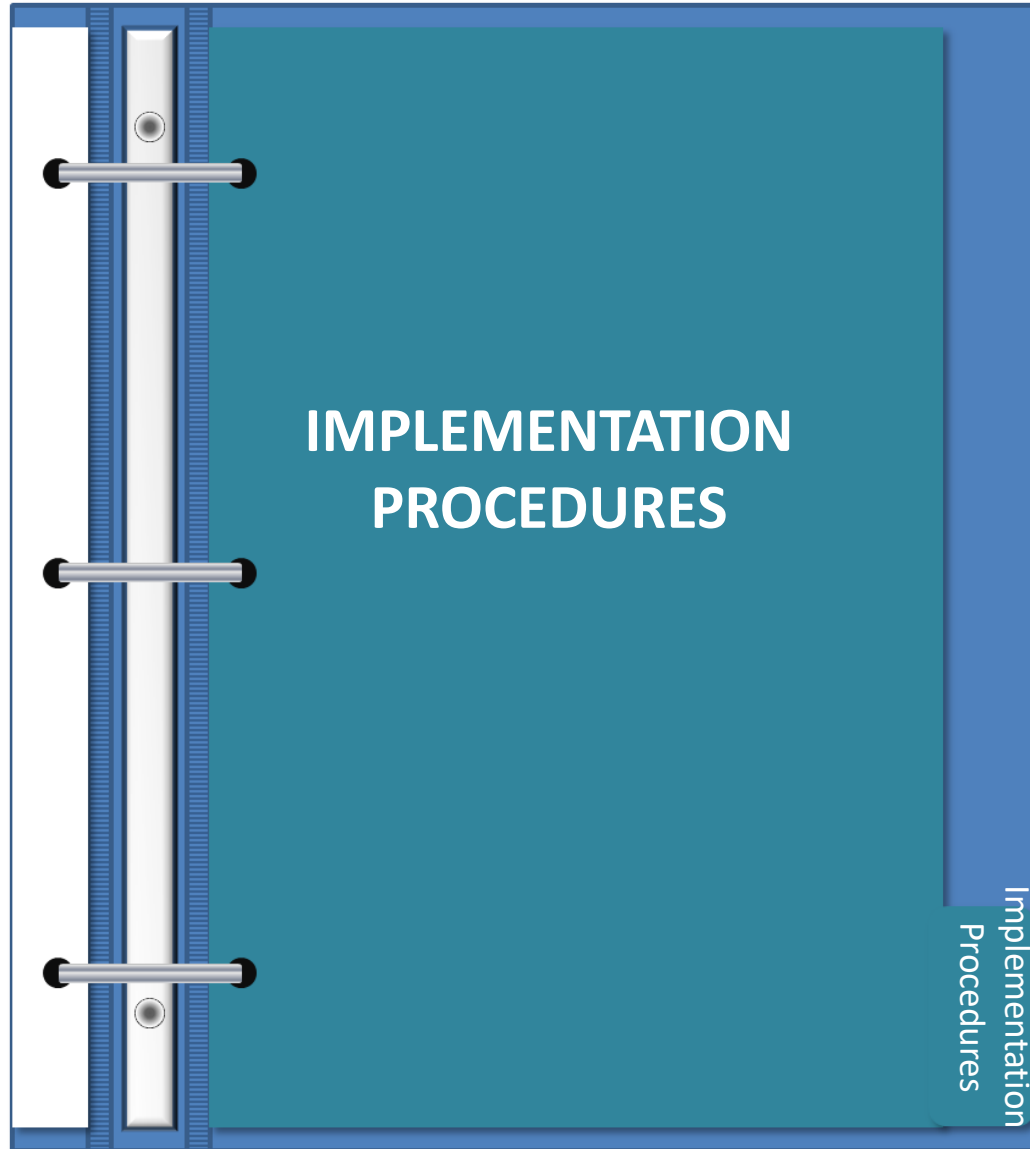
Supply-chain preventive controls

Recall Plan



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

Implementation Procedures

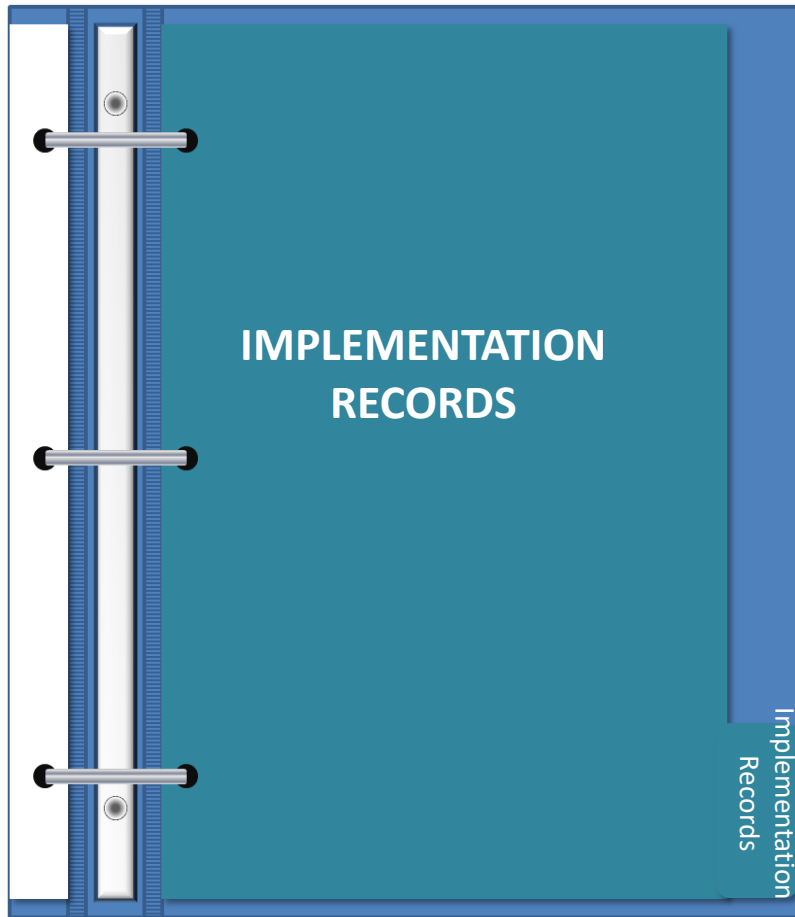


Examples that may be required include:

- Validation studies
- Procedures for monitoring, verification and corrective action

What Records Are Required?


Implementation Records



- Preventive control monitoring data
- Corrective actions taken
- Verification (if applicable) activities
- Validation documentation (if applicable)
- Supply-chain program implementation
- Applicable training
- Retained at least 2 years.
- Reevaluate the whole food safety at least every 3 years.



Exemption Attestation

A photograph of the interior of a stone dome, likely a well or a small tower. The dome is constructed from large, rectangular stone blocks arranged in concentric rings. A central opening at the top of the dome allows bright light to stream in, creating a strong contrast with the dark interior. The text "Exemption Attestation" is overlaid in white, sans-serif font across the upper portion of the dome.

IV. WHO IS EXEMPT FROM THE REQUIREMENTS FOR HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS OR SUBJECT TO MODIFIED REQUIREMENTS?

Table 2--Exemptions and Modified Requirements for Part 117

Exemption or Modified Requirement	Conditions
<p><i>Qualified Facilities</i> – businesses (when including the sales by any subsidiaries, affiliates, and any entity of which the facility is a subsidiary or affiliate) with average annual sales of less than \$500,000 with at least half the sales to consumers or to local retailers or restaurants or Indian reservation (within the same state or within 275 miles) or very small businesses as defined below.</p> <p><i>Very small businesses</i> (including any subsidiaries or affiliates) averaging less than \$1,000,000 (adjusted for inflation) -- in both sales of human food <i>plus</i> the market value of human food that is manufactured, processed, packed, or held without sale (e.g. held for a fee), per year during the 3-year period preceding the current calendar year.</p> <p>(21 CFR 117.5(a))</p>	<p>To be eligible for modified requirements, a qualified facility is required to notify FDA about its status; and attest that it is either:</p> <ol style="list-style-type: none">1. Addressing identified hazards through preventive controls and monitoring the preventive controls; or2. Complying with applicable <i>non-Federal</i> food safety regulations, and notifying consumers of the name and complete business address of the facility where the food was manufactured or processed. <p>A qualified facility must submit these notifications to FDA during the same two year timeframe that the facility is required to update its facility registration.</p> <p>An otherwise Qualified Facility that does NOT notify FDA is subject to the requirements for Hazard Analysis and Preventive Controls.</p>

21 CFR Part 117.5 (a) Except as provided by subpart E of this part, subparts C and G of this part do not apply to a qualified facility. Qualified facilities are subject to the modified requirements.

- **Subpart A: General Provision**
- **Subpart B: Current Good Manufacturing Practices**
- **Subpart C: Hazard Analysis and Risk-Based Controls**
- **Subpart D: Modified Requirements**
- **Subpart E: Withdrawal of Qualified Facility Exemption**
- **Subpart F: Requirements Applying to Records that must be Established and Maintained**
- **Subpart G: Supply Chain Program**

3. When must I submit my first attestation to FDA to comply with the Preventive Controls for Human Food Rule?

You must submit your first attestation to FDA:

- By December 17, 2018, if your facility begins manufacturing, processing, packing, or holding food before September 17, 2018; or
- Before beginning operations, if your facility begins manufacturing, processing, packing, or holding food after September 17, 2018.

(21 CFR 117.201(c)(2)(i)).

Google “Qualified Facility Attestation”

Instructions and Guidance

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/ucm496263.htm>

Form

<https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM620461.pdf>



Many Retailers Will Be Looking Anyway

Food Safety Plan Common Challenges

- **Think through your Process Flow: Processing steps vs process description.**
- **Don't over think your hazards.**
- **Remember it is a dialog, if you feel strongly justify your case in writing and talk with your inspector.**
- **I am a small cheese maker how to deal with my suppliers?**
 - **Ingredients – Do you do diligence buy from reputable companies or develop your own kill step**
 - **Cleaning Chemicals – Look for another supplier**
- **Environmental Monitoring**
 - **Start small, start from the outside in.**
- **Paperwork – K-I-S**

The FDA Top Five -2018

1. Hazard Analysis - either not done, or not done completely or satisfactorily
2. Sanitation Controls not in place
3. Sanitation Verification of control not being completed/documentated
4. Allergen controls not in place
5. Equipment design not sanitary



The FDA Top 6 - 2019



1. 21.CFR.117.130(a)(1) Hazard Analysis: Identification of Hazard
2. 21.CFR.117.126(a)(1) Food Safety Plan
3. 21.CFR.117.165(b) Sanitation Controls Verification Procedures: Establish & Implement
4. 21.CFR.117.145(a) Process Controls: Monitoring Procedures: Establish & Implement
5. 21.CFR.117.145(a) Sanitation Controls Verification Procedures: Establish & Implement
6. 21.CFR.117.135(a)(1) Preventive Controls: Identify

Proposed Food Traceability List

Foods	Description
Cheeses, other than hard cheeses	Includes all cheeses made with either pasteurized or unpasteurized milk, other than hard cheeses. Includes soft ripened/semi-soft cheeses (e.g., brie, camembert, feta, mozzarella, taleggio, blue, brick, fontina, monterey jack, and muenster) and soft unripened/fresh soft cheeses (e.g., cottage, chevre/goat, cream, mascarpone, ricotta, queso blanco, queso fresco, queso de crema, and queso de puna).
Shell eggs	Shell egg means the egg of the domesticated chicken
Nut butter	Includes all types of tree nut and peanut butters; does not include soy or seed butters
Cucumbers (fresh)	Includes all varieties of cucumbers
Herbs (fresh)	Includes all types of herbs, such as parsley, cilantro, basil, etc.
Leafy greens	Includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and R watercress. chard. aruoula. spinach. nak choi. sorrel. endive. etc.



FSMA Proposed Rule for Food Traceability

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The FDA is proposing to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List. The proposed rule, “Requirements for Additional Traceability Records for Certain Foods” (Food Traceability Proposed Rule) is a key component of the FDA’s New Era of Smarter Food Safety Blueprint and would implement Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The proposed requirements would help the FDA rapidly and effectively identify recipients of those foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death. The comment periods for the proposed rule and information collection provisions have been extended and will now be available for public comment until February 22, 2021.

- [Federal Register Notice](#)
- [Docket No. FDA-2014-N-0053](#)
- [Public Meetings page](#)

Content c
01/12/202

Regulated
Food & Bev

Practical Tools???



Resources

The Safe
Cheesemaking
Hub

www.safecheesemaking.com

Develop Your Foundational Food Safety



This online course was developed to assist artisan and farmstead cheese-makers in developing their food safety programs and complying with food safety regulations and standards. It was developed by a collaborative group of food safety and cheese experts from the University of Wisconsin-Madison, University of Connecticut, Cornell University, and NC State University. This course is intended to equip artisan and farmstead cheese-makers with basic knowledge about food safety concepts and serve as a primer for further training programs such as how to develop and implement a preventive controls food safety management plan. The course begins with a welcome letter and orientation to online learning. There is a series of five lessons, each of which consists of an interactive learning module with professional voiceover, video, and an accompanying quiz:

- Lesson 1: Importance of Food Safety
- Lesson 2: Regulations and Standards
- Lesson 3: Food Safety Hazards
- Lesson 4: Good Manufacturing Practices and Process Controls
- Lesson 5: Environmental Pathogen Monitoring and Testing

<https://units.cals.ncsu.edu/foodsafety/courses/>

The cost of developing this course was funded by the [Innovation Center for U.S. Dairy](#).

Dairy Science and Sanitation



The Dairy Science and Sanitation Workshop is tailored to dairy processing personnel and is designed to help participants understand the basic principles of dairy science and food safety.

The course also emphasizes dairy processing establishment needs related to dairy sanitation to ensure that proper programs are conducted in their facilities.

The course is delivered online and self-paced and is available in both English and Spanish (language delivery preference available on the registration form.)

<https://cals.cornell.edu/dairy-extension/>



Learn the GMP Regulations Part 117

This Good Manufacturing Practices (GMPs) Internet Course is designed to review the requirements of *Part 117 Subpart B* – Current Good Manufacturing Practice in Title 21 of the U.S. Code of Federal Regulations Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. As part of the FDA's Food Safety Modernization Act (FSMA), several revisions were made to the current GMPs regulation to update and clarify it. The regulation outlines the basic sanitary controls that are required for all food processing plants, wholesale or distribution firms, and warehouses or food storage facilities that handle, store or process FDA regulated food. This course provides the text of each section of this regulation (21 CFR Part 117 Subpart B) along with an explanation of its intent, examples and strategies for compliance with these new requirements as well as resources for additional information.

The course consists of 12 different Modules

- Module 1: GMP Regulation & Training
- Module 2: Food Safety: Microbes & Allergens
- Module 3: Personnel: Health & Hygiene
- Module 4: Plant Grounds & Pest Control
- Module 5: Plant Construction & Design
- Module 6: Sanitary Facilities: Water, Plumbing & Toilets
- Module 7: Sanitary Operations: Cleaning & Sanitizing
- Module 8: Equipment & Utensils
- Module 9: Plant Operations & Raw Materials
- Module 10: Manufacturing Operations: Process Controls
- Module 11: Warehousing, Food Disposition & Defects
- Module 12: Building Sanitation Procedures

Each module concludes with a quiz to test your knowledge. Completing each quiz is required to receive the Certificate of Course Completion, as described below.

<https://instituteforfoodsafety.cornell.edu/>

Multi-Modal Food Safety Plan Education



Self-paced online
modules on Food Safety
Plan Components



Live, virtual office hours
with food safety experts



In-Person Conference
Workshops



Food Safety Plan Overview Summary

- A written Food Safety Plan, specific to the facility, is required to include a hazard analysis
- When hazards requiring a preventive control are identified, the following are required, as appropriate:
 - Preventive controls
 - Process, food allergen, sanitation, supply-chain and others determined through the hazard analysis process
 - A recall plan
 - Implementation procedures
 - E.g., validation studies and monitoring, corrective actions and verification procedures
- The format is flexible