Preventive Controls for Human Food



Participant Manual

Second Edition – October 2024

(Version 2.0)

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA Participant Manual

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

TRAINING CURRICULUM

Second Edition – October 2024

Version 2.0

U.S. Food and Drug Administration Recognition

This course developed by the Food Safety Preventive Controls Alliance (FSPCA) is the "standardized curriculum" recognized by the U.S. Food and Drug Administration (FDA); successfully completing this course is one way to meet the requirements for a "preventive controls qualified individual." Note: Under the Preventive Controls for Human Food rule, the responsibilities of a "preventive controls qualified individual" are to oversee or perform 1) preparation of the Food Safety Plan, 2) validation of the preventive controls, 3) records review, 4) reanalysis of the Food Safety Plan.

Developed by

FSPCA®
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

Version 2.0 addresses new regulatory guidance, reflects updated information and references, and adds additional application examples to support small- to mid-sized processors. Sections have also been reorganized to support the development of key concepts emphasizing the 7 principles of HACCP consistent with Codex Alimentarius General Principles of Food Hygiene, CXC 1-1969 (2023).

FDA

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH ILLINOIS TECH
Innovation Through Collaboration

FSPCA® FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FSPCA Participant Manual

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

TRAINING CURRICULUM

Second Edition – October 2024

Version 2.0

Disclaimer

The information provided by the Food Safety Preventive Controls Alliance (FSPCA) is for training purposes only. The FSPCA is not your attorney and cannot provide you with legal advice. The FSPCA curriculum is intended as a training tool to assist companies in complying with the FDA Food Safety Modernization Act (FSMA) preventive controls regulation; however, following this curriculum does not ensure compliance with the law or FDA's regulations. For advice regarding the legal compliance with FSMA, please consult your legal counsel.

The information provided by the FSPCA will vary in applicability to each food manufacturer. It is not possible for the FSPCA training curriculum to address every situation. Companies should implement the practices and programs that will function best to produce safe foods based on the nature of their individual operations. FSPCA materials do not outline the only approach to developing and implementing a Food Safety Plan. Companies can follow any approach that satisfies the requirements of the applicable statutes and regulations related to FSMA. The information provided by FSPCA does not create binding obligations for the Food and Drug Administration or industry.

FSPCA does not guarantee the accuracy, adequacy, completeness, or availability of any information provided in its curriculum and is not responsible for any errors or omissions or for any results obtained from the use of such information. FSPCA gives no express or implied warranties, including but not limited to, any warranties of merchantability or fitness for a particular purpose or use. In no event shall FSPCA be liable for any indirect, special, or consequential damages in connection with any use of this training curriculum.

FSPCA®

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE (FSPCA)

2024 FSPCA Executive Advisory Board (EAB)

Martin Bucknavage, Pennsylvania State University, University Park, PA

Claudia Coles, Seafood Products Association, Seattle, WA

David A. Fairfield, National Grain and Feed Association (NGFA), Waukee, IA

Kathy Gombas (Chair), FSMA Solutions, Pebble Beach, CA

Chris Lincecum, Cooperative Farmers Elevator (CFE), Rock Rapids, IA

Modestar Liyokho, Kerry Inc., Zionsville, IN

Tania Martinez, Demos Global Group, Inc., Miami, FL

Amy Philpott, Philpott PR Solutions, LLC, Washington, DC

Juan L. Silva, Mississippi State University, Mississippi State, MS

Katherine Simon, Minnesota Department of Agriculture, Saint Paul, MN

Douglas Stearn (FDA Ex Officio Member), U.S. FDA, College Park, MD

Jennifer Thomas (FDA Ex Officio Member), U.S. FDA, College Park, MD

2024 FSPCA Management

Brian Schaneberg, Institute for Food Safety and Health (IFSH), Chicago, IL

Jason Wan, Institute for Food Safety and Health (IFSH), Chicago, IL

Dawn Johnson, Institute for Food Safety and Health, Chicago, IL

Gerald Wojtala, International Food Protection Training Institute (IFPTI), Portage, MI

Steven Mandernach, Association of Food and Drug Officials (AFDO), York, PA

2024 Preventive Controls for Human Food (PCHF) Curriculum Development Team

Martin Bucknavage (Co-Chair), Pennsylvania State University, University Park, PA

Claudia Coles (Co-Editor), Seafood Products Association, Seattle, WA

Kathy Gombas (Lead Editor), FSMA Solutions, Pebble Beach, CA

Connie Halvorsen (Instructional Design), International Food Protection Training Institute, Portage, MI

Lynette Johnston, North Carolina State University, Raleigh, NC

Ruth Petran (Co-Editor), Ruth Petran Consulting, LLC, Saint Paul, MN

Juan L. Silva, Mississippi State University, Mississippi State, MS

Katherine Simon (Co-Chair), Minnesota Department of Agriculture, Saint Paul, MN

Jason Wan (Co-Editor), Institute for Food Safety and Health, Chicago, IL

Edith Wilkins (Co-Editor), Castle Rock, CO

2024 FSPCA Preventive Controls for Human Food (PCHF) Curriculum Review Team (FDA)

Deb DeVlieger, U.S. FDA (retired), Bainbridge Island, WA

Lillian Hsu, U.S. FDA, Silver Spring, MD

Donald Kautter, U.S. FDA, College Park, MD

Matthew Noonan, U.S. FDA, College Park, MD

Jenny Scott, U.S. FDA (retired), Laurel, MD

Brian Yaun, U.S. FDA, Silver Spring, MD

2024 FSPCA Preventive Controls for Human Food (PCHF) Curriculum Review Team

Kimberly L. Anderson, California Department of Public Health, Sacramento, California and (formerly) Iowa State University, Ames, IA

Elise Forward, Forward Food Solutions, River Falls, WI

Richard Kralj, Pennsylvania State University, University Park, PA

Tania Martinez, Demos Global Group, Inc., Miami, FL

Warren Stone, Zone One Consulting, LLC., Napa, CA

Wendy White, Georgia Institute of Technology GaMEP, Atlanta, GA

Hazard Analysis and Preventive Controls for Human Food Training

The Food Safety Preventive Controls Alliance developed this training curriculum in Food Safety Preventive Controls compliant with the FDA's *Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food* regulations. For the most current course information, please consult the FSPCA website (www.fspca.net)

This publication was developed by the Food Safety Preventive Controls Alliance (FSPCA) and was supported, in part, by a grant from the U.S. Food and Drug Administration (FDA) to the Illinois Institute of Technology's Institute for Food Safety and Health (IFSH). The views expressed herein do not necessarily reflect the views of these organizations.

Direct all inquiries to the FSPCA at fspca@iit.edu

TABLE OF CONTENTS

Course Description

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food regulation (referred to as the Preventive Controls for Human Food regulation) is intended to ensure safe manufacturing/processing, packing, and holding of food products for human consumption in the United States. The regulation requires that certain activities must be completed by a "Preventive Controls 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 be otherwise qualified through job experience to develop and apply a food safety system" (see Chapter 16: Regulation Overview, and Appendix 1). This course developed by the FSPCA is the "standardized curriculum" recognized by FDA; successfully completing this course is one way to meet the requirements for a "Preventive Controls Qualified Individual."

Target Audience

The target audience for the Preventive Controls for Human Food curriculum are companies, especially small and medium-sized, that produce human food and must comply with the Preventive Controls for Human Food regulation under the Food Safety Modernization Act (FSMA). Individuals in academia or government may also find this course useful.

Course Overview

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food participant course is a standardized, industry-oriented training that provides participants with the knowledge that is needed to create a Food Safety Plan to comply with the Preventive Controls for Human Food regulation. The participant course content is focused on the food safety activities and documentation that support the creation and implementation of a preventive controls Food Safety Plan.

The FSPCA training materials include the training manual including slides, explanations of key terms and concepts, exercises using Food Safety Plan Teaching Examples, exercise workbook, and reference material. The training materials are designed to meet the requirements for training under Title 21 Code of Federal Regulations (CFR) 117.180(c)(1) for the Preventive Controls Qualified Individual who conducts certain Food Safety Plan activities.

Purpose

Explore the regulatory requirements of the U.S. Food and Drug Administration's (FDA) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation.

Course Goal

Develop a Food Safety Plan and implement preventive controls to mitigate and control specific hazards.

Course Objectives

1. Describe the oversight of the preparation of Food Safety Plans.
2. Review the verification of preventive controls.
3. Review relevant records.
4. Analyze existing Food Safety Plans.
5. Recognize resources within the curriculum for development of a Food Safety Plan.

Chapter Learning Objectives

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
Chapter 0: Preface: Overview of the FSPCA Preventive Controls for Human Food Participant Course	
Upon completion of this chapter, participants will be able to describe FSPCA and FSPCA Preventive Controls for Human Food curriculum.	Upon completion of this chapter, participants will specifically be able to: 1. Describe FSPCA. 2. Describe FSPCA Preventive Controls for Human Food Curriculum. 3. Describe the course materials and format.
Chapter 1: Food Safety Plan Overview for Preventive Controls for Human Food	
Upon completion of this chapter, participants will be able to describe a Food Safety Plan and explain Preventive Controls.	Upon completion of this chapter, participants will specifically be able to: 1. Describe the concept of preventive controls. 2. Explain the difference between Hazard Analysis and Critical Control Points (HACCP) and preventive controls. 3. Explain the benefits of developing and implementing a Food Safety Plan. 4. Describe the elements, both required and recommended, in building a Food Safety Plan. 5. Identify the responsibilities of a Preventive Controls Qualified Individual (PCQI).
Chapter 2: Current Good Manufacturing Practice and Other Prerequisite Programs for Human Food	
Upon completion of this chapter, participants will be able to recognize the importance of prerequisite programs and GMPs as part of a	Upon completion of this chapter participants will specifically be able to: 1. Define prerequisite programs. 2. Recognize the importance of prerequisite programs in a food safety system.

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
company's food safety system and how these programs interact with the Food Safety Plan.	3. Identify basic requirements of Good Manufacturing Practice (GMP) for human food. 4. Explain how prerequisite programs (including GMP) are foundational to a Food Safety Plan. 5. Explain how prerequisite programs (including GMP) can mitigate hazards.
Chapter 3: Biological Food Safety Hazards for Human Food	
Upon completion of this chapter, participants will be able to identify biological hazards for human food and ways to control these hazards.	Upon completion of this chapter participants will specifically be able to: 1. Define the term "hazard." 2. Recognize the significant impact of biological hazards. 3. Recognize potential biological hazards, their sources, and contributing factors. 4. Identify potential controls for these hazards.
Chapter 4: Chemical, Physical, and Economically Motivated Food Safety Hazards for Human Food	
Upon completion of this chapter, participants will be able to identify chemical, physical, and economically motivated food safety hazards, and potential controls for these hazards.	Upon completion of this chapter participants will specifically be able to: 1. Identify chemical (including radiological) food safety hazards. 2. Identify physical food safety hazards. 3. Identify economically motivated food safety hazards. 4. Recognize potential chemical and physical hazards, their sources, and contributing factors. 5. Identify potential controls for chemical, physical, and economically motivated food safety hazards.
Chapter 5: Preliminary Steps in Developing a Food Safety Plan for Human Food	
Upon completion of this chapter, participants will be able to perform the preliminary steps important for developing a Food Safety Plan.	Upon completion of this chapter participants will specifically be able to: 1. Assemble the Food Safety Team. 2. Describe the product and its distribution. 3. Describe the intended use and consumers of the food. 4. Develop a flow diagram and description of the process. 5. Verify the flow diagram.

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
Chapter 6: Hazard Analysis for Human Food	
Upon completion of this chapter, participants will be able to perform a hazard analysis for human food.	Upon completion of this chapter participants will specifically be able to: 1. Define the different types of food hazards. 2. Explain why a hazard analysis is important. 3. Explain the two-step process to conduct a hazard analysis: a. Identify all potential hazards for ingredients and manufacturing steps, and b. Evaluate and determine which potential hazards will require a preventive control based on severity and likelihood of occurrence. 4. Identify hazard analysis resources: a. Use the FDA Hazard Guide in conducting ingredient hazard identification. 5. Describe E.G. Food Company's hazard analysis.
Chapter 7: Preventive Controls Determination for Human Food	
Upon completion of this chapter, participants will be able to define preventive controls and explain the requirements and exceptions.	Upon completion of this chapter participants will specifically be able to: 1. Define preventive controls. 2. Explain preventive controls requirements and exceptions. 3. Describe examples of preventive controls. 4. Explain preventive controls considerations. 5. Describe E.G. Food Company's preventive controls. 6. Describe preventive controls management components.
Chapter 8: Process Preventive Controls for Human Food – Parameters and Values, including Critical Limits	
Upon completion of this chapter, participants will be able to identify the principles for process preventive controls specific to establishing parameters and values.	Upon completion of this chapter participants will specifically be able to: 1. Define process preventive controls. 2. Establish parameters and values for process preventive controls (e.g., critical limits). 3. Describe use of operating limits.

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
Chapter 9: Process Preventive Controls for Human Food – Monitoring and Corrective Action	
Upon completion of this chapter, participants will be able to identify key principles for process preventive controls with a focus on monitoring procedures and corrective actions.	Upon completion of this chapter participants will specifically be able to: 1. Identify monitoring procedures for process preventive controls, including Critical Control Points (CCPs). 2. Identify corrective actions for process control deviations.
Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping	
Upon completion of this chapter, participants will be able to identify the principles for process preventive controls with a focus on verification procedures, the importance of validation, and recordkeeping requirements.	Upon completion of this chapter participants will specifically be able to: 1. Define validation and verification. 2. Identify verification procedure requirements for: a. calibration, b. product sampling and testing, and c. record review. 3. Describe general information on required records. 4. Explain how to conduct a record review. 5. Explain requirements for record retention.
Chapter 11: Food Allergen Preventive Controls for Human Food	
Upon completion of this chapter, participants will be able to identify allergen preventive controls when the hazard analysis requires them.	Upon completion of this chapter participants will specifically be able to: 1. Recognize that the hazard analysis may identify hazards that require allergen preventive controls. 2. Recognize the role of Good Manufacturing Practice (GMP) and preventive controls in the management of allergens. 3. Explain required food allergen preventive controls: a. allergen cross-contact prevention, and b. allergen labeling. 4. Explain allergen preventive control options.
Chapter 12: Sanitation Preventive Controls for Human Food	
Upon completion of this chapter, participants will	Upon completion of this chapter participants will specifically be able to:

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
be able to identify sanitation preventive controls when the hazard analysis requires them.	1. Recognize that the hazard analysis may identify hazards that require sanitation preventive controls. 2. Recognize the role of Good Manufacturing Practice (GMP) and preventive controls in the management of environmental hazards. 3. Explain required sanitation preventive control elements and options.
Chapter 13: Supply-Chain Preventive Controls for Human Food	
Upon completion of this chapter, participants will be able to identify supply-chain preventive controls and understand how these link to the hazard analysis.	Upon completion of this chapter participants will specifically be able to: 1. Define supplier, receiving facility, and customer. 2. Recognize that the hazard analysis may identify hazards that require a supply-chain preventive control. 3. Explain disclosures and customer written assurances. 4. Explain required supply-chain program elements. 5. Describe supply-chain program records.
Chapter 14: Food Safety Plan Implementation and Management for Human Food	
Upon completion of this chapter, participants will be able to describe the implementation and management of the Food Safety Plan and the PCQI's role in the management of the Food Safety Plan.	Upon completion of this chapter participants will specifically be able to: 1. Describe how the Food Safety Plan implementation relates to the facility's food safety system. 2. Recognize the importance of training in supporting the implementation of a Food Safety Plan. 3. Explain the regulatory requirements for reanalysis of the Food Safety Plan. 4. Explain the regulatory requirements of the Preventive Controls Qualified Individual as it applies to maintaining the Food Safety Plan.

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
Chapter 15: Recall Plan for Human Food	
Upon completion of this chapter, participants will be able to define what a recall is and describe the requirements of a recall plan.	Upon completion of this chapter participants will specifically be able to: 1. Define recall and recall classifications I, II, and III. 2. Recognize the requirements of a recall plan. 3. Identify resources for developing a recall plan. 4. Describe elements of a written recall plan: a. notification, b. effectiveness checks, and c. disposition of product.
Chapter 16: Regulation Overview – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	
Upon completion of this chapter, participants will be able to discuss the Preventive Controls for Human Food regulation and FDA's regulatory oversight.	Upon completion of this chapter participants will specifically be able to: 1. Describe the major components (including requirements) of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food regulation. 2. Explain how to determine applicability of the requirements based on the food facility type. 3. Identify exemptions and modified requirements applicable to certain facilities.
Appendices: Upon review of the appendices, participants will be able to recognize the resources available in the curriculum to assist in the development of a Food Safety Plan.	Upon review of the appendices, participants will specifically gain knowledge of: 1. Appendix 1: FDA Regulation on cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food 2. Appendix 2: Food Safety Plan Worksheets 3. Appendix 3: Food Safety Plan Teaching Example – Omelet 4. Appendix 4: Foodborne Pathogen Supplementary Information 5. Appendix 5: Sanitation Basics for Human Food o Explain general sanitation basics. o Describe basic cleaning and sanitizing principles.

Terminal Learning Objectives (TLOs)	Enabling Learning Objectives (ELOs)
	6. Appendix 6: Hygienic Zoning and Environmental Monitoring for Human Food o Explain hygienic zoning concepts for managing environmental pathogens. o Describe environmental monitoring principles to verify cleaning and sanitizing preventive controls. 7. Appendix 7: Regulatory Oversight for Preventive Controls for Human Food o Identify which procedures and records you need to have available based on FDA's inspection process. o Describe FDA's regulatory enforcement actions. 8. Appendix 8: Definitions

Course Completion Requirements

To successfully complete this course and receive a course certificate, each participant is required to:

- Be on time and attend the entire course.
- Participate in the class discussions and exercises and respond to knowledge checks.

Participant Expectations

- To successfully complete the course, each participant is expected to attend each session and participate in each group exercise.
- To assess participation, instructors will observe participants as they contribute to group discussions. Participation is evidenced by asking questions, offering opinions, and/or debating opinions and answers, and specific criteria contained in each activity's rubric.
- Proficiency (demonstration of knowledge, skill, or abilities) for each activity will be assessed by the instructors. Constructive feedback will be provided by both the instructors and the other participants.

Preface: Overview of the FSPCA Preventive Controls for Human Food Participant Course

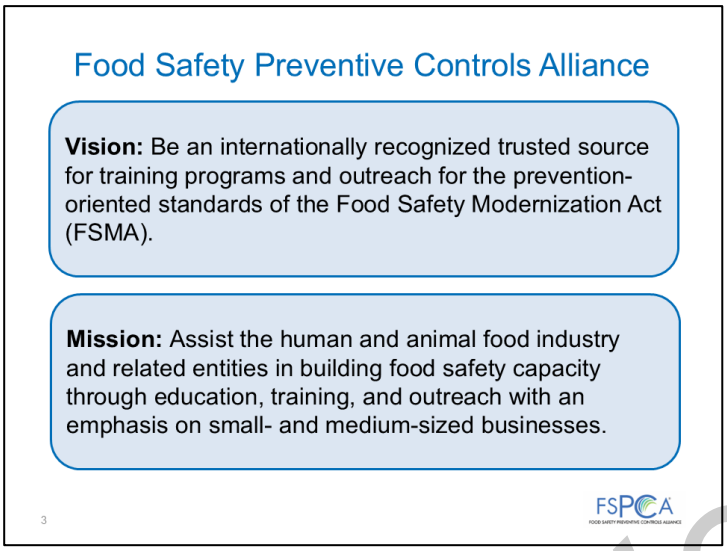
Slide 1: Preface: Overview of the FSPCA Preventive Controls for Human Food Participant Course

Slide 2: Food Safety Preventive Controls Alliance (1 of 2)

The Food Safety Preventive Controls Alliance (FSPCA) program was established in 2011 as part of a federal grant from FDA to the Institute for Food Safety and Health at the Illinois Institute of Technology. The purpose of this broad-based alliance is to develop and maintain a cost-effective education and training program to assist the food industry with understanding the Preventive Controls regulation requirements applicable to their facilities.

FSPCA is a public private alliance with representation from industry, academia, and government, and is based on collaboration among federal and state regulatory officials, academic food safety researchers and educators, and food industry.

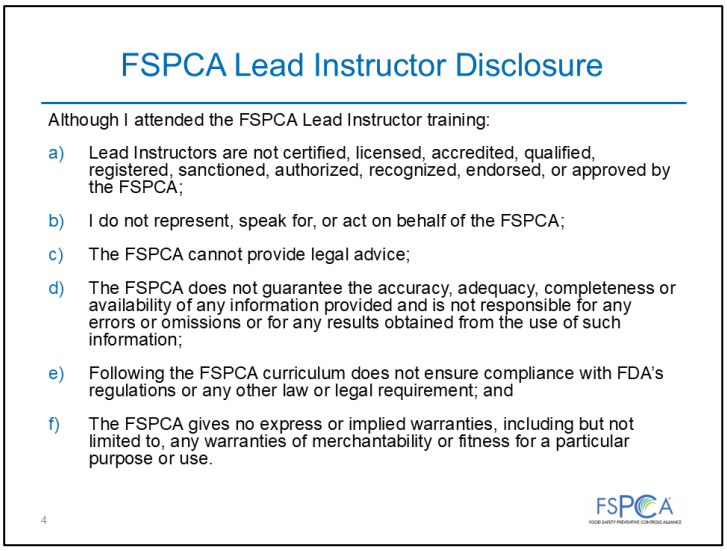
Slide 3: Food Safety Preventive Controls Alliance (2 of 2)



FSPCA's Vision is to be an internationally recognized trusted source for training programs and outreach for the prevention-oriented standards of the Food Safety Modernization Act (FSMA).

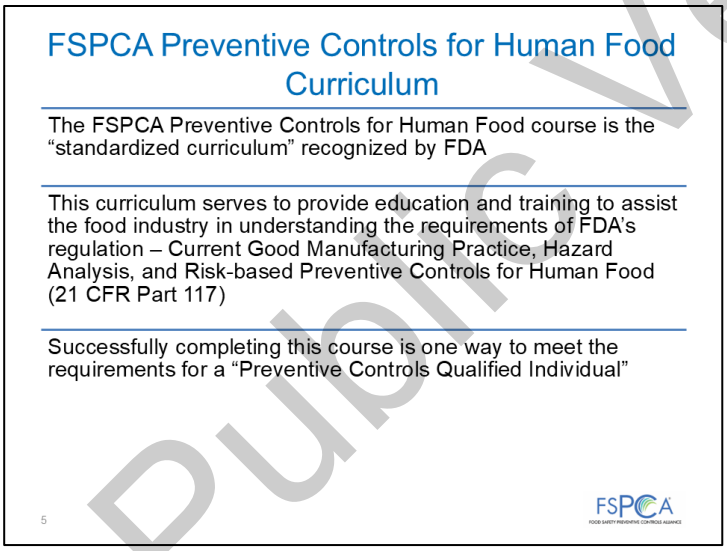
FSPCA's Mission is to assist the human and animal food industry and related entities in building food safety capacity through education, training, and outreach with an emphasis on small- and medium-sized businesses.

Slide 4: FSPCA Lead Instructor Disclosure



This slide covers the FSPCA Lead Instructor disclosure required by FSPCA for educational purposes.

Slide 5: FSPCA Preventive Controls for Human Food Curriculum



This course developed by FSPCA is the "standardized curriculum" recognized by FDA; successfully completing this course is one way to meet the requirements for a "Preventive Controls Qualified Individual."

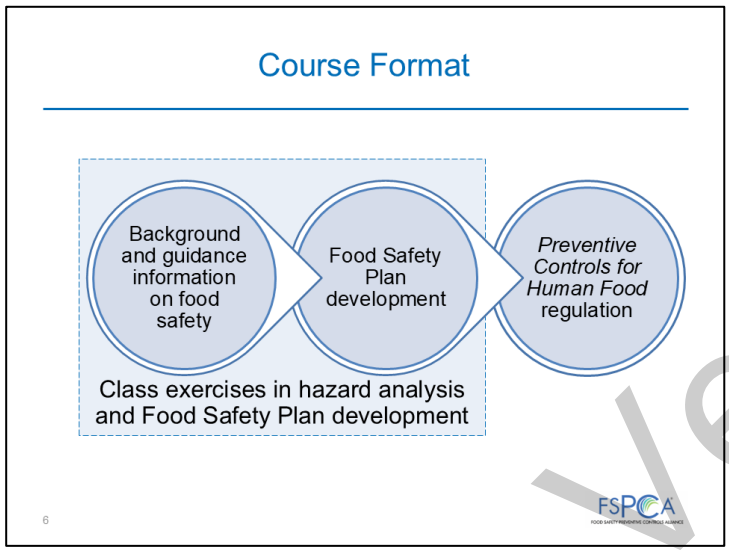
Note that under the Preventive Controls for Human Food regulation, the responsibilities of a "Preventive Controls Qualified Individual" are to oversee or perform: 1) Preparation of the Food Safety Plan; 2) Validation of the preventive controls; 3) Records review; and 4) Reanalysis of the Food Safety Plan. More details on this will be discussed later in the course.

This curriculum will provide the education and training needed to understand the requirements of 21 CFR Part 117, Current Good Manufacturing Practice, Hazard

Analysis, and Risk-Based Preventive Controls for Human Food (also referred to as the Preventive Controls for Human Food regulation).

This chapter reviews the format for the course and provides a brief overview of how preventive controls build on established food safety principles. The chapter then explores the responsibilities of a Preventive Controls Qualified Individual to help that individual understand the tasks that they will be expected to either complete or oversee.

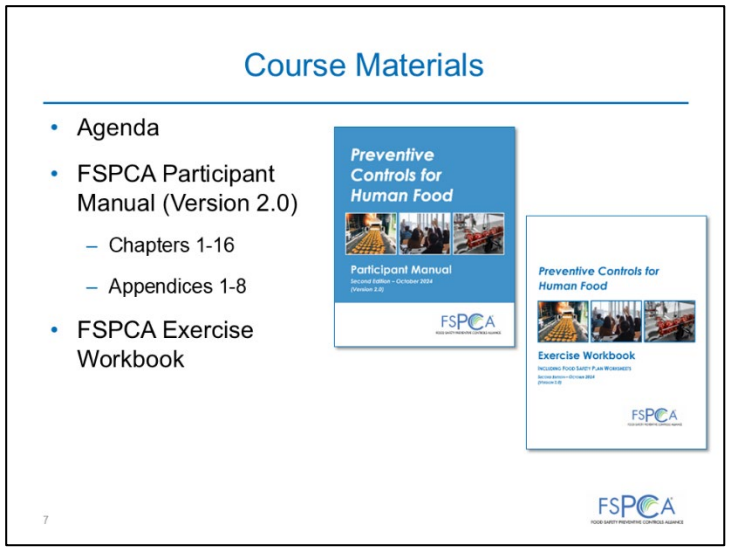
Slide 6: Course Format



The FSPCA Preventive Controls for Human Food Course is divided into three parts:

1. The first part defines the contents of a Food Safety Plan, reviews foundational programs such as Good Manufacturing Practices (GMPs), provides information about specific food hazards and discusses the underlying principles used in food safety preventive controls systems. Learning how to apply these practices and principles will provide a better understanding of how a systematic approach can help to assure the safety of food. As each principle is discussed, course participants will progressively develop a Food Safety Plan for a model food product produced by a fictional company. This background information will help the course participants understand how to put together each section of a Food Safety Plan and how these sections relate to a complete preventive controls program and safe food processing.
2. The second part includes practical exercises that introduce course participants to the process of developing a Food Safety Plan, including identification of tools and implementation tasks. During this part, the course participants will be divided into teams to develop a simplified Food Safety Plan for a selected food product.
3. The third part explains the requirements of the Preventive Controls for Human Food regulation.

Slide 7: Course Materials

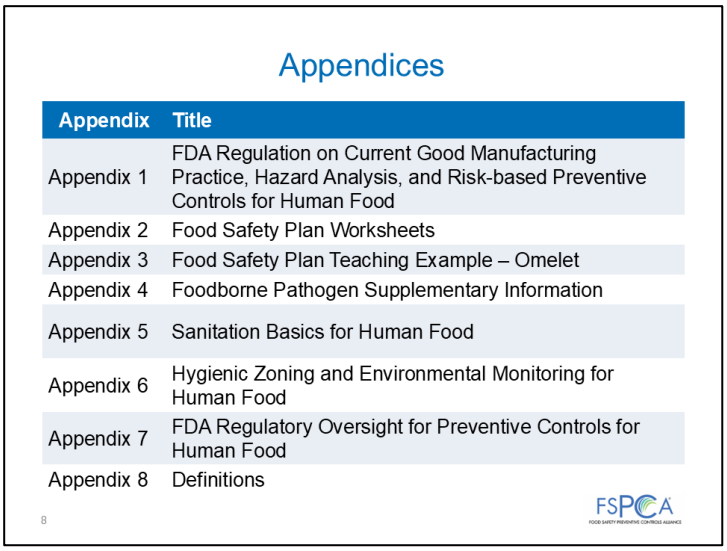


The course participant manual includes sixteen (16) chapters with presentation slides, supporting text, explanations of key terms and concepts, and credible references, and appendices including a model Food Safety *Plan Teaching Example*. *The course materials also include Food Safety Plan Teaching Examples for various products for* completing course exercises and an exercise workbook.

Become familiar with the participant manual and use it as a reference. The participant manual contains forms that can help participants to develop a Food Safety Plan and resources to help participants locate other basic information to include in a Food Safety Plan.

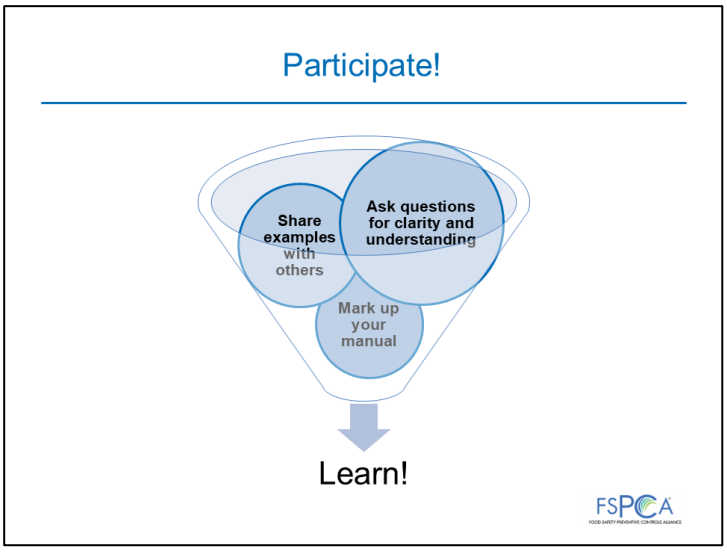
There are many definitions to understand when learning about preventive controls for human food. Definitions of many commonly used terms are listed in Appendix 8 of the Participant Manual. Refer to these pages as needed while participating in the course.

Slide 8: Appendices



There are eight appendices in the participant manual that will be used throughout the course.

Slide 9: Participate!



Prevention-based food safety management can be integrated into any operation; however, the process can seem complicated until the basic concepts are understood. Asking questions and contributing first-hand experiences during course discussions can help everyone better understand and apply the concepts. This course includes class engagement and exercises. The more the course participants contribute to these exercises, the less complicated the system will seem and the easier it will be for them to develop and implement an effective Food Safety Plan.

Slide 10: FSPCA Contact Information

FSPCA Website

The QR Code provided will access the FSPCA Website.

Slide 11: Knowledge Check

***Participants do NOT have this slide*.**

Slide 12: Introductions

Introduce yourself to the group by providing:

1. Name,
2. Employer,
3. Products you make, and
4. What you hope to get out of the course.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

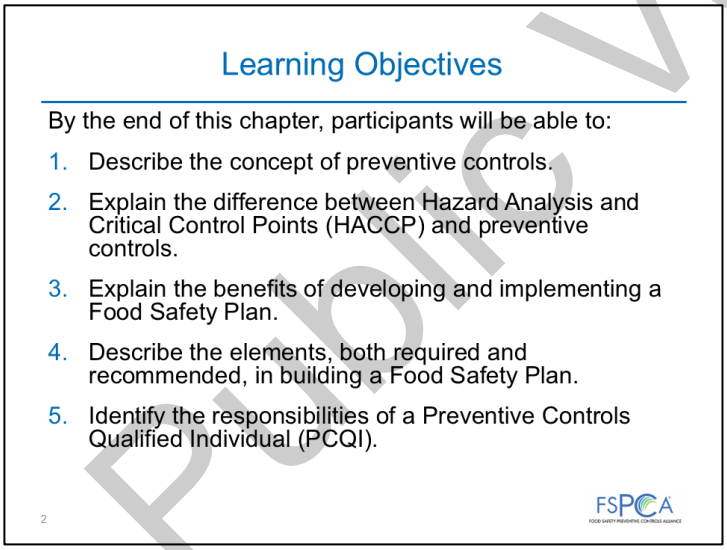
FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

Chapter 1: Food Safety Plan Overview for Preventive Controls for Human Food

Slide 1: Chapter 1: Food Safety Plan Overview for Preventive Controls for Human Food

Slide 2: Learning Objectives

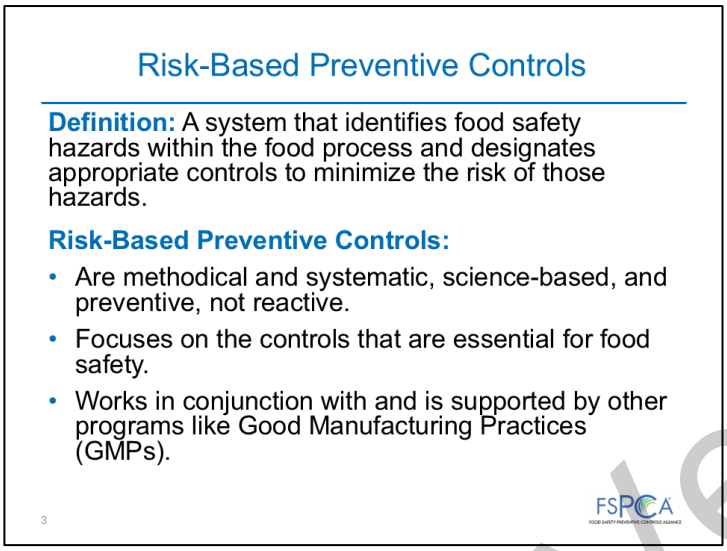


A Food Safety Plan is the primary document which guides the preventive controls food safety system. A Food Safety Plan, as required in the Preventive Controls for Human Food regulation, is developed using a systematic approach to identify and evaluate those hazards that require preventive controls and then to establish preventive controls for those hazards to prevent foodborne illness or injury.

This chapter provides a brief discussion of the systematic approach involved in building a Food Safety Plan which is consistent with the well-established food safety principles of Hazard Analysis and Critical Control Points (HACCP).

This chapter also provides an overview of the components of a Food Safety Plan needed to comply with the Preventive Controls for Human Food regulation, including the responsibilities of a Preventive Controls Qualified Individual. Additionally, this overview will help visualize how to structure a Food Safety Plan specific to the operation. Each component is covered in more detail later in the course.

Slide 3: Risk-Based Preventive Controls

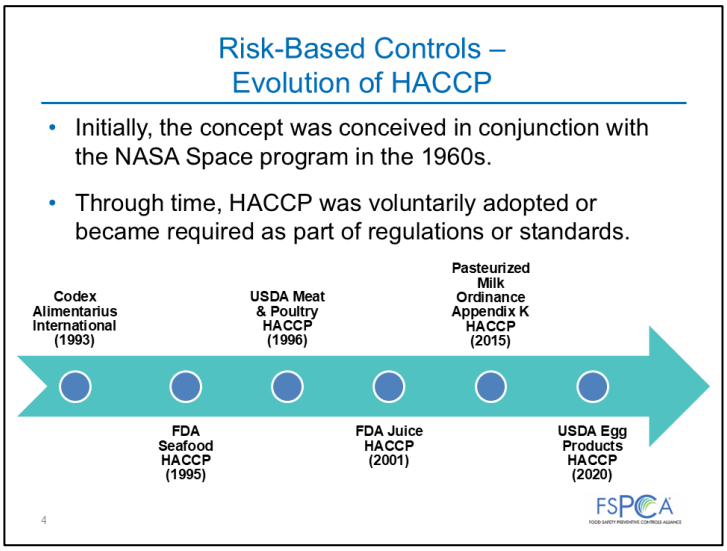


A proactive and systematic science-based approach to food safety emphasizing the preventive controls approach has been universally accepted and adopted throughout the world because it helps to focus attention on the most important areas to prevent food safety issues rather than reacting to problems as they arise. The goal of a Food Safety Plan is to prevent hazards in food. This is accomplished through a risk-based approach. This scientifically based approach is methodical and systematic in that it evaluates the inputs including raw materials and other ingredients and process steps to identify potential hazards, determine the risk of those hazards and establish controls to significantly minimize or eliminate that risk.

Preventive control programs are structured to work in conjunction with and be supported by other relevant programs such as Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs) and sanitary transportation practices as the basis for food safety management.

Successful application of preventive controls approaches—as established within the Preventive Controls for Human Foods regulation—helps minimizes the risk of producing products that can harm consumers.

Slide 4: Risk-Based Controls – Evolution of HACCP

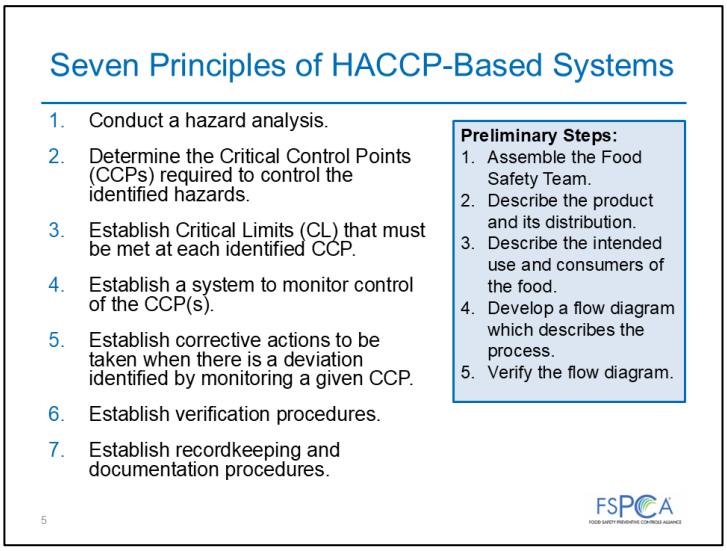


Risk-based approaches to managing food safety were pioneered during development of food for the U.S. space program in the 1960s. At that time, end-product testing was the focus of quality control programs. It became evident that the end-product testing necessary to provide assurance that food was safe would be so extensive that little food would be available for space flights. The focus shifted to preventing hazards through product formulation and process control in a risk-based manner. The concept was called Hazard Analysis and Critical Control Point (HACCP), before HACCP-based systems were mandated by regulation, and HACCP programs evolved over time.

Starting in the 1990s, the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission (Codex) published guidelines for the application of HACCP principles. In the mid-1990s, USDA issued regulations requiring HACCP for the production of meat and poultry and FDA issued requirements for HACCP for the seafood industry. In the early 2000s, FDA issued HACCP regulations for juice products in response to outbreaks of foodborne illness linked to apple juice. In 1999, the National Conference on Interstate Milk Shipments (NCIMS) initiated a voluntary dairy HACCP pilot program for Grade A dairy plants to test the concept that a HACCP program could function as an equal alternative to the long-used numerical ratings to measure a plant's compliance. Details from the Grade A dairy HACCP pilot program was added to the Pasteurized Milk Ordinance in an Appendix in 2015. And in 2020, USDA published regulations for egg products regulated by USDA.

HACCP principles are endorsed by many countries including Australia, Canada, New Zealand, and the European Union countries.

Slide 5: Seven Principles of HACCP-Based Systems



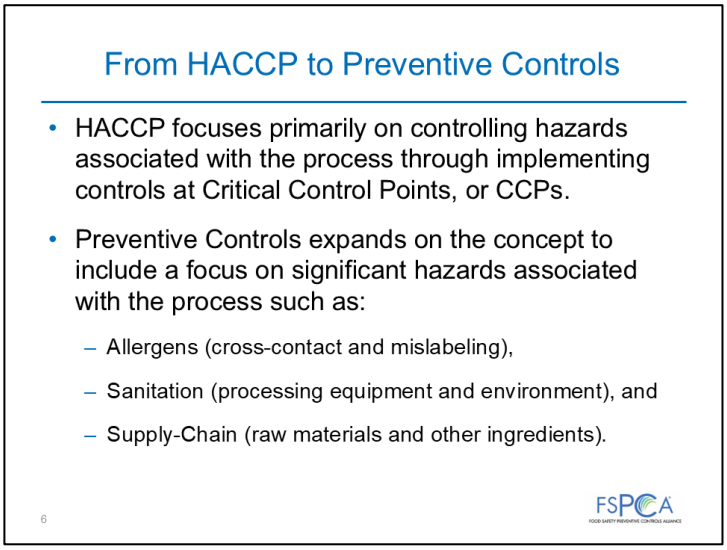
From the early development of HACCP, seven principles, listed above, were used to apply HACCP to food processes. These principles include conducting the hazard analysis, determining the critical control point (CCP), establishing critical limits, establishing monitoring procedures, establishing corrective actions, establishing verification procedures, and establishing recordkeeping and documentation. A quick review of these principles is useful to understand how the Preventive Controls for Human Food regulation builds on the risk-based HACCP approach.

In a HACCP system, a hazard analysis identifies ingredient/raw material-related and process-related hazards that—in the absence of a control—present a food safety risk. For those identified hazards, Critical Control Points (CCPs) are established which are essential to prevent the hazard from causing illness or injury. For each CCP, critical limits are determined to ensure the operating conditions in the process are met so as to effectively control the identified hazard. Monitoring of the CCPs demonstrates that critical limits are met and provides documentation of process compliance. Corrective actions are taken in response to when a critical limit is not met, referred to as a deviation, and enables swift action preventing expansion of a food safety issue. All monitoring and corrective actions are recorded and verified to ensure the system is operating as intended. Records also provide data to others, such as inspectors, auditors, and management staff, to show that the system is operating as intended. More information on each of these principles is discussed in this course, where appropriate, recognizing that a HACCP Plan essentially addresses most of the requirements for process preventive controls.

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) reconvened a HACCP Working Group in 1995. That committee identified the five preliminary tasks that need to be accomplished before application of the seven HACCP principles to a specific product and process. These steps are: 1) Assemble a HACCP Team; 2) Describe the Food and its Distribution; 3) Describe the Intended Use and Consumers of the Food; 4) Develop a Flow Diagram Which Describes the Process; and 5) Verify the Flow Diagram. These preliminary steps and the seven principles

(termed the "12 Steps of HACCP") were employed for development of HACCP Plans to meet the stated food safety goals.

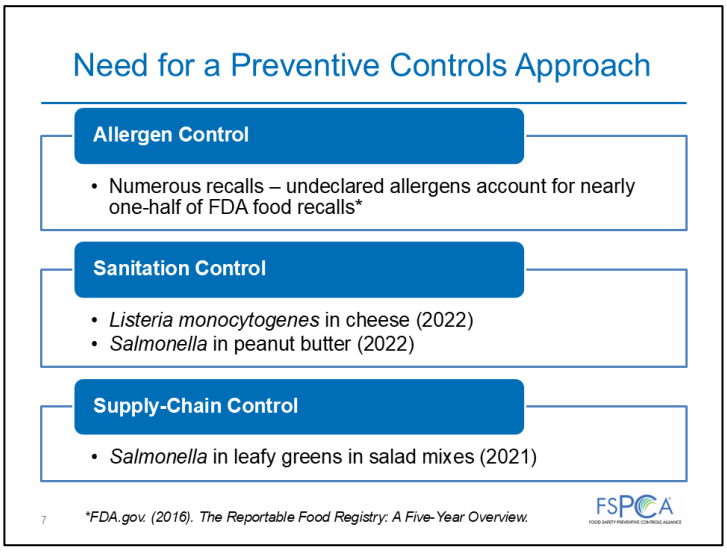
Slide 6: From HACCP to Preventive Controls



HACCP focuses on preventing hazards related to the process by establishing CCPs at relevant points in the process. The Preventive Controls for Human Food regulation takes a broader preventive focus, identifying potential risks and implementing appropriate controls to proactively address food safety hazards associated with allergens and sanitation, as well as those under the control of the ingredient/raw material supplier.

Allergen controls focus on preventing cross-contact (unintended allergen presence) and mislabeling (undeclared allergens). Sanitation controls may be used to clean processing equipment food-contact surfaces to control pathogen cross-contamination and food allergen cross-contact and to clean the facility's processing environment to prevent recontamination from environmental pathogens in ready-to-eat foods exposed to the environment before packaging. Supply-chain controls are aimed at ingredients/raw materials that may pose hazards in a product where the supplier is controlling those hazards.

Slide 7: Need for a Preventive Controls Approach



This slide provides a few examples of outbreaks and recalls that occurred when preventive controls were lacking.

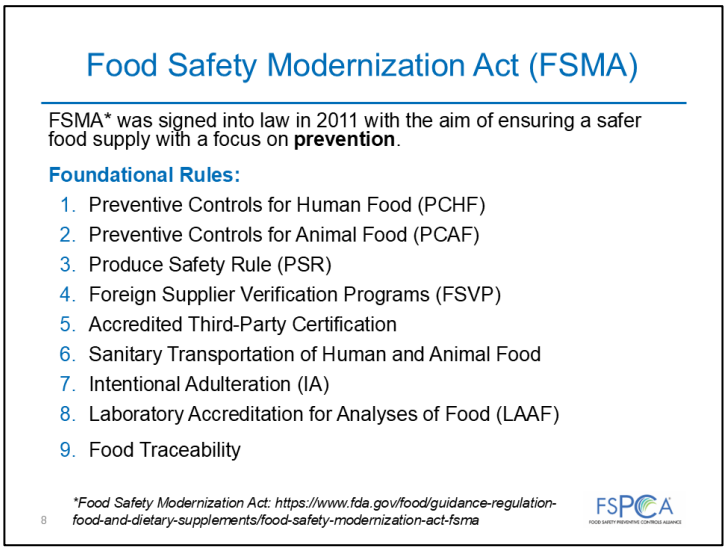
Undeclared allergen reports have steadily increased since the inception of the FDA's Reportable Food Registry (RFR). In the first year, 30% of RFR reports were related to allergens and that has risen to 50% of reports more recently. The bakery commodity group accounted for the most allergen mislabeling reports.

Failures in sanitation have resulted in outbreaks. *Listeria monocytogenes* contamination in brie and camembert cheese was linked to 6 illnesses that resulted in 5 hospitalizations in a multistate outbreak in 2022. Twenty-one (21) illness cases of *Salmonella* Senftenberg (*S.* Senftenberg) were linked to ready-to-eat peanut butter in 2022. In both cases, the outbreak strains were found in the facility through environmental sampling.

Illnesses also have been linked to supplied ingredients. In 2021, thirty-one (31) *Salmonella* illnesses were linked to multiple types of salad products that contained contaminated leafy greens.

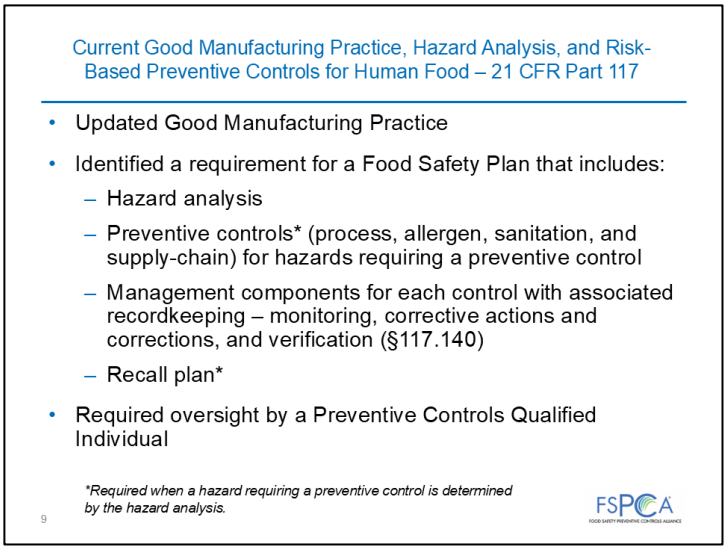
Learning from past outbreaks and recalls can help protect consumers and businesses from similar unfortunate incidents.

Slide 8: Food Safety Modernization Act (FSMA)



The U.S. Congress passed the Food Safety Modernization Act (FSMA), a law that amended the Food, Drug, and Cosmetic (FD&C) Act, which the President signed in 2011. FSMA builds on the food safety foundation of the FD&C Act and places more emphasis on preventing food safety hazards. The FSMA law required FDA to write nine regulations shown above along with numerous guidance documents. The scope of this course is the Preventive Controls for Human Foods regulation. Some of these other regulations may have an impact on a facility's Food Safety Plan, which will be discussed in subsequent chapters.

Slide 9: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food – 21 CFR Part 117

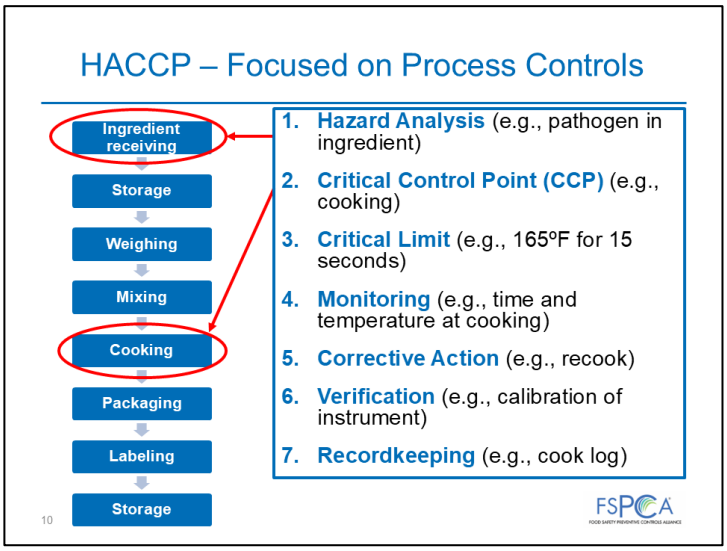


§ = Section: This symbol (§) refers to a specific section within the regulation. For example, on the slide to the left, the symbol is used at the end of the third sub-bullet, and is equivalent to writing out the full reference, "21 CFR 117.140."

On September 17, 2015, the final regulations on Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food were issued by the FDA to meet the FSMA law and are published in 21 CFR Part 117. The regulation focuses on a preventive approach to food safety and establishes new requirements for a Food Safety Plan including hazard analysis and risk-based preventive controls as mandated by FSMA and modernizes longstanding Current Good Manufacturing Practices (CGMPs). These requirements include: a comprehensive hazard analysis; identified preventive controls (e.g., process, allergen, sanitation, and supply-chain), for each hazard requiring a preventive control; management components for each preventive control to include monitoring, corrective actions, verification; a recall plan; and recordkeeping.

These activities and their implementation must be performed or overseen by a Preventive Controls Qualified Individual as required by the regulation.

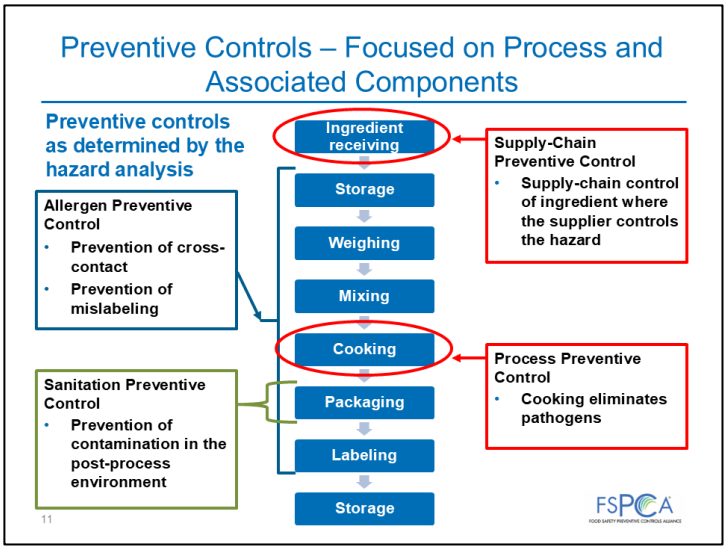
Slide 10: HACCP – Focused on Process Controls



Traditional HACCP focuses on the process control specific to a food type, identifying hazards at each step that need control within the process itself and defining the parameters for their management.

A generic example is shown on the slide associated with a hazard from a possibly pathogen contaminated ingredient that is controlled with a cook CCP. The cooking critical limit is 165°F for 15 seconds. This is monitored by measuring the time and temperature at cooking and a corrective action of recooking is taken if the critical limit is not met. Records of these activities are kept on the cook log. Verification includes calibration of the temperature monitoring instrument.

Slide 11: Preventive Controls – Focused on Process and Associated Components



Under the Preventive Controls for Human Food regulation, hazards are identified through the hazard analysis process, and for those hazards determined to require a preventive control (i.e., are significant), based on severity and likelihood of occurrence, a preventive control is required. As mentioned, the preventive controls include controls beyond the process-related CCPs identified in the HACCP framework, including food allergen controls, sanitation controls, and supply-chain controls.

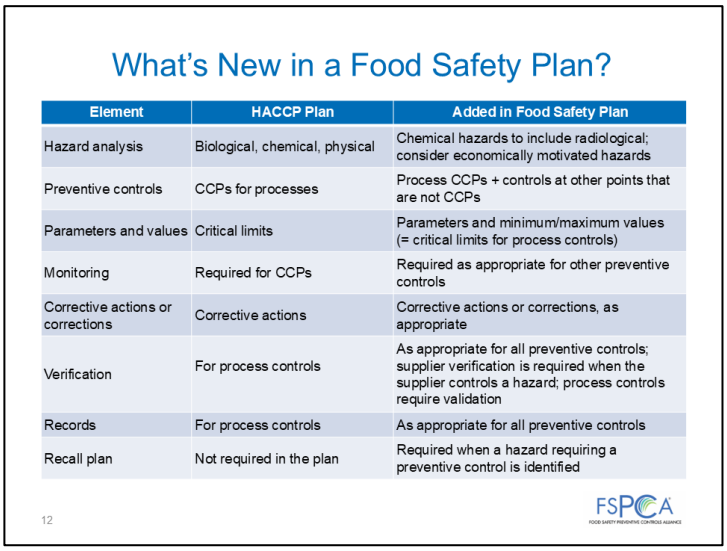
There are other differences beyond these additional preventive controls.

The preventive controls approach recognizes that critical limits may not be required for some preventive controls. Critical limits are defined by NACMCF as: "A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level, the occurrence of a food-safety hazard." Rather, the broader term, "parameters and values," supports identification of a frequency or other metric to assess control, rather than setting a precise minimum or maximum value to which a parameter must be controlled.

Another difference is related to handling certain out-of-control situations at a preventive control where product is not at risk. In these cases, the regulation allows for corrections—those immediate actions, such as re-cleaning a line before start-up—that can be taken without the formality of a corrective action because no product was produced on the equipment.

So, while the Food Safety Plan is HACCP-based, there are differences from HACCP that are important to understand.

Slide 12: What's New in a Food Safety Plan?

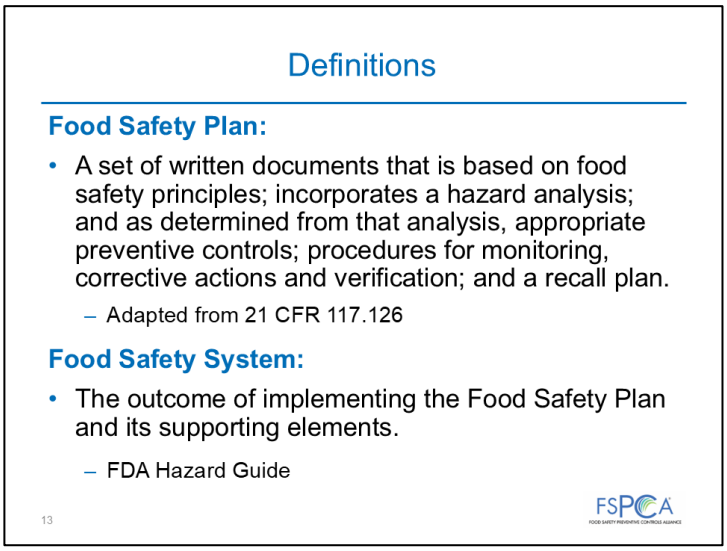


Element	HACCP Plan	Added in Food Safety Plan
Hazard analysis	Biological, chemical, physical	Chemical hazards to include radiological; consider economically motivated hazards
Preventive controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs
Parameters and values	Critical limits	Parameters and minimum/maximum values (= critical limits for process controls)
Monitoring	Required for CCPs	Required as appropriate for other preventive controls
Corrective actions or corrections	Corrective actions	Corrective actions or corrections, as appropriate
Verification	For process controls	As appropriate for all preventive controls; supplier verification is required when the supplier controls a hazard; process controls require validation
Records	For process controls	As appropriate for all preventive controls
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified

Elements of a Food Safety Plan that differ from HACCP include:

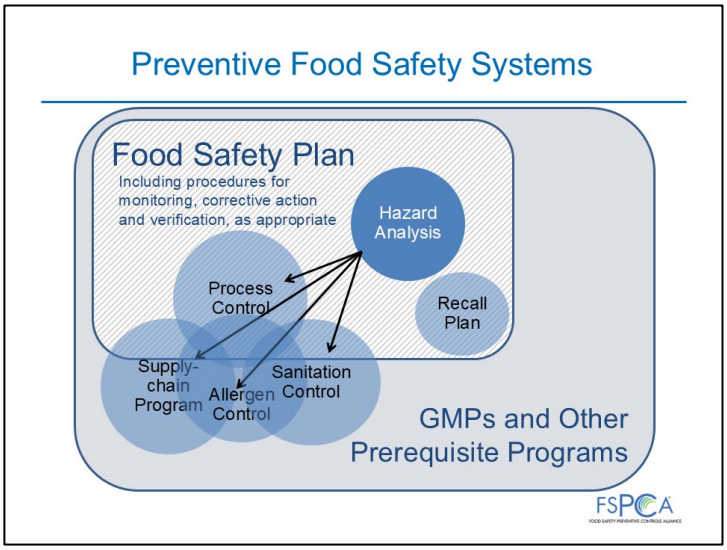
- Broader considerations of hazard types, including radiological hazards as a subset of chemical hazards and where economically motivated hazards could pose a risk.
- Preventive controls include additional controls to those that are process related.
- Monitoring of the implementation of other preventive controls in addition to CCPs.
- Corrective actions taken for other preventive controls in addition to CCPs. Addition of corrections to recognize that some preventive controls may not require all of the required elements for corrective actions (e.g., sanitation failures can sometimes be corrected by re-cleaning (before production begins), without holding product because no product was produced on the equipment).
- Verification is required for all preventive controls and includes supplier verification when a supplier controls the identified hazard. Validation is a verification activity and required for process controls as appropriate to the nature of the process control.
- Records are required when preventive controls are identified, including controls that are not process controls.
- A recall plan is a required part of the Food Safety Plan when a hazard requiring a preventive control is identified.

Slide 13: Definitions



The Food Safety Plan is the primary element of a company's food safety system. The Food Safety Plan is the hazard analysis along with appropriate preventive controls and its management components needed for each identified hazard. The food safety system is the overall food safety efforts of a company that include the Food Safety Plan and supporting elements which include GMPs and prerequisite programs.

Slide 14: Preventive Food Safety Systems



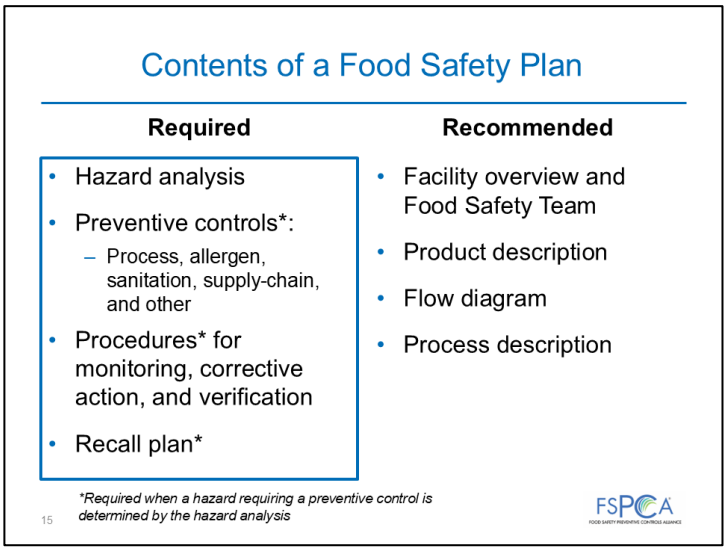
GMPs are required because they form the foundation for the Food Safety Plan. Developing a Food Safety Plan helps to focus most of the activities on what matters most for food safety.

The Food Safety Plan is a dynamic document, which must be kept current if changes are made to the system or to equipment, when new products and/or ingredients are added, or new hazards are identified. The diagram above shows that the Food Safety Plan includes several elements Including the hazard analysis and the preventive controls, along with a recall plan.

Many GMPs and other prerequisite programs support but are not included in the Food Safety Plan although they are important parts of the food safety system.

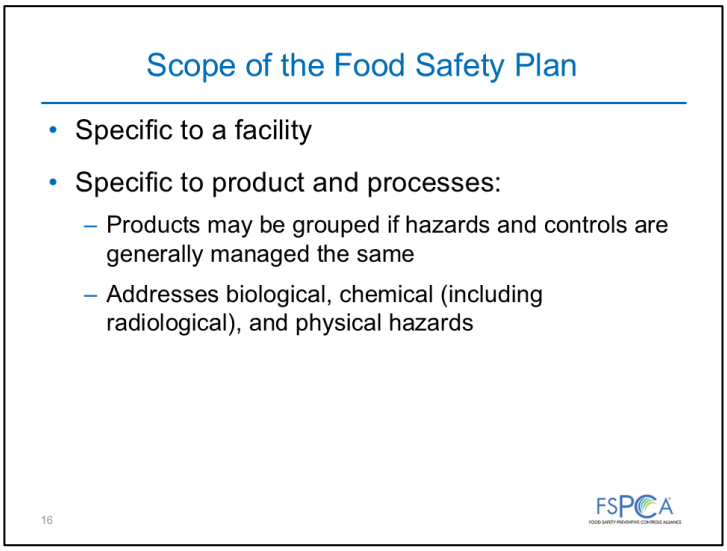
However, as can be seen in the diagram above, there are elements of the prerequisite programs that can become part of the Food Safety Plan.

Slide 15: Contents of a Food Safety Plan



The required elements of a food safety plan include the hazard analysis and any preventive controls with management components that were determined as needed to control identified significant hazards. A recall plan also is required when the hazard analysis has identified hazards requiring a preventive control. Other elements such as facility overview, Food Safety Team, product description, flow diagram, and process description are not required by the regulation but are recommended because they are useful in developing the Food Safety Plan. For the facility, it is helpful to have a designated Food Safety Team and have a written facility overview. For each Food Safety Plan, it is recommended that there is a written product description, a flow diagram, and a process description which are very helpful when conducting the hazard analysis. These elements will be discussed further in Chapter 5.

Slide 16: Scope of the Food Safety Plan



Food Safety Plans are specific to a facility and specific to a food process, or product type. It is possible to group products under one Food Safety Plan provided that the process is similar with the same hazards and controls. This includes differences in formulation including allergens or packaging types provided it is clearly identified in the Food Safety Plan. Some facilities may decide to organize Food Safety Plans by unit operations in production (e.g., making a blend that is used in several products), to reduce overlap or avoid inconsistency. The organization of the Food Safety Plan is decided by the Food Safety Team.

Considerations for the scope of the Food Safety Plan:

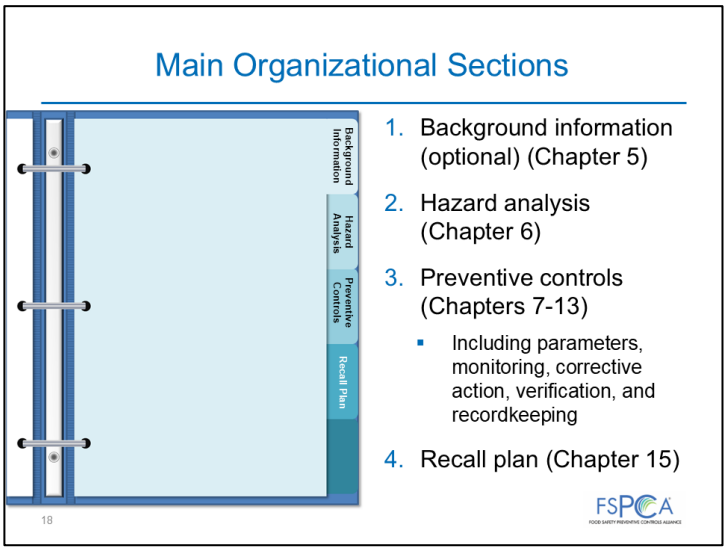
- Determine the specific product(s) and process(es) that the Food Safety Plan will address;
- Define the part of the food chain to be considered (e.g., products sold to retail may have different considerations than those sold to foodservice, to manufacturers or directly to the consumer); and
- Address biological, chemical (including radiological), and physical hazards associated with the above.

Slide 17: **Food Safety Plan Format is Flexible**

The specific format of a Food Safety Plan is not defined in the regulation. The facility Food Safety Team can organize the required information in a manner that fits the systems, the needs of employees, the needs of customers and the requirements of the regulation. A Food Safety Plan should be easy to understand, implement and manage, kept up to date, and organized and accessible for regulatory inspection.

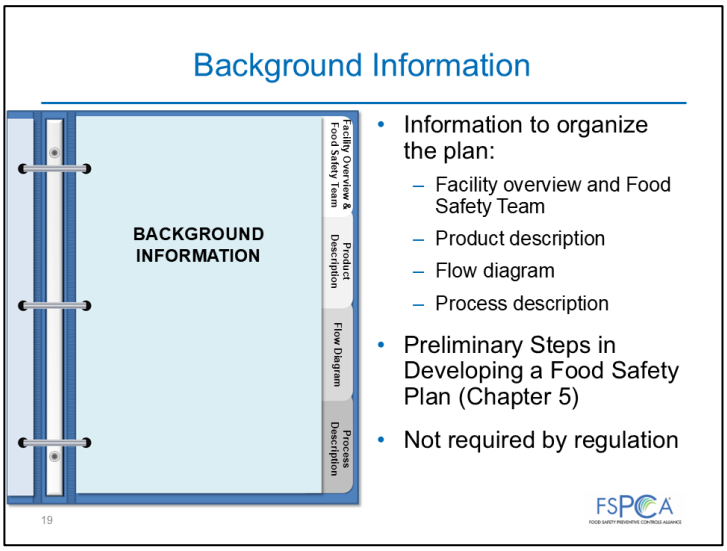
The following is an example of how a Food Safety Plan might be organized, using a binder example. Note that there is no requirement that all components of a Food Safety Plan even be in a binder, this is just an example.

Slide 18: Main Organizational Sections



This course is organized around building a Food Safety Plan. In this example, there are four main sections or tabs for the Food Safety Plan, including recommended background information, and the required hazard analysis, preventive controls, recall plan and implementation records. Each main section's components are reviewed in more detail in subsequent chapters of this course.

Slide 19: Background Information

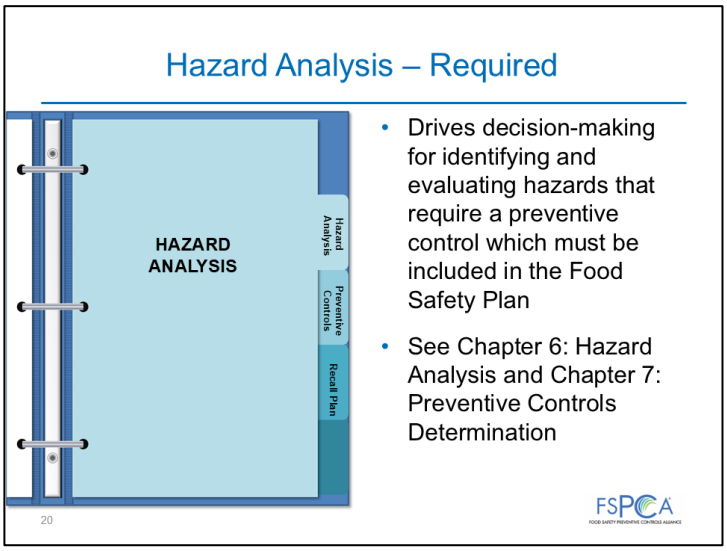


The information behind the Background Information tab is covered in Chapter 5: Preliminary Steps in Developing a Food Safety Plan. Background information is not required by regulations but provides a framework for organizing the Food Safety Plan, for conducting the hazard analysis, and for explaining the plan to others. Remember, anything included as part of the plan may be subject to regulatory access and review. A brief description of the facility or company may be included.

Listing members of the Food Safety Team, along with any training, could be included in this section.

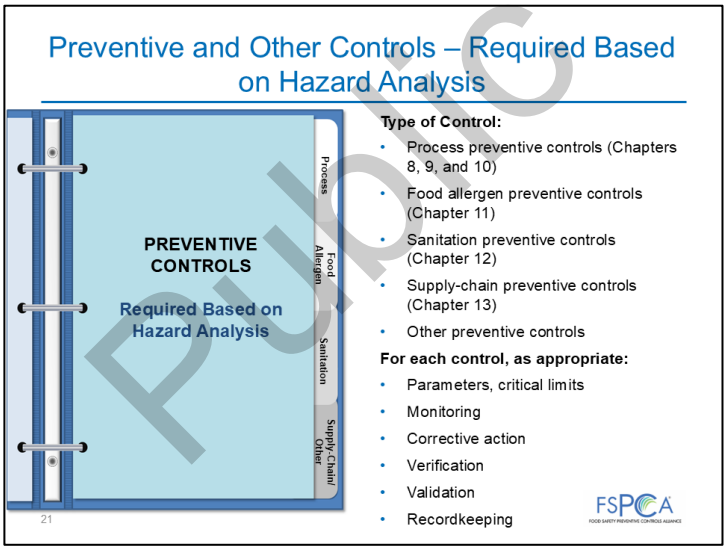
The product description section identifies important characteristics of the product including ingredients and packaging used that may impact food safety. An accurate flow diagram is recommended to ensure that all steps of the process are evaluated to identify food safety hazards and it serves as a useful organization format for the required written Food Safety Plan. Finally, the process description can provide information needed to fully understand how the product is made, which is helpful for understanding the types of preventive controls applied. A facility can use other documents to meet these goals if that works for the operation.

Slide 20: Hazard Analysis – Required



The hazard analysis drives decision-making on which hazards require a preventive control. Thus, the hazard analysis forms the basis for other required elements in the Food Safety Plan. Careful analysis of the hazards that may be relevant for the food product and the process will help to focus the controls on what matters most. More information will be reviewed in Chapter 6: Hazard Analysis and Chapter 7: Preventive Controls Determination.

Slide 21: Preventive and Other Controls – Required Based on Hazard Analysis



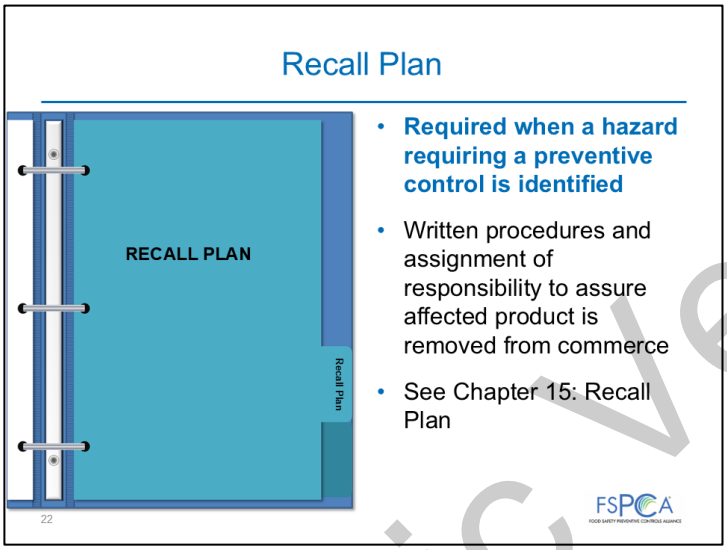
The preventive controls section describes the essential controls that ensure a safe food product is produced. The required preventive controls for a specific food product are determined through the hazard analysis process, which considers the nature of the preventive control and its role in the facility's food safety system.

Process preventive controls are discussed in Chapters 8-10, food allergen preventive controls are covered in Chapter 11, and sanitation preventive controls are discussed in Chapter 12.

Supply-chain preventive controls include supplier approval and verification activities for ingredients and raw materials that have hazards for which the control is applied by the supplier. These ingredients are identified through hazard analysis. Chapter 13: Supply-Chain Program discusses supplier related activities.

In some cases, there may be other controls used by a facility as part of their food safety system, such as transportation controls, which would also be included here.

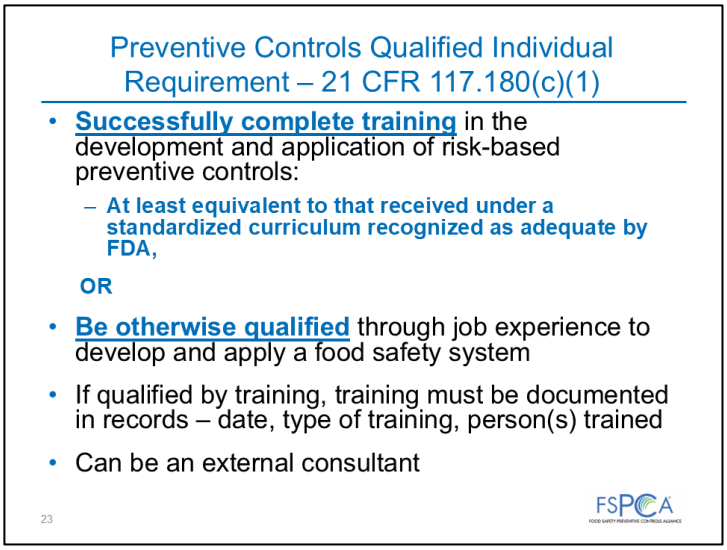
Slide 22: Recall Plan



A recall plan is also required in the Preventive Controls for Human Food regulation when in the hazard analysis, a hazard requiring a preventive control is identified.

Recall plans will be discussed in Chapter 15.

Slide 23: Preventive Controls Qualified Individual Requirement – 21 CFR 117.180(c)(1)



A Preventive Controls Qualified Individual is required by the Preventive Controls for Human Food regulation. This person is 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 the FDA. This course developed by FSPCA is the "standardized curriculum" recognized by FDA. Successfully completing this course is one way to meet the requirements for a Preventive Controls Qualified Individual.

It is not required that the Preventive Controls Qualified Individual take this course however, since the regulation also states that a Preventive Controls Qualified Individual can be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform Preventive Controls Qualified Individual functions if such experience has provided the individual with knowledge at least equivalent to that provided through the standardized curriculum.

If qualified by training, the Preventive Controls Qualified Individual's training must be documented in training records including the name of the person trained, the type of training, and the date of the training.

The Preventive Controls Qualified Individual may be an employee of the facility but can also be an individual secured through other mechanisms, such as a consulting contract or a company corporate food safety expert, to lead the development of the plan. In some situations, more than one Preventive Controls Qualified Individual may be needed to effectively develop and implement a Food Safety Plan. More detail on the different parts of the Food Safety Plan is provided within the course.

Slide 24: Preventive Controls Qualified Individual Responsibilities – 21 CFR 117.180(a)

The 21 CFR 117.3 definitions for "Preventive Controls Qualified Individual," as well as the 21 CFR 117.180 requirements applicable to a Preventive Controls Qualified Individual are available in Appendix 1.

Under the regulation, certain tasks must be performed or overseen by the Preventive Controls Qualified Individual. These include:

(1) preparation of the Food Safety Plan,

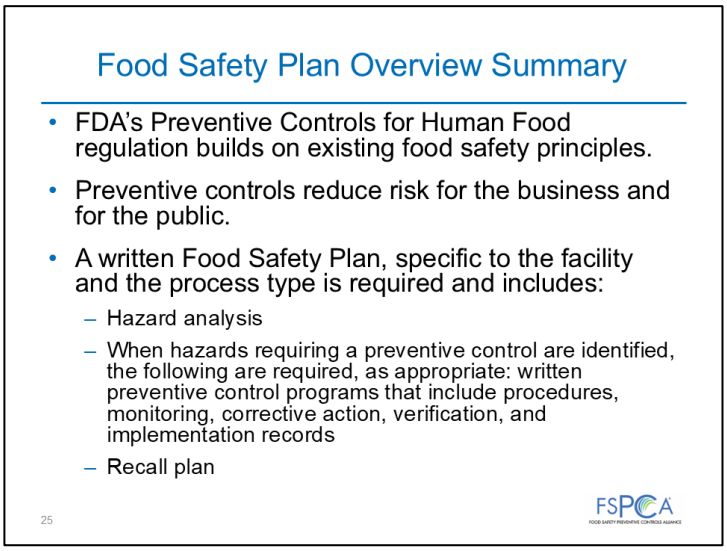
(2) validation of the preventive controls including justification for validation timeframe exceeding 90 days and determination that validation is not required,

(3) records review including justification for review of monitoring and corrective action records timeframe exceeding 7 working days, and

(4) reanalysis of the Food Safety Plan including determination that the timeframe for reanalysis and additional preventive controls validation can exceed the first 90 days of production of the applicable food.

The term, oversee, infers that a Preventive Controls Qualified Individual will watch over and direct an activity, a group of workers, etc. in order to ensure a satisfactory outcome or performance of assigned activities. This could involve ensuring that individuals have had the proper training to perform assigned activities.

Slide 25: Food Safety Plan Overview Summary (1 of 2)

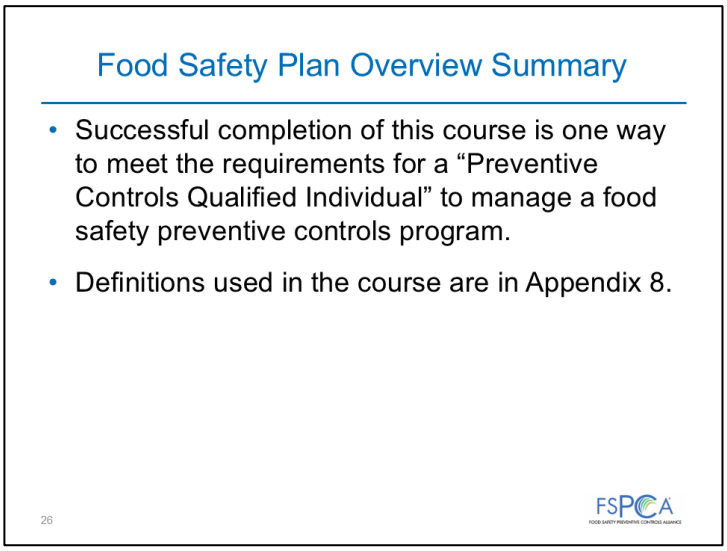


In summary, the Food Safety Plan is a written document specific to the facility. It must contain a written hazard analysis and separate plans or programs that address process preventive controls, allergen preventive controls, sanitation preventive controls, supply-chain programs, and other preventive controls determined to be necessary by the hazard analysis.

When hazards requiring a preventive control are identified, written programs that include procedures, monitoring, corrective action, verification, and implementation records must be included. The Food Safety Plan also must contain a recall plan for food where a hazard requiring a preventive control has been identified. There is no required format for these documents or for the Food Safety Plan itself.

Some facilities may combine different Food Safety Plan sections, while some may separate sections. There is no requirement that all parts of the Food Safety Plan be in one location. The important point is that the whole Food Safety Plan is organized in a way that identifies hazards requiring a preventive control so that 1) the hazards are effectively managed and 2) the facility has records that demonstrate these preventive controls are in place and being consistently implemented. The Plan documents should be organized and easily retrievable when needed (e.g., for inspections or audits). Each of the elements of a Food Safety Plan is discussed in subsequent chapters, using examples from a hypothetical food operation.

Slide 26: Food Safety Plan Overview Summary (2 of 2)



By successfully completing this course, course participants will meet the training requirements for a "Preventive Controls Qualified Individual" who can oversee a food safety preventive controls program. Participants may need assistance from technical experts or resources to develop certain elements of a food safety program. Additional resources will be discussed in chapters later in the course.

The remainder of this course will teach participants how to develop a risk-based Food Safety Plan and implement preventive controls to help mitigate and control hazards specific to a food product and process. Preventive controls reduce potential food safety issues for the public and for businesses as well.

The definitions used in this course are in Appendix 8 of the Participant Manual.

Participation is vital for understanding the material. Shared experiences and questions can help all participants in the course as well, so participation is highly encouraged.

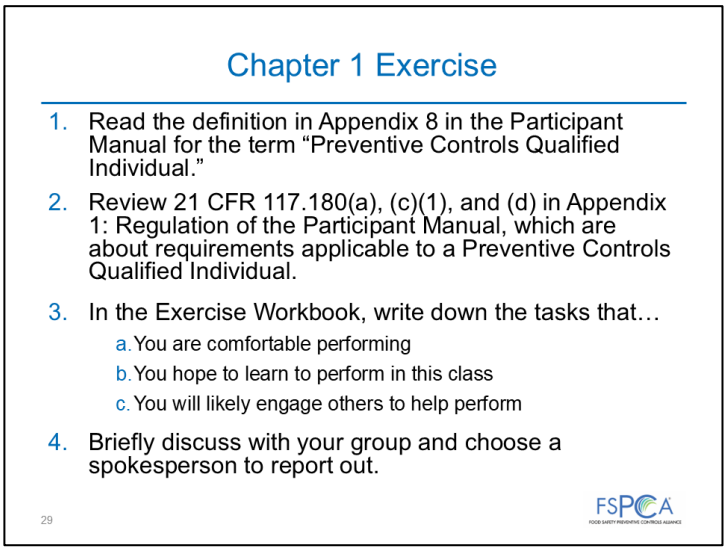
Slide 27: Knowledge Check 1

Participants do NOT have this slide.

Slide 28: Knowledge Check 2

Participants do NOT have this slide.

Slide 29: Chapter 1 Exercise



Read the definitions in Appendix 8 in the Participant Manual for the term "Preventive Controls Qualified Individual," and review 21 CFR 117.180 (a), (c), and (d) in Appendix 1: Regulation of the Participant Manual, which are about requirements applicable to a Preventive Controls Qualified Individual.

Write down the tasks that…

1. You are comfortable performing,
2. You hope to learn to perform in this class, and
3. You will likely engage others to help perform.

Briefly discuss at table or in breakout room and pick a spokesperson to summarize the discussion for the rest of the class. Report out when called upon.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

CODEX ALIMENTARIUS International Food Standards (CXC 1-1969: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf

FDA Recall Data Dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm

FDA RFR Data Dashboard: https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard?utm_medium=email&utm_source=govdelivery

FDA Reportable Food Registry Five Year Overview of Targeting Inspection Resources and Identifying Patterns of Adulteration: https://www.fda.gov/media/97862/download

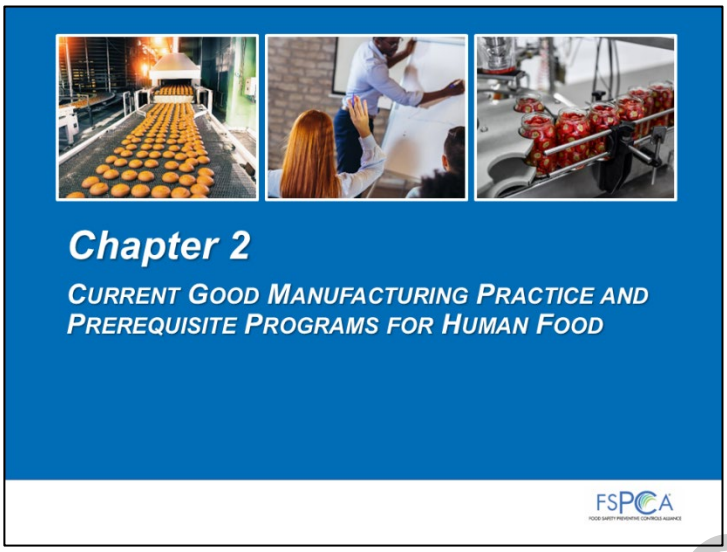
FDA Reportable Food Registry for Industry: https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry

HACCP Principles and Application Guidelines: National Advisory on the Microbiological Criteria for Foods https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines

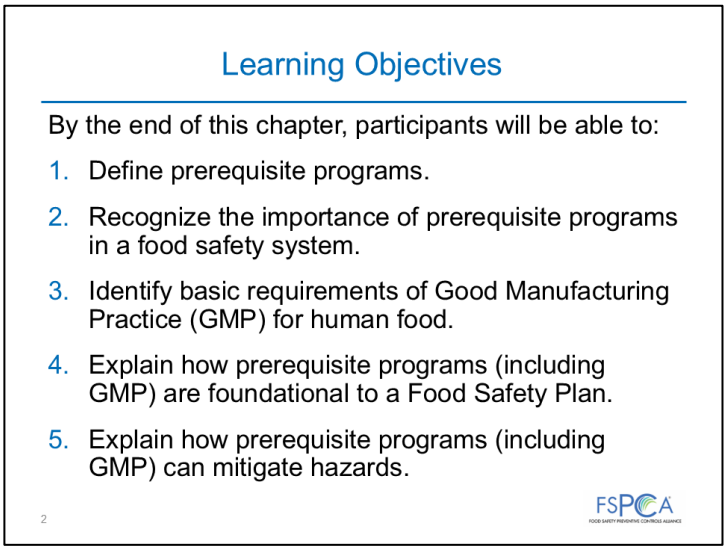
Information on FSMA regulations and guidance documents: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

Outbreak Data: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

Slide 1: Chapter 2: Current Good Manufacturing Practice and Prerequisite Programs for Human Food



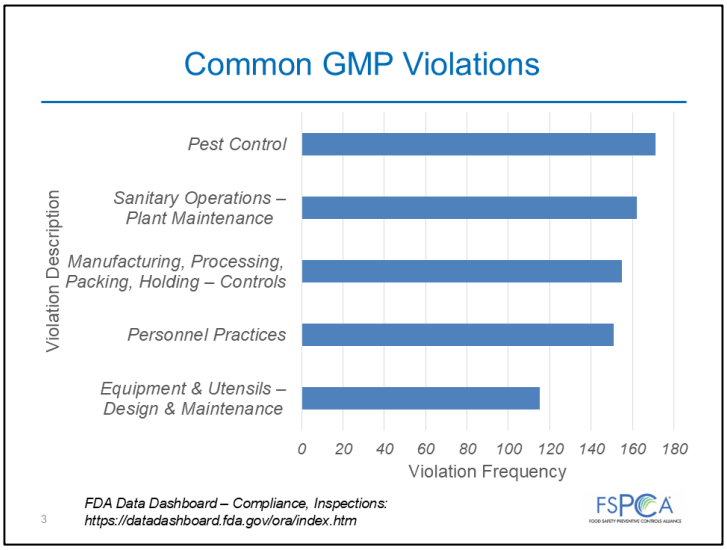
Slide 2: Learning Objectives



It is assumed that course participants are familiar with basic Good Manufacturing Practices (GMPs), thus this chapter provides only an overview. Compliance with 21 CFR Part 117, Subpart B GMPs is mandatory. See "Additional Reading" at the end of the chapter for resources.

The Food Safety Plan is not a stand-alone program, but rather part of a larger food safety system. The foundational programs that are part of the food safety system are frequently termed "prerequisite programs." The term was coined to indicate that they should be in place before HACCP-based systems, which include preventive controls, are implemented to effectively mitigate risks from foodborne hazards. The Current Good Manufacturing Practice (CGMP)provisions in 21 CFR Part 117, Subpart B address requirements for many prerequisite programs. There are other programs that are likely to apply to most facilities, such as supplier and manufacturing specifications.

Slide 3: Common GMP Violations

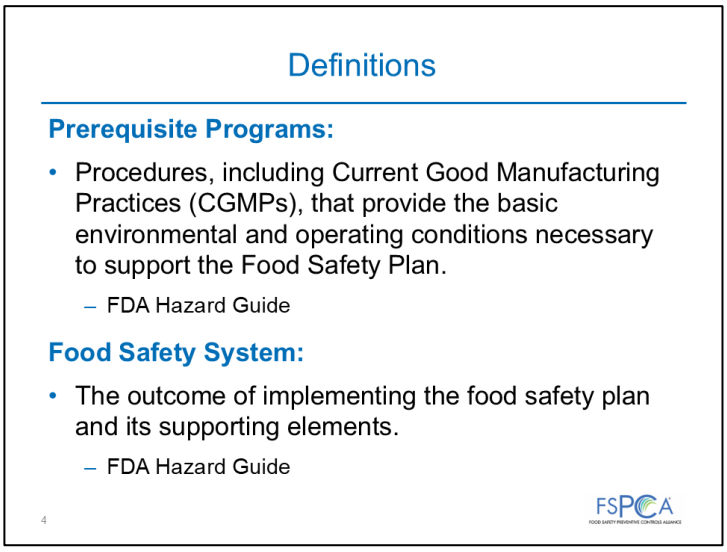


The violations listed on the slide are the top GMP-related violations for food operations. Many of these violations are on a list from year to year and reflect common failures in addressing GMPs. Below are specific FDA inspectional observations relevant to GMP deficiencies:

- "The equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against [allergen cross-contact] [contamination]."
- "The facility did not clean and sanitize utensils or equipment in a manner that protects against [allergen cross-contact] [contamination]."
- "The facility did not take a reasonable measure or precaution related to personnel practices."
- "The facility did not conduct operations under conditions and controls necessary to minimize the potential for [growth or survival of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]."
- "The plant was not [constructed] [designed] to facilitate maintenance and sanitary operations."
- "The facility did not maintain the plant [in a clean and sanitary condition] [in adequate repair]."
- "The facility did not [exclude pests from the food plant] [use pesticides under precautions and restrictions] to protect against contamination of food."

This list demonstrates the importance of establishing and implementing the various prerequisite programs within a food operation. Once in place, those charged with overseeing these programs should ensure compliance. These programs are foundational to the development of the Food Safety Plan.

Slide 4: Definitions

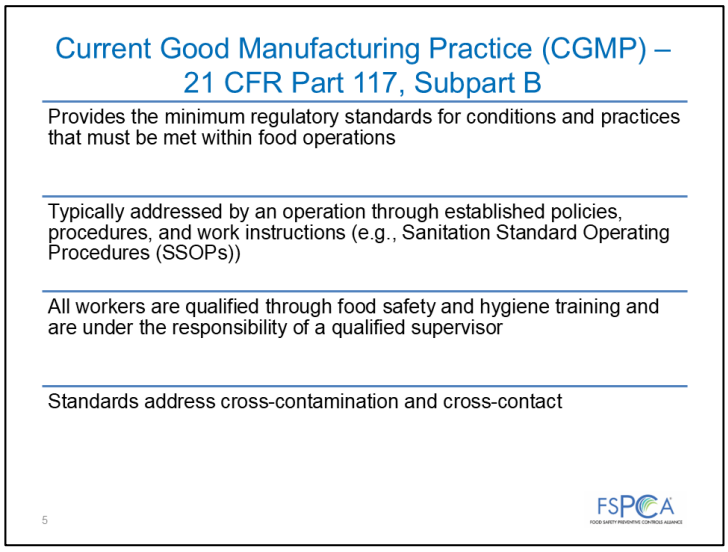


Prerequisite programs provide the basic environmental and operating conditions necessary to support the Food Safety Plan and in some cases these programs will be part of the Food Safety Plan. Many of these programs are established by regulation. (e.g., GMPs).

The specific prerequisite programs to be developed and implemented may vary depending on the type of food produced and the facility where the food is processed or held. Some people use the terms "prerequisite program," "GMP," "CGMP" (Note: The "C" in "CGMP" refers to the term," Current," as it is used in the "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" regulation), "good hygienic practice" and "Sanitation Standard Operating Procedures (SSOPs)" interchangeably. The important thing to remember is that these are foundational programs included in an overall food safety system. Without these programs, the Food Safety Plan may not successfully prevent food safety issues. Remember that the Food Safety Plan focuses on what matters most to ensure the safety of the food being produced.

The prerequisite programs need to be implemented as supporting elements of the overall food safety system in the facility.

Slide 5: Current Good Manufacturing Practice (CGMP) – 21 CFR Part 117, Subpart B



Cross-contamination: Unintentional transfer of a pathogens or other contaminants to a food, a food-contact surface, or a food packaging material.

Allergen cross-contact: Unintentional incorporation of a food allergen into a food.

Current GMPs (or CGMPs) per 21 CFR Part 117 apply to all facilities that manufacture, process, pack, or hold FDA-regulated human food for sale in the United States. GMPs are the minimum sanitary and processing requirements or standards for producing safe and wholesome food. GMPs address personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, and warehousing and distribution. They also provide for the requirements for holding and distribution of human food by-products for use as animal food as well as defect action levels for natural or unavoidable defects that at low levels are not hazardous to health.

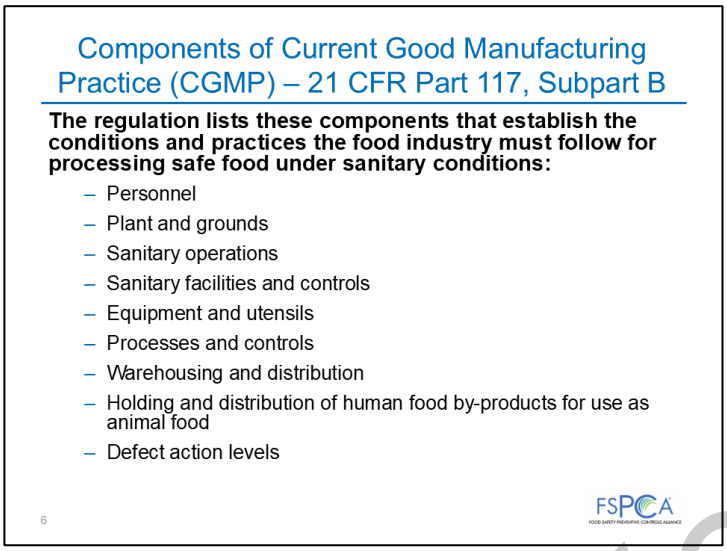
GMPs typically are addressed by an operation through established policies, work instructions, Standard Operating Procedures (SOPs), such as Sanitation Standard Operating Procedures (or SSOPs). The 21 CFR Part 117, Subpart B does not require written procedures, monitoring, or recordkeeping with the exception for training records. However, written procedures, monitoring, and recordkeeping are recommended as part of a facility's SOPs within established prerequisite programs to manage the GMPs and document the results to demonstrate compliance to these programs. Written SOPs also are helpful for employee training. The rest of this chapter highlights basic GMPs that ensure products are processed under sanitary conditions.

Employee education and training is an important part of prerequisite program implementation. Worker training specifically for qualified individuals is discussed later in this chapter.

There may be some instances where a specific GMP task is so important to the safety of the product that the task is designated as a preventive control in a Food Safety Plan. The need for a preventive control is determined during the hazard analysis and if cross-contamination (in a ready-to-eat food) or allergen cross-contact issues are identified as likely to occur then these hazards would need to be addressed in written sanitation or allergen preventive controls rather than relying on a GMP. Chapter 6 and 7: Hazard

Analysis and Preventive Control Determination will provide more information on the decision-making process. This chapter focuses on basic GMP requirements.

Slide 6: Components of Current Good Manufacturing Practice (CGMP) – 21 CFR Part 117, Subpart B



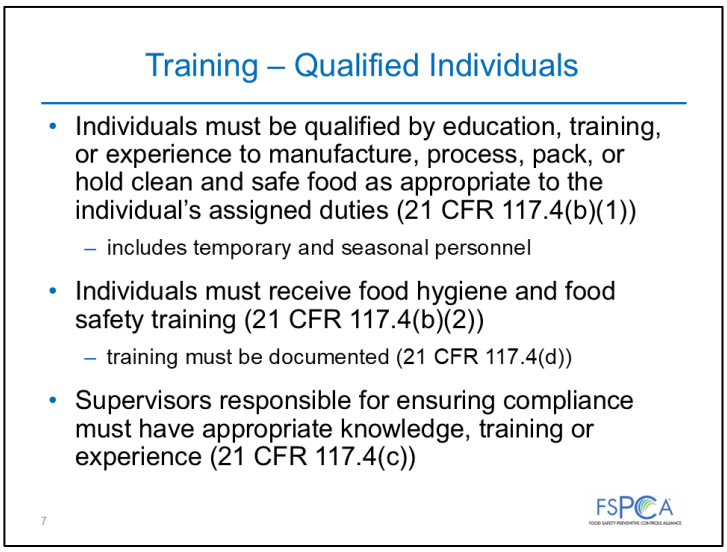
Definitions:

***Defect action level*:** A level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated"and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act. (21 CFR 117.3)

Adulteration: "A violation of the Federal Food, Drug, and Cosmetic Act which includes products that are defective, unsafe, not shown to be safe, filthy, or produced under insanitary conditions."

These nine (9) elements are the components of GMPs from the regulation's Subpart B that will be covered in more detail in this chapter, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, and warehousing and distribution.

Slide 7: Training – Qualified Individuals



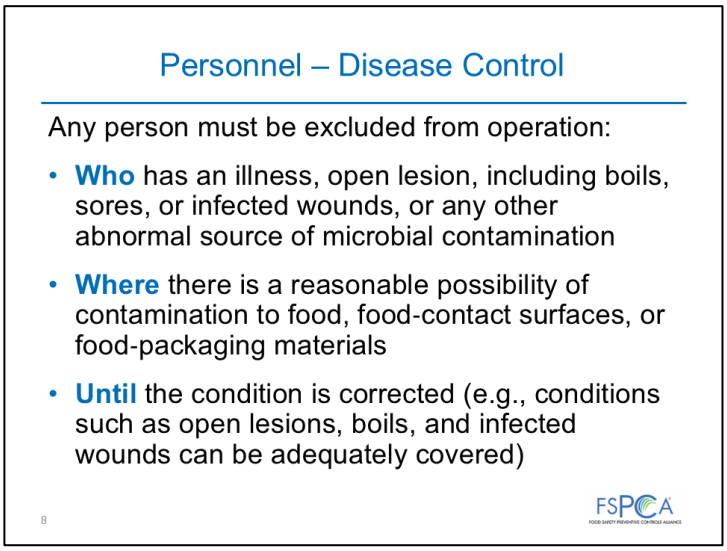
Employee education and training is an important prerequisite program since all employees need to have the education, training, or experience in line with their assigned duties.

The regulation requires that all employees who are engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties, and, this training must be documented, and records maintained.

Employees should also be trained to perform their job tasks (assigned duties) and how their work can impact the safety of the product.

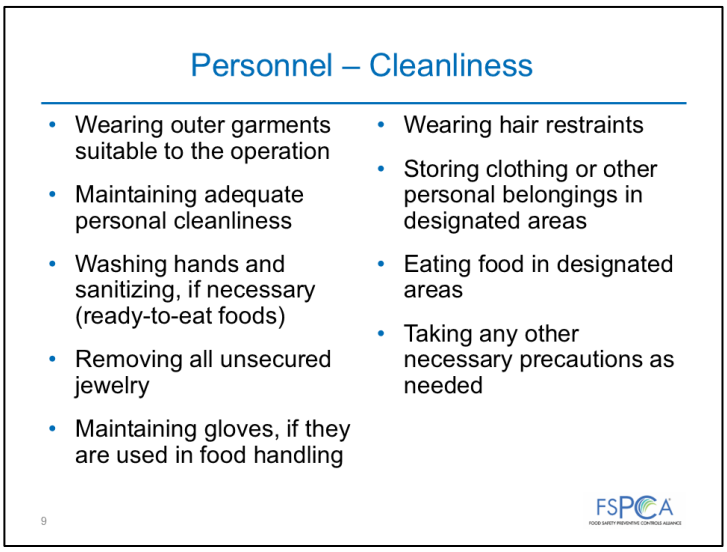
Supervision of employee hygiene practices and food safety, and supervisors setting good hygiene and food safety examples also are an important part of the system to ensure compliance with GMPs. Supervisors must be qualified to carry out the responsibilities of employee training and oversight.

Slide 8: Personnel – Disease Control



Food handlers with vomiting, diarrhea, jaundice, sore throat with fever, wounds, or open lesions could be a source of microbiological contamination that could lead to foodborne illness. Establishments must make sure that sick people are excluded from the food operation and may not return until the condition is resolved.

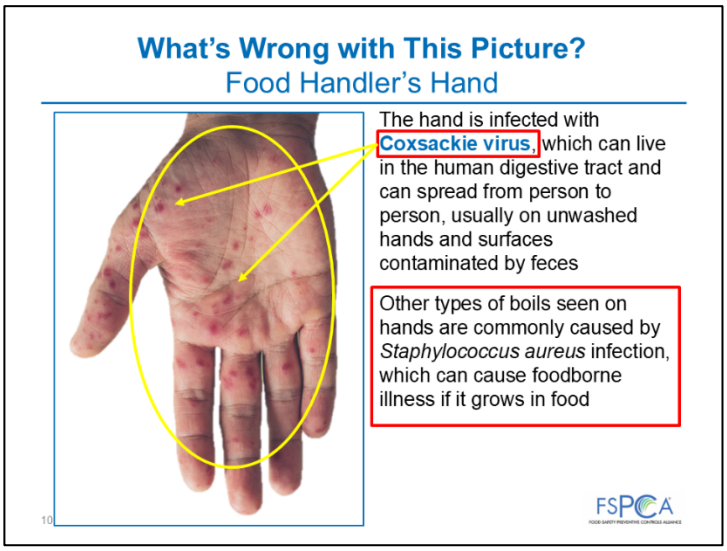
Slide 9: Personnel – Cleanliness



People can be the source of potential contaminants in the processing environment so individuals should understand the importance of maintaining personal cleanliness. Clothing must be tidy. Uniforms, smocks, gloves, dedicated footwear, color coding and other clothing options and their proper storage should be considered depending upon the needs of the operation. Hair should be restrained. Proper handwashing, including hand sanitizing when handling ready-to-eat foods, is essential to prevent cross-contamination and allergen cross-contact. This should be done each time employees are away from the workstation. Jewelry may introduce a physical hazard in the food process, so it needs to be effectively managed as part of the prerequisite programs. Eating should be done in designated areas only.

A facility's personal hygiene program should ensure that employees are meeting the GMP requirements.

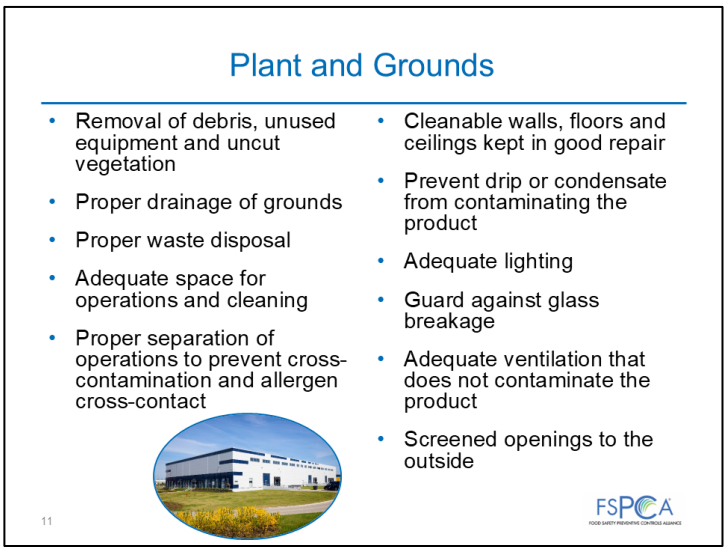
Slide 10: What's Wrong with this Picture? Food Handler's Hand



Microorganisms such as the Coxsackie virus, shown on the slide, or *Staphylococcus aureus* which can result in infected boils on hands, are contaminants transferred by people to food, which can result in human illness.

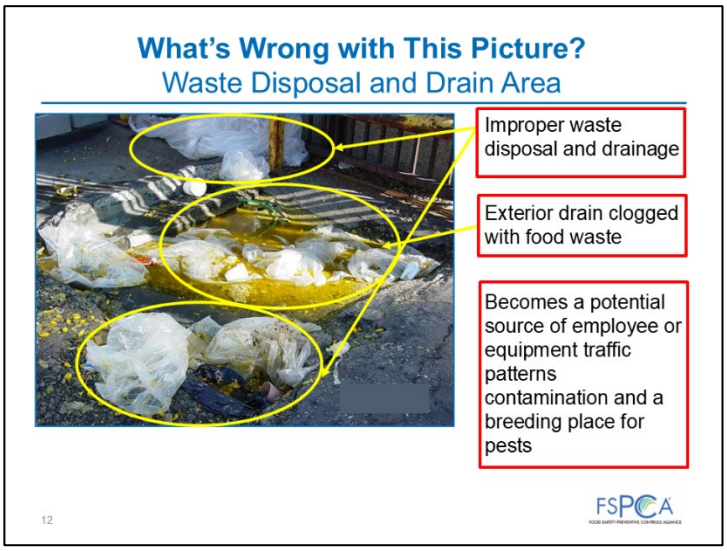
Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real-world examples.

Slide 11: Plant and Grounds



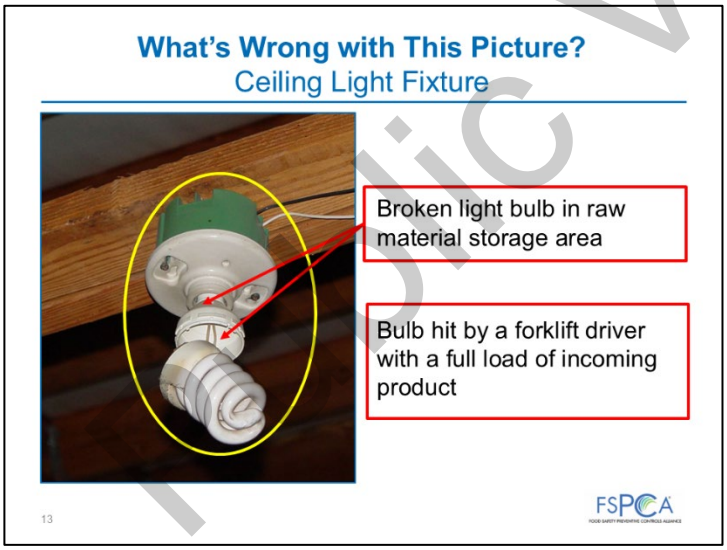
GMPs for the plant and grounds, as summarized in the slide, ensure that the buildings and structures are suitable for food-production purposes and limit the potential for pathogen recontamination. For example, it is important to keep the grounds outside the food facility clean and free from standing water and vegetation Waste should be collected and disposed of frequently. Inside the facility, there should be adequate space and proper separation within the operations (e.g., between cooked and raw products and between food with different allergen profiles, if applicable), to minimize the potential for cross-contamination and cross-contact to facilitate cleaning. Walls, floors, and ceilings should be maintained in a state of good repair. Dripping condensate should be prevented or minimized, especially where there is exposed product. Other elements include adequate lighting and ventilation, glass breakage prevention, and measures to prevent pest entry such as screened door and window openings.

Slide 12: What's Wrong with this Picture? Waste Disposal and Drain Area



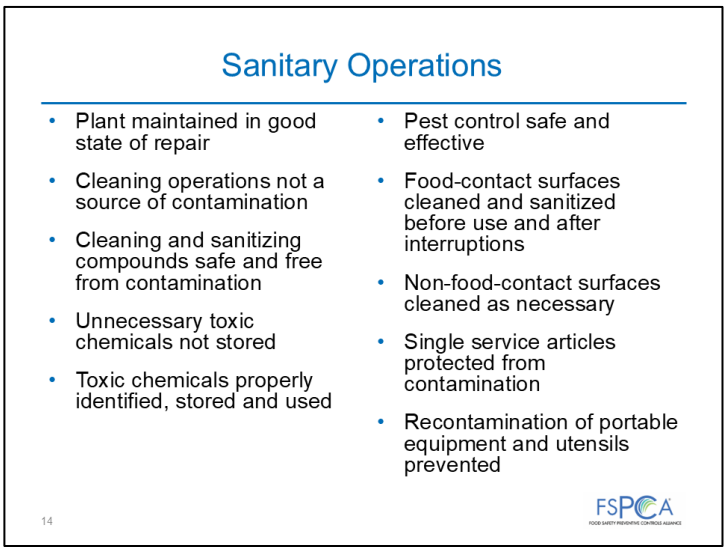
The inadequate drainage shown in this slide may contribute to employee or equipment traffic patterns contamination or providing a breeding place for pests. Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real-world examples.

Slide 13: What's Wrong with this Picture? Ceiling Light Fixture



Unshielded light bulbs, in addition to fixtures, skylights, or other glass suspended over exposed food in any step of food preparation can contaminate food with glass. Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real-world examples.

Slide 14: Sanitary Operations



These GMPs cover specific standards for a facility to operate in a sanitary manner.

Toxic Chemical Storage: Certain potentially toxic chemicals are essential for effective plant operations. Only chemicals to be used in the facility should be allowed in the facility. These chemical (including cleaning and sanitizing chemicals, laboratory testing chemicals, and chemicals needed for plant and equipment maintenance (e.g., lubricants), should be stored in a secured location with restricted access, labeled appropriately, and used following prescribed instructions. These toxic chemicals are not to be used where food is processed or exposed.

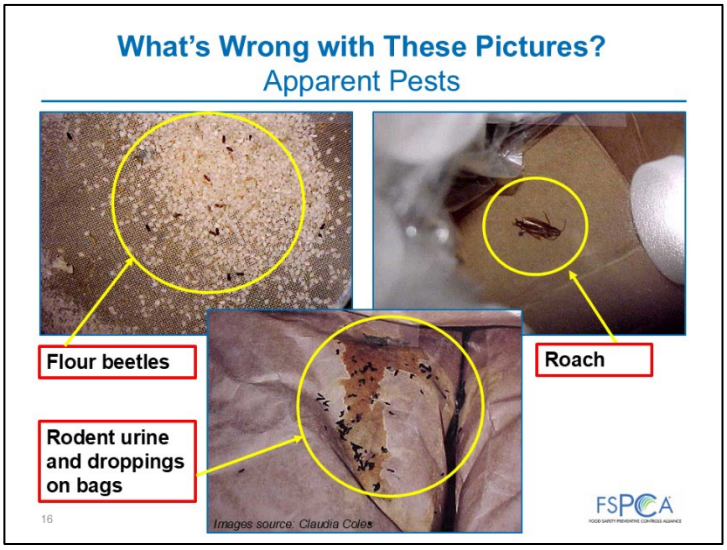
Precautions are necessary for the use of insecticides and rodenticides. Some pest control chemicals require an operator to be licensed for use of the chemicals. These toxic chemicals are generally used only outside of the processing facility unless special precautions are taken. For example, thorough cleaning of all food-contact surfaces after chemical use would be necessary if insecticides were used to treat an internal infestation.

Pest Control: Pests, such as rodents, birds, insects, amphibians, reptiles, and feral or domestic animals must be excluded or controlled in all areas of a food processing or food storage facility. The presence of pests can impact the overall sanitation of a facility, so it is important to ensure the effectiveness of pest control. Even if pest control services are contracted with another company, the food facility management must ensure there are no pests in the facility. Measures that prevent pest entry and harborage are key, and include eliminating holes that allow entry, removing vegetation or unnecessary structures and prompt cleaning of food waste and other debris.

Slide 15: What's Wrong with this Picture? White and Brown Sugar at a Bakery

The Comet cleaning chemical shown in this slide is not properly stored away from the food preparation areas and could contaminate the ingredients used for making a food product. Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real world examples.

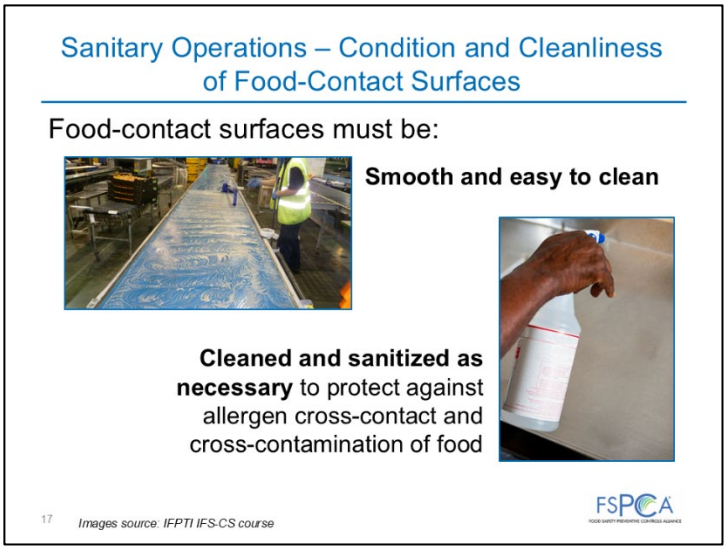
Slide 16: What's Wrong with this Picture? Apparent Pests



Rodents and insects are a potential source of pathogens in food operations and these pathogens can be transmitted through food. The presence of rodent feces and insects, either dead or alive, is evidence of pest activity which is not permitted in a food handling facility. A pest control professional should be consulted to help identify and resolve pest infestation situations, and to proactively work with food facility operators to eliminate any infestation.

Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real world examples.

Slide 17: Sanitary Operations – Condition and Cleanliness of Food-Contact Surfaces



Sanitation of food-contact surfaces is one of the most important aspects for pathogen and allergen control. Food-contact surfaces must be cleanable. Surfaces should be made of a material that is non-absorbent and can withstand the cleaning process. Materials such as stainless steel or hard food-grade plastic are commonly used in food operations. Food-contact surfaces should be smooth, not having pits or grooves which provide opportunities for microbial harborage. Surfaces should be accessible to allow adequate cleaning and sanitizing. The cleaning and sanitizing method should be appropriate to the given application.

Different methods of cleaning may be relevant in different facility environments. In dry processing operations, water use is generally discouraged because it can infiltrate cracks, crevices, and difficult-to-clean areas, establishing potential harborage sites for environmental pathogens. So, in these types of operations, specific dry cleaning and sanitizing methods are used. Wet processing environments typically use detergent and potable water at a suitable temperature for cleaning, followed by sanitizing with a sanitizer that is registered for food-contact surface applications, such as chlorine, quaternary ammonium, or iodine-based compounds.

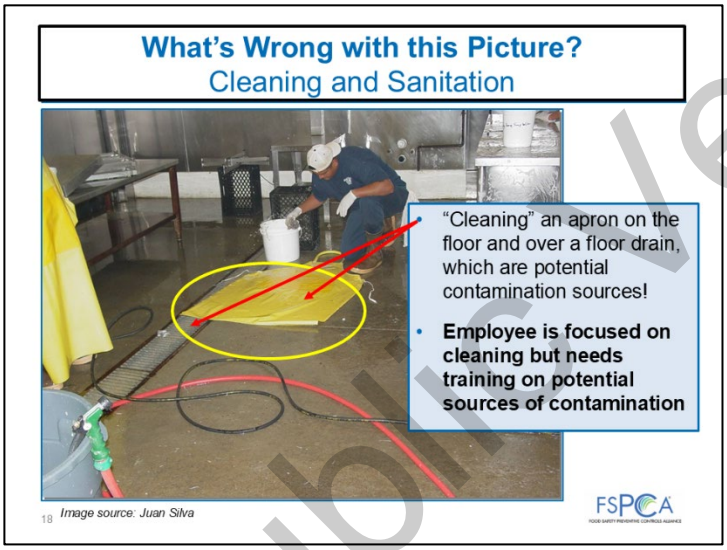
The types of food being processed also are an important consideration. Different food types (e.g., high in fat, high in protein), often require different cleaning chemicals. This becomes important when discussing allergen removal. It is important to note that the cleaning step of the sanitation process is more important for allergen removal compared to the sanitizing step which has less impact. For proper sanitation, it is important to follow the chemical manufacturer's use instructions to ensure efficacy and regulatory compliance.

The Preventive Controls for Human Food regulation requires documentation of sanitation controls for hazards requiring a preventive control in a Food Safety Plan. Only those sanitation procedures that address hazards requiring a preventive control (e.g., sanitation to address environmental pathogens in ready-to-eat foods if relevant), must

be documented in a Food Safety Plan. This is discussed further in Chapter 12: Sanitation Preventive Controls.

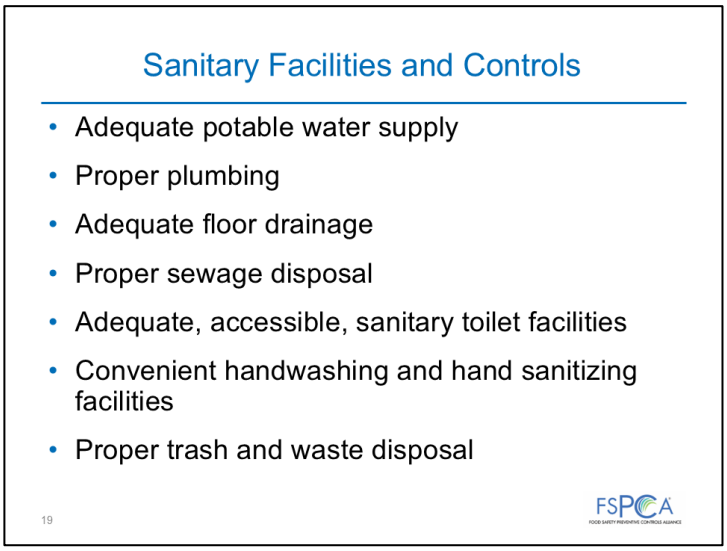
In addition to cleaning and sanitizing food-contact surfaces, non-food-contact surfaces must be cleaned and sanitized. Regular cleaning of non-food-contact surfaces is needed to maintain the overall sanitary environment. While non-food-contact surfaces do not normally require the sanitizing step for facilities that make ready-to-eat products which are exposed to the environment prior to packaging, cleaning, and sanitizing of certain non-food-contact surfaces may be included as a sanitation preventive control in a Food Safety Plan to minimize the potential for ready-to-eat food product contamination with environmental pathogens. This is discussed further in Chapter 12: Sanitation Preventive Controls. Additional information on general cleaning and sanitation is discussed in Appendix 5: Sanitation Basics, including information on potential spread of contamination by inappropriate use of high-pressure hoses through creation of aerosols.

Slide 18: What's Wrong with this Picture? Cleaning and Sanitation



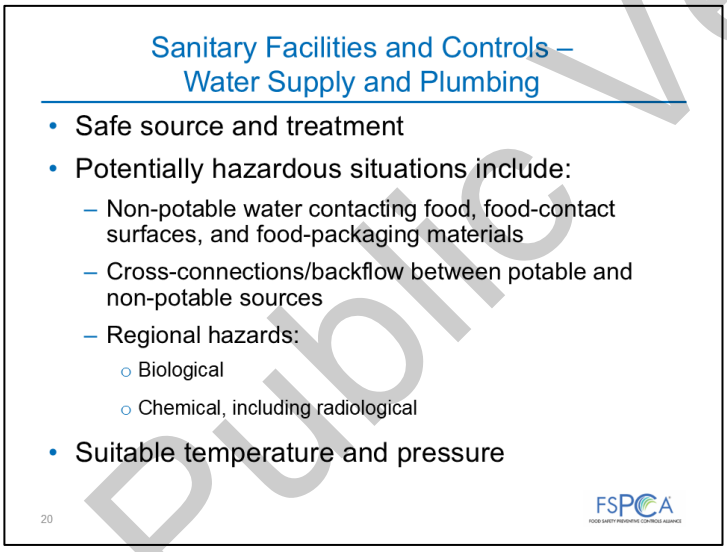
As shown on this slide, the employee is inappropriately cleaning his apron on the floor which could contaminate the apron with environmental pathogens. This creates a situation where the employee wearing the apron could contaminate food products with pathogens. Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real world examples.

Slide 19: Sanitary Facilities and Controls



Sanitary facilities and controls include the water supply, plumbing, drainage, sewage disposal, toilet facilities, handwashing facilities, and trash and waste disposal.

Slide 20: Sanitary Facilities and Controls – Water Supply and Plumbing



Definition: *Potable water*: Water that meets the standards for drinking purposes of the State or Local (county, city), Tribal, or Territorial authority having jurisdiction, or water that meets the standards prescribed by the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR Part 141).

Water that contacts food, food-contact surfaces, and food-packaging materials must be potable; that is, it must be safe and suitable for human consumption.

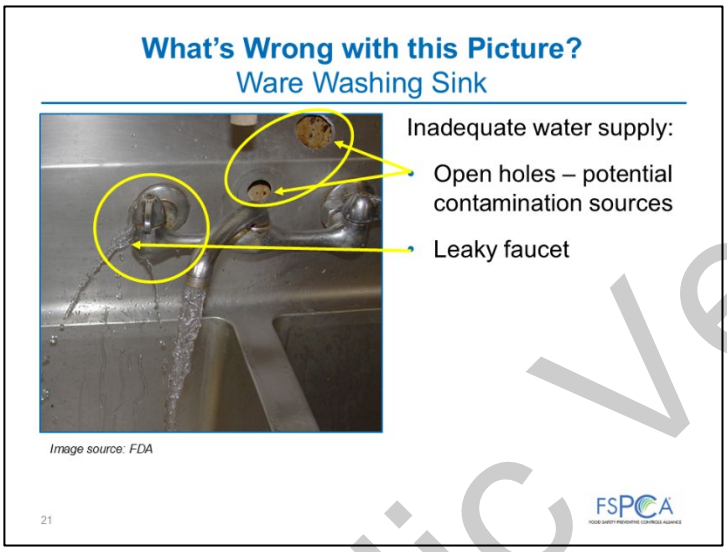
The water must come from a trusted safe source and the plumbing system must be designed and maintained to ensure its safety. In many regions, the local or regional water treatment authority is responsible for assuring the safety of the water source and conveyance to the building. In these situations, a food facility should maintain regular water quality tests from the water authority, at least annually. A food facility using a private water system (e.g., wells), is directly responsible for adequately monitoring the safety of the water source and should maintain documentation of actions taken, such as water quality test results. Municipalities in many regions can provide guidance.

Developed regions typically have mature water safety programs, while developing regions may not have uniform delivery of safe water supplies. Potential hazards and controls must be considered when water is used as an ingredient, for processing, or for cleaning purposes in a food facility.

To maintain safe water within the facility, cross-connections between potable and non-potable water lines must be prevented. There must be no cross-connection or backflow potential between the water supply and piping for wastewater or sewage.

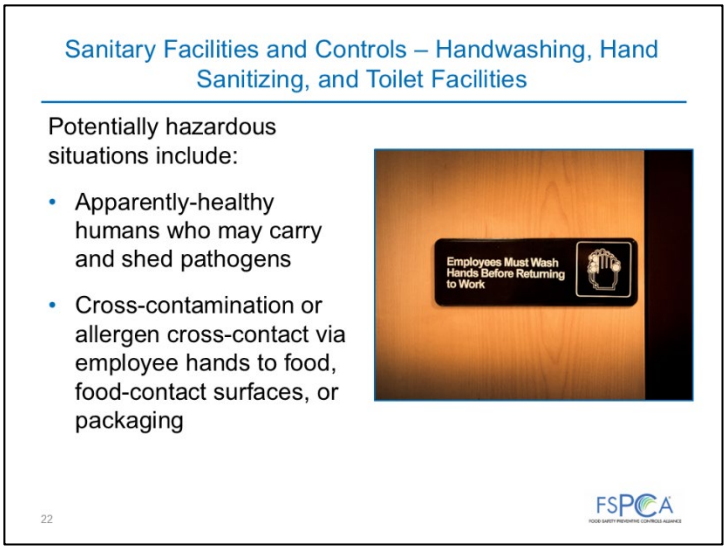
The temperature and pressure of the water must be suitable for the facility's use. For example, hot water may be needed for effective cleaning and sanitizing.

Slide 21: What's Wrong with this Picture? Ware Washing Sink



The leaking faucet with the exposed insulation shown in this slide could introduce microbial contaminates resulting in contamination of utensils and food-contact surfaces in addition to contaminating employees' hands. Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real-world examples.

Slide 22: Sanitary Facilities and Controls – Handwashing, Hand Sanitizing, and Toilet Facilities (1 of 2)

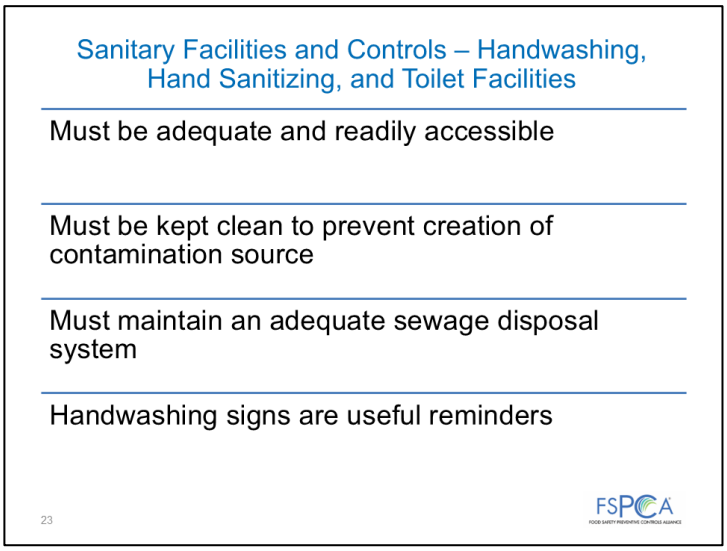


Employees' hands, as a source of contamination in food operation, requires ongoing attention. Improperly cleaned hands can contaminate food through transfer of pathogens from employees who are ill or may be shedding pathogens. Cross-contamination of pathogens from employees also could result from handling raw materials, rubbish/waste, and insanitary objects (e.g., water hose nozzle laying on floor, maintenance tools, or after using the toilet facilities).

In addition, improperly cleaned hands can result in cross-contact of food allergens from employees handling allergenic ingredients and insanitary objects (e.g., utensils, maintenance tools, etc. Proper handwashing by employees is essential for food safety).

Supervisors must enforce handwashing procedures to ensure that an employee's hands are not a source of contamination to food, food-contact surfaces, or food-packaging materials.

Slide 23: Sanitary Facilities and Controls – Handwashing, Hand Sanitizing, and Toilet Facilities (2 of 2)



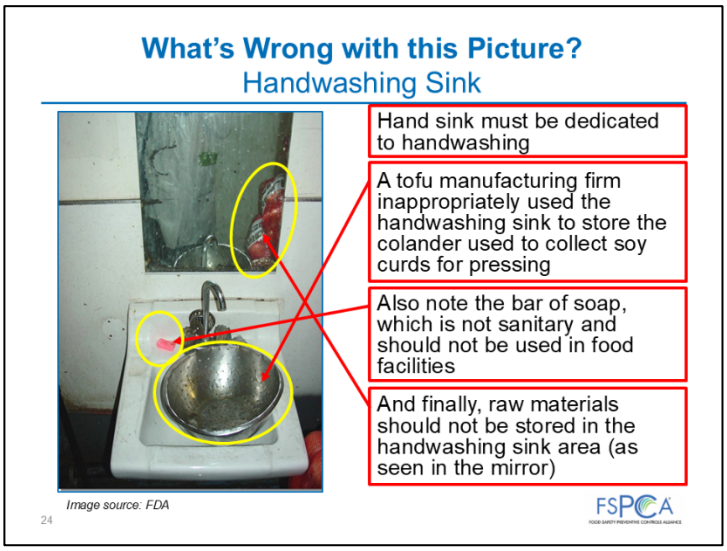
FDA current policy is that handwashing and hand sanitizing are necessary for those employees who handle ready-to-eat food, or food packaging materials or food-contact surfaces for ready-to-eat products

Each food facility must provide adequate handwashing and toilet facilities. Handwashing stations should be dedicated to handwashing only and provided in convenient locations, making them accessible and more likely to be used. Handwashing and, where appropriate, hand sanitizing facilities should be at each location where good sanitary practice requires hand hygiene. Effective hand hygiene training should be accompanied by available handwashing supplies that remove food soils from hands (e.g., soap, running water at a suitable temperature). At this time, there is no established regulatory requirement for water temperature except that the water should be warm. Single-use towels or suitable drying devices should be provided to prevent recontamination of employee hands. Wet hands are more prone to spreading contamination than dry hands. Handwashing signs are useful reminders of hand hygiene for employees.

Readily accessible toilet facilities must be maintained in sanitary condition and not be a source of contamination. Toilet facilities should be located away from food processing areas, whenever possible, and have self-closing doors that do not open directly into processing areas and have adequate signage. Additionally, toilet facilities should be in good repair (e.g., not leaking), and should be properly supplied with personal hygiene products, including handwashing supplies.

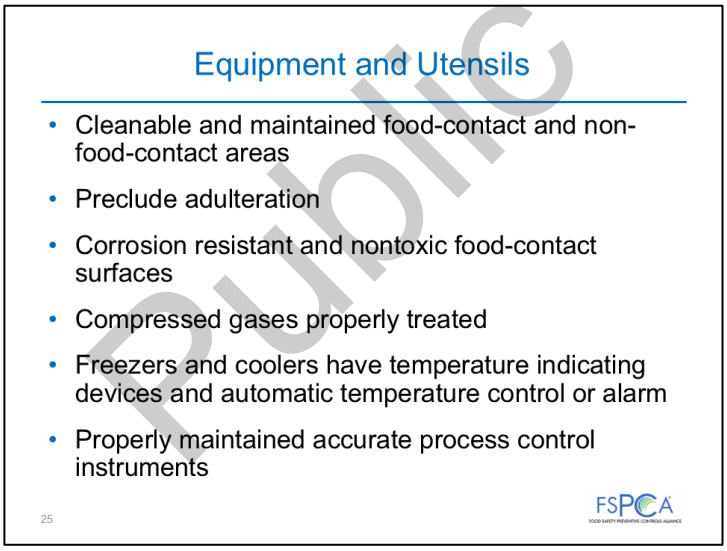
An adequate sewage disposal system is required. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming and attractant and harborage of pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

Slide 24: What's Wrong with this Picture? Handwashing Sink



The hand sink for employee handwashing as shown in this slide is not dedicated for handwashing only—it is also used for ware washing and storing raw materials. Ware washing and storing raw materials in an employee handwashing station as well as unclean soap could result in pathogen cross-contamination as well as allergen cross-contact. Slides like these are included to illustrate the general points regarding GMPs and prerequisite programs made with real-world examples.

Slide 25: Equipment and Utensils

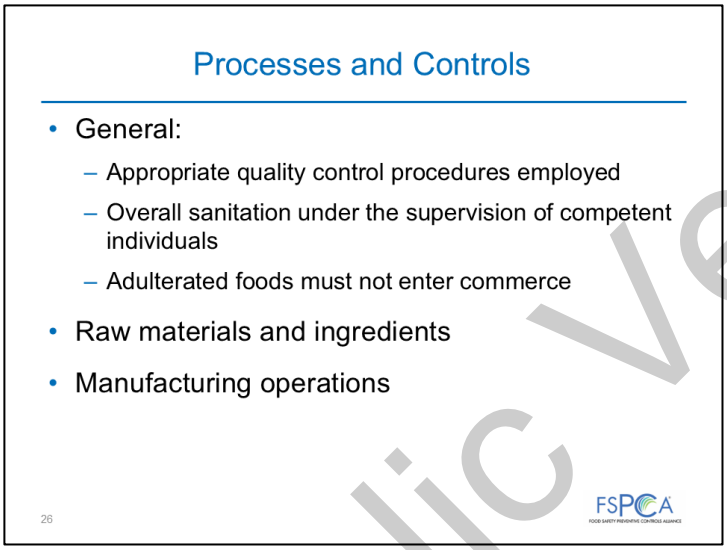


Equipment, including utensils, must be designed to be adequately cleaned and maintained in a sanitary condition. For example, food-contact surfaces must be made of corrosion-resistant and non-toxic materials to prevent the adulteration of food (e.g., lubricants, fuel, metal fragments, heavy metals). Seams on food-contact surfaces must be smoothly bonded or maintained to ensure cleanability and minimize accumulation of food particles and organic matter. Also, compressed air or other gases mechanically

introduced into food or used to clean food-contact surfaces must be treated in such a way that food is not contaminated with adulterants.

Instruments and controls used for measuring or recording temperatures, pH, acidity, water activity or other conditions that control or prevent growth of undesirable microorganisms in food must be accurate and precise and adequately maintained. For example, cooling equipment, such as freezers and coolers, must be equipped with temperature-indicating devices, such as thermometers or chart recorders. Automatic temperature controls or a temperature alarm system will help to ensure that the proper temperatures are maintained. Thermometers and similar temperature measuring equipment must be accurate (close to the correct measure), precise (appropriately narrow +/- range) and maintained in good operating condition.

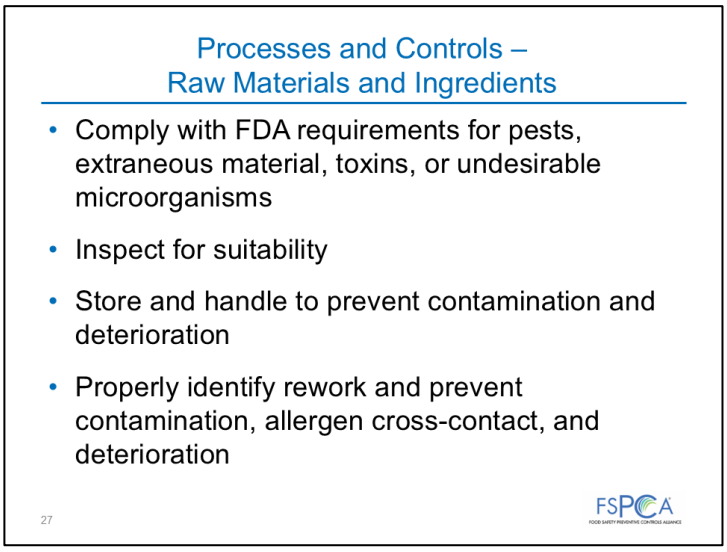
Slide 26: Processes and Controls



Processes and controls used for food must ensure that the food remains suitable for human consumption. This provision of the GMPs identifies general and more specific requirements for raw materials, ingredients, rework, and manufacturing operations. Adequate precautions must be taken to ensure and verify that processing steps do not contribute to microbial, extraneous-material, and chemical contamination including allergen cross-contact or pathogen contamination.

Appropriate quality control procedures are required to assure operational controls are successful. Some tasks may require special oversight. For example, overall sanitation of the facility must be supervised by qualified individuals who understand what it takes to maintain appropriate sanitary conditions in a food facility.

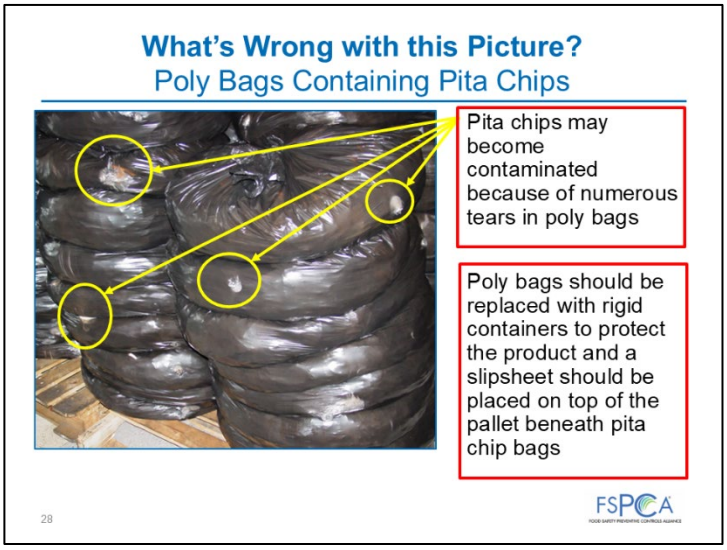
Slide 27: Processes and Controls – Raw Materials and Ingredients



Raw materials must be free from pests, extraneous material (e.g., string, plastic, metal, etc.), chemical contaminants such as mycotoxins, and undesirable microorganisms. A food facility is responsible for assuring safe raw materials using techniques appropriate for the specific material and source. Raw materials must be inspected for suitability. They must be stored and handled to prevent contamination (e.g., properly packaged), and deterioration (e.g., appropriate time, temperature, and humidity conditions). The requirement to prevent contamination during ingredient handling also applies to thawing activities when used in the process. If rework is used, a facility must ensure that it is properly identified, stored, and handled to prevent contamination, allergen cross-contact, and deterioration.

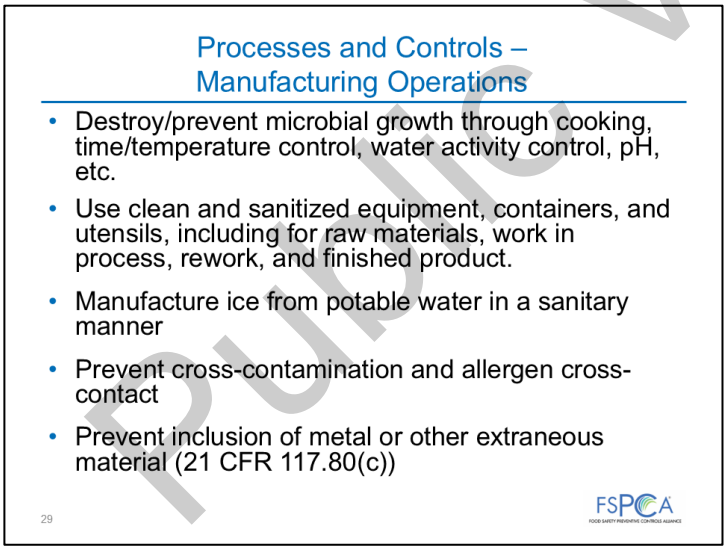
All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, the FDA may allow the food to be treated or processed to eliminate the contamination (see 21 CFR 117.80(a)(6)).

Slide 28: What's Wrong with this Picture? Poly Bags Containing Pita Chips



The ready-to-eat pita chips shown in this slide are not properly packaged or stored in appropriate bags to minimize contamination from the environment. Slides like these are included to illustrate the general points made regarding GMPs and prerequisite programs with real world examples.

Slide 29: Processes and Controls – Manufacturing Operations



All food manufacturing operations must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

Measures taken to destroy or prevent the growth of undesirable microorganisms such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated. For example, the use of time and temperature combinations that kill pathogens of concern during

pasteurization and cooking, or that prevent the growth of microorganisms during cooling in refrigeration and freezing processes are essential for food safety. Rapid cooling or further processing without delay of blanched foods is necessary to prevent microbial growth. Certain bacteria, called thermophiles (thermo=heat, phile=loving), can grow at warm to hot temperatures. Minimizing thermophile growth can be achieved through proper temperature control of the food product and timely cleaning of the food-contact surfaces. Certain moist foods such as batters, breading, sauces, gravies, and stuffing can support rapid growth of microorganisms. High moisture foods must be protected from contamination and bacterial growth through the use of quality ingredients, heat treatment, time/temperature controls, and physical protection such as covers. Conversely, dry foods that depend on reduced water activity to control microbial growth must have parameters (e.g., soluble solids/water ratio or water activity), monitored to assure that growth will be prevented and then must be protected from moisture pickup. Factors that influence microbial growth are discussed in more detail in Chapter 3: Biological Food Safety Hazards.

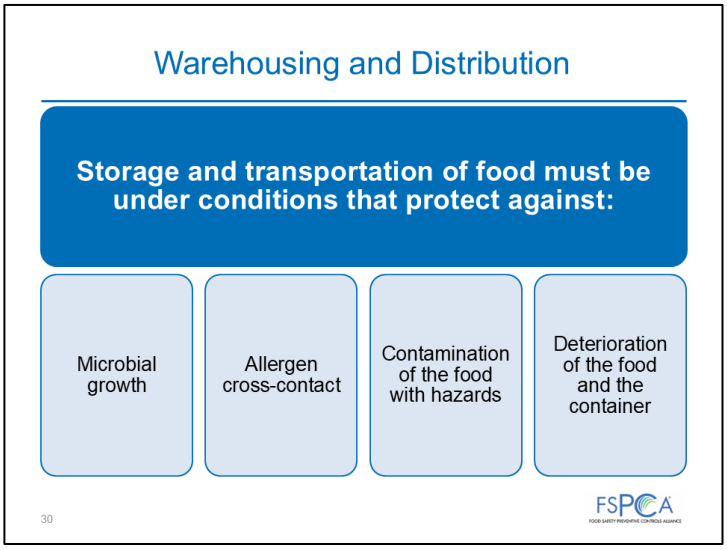
Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or food products must be constructed, handled, maintained, and cleaned in a manner that protects against allergen cross-contact and against contamination. Equipment, containers, and utensils must be cleaned and sanitized as necessary to ensure they do not become the source of contamination. This may require disassembly of equipment to facilitate cleaning.

When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with 21 CFR 117.37(a) as discussed on an earlier slide in this chapter. Ice machines, like other food processing equipment, should be cleaned and sanitized periodically.

Effective measures must be taken to protect food products from allergen cross-contact and from contamination by raw materials or refuse. Exposed food on conveyors in the ambient environment, as well as in freezers and coolers must also be protected from potential contamination sources.

Adequate measures must be taken to protect against the inclusion of metal or other extraneous matter in food products. The use of sieves, magnets, and metal detectors can be useful to prevent inclusion of metal and extraneous material, or to detect metal if such contamination does occur.

Slide 30: Warehousing and Distribution



Sanitary conditions apply not only to manufacturing areas, but also to warehousing and distribution facilities. Microbial growth of pathogens must be prevented. Allergen cross-contact must also be prevented. GMPs require that food is protected from biological, chemical (including radiological), and physical hazards, as well as from deterioration during warehousing and distribution.

Slide 31: Holding of Human Food By-Product

FDA Guidance Human Food By-Products for Use as Animal Food

Food companies often send unusable human food or human food by-product materials to the animal food supply-chain. Food may be unsalable to humans for quality or safety reasons but could be safe (or made safe) for animals to consume. By-products might be sent to animal feed converters, manufacturers, wholesalers, or directly to animal producers. Products may be fed directly to animals or, if necessary, processed to mitigate any hazards. Some examples of human food by-products used for animal food include:

- Wheat middlings, which are generated while processing wheat for flour;
- Grain products (hulls, bran, germ, gluten meal, grits, and meals) from other grain processing operations;
- Peels, rinds, pomace, pulp, culls, or other similar material generated from processing fruits or vegetables for human consumption; and
- Human food such as potato chips, cookies, bread, pastry products, and pasta that is not adulterated and is safe for use as animal food but is not acceptable as human food for quality reasons such as the wrong size, shape, color, or texture.
- Human food and human food by-products held and sent to the animal food supply-chain in general are not subject to the requirements for Hazard Analysis and Risk-based Preventive Controls for Animal Food but must comply with specific holding and distribution GMPs to keep the by-product safe (21 CFR 117.95 and 21 CFR 507.28).

Requirements are as follows:

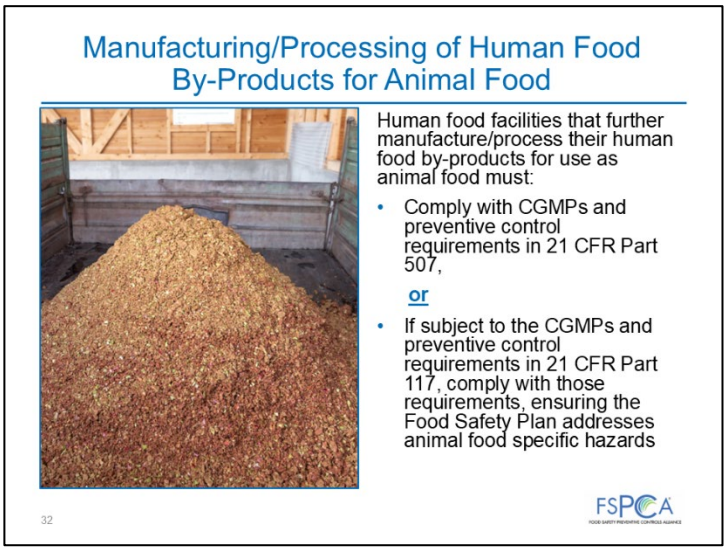
(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and

(3) During holding, human food by-products for use as animal food must be accurately identified.

- Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.
- Shipping containers (e.g., totes, drums, and tubs), and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

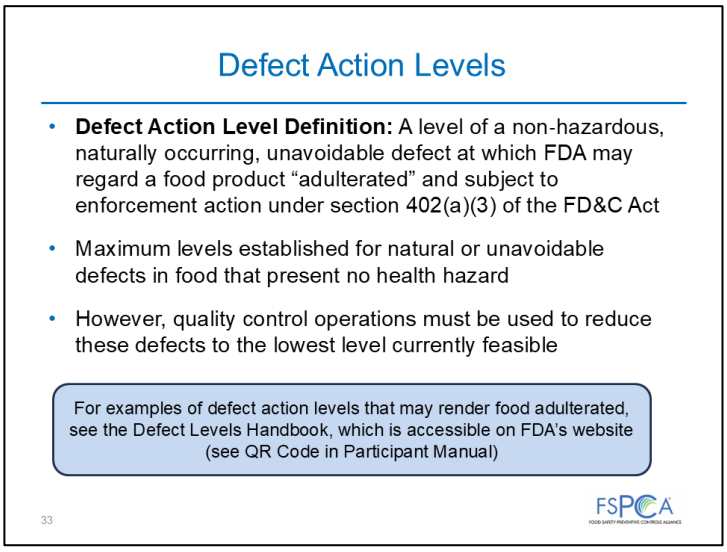
Slide 32: Manufacturing/Processing of Human Food By-Products for Animal Food



In general, human food facilities that further manufacture/process human food by-products for use as animal food must comply with the Preventive Controls for Animal Food regulation in 21 CFR Part 507. However, human food facilities can choose to follow either the human food CGMP and preventive controls requirements in 21 CFR Part 117, or the animal food CGMPs and preventive controls requirements in Part 507. If the human food facility chooses to follow the requirements in 21 CFR Part 117 for their animal food, the Food Safety Plan for that food must address hazards associated with the animal food, such as nutrient deficiencies or toxicities for the intended animal species.

Note: If the human food facility is exempt from the preventive controls requirements (e.g., the food handling is regulated under seafood HACCP but is subject to the preventive controls requirements in 21 CFR Part 507), the facility must follow the preventive controls requirements in 21 CFR Part 507 for the further manufacturing/processing, packing, or holding of the food for animals.

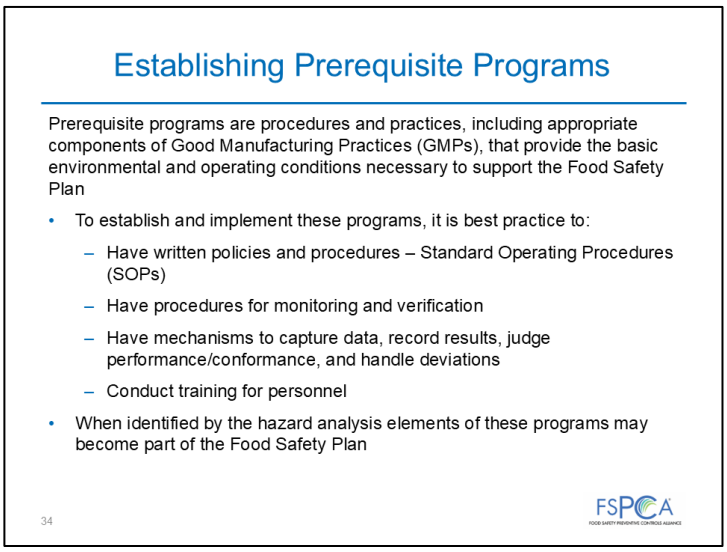
Slide 33: Defect Action Levels



Defect Levels Handbook

Even when produced under GMPs, some foods contain natural or unavoidable defects that do not present a hazard to health. The FDA set these action levels because it is economically impractical to grow, harvest or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects. FDA establishes maximum levels for these defects and will use these levels when deciding whether to recommend regulatory action. The manufacturer is still responsible for managing these defects and trying to keep them to the lowest level currently feasible. For example, a few pit fragments in pitted dates, olives and prunes may be considered unavoidable, even when in compliance with GMPs. However, the mixing of food containing defects above the defect action level with another lot of food with low levels is not permitted. In this circumstance, the entire batch would be considered adulterated regardless of the level present.

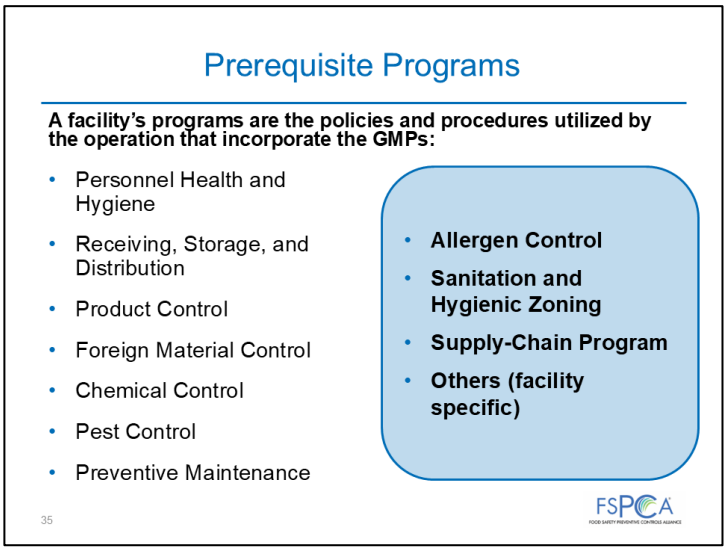
Slide 34: Establishing Prerequisite Programs



Prerequisite programs are the facility's policies and procedures or a set of procedures (SOPs or Standard Operating Procedures) that incorporate Good Manufacturing Practices to provide the basic environmental and operating conditions for a food facility to produce safe and wholesome food. These programs work in conjunction with the facilities Food Safety Plan(s) and in some cases, can become a component within the Food Safety Plan.

It is common industry practice for prerequisite programs to be written, monitored, and verified to be most effective. Recording data about and reviewing results of prerequisite programs can allow food facility performance to be measured and the ability to react to deviations from program standards if they occur. If identified in the hazard analysis, certain prerequisite programs could be elevated to be part of a Food Safety Plan.

Slide 35: Prerequisite Programs



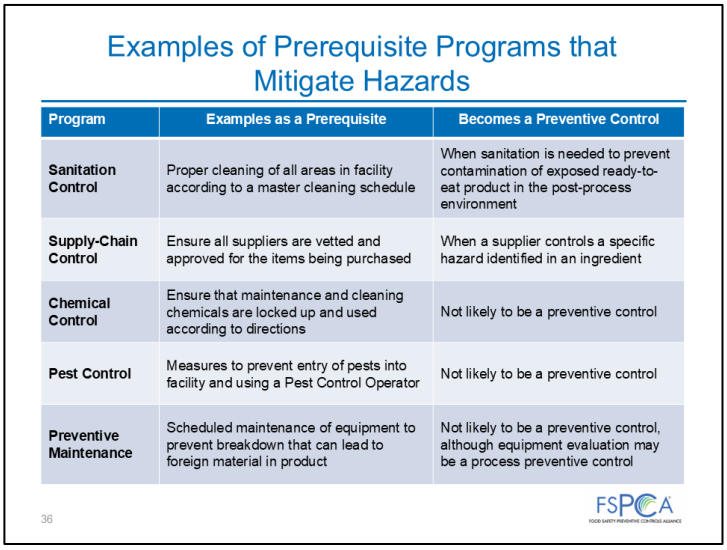
Portions of the programs highlighted in the blue rectangle box (allergen control, sanitation control, supply-chain program, and possibly others that are facility-specific) become preventive controls based upon the outcome of the hazard analysis.

A facility will normally employ some form of the listed prerequisite programs as part of their food safety system. These programs integrate the GMPs into actionable procedures that address areas such as personnel health and hygiene, receiving and distribution, etc.

As previously stated, some of these programs are likely to have components that integrate into the company's Food Safety Plan, and in some cases, can become preventive control components.

It is important to clarify that this is not a comprehensive list but rather common programs that are widely implemented by the food industry. There may be others that are specific to the facility.

Slide 36: Examples of Prerequisite Programs that Mitigate Hazards



Examples of Prerequisite Programs that Mitigate Hazards

Program	Examples as a Prerequisite	Becomes a Preventive Control
Sanitation Control	Proper cleaning of all areas in facility according to a master cleaning schedule	When sanitation is needed to prevent contamination of exposed ready-to-eat product in the post-process environment
Supply-Chain Control	Ensure all suppliers are vetted and approved for the items being purchased	When a supplier controls a specific hazard identified in an ingredient
Chemical Control	Ensure that maintenance and cleaning chemicals are locked up and used according to directions	Not likely to be a preventive control
Pest Control	Measures to prevent entry of pests into facility and using a Pest Control Operator	Not likely to be a preventive control
Preventive Maintenance	Scheduled maintenance of equipment to prevent breakdown that can lead to foreign material in product	Not likely to be a preventive control, although equipment evaluation may be a process preventive control

36

FSPCA

There are cases where prerequisite programs may be elevated to preventive controls based on the Hazard Analysis and these cases are specific to situations in the facility.

Sanitation aimed at the proper cleaning of all areas of the facility such as a master cleaning schedule would be a prerequisite program. However, specific elements of the cleaning process may become a preventive control when they are needed to ensure the absence of biological hazards (environmental pathogens) in an area of the facility where ready-to-eat foods are exposed to the environment post-process before packaging and therefore are susceptible to contamination. When equipment cleaning is necessary to prevent allergen cross-contact from allergens contained in a preceding product, cleaning procedures may also become a preventive control.

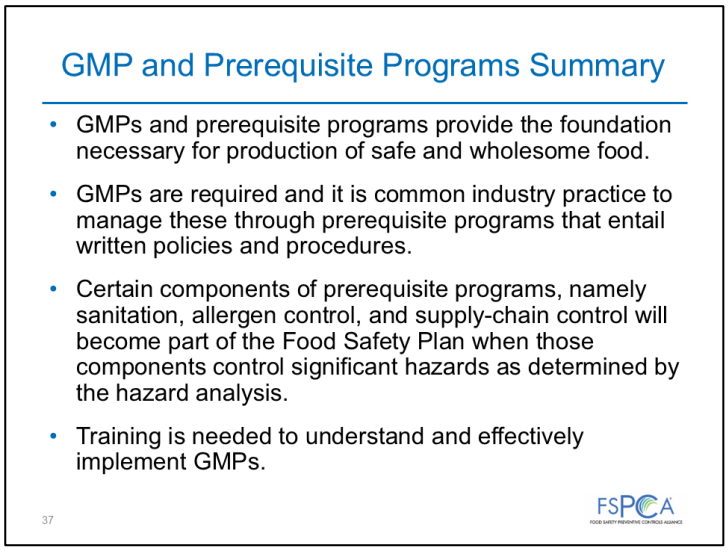
Controls to ensure that all suppliers are evaluated and approved for all purchased ingredients or raw materials is a prerequisite program. When a supplier controls a specific hazard in an ingredient they supply (e.g., roasting nuts in a validated process), specific supplier control elements may become a preventive control.

Chemical controls are typically prerequisite programs that are focused on proper storage, labeling, and use of chemical products. These types of controls are less likely to become a preventive control.

Likewise, pest control such as contracting with a professional pest control operator to prevent entry of pests into the facility is a prerequisite program and is unlikely to be elevated to a preventive control.

Preventive maintenance systems including performing scheduled fixes on equipment to prevent breakdowns or deterioration that could lead to foreign material in product is considered a prerequisite program. While is unlikely that preventive maintenance would become a preventive control, the evaluation of specific equipment (e.g., inspecting blades on a grinder), might become a preventive control.

Slide 37: GMP and Prerequisite Programs Summary



"PCHF Food Facility Type and Applicable Regulations Table" (Form_0064): *On FSPCA's website, click on the PC Human Food tab drop down menu, select "Preventive Controls Qualified Individual," scroll over and click on "Materials and Resources, and then click on "PCHF Food Facility Type and Applicable Regulations Table" under "Additional Resources" near the bottom of the web page.*

Good Manufacturing Practices and prerequisite programs must be in place to provide a solid foundation for a Food Safety Plan.

These programs establish the foundation for effectively implementing the food safety system. GMPs are required by regulation, and most elements are managed as prerequisite programs to support a Food Safety Plan. GMPs are implemented by workers, frequently through written instructions such as SOPs. The course provided a brief overview of GMPs. Because all GMPs are required, additional training or in-depth reading of the GMP regulations is important to ensure that the specific requirements are addressed.

This course cannot discuss all prerequisite programs in detail. Depending on the product and/or business, there may be additional programs to consider and implement.

Slide 38: Knowledge Check 1

Participants do NOT have this slide.

Slide 39: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

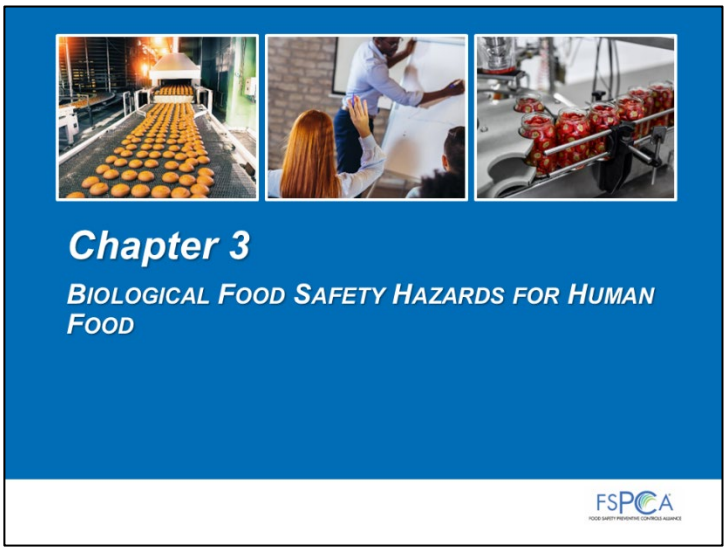
FSPCA's FORM_0064: PCHF Food Facility Type and Applicable Regulations Table: https://www.fspca.net/_files/ugd/38787b_36aaa0cf07814867a0c74a2257cccc1a.pdf

FDA Data Dashboard: https://datadashboard.fda.gov/ora/index.htm

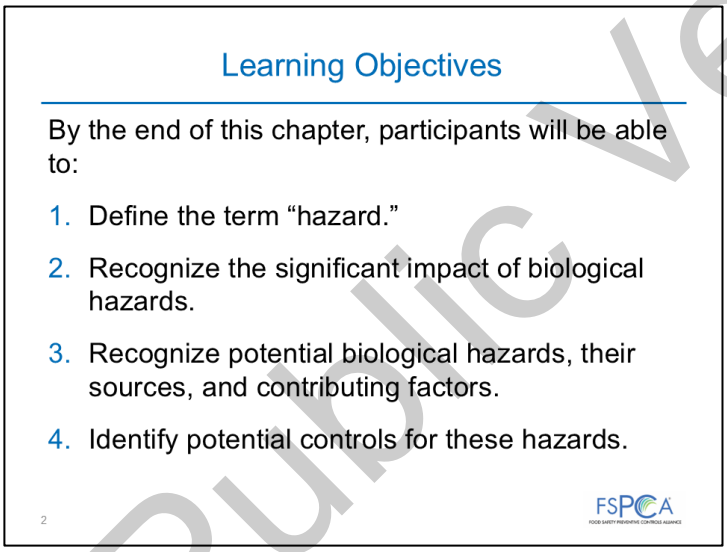
FDA Food Defect Levels Handbook: https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook

FDA Guidance Human Food By-Products for Use as Animal Food: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-239-human-food-products-use-animal-food

Slide 1: Chapter 3: Biological Food Safety Hazards for Human Food

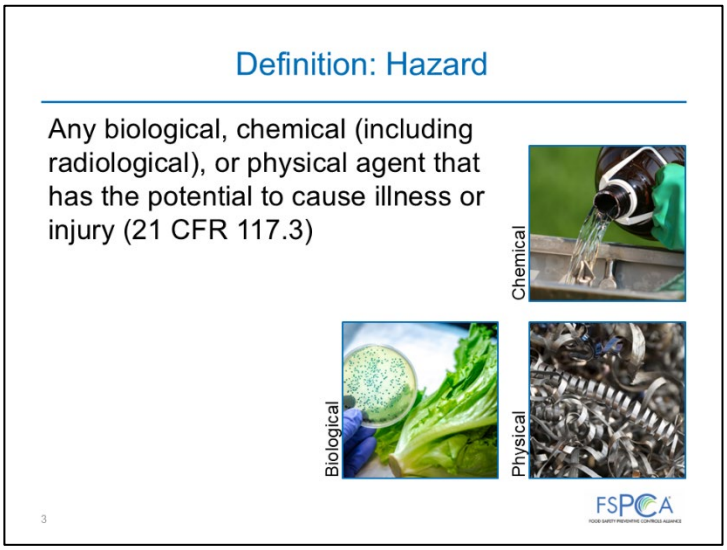


Slide 2: Learning Objectives



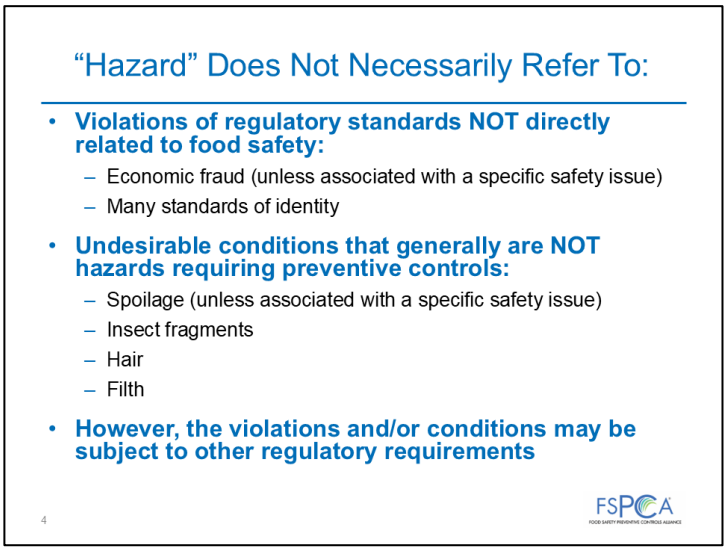
In developing or modifying a Food Safety Plan, it is important to be aware of the potential hazards that are associated with the food products and processes under consideration. When hazards are understood, preventive measures can be implemented to control those hazards, thus preventing illness or injury. This chapter introduces the definition of the term "hazard," discusses biological hazards that are commonly of concern in food processing plants and facilities holding food products, and reviews potential controls for biological hazards.

Slide 3: Definition: Hazard



The Preventive Controls for Human Food regulation defines hazard as "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury." Biological hazards include pathogenic bacteria, viruses, and parasites. Chapter 4: Chemical, Physical, and Economically Motivated Hazards covers chemical (including radiological) and physical hazards mentioned in the definition. Information from this chapter on biological hazards and Chapter 4 on chemical, physical, and economically motivated hazards is useful for conducting a hazard analysis for a food, to determine which hazards will require a preventive control. The hazard analysis process is discussed in Chapter 6: Hazard Analysis, and Chapter 7: Preventive Controls Determination.

Slide 4: "Hazard" Does Not Necessarily Refer To:



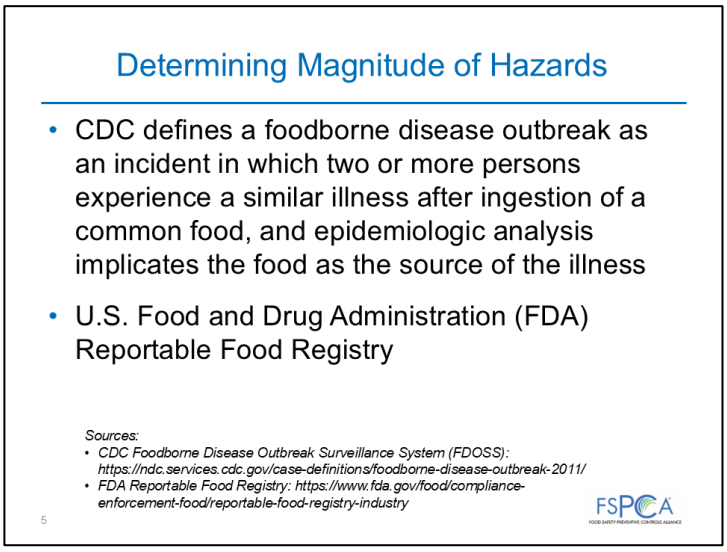
The terms filth, foreign material, or extraneous material can be used interchangeably. The terms refer to any type of matter that does not obviously belong in a food product.

– Adapted from FDA's ORA Lab Manual, (Section 4)

It is important to understand that, for the purposes of food safety, the term "hazard" refers only to the conditions or contaminants in food that have the potential to cause illness or injury to people. Many conditions are highly undesirable in food, such as the presence of insects, hair, filth, or spoilage. Economic fraud and violations of regulatory food standards are also undesirable. All of these defect conditions should be controlled in food processing; however, many times they are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a Food Safety Plan. The Preventive Controls for Human Food regulation does consider decomposition to be a potential food safety hazard when biogenic amines or other toxic substances are produced that may cause illness or injury.

How a hazard is addressed in a Food Safety Plan depends on both the likelihood of its occurrence in the absence of its control, and in the severity of the illness or injury that would result if the food were consumed. The difference between a known or reasonably foreseeable hazard and a hazard requiring a preventive control is explained in Chapter 6: Hazard Analysis for Human Food. The current chapter provides a general discussion of potential biological hazards in food products.

Slide 5: Determining Magnitude of Hazards

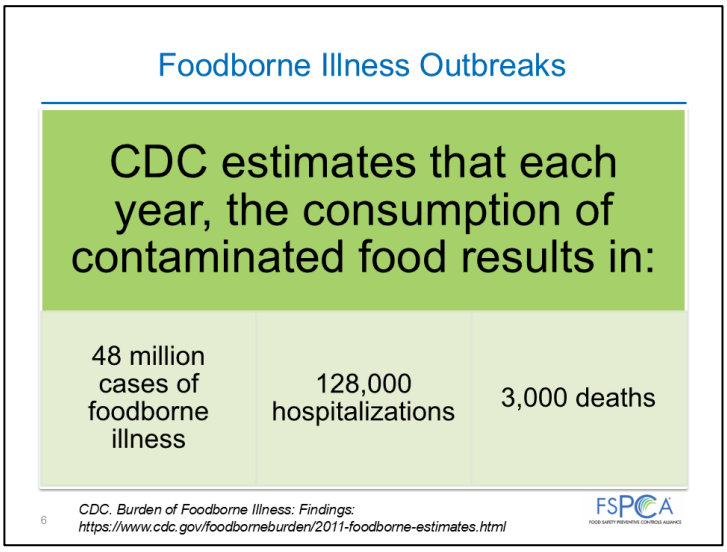


FDA Reportable Food Registry (RFR) for Industry

To gain an understanding of the issues related to hazards encountered in the food supply-chain in terms of size and scope, two governmental reporting systems are commonly used. The United States Centers for Disease Control and Prevention (CDC) reports outbreak data that provides information on those hazards responsible for foodborne illness cases. CDC defines a foodborne disease outbreak as an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness.

The other source for understanding the issues of hazards specific to product types encountered in food supply-chain is FDA's Reportable Food Registry. The Reportable Food Registry (RFR or the Registry) is an electronic portal for industry to report when there is a reasonable probability that an article of food will cause serious adverse health consequences in humans or animals. Foods listed in the Reportable Food Registry are examples of food products and hazards that can cause serious adverse health consequences or death to humans or animals. The Registry helps the FDA better protect public health by enabling the tracking of patterns and targeting inspectional resources.

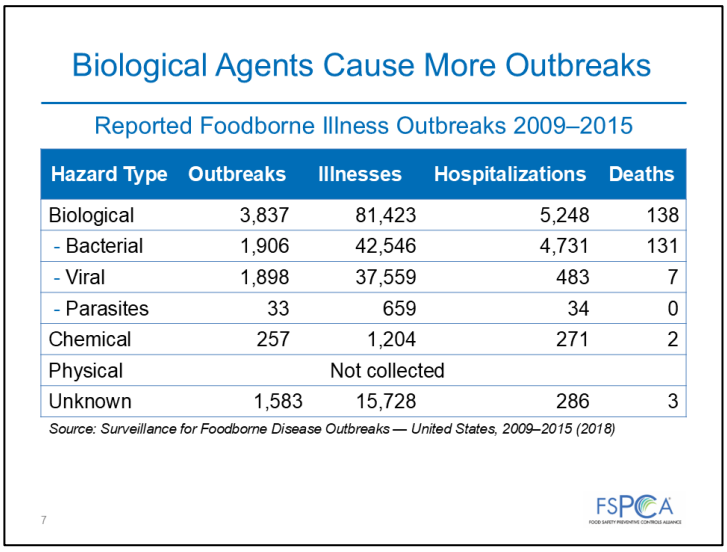
Slide 6: Foodborne Illness Outbreaks



Published in 2011, the CDC's estimates of the burden of foodborne illness in the United States provide the most accurate picture of known pathogens and unspecified agents causing foodborne illness in the United States. These estimates serve as a foundation for food safety by answering the important question of, "How many foodborne illnesses occur every year?" These estimates are known as the burden of foodborne illness.

Note that the data may be updated in the future as CDC re-assesses estimates.

Slide 7: Biological Agents Cause More Outbreaks



Biological Agents Cause More Outbreaks

Reported Foodborne Illness Outbreaks 2009–2015

Hazard Type	Outbreaks	Illnesses	Hospitalizations	Deaths
Biological	3,837	81,423	5,248	138
- Bacterial	1,906	42,546	4,731	131
- Viral	1,898	37,559	483	7
- Parasites	33	659	34	0
Chemical	257	1,204	271	2
Physical		Not collected		
Unknown	1,583	15,728	286	3

Source: Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015 (2018)

7

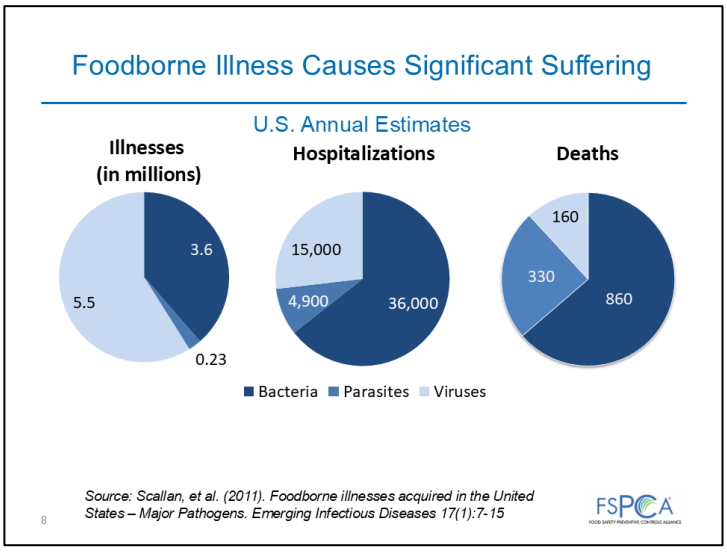
FSPCA

CDC surveillance data include confirmed and suspected foodborne illnesses that are reported by states. These numbers are just the tip of the iceberg and do not include adjustment factors for under reporting.

The Centers for Disease Control and Prevention (CDC) surveillance data on foodborne disease outbreaks (i.e., two or more persons experience a similar illness after ingestion of a common food), are illustrated above. The number of illnesses reported is just the "tip of the iceberg" because many foodborne illnesses are not reported to CDC, however, the data is useful in understanding the types of hazards that are likely to cause illness.

Biological hazards, including pathogenic bacteria, viruses, and parasites, are the most frequently reported hazard group associated with foodborne illness in the United States. Chemical agents are also reported, but as shown on the slide, reported numbers are much lower than those for biological hazards. Food allergen reactions may not be captured in the CDC data because an "outbreak" requires two (2) or more people from separate households to be ill from the common food, but allergenic reactions are sporadic and likely involving only one person at a time. CDC surveillance systems do not report physical hazard outbreaks.

Slide 8: Foodborne Illness Causes Significant Suffering



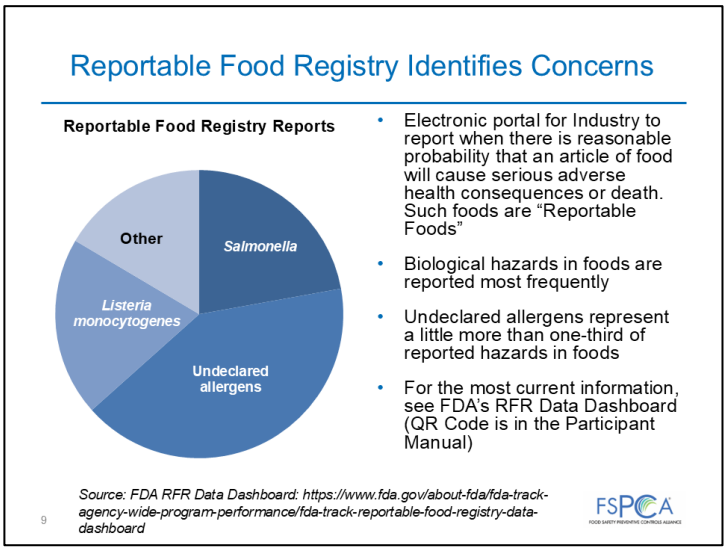
Pathogenic bacteria, parasites, and viruses are different kinds of biological hazards. Control strategies are discussed later.

The impact on human health from food contamination varies with the type of agent. While viruses and bacteria are the most common foodborne pathogens, outbreaks associated with viruses such as Norovirus, tend to be large, often due to the nature of how the virus spreads. However, the resulting illness is less likely to result in hospitalizations or death. Outbreaks associated with bacterial pathogens tend to be more serious in terms of human health impact. Parasitic infections seldom occur, but when they do, their impact is serious.

Estimates of foodborne illness can be used to prioritize food safety policy and interventions. Scallan, et al., used data from active and passive surveillance and other sources to estimate that each year, 31 major pathogens acquired in the United States caused 9.4 million episodes of foodborne illness, 55,961 hospitalizations and 1,351 deaths.

The goal of the hazard analysis, to be discussed further in Chapter 6, is to identify what biological hazards can be introduced into a food product from ingredients and other raw materials, from food processing equipment and the facility environment used to make the final product, and from people handling the product during harvesting or processing. Once identified, the Food Safety Team will evaluate those hazards and determine which hazards will require a preventive control.

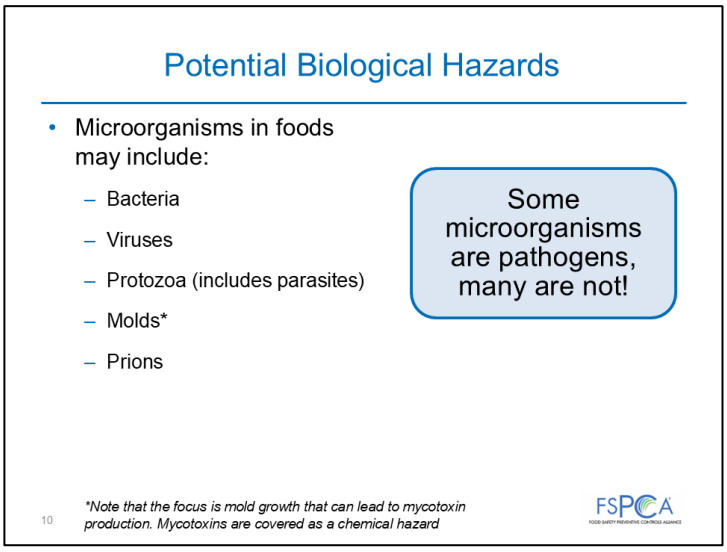
Slide 9: Reportable Food Registry Identifies Concerns



FDA RFR Data Dashboard

As discussed earlier, a useful source of information on the hazards that may be present in different foods is FDA's Reportable Food Registry (see Additional Reading at the end of the chapter). This registry collects information from the food industry and from public health authorities on foods and feed that are likely to cause serious adverse health consequences or death to humans or animals if they are used. As shown in the pie chart on the slides, biological hazards represent the primary category of hazards reported through the registry for human food. However, undeclared allergens in human food represent more than one third of the reports. These are discussed in Chapter 4: Chemical, Physical, and Economically Motivated Hazards.

Slide 10: Potential Biological Hazards



Definition: *Pathogen:* A microorganism of public health significance. (21 CFR 117.3)

In this course, the term is generally used to refer to microorganisms that cause illness through the consumption of food.

Microorganisms are living life forms that are too small to see with the human eye. Microorganisms are present in air, dirt, water, skin, hair, plants and numerous other sources like saliva and air expelled with coughs and sneezes. Microorganisms are classified into various groups including bacteria, viruses, protozoa, and molds.

Many microorganisms are beneficial. Certain kinds of molds and/or bacteria help make cheese, sour cream, yogurt, sausage, pickles, sauerkraut, and other fermented products. These microorganisms are intentionally added to foods, and they cause no harm. People come into contact with thousands of kinds of molds and bacteria, viruses, and protozoa daily with no ill effect. In fact, bacteria live naturally on our skin, in human noses, mouths and in the digestive tract. They play an important role in digesting food and are part of a healthy human system.

The focus is on those specific microorganisms considered biological hazards in food because they can cause illness and injury. There are more than 30 different known foodborne pathogens. This includes types among the groups of bacteria, viruses, and parasites.

Some molds produce hazardous toxins called mycotoxins, which are considered chemical hazards in this course (See Chapter 4: Chemical, Physical, and Economically Motivated Food Safety Hazards).

Prions are typically considered a biological hazard and are proteins that can cause "mad cow disease" (or in technical terms, bovine spongiform encephalopathy, or BSE) and similar diseases in other animals including certain types of game. Prions are not covered in this course but see the FDA's Bad Bug Book listed in "Additional Reading" for more information applicable to a facility processing game animals under FDA authority.

Slide 11: Understanding Food Contamination (1 of 2)

The reality is that foods can become contaminated anywhere along the food supply-chain, so controls may be needed at multiple points.

Sources of biological hazards include:

- Supplier level – Ingredients that may be contaminated from the field during growing and harvesting or at the supplier's processing facility.
- During transportation – Pest contamination during transport can introduce microorganisms.
- During processing – Cross-contamination of equipment and/or the environment if they are not cleaned and sanitized properly.
- From personnel – People handling food.

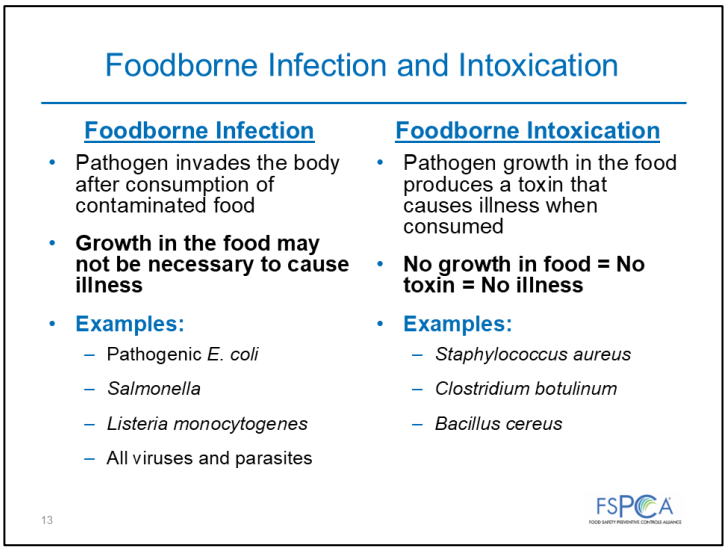
Foodborne illness can occur when there is the lack of control at these points.

Slide 12: Understanding Food Contamination (2 of 2)

As mentioned, lack of control at specific points in the food supply-chain can result in contaminated food. Two important categories of food that will have specific controls are 1) those foods that support the growth or survival of pathogenic organisms; and 2) those foods that are considered ready-to-eat.

Foods that support the growth or survival of pathogenic microorganisms will need controls such as time-and-temperature control to limit pathogen growth if present in the product. In the latter, ready-to-eat foods will be consumed without any further preparation by the consumer, so any pathogens present on the product will be consumed along with the product.

Slide 13: Foodborne Infection and Intoxications



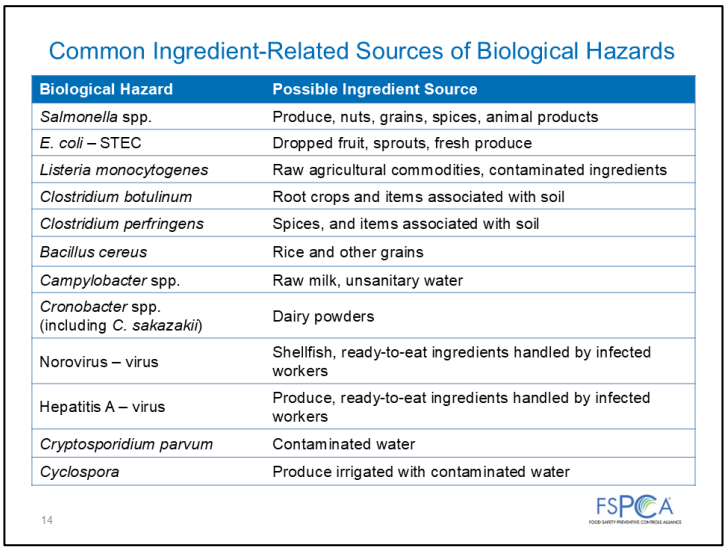
Foodborne pathogens may cause illness in humans by either infection or intoxication after the food is eaten.

Foodborne infections are caused after consuming live pathogens from contaminated food which then grow in the human body, usually in the intestinal tract, and cause illness. Because growth in the body is required for an infection, considerable time can pass before symptoms occur—typically between 24-72 hours but sometimes even longer (e.g. weeks). Viruses, parasites, and many bacteria in food can cause foodborne infections. It is important to note that growth in food may not be necessary to cause illness. For example, some infectious bacteria, such as *E. coli* O157:H7, can present a potential hazard simply due to its presence in the food when consumed, whereas other bacterial pathogens require growth to a level that can make people ill. The specific symptoms depend on the pathogen and the susceptibility of the person eating the food, and can include nausea, vomiting, diarrhea, and sometimes fever. Illness can sometimes lead to hospitalization and even death.

Foodborne intoxication is caused by consuming foods with pre-formed toxins produced by high numbers of certain bacteria (e.g., *Staphylococcus aureus, Clostridium botulinum* and certain strains *Bacillus cereus)*. Symptoms from foodborne intoxication usually occur more rapidly than those from a foodborne infection, and illness can occur as soon as a few hours after consumption. Restricting growth of toxin-forming pathogens in food will prevent the risk of foodborne intoxication. If toxins are in food, reheating the food will not necessarily inactivate the toxin and make the food safe.

See Appendix 4: Foodborne Pathogen Supplementary Information for information on different foodborne pathogens, including symptoms, and parameters that can control growth.

Slide 14: Common Ingredient-Related Sources of Biological Hazards



Common Ingredient-Related Sources of Biological Hazards

Biological Hazard	Possible Ingredient Source
Salmonella spp.	Produce, nuts, grains, spices, animal products
E. coli – STEC	Dropped fruit, sprouts, fresh produce
Listeria monocytogenes	Raw agricultural commodities, contaminated ingredients
Clostridium botulinum	Root crops and items associated with soil
Clostridium perfringens	Spices, and items associated with soil
Bacillus cereus	Rice and other grains
Campylobacter spp.	Raw milk, unsanitary water
Cronobacter spp. (including *C. sakazakii*)	Dairy powders
Norovirus – virus	Shellfish, ready-to-eat ingredients handled by infected workers
Hepatitis A – virus	Produce, ready-to-eat ingredients handled by infected workers
Cryptosporidium parvum	Contaminated water
Cyclospora	Produce irrigated with contaminated water

14

FSPCA

The table on the slide lists examples of common biological hazards and in what foods they are found most frequently. Note this table of common sources of biological hazards is not an exhaustive list and provides only broad discussion groups.

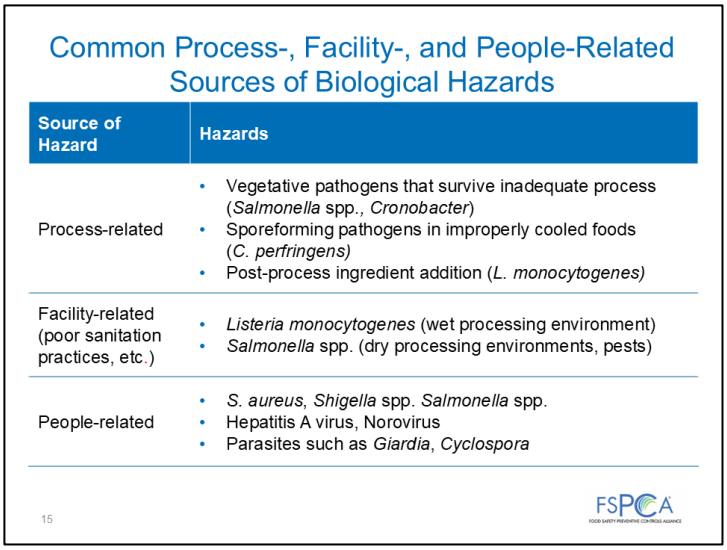
The biological hazards are bacterial pathogens (e.g., *Salmonella* spp., *Listeria monocytogenes*, *Clostridium botulinum*, and Shiga-toxin producing *Escherichia coli* (STEC) such as O157:H7), that may be associated with foods that can cause consumer illness or disease.

Cronobacter spp. (including *C. sakazakii*) has emerged more recently as a hazard largely for powdered infant formula rather than a hazard applicable to foods for the general population. It can survive in dry environments. Note that infant formula is covered under the Preventive Controls for Human Food regulation in addition to 21 CFR Part 106 and Part 107.

The other biological hazards, viruses (e.g., Norovirus and Hepatitis A), and parasites (e.g., *Cryptosporidium* spp. and *Giardia intestinalis*), are also known to cause illness or disease, but these would generally be addressed by following worker hygiene and disease controls provisions of GMPs in 21 CFR Part 117 and 21 CFR Part 112 "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." on farms that supply raw agricultural commodities to processing facilities.

Chapter 6: Hazard Analysis will cover more details about resources that can be used to identify potential ingredient-related biological hazards (e.g., FDA Hazard Guide).

Slide 15: Common Process-, Facility-, and People-Related Sources of Biological Hazards



Common Process-, Facility-, and People-Related Sources of Biological Hazards

Source of Hazard	Hazards
Process-related	• Vegetative pathogens that survive inadequate process (*Salmonella* spp., *Cronobacter*) • Sporeforming pathogens in improperly cooled foods (*C. perfringens)* • Post-process ingredient addition (*L. monocytogenes)*
Facility-related (poor sanitation practices, etc.)	• *Listeria monocytogenes* (wet processing environment) • *Salmonella* spp. (dry processing environments, pests)
People-related	• *S. aureus*, *Shigella* spp. *Salmonella* spp. • Hepatitis A virus, Norovirus • Parasites such as *Giardia*, *Cyclospora*

15

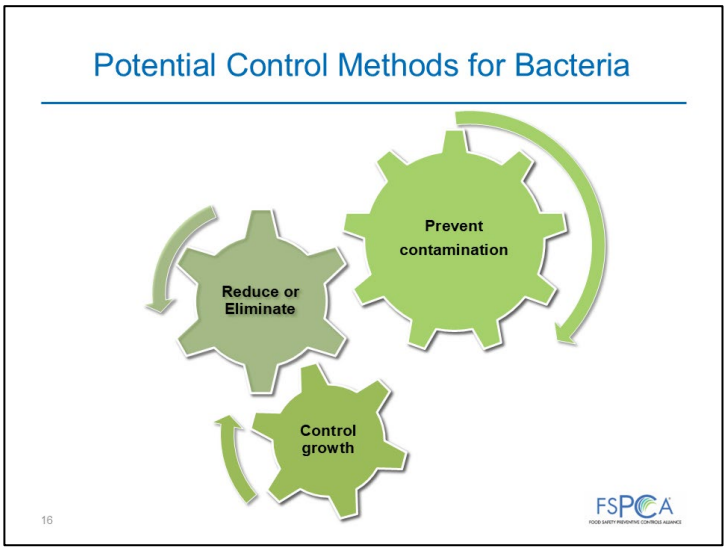
FSPCA

There are many potential sources of biological hazards from the process itself, referred to as process-related hazards. These types of hazards could include survival of pathogens if the process is not adequate to inactivate them, improper cooling that could allow outgrowth of spores, or contamination from ingredients added after the process control.

Other potential sources of biological hazards could include the facility itself, referred to as facility-related hazards. *Listeria monocytogenes* is typically more of a concern in wet processing environments and *Salmonella and Cronobacter* in dry environments.

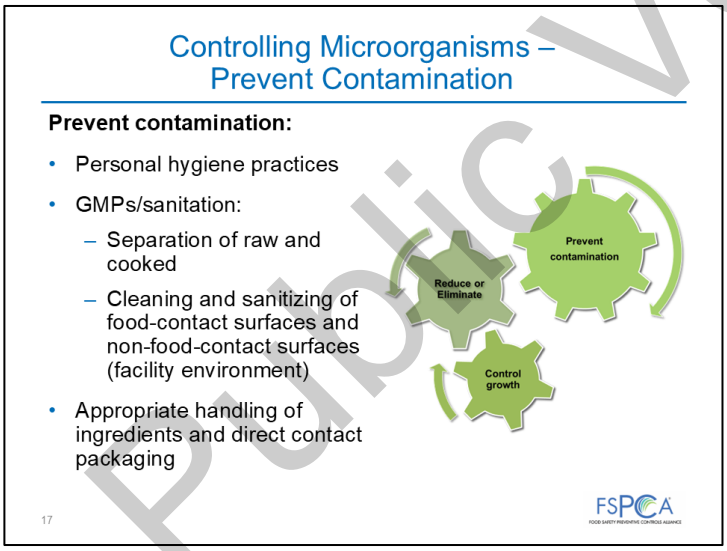
People (food handlers) can also be a source of hazards from shedding in their vomit or feces (*Shigella, Salmonella*, Hepatitis A, Norovirus, or parasites), or from skin lesions or wounds (*Staphylococcus aureus*). Food handling hygienic practices are essential when handling products post-process. Chapter 6: Hazard Analysis will cover more details about resources that can be used to identify potential process-, facility-, and people - related biological hazards (e.g., FDA Hazard Guide).

Slide 16: Potential Control Methods for Bacteria



Three basic strategies can be used to control bacterial pathogens in food: 1) Prevent contamination; 2) Reduce or eliminate the bacterial pathogens; and 3) Control the growth of the bacterial pathogens.

Slide 17: Controlling Microorganisms – Prevent Contamination



The primary "Prevent Contamination" approaches include personal hygiene practices, GMPs/sanitation, and appropriate handling of ingredients and direct contact packaging.

Keeping pathogens out of food can be accomplished through the practice of good personal hygiene by food workers. These practices would include:

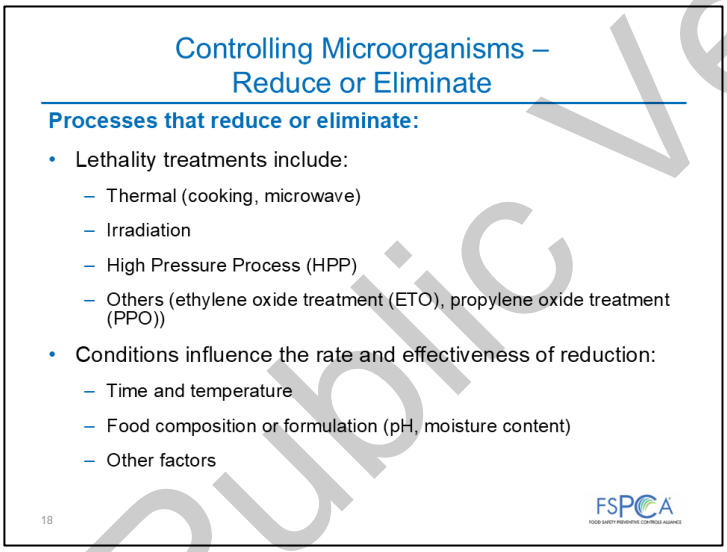
- Wearing outer garments suitable to the operation to protect against cross-contamination of food, food-contact surfaces, or direct food-packaging materials;

- Maintaining adequate personal cleanliness;
- Washing hands thoroughly to protect against contamination with undesirable microorganisms; and
- Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

Preventing cross-contamination of food can also be accomplished through effective sanitation practices. These practices would include the cleaning and sanitizing of utensils, equipment, and the facility environment to protect against cross-contamination of food, food-contact surfaces, or direct food-packaging materials.

Appropriate handling of ingredients and other raw materials and food-contact packaging is essential to minimize the introduction of pathogens into the facility and the food. Certain ingredients and other raw materials can be the source of pathogens, and if those items are not properly processed, contamination will be present in the finished product. Another concern is that those items can be the source for cross-contamination in the processing environment, so controls must be in place to prevent cross-contamination.

Slide 18: Controlling Microorganisms – Reduce or Eliminate



Inactivation and elimination are terms that refer to reducing pathogens to a level which is no longer a public health concern. Thermal treatments such as cooking/pasteurization/retorting processes are frequently used to destroy pathogens, Other processing techniques such as irradiation, high pressure treatments, antimicrobial chemicals (e.g., sanitizers), acidification, ultrasound and pulsed light may also be applied to food or to food-contact surfaces to destroy pathogens. All food processing techniques must be validated to the specific food and processing conditions to ensure effective and consistent control of the pathogens of concern in the specific food. Process validation is important to establish the necessary parameters taking into consideration the factors that may influence the rate of pathogen inactivation or

elimination. These factors may include the specified time and temperature, food composition or formulation (e.g., pH, moisture content).

For example, for cooking to be successful, the food must reach an adequate temperature for a long enough time to kill the microorganisms of concern. Higher temperatures kill faster than lower temperatures. The required temperature depends on the food, the pathogen of concern and the time involved. Adequate cooking temperatures may be established for certain pathogens and/or foods (see white text box below). Other validated time/temperature combinations may also be appropriate.

Ethylene Oxide (EtO) or Propylene Oxide (PPO) are used to reduce microbial contamination, such as by the spice industry against *E. coli* and *Salmonella*.

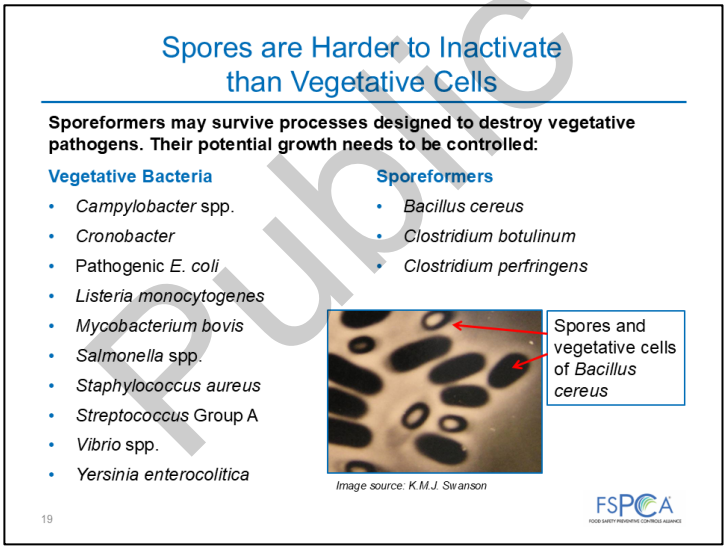
Appendix 4: Foodborne Pathogen Supplementary Information provides time and temperature guidance for controlling pathogen growth and toxin formation as well as inactivation of *Listeria monocytogenes*.

FDA Food Code provides safe cooking time and temperature combinations for a variety of foods (see Additional Reading).

FDA Dairy Hazard Guide also provides safe cooking temperatures for certain products (see Additional Reading).

Other validated time and temperature combinations may also be appropriate for certain foods.

Slide 19: Spores are Harder to Inactivate than Vegetative Cells



Definitions:

Spore: A dormant, resistant form of certain bacteria

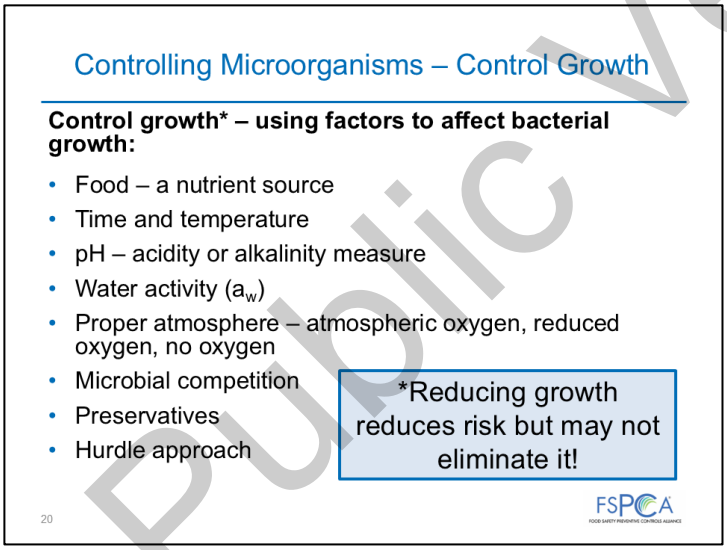
Vegetative cell: The growing form of bacteria

Bacterial hazards can be classified as bacterial pathogens which exist only in the vegetative state (non-sporeformers) and those that can form spores (sporeformers); both need to be considered. Bacterial sporeformers are notable for their ability to produce spores which can survive harsh conditions that destroy other pathogens. Spores are similar to a seed in that they have a hard, resistant structure that allows survival through harsh conditions.

In the photo above, the bright ovals are heat resistant *Bacillus cereus* spores and the larger, dark rod-shaped bacteria are *Bacillus cereus* in its vegetative state. Spores are not hazardous as long as they remain in the spore state. Spores are very resistant to heat, chemicals and other treatments that would normally kill vegetative forms of both sporeformers and non-sporeformers. When spores survive a processing step designed to kill vegetative bacteria, they may become a hazard in the food if they are exposed to favorable conditions that allow germination and growth and subsequent toxin production. This can be particularly serious when a processing step has removed most of the existing competitive microflora, leaving the spores to grow unabatedly provided conditions are right. The processing steps used to kill spores are often much more severe than those necessary to kill vegetative cells because spores are more resistant. It is very important to consider the potential for growth of spores and control them appropriately. It is important to note that in some cases, destroying one type of hazard can provide an opportunity for other hazards to emerge because competition is eliminated.

Some types of microorganisms are more resistant than others to inactivation methods; thus, it is important to understand the potential of pathogens of concern in a specific food and of sporeformers and have the proper controls. Validation is the demonstration that the controls applied actually control these hazards (discussed in Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping).

Slide 20: Controlling Microorganisms – Control Growth



The USDA-ARS Pathogen Modeling Program (PMP) Online (available at the link below) and similar models exist to evaluate potential for growth.

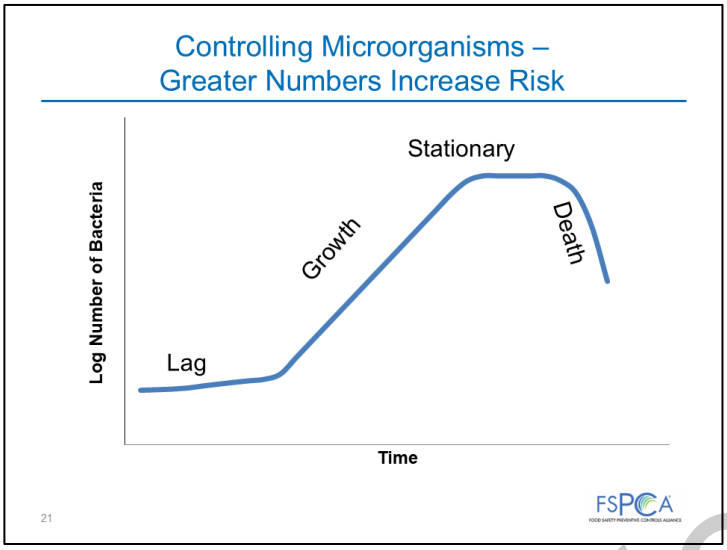
https://pmp.errc.ars.usda.gov/

Bacteria have certain requirements to live and grow in food, including a nutrient source, time and temperature, a suitable pH, water available in the food, the proper atmosphere, and other factors. Microbial competition and the presence of preservatives may also affect the growth of bacterial pathogens. If conditions are not favorable for growth, some bacteria die while others persist until their growth requirements are met.

Controlling a combination of these factors with the purpose of restricting pathogen growth is called the "hurdle approach." More information about this is found in the upcoming slides.

It is worth noting that growth inhibition does not necessarily mean that the pathogen is killed. Many pathogens can survive in conditions that prevent growth and may cause disease.

Slide 21: Controlling Microorganisms – Greater Numbers Increase Risk



Keeping microorganisms from growing can be an important control when the process does not kill potential pathogens (e.g., spores), or when products may become re-contaminated after a lethal process (e.g., ready-to-eat products that are exposed to the environment after cooking before packaging). Preventing growth also may reduce the risk of foodborne disease because some pathogens must grow to a sufficiently high number to present a hazardous situation, such as when toxin production or a high infectious dose is needed to cause illness. Time and temperature, the level of acidity (pH), available water (water activity or a_w), the right level of oxygen (atmosphere), the presence of competition by other bacteria and preservative use can all influence growth of potentially harmful bacteria.

It can sometimes take bacteria a bit of time to start growing (lag phase), but then under favorable conditions it takes off and grows rapidly with one bacterium dividing into two, two into four, four into eight, eight into sixteen, and so on (growth phase). Under ideal conditions, some bacteria double every 20 minutes; thus, one bacterium can multiply to more than 30,000 in 5 hours and over 16 million in eight hours. If relevant, toxin formation usually occurs during exponential growth. Growth continues until it runs out of what it needs to keep multiplying (stationary phase), and then it can start dying off (death phase). Even after death of the organism, any toxin it produced will remain active, and could lead to a food intoxication. Ideally, growth will be prevented due to the nature of the food itself or through application of preventive controls.

Logarithmic Scale

A logarithmic (log) scale is used to plot microbial growth because of the rapid increase in numbers. Simply put, there is a 10- fold difference between each unit on a log. For example, a log unit of 2 is 10 times more than a log unit of 1; similarly, a log unit of 5 is ten times more than a log unit of 4.

For example,

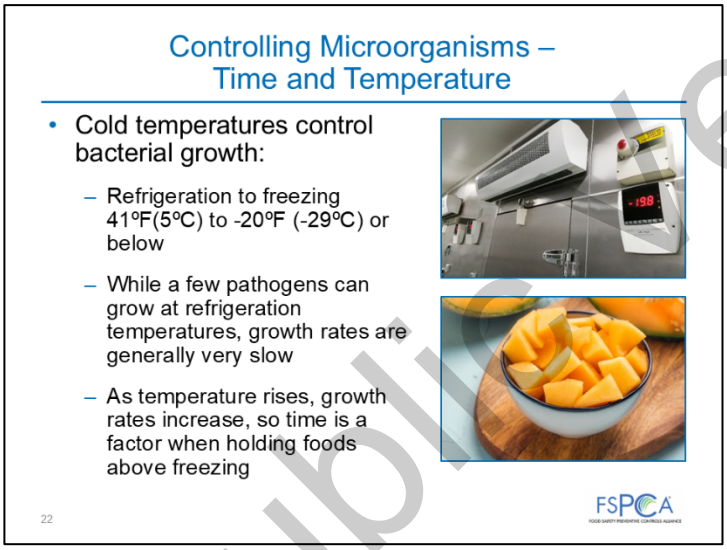
Log 3 = 1000

Log 4 = 10,000

Log 5 = 100,000

Etc.

Slide 22: Controlling Microorganisms – Time and Temperature (1 of 2)

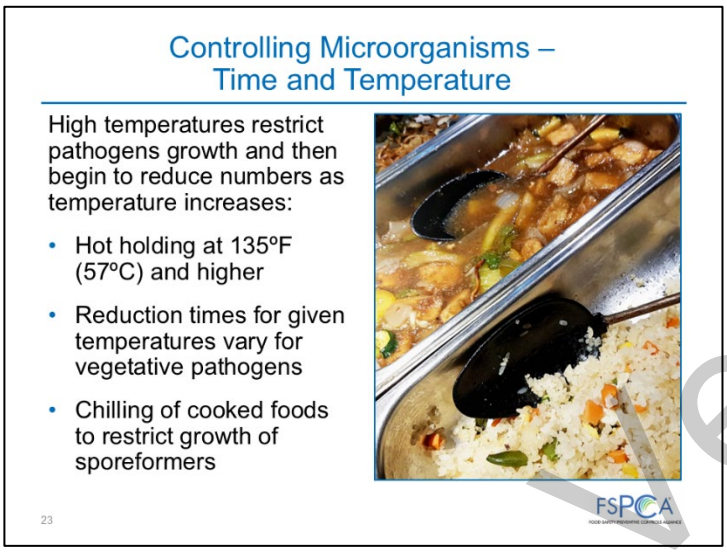


Cold temperatures typically control bacterial growth, however, some pathogens can grow at refrigeration temperatures, such as *Listeria monocytogenes*. As temperatures rise, growth rates increase. Improper holding temperatures for food may allow foodborne bacteria to multiply as discussed in the previous slide. Very rapid growth of foodborne pathogens can occur between 77° to 104°F (25° to 40°C). The range of temperature that supports pathogen growth varies considerably depending on the specific organism (see Appendix 4) and other characteristics of the food. Guidelines have been developed for how long food can be held at potential growth temperatures. For example, cooling models have been developed for *Clostridium perfringens* because of the potential for its rapid growth and toxin formation if there is prolonged or inadequate cooling of soups and sauces. The direct temperature of the food is the primary control of the organism, not the temperature of the environment in which the food is held. For example, even if a refrigerator or cooler is at the proper temperature, food placed in it may not cool down rapidly if the container is large or

constructed with insulating layers. See Table A4-2 in Appendix 4: Foodborne Pathogen Supplementary Information for guidelines on the maximum, cumulative time, and food temperature combinations for controlling growth and toxin formations for foodborne pathogenic bacteria.

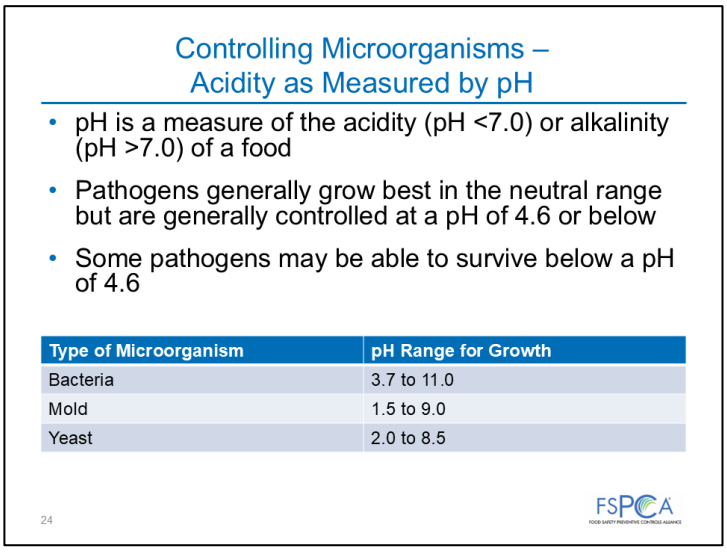
In general, holding food at temperatures between the proper refrigeration temperature for the product and 135°F (57°C) should be avoided. This is the "danger zone" within which bacterial pathogens can grow.

Slide 23: Controlling Microorganisms – Time and Temperature (2 of 2)



Pathogens typically grow at temperatures up to 135°F (57°C), so, holding hot foods above this temperature limits growth of microorganisms. As stated earlier, sporeforming bacteria such as *Bacillus cereus* can be activated with a cooking step, but chilling of cooked foods can restrict its growth and possible toxin production.

Slide 24: Controlling Microorganisms – Acidity as Measured by pH

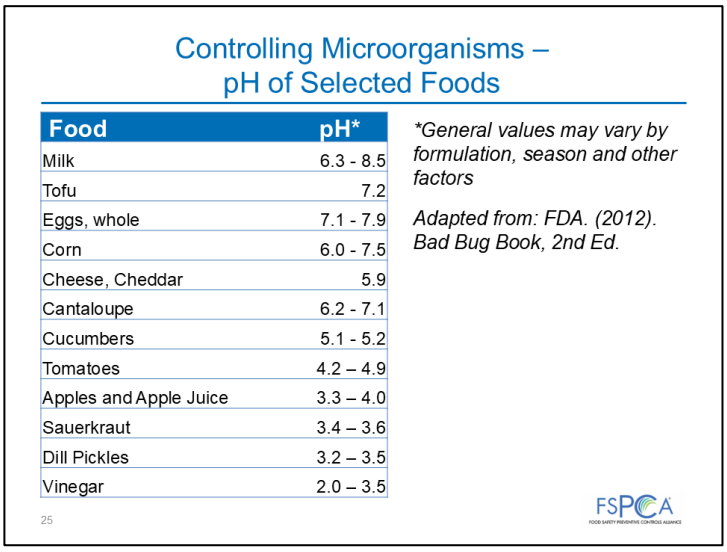


The pH of a food is a measure of its acidity or alkalinity. Foods with a pH less than 7.0 are acidic. The pH of a food can be measured using a pH meter or pH paper.

A pH below 4.6 prevents the growth of many bacterial pathogens, such as *Clostridium botulinum*, which is a deadly pathogen. However, some pathogens can grow or survive below 4.6 pH, depending on the food, temperature, and other factors (see Appendix 4: Foodborne Pathogen Supplementary Information). For example, *Salmonella*, the most common bacterial hazard associated with foodborne illness, has been reported to have a minimum growth pH of as low as 3.7.

While a low pH may prevent bacterial growth, some pathogens can survive! Do not assume that a low pH will necessarily kill a pathogen.

Slide 25: Controlling Microorganisms – pH of Selected Foods



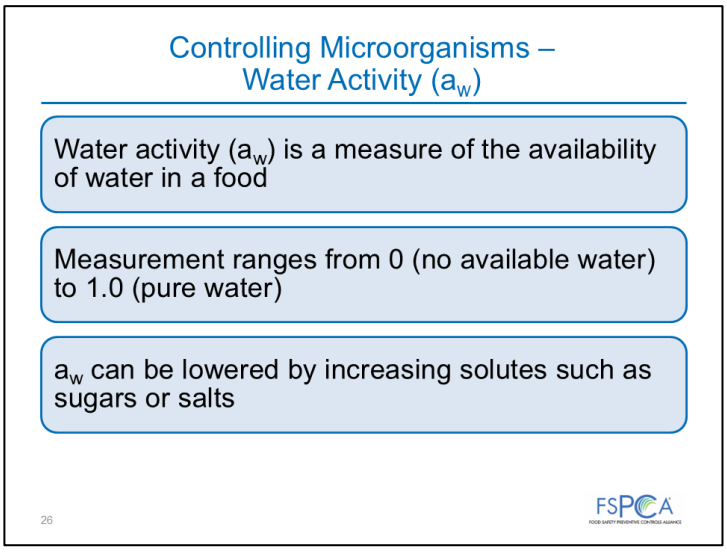
Note: Sometimes, the addition of other ingredients can change the pH or water activity of a food. Pay attention to this if these factors are used to control growth.

pH is a measure of acidity. Notice that some foods (e.g., lemons and vinegar), have very low pH values where pathogen growth will not occur. Others (e.g., milk and eggs), have pH values where growth is likely if other conditions such as temperature are favorable.

Clostridium botulinum growth is inhibited by a pH <4.6 but other pathogens may grow or survive below this pH value. See Appendix 4 for more information.

If the safety of a product depends on pH, the facility must use a reliable pH test method. FDA methods for measuring pH of acidified foods are found in 21 CFR 114.90 – Methodology.

Slide 26: Controlling Microorganisms – Water Activity (a_w) (1 of 2)

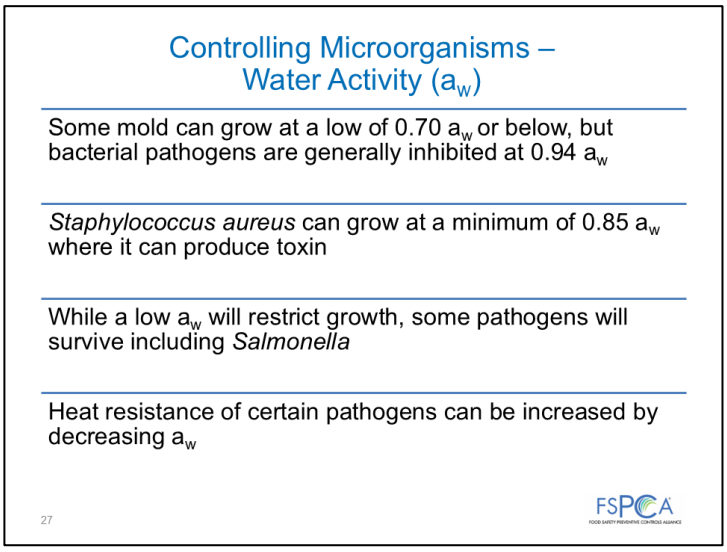


Definition: *Water activity (a_w):* A measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. (21 CFR 117.3)

All forms of life require water to grow, but it must be available (that is, not bound up with other molecules) to allow for growth.

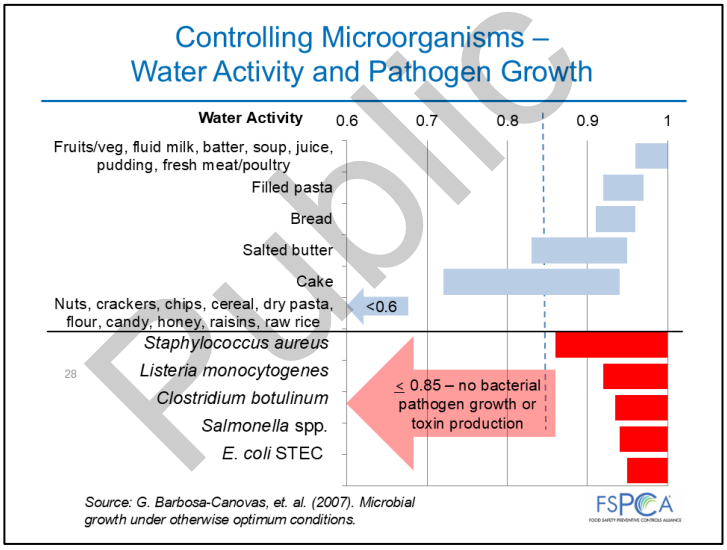
Water activity (a_w) is a term used to describe the availability of water (free moisture) in a food. Pure water has a water activity of 1.0. Adding solutes such as salt, sugar, and similar food ingredients can reduce the availability of water for microbial growth. Think about sea water—some species thrive in the ocean, rather than in a freshwater lake. The same is true for microorganisms.

Slide 27: Controlling Microorganisms – Water Activity (a_w) (2 of 2)



Growth of pathogenic bacteria is restricted when the a_w is $\leq$ 0.85. *Staphylococcus aureus* is the only foodborne pathogen that grows below 0.94 a_w, the level below which most pathogens are inhibited from growing. But the pathogenic bacteria will continue to survive, and the heat inactivation requirements may be increased under conditions of lowered a_w especially for pathogens like *Salmonella*. This means higher levels of heat or longer heating times may be required in low a_w foods for pathogen inactivation.

Slide 28: Controlling Microorganisms – Water Activity and Pathogen Growth



The report Evaluation and Definition of Potentially Hazardous Foods provides information on pH and a_w combinations that prevent foodborne pathogen growth. See Additional Reading.

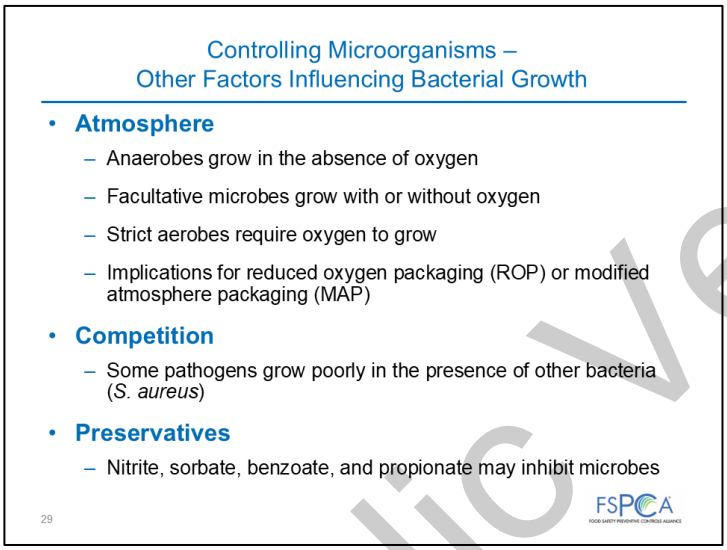
Also see Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping.

Many fresh foods have aW values above 0.96, which supports the growth of pathogens. There are also many dry foods with aW values below 0.6, which inhibits pathogen growth, although some bacteria, such as Salmonella, can survive for long periods of time. In between, there is a range of foods that may have aW values that support growth of some pathogens. Growth of pathogenic bacteria stops when the aw is < 0.85. Staphylococcus aureus is the only foodborne pathogen that grows below 0.94 aw and

it can produce toxin down to an a_w of 0.86. Details on a_w limits for specific pathogens are provided in Appendix 4: Foodborne Pathogen Supplementary Information.

It is important to recognize that the range of a_w values for some food categories can be quite broad. Specific measurements are needed for these types of products if a_w is used as a growth control strategy. For foods that have different components (such as a donut with a cream filling) the pH and a_w may be quite different in the components. In the donut example, the filling may be acidic and have a high a_w, while the doughnut part may have a near neutral pH and a lower a_w. The interface between the filling and the donut may be "just right" for microbial growth, which may be an issue if contamination of the interface is reasonably likely to occur.

Slide 29: Controlling Microorganisms – Other Factors Influencing Bacterial Growth



Note: Combinations of the factors that inhibit microbial growth can increase effectiveness and, in some cases, may even provide a level of inactivation. Data are needed to demonstrate that this occurs.

Other factors that may influence the growth of microorganisms include atmosphere, microbial competition, and preservatives.

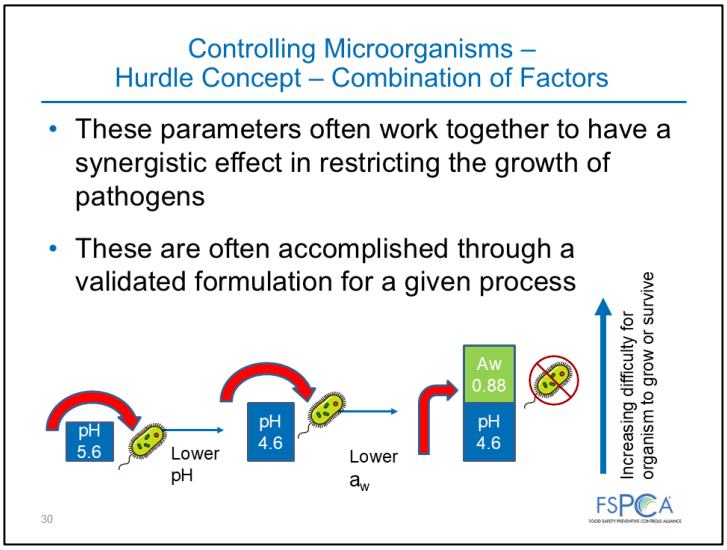
Some pathogens prefer to grow at the concentrations of oxygen present in the air we breathe; others prefer or even require little or no oxygen before they can grow. Of particular concern for food safety are anaerobic conditions (very low or no oxygen) that favor the pathogen *Clostridium botulinum*. Changing the packaging to control oxygen levels may change the hazards of concern for a food. For example, creation of anaerobic conditions through packaging can inhibit spoilage organisms and extend shelf life. The reduced oxygen packaging (ROP) process creates an anaerobic environment, which favors the growth of two pathogens: *Clostridium botulinum* and *Listeria monocytogenes*. ROP is often used to extend shelf life, which can provide more time for toxin production or pathogen growth if pathogens are present, and temperatures are suitable for growth. Pathogens can also be introduced into a treated product after packaging if there is a lack of container integrity. This anaerobic environment and longer shelf-life may provide an opportunity for unanticipated hazards, such as growth of *Clostridium botulinum*. Such changes should be carefully considered and studies to validate product safety may be necessary.

When there is little competition for nutrients, bacteria can reproduce rapidly. Conversely, the presence of other bacteria can inhibit the growth of certain pathogens. For example, production of toxin by *Staphylococcus aureus* may be suppressed when competitive bacteria are present. Fermented products like yogurt, which have high levels of active cultures, inhibit the growth of pathogens when fermentation proceeds at the normal rate.

Preservatives, like nitrite, sorbate, benzoate, and propionate when formulated into food products, may slow, or prevent the growth of pathogens as well as spoilage microorganisms. The effectiveness of these preservatives depends on many factors. Thus, when relying on preservatives to control pathogen growth, validation is essential to ensure efficacy (See Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping). If not used at approved concentrations, some preservatives may be chemical hazards (see Chapter 4 Chemical, Physical, and Economically Motivated Food Safety Hazards for Human Food for more information).

For many foods, bacterial growth often is controlled using one or more of the factors described above to make the food unsuitable for pathogen growth. Some preservation methods remove water, making this essential component unavailable to bacteria. For example, baking bread or crackers removes water from the food. Acidification is also a common method of preservation (for example, pickles), as is refrigeration (which slows growth), or freezing (which prevents pathogen growth entirely).

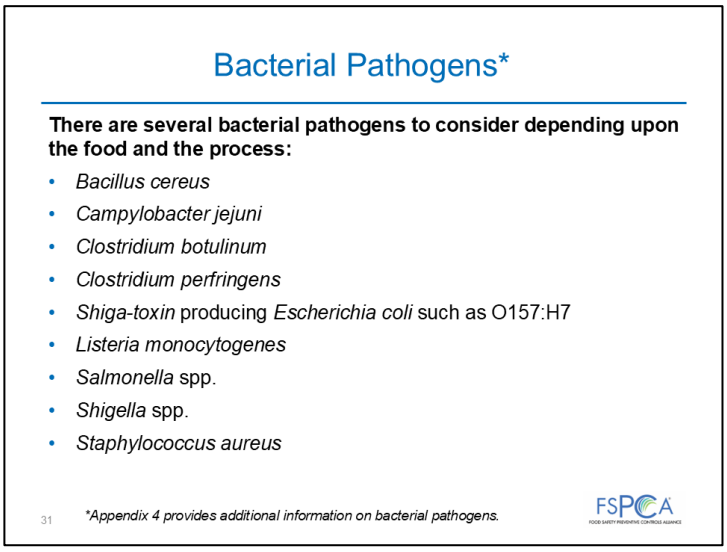
Slide 30: Controlling Microorganisms – Hurdle Concept – Combination of Factors



The combinations of factors such as pH and a_w may inhibit organisms at levels where the individual factor alone would not. Some people refer to this as the "hurdle approach." Using a combination of factors frequently requires expert knowledge to develop a stable combination.

In the example on the slide, the organism is able to overcome a pH of 5.6 and grow. Even when the pH is lowered to 4.6, growth still occurs. It is only through adding new hurdles such as decreasing water activity to 0.88 or adding a preservative such as phosphate that growth is halted. Combining such factors can help in limiting growth of harmful organisms in foods. Certain hard cheese products including Pecorino or Asiago cheeses use a combination of lower pH and a_w values along with bacteriocins produced by lactic acid bacteria, that prevent pathogen growth.

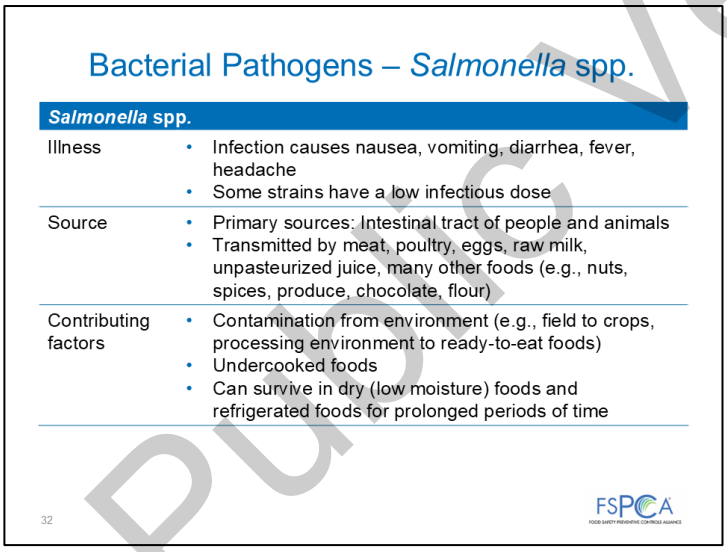
Slide 31: Bacterial Pathogens



See Appendix 4: Foodborne Pathogen Supplementary Information for similar information for other bacterial pathogens. Understanding the characteristics of the pathogens of concern for the foods that a facility produces is important to select appropriate preventive controls.

These are the primary bacterial pathogens which commonly can be found in certain foods and cause illness that could be considered as biological hazards.

Slide 32: Bacterial Pathogens – *Salmonella* spp.



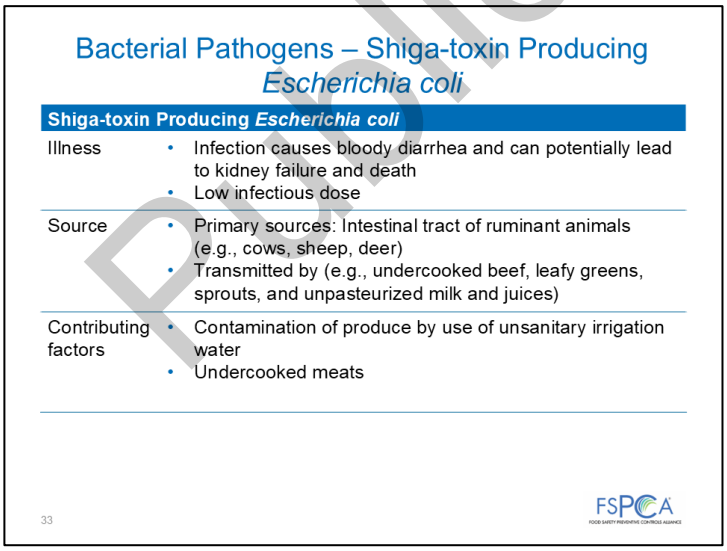
Salmonella is among the most common causes of bacterial foodborne illness. The infection causes diarrhea, fever, abdominal cramps, and vomiting. Occasionally, *Salmonella* may cause bloodstream infections and death. Severe cases may also result in reactive arthritis. Foodborne illness symptoms generally appear 12 to 72 hours after eating contaminated food. The intestinal tract of animals is the primary source of *Salmonella*, thus raw animal products (meat, poultry, eggs, and milk products) are frequently associated with outbreaks.

Many foods have been associated with outbreaks, such as unpasteurized (raw) milk, shell eggs, spices, tree nuts, yeast, coconut, sauces, cake mixes, cream-filled desserts, gelatin, peanut products, chocolate and cocoa, and soy ingredients.

The initial source of contamination is the intestinal tract of animals. In addition to animals and eggs being the source of *Salmonella*, *Salmonella* is spread in the natural environment where it can contaminate raw materials such as grain crops, produce, nuts, and spices. Good Agricultural Practices (GAPs) and compliance with the Produce Safety regulation in 21 CFR Part 112, play a key role in minimizing this contamination, but processing controls are normally employed as well. The food processing environment can become the source of contamination when *Salmonella* establishes itself through contamination resulting from poor procedures involving raw material handling, facility maintenance, pest control, etc. Once in the facility, *Salmonella* is an environmental biological hazard capable of cross-contaminating exposed post-processed product prior to packaging.

Salmonella grows with or without air, grows best at human body temperature, grows very poorly at refrigeration temperatures, does not grow above 115°F (46°C), and some strains of *Salmonella* can grow to a pH as low as 3.7. *Salmonella* is easily killed at traditional cooking temperatures in high moisture products but has shown to have significant heat resistance in dry foods such as nuts and flour. Along with this, it has been shown to survive for extended times in dried state, whether that is in a dry product such as peanut butter or in a dry processing facility. It is best to keep dry environments dry when *Salmonella* is a potential concern since moisture can allow it to grow. Attempts to wet-clean dry processing environments have been shown to spread contamination and increase the risk of product contamination because of growth in environmental niches like cracks and crevices that cannot be reached by sanitizers.

Slide 33: Bacterial Pathogens – Shiga-toxin Producing *Escherichia coli*



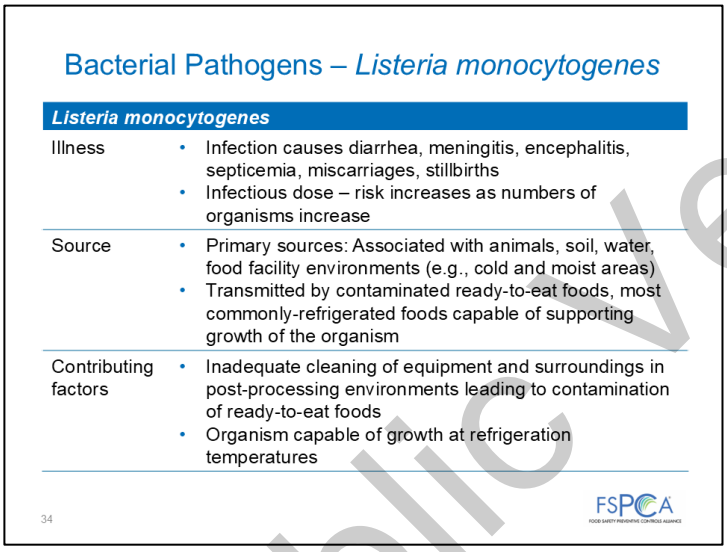
Most strains of *E. coli* bacteria are harmless, but some strains produce a toxin (Shiga toxin) that can cause serious illness, including bloody diarrhea, blood-clotting problems, kidney failure, and death from consumption of low numbers of cells. Some people get the less serious form of the infection, which can range from no symptoms

to diarrhea that starts out watery, then turns bloody. But the infection sometimes progresses into a life-threatening form of the illness that causes kidney failure and other problems, with children and people with weak immune systems being at especially high risk.

E. coli O157:H7 has caused outbreaks of foodborne illness and is primarily found in the intestinal tracts of ruminants. The outbreaks have been traced to many kinds of foods; for example, undercooked ground meats, unpasteurized ("raw") milk, unpasteurized fruit juice, lettuce, spinach, sprouts, and, more recently, commercially manufactured frozen cookie dough that had been contaminated with *E. coli* O157:H7 from wheat flour.

Contributing factors include produce that has been contaminated by unsanitary irrigation water and contaminated meats that are not cooked appropriately.

Slide 34: Bacterial Pathogens – *Listeria monocytogenes*



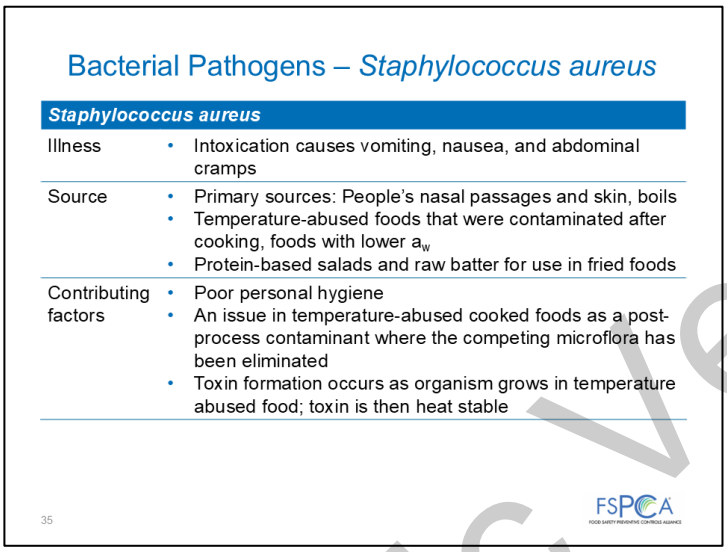
Listeria monocytogenes is one of the leading causes of death due to foodborne illness. For those with normal functioning immune systems, the symptoms resulting from infection are limited to nausea and diarrhea which may last for a few days. However, *Listeria monocytogenes* poses the greatest risk to those in high-risk categories where there are issues with the immune system. For example, the elderly where the immune system begins to fail, the very young who do not have a fully functional immune system, women who are pregnant where there is certain level of immunosuppression, and those who have immune diseases or are taking immuno-suppressing medications. In these persons, the pathogen can enter and infect the bloodstream (septicemia) and impact the nervous system (meningitis)

Listeria monocytogenes originates in agricultural environments, especially farms with animals such as cows and sheep, however, many strains of bacteria involved in foodborne illness outbreaks are strains that have adapted to and become persistent in food processing facilities. The types of foods typically involved are those that are ready to eat, refrigerated and capable of supporting growth. Examples include raw or under-

pasteurized milk; cold smoked fish and other seafood; meats including deli meats and hot dogs; cheeses (especially soft cheeses); and fresh vegetables.

Listeria monocyotogenes can become a serious contamination concern within a processing facility once it becomes established in the facility environment and equipment. *Listeria* is hardy; it tolerates salty environments and can grow at refrigeration temperatures, unlike many other foodborne bacteria. It forms biofilms which allows it to attach to processing equipment in areas such as within flume systems and can find harborage in niche environments such as cracks in equipment and crevices in floors and walls.

Slide 35: Bacterial Pathogens – *Staphylococcus aureus*

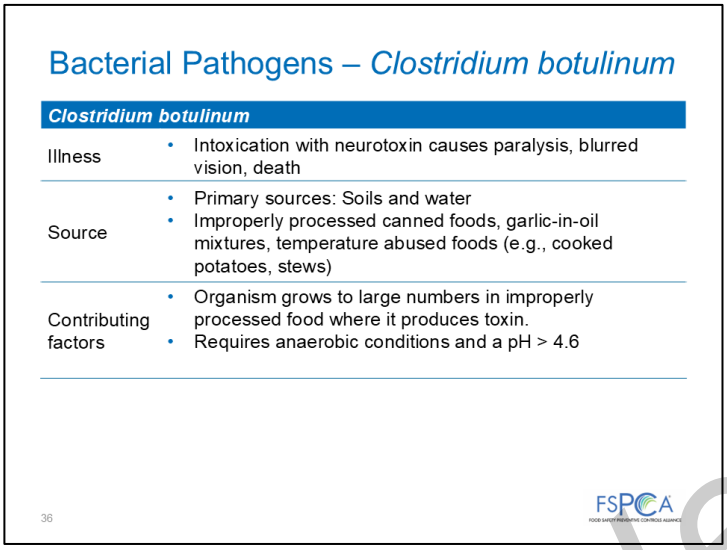


Staphylococcus aureus, often called "*Staph*" for short, causes a foodborne intoxication when it grows to high numbers in temperature abused food. In these foods, *Staphylococcus aureus* produces a heat stable toxin (enterotoxins) as it grows to high levels. These enterotoxins are typically not destroyed by cooking, although the bacterium itself can be destroyed by heat. These toxins can cause nausea, stomach cramps, vomiting, and diarrhea. In more severe cases, the toxins may cause loss of body fluid (dehydration), headache, muscle cramps, and temporary changes in blood pressure and heart rate. The illness usually is intense, but normally lasts from just a few hours to a day. The toxins are fast-acting; they cause symptoms within 1 to 7 hours after contaminated food is eaten.

The organism is commonly found on the skin and within the nasal passages of humans and becomes a contaminate in food during improper handling by people. Outbreaks often have been linked to foods that were improperly handled during processing and then were temperature abused by not using proper refrigeration. Examples of foods that have been linked to *Staph* poisoning include meat and meat products; poultry and egg products; salads, such as egg, tuna, chicken, potato, and macaroni; bakery products, such as cream-filled pastries, cream pies, and chocolate éclairs; sandwich fillings; milk and dairy products; and batters.

Factors that can contribute to outbreaks include food handlers' poor personal hygiene, especially inadequate handwashing, and poor temperature control especially of heat-treated foods in which competitive organisms may have been eliminated.

Slide 36: Bacterial Pathogens – *Clostridium botulinum*

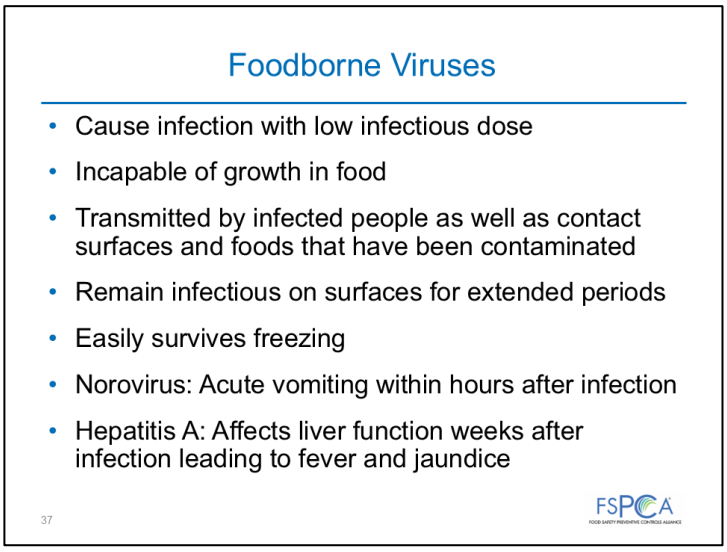


Clostridium botulinum is an anaerobic, sporeforming rod that can cause intoxication. Botulism is the illness that can be the result and is a serious, sometimes fatal, disease caused by a potent neurotoxin formed during growth of *Clostridium botulinum*. The infection results in flaccid paralysis of muscles, including those of the respiratory tract.

Commonly found in soil and water, the spores are heat-resistant and can survive in foods that are incorrectly or minimally processed. Any food conducive to outgrowth of the spores and subsequent toxin production can be associated with botulism. Outbreaks have involved canned foods, garlic-in-oil, and temperature abused foods (cooked potatoes, stews).

A hazardous situation can occur when food processing allows spore survival and growth, and eventual toxin formation. Often this is associated with improperly processed canned foods, but almost any type of food that is anaerobic and not very acidic (pH above 4.6) and temperature abused can also support growth and toxin production by *Clostridium botulinum*. Examples of outbreaks have included garlic in oil mixtures, cooked potatoes, etc.

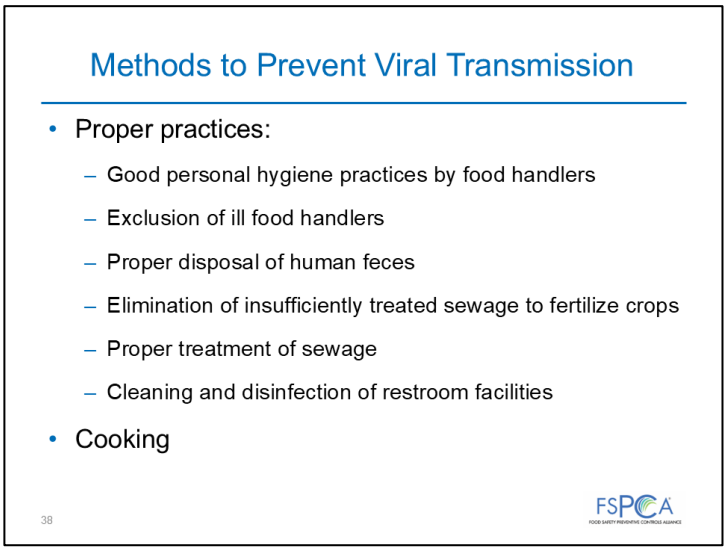
Slide 37: Foodborne Viruses



Viruses transmitted by foods cause infections often with low numbers of viral particles consumed from a food that is contaminated. The viruses will not grow in the food, but their presence will cause illness. The virus may also come directly from an infected person who in turn contaminates food, or food-contact surfaces that have been contaminated with infectious viral particles, where they may remain infectious for extended timeframes. They can also survive in a frozen state.

The most common foodborne viral hazards are Norovirus (the leading cause of foodborne illness in the United States) and Hepatitis A virus. Other viruses, such as rotavirus, may occasionally be associated with foodborne illness, and more may be identified in the future. While the vast majority of viral outbreaks occur in foodservice settings, outbreaks have been associated with processed foods as well. For example, a large Norovirus outbreak occurred in Germany that was associated with frozen strawberries imported from China.

Slide 38: Methods to Prevent Viral Transmission



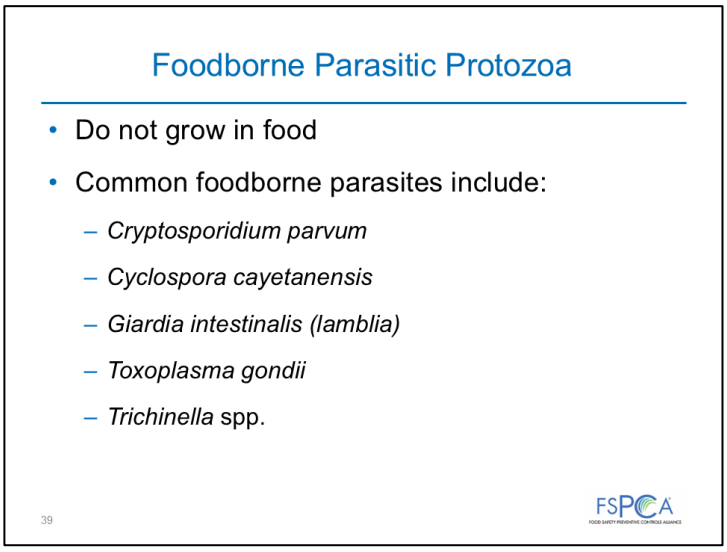
Viruses can infect consumers through contact with infected people or contaminated food or water. People who are ill from a viral illness can shed viruses in very high numbers in vomit or feces. Even when they recover from the illness and no longer show outward signs of illness, people can still shed the virus in saliva and feces.

Transmission of viruses to foods is usually related to poor employee hygienic practices such as improper handwashing or working while actively shedding viruses. Therefore, prohibiting people with viral illnesses from coming into direct contact with food reduces the chance for foodborne transmission of viruses. Person-to-person transmission is very common for viruses associated with foodborne illness outbreaks. This is another reason for requiring ill individuals to stay home from work—it prevents other workers from contracting the disease and spreading it to food. Outbreaks have been traced to foods, especially crops exposed to inappropriately treated water. This may be rare in developed countries but may be a concern in certain regions of the world.

Thorough cooking is also an effective control mechanism, and most foods associated with viral foodborne outbreaks are ready-to-eat. There is some evidence that high-pressure processing may also be effective in reducing the risk of transmitting foodborne viruses, and exploration of validated processes for specific foods is necessary for this control strategy.

> Norovirus is resistant to typical sanitizer concentrations used for food-contact surfaces. An EPA registered disinfectant with claims against Norovirus should be used. A general list of these products is available through EPA and the term "Norovirus," or "Norwalk-virus" will appear on an EPA-registered disinfectant label. Carefully follow manufacturers' label instructions for use. For example, if used on a food-contact surface, the sanitizer may need to be rinsed from the surface after treating and follow with a sanitizer at the appropriate concentration before using the equipment.

Slide 39: Foodborne Parasitic Protozoa



Like viruses, foodborne parasites do not grow in food. Major foodborne parasites in the United States include *Cryptosporidium parvum, Cyclospora cayetanensis, Giardia intestinalis (lamblia), Toxoplasma gondii*, and *Trichinella* spp.

Cryptosporidium parvum is a rarely reported parasite but is notable for its resistance to chemical agents, including standard levels of chlorine. It is sensitive to drying and ultraviolet light. *Cryptosporidium* causes diarrhea, and infection can be fatal for immunocompromised people. Foodborne outbreaks have involved apple cider and unpasteurized milk, as well as contaminated water.

Cyclospora cayetanensis is a parasite that has seen more reported outbreaks in recent times. It causes prolonged diarrhea. Death rarely occurs. Outbreaks are frequently associated with fruits (berries), leafy green and other salads, and herbs like basil.

Giardia intestinalis (or *lamblia*), like other parasites, causes diarrhea and is the most common parasitic cause of diarrhea in the United States. Contaminated water is the primary source for outbreaks, but food and people spread the disease, and only one cyst may be enough to cause illness. Illness occurs about 2 weeks after eating contaminated food, so tracing the source of illness can be very difficult. Foodborne outbreaks with identified vehicles include ice, lettuce-based salads, chicken salad and unspecified vegetables.

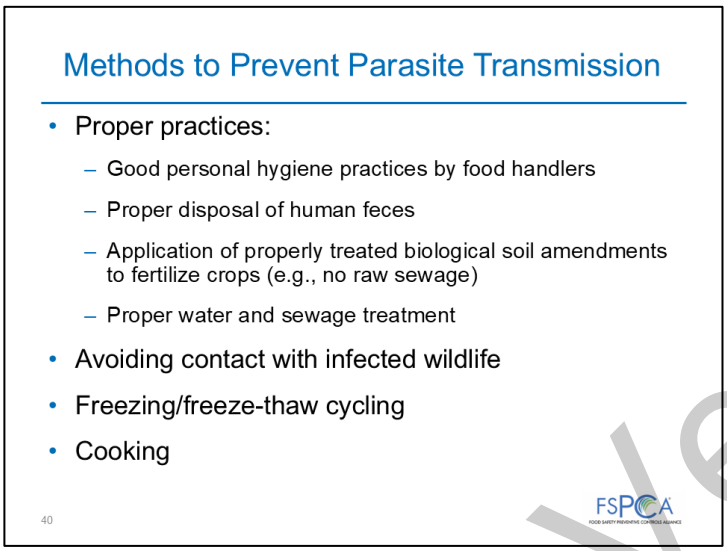
Toxoplasma gondii is a parasite and a leading cause of death from foodborne illness in the United States, particularly for babies infected in the womb and people with suppressed immune systems. People infected with Toxoplasma may be asymptomatic, but it can spread to a variety of organs including the brain, eyes, heart, and other muscles. Raw meat products and cat feces are the primary source of this parasite. Freezing food to ≤9°F (-13°C) for 24 hours or more usually prevents infectivity. Cooking meats to recommended temperatures is also an effective control measure.

Trichinella spp. is the parasite that causes trichinosis, which is associated with consumption of raw meat products. In the past, pork was the primary type of meat involved; however, transmission through commercially raised pork is now rare.

Trichinellosis is more commonly associated with game meat. As with other parasites, *Trichinella* is susceptible to freezing and cooking.

While foodborne parasite outbreaks are reported less frequently in the United States. than viral or bacterial agents, it is important to recognize potential issues and sources and control for these agents. Parasitic foodborne and water-associated diseases are more common in countries with poor sanitation.

Slide 40: Methods to Prevent Parasite Transmission

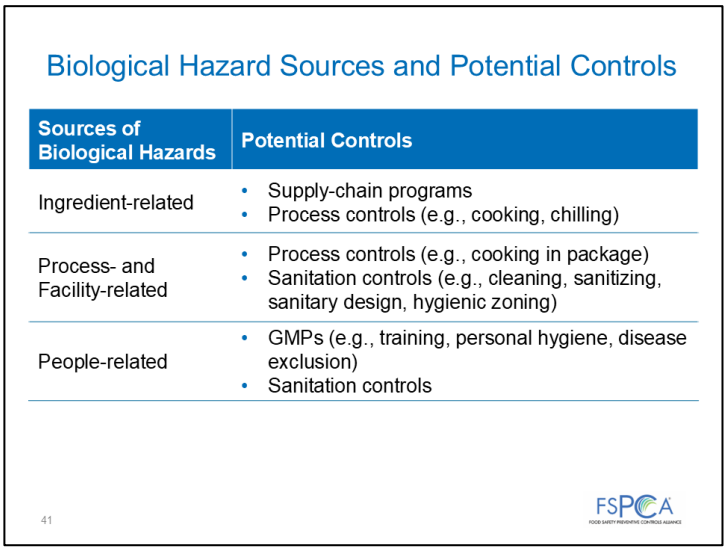


Consumer exposure to parasites depends on food selection, cultural habits, and preparation methods. Some parasites may be transmitted through food or water that is contaminated by fecal material shed by infected hosts or by consuming infected animal tissue. Methods of preventing transmission of parasites to foods by fecal contamination include good personal hygiene practices by food handlers, elimination of insufficiently treated animal waste to fertilize crops, and proper water and sewage treatment.

In specific instances, freezing can be used to destroy parasites in food. Freeze/thaw cycles can prevent infectivity of *Giardia*, *Cryptosporidium, Cyclospora, Trichinella spp*., and seafood-related parasites (which are not covered in this training).

Parasitic infections are normally associated with raw or undercooked foods because cooking procedures that destroy pathogenic vegetative bacteria also kill foodborne parasites.

Slide 41: Biological Hazard Sources and Potential Controls



As previously discussed, biological contamination of food products typically comes from one of three different sources: 1) ingredients; 2) the processing environment, including facility environment, and processing equipment; or 3) people. Controls are needed to manage the hazards introduced from these sources.

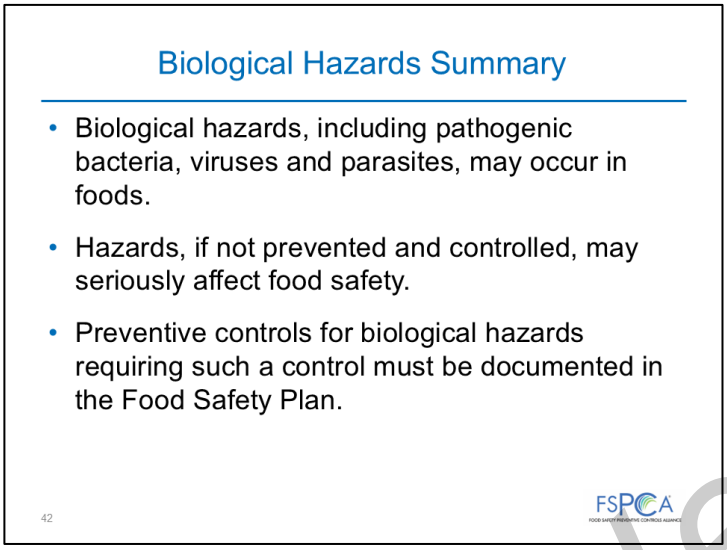
For example, sometimes ingredient-related hazards can be reduced to a safe level by using process controls such as a cooking procedure or maintained at a safe level using temperature control. However, not all products receive a cooking step or temperature control, and cooking may not be effective against some pathogens. In many cases the preventive control for the hazard is done by the supplier. In these cases, if an ingredient has a history of being a potential source of a particular biological hazard, a supply-chain program may be required. This is determined through Hazard Analysis (See Chapters 6 and 7: Hazard Analysis and Preventive Controls Determination).

The processing environment (which includes the facility environment, and processing equipment) is a potential source of environmental pathogens and cross-contamination. Cross-contamination occurs when pathogens are transferred from raw products to processed or ready-to-eat products. Direct contamination can occur when raw product comes in direct contact with ready-to-eat foods. Indirect cross-contamination occurs when a food-contact surface is used for both a raw product and ready-to-eat product, such as putting cooked product back into the raw product container. Cutting boards, worktables, tools, and utensils, particularly those with hard to clean surfaces, are other common sources of cross-contamination. Cooking a product in- package can prevent recontamination, but cooking in-package is not possible for many products. Effective sanitation controls, including cleaning, sanitizing, and zoning, are useful to reduce the likelihood of post-process cross-contamination. An environmental monitoring program must be used to verify the effectiveness of the sanitation preventive controls. These types of controls are discussed in Chapter 12: Sanitation Preventive Controls.

People with an illness or infection may potentially contaminate the product. Transmission of pathogens by ill employees can typically be controlled when addressed

by GMPs and training, which is discussed in Chapter 2: Good Manufacturing Practices and Other Prerequisite Programs. People can also serve as a vector for transmission of pathogens from a raw product to a ready-to-eat product. Effective handwashing procedures are needed to prevent such transfer.

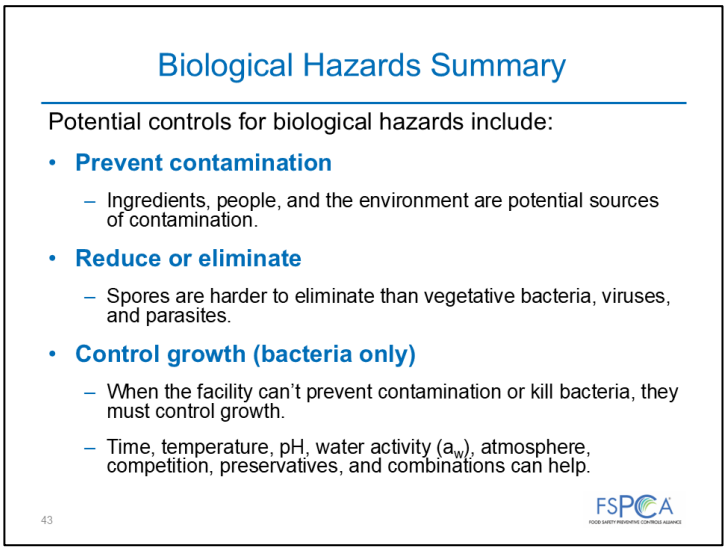
Slide 42: Biological Hazards Summary (1 of 2)



Determining which biological hazards require a preventive control for a specific food is covered in Chapter 6: Hazard Analysis and Chapter 7: Preventive Controls Determination.

In summary, biological hazards can present a food safety risk if not controlled. The severity of the risk depends on a number of factors, including the consequence of exposure and frequency that the hazard is observed with or without controls in place. Preventive controls must be designed, documented, and implemented for all biological hazards requiring a preventive control as determined by the hazard analysis process. Because there are many potential hazards that could be considered in the production of food, it is important to identify those that are of such importance that they must be managed using a preventive approach. This will enable the Food Safety Team to focus resources on the most important hazards. The hazard analysis process is an important step to identify those hazards requiring a preventive control. This is addressed in Chapters 6 and 7: Hazard Analysis and Preventive Control Determination.

Slide 43: Biological Hazards Summary (2 of 2)



Remember the three main strategies to control biological hazards: 1) Prevent contamination; 2) Reduce or eliminate them; and 3) Control growth. Strategies to prevent contamination must address ingredients, people, and the environment, as relevant to the product being produced. When reducing or eliminating pathogens are considered, remember that spores are harder to kill than vegetative bacteria, frequently requiring heating under pressure to achieve effective temperatures. Finally, preventing growth may be necessary and examples include time, temperature, pH, water activity (a_w), atmosphere, competition, preservatives, or combination of these.

Slide 44: Knowledge Check 1

Participants do NOT have this slide.

Slide 45: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

Barbosa-Canovas, G. et al. (2007). *Water Activity in Foods: Fundamentals and Applications,* Blackwell Publishing, and the Institute of Food Technologists

CDC Estimates of Foodborne Illness in the U.S.: https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html

CDC Outbreak Data: https://www.cdc.gov/outbreaks/index.html

EPA: Difference Between Disinfect, Sanitize, and Clean Surfaces: https://www.epa.gov/coronavirus/whats-difference-between-products-disinfect-sanitize-and-clean-surfaces

FDA. (2012). Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook – 2nd Edition): https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition

FDA Bovine Spongiform Encephalopathy (BSE): https://www.fda.gov/animal-veterinary/compliance-enforcement/bovine-spongiform-encephalopathy

FDA. (2022). Food Code 2022: https://www.fda.gov/food/fda-food-code/food-code-2022

FDA. (2004). Guidance for Industry: Juice HACCP Hazards and Controls Guidance 1st Edition; Final Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first

FDA. (2022). Guidance for Industry: Fish and Fishery Products Hazards and Controls: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-fish-and-fishery-products-hazards-and-controls

FDA. (2014). Dairy Grade A Voluntary HACCP: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/dairy-grade-voluntary-haccp

FDA. (2014). Foodborne Illness-Causing Organisms in the U.S. What You Need to Know: https://www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses

FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/media/100002/download

FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 3: https://www.fda.gov/media/99558/download

FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Appendix 1: https://www.fda.gov/media/99581/download

FDA's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Appendix 3: https://www.fda.gov/media/99598/download

FDA's Office of Regulatory Affairs (ORA) Lab Manual (Section 4): https://www.fda.gov/science-research/field-science-and-laboratories/field-science-laboratory-manual

FDA Reportable Food Registry: https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry

FDA Reportable Food Registry Data Dashboard: https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard

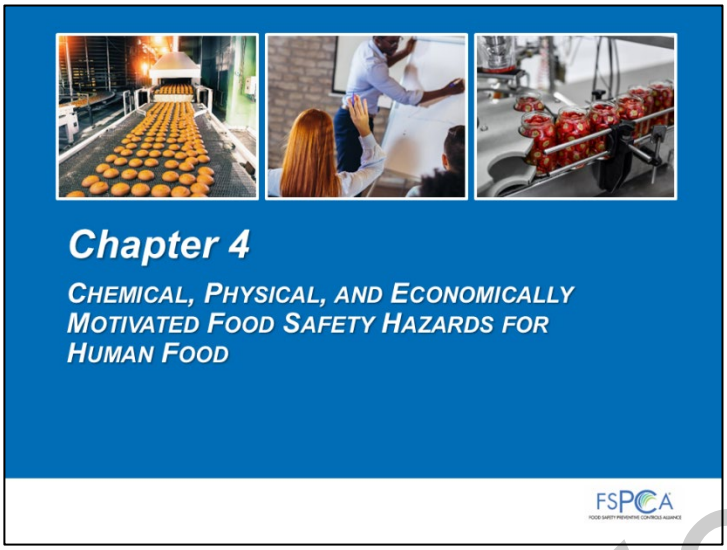
International Commission on Microbiological Specifications for Foods (ICMSF). (1996). *Microorganisms in Foods 5: Microbiological Specifications of Food Pathogens.* Blackie Academic and Professional, New York

ICMSF. (2005). Microorganisms in Foods 6: Microbial Ecology of Food Commodities. Kluwer Academic/Plenum Publishers, New York

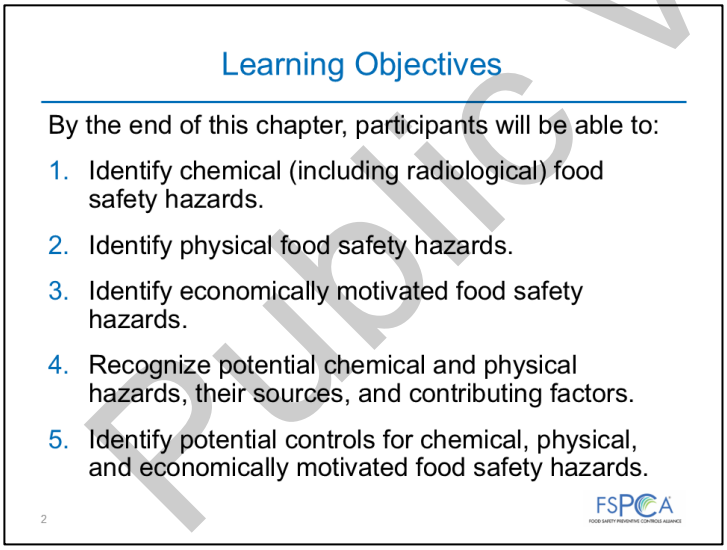
Scallan, et. al. (2011). Foodborne illnesses acquired in the United States – Major Pathogens. *Emerging Infectious Diseases 17*(1):7-15

Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015 (2018).

Slide 1: Chapter 4: Chemical, Physical, and Economically Motivated Food Safety Hazards for Human Food



Slide 2: Learning Objectives



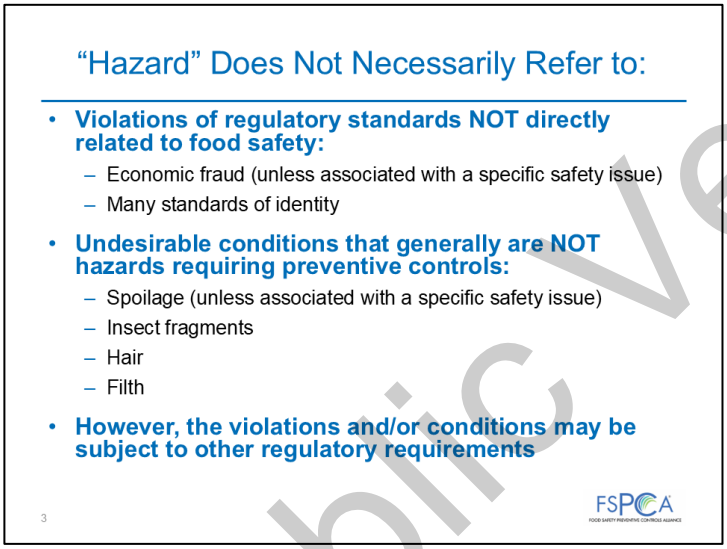
As with biological hazards, in developing or modifying a Food Safety Plan, it is important to be aware of the potential chemical and physical hazards associated with the food products and processes under consideration. It is also important to be aware that economically motivated hazards may be introduced. When these hazards are understood, preventive measures can be implemented to control them, thus preventing illness or injury. This section builds on the overview information presented in Chapter 3: Biological Food Safety Hazards and discusses chemical hazards that are ingredient-related and process-related hazards commonly of concern in food

processing facilities and those holding food products. Radiological hazards, which are encountered less frequently, are discussed under chemical hazards. This chapter also addresses physical hazards and economically motivated hazards that may be associated with specific types of food or food production practices.

As with biological hazards, information from this chapter is useful for conducting a hazard analysis for a food. The hazard analysis process is discussed in Chapter 6: Hazard Analysis, and Chapter 7: Preventive Controls Determination.

Recall that the Preventive Controls for Human Food regulation defines hazard as "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury." Chemical hazards include food allergens, mycotoxins, toxic chemicals, radiological agents, etc.; and physical hazards include metal, glass, hard plastic and other objects that can cause injury.

Slide 3: "Hazard" Does Not Necessarily Refer To:

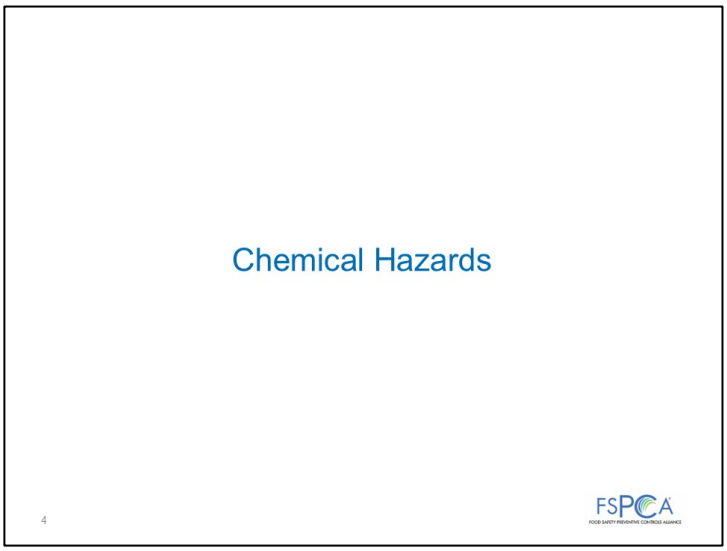


The terms "filth," "foreign material," or "extraneous material" can be used interchangeably. It refers to any type of matter that does not obviously belong in a food product.

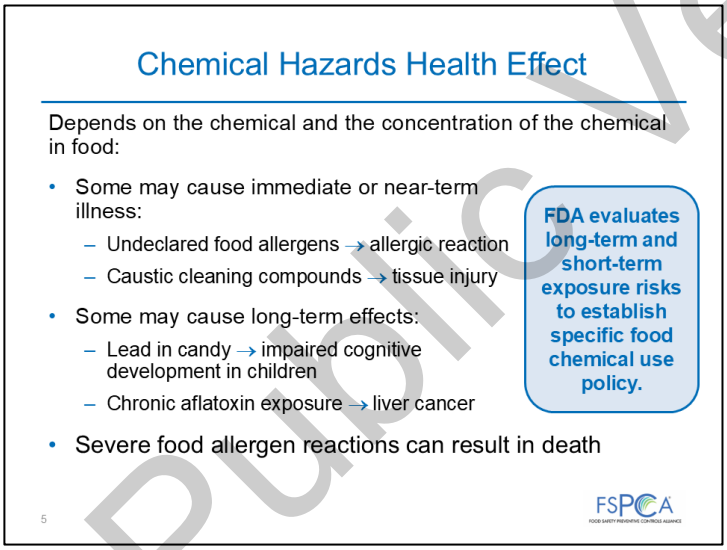
– Adapted from ORA Lab Manual, Section 4

This slide from the previous chapter identifies many conditions that are highly undesirable in food, such as the presence of insects, hair, filth, or spoilage, but that are not necessarily food safety hazards. Economic fraud and violations of regulatory food standards are equally undesirable. All of the defects on this slide should be controlled in food processing or through GMPs, however, many times they are not directly related to the safety of the product. Unless these conditions directly affect food safety, they are not included in a Food Safety Plan. For example, decomposition can be a food safety hazard when biogenic amines or other toxic substances are produced. An example of economic fraud that involves a potential food safety issue might be substituting a less expensive ingredient that has a food allergen for a more expensive ingredient that does not contain the allergen.

Slide 4: Chemical Hazards



Slide 5: Chemical Hazards Health Effects



Action Levels for Poisonous or Deleterious Substances

Action Levels for Lead in Food Intended for Babies and Young Children

Action Levels for Poisonous or Deleterious Substances in Human and Animal Feed contains information on levels of chemicals that are prohibited in certain foods (access using the QR Code above). The link is also available in the Additional Reading, Resources, and References list at the end of the chapter.

The presence of a chemical residue in a food is not always a hazard and may be unavoidable. The amount and type of chemical substance determines whether it is a hazard or not. Some chemical hazards can cause r injury, illness or death such as food allergens (discussed below) or high concentrations of certain chemicals. Other

chemical hazards require exposure over a prolonged period to have a toxic effect in humans, such as lead contamination of candy resulting in impaired cognitive development in children and cancers caused by certain toxins in food.

The safety of chemicals used in food and food processing must be evaluated on a use-by-use basis. Regulatory limits are set for many chemical contaminants. These limits consider long-term and short-term exposure consequences, quantity, toxic potency, and potential benefits like antimicrobial activity, and similar properties. FDA action levels for specific hazardous chemicals in specific commodities are published in "Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed."

If there is no tolerance, action level or other regulatory limit for a specific hazardous chemical in a specific food product, concentrations must be below the limit of current standards for analytical testing. FDA will do a case-by-case evaluation for heavy metals if there is no tolerance, action level, or regulatory limit established.

The FDA has a listing of chemicals that once were used, or were proposed for use, that are not permitted in food. Listed in 21 CFR Part 189: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-189

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

Authority: 21 U.S.C. 321, 342, 348, 371, 381. Source: 42 FR 14659, Mar. 15, 1977, unless otherwise noted.

Editorial Note: Nomenclature changes to part 189 appear at 61 FR 14482, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001; 70 FR 40880, July 15, 2005; and 70 FR 67651, Nov. 8, 2005.

Subpart A—General Provisions

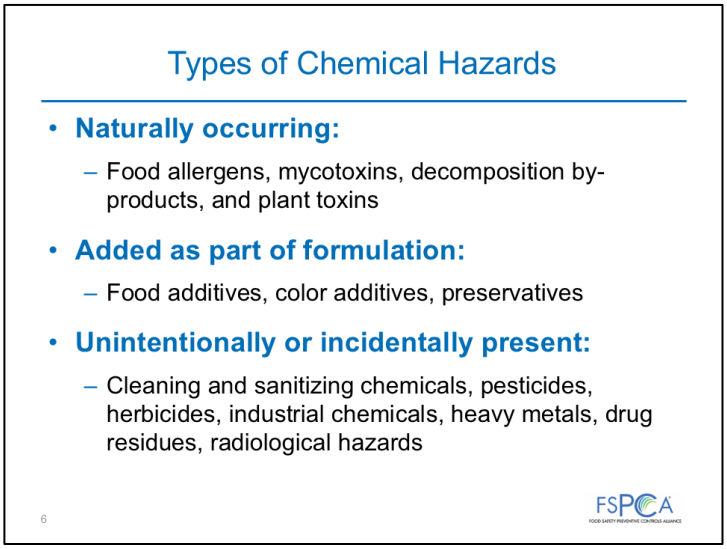
§189.1 Substances prohibited from use in human food.

(a) The food ingredients listed in this section have been prohibited from use in human food by the Food and Drug Administration because of a determination that they present a potential risk to the public health or have not been shown by adequate scientific data to be safe for use in human food. Use of any of these substances in violation of this section causes the food involved to be adulterated in violation of the act.

(b) This section includes only a partial list of substances prohibited from use in human food, for easy reference purposes, and is not a complete list of substances that may not lawfully be used in human food. No substance may be used in human food unless it meets all applicable requirements of the act.

(c) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish, amend, or repeal a regulation under this section on the basis of new scientific evaluation or information. Any such petition shall include an adequate scientific basis to support the petition, pursuant to part 10 of this chapter, and will be published for comment if it contains reasonable grounds.

Slide 6: Types of Chemical Hazards



As previously mentioned, naturally occurring chemical hazards include those present in a food or produced in the natural environment unrelated to human activity. Naturally occurring chemicals include food allergens; mycotoxins; decomposition by-products; and plant toxins.

For example, some cheeses and other food may contain histamine as a result of microbial fermentation converting histidine to histamine. Some people are sensitive to low levels; others require exposure to high levels produced in very ripe products of fermentation (Stratton et al. 1991). Extended fermentation can result in decomposition of the food.

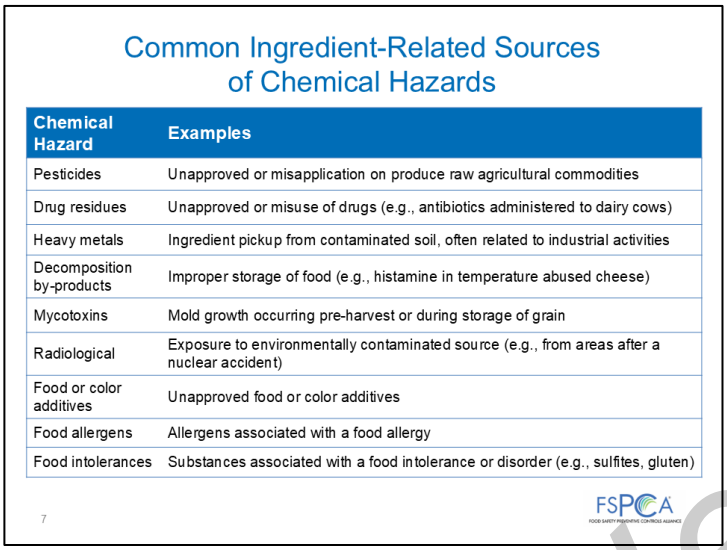
Another type of naturally occurring chemicals are plant lectins. Phytohaemagglutinin (PHA) is a lectin found in raw or undercooked beans. They are proteins that bind to carbohydrates and some plants produce them as a natural defense mechanism. In canned and properly cooked kidney beans, the low levels of PHA will not affect humans, but at high levels in raw beans, PHA can lead to nausea, severe vomiting, and diarrhea. Adequate cooking will remove and destroy this toxin.

Other process-contaminant hazards in certain plant-based foods include acrylamide in certain plant-based foods, and 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters in refined oils.

Chemicals that are added as part of the formulation are part of the food itself, but if too much or too little is added, health risks can occur. Yellow #5 or sulfites are examples of additives that can become a hazard when they are improperly added. A chemical hazard due to misformulation could also involve preservatives if a manufacturer accidentally adds the preservative such as sodium benzoate in excess of a maximum use level (exceeds 0.1% in the finished food).

Unintentionally or incidentally present chemicals may inadvertently get into the food. These may be present in the processing plant (sanitation chemicals), come in with agricultural items (pesticides, herbicides), or be introduced via other routes.

Slide 7: Common Ingredient-Related Sources of Chemical Hazards



Common Ingredient-Related Sources of Chemical Hazards

Chemical Hazard	Examples
Pesticides	Unapproved or misapplication on produce raw agricultural commodities
Drug residues	Unapproved or misuse of drugs (e.g., antibiotics administered to dairy cows)
Heavy metals	Ingredient pickup from contaminated soil, often related to industrial activities
Decomposition by-products	Improper storage of food (e.g., histamine in temperature abused cheese)
Mycotoxins	Mold growth occurring pre-harvest or during storage of grain
Radiological	Exposure to environmentally contaminated source (e.g., from areas after a nuclear accident)
Food or color additives	Unapproved food or color additives
Food allergens	Allergens associated with a food allergy
Food intolerances	Substances associated with a food intolerance or disorder (e.g., sulfites, gluten)

7

FSPCA

Common ingredient-related hazards include pesticides, drug residues, heavy metals, decomposition by-products such as histamine, mycotoxins, radiological hazards, unapproved food and color additives, food allergens, and substances associated with a food intolerance or food disorder. Some ingredient-related chemical hazards are natural components of food, such as food allergens, or are produced in the natural environment, such as mycotoxins, whereas other ingredient-related hazards (e.g., pesticides, drug residues, heavy metals), are contaminants of raw materials and other ingredients.

Certain pesticides can be applied directly to food or crops to control weeds, insects, or microbial contamination. Other pesticides cannot be applied directly to food (e.g., for rodent control). Pesticides can be used legally only if they are registered with the appropriate authority and used according to conditions described on the label.

Drugs are an important part of animal health, welfare, and management, but may present a chemical hazard when not used appropriately

Heavy metals such as arsenic, lead, and cadmium may accumulate in plants if the growing environment has high concentrations of these chemical hazards.

Chemical hazards can also form due to decomposition if the food product is not stored appropriately (e.g., histamine in temperature abused cheese).

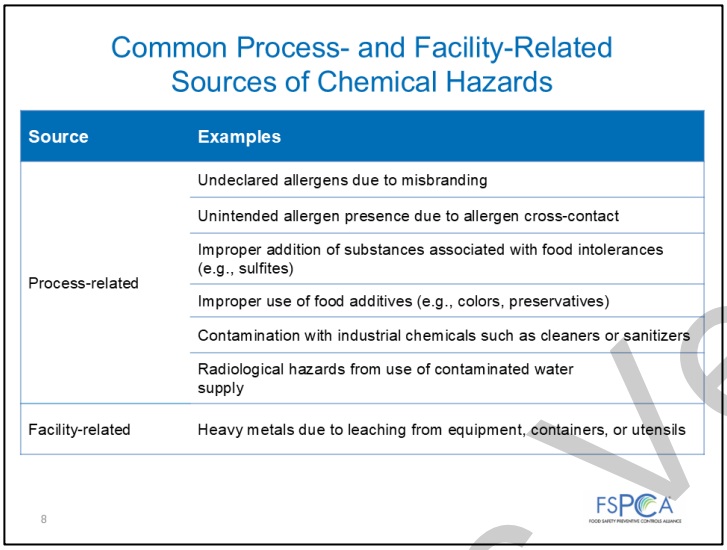
Mycotoxins are chemical hazards produced by certain types of molds when extensive growth occurs on commodities of concern.

Radiological hazards from an environmentally contaminated source are rarely encountered in food; however, when they do occur, radiological hazards can present a risk.

Other ingredient-related chemical hazards include food and color additives. The potential risk to consumers increases when these substances are not properly controlled, such as exceeding the usage rates or accidentally introducing an additive into a food for which it was not approved.

Food allergens and substances associated with a food intolerance or food disorder (e.g., sulfites, gluten), can be ingredient-related hazards but they can also be process-related due to misformulation.

Slide 8: Common Process- and Facility-Related Sources of Chemical Hazards



Common Process- and Facility-Related Sources of Chemical Hazards

Source	Examples
Process-related	Undeclared allergens due to misbranding
	Unintended allergen presence due to allergen cross-contact
	Improper addition of substances associated with food intolerances (e.g., sulfites)
	Improper use of food additives (e.g., colors, preservatives)
	Contamination with industrial chemicals such as cleaners or sanitizers
	Radiological hazards from use of contaminated water supply
Facility-related	Heavy metals due to leaching from equipment, containers, or utensils

8

FSPCA

Chemical hazards can also be process or facility/environment related.

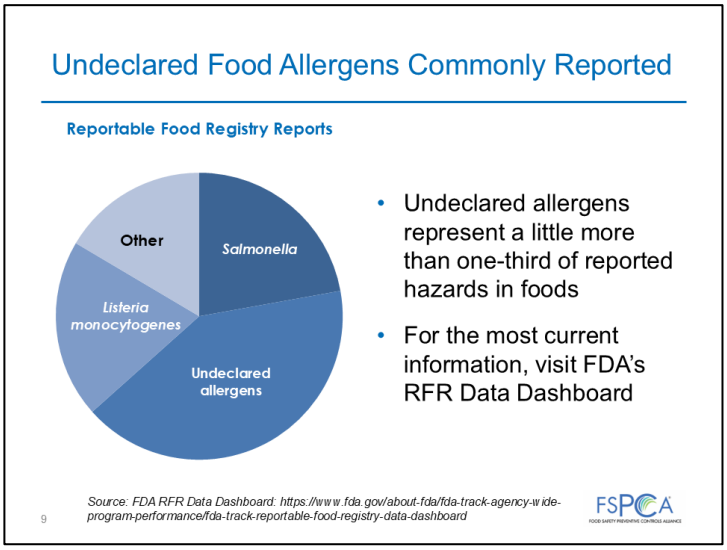
Undeclared allergens can result from mislabeling within the process. Mislabeling can occur due to incorrect label design and/or incorrect label application or use of a product label. Cross-contact results from the unintentional incorporation of a food allergen into foods that are not intended to include those allergens.

A food ingredient can be a chemical hazard if it is added in excess of a maximum use level. For example, sodium benzoate is permitted for use in food as an antimicrobial agent with a maximum use level of 0.1% in the food. A chemical hazard due to misformulation could occur if a manufacturer accidentally adds sodium benzoate such that it exceeds 0.1% in the finished food.

Industrial chemicals are another example of process-related chemical hazards that could contaminate food during production (e.g., if chemicals used to clean a production line are not adequately removed from the production line). Radiological hazards can become incorporated into food through the use of water that contains the radionuclides during food production or manufacture.

Facility related hazards can include contaminants from the food processing environment that can contaminate food during production (e.g., if heavy metals are leaching from containers or utensils).

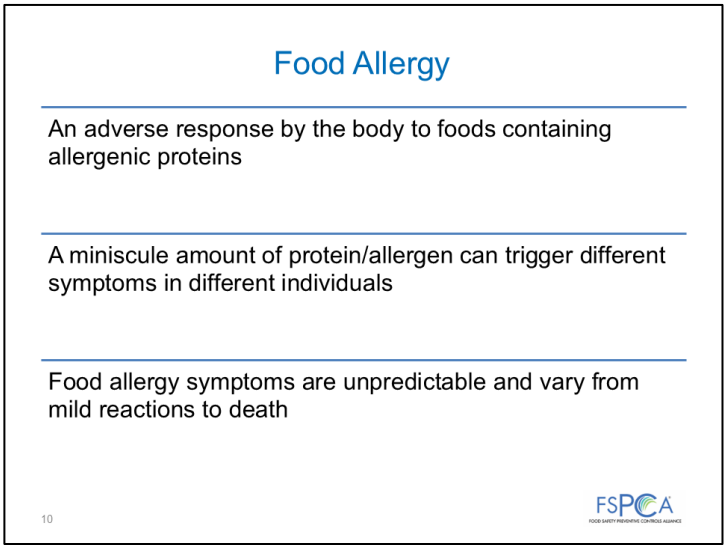
Slide 9: Undeclared Food Allergens Commonly Reported



FDA RFR Data Dashboard

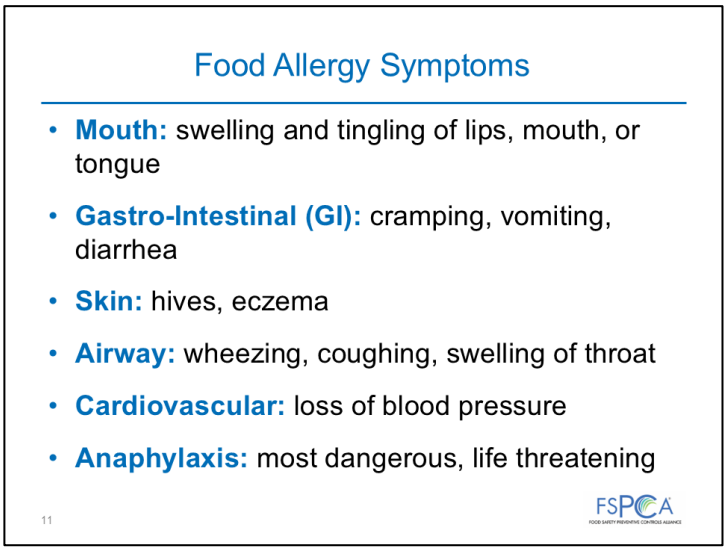
A useful source of information on the hazards that may be present in different foods is the FDA's Reportable Food Registry (see the QR Code above and to the right of the slide or "Additional Reading" at the end of the chapter). This registry collects information from the food industry and from public health authorities on foods or feed that are likely to cause serious adverse health consequences or death to humans or animals if they are used. Biological hazards represent the primary category of hazards reported through the registry. However, undeclared allergens in human food represent more than one third of the reports. These are discussed later in this chapter.

Slide 10: Food Allergy



Food allergens are naturally present in certain foods and these foods are examples of ingredients normally used in food that do not present a chemical hazard for most people. However, they can be life-threatening for those with a food allergy. It is estimated that food allergies affect four to six percent of children and two to three percent of adults in the United States. The presence of undeclared allergens in food is a major cause of product recalls. A food allergen reaction is the body's immunological response to proteins in the food that the body sees as foreign. These reactions can be fast-acting yet also unpredictable and should not be confused with food intolerance, such as lactose intolerance.

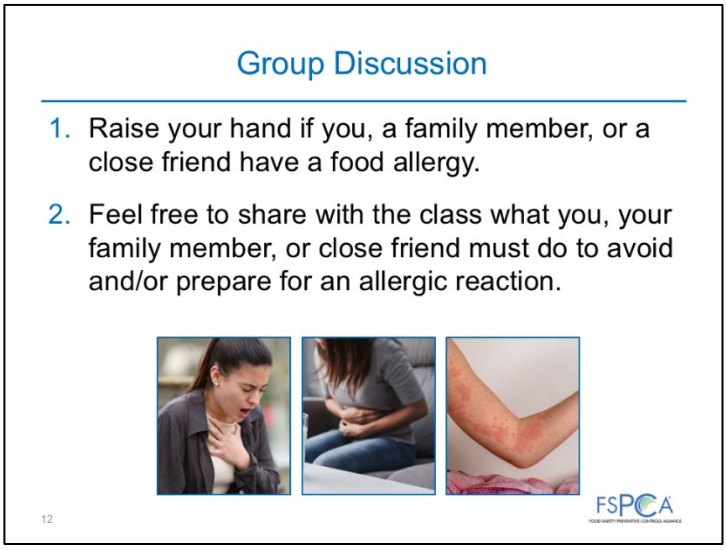
Slide 11: Food Allergy Symptoms



People with food allergies can experience a variety of symptoms that can be mild to severe and can affect different systems in the body. The severity of the response depends on the amount of the allergen consumed and individual sensitivity. Mild allergic responses can be treated with antihistamine, but serious reactions like anaphylaxis are treated with epinephrine. Anaphylaxis is a generalized reaction, which can include multiple organ failure, any of the symptoms listed above, severe loss of blood pressure, and cardiac arrhythmia. This reaction can be fatal. In the U.S., tens of thousands of emergency room visits and 150-200 deaths per year can be attributed to anaphylactic reactions.

Reactions usually occur between 1 minute and 30 minutes after exposure but may take up to 2 hours. Food allergy sufferers may experience multiple severe reactions in their lifetime. Children with asthma and multiple food allergies are at increased risk for anaphylaxis. Milk, soy, and egg allergies may be outgrown; but peanut, tree nut and shellfish allergies often persist throughout life—although individual reactions may vary.

Slide 12: Group Discussion



Participate in the whole group discussion.

Slide 13: Major Food Allergens in United States

The FDA has responses to frequently asked questions related to food allergens on their website. See Additional Reading at the front of this chapter or search the FDA website.

In the United States, the Food Allergen Labeling and Consumer Protection Act of 2004 mandated labeling of the original eight (8) allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. Sesame became the ninth major food allergen through the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act, a federal law passed in 2021, that took effect in January 2023.

Most food allergies are reactions to these food items.

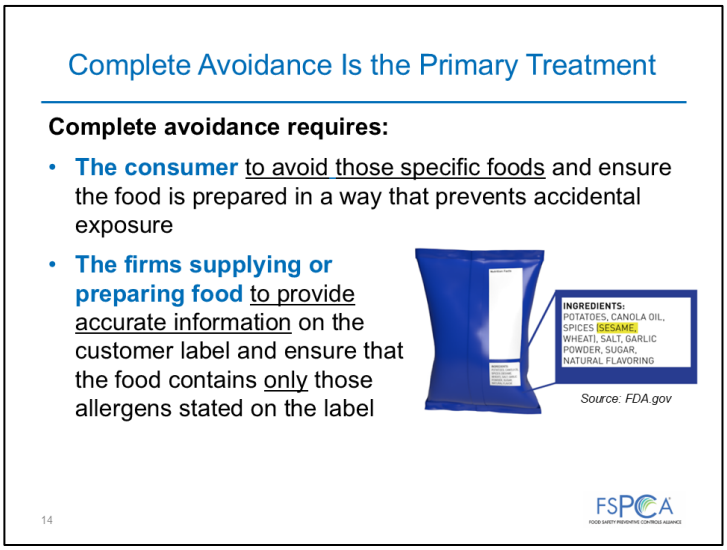
Labeling of these major food allergen groups (if present) is required along with identifying the specific allergen. Specifically for tree nuts, fish, and crustacean shellfish the specific type of tree nut, fish, and shellfish must be labeled. Note that shellfish includes crab, lobster, or shrimp which are crustaceans, but not molluscan shellfish (e.g., oysters, clams, mussels, or scallops).

The FDA has published more specific information about what is considered within each category of allergens. For example, almonds, coconut, lychee, walnuts, pecans, etc., are all considered "tree nuts."

https://www.fda.gov/industry/fda-basics-industry/section-201qq-act-defines-term-major-food-allergen-include-tree-nuts-addition-three-examples

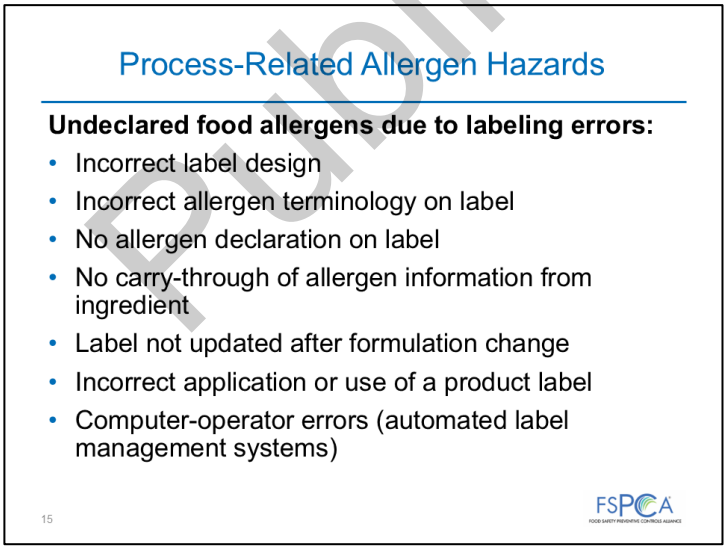
The FDA's labeling regulations do NOT address advisory labeling, which may also be referred to as "precautionary labeling." FDA also does not address threshold limits of allergens present.

Slide 14: Complete Avoidance is the Primary Treatment



Food allergy sufferers must practice complete avoidance of food allergens in order to avoid allergic reactions. Sometimes, the ability to practice avoidance depends on factors outside the control of the individual. Proper labeling of food products along with strict monitoring of labels is required for avoiding specific allergens. Food processors must have accurate information about their ingredients and understand their processing conditions related to allergen cross-contact opportunities to fully assess their own products. Accurate allergen labeling is required to be addressed in the Food Safety Plan.

Slide 15: Processed-Related Allergen Hazards (1 of 2)

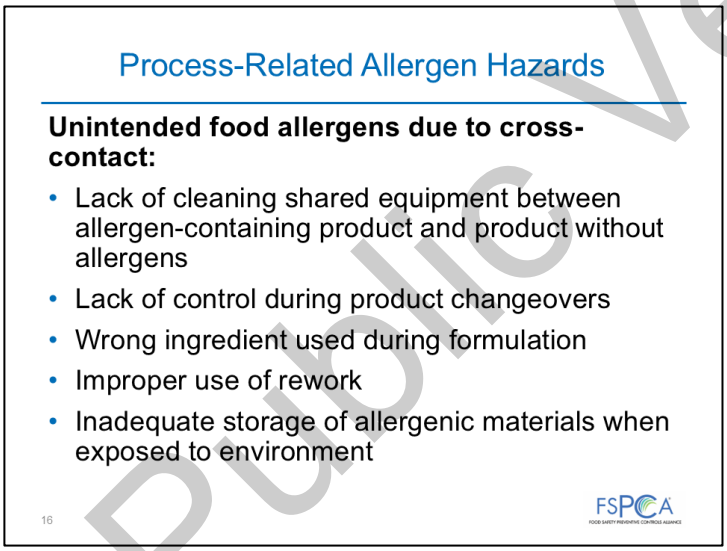


Allergen labeling must be addressed in the Food Safety Plan, which is consistent with the observation that most allergen recalls are related to labeling errors. Examples include:

- Using incorrect label design;
- Using incorrect allergen terminology on labels (not labeling butter with the term "milk"), which is required by labeling regulations;
- Not declaring an allergen on the label;
- Not carrying allergen information through to the label from an ingredient;
- Not declaring allergens that are in processing aids; and
- Using the wrong label or package for a product.

Sometimes computer-operator errors can occur with automated label management systems. This can be caused by mis-entry of information by the label supplier, resulting in incorrect labels being printed. This can also occur within a facility where the possibility exists to print and apply labels in-house even when incorrect allergen ingredients were entered into the computer system.

Slide 16: Processed-Related Allergen Hazards (2 of 2)

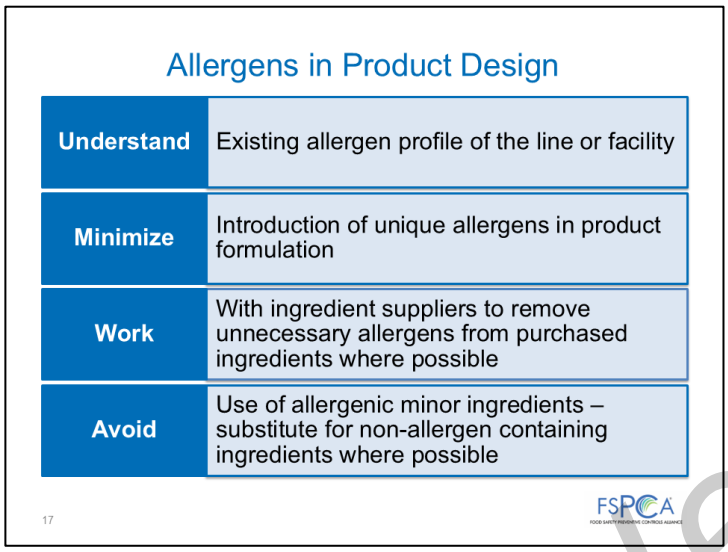


Unintended food allergens due to cross-contact can occur due to lack of cleaning shared equipment between allergen-containing product and product without allergens; lack of control during product changeovers; wrong ingredient used during formulation; improper use of rework; and inadequate storage of allergenic materials when exposed to the environment.

Many of the other causes listed on the slide are related to lack of knowledge of the issue or inadequate management of change. Ensuring that all relevant people are aware of potential allergen issues can minimize the potential for harming a person with a food allergy and can help avoid a recall.

Understanding how undeclared or unintended allergens get into products is the starting point for developing an effective allergen management program. Chapter 11: Food Allergen Preventive Controls.

Slide 17: Allergens in Product Design



Jackson et al. (2008) review of *Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-contact in Food-processing Operations* outlines components of a comprehensive allergen control plan, which meets or exceeds the requirements for preventive controls compliance.

See Additional Reading, Resources, and References at the end of the chapter.

While not required by the Preventive Controls for Human Food regulation, product design can play an important role in minimizing food allergen hazards in production. For example, some products require a protein source as a foaming agent, and egg, soy or milk protein can potentially have the same functionality. If a product developer knows the allergen profile for a production line, they may be able to choose ingredients with the same allergens, thus reducing allergen cross-contact concerns.

Consider only adding new allergens to products when they make an important difference in the taste or functionality of the product. If an allergen-containing ingredient is required, consider different formats to reduce allergen cross-contact issues. For example, it is difficult to make walnut brownies without introducing walnuts, but if making a mix, a separate packet containing walnuts could be used instead of loose walnuts in the mix to minimize the exposure of equipment to tiny pieces of walnuts that make cleaning difficult.

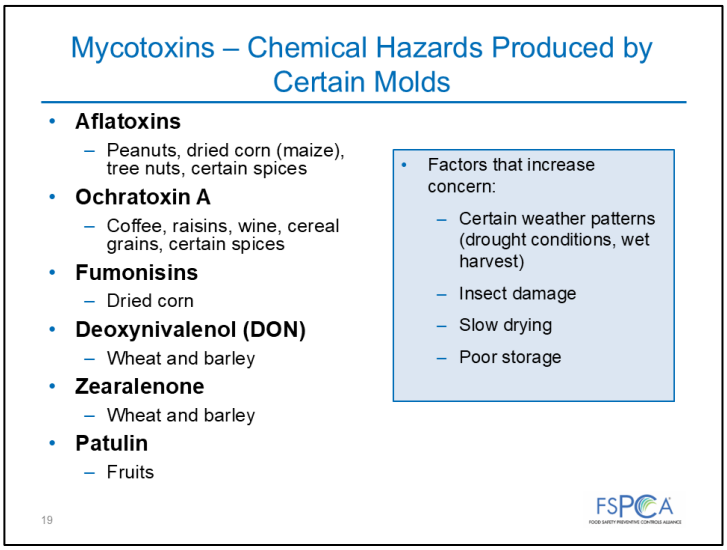
Before a new allergen is added to an existing product or line, consider the potential costs to manage the new allergen in the project plan. This can help determine if the change is really beneficial. If adding a new allergen to an existing formula, including a label element such as "New formula" is useful to alert allergic consumers that a new allergen is in a product. Many food-allergic consumers are very brand loyal.

Jackson's, et al., 2008, review of *Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-contact in Food-processing Operations* outlines components of a comprehensive allergen control plan, which meets or exceeds the requirements for preventive controls compliance.

Slide 18: Allergen Control May Be Needed

This slide describes scenarios when allergens might pose risks to help explain when allergen controls could be needed. Note that this not an all-inclusive list—these are examples of when such controls might need to be considered.

Slide 19: Mycotoxins – Chemical Hazards Produced by Certain Molds



Mycotoxins are chemical hazards produced by certain types of molds when growth occurs on commodities of concern. Aflatoxins are a type of mycotoxin that is produced by certain molds that grow on commodities like corn, peanuts, and others in the field or during storage. Other mycotoxins, such as ochratoxin A, fumonisins, deoxynivalenol (DON or vomitoxin) and zearalenone can present a hazard in crops such as grains, fruits, and tree nuts. Patulin is a potential issue on certain fruits.

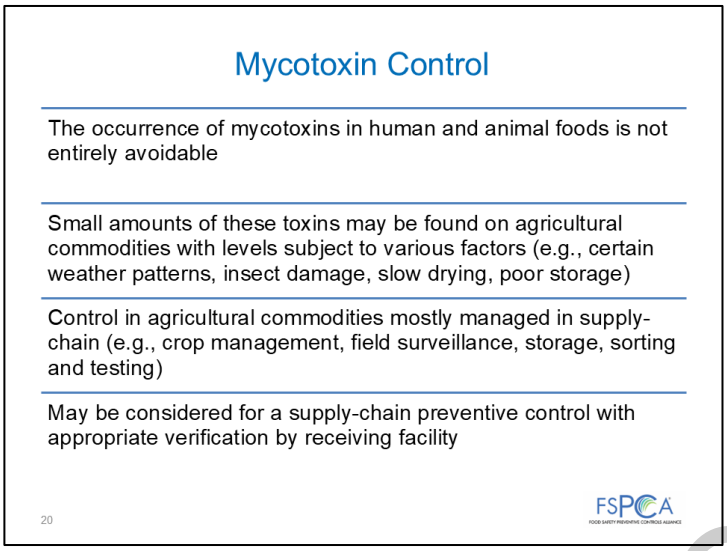
The molds that produce mycotoxins typically become established in commodities of concern under stressful growing conditions before harvest. The molds can also grow during storage of grains when the grain contains moisture above a certain level, and which may vary by crop and mold type. For a given harvest, if local growing conditions have been good, mycotoxin formation may not be a problem. However, when stressful growth conditions for crops or particularly wet harvest seasons for some crops occur, mycotoxins are a risk. Conditions such as insect damage and drought stress can also promote the formation of mycotoxins. Mycotoxins can enter the food chain though secondary channels, for example, moldy aflatoxin B1 containing grain fed to cows can be metabolized to produce aflatoxin M1 by cows and passed into their milk.

A variety of controls throughout the supply-chain can be applied to reduce the potential for mycotoxin formation. First, there are controls associated with harvest including those that prevent incoming grain with preformed toxin from mold growth in the field. Controls must also be in place after harvest to prevent mycotoxin development during handling and storage. Mold (and potentially preformed toxin) will be present on incoming grains. Rapid drying can prevent mold growth and mycotoxin formation during storage, while slow drying can increase the risk of mold growth. If handling and storage conditions are not dry, these conditions may lead to mold growth and mycotoxin formation.

For other commodities such as fruit, color sorting may be helpful. Testing of the product at various stages can be done to reject material with unacceptable concentrations, such as with fruit juice concentrate. It is important to note that studies looking at the

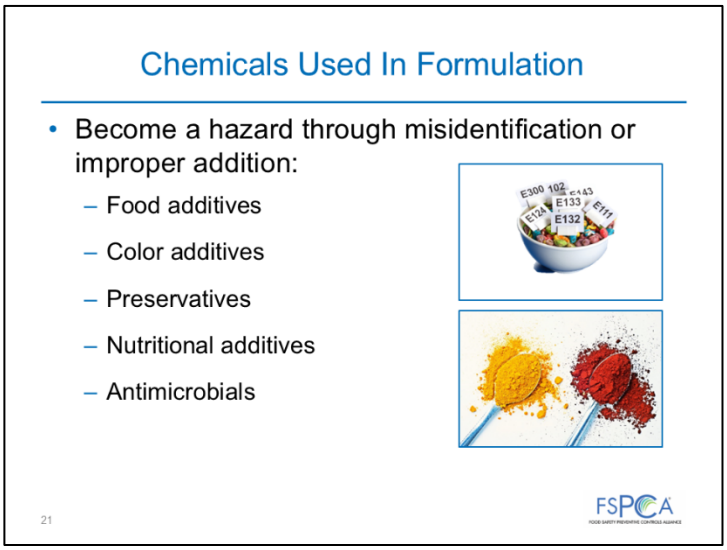
effect of processing on mycotoxins have demonstrated that while some reduction may occur, complete elimination is not achievable (Milani and Maleki 2014).

Slide 20: Mycotoxin Control



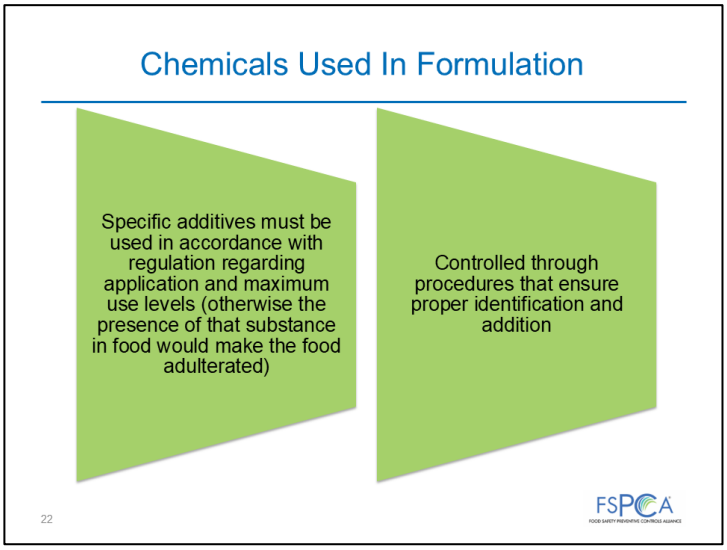
It is important to be aware of the conditions (e.g., weather, insects), that could allow mold growth and therefore, cause mycotoxins to increase to harmful levels. Controls are then applied where these conditions might occur typically outside of the receiving facility.

Slide 21: Chemicals Used In Formulation (1 of 2)



Some chemical substances are added during formulation. They include food additives, color additives, preservatives such as sulfites, and nutritional additives such as vitamin A and D fortification in milk. Other chemicals may be used in processing (e.g., antimicrobials used in wash water for fresh-cut produce). All of these substances are intended to be used at safe levels but could become a chemical hazard if they are added in excess of a maximum use level. "Maximum use level" is defined in Appendix 8: Definitions and is discussed on the next slide.

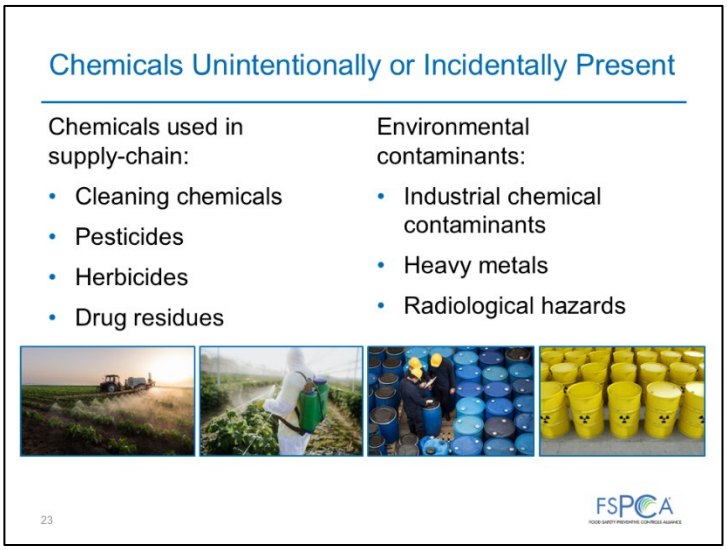
Slide 22: Chemicals Used In Formulation (2 of 2)



Action Levels for Poisonous or Deleterious Substances

FDA sets the maximum use levels (concentration, manner of use and maximum allowable residues) for certain chemical substances in food (see Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed). Keeping within these limits is important for safety as well as regulatory compliance. These chemical substances are not hazardous if properly applied and controlled. Potential risks to consumers increase when these substances are not properly controlled, such as exceeding the recommended usage rates or accidentally are introduced in the wrong place or food.

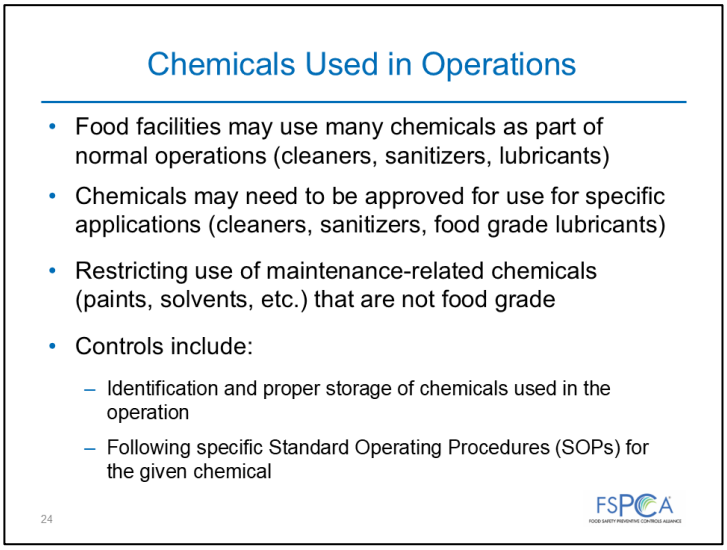
Slide 23: Chemicals Unintentionally or Incidentally Present



Chemicals can become part of a food without being intentionally added. These incidental chemicals might already be in a food ingredient when it is received through the supply-chain. For example, fruits or vegetables may contain small but legal residues of approved pesticides. Packaging materials that are in direct contact with ingredients or the product can be a source of incidental chemicals, such as inks. Cleaning and sanitizing chemicals are necessary to maintain a sanitary environment for the production of food products, and small amounts of sanitizers may remain on equipment surfaces. It is important to follow label instructions to ensure their safe use. Proper sanitary design can help manage residual sanitation chemicals, such as through elimination of dead heads in equipment.

Most incidental chemicals from the environment have no effect on food safety and others are only a concern if they are present in excessive amounts. Incidental chemicals also include accidental additions of prohibited substances. A brief discussion of pesticides, herbicides, industrial chemicals, heavy metals, drug residues, and radiological hazards follows.

Slide 24: Chemicals Used in Operations

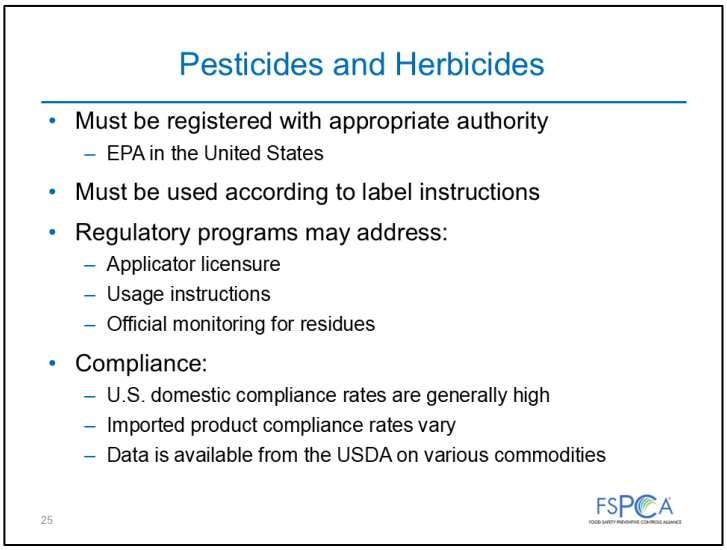


Some chemicals need to be used in the facility to keep the food operation running smoothly and efficiently. These include chemicals used as part of maintenance and sanitation operations. Chemicals used in the food facility must be approved for use and used appropriately so they do not pose risks to the food that is being produced.

The possibility of a cleaning and sanitizing chemical or lubricant making minor contact with food always exists. Since these items are not technically food ingredients, this incidental contact should not lead to the contamination of the food. To be registered as a lubricant or sanitizer that allows for incidental contact, the product must be formulated in accordance with the FDA Code of Federal Regulations, 21 CFR Part 178 or have GRAS status. The 21 CFR gives guidance on ingredients by providing a specific list of chemical compounds and additives which are allowed.

Other chemicals have more restricted uses. They must be identified and properly stored to avoid contact with foods. In some situations, maintenance chemicals such as coolants need controls to prevent and detect accidental release into product.

Slide 25: Pesticides and Herbicides



Certain pesticides can be applied directly to food or crops to control weeds, insects, or microbial contamination. Other pesticides cannot be applied directly to food (e.g., for rodent control). Pesticides can be used legally only if they are registered with the appropriate authority (see below) and used according to conditions described on the label. Numerous U.S. regulatory programs address aspects of pesticide usage, like applicator licensure, usage instructions on the label, official monitoring of pesticide residues in foods, and enforcement actions against violators. Experience in the United States has demonstrated that fruits and vegetables grown in the United States have a high level of compliance with U.S. pesticide tolerance regulations and the occurrence of unlawful pesticide residues in food is likely to be infrequent and unlikely to have a significant public health impact. Because of this, pesticide use in the United States is frequently managed through application of GMPs.

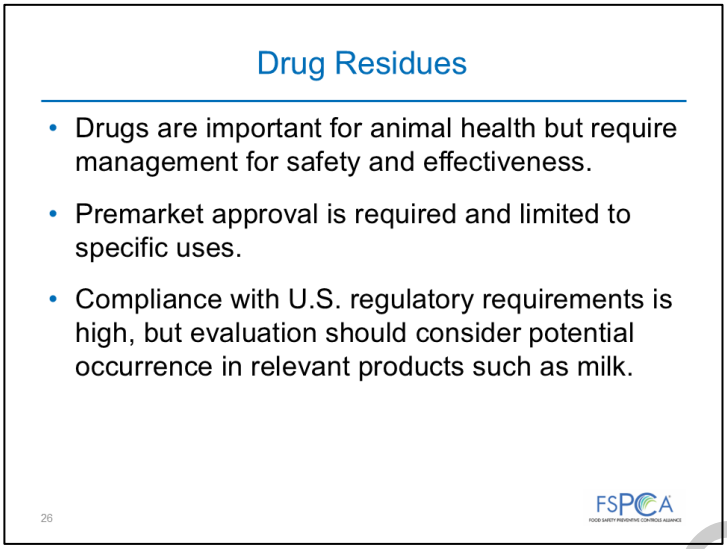
The U.S. Environmental Protection Agency (EPA) registers pesticides for use in the United States, establishes label instructions for use, and sets tolerances for residues of pesticides in food based on safety and conditions of use. The FDA tests the food for pesticide residues for compliance with U.S. tolerances. If a U.S. tolerance has not been established for a particular pesticide in a commodity, then any amount measured may be considered violative. Therefore, check to see if pesticides used in foods, that are imported are in compliance with U.S. pesticide laws.

Within the U.S., compliance rates for pesticide compliance are typically high; import compliance rates may vary though. Per the latest EPA pesticide data (2021), the rate of samples with violations (not presence/absence of residues) varied by commodity and country. Thus, it is not always that imported produce has a higher violation rate than domestic products. In many cases it is because some commodities do not have an established tolerance.

It is key to note that not all countries have the same requirements as the United States, but all imported produce must meet U.S. requirements, which can be different than the country where they are grown. It is important to be aware of the criteria about the

specific commodity and what might impact its pesticide status (e.g., where grown, the local requirements, etc.), to determine what controls might be needed.

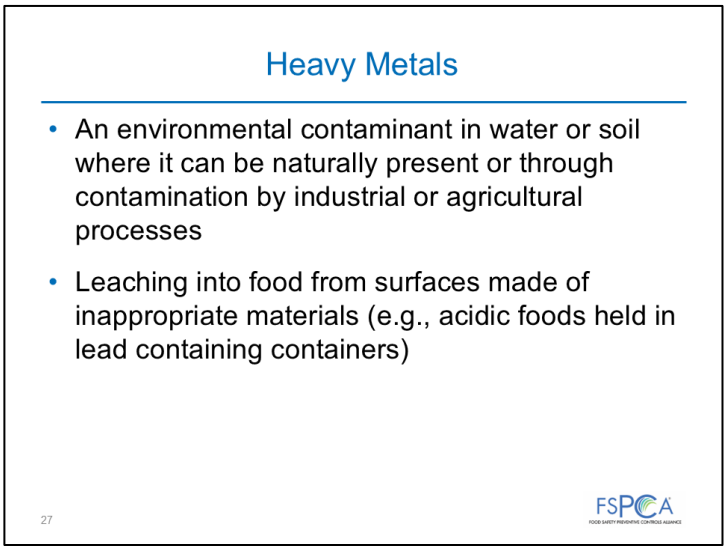
Slide 26: Drug Residues



Drugs are an important part of animal health, welfare, and management, but may present a chemical hazard in foods originating from these animal sources when the potential chemical hazards are not managed appropriately. The presence of inappropriate drug residues in food may cause short term effects on consumers, allergic reactions, or chronic toxic effects.

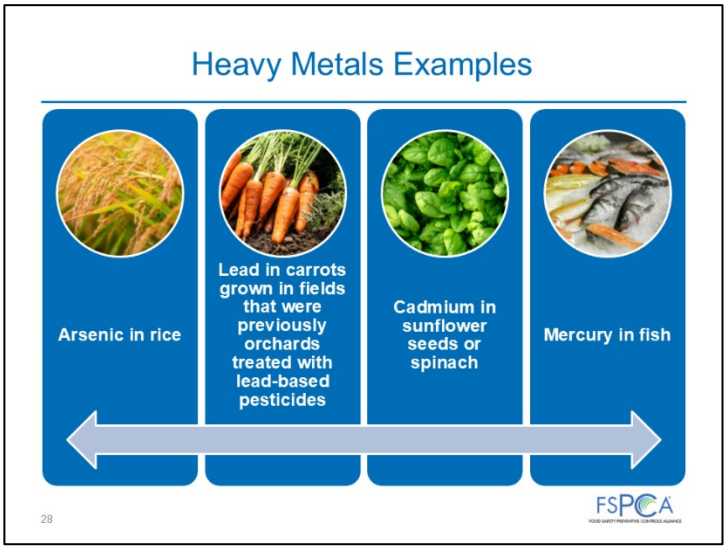
Animal drugs require premarket approval before they can be legally used. Drug residues (e.g., antibiotics administered to dairy cows), present in food derived from an animal (such as milk) can be a hazard if a tolerance has not been established for the food, or if such a tolerance is exceeded. If drug residues are identified as a hazard requiring a preventive control in the hazard analysis, the application of a supply-chain program would be considered as a preventive control.

Slide 27: Heavy Metals



Heavy metals, including arsenic, lead, cadmium, and mercury, may be of concern in certain foods as a result of agricultural practices (e.g., use of pesticides containing heavy metals or because crops are grown in soil containing elevated levels of heavy metals due to industrial waste), or the leaching of heavy metals from equipment, containers or utensils that come in contact with foods. GMP controls, such as the controls on equipment and utensils in 21 CFR 117.40, generally can control chemical hazards such as heavy metals that can leach from food-contact surfaces.

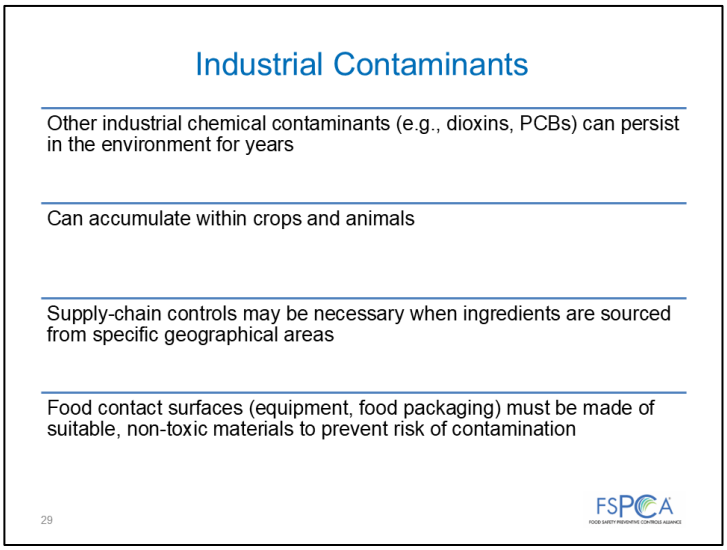
Slide 28: Heavy Metals Examples



Heavy metals such as arsenic, lead, and mercury may accumulate in fish or plants if the growing environment has high concentrations of these chemical hazards. Examples include arsenic accumulation in rice, lead accumulation in carrots grown in fields that previously were orchards treated with lead-based pesticides, and mercury accumulation in large fish. Cadmium is mined and then released into the environment mainly through air dispersal during smelting. Once in the environment, it then can move through the soil and be taken up by certain plants, such as rice, other cereal grains, potatoes, and other vegetables. Assessment of the growing region prior to use can help to avoid these hazards.

Consumption of heavy metals in foods can lead to adverse health consequences. For example, lead exposure can impair cognitive development in children. Consumption of inorganic arsenic has been associated with cancer, skin lesions, developmental effects, cardiovascular disease, neurotoxicity, and diabetes in humans.

Slide 29: Industrial Contaminants



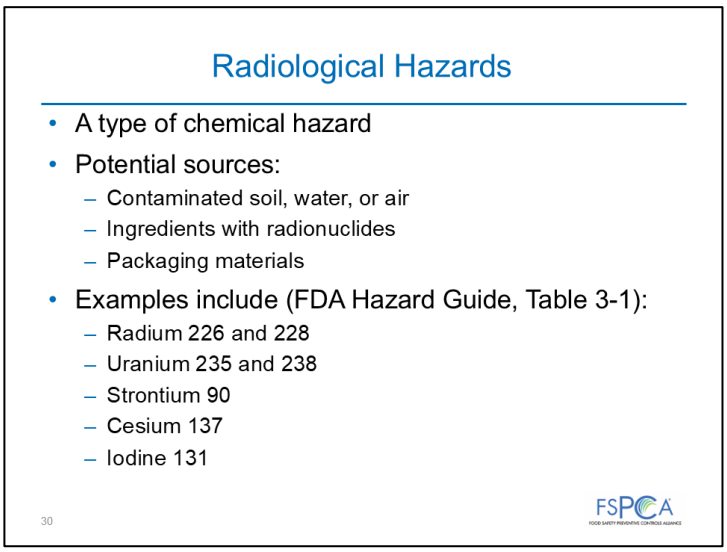
Food crops can be harvested from areas that are contaminated by varying amounts of industrial chemicals including dioxins and polychlorinated biphenyls (PCBs). "Dioxins" is a collective term for a group of environmental contaminants that includes certain dioxin, furan and dioxin-like PCB compounds that are found throughout the world. They are released into the air from combustion processes, such as commercial or municipal waste incineration and from burning fuels, such as wood, coal, or oil. Burning of household trash and forest fires can also result in the release of dioxins and furans into the environment. Accidental or intentional release of transformer fluids has resulted in the presence of PCBs in the environment.

Because dioxins break down very slowly, dioxins released in the past from both man-made and natural sources still exist in the environment and cannot be quickly reduced. Dioxins can be deposited on plants that are then eaten by animals. Thus, they may be concentrated in the food chain so that livestock, fish, and shellfish can have higher concentrations than the plants, water, soil, or sediments around them. An evaluation of the potential for contamination of crops by dioxin and related materials may be worth considering.

PFAS (per- and polyfluoroalkyl substances) are widely used, long lasting chemicals, components of which break down very slowly over time. PFAS are found in water, air, fish, and soil at locations across the nation and the globe and are found in the blood of people and animals all over the world. Scientific studies have shown that exposure to some PFAS in the environment may be linked to harmful health effects in humans and animals, but there are thousands of PFAS chemicals, and they are found in many different consumer, commercial, and industrial products. This makes it challenging to study and assess the potential human health and environmental risks. The EPA researchers and partners across the country are working hard to answer critical questions about PFAS.

Supply-chain controls can be ways to manage these risks.

Slide 30: Radiological Hazards

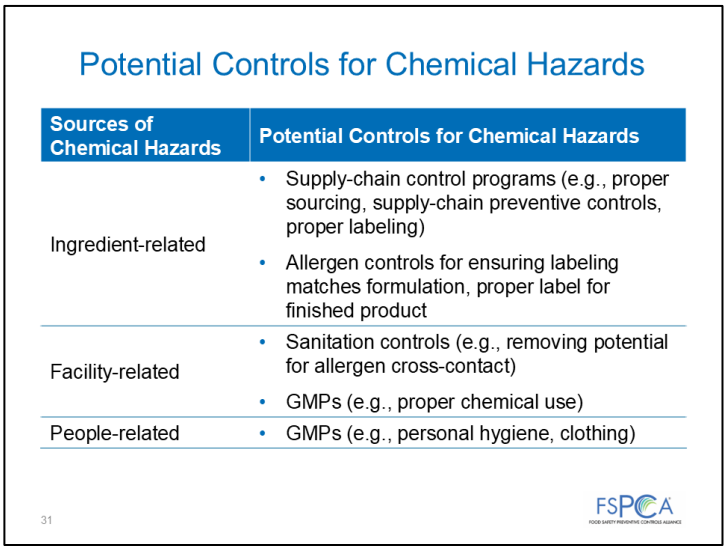


Frequently a certificate can be obtained from a municipal water supplier that demonstrates compliance of water to U.S. Environmental Protection Agency (EPA) standards for radionuclides.

Radiological hazards are rarely encountered in food, however, when they do occur, radiological hazards can present a health risk. According to the World Health Organization (WHO), typical levels of radiological hazards in food would have to be consumed over a period of time to present a risk (see "Additional Reading" at the end of this chapter). Examples of radiological hazards include radionuclides such as radium-226, radium-228, uranium-235, uranium-238, strontium-90, cesium-137, and iodine-131. The most common way these radionuclides are incorporated into foods is through use of water that contains a radionuclide during food production or manufacture. For example, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium has been detected in private wells. This should be considered in the hazard analysis in these regions but would not be applicable in most regions.

Radiological hazards also may result from accidental contamination, such as contamination arising from accidental release from a nuclear facility or damage to a nuclear facility from a natural disaster. In 2011, radioactivity was detected in milk, vegetables, and seafood produced in areas neighboring a nuclear power plant damaged during an earthquake and tsunami in Japan.

Slide 31: Potential Controls for Chemical Hazards



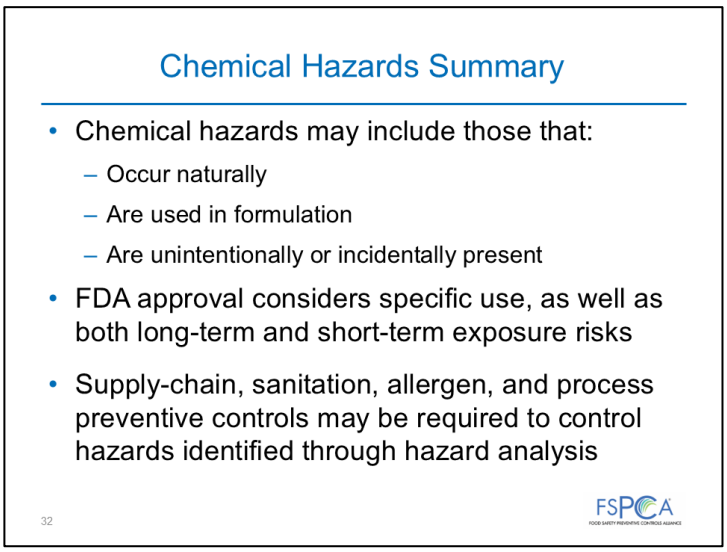
Many chemical hazards can be effectively managed through GMPs and other prerequisite programs. The hazard analysis process determines the chemical hazards requiring a preventive control. Understanding where the facility's ingredients come from and assuring the supplier has appropriate controls in place to manage chemical hazards is the first step in managing such hazards. This may require a supply-chain program as a preventive control.

Sanitation preventive controls can be an important preventive control for allergens if products with different allergen profiles are manufactured. Allergen labeling is important and requires allergen controls if any of the facility's ingredients or raw materials contain food allergens (see Chapter 11: Food Allergen Preventive Controls).

Process preventive controls may be relevant to certain potential chemical hazards depending on the nature of the product.

Consider the fact that GMPs including proper chemical use and personal hygiene practices can be part of controls for chemical hazards.

Slide 32: Chemical Hazards Summary

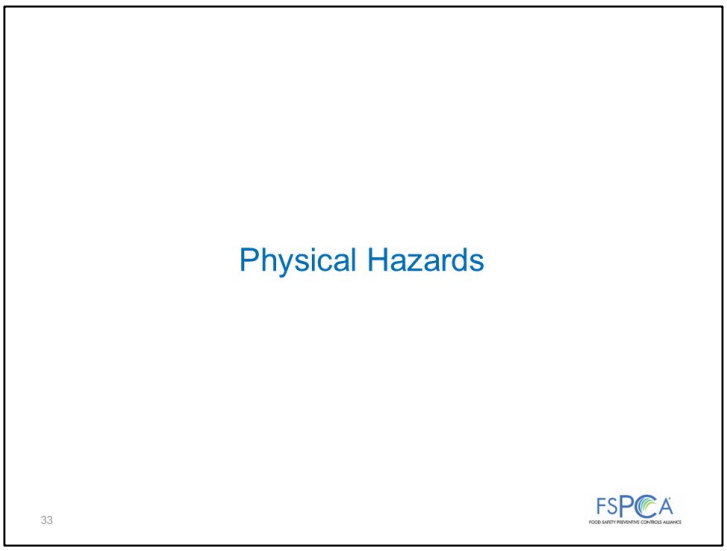


Chemical hazards can enter food as naturally occurring substances (e.g., allergens), as ingredients or raw materials that are part of the formulation but may be misused, and as unintentionally or incidentally present substances. The top cause of recalls is related to food allergens.

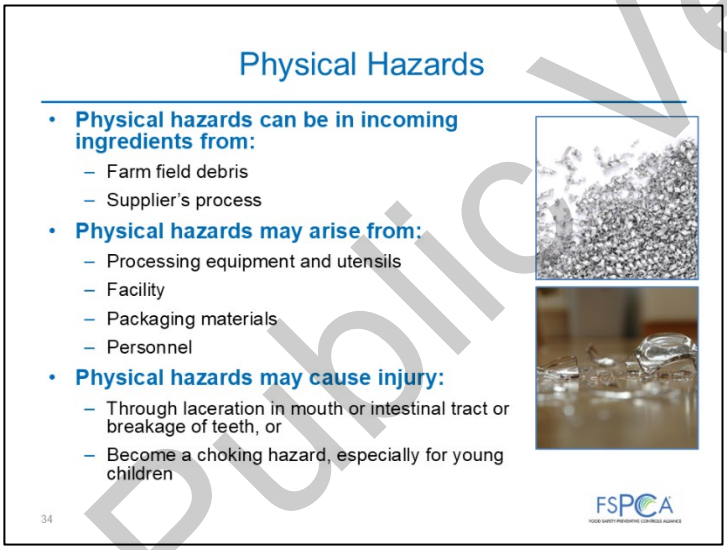
Allowable levels, if any, are established by FDA (or EPA for pesticides), which also provides guidance on potential controls for many chemical substances.

A supply-chain program may play a key role in managing chemical hazard risks in incoming raw materials and ingredients. Sanitation, allergen, and process preventive controls may also be important controls, depending on the product and process and results of the hazard analysis.

Slide 33: Physical Hazards



Slide 34: Physical Hazards



FDA has taken action when physical hazards that are hard, sharp, and pointed and 0.3 inches (7 mm) to 1.0 inches (25 mm) in length could be present in a food.

CPG Sec 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects

In addition to identifying biological and chemical hazards, the Food Safety Team must also conduct a hazard analysis to identify and evaluate known or reasonably foreseeable physical hazards (such as stones, glass, and metal fragments). See 21 CFR 117.130(b)(1)(iii). Physical hazards include any potentially harmful extraneous matter not normally found in food that can cause injury though laceration in the mouth or intestinal tract or through breakage of teeth. Depending on the size and shape of the object, it may cause choking in young children or have other adverse effects. The FDA's Health Hazard Evaluation Board has supported regulatory action against products with hard, sharp, and pointed fragments of 0.3 inches (7 mm) to 1.0 inches

(25 mm) in length (see FDA 2005 in Additional Reading at the end of the chapter). Such fragments have been shown to be a hazard to consumers.

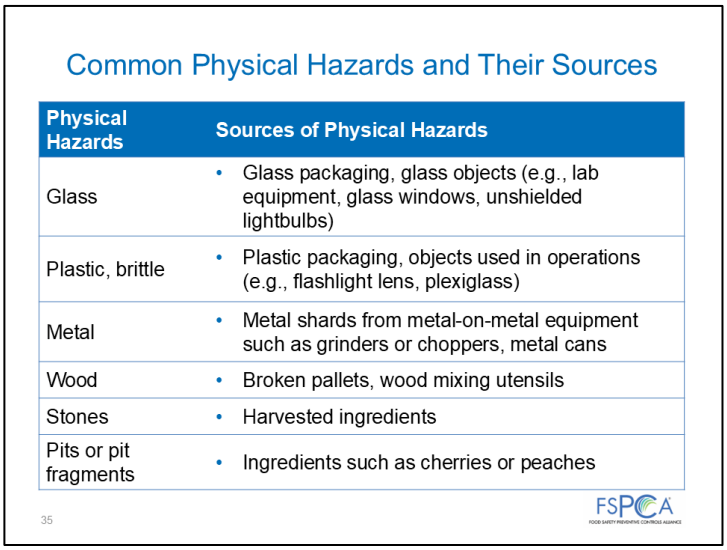
Physical hazards can be either ingredient-related or process-related. Ingredient-related hazards may inherently be in the ingredient due to harvesting practices. For example, metal, glass, plastic and/or stones may come from farm field debris and show up in ingredients harvested from the field (e.g. produce, spices). In addition, physical hazards in ingredients can also be introduced from the supplier's manufacturing facility or processing equipment which are referred to as process-related hazards. Process- and facility-related physical hazards can be introduced into food products from poorly designed or maintained facilities or equipment, the application of faulty procedures, or improper employee practices.

The table below provides a quick overview of potential process-related physical hazards.

PHYSICAL HAZARDS	Metal: Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations, and some metal equipment has parts that can break or fall off, such as wire-mesh belts.
	Glass: When product packed in glass. For example, a product packaged in glass containers could introduce glass fragments if a container breaks.
	Hard Plastic: For example, hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets, or other containers develop fatigue, crack, and break as they wear, or when plastic sieves and screens deteriorate.

Keep in mind that not all foreign objects found in food during food processing or holding present a true food safety risk. Objects like string, paper, or egg shell, for example, may occur but are unlikely to present a threat to health in most situations. The Food Safety Team should address in their Food Safety Plan only those hazards that are reasonably likely to cause injury; controls on other foreign material could be addressed with GMPs.

Slide 35: Common Physical Hazards and Their Sources



Common Physical Hazards and Their Sources

Physical Hazards	Sources of Physical Hazards
Glass	• Glass packaging, glass objects (e.g., lab equipment, glass windows, unshielded lightbulbs)
Plastic, brittle	• Plastic packaging, objects used in operations (e.g., flashlight lens, plexiglass)
Metal	• Metal shards from metal-on-metal equipment such as grinders or choppers, metal cans
Wood	• Broken pallets, wood mixing utensils
Stones	• Harvested ingredients
Pits or pit fragments	• Ingredients such as cherries or peaches

35

FSPCA

Glass Hazards: Glass fragments can cause injury to the consumer. Glass inclusion can occur whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Glass fragments originating from other sources must be addressed (e.g., through GMPs), and many facilities that do not pack in glass prohibit the presence of glass in the production environment to reduce the risk of glass getting into the product.

Plastic: Plastic is frequently used as a substitute for glass or wood in food handling areas. In selecting plastic material, the use of less brittle material will reduce the need to consider plastic as a true risk to human health. Loose plastic may also be a potential choking hazard.

Metal Hazards: Metal-to-metal contact in equipment can introduce metal fragments into products. Examples include mechanical cutting and blending operations and equipment that has parts that can break or fall off, such as wire-mesh belts or screens. Fine metal shavings may not present a hazard, but hard and sharp fragments of the size noted above are a hazard to consumers. This hazard can be controlled by subjecting the product to metal detection devices or by regular inspection of at-risk equipment for signs of damage.

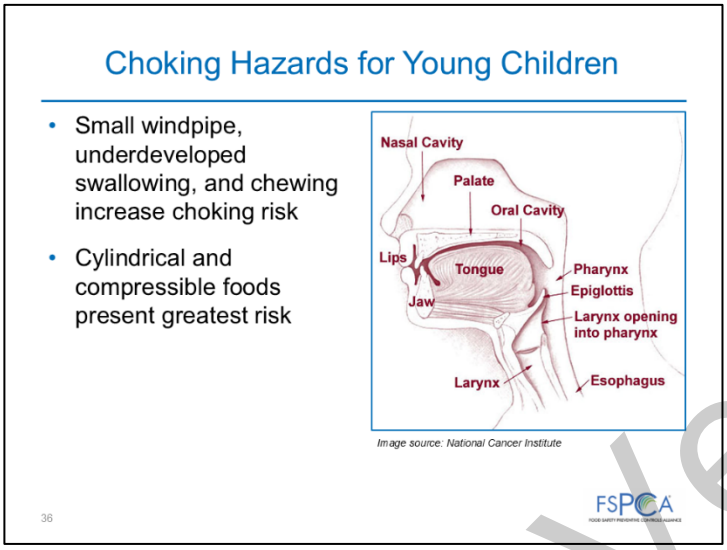
Wood: Like other potential physical hazards, wood can present a potential choking hazard and less commonly a potential hazard for cuts in the mouth in certain situations. The hazard of cuts depends on sharpness of the edges of the wood, which may not be an issue in a moist food product. Many facilities avoid the need to consider wood as a hazard by limiting or prohibiting the presence of wood in areas where food is exposed. Others may consider the history of complaints to determine if a true health hazard exists.

Stones: Certain ingredients, especially those of plant origin, may occasionally have stones present in the raw material. Depending on the size and shape of the stones, they may present a hazard for dental injury or choking. Stones frequently are heavier than

the ingredient material, thus washing steps, flotation, riffle tanks and similar steps can remove stones from a process. The Food Safety Team should assess the frequency of observation of stones from their source of supply to determine if they present a hazard requiring a preventive control.

Pits: Pits can be a risk in ingredients that contain them, posing a choking hazard.

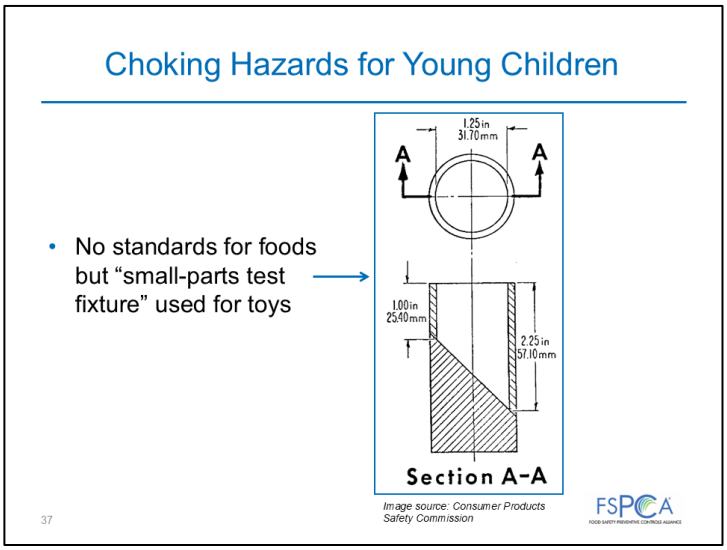
Slide 36: Choking Hazards for Young Children (1 of 2)



Choking occurs when a person cannot breathe because an object blocks the airway (windpipe, esophagus). The potential for a choking hazard is a consideration for foods specifically targeted to young children because of their smaller windpipe, and because of their swallowing mechanism and ability to chew are less developed than that of an adult. This is emphasized in the anatomical diagram.

Foods that are frequently associated with choking in children include those that have a cylindrical shape and can be compressed, which allows them to wedge in a child's throat. Foods that present a high risk for a child's choking hazard include hotdogs and similar sausages, round candy, whole grapes, nuts/peanuts/seeds, raw carrots, apples, popcorn, chunks of peanut butter, marshmallows and chewing gum.

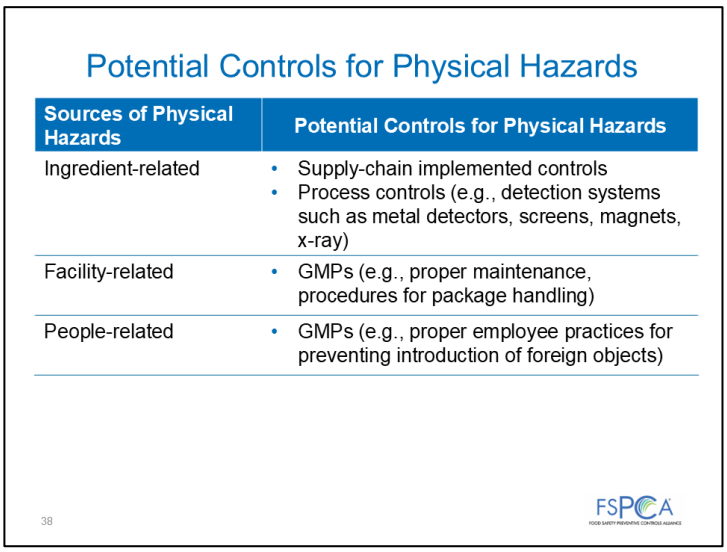
Slide 37: Choking Hazards for Young Children (2 of 2)



The American Academy of Pediatrics article on "Prevention of Choking Among Children" provides background information on reducing this hazard for food products (see "Additional Reading" at the end of this chapter).

While standards related to choking hazards for foods intended for children do not exist, the Consumer Products Safety Commission has standards for children's toys, including a small-parts test fixture (SPTF) that is used to assess whether a piece size presents a potential choking hazard for young children. This device, pictured in the figure above, may be useful to evaluate foods. If the product fits into the cylinder, it may be a choking hazard for young children. Manufacturers designing food specifically for young children may wish to consider this to evaluate whether the food represents a risk and redesign the product if that is the case.

Slide 38: Potential Controls for Physical Hazards



Sources of physical hazards are wide ranging and can include contamination in raw materials and other ingredients and flaws in the design of the facility or its equipment. In addition, improper procedures, or the lack thereof and their implementation by employees can result in physical hazards being generated.

For managing hazards in ingredients, a firm can rely on its supplier to control the hazards through a supply-chain program, and/or the firm can have process controls within their facility such as metal detection and the use of screens which can be effective strategies.

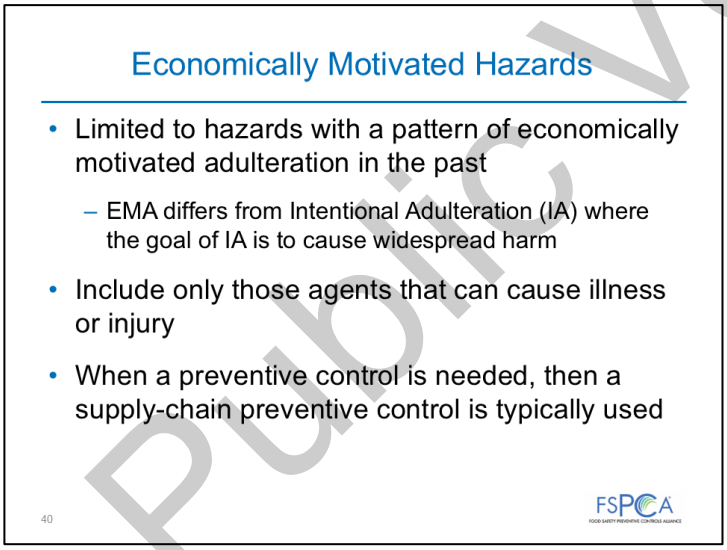
GMPs can help manage hazards in the facility or hazards introduced from people. Proper maintenance helps to ensure that glass used in the facility is properly shielded and maintained (e.g. lights, gauges). Preventive maintenance can be used to assure equipment remains intact so pieces (such as nuts and bolts) do not come loose or vibrate off, and also to detect equipment deterioration and shedding when used over the recommended service life.

Having established procedures to handle packaging materials can help prevent extraneous paper or corrugate from getting into foods.

Employees must follow GMPs to avoid the inadvertent introduction of foreign objects (such as a pen from a shirt pocket) falling into the product stream.

Slide 39: Economically Motivated Hazards or Economically Motivated Adulteration

Slide 40: Economically Motivated Hazards



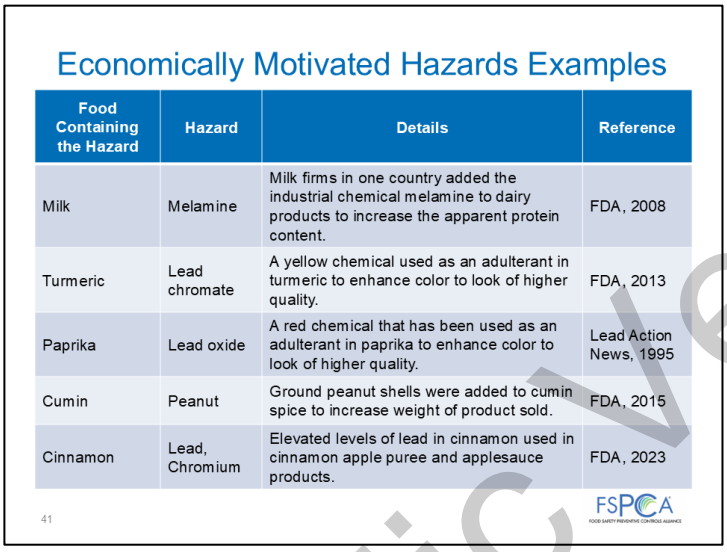
While it is a rare occurrence, hazards may be introduced into food for the purposes of economic gain. Economically motivated hazards or economically motivated adulteration that affects product integrity or quality, but not food safety, should not be addressed in a Food Safety Plan, however, food safety hazards could arise from economically motivated adulteration.

It is important to be aware when something might be a potential economically motivated adulteration hazard. Examples include changes in worldwide economic situations or in price, change in sources or suppliers, or shortages.

The Preventive Controls for Human Food regulation states that the hazard analysis hazard identification must consider hazards that may be intentionally introduced for purposes of economic gain as well as other reasons. A Congressional Research Service (2014) report provides information on economically motivated adulteration of food and food ingredients. Everstine, et al., 2014, identified 137 unique incidents in 11 food categories (See "Additional Reading" at the end of the chapter).

Economically motivated hazards are typically managed through the facility's supply-chain program. Remember, the facility only needs to focus on economic adulteration that has a history of resulting in a hazard in food.

Slide 41: Economically Motivated Hazards Examples



Examples where economically motivated adulteration hazards have occurred in the past, may prompt inclusion of an economically motivated adulteration preventive control if risks to humans might result.

An example of a widespread incident of economically motivated adulteration occurred in China, where melamine, a nitrogen-rich industrial by-product, was added to diluted dairy products by some milk firms to increase the apparent protein content. This resulted in more than 290,000 ill infants and 6 deaths in that country. In light of this incident, recognizing the potential for melamine to be an economically motivated adulterant in milk products from a country where melamine adulteration has occurred is prudent. Conversely, since none of this adulterated milk was exported to the United States and no U.S. suppliers have been a source of food safety problems due to milk products adulterated for economic gain, the FDA does not expect a facility to consider the potential for melamine to be an economically motivated hazard when using domestic milk products, or milk products from other countries with no history of melamine adulteration.

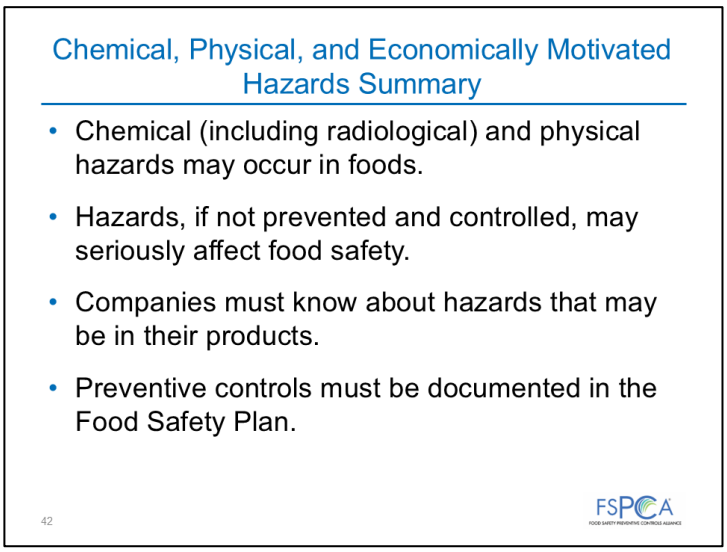
Another example of economically motivated adulteration is the addition of dyes (containing lead) to ingredients such as spices or candy to enhance color. Lead can accumulate in the body over time and cause health problems such as impaired

cognitive development in children. Lead chromate, a chemical with a vibrant yellow color, has been an adulterant in turmeric to change the color (FDA, 2013). Lead oxide, a red chemical, was an adulterant in paprika to enhance its color, resulting in dozens of illnesses and several deaths in Hungary (Anon, 1995). Sudan I, an orange-red powder, used to be added to chili powder as a coloring agent, but is now banned in many countries because it is classified as a Category 3 carcinogen (IARC, 2014). Contamination of an ingredient prepared using chili powder containing Sudan I led to a massive recall of food products in the United Kingdom (UK Food Standards Agency, 2005).

The FDA discovered another economically motivated adulteration incident when it determined that ground peanut shells were added to cumin to increase its weight with a less expensive "filler" product. However, the addition of peanut products led to allergen concerns in the spice from the peanut residues.

In 2023, the FDA investigated reports of children with elevated blood lead levels indicating potential acute lead toxicity. The FDA's investigation found apple cinnamon fruit puree and cinnamon-flavored applesauce as the source of the lead contamination originating from discount cinnamon. FDA's leading hypothesis is that this contamination event was the result of economically motivated adulteration of the cinnamon used in the applesauce.

Slide 42: Chemical, Physical, and Economically Motivated Hazards Summary



Chemical (including radiological) and physical hazards can present a food safety risk if not controlled. The severity of the risk can depend on a number of factors, including the consequence of exposure and the frequency of exposure. Preventive controls must be designed, documented, and implemented for all food safety hazards determined to be significant and therefore requiring a preventive control. Because there are many potential hazards that could be considered in the production of food, it is important to identify those that are of such importance that they must be managed using preventive controls to ensure that the facility will be able to focus resources on these hazards every time. The hazard analysis process is an important step to identify those hazards requiring a preventive control. This is addressed in Chapter 6: Hazard Analysis, and Chapter 7: Preventive Controls Determination.

Slide 43: Knowledge Check 1

Participants do NOT have this slide.

Slide 44: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

The preamble to the final regulation, as well as the proposed and supplemental regulation may provide additional information on economically motivated hazards in human food. Additional reading on other topics is below and on the FSPCA website.

American Academy of Pediatrics. (2010). Policy Statement – Prevention of Choking Among Children. *Pediatrics 125*(3), 601-607.

Anon. (1995). Adulteration of paprika in Hungary. *LEAD Action News 3*(3).

Congressional Research Service Report Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients: https://crsreports.congress.gov/product/pdf/R/R43358/4

Environmental Protection Agency. (n.d.). Per- and Polyfluoroalkyl Substances (PFAS). https://www.epa.gov/pfas

Everstine, K., Spink, J., Kennedy, S. (2013). Economically motivated adulteration (EMA) of food: common characteristics of EMA Incidents, *J Food Protection 76*:723-735.

FDA. (2004). Guidance for Industry: Juice HACCP Hazards and Controls Guidance 1st Edition; Final Guidance.

FDA. (2005). Foods - Adulteration Involving hard or Sharp Foreign Objects, Compliance Policy Guidelines, 555.425.

FDA. (2013). Best Value, Inc., Recalls PRAN Brand turmeric powder due to elevated levels of lead. October 16, 2013.

FDA. (2014. Chemical Contaminants.

FDA. (2014). Dairy Grade A Voluntary HACCP. FDA.

FDA Compliance Policy Guide 555.425 Foods, Adulteration Involving Hard or Sharp Foreign Objects: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555425-foods-adulteration-involving-hard-or-sharp-foreign-objects

FDA Guidance for Industry: Action Levels for Lead in Food Intended for Babies and Young Children: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children

FDA Guidance on Action Levels for Poisonous or Deleterious Substances in Human and Animal Feed: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed

FDA. (2006a) Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance.

FDA Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-allergen-labeling-exemption-petitions-and-notifications

FDA Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/media/100002/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Appendix 1: https://www.fda.gov/media/99581/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 3: https://www.fda.gov/media/99558/download

FDA Inventory of Petitions Received under 21 U.S.C. 343(w)(6) for Exemptions from Food Allergen Labeling: https://www.fda.gov/food/food-labeling-nutrition/inventory-petitions-received-under-21-usc-343w6-exemptions-food-allergen-labeling

FDA Natural Toxins in Food: https://www.fda.gov/food/chemical-contaminants-pesticides/natural-toxins-food

FDA. (2022) Office of Regulatory Affairs Lab Manual (Section 4).

FDA Pesticide Residue Monitoring Program Reports and Data on FDA's website: The webpage has annual reports that have been prepared to summarize results of the U. S. Food and Drug Administration's (FDA) pesticide residue monitoring program for food products https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data

FDA Process Contaminants in Food: 3-Monochloropropane-1,2-diol (MCPD) Esters and Glycidyl Esters: https://www.fda.gov/food/process-contaminants-food/3-monochloropropane-12-diol-mcpd-esters-and-glycidyl-esters

FDA. (2014.) Reportable Foods Registry.

FDA. (2022 - present) Reportable Food Registry Data Dashboard

FDA RFR Data Dashboard: https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-reportable-food-registry-data-dashboard?utm_medium=email&utm_source=govdelivery

FDA Recall Data Dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm

FDA Reportable Food Registry: https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry

FDA. (2006b). Supporting document for recommended maximum level for lead in candy likely to be consumed frequently by small children, November 2006.

Food Allergy Research and Resource Program (FARRP) – University of Nebraska-Lincoln: Institute of Agriculture and Natural Resources: https://farrp.unl.edu/allergen-control-food-industry

Food Allergy Research and Resource Program (FARRP) – University of Nebraska-Lincoln: Institute of Agriculture and Natural Resources: Components of an Effective Allergen Control Plan – A Framework for Food Processors: https://farrp.unl.edu/3fcc9e7c-9430-4988-99a0-96248e5a28f7.pdf

Foreign Agricultural Service – U.S. Department of Agriculture (FAS-USDA): Maximum Residue Limits (MRL) Database: https://fas.usda.gov/maximum-residue-limits-mrl-database

Gendel, S.M., & Zhu, J. (2013). Analysis of U.S. Food and Drug Administration food allergen recalls after implementation of the Food Allergen Labeling and Consumer Protection Act. *J Food Protection* 76(11):1933-1938.

IARC (International Agency for Research on Cancer). (2014). *Agents classified by the IARC Monographs,* Volumes 1-109," January 14, 2014.

Leibler, J.H., et al. (2018). Lead Exposure to children from consumptio9n of backyard chicken eggs. J. Env. Res, https://pubmed.ncbi.nlm.nih.gov/30125763/

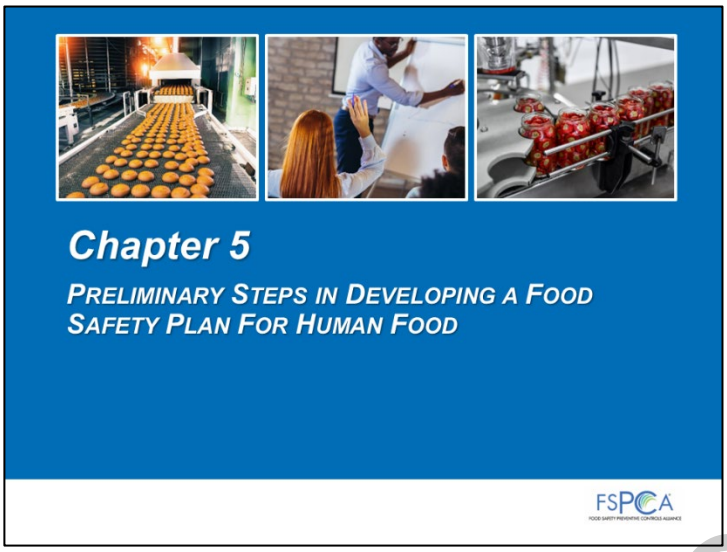
Milani, J. and G. Maleki. 2014. Effects of processing on mycotoxin stability in cereals. *J. Sci. Food Agr. 94,* 2372-2375.

Radionuclides in water: Radionuclides, U.S. Geological Survey:
https://www.usgs.gov/publications/radionuclides-surface-water-and-groundwater

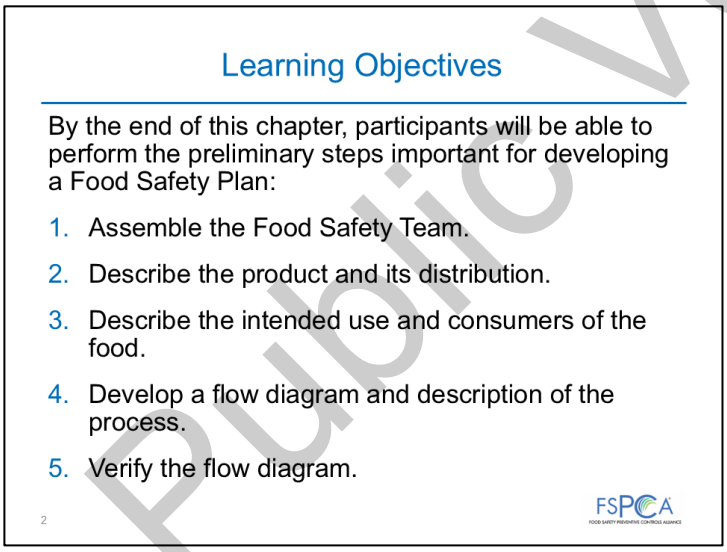
Stratton J.E., Hutkins, R.W., & Taylor, S.L. (1991). Biogenic amines in cheese and other fermented foods: a review. *J. Food Protection 54*(6), 460-470.

U.K. Food Standards Agency. (2005). Sudan I timeline, February 24, 2005. *World Health Organization. 2011.* FAQs: Japan nuclear concerns.

Slide 1: Chapter 5: Preliminary Steps in Developing a Food Safety Plan for Human Food



Slide 2: Learning Objectives

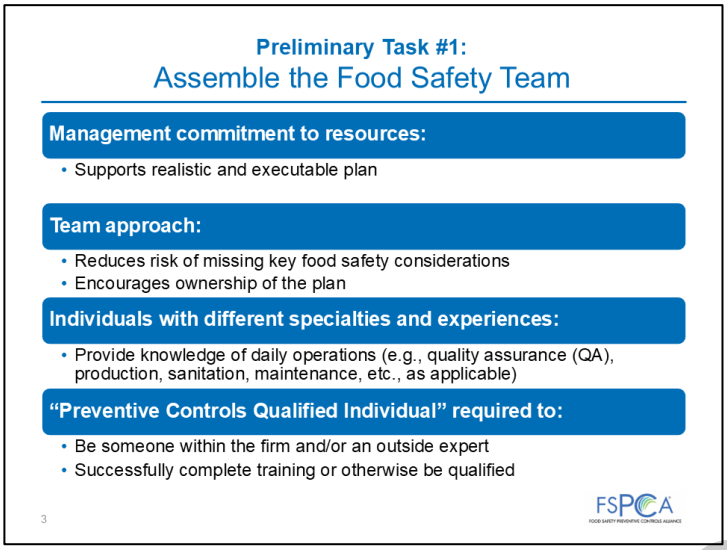


Before building a Food Safety Plan, organizing information is important. These five preliminary steps involve gathering information about the products, processes, and facility operations to build a complete picture of the facility. This information helps to identify potential hazards and preventive control measures when developing a Food Safety Plan.

These preliminary steps are not required by the Preventive Controls for Human Food regulation, but the information is useful to provide a sound basis for applying preventive controls principles. These steps are also consistent with U.S. and internationally recognized principles for developing Hazard Analysis and Critical Control Point

(HACCP)-based food safety controls. A discussion of each of the five preliminary steps follows, with examples to illustrate the process.

Slide 3: Preliminary Task #1: Assemble the Food Safety Team



Definition: Preventive Controls Qualified Individual: 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.

Assembling a Food Safety Team is an important step in building a Food Safety Plan. Management commitment is extremely important to ensure that enough resources are dedicated to this effort. Effective food safety management not only protects the food, it also protects the business from the risk of a food safety incident or a regulatory non-compliance issue. To develop and implement an effective Food Safety Plan, a budget, resources, and support for change management, potential changes in equipment, and new procedures may be required. Without management commitment at all levels, it may be difficult to implement an effective Food Safety Plan. Top management commitment to food safety sends a strong message to all personnel that the food safety system is vitally important to the company.

Although one person may be able to analyze hazards and develop a Food Safety Plan successfully, many companies find it helpful to build a Food Safety Team. When only one person develops a Food Safety Plan, some key points can be omitted or misunderstood in the process. The team approach minimizes the risk of missing key points or misunderstanding aspects of the operation. It also encourages ownership of the Food Safety Plan, builds company involvement, and brings together people with different areas of expertise. At least one member of the Food Safety Team should be a Preventive Controls Qualified Individual, who has successfully completed this FDA recognized food safety training curriculum or who is otherwise qualified through job experience to develop a Food Safety Plan. The Preventive Controls Qualified Individual does not have to be an employee of the facility, but it is beneficial for a facility to have at least one Preventive Controls Qualified Individual on staff for Food Safety Plan implementation activities.

The team should consist of individuals with different specialties and experience with the facility's processes and procedures. The Food Safety Team should include members

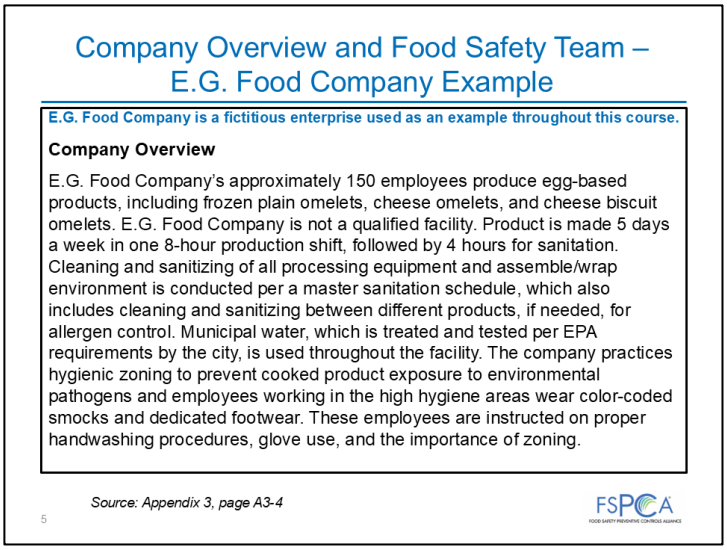
who are directly involved with the daily operations of the facility, and may include personnel from maintenance, production (including equipment operators), sanitation, quality assurance, engineering, purchasing, and laboratory, if applicable. These individuals develop a Food Safety Plan under the oversight of a Preventive Controls Qualified Individual and verify ongoing implementation of the food safety system. The team members should be knowledgeable about food safety hazards and food safety principles. When issues arise that cannot be resolved internally, it may be necessary to enlist outside expertise. In small companies, the responsibility for writing the Food Safety Plan may fall to one person. If it is possible to build a Food Safety Team in a small company, employees knowledgeable of various functions, including owners, should be members of the Food Safety Team. Universities, cooperative extension, consulting groups and trade associations can provide additional assistance through Food Safety Plans, published guidance and, in some cases, personal assistance.

Slide 4: Food Safety Team's Responsibilities

In addition to writing and developing the Food Safety Plan, the Food Safety Team provides oversight of the implementation of the Food Safety Plan during the daily operations of the facility. This includes ensuring that personnel are trained to perform their assigned duties.

Members of the Food Safety Team may also be tasked with the development and implementation of Standard Operating Procedures (SOPs) as part of the prerequisite programs, especially where those procedures support the Food Safety Plan.

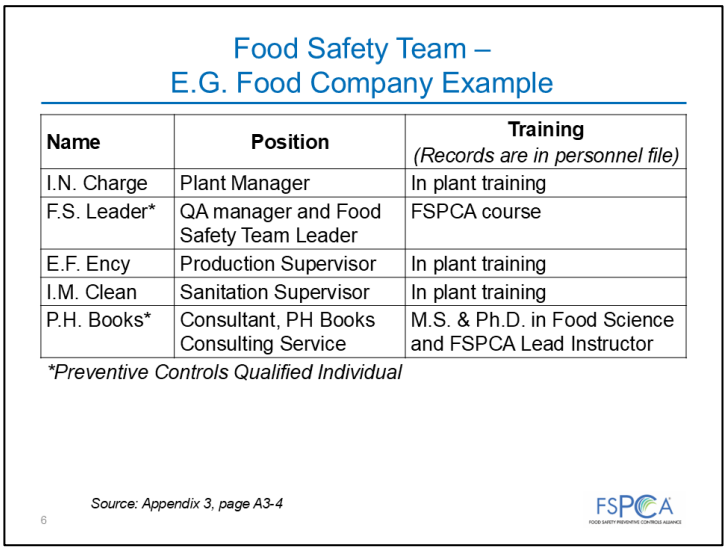
Slide 5: Company Overview and Food Safety Team – E.G. Food Company Example



This is from the E.G. Food Company Example of a Food Safety Plan, Appendix 3, (page A3-4) in the Participant Manual.

Throughout the class a fictional frozen omelet manufacturer, the E.G. Food Company, is used to provide an example. The above slide contains a description of this fictitious company, with some information about how the organization operates. This description helps visualize the operation.

Slide 6: Food Safety Team – E.G. Food Company Example



Food Safety Team –
E.G. Food Company Example

Name	Position	Training *(Records are in personnel file)*
I.N. Charge	Plant Manager	In plant training
F.S. Leader*	QA manager and Food Safety Team Leader	FSPCA course
E.F. Ency	Production Supervisor	In plant training
I.M. Clean	Sanitation Supervisor	In plant training
P.H. Books*	Consultant, PH Books Consulting Service	M.S. & Ph.D. in Food Science and FSPCA Lead Instructor

**Preventive Controls Qualified Individual*

Source: Appendix 3, page A3-4

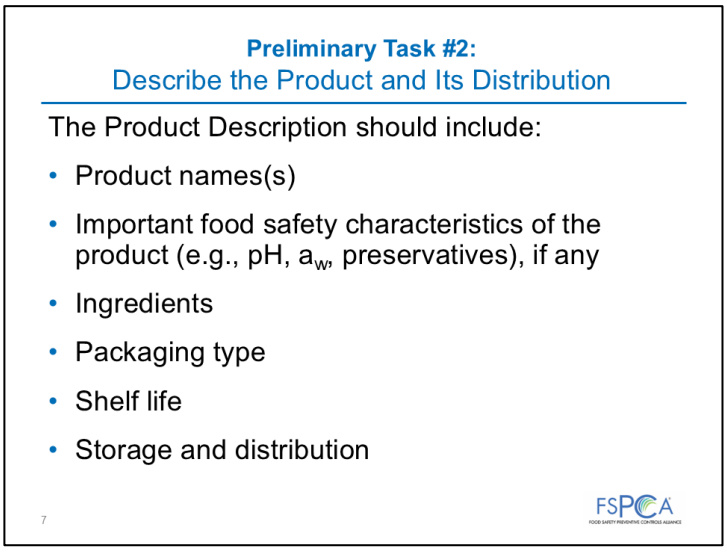
6

E.G. Food Company's Food Safety Team consists of four employees—the plant manager (I.N. Charge), the quality assurance manager (F.S. Leader), the production supervisor (E.F. Ency), and the sanitation supervisor (I.M Clean). All have undergone food safety training and use references such as FDA guidance documents. Additionally, an external food safety consultant (P.H. Books), has been brought in by the E.G. Food Company to assist with the development of the Food Safety Plan. The consultant may be tasked with ongoing work such as performing the annual review of the Food Safety Plan as well as making any needed modifications to the plan. The facility collected input for the sanitation program from the sanitation chemical supplier and included aspects such as the appropriate cleaning and sanitation compounds as well as proper procedures for its sanitation procedures.

As a reminder, documenting the Food Safety Team members is optional and not required by the Preventive Controls for Human Food regulation.

The Appendix 3: Food Safety Plan Teaching Example, contains a full Food Safety Plan, which will be used for examples throughout the course.

Slide 7: Preliminary Task #2: Describe the Product and Its Distribution



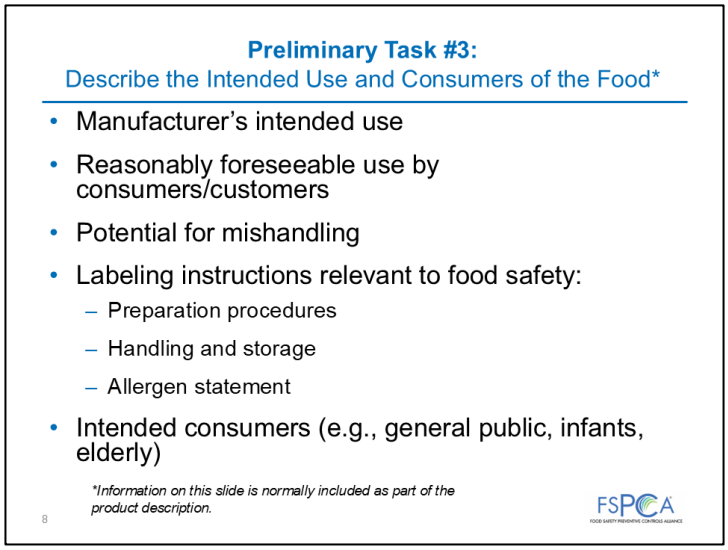
Understanding basic information about a product and its distribution helps to determine what specific food safety controls are necessary through the distribution cycle. The Food Safety Team should describe the product(s), food safety characteristics, ingredient(s) used, the type of packaging, shelf-life expectations, and the methods of storage and distribution. Information on intrinsic properties of products or factors that can influence the growth of pathogens (e.g., pH, water activity, preservatives, if any), is important. Along with this, an understanding of how these elements impact food safety with regard to potential food safety hazards that may require preventive controls.

A Product Description form is a helpful record to capture product and distribution information. Appendix 2 contains template forms for review and use. Other formats may be used, rows may be deleted, and a simple paragraph format is also acceptable. The Preventive Controls for Human Food regulation does not mandate capturing this information, however, the information contained in this form can be useful to provide an overview of the product to an independent auditor (e.g., when an audit is required by a customer), or a food safety consultant who is helping the Food Safety Team to develop a Food Safety Plan. The information contained in this form may also be useful if a recall is needed. Additional details on recalls can be found in Chapter 15: Recall Plan for Human Food.

There may be other information that could impact food safety/hazard analysis beyond what is documented in the product description.

When identifying the ingredients used, collecting information on processing aids as well as other allergens handled in the facility can help to give a more holistic view of the operation to help with identifying possible hazards that may be specific to the facility. This will help to ensure that the hazard analysis is complete by considering other potential concerns.

Slide 8: Preliminary Task #3: Describe the Intended Use and Consumers of the Food

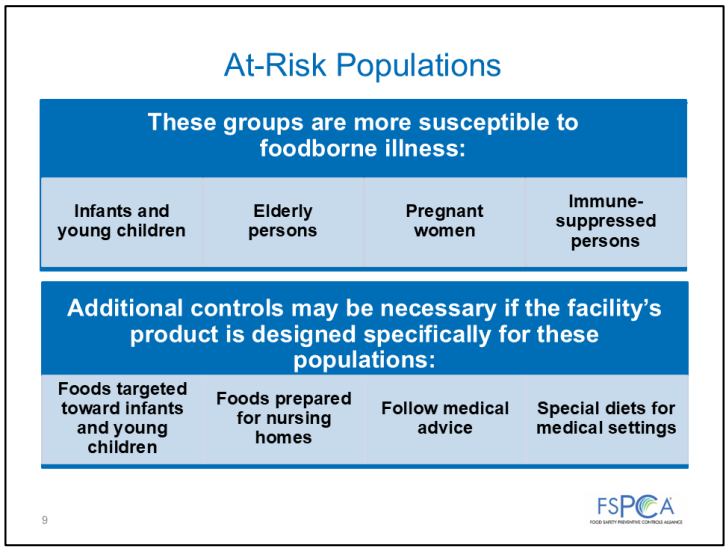


Intended use of the product refers to its anticipated use by end-users (e.g., other food processors, consumers etc.). Most foods are likely to be intended for the general public. The Food Safety Team should consider these questions:

1. What is the intended use of the product (e.g., retail, food service, further processing)?
2. What is the potential for mishandling by the consumer and unintended use by them?
3. What handling and preparation procedures are required of the end users? For example, is the product ready-to-eat, or does it require further preparation such as reheating, cooking, etc.?
4. Who are the intended consumers of the product?
5. Is the product intended specifically for use by immune-compromised individuals or other susceptible groups?

Answering these questions provides valuable information for the Food Safety Team as they proceed to the hazard analysis (see Chapter 6: Hazard Analysis).

Slide 9: At-Risk Populations



Intended consumers may be members of the general public or a specific segment of the population that is more sensitive to certain hazards, typically referred to as "at-risk" or "susceptible" populations. These groups include:

Infants and young children: Infants and young children do not have a fully developed immune system and are more likely to develop certain types of foodborne illnesses such as infections by bacterial pathogens. Choking hazards from the food itself or packaging material (e.g., small caps), may also be a concern for this group.

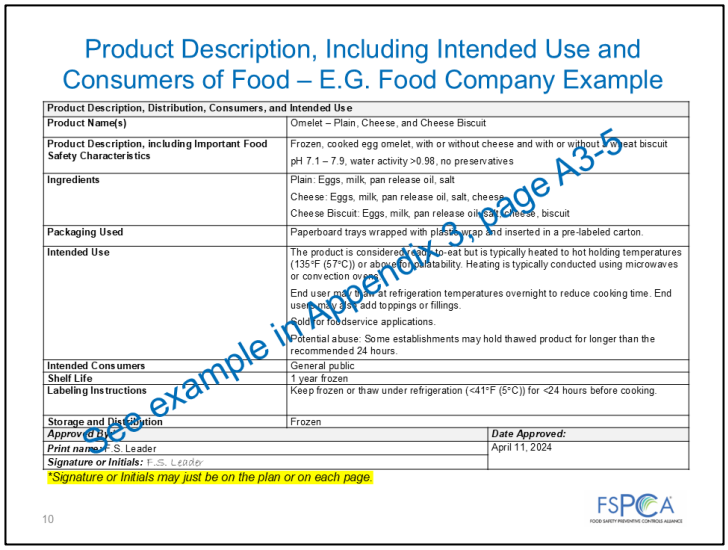
Elderly persons: As people age, their immune systems naturally weaken. Elderly persons tend to be more susceptible to infections by foodborne bacterial pathogens than the general population, and illnesses may also be more severe.

Pregnant women: Some pathogens, such as *Listeria monocytogenes* and *Toxoplasma gondii*, are particularly harmful to the developing fetus. Manufacturers of foods targeted specifically toward pregnant women should control potential sources of these pathogens.

Immune-suppressed persons: Other factors can weaken the immune system. For example, persons who are HIV positive, have had organ transplants, are undergoing chemotherapy for cancer, or who regularly take acid-reflux or immunosuppressive drug therapies are particularly susceptible to developing illnesses caused by foodborne pathogens. As modern medical treatments improve, it is important to recognize that a relatively large percentage of the population fits in this category.

While food targeted to the general population may be consumed by these vulnerable groups, food specifically designed for susceptible populations (e.g., for hospitals, nursing homes), may require more stringent controls because these foods will be consumed by at-risk populations.

Slide 10: Product Description, Including Intended Use and Consumers of Food – E.G. Food Company Example



Product Description, Including Intended Use and Consumers of Food – E.G. Food Company Example

Product Description, Distribution, Consumers, and Intended Use	
Product Name(s)	Omelet – Plain, Cheese, and Cheese Biscuit
Product Description, including Important Food Safety Characteristics	Frozen, cooked egg omelet, with or without cheese and with or without a wheat biscuit pH 7.1 – 7.9, water activity >0.98, no preservatives
Ingredients	Plain: Eggs, milk, pan release oil, salt Cheese: Eggs, milk, pan release oil, salt, cheese Cheese Biscuit: Eggs, milk, pan release oil, salt, cheese, biscuit
Packaging Used	Paperboard trays wrapped with plastic wrap and inserted in a pre-labeled carton.
Intended Use	The product is considered ready-to-eat but is typically heated to hot holding temperatures (135°F (57°C)) or above for palatability. Heating is typically conducted using microwaves or convection ovens. End user may thaw at refrigeration temperatures overnight to reduce cooking time. End user may add toppings or fillings. Sold for foodservice applications. Potential abuse: Some establishments may hold thawed product for longer than the recommended 24 hours.
Intended Consumers	General public
Shelf Life	1 year frozen
Labeling Instructions	Keep frozen or thaw under refrigeration (<41°F (5°C)) for <24 hours before cooking.
Storage and Distribution	Frozen

Approved By:	Date Approved:
Print name: F.S. Leader	April 11, 2024
Signature or Initials: F.S. Leader	

*Signature or Initials may just be on the plan or on each page.

10

FSPCA

See example in Appendix 3, page A3-5

Downloadable Food Safety Plan worksheets are available on the FSPCA website. The worksheets are also available in Appendix 2 of the Participant Manual.

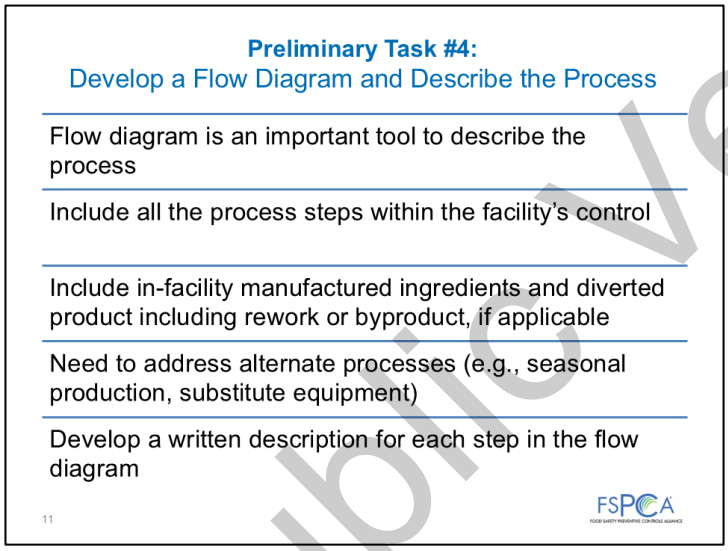
On the slide above is an example of a product description that will be used to illustrate the progressive development of a Food Safety Plan for omelet products produced by the fictitious E.G. Food Company. Note that in this example, the potential for abuse is identified in the "Intended Use" section.

The Product Description, Distribution, Consumers, and Intended Use form described below and located in Appendix 2 can be used to record this information. This information helps to assure an accurate hazard analysis but is not required in the regulation.

Elements of a Complete Product Description and Intended Use Form	
Product name(s)	May include more than one product with similar processing and hazard profile
Product description, including important food safety characteristics	A general description of the product and processing method, assembly, and group or type of products included in the category. If it is relevant to product safety, intrinsic properties like preservatives, water activity (a_w) and pH should be listed here.
Ingredients	A simple listing of ingredients including processing aids, which may be grouped or transferred from the product label, if convenient. This could also be an attachment (a list or a recipe) or reference ingredient specification numbers, which would provide more detailed information.
Packaging used	A general description of the packaging, including method or type such as hermetically sealed container, modified atmosphere, or vacuum packaging, if used. This may impact the hazards of concern.

Intended use	Describe the normal expected use of the food (e.g., ready-to-eat, ready-to-cook, raw), and if useful, where it is sold (e.g., retail, foodservice, schools, long term care facilities etc.). May describe a complex distribution system if desired (e.g., frozen distribution with refrigerated or ambient display, use for further processing, etc.). If unintended use or abuse is likely to occur (e.g., eating raw cookie dough), this should be identified.
Shelf life	List intended shelf-life, if relevant to potential microbial growth or age-induced toxin formation.
Labeling instructions	Include label instructions relevant to food safety. This may include refrigeration, cooking instructions etc., if relevant.
Storage and distribution	List the method of distribution (e.g., refrigerated, frozen, ambient).

Slide 11: Preliminary Task #4: Develop a Flow Diagram and Describe the Process



A flow diagram provides an important visual tool the Food Safety Team can use to describe the process. When developing a process flow diagram, it is important to include all the process steps within the facility's control—from receiving ingredients and packaging through final product storage—including the use of water and ice as an ingredient, rework, in-facility manufactured ingredients, and diverted by-product, if applicable. Each process step should be considered in detail and the information expanded to include all relevant process information. Information may include:

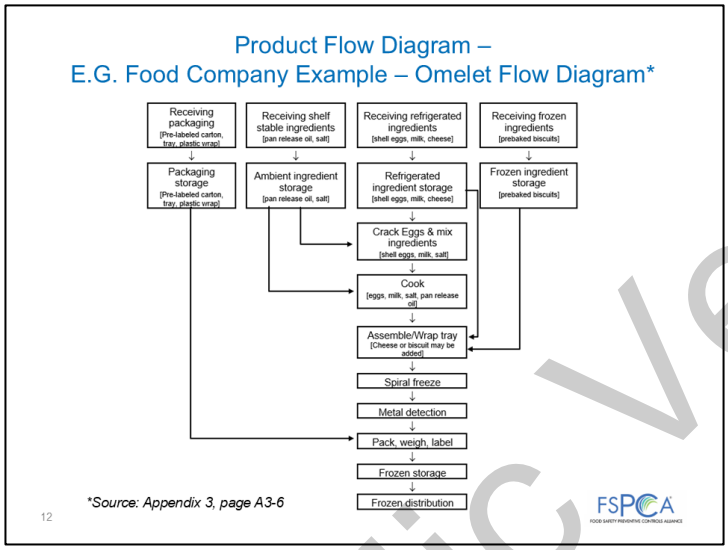
- All ingredients and packaging used;
- Where raw materials, ingredients and intermediate products enter the flow;
- The sequence and interaction of all steps in the operation including in-facility manufactured product if appliable and alternate processes that could be used. An example of substitute equipment or seasonal production could be the use of

fresh produce when it's available in season, then reverting to frozen when it is not available;

- Where product reworking and recycling take place in the process; and
- Where product is diverted to waste or rework, if applicable. An example in dairy processing is the flow diversion valve which re-routes improperly pasteurized product back to the beginning of the heating process.

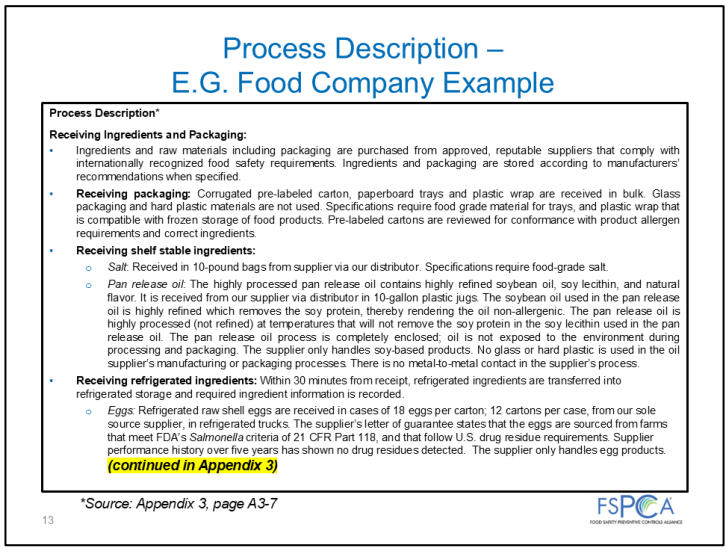
The product flow diagram for the E.G. Food Company Omelet example appears on the next slide.

Slide 12: Product Flow Diagram – E.G. Food Company Example – Omelet Flow Diagram



The E.G. Food Company's product flow diagram shows the receipt of their ingredients and packaging, as well as the storage of the ingredients and packaging. Each processing step is outlined in the flow diagram showing the crack eggs and mix step, cook step, omelet assembly/wrap step that includes the post-process addition of the ingredients cheese and biscuits, spiral freezing, metal detection, and packing into pre-labeled carton after which the product is placed into frozen storage and finally distributed under frozen conditions. Each step shown in the flow diagram will inform the hazard analysis process.

Slide 13: Process Description – E.G. Food Company Example

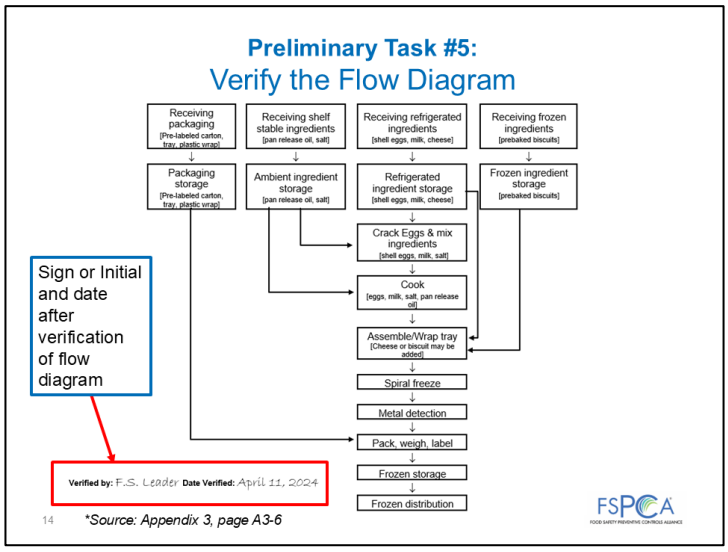


A written process description is useful to explain what happens at each of the process steps and can contain more detail than the flow diagram. This description can be used as a working reference for the development of the Food Safety Plan, particularly the hazard analysis. The Food Safety Team may already have other documents that contain similar information, such as product specifications, recipes or work instructions that can be used in place of the description illustrated in this chapter.

It is important to know what occurs at each process step. For example, information which may have an impact on food safety such as the maximum length of time that the product could be exposed to unrefrigerated temperatures, the maximum room air temperature, or the internal product temperature after a process is important to know for an accurate hazard analysis.

The beginning of the process description from the E.G. Food Company example appears above. See Appendix 3: Food Safety Plan Teaching Example for the full process description.

Slide 14: Preliminary Task #5: Verify the Flow Diagram

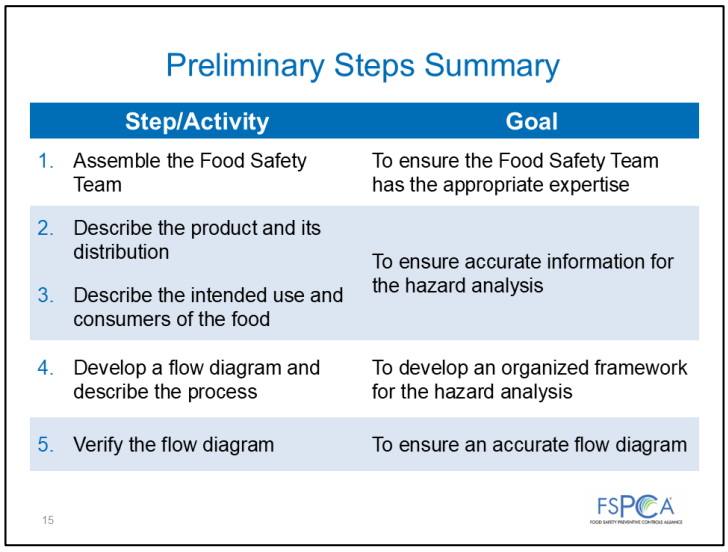


The steps in the flow diagram are used to organize the hazard analysis and determine preventive controls, which are discussed in Chapter 6: Hazard Analysis, and Chapter 7: Preventive Controls Determination. Since the accuracy of the process flow is critical to conducting a hazard analysis, the steps outlined in the chart should be verified at the facility. If one step is missed, a food safety hazard requiring a preventive control may be missed. Include every handling, processing, and holding step for the product, as well as ingredients and packaging.

The Food Safety Team should walk through the facility and make any changes required in the flow diagram. At the same time, the team should make observations related to sanitation, potential for cross-contamination or allergen cross-contact, and potential harborages or introduction points for environmental pathogens. The walk-through allows each team member to gain an overall picture of how the product is made. It may be helpful to invite additional plant personnel to review the diagram during the walk-through. Many times, operators can identify issues that may be overlooked by management or the Food Safety Team. The complete, verified flow diagram should be retained and periodically evaluated as a food safety record and as part of the Food Safety Plan. A signature or initials is used to indicate that the flow diagram has been verified.

Food Safety Plans are dynamic and must be updated to reflect any changes in process or food safety considerations. Therefore, any significant changes to the ingredients and packaging used, and the process, should be accurately reflected in the product flow diagram, and the Food Safety Team must evaluate if these changes have an impact on the hazard analysis and preventive controls in place.

Slide 15: Preliminary Steps Summary



It is important to have the right people in place, and information available on the ingredients, packaging and processes used before applying preventive controls principles to develop a Food Safety Plan. Preliminary steps include:

1. Assembling the Food Safety Team and ensuring that there are multi-disciplinary perspectives who can provide appropriate expertise into process. The goal is to get varied input to help ensure that an accurate assessment of the food safety hazards that exists for the products being produced;
2. Preparing an accurate description of the product and its distribution to understand the characteristics of the product and ensure that potential hazards are not overlooked;
3. Identifying the intended use and consumers to ensure that preventive controls used will protect the safety of consumers during intended use and acknowledge potential misuse of the product, as well as ensuring that potential hazards are not overlooked;
4. Creating a process flow diagram that provides the organizational framework for conducting the hazard analysis, which identifies preventive controls to prevent food safety risks for the consuming public; and
5. Verifying the flow diagram and operational conditions to avoid overlooking sources of potential hazards.

If a facility produces more than one product and several Food Safety Plans are needed, it is recommended that the Food Safety Team keep its task simple by only attempting to develop one plan at a time. The team could have the first plan reviewed by an external expert before addressing additional plans. This can help to ensure they correctly identify the hazards requiring preventive controls.

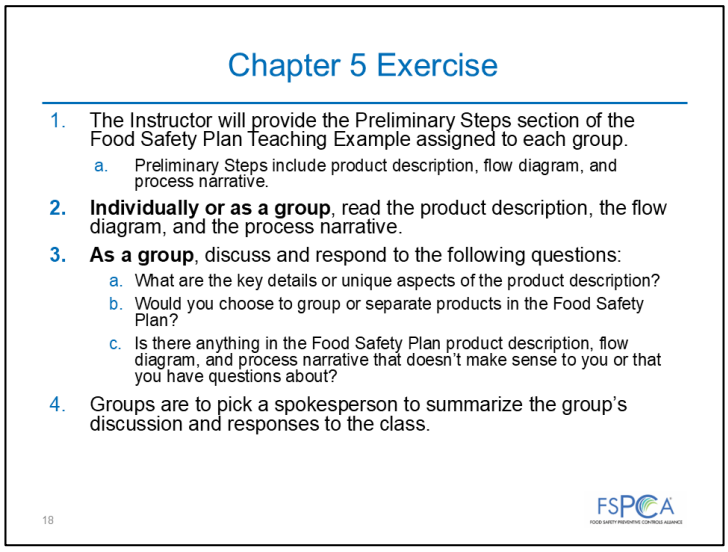
Slide 16: Knowledge Check 1

Participants do NOT have this slide.

Slide 17: Knowledge Check 2

Participants do NOT have this slide.

Slide 18: Chapter 5 Exercise



1. The Instructor will provide the Preliminary Steps section of the Food Safety Plan Teaching Example assigned to each group.
    a. Preliminary Steps include product description, flow diagram, and process narrative.
2. Individually or as a group, read the product description, the flow diagram, and the process narrative.
3. As a group, discuss and respond to the following questions:
    a. What are the key details or unique aspects of the product description?
    b. Would you choose to group or separate products in the Food Safety Plan?
    c. Is there anything in the Food Safety Plan product description, flow diagram, and process narrative that doesn't make sense to you or that you have questions about?
4. Groups are to pick a spokesperson to summarize the group's discussion and responses to the class.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

CODEX ALIMENTARIUS International Food Standards (CXC 1-1969: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf

FAO/WHO. (2003). Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application Annex to CAC/RCP 1-1969, Rev. 4 - 2003

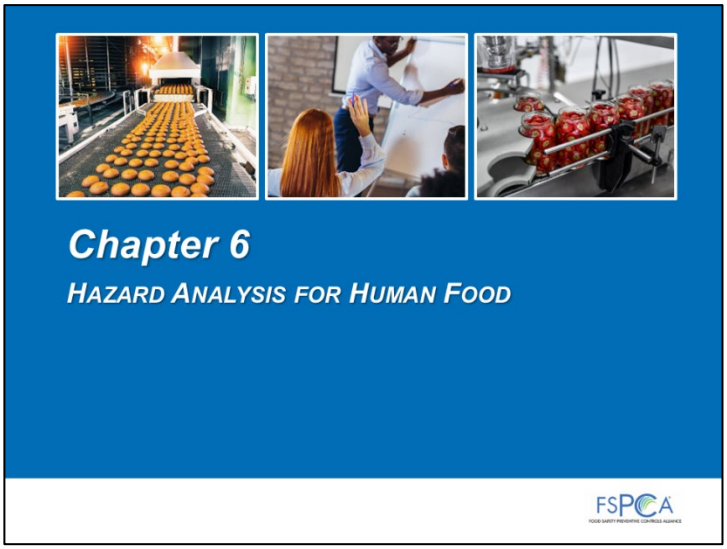
FDA. (2014). Dairy Grade A Voluntary HACCP: https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/dairy-grade-voluntary-haccp

Food Safety Plan worksheets on FSPCA Website: https://www.fspca.net/pc-human-food-preventive-controls-qualified-individual

National Advisory Committee on Microbiological Criteria for Foods. (1998). Hazard Analysis and Critical Control Point Principles and Application Guidelines. Journal of Food Protection 61(9), 1246-1259.

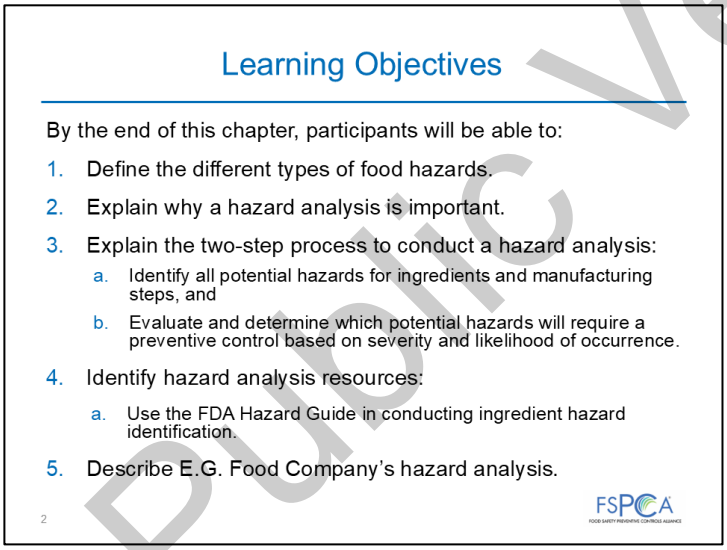
National Advisory Committee on Microbiological Criteria for Foods Hazard Analysis and Critical Control Point Principles and Application Guidelines. https://www.fda.gov/food/hazard-analysis-critical-control-point-haccp/haccp-principles-application-guidelines

Slide 1: Chapter 6: Hazard Analysis for Human Food



The chapter focuses on the Hazard Analysis concept and process.

Slide 2: Learning Objectives

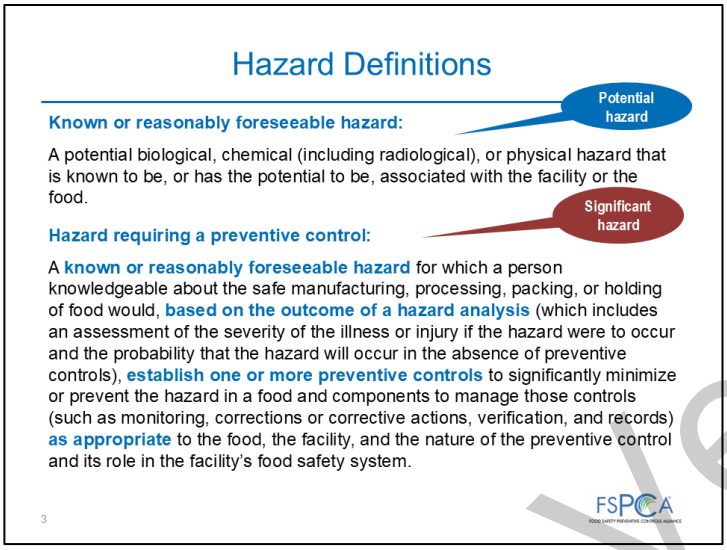


Following the preliminary steps, the next step in developing a Food Safety Plan is to conduct a hazard analysis of all ingredients and process steps used to manufacture the food product. During the hazard analysis process, the Food Safety Team will have a brainstorming session to identify potential food safety hazards and evaluate which of the potential hazards will require a preventive control. The hazard analysis depends on several factors including the food product that is being manufactured; information about the food product description, intended use, and distribution; the raw materials and ingredients used in the food product and the suppliers; types of packaging materials; the activities conducted at each step in the manufacturing process steps; equipment used to make the food product; the facility environment, and other factors.

Once the hazards requiring a preventive control are determined, the specific preventive controls will need to be identified to help ensure the safety of the product.

This slide describes the objectives of the chapter including hazard definitions, why a thorough hazard analysis is important, the necessary steps in conducting the hazard analysis, available resources including the FDA Hazard Guide, and the E.G. Food Company hazard analysis example.

Slide 3: Hazard Definitions



The Preventive Controls for Human Food regulation includes definitions for several types of hazards. These include:

Known or reasonably foreseeable hazard (potential hazard): A potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

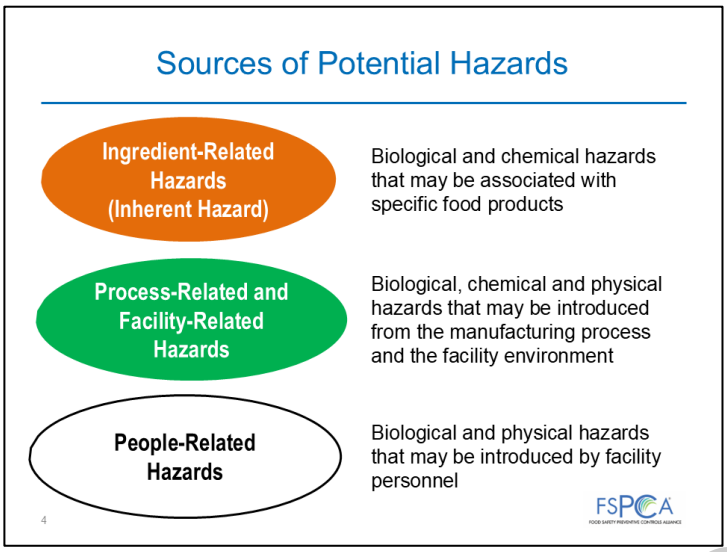
Hazard requiring a preventive control (significant hazard): A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.

The regulation also defines "preventive controls" as follows:

Preventive controls: Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current

scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis.

Slide 4: Sources of Potential Hazards



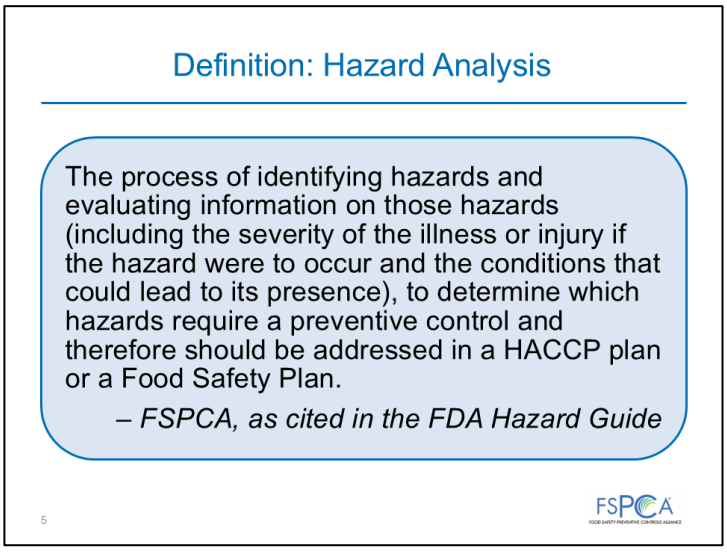
When conducting a hazard analysis, the Food Safety Team must consider the potential for biological, chemical, and physical hazards related to raw materials and other ingredients (ingredient-related hazards), manufacturing processes (process-related hazards), and the food-production environment (facility-related hazards).

Ingredient-related hazards are those inherent hazards that may be associated with a specific food product (e.g., *Salmonella* in untreated black pepper). Ingredient-related hazards introduced from raw materials and other ingredients primarily consist of biological and chemical hazards, although physical hazards may also occasionally occur in some raw ingredients (e.g., during harvesting of crops).

Process- and facility-related hazards are biological, chemical, and physical hazards that originate from the manufacturing process (process-related) and from the food-production environment (facility-related). Because each facility is unique in its food products, operations, processes, and physical facility, process- and facility-related hazards can be specific to each facility. In addition to process- and facility-related hazards, hazards such as mycotoxins or physical hazards in raw materials could be introduced during the growing and harvesting of crops which would be considered process-related versus being inherent to the raw material.

People-related biological and physical hazards may be introduced by facility personnel due to handling of the product during processing and/or packaging. Typically, potential people-related hazards are controlled by following GMPs (e.g., worker hygiene and disease control).

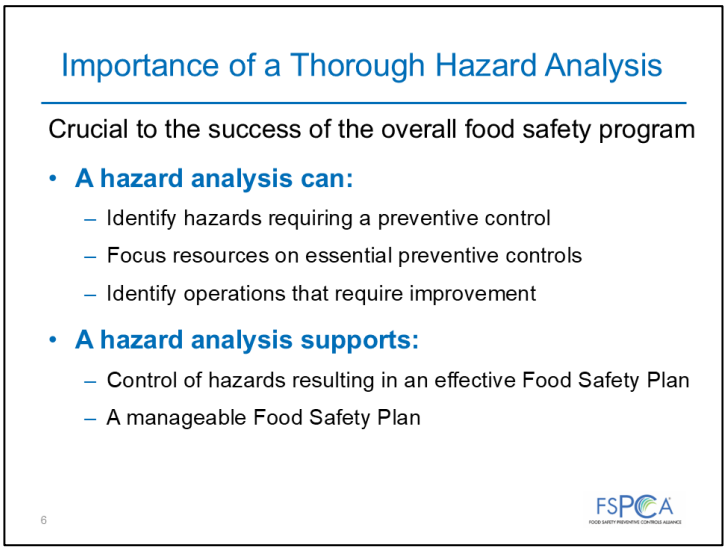
Slide 5: Definition: Hazard Analysis



For this course, hazard analysis is defined as indicated on the slide. The purpose of the hazard analysis is to identify a list of potential food safety hazards and then evaluate and determine which of those hazards may require a preventive control because they have been determined to be severe and reasonably likely to cause injury or illness in the absence of control. Once these significant hazards are identified, then preventive controls that are essential to prevent illness or injury can be determined. Only those hazards that pose a risk to the health of consumers should be included in the Food Safety Plan.

The regulation does not require facilities to completely redo existing HACCP plans. If a HACCP plan exists, the hazard analysis should be assessed to determine if there are any gaps. The hazard analysis may need adjustments to identify other types of controls including allergen, sanitation, supply-chain, and potentially other preventive controls in addition to those addressed in a traditional HACCP plan.

Slide 6: Importance of a Thorough Hazard Analysis



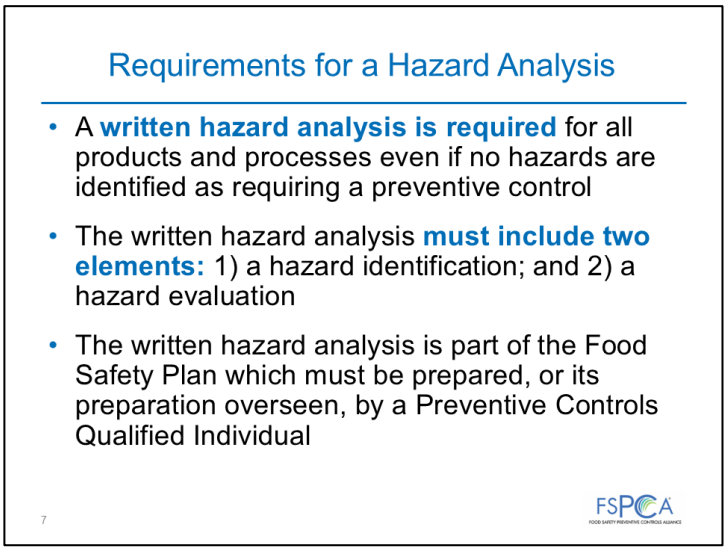
Conducting a complete and accurate hazard analysis is one of the most crucial steps in developing an effective, risk-based Food Safety Plan.

The hazard analysis process serves as a systematic approach in identifying and evaluating potential hazards for each type of food product to determine whether there are any hazards requiring a preventive control.

A proper hazard analysis allows the company to focus limited resources on the most important controls and identify where operational improvements are needed.

A thorough hazard analysis supports an effective and manageable Food Safety Plan that controls identified hazards. Conversely, an improper hazard analysis may miss identifying a hazard that requires a preventive control or identify too many controls for hazards that are not reasonably likely to cause illness or injury, which results in a system that cannot be effectively managed by available resources.

Slide 7: Requirements for a Hazard Analysis

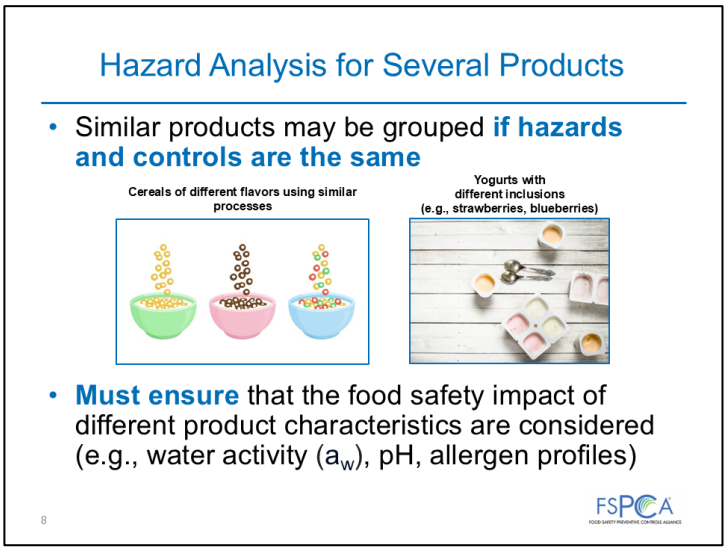


In 21 CFR 117.130, the regulation requires that a hazard analysis, for each type of food manufactured, processed, packed, or held at a facility, must be written, regardless of whether any hazards requiring a preventive control are identified. Note, it's possible that a facility may not identify any hazards requiring a preventive control. Even in this case the facility must have a written hazard analysis documenting that they did in fact consider all potential hazards associated with ingredients, the food product(s) process steps, and the facility's environment.

The regulation also requires that the hazard analysis include: 1) Hazard identification of potential biological, chemical (including radiological), and physical hazards and 2) Hazard evaluation of the hazards identified including assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazards will occur in the absence of preventive controls.

The written hazard analysis is part of the Food Safety Plan, which must be prepared, or its preparation overseen, by one or more Preventive Controls Qualified Individuals (21 CFR 117.126(a)(2)).

Slide 8: Hazard Analysis for Several Products



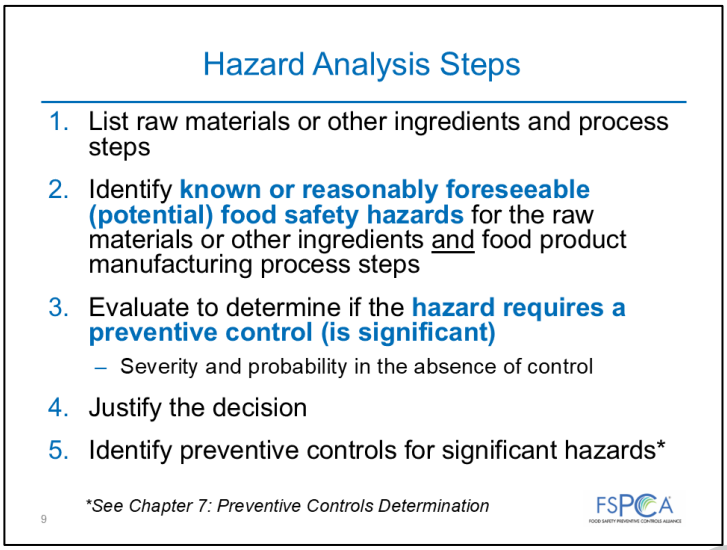
Similar products may be grouped together in a single hazard analysis if the food safety hazards and controls are essentially the same for all the products (e.g., different flavors of cereals, yogurts with different inclusions (e.g., fruit)). However, it must be ensured that different product characteristics such as pH, water activity or allergen profiles are considered within the group as these might result in the identification of different hazards among the products. If there are significant differences, this may result in some of the products being moved to their own hazard analysis.

A common hazard analysis may be used for a group of products that are similar in formulation, have similar processing steps, and are otherwise prepared and packaged in a similar manner. For example, the hazard analysis and Food Safety Plan for the E.G. Food Company groups three different omelets into one hazard analysis and one Food Safety Plan. It is important to note, however, that different formulations can have a dramatic impact on product characteristics (e.g., pH, different allergens), and these factors must be carefully considered in the hazard analysis. While the E.G. Food Company groups the three omelets in the same hazard analysis, other companies may wish to address the cheese omelet biscuit in a separate plan because of the wheat allergen in the biscuit. The Food Safety Team must organize the information in a meaningful way to communicate the significant risks to the staff at the facility.

The hazard analysis and Food Safety Plan will likely be different for the same product produced in different facilities. The Food Safety Team must take into account the unique characteristics, raw materials or other ingredients, equipment and procedures used at their facility when preparing the Food Safety Plan specific for their facility. However, it is perfectly reasonable for the team to refer to generic HACCP or preventive control models, hazards and control guides, and decision trees to help them with their deliberations. Generic Food Safety Plans, however, will rarely consider all of the specific aspects in an actual facility, thus they are for teaching or guidance purposes only. Other hazard analysis models and decision trees may be available from other reputable sources. As a word of caution, these resources may not consider hazards

associated with sanitation, allergens and supply-chain programs to the extent required for Food Safety Plans under the Preventive Controls for Human Food regulation.

Slide 9: Hazard Analysis Steps



A sequence of five (5) steps is followed to complete a thorough hazard analysis, and each of the items listed in the slide is discussed in this chapter. Before the five-step hazard analysis process can begin, the Food Safety Team needs to gather and review information about the facility and the food product(s) as discussed in Chapter 5: Preliminary Steps in Developing a Food Safety Plan. This would include information about the product description, intended use, and distribution; the raw materials and ingredients used in making the food product and the activities conducted at each process step utilizing the flow diagram and process narrative.

Step 1: List all the raw materials or other ingredients used in the food product and also list the process steps identified in the flow diagram for manufacturing the food product.

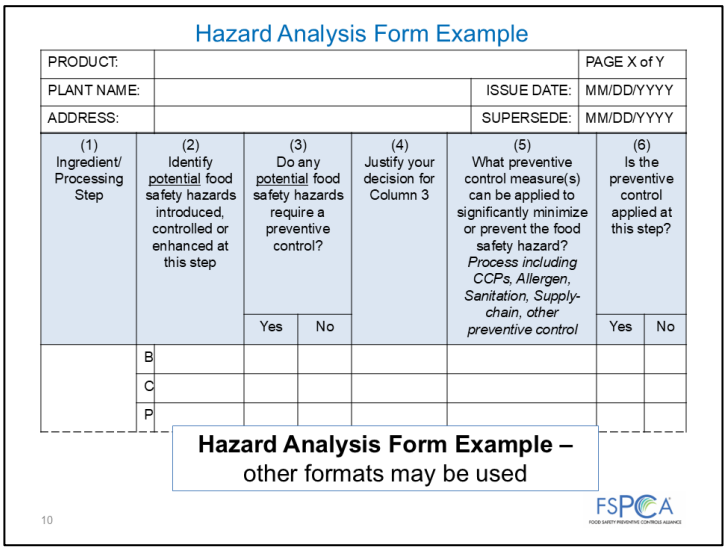
Step 2: Identify potential biological, chemical, and physical hazards that are ingredient-related (hazards that are introduced from raw materials and other ingredients) and those that may be introduced, controlled, or enhanced at each process step described on the flow diagram (process- and facility-related hazards).

Step 3: Evaluate each hazard by assessing severity and probability to determine whether the hazard poses a significant risk to the end user or consumer in the absence of a preventive control.

Step 4: Justify the decision made in step 3.

Step 5: identify preventive controls for those hazards justified as requiring a preventive control. More information on step 5 is covered in Chapter 7: Preventive Controls Determination.

Slide 10: Hazard Analysis Form Example



This hazard analysis form can be found in Appendix 2: Food Safety Plan Worksheets. The worksheets are also available on FSPCA's website (see QR Code below this textbox).

(PC Human Food—>Preventive Controls Qualified Individual—>Materials and Resources—>PCHF Workaids)

A hazard analysis form can be used to ensure ingredients as well as process steps are analyzed, and the results are documented. When assessing process steps, it's important to consider allergens in other products when conducting the hazard analysis to ensure that allergen cross-contact is considered. In addition, it's important to assess process steps where environmental pathogens from the processing environment may be introduced into ready-to-eat food products that are exposed to the environment prior to packaging and where that packaged food does not receive a lethal treatment post-packaging.

Column 1: List (1) raw materials or other ingredients used in the process as a means of identifying hazards associated with an ingredient, and (2) processing steps. The process flow diagram recommended as a preliminary step can help identify the processing steps that are to be included in the hazard analysis.

Column 2: List the results of the hazard identification (i.e., the food safety hazards that potentially could be introduced, controlled, or enhanced at this step (known or reasonably foreseeable hazards)). Include all ingredient-related hazards, process-related hazards, and facility-related hazards that may be introduced from the environment.

Column 3: Record the conclusions of the hazard evaluation (i.e., the determinations of whether each listed potential food safety hazard requires a preventive control (Yes/No)).

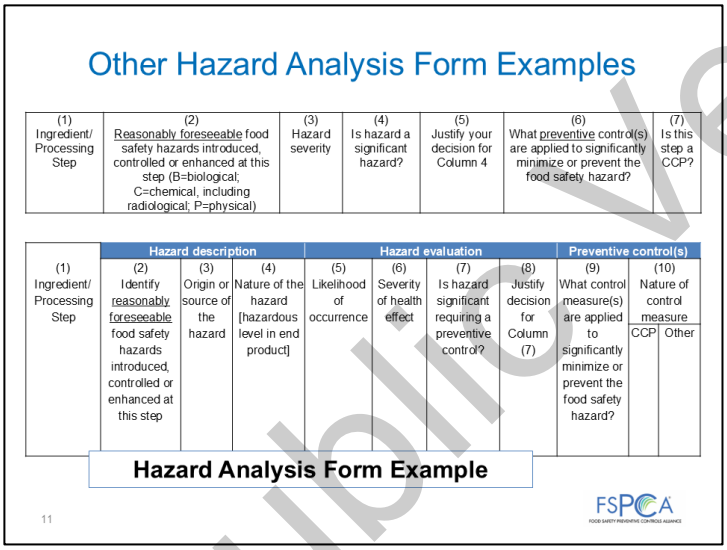
Column 4: Record the reasons that led to the conclusions of the hazard evaluation (i.e., the Yes/No conclusions listed in Column 3). Explaining the reasons for a "No" conclusion can be just as important as explaining the facility's reasons for a "Yes" conclusion. To be thorough and to have readily available answers to questions about the hazard analysis, it may be useful to take a conservative approach by listing (in Column 2) several potential hazards even though they clearly do not require a preventive control (especially when there has been significant debate over whether something is actually a potential hazard for the facility) and explain the reasons for "No" conclusion. This can

be useful both during the Food Safety Team's review of their food safety plan and during review of the Food Safety Plan by others (e.g., if an inspector or auditor questions whether a particular hazard was considered). It may also be helpful to record extended debate on Food Safety Team meeting notes that can be filed for future reference. This may also be useful later for reminding the Food Safety Team as to why certain decisions were made.

Column 5: identify preventive controls that will significantly minimize or prevent the food safety hazard (e.g., process, allergen, sanitation, supply-chain or other), for those hazards identified as requiring a preventive control (i.e., a "Yes" in Column 3).

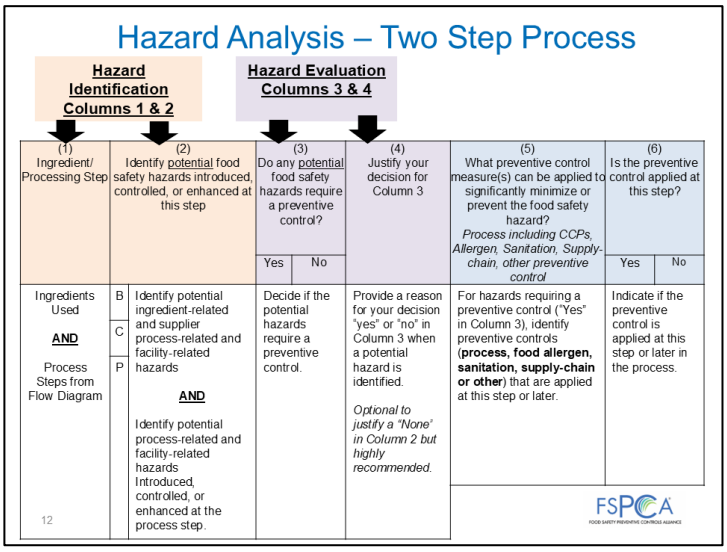
Column 6: Because the worksheet breaks the production process into multiple steps, and the preventive control may be applied at a step in the process other than the step where the hazard was listed, specify whether the preventive control will be applied at this particular step (Yes/No). It is important to note that identifying a hazard at a processing step as one that requires a preventive control does not mean that the hazard must be controlled at that processing step.

Slide 11: Other Hazard Analysis Form Examples



Keep in mind that other formats may be used to document the hazard analysis. The slide above represents two additional formats and others may be used as well. Whatever format is used, the Food Safety Team must assure that it addresses hazards requiring other control measures in addition to CCPs, including allergen, sanitation, supply-chain, and other preventive controls as applicable to the facility and food product.

Slide 12: Hazard Analysis – Two Step Process (1 of 2)



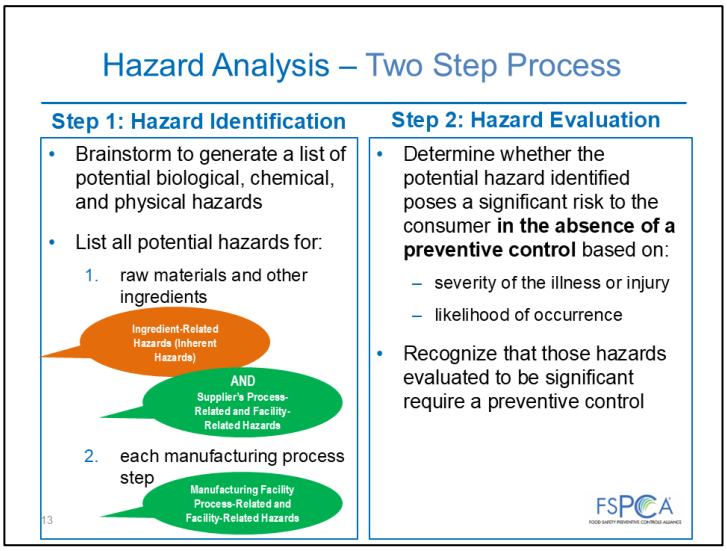
Shown here is an example hazard analysis worksheet where Columns 1 and 2 document the hazard identification step and Columns 3 and 4 document the hazard evaluation step.

In Column 1, list all the ingredients used in the food product(s) being analyzed as well as the process steps in making the food product(s). In Column 2, list all the potential hazards identified from the Food Safety Team's brainstorming exercise. The evaluation information is noted (in Column 3) with a "yes" or "no" response for each of the identified hazards (based on the hazards severity and likelihood of occurrence). Column 4 lists the justification for the hazard evaluation decision.

The Food Safety Team may wish to include lines on the form to ensure that each of the three types of potential hazards is considered in the analysis:

- **Biological (B) hazards,** including bacteria, viruses, parasites.
- **Chemical (C) hazards,** including radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, mycotoxins, heavy metals, decomposition, and unapproved food or color additives.
- **Physical (P) hazards,** including potentially harmful extraneous matter that may cause choking, injury, or other adverse health effects.

Slide 13: Hazard Analysis – Two Step Process (2 of 2)



The hazard analysis process is conducted in two steps – hazard identification and hazard evaluation:

Step 1: The hazard identification process is basically a brainstorming exercise where the Food Safety Team first generates a list of potential "known or reasonably foreseeable" biological, chemical (including radiological) and physical food safety hazards in the raw materials and other ingredients which would include inherent hazard associated with the raw materials and other ingredients AND the supplier's process and facility-related hazards introduced while making the raw material and other ingredients. Second, the Food Safety Team would also generate a list of the potential hazards that may be introduced, controlled, or enhanced at each process step used to manufacture the finished food product as described in their product flow diagram.

Step 2: The hazard evaluation determines whether the potential hazards identified pose a significant risk to consumers in the absence of a preventive control based on severity of illness or injury and likelihood of occurrence. For hazards deemed to be significant through the hazard evaluation process, there must be a preventive control in place.

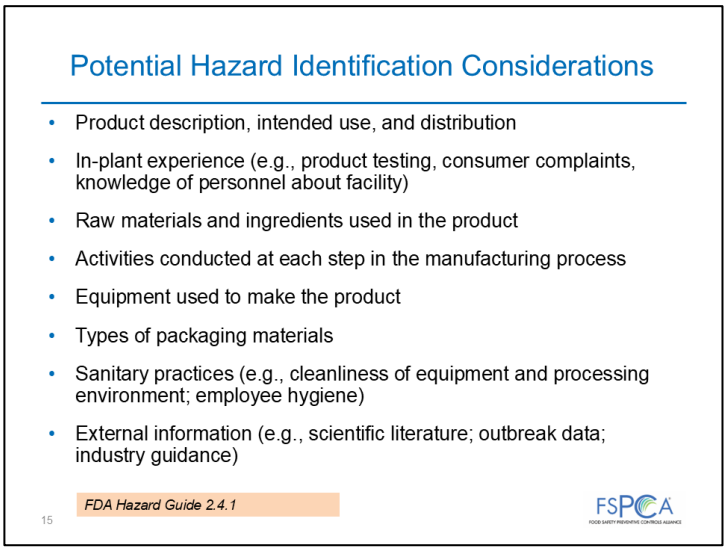
Slide 14: Step 1: Potential Hazard Identification

When identifying potential hazards, one must consider the hazards introduced at the supplier level: Inherent hazards historically associated with a raw material and other ingredient AND process- and facility-related hazards introduced by the supplier's process.

Examples of the supplier level hazards: Ingredient with inherent hazards (*Salmonella* in untreated peppercorns), AND supplier process-related hazards regarding allergen cross-contact using a shared conveyor belt for processing products with and without allergens.

Examples of process- and facility-related hazard at the food product manufacturing facility are packing in glass (potential glass hazard) and use of a ribbon blender (potential metal hazard from metal-to-metal contact).

Slide 15: Potential Hazard Identification Considerations



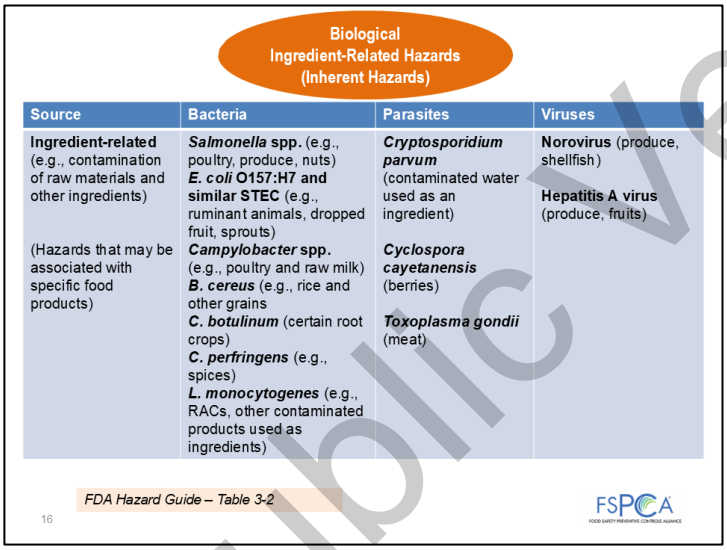
The following potential hazard identification considerations are from the FDA Hazard Guide 2.4.1. These should be considered by the Food Safety Team as they generate their list of hazards potentially associated with a food or process (the "known or reasonably foreseeable hazards"):

- Information about the product description, intended use, and distribution.
- In-plant experience regarding the likelihood of hazards being associated with the finished products. This may include information from product testing results, consumer complaints, or knowledge of facility personnel about the condition, function, and design of the facility that may be relevant to contamination.
- Raw materials and ingredients used in the product. Hazards, such as food allergen hazards or pathogens known to be associated with specific types of foods, may be introduced during product formulation. For example, mayonnaise is formulated with egg, which is a food allergen; "egg" must be included on the label and the mayonnaise may be a source of allergen cross-contact in the facility.
- Activities conducted at each step in the manufacturing process. Some processes may introduce hazards (e.g., a broken chopping blade can introduce metal fragments; a broken glass container can introduce glass fragments; and improper cooling can allow low numbers of microbial pathogens to increase).
- Equipment used to make the product. Some types of equipment are more difficult to clean than others or are more prone to damage, which may increase the risk of hazards (e.g., biological, or physical), being introduced into the product.
- Types of packaging and packaging materials. Reduced oxygen packaging, used to increase shelf life (e.g., potato salad packaged in a plastic container with a snap lid), may create an environment that supports the growth of *Clostridium botulinum* (*C. botulinum*).

- Sanitary practices. The facility should consider the sanitary conditions within the processing facility (e.g., the cleanliness of equipment and the processing environment), and employee hygiene when identifying hazards. Hard-to-clean equipment may result in pathogen harborage sites. Producing foods with different food allergens on the same line may result in allergen cross-contact.
- External information. Sources may include scientific papers, epidemiological studies (e.g., data from previous outbreaks associated with ingredients or processes relevant to a product), information from applicable government or industry food safety guidance documents, and historical data for similar products, if available.

After reviewing all the relevant information, the Food Safety Team can then develop a list of potential biological, chemical, and physical hazards that may be ingredient-related (associated with the raw materials and other ingredients) and process- and facility-related (introduced, increased (e.g., due to pathogen growth), or controlled at each process step described on the flow diagram).

Slide 16: Biological Ingredient-Related Hazards (Inherent Hazards)



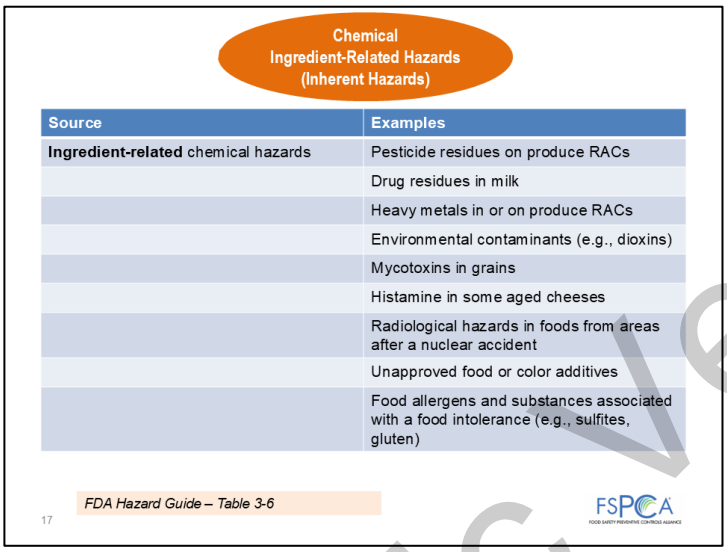
In the FDA Hazard Guide, the FDA has provided a Quick Reference Guide for Common Sources of Biological Hazards (Table 3-2) to help the Food Safety Team identify potential ingredient-related biological hazards associated with specific food products. The FDA Hazard Guide also contains Appendix 1 which has tables listing the most relevant food-related biological hazards for specific food products.

The biological hazards are bacterial pathogens (e.g., *Salmonella* spp., *Listeria monocytogenes*, *Clostridium botulinum*, and Shiga-toxin producing *Escherichia coli* (STEC) such as O157:H7), that may be associated with foods that can cause consumer illness or disease. The other biological hazards, viruses (e.g., norovirus and hepatitis A), and parasites (e.g., *Cryptosporidium* spp. and *Giardia intestinalis*), are also known to cause illness or disease, but these would generally be addressed by following GMPs (e.g., worker hygiene and disease control), in facilities and the FDA regulation titled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human

Consumption" (21 CFR Part 112) (e.g., worker hygiene and disease control, water safety), on farms that supply raw agricultural commodities to processing facilities.

Note, the FDA did not list the biological hazard *Cronobacter* spp. (including *C. sakazakii*) because *Cronobacter* spp. (including *C. sakazakii*) is largely a hazard for powdered infant formula rather than a hazard applicable to foods for the general population. However, FDA recommends considering *Cronobacter* spp. (including *C. sakazakii*) as a known or reasonably foreseeable ("potential") biological hazard for milk powders when they are destined for use in dry blended powdered infant formula products.

Slide 17: Chemical Ingredient-Related Hazards (Inherent Hazards)



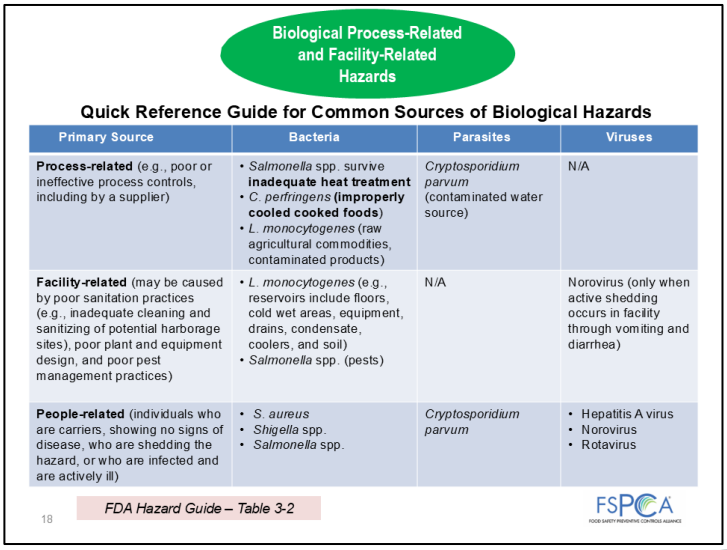
In the FDA Hazard Guide, the FDA has provided a Quick Reference Guide for Common Sources of Chemical Hazards (Table 3-6) to help the Food Safety Team identify potential ingredient-related chemical hazards. The FDA Hazard Guide also contains Appendix 1 which has tables listing the most relevant food-related chemical hazards for specific food products.

The chemical hazards listed are pesticide and drug residues, heavy metals, environmental contaminants, histamine due to decomposition, natural toxins (e.g., mycotoxins), radiological hazards, unapproved food and color additives, food allergens, and substances associated with a food intolerance or food disorder). Keep in mind that the list of chemical hazards listed is not an exhaustive list, there may be others the Food Safety Team may consider based on their knowledge and experience.

Food products can become contaminated with chemical hazards that are introduced at any stage in food production and processing. Some ingredient-related chemical hazards are natural components of food, such as food allergens, or are produced in the natural environment, such as mycotoxins, whereas other ingredient-related hazards (e.g., pesticides, drug residues, heavy metals, environmental contaminants), are contaminants of raw materials and other ingredients. Some process-related chemical hazards may be included in product formulation (e.g., sulfites that are a hazard for those consumers who are sensitive to them), whereas other process-related chemical

hazards may be unintentionally introduced into food, such as industrial chemicals used in a facility for purposes other than food production.

Slide 18: Biological Process-Related and Facility-Related Hazards



In the FDA Hazard Guide, FDA has provided a Quick Reference Guide for Common Sources of Biological Hazards (Table 3-2) to help the Food Safety Team identify potential pathogens by biological classification and potential sources or entry points in their facility. The potential hazards listed in Table 3-2 will not apply to all facilities.

Process-related hazards (e.g., poor, or ineffective process controls):

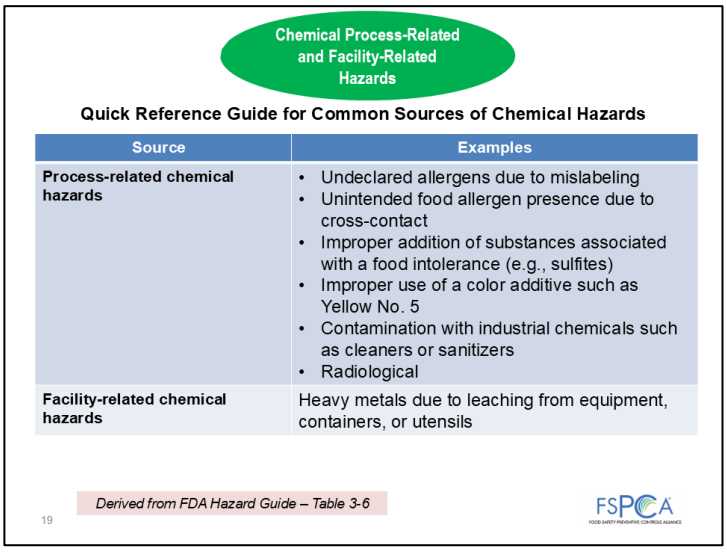
- Survive processing that was intended to significantly minimize the pathogen;
- Increase in number due to poor time/temperature control or due to the food's formulation; or
- Selectively grow, and/or produce toxin, in a food as a result of using reduced oxygen packaging.

Facility-related hazards—may be caused by poor sanitation practices (e.g., inadequate cleaning and sanitizing of potential harborage sites), poor facility and equipment design and maintenance, and poor pest management practices.

- Food processing equipment (e.g., insanitary equipment and utensils);
- Cross-contamination between raw and cooked products;
- Air; or
- Contaminated water or sewage; or

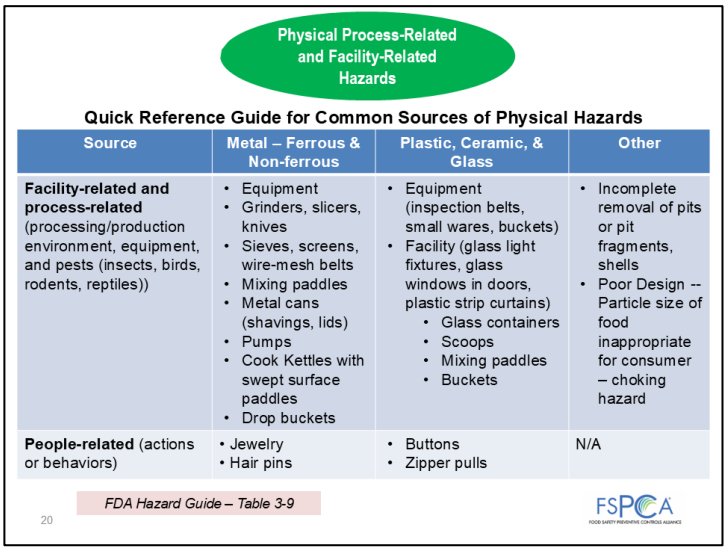
People-related hazards (e.g., due to people handling the product during packing or processing). Such people-related hazards are commonly controlled by following GMPs (e.g., worker hygiene and disease control).

Slide 19: Chemical Process-Related and Facility-Related Hazards



In the FDA Hazard Guide, FDA has provided a Quick Reference Guide for Common Sources of Chemical Hazards (Table 3-6) to help the Food Safety Team identify potential process-related chemical hazards (e.g., undeclared food allergens due to mislabeling or unintended food allergen presence due to cross-contact), substances introduced by misformulation, or unintentionally introduced into food, such as industrial chemicals used in a facility for purposes other than food production. The table also identified facility-related hazards (e.g., heavy metals due to leaching from equipment, containers, or utensils).

Slide 20: Physical Process-Related and Facility-Related Hazards



The FDA Hazard Guide, Table 3-9 is a Quick Reference Guide to help the Food Safety Team identify common sources of these physical hazards.

Process-related and facility-related common physical hazards include metal, glass, and hard plastic. Physical hazards are broadly classified as "hard/sharp" physical hazards and "choking" hazards. Both categories can cause injury to the consumer. These injuries may include dental damage, laceration of the mouth or throat, laceration, or perforation of the intestine, and choking and may even lead to death. Because physical hazards cover a broad range of contaminants, (e.g., glass, metal, plastic, wood, and stones), such contamination can occur throughout the processing facility, including the receiving dock for ingredients and supplies.

Metal: Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations, and some metal equipment has parts that can break or fall off, such as wire-mesh belts. FDA's Health Hazard Evaluation Board (FDA, 2005e; Olsen, 1998) has supported regulatory action against products with metal fragments of 0.3 in. (7 mm) to 1.0 in. (25 mm) in length. Such fragments have been shown to be a hazard to consumers. Metal hazards can be controlled by the use of metal detection devices or by regular inspection of at-risk equipment for signs of damage.

Glass: Glass fragments can be introduced into food whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Ingesting glass fragments can cause injury to the consumer. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of the same size as is noted for metal. Most products packed in glass containers are intended to be a ready-to-eat commodity. In the facility's hazard analysis, the facility should consider the potential for glass fragments to originate from sources other than glass containers used in packaging. For example, some facilities that do not pack in glass prohibit the presence of glass in the production environment to reduce the risk of glass

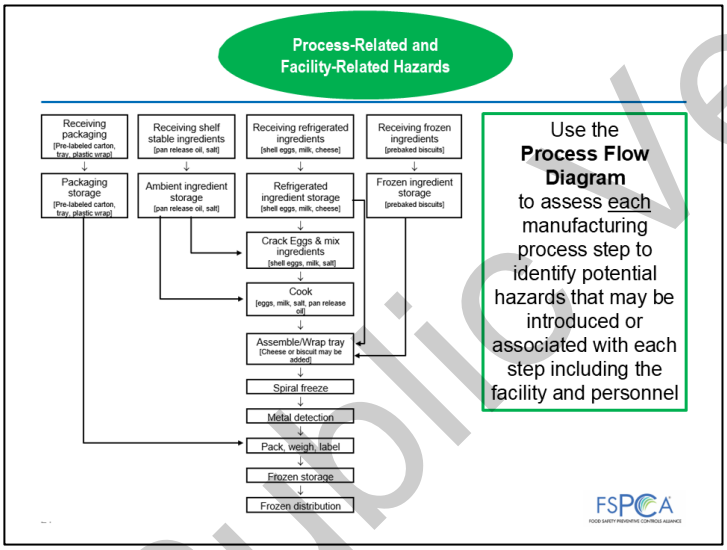
getting into the product. The facility can address glass fragments originating from sources such as overhead light fixtures through CGMPs.

Hard Plastic: Hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets, or other containers develop fatigue, crack, and break as they wear. Hard plastic also can be introduced into food when plastic sieves and screens deteriorate. The facility should examine items to determine whether they are worn and remove worn items before they break, especially if they cannot be effectively cleaned (e.g., because of small cracks).

For example, equipment that has food-contact surfaces that could break during food processing and could result in physical debris being deposited in the food product. Another example is production equipment that has nuts and bolts that could fall out during production.

People-related sources of physical hazards are generally addressed by following GMPs, (e.g., a facility's GMP policy that prohibits employees from wearing jewelry and hair pins in the processing facility).

Slide 21: Process-Related and Facility-Related Hazards



One effective approach to identifying and documenting potential biological, chemical, and physical process- and facility-related hazards is to first develop a process flow diagram to explain what happens at each of the process steps used to manufacture the food product(s) in a specific facility.

The purpose of a process flow diagram is to provide a clear, simple description of the steps involved in the processing of the food product and its associated ingredients as they "flow" from receipt to distribution.

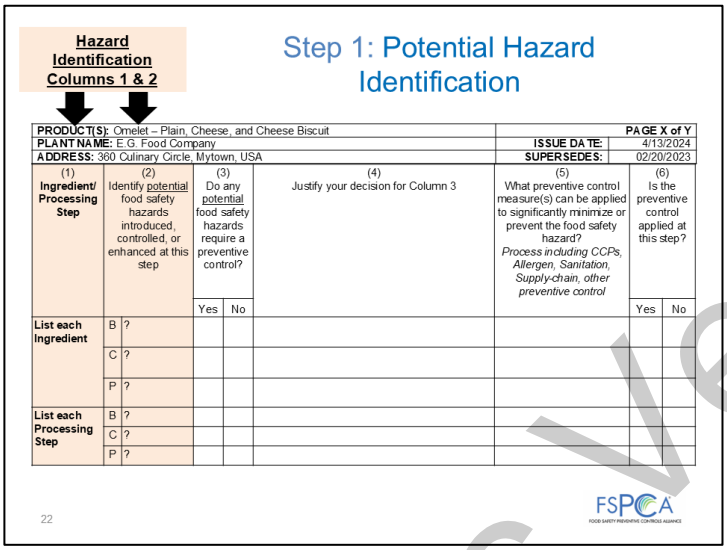
The process flow diagram should cover all steps in the process that the facility performs, including receiving and storage steps for each raw material or other ingredient, as well as preparation, processing, packaging, storage, and distribution of the product.

Additionally, the process flow diagram should identify the equipment (e.g., pumps, surge tanks, hoppers, fillers), used in the operations.

An accurate process flow diagram serves as a useful organizational format for elements of the Food Safety Plan because it identifies each of the steps that must be evaluated in the hazard analysis.

After reviewing all the relevant information from the flow diagram, the Food Safety Team can document the list of raw materials and other ingredients and the process steps by completing Columns 1 of the Hazard Analysis form.

Slide 22: Step 1: Potential Hazard Identification

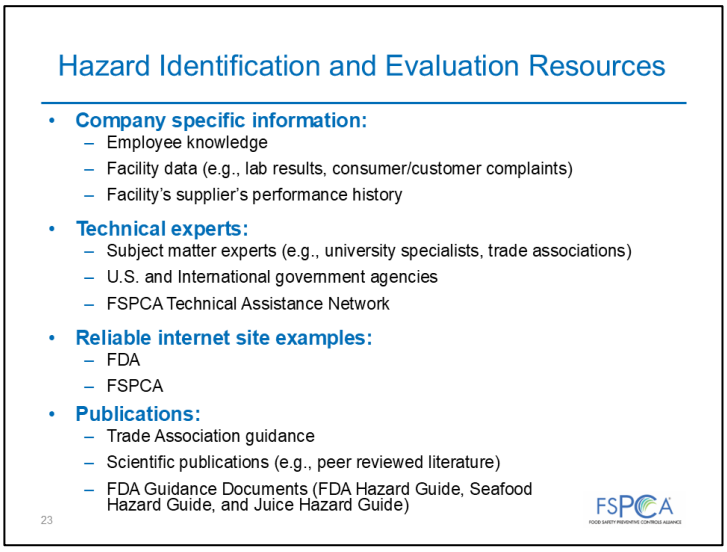


After reviewing all the relevant information from the flow diagram, the Food Safety Team can now document the list of raw materials and other ingredients and the process steps by completing Column 1 of the Hazard Analysis form

Many companies perform a separate ingredient hazard analysis for each of the ingredients used in the facility. This is a useful approach, especially for facilities that use many ingredients in multiple products. While some companies may conduct a separate hazard analysis for all the ingredients, another common approach is to analyze each ingredient at the point of receipt including the receiving step for that ingredient. Either way is acceptable.

The next step will be the identification of potential hazards introduced, controlled, or enhanced at each step. There are several resources available to the Food Safety Team to accomplish this.

Slide 23: Hazard Identification and Evaluation Resources



FSPCA's Technical Assistance Network (TAN)

Google Scholar can be a useful tool to search for peer-reviewed literature.

To conduct an accurate hazard analysis (identification & evaluation), the Food Safety Team should gather information from a variety of credible sources and use the information that best applies to their situation. Some of the most useful sources of information are described on this slide. Sources of information include company knowledge and facility data as well as information from technical experts including subject matter experts, government agencies, and the FSPCA.

Company specific information: One source of information for the hazard analysis is company-specific information including information from employees, facility data, and suppliers.

- Facility employees know their operation better than anyone. Experience is an excellent source of information. They may already have knowledge about hazards that can affect their product and may already have preventive controls implemented to control those hazards.
- Data from in-facility practices that may be relevant to contamination, including results from lab testing, consumer/customer complaints, and what the facility personnel inherently know about the condition, function, and design of the processing equipment and environment from having worked in the facility.
- Evaluation of a facility's supplier's performance is critical when evaluating hazards in raw materials and other ingredients. More discussion on evaluating supplier performance is discussed in Chapter 13: Supply-Chain Preventive Controls for Human Food.

Technical experts: Some food safety professionals have in-depth expertise related to specific types of foods or processes. These can include subject matter experts from universities or trade associations or process authorities. They use scientific methods to determine the proper parameters (e.g., time, temperature, flow rate, water activity, pH, packaging oxygen levels, etc.), to prevent, eliminate, or reduce pathogens to acceptable levels. Technical experts are a key source for validating the adequacy of a process to ensure that identified controls will control the hazards. They can also

provide technical advice for developing a Food Safety Plan and implementing appropriate corrective action procedures.

- **U.S. and International government agencies:** International, and U.S. Federal, State, Local (may be known as county, city, regional), Tribal, or Territorial agencies may be able to assist in understanding and meeting regulatory requirements. Some U.S. state regulatory groups have a food safety task force that provides training opportunities periodically. Websites and call-in Q&A phone lines that provide useful information from government agencies may also be available.
- **FSPCA Technical Assistance Network (TAN):** FSPCA's TAN is a network of volunteer food safety experts who provide technical assistance to small and medium-sized businesses to enhance industry's understanding of the FDA's Preventive Controls for Human Food regulation. These experts are available to answer scientific and technical questions regarding identifying and evaluating hazards and developing a Food Safety Plan. Inquiries may be submitted through a web form or by mail. See FSPCA's website.

Reliable Internet Sites: Information on key food safety hazards and controls is available for free online. **WARNING:** Be sure to use peer reviewed and other credible sources when seeking information on the web to avoid the use of inaccurate information.

- **FDA Website** contains regulatory guidance documents related to the Preventive Controls regulation as well as their FSMA Technical Assistance Network (TAN) Frequently Asked Questions about the interpretation of the Preventive Controls for Human Food regulation.
- **FSPCA Website** contains resource materials, Food Safety Plan worksheets, training course information, and the FSPCA Technical Assistance Network.
- **Trade Association Websites:** The American Frozen Food Institute (AFFI) provides food safety information related to frozen products. The Consumer Brands Association provides food safety technical guidance on specific topics on the website to share industry model practices. Some information is available for a fee; other information is available at no charge. Look for resources, research tools and technical guidance and tools information.

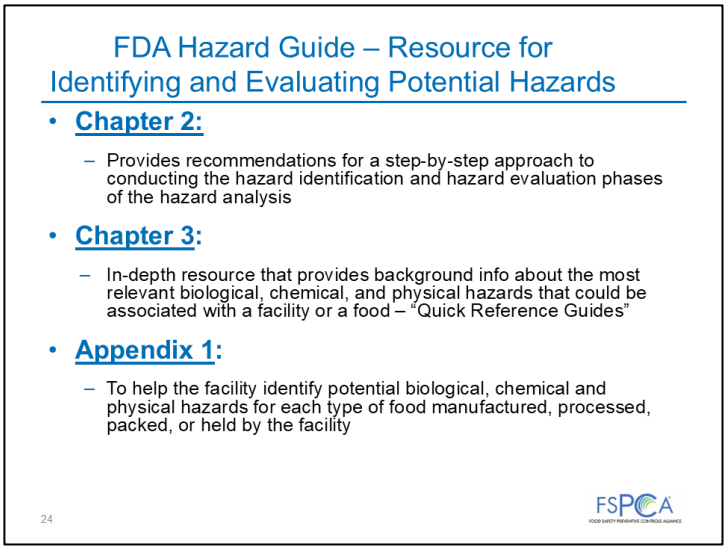
Publications are another type of information source that facilities may use in developing a Food Safety Plan. It is important to use credible publications for this purpose. The slide above lists general sources of credible information, and each type is described below.

- **Trade Association Guidance:** As previously discussed, several trade associations have guidance documents including model recall plans, generic Food Safety Plans, and other information. While generic Food Safety Plans may be available for products related to the facility's operations, use these with caution, as each facility's Food Safety Plan should be specific for the particular product and how it is made in the facility
- **Scientific Publications (e.g., peer reviewed literature):** Scientific publications are another useful source of information for developing a Food Safety Plan. The search tool Google Scholar may be useful to identify peer reviewed literature.

Trade journals often provide general information on potential hazards and controls. Articles on specific processes or products can also be useful. These trade journals are usually made available to industry at no charge, and many are accessible online.

- **Peer-reviewed Scientific Journals** and other sources of technical literature (e.g., Codex Alimentarius Commission, the Food and Agriculture Organization, and the World Health Organization), provide considerable information on foodborne hazards, including their occurrence, their potential growth in foods (e.g., for biological hazards), and their control. Codex maintains internationally recognized codes of practice that are based on scientific literature and which are available in several languages.
- **FDA's Bad Bug Book** provides technical information on foodborne pathogens in plain language.
- **Microbial Modeling Programs (e.g., USDA Pathogen Modeling Program or ComBase)**, are available online and can be used to explore the potential for growth under a variety of conditions. Keep in mind that these models may not reflect exactly what will occur in a particular food, but they can indicate relative risk of different handling scenarios
- **FSPCA's Preventive Controls for Human Food Training Curriculum** is one of the best and most accessible food safety resources available to develop and modify a preventive controls Food Safety Plan. This training curriculum covers steps for developing a Food Safety Plan using the Food Safety Plan Teaching Examples (model food plans). The chapters cover prerequisite programs; biological, chemical (including radiological) and physical hazards encountered in foods and basic information on how these hazards can be controlled; and elements of process, food allergen, sanitation, and supply-chain program preventive controls. The Preventive Controls for Human Food regulation also in the manual is an excellent resource. Many references were used in the development of the material in this training curriculum. Refer to the "Additional Reading" section of each chapter for additional references.
- **FDA Guidance Documents (e.g., FDA Hazard Guide, Seafood HACCP Hazard Guide, Juice HACCP Hazard Guide):** The FDA has published several hazard guides to help manufacturers/processors identify and evaluate food safety hazards in specific food commodities. These include the FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food Guidance (referred to as the FDA Hazard Guide); the FDA Fish and Fishery Products Hazards and Controls Guidance (referred to as the Seafood Hazard Guide); and the FDA Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (referred to as the Juice Hazard Guide). The recommendations included in the FDA hazard guides are not binding FDA requirements. Use of the hazard guides in developing Food Safety Plans is not mandatory. Processors and importers are free to choose other control measures that provide an equivalent level of safety assurance in addition to those listed in the guides. There may also be circumstances where a hazard identified in a guide may not apply to a product because of conditions specific to the processor.

Slide 24: FDA Hazard Guide – Resource for Identifying and Evaluating Potential Hazards



FDA Hazard Guide
Full Guide

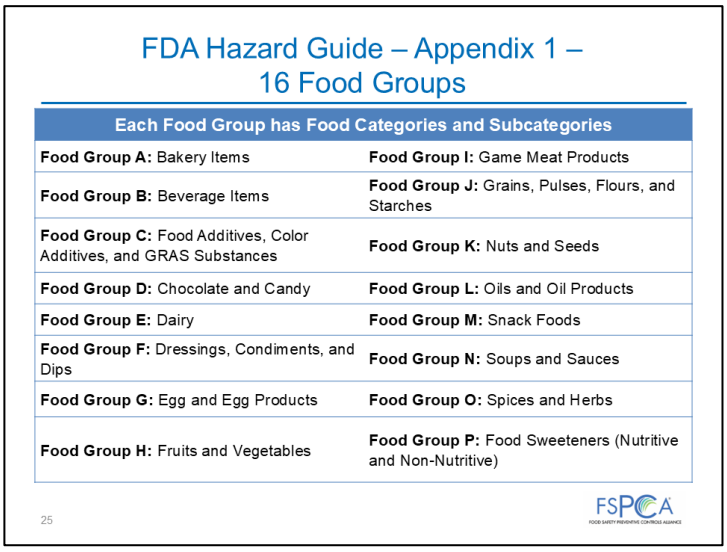
There are two chapters and one Appendix in the FDA Hazard Guide that are particularly helpful in conducting a hazard analysis.

The guidance provided in Chapter 2 is intended to help the Food Safety Team conduct a hazard analysis in accordance with the Preventive Controls for Human Food regulation requirements in 21 CFR Part 117. The information in Chapter 2 provides recommendations for a step-by-step approach to conducting the hazard identification and hazard evaluation phases of the hazard analysis to determine those known or reasonably foreseeable hazards (potential hazards) requiring a preventive control.

Chapter 3 of the guidance is an in-depth resource that provides background information about the most relevant biological, chemical, and physical hazards that could be associated with a facility or a food. The chapter also addresses ingredient-related hazards, process-related hazards, and hazards that may be introduced from the food-production environment (facility-related hazards). Chapter 3 includes several "Quick Reference Guides" to help the Team identify common sources of biological, chemical, and physical hazards.

The guidance in Appendix 1 is intended to help the Food Safety Team identify known or reasonably foreseeable biological, chemical, and physical hazards for each type of food manufactured, processed, packed, or held at the facility. Appendix 1 lists the most relevant food-related biological and chemical hazards and discusses the most relevant process-related and facility-related biological, chemical, and physical hazards.

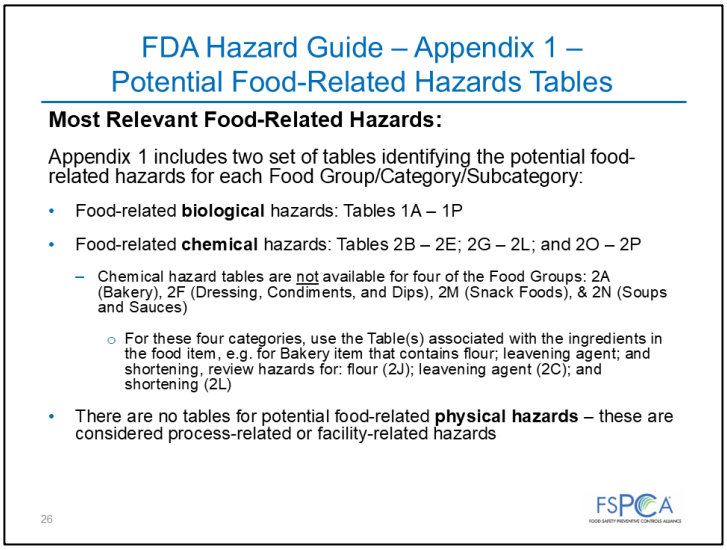
Slide 25: FDA Hazard Guide – Appendix 1 – 16 Food Groups



The PCHF requirements apply to a broad array of food products. Therefore, FDA developed Appendix 1 in a way to show potential hazards associated with specific types of food products. In doing so, FDA has identified 16 Food Groups and Food Categories and Food Subcategories within each Food Group.

Food Group A: Bakery Items	**Food Group I:** Game Meat Products
Food Group B: Beverage Items	**Food Group J:** Grains, Pulses, Flours, and Starches
Food Group C: Food Additives, Color Additives, and GRAS Substances	**Food Group K:** Nuts and Seeds
Food Group D: Chocolate and Candy	**Food Group L:** Oils and Oil Products
Food Group E: Dairy	**Food Group M:** Snack Foods
Food Group F: Dressings, Condiments, and Dips	**Food Group N:** Soups and Sauces
Food Group G: Egg and Egg Products	**Food Group O:** Spices and Herbs
Food Group H: Fruits and Vegetables	**Food Group P:** Food Sweeteners (Nutritive and Non-Nutritive)

Slide 26: FDA Hazard Guide – Appendix 1 – Potential Food-Related Hazards Tables



FDA Hazard Guide Appendix 1

FDA organizes the information regarding potential food-related hazards in Appendix 1 as follows:

Tables 1A through **1P**, list the most relevant food-related biological hazards in Food Subcategories in the 16 **Food Groups**.

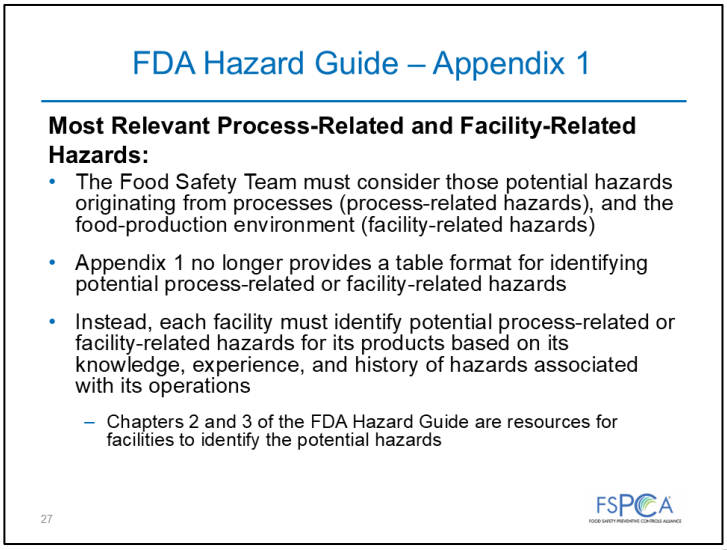
- These **Tables** are marked (with an "X") for those food-related biological hazards that FDA identified as potential hazards for subsequent hazard evaluation by a facility that produces food products in those Food Subcategories to determine which hazards require a preventive control, as appropriate to the facility and its food products. In some cases, footnotes are provided at the bottom of tables to provide more detail about the product categories and/or potential hazards.

Tables for 12 of the 16 **Food Groups**, **Tables 2B, 2C, 2D, 2E, 2G, 2H, 2I, 2J, 2K, 2L, 2O, and 2P** list the most relevant food-related chemical hazards in Food Subcategories.

- These **Tables** are marked (with an "X") for the most relevant food-related chemical hazards that FDA identified as potential hazards for subsequent hazard evaluation by a facility that produces food products in those Food Subcategories to determine which hazards require a preventive control as appropriate to the facility and its food products. In some cases, footnotes are provided at the bottom of tables to provide more detail about the product categories and/or potential hazards.
- In 4 of these **16 Food Groups** (i.e., Bakery Items; Dressings, Condiments, and Dips; Snack Foods; and Soups and Sauces), the potential chemical hazards depend on the ingredients used. Therefore, FDA recommends for the 4 **Food Group** (i.e., **Food Groups 2A, 2F, 2M, and 2N**), that the Food Safety Team refer to the **Tables** most applicable to the ingredients used in the Bakery Items; Dressings, Condiments, and Dips; Snack Foods; and Soups and Sauces.

There are no tables for potential **physical hazards.** These are considered process-related or facility-related hazards.

Slide 27: FDA Hazard Guide – Appendix 1

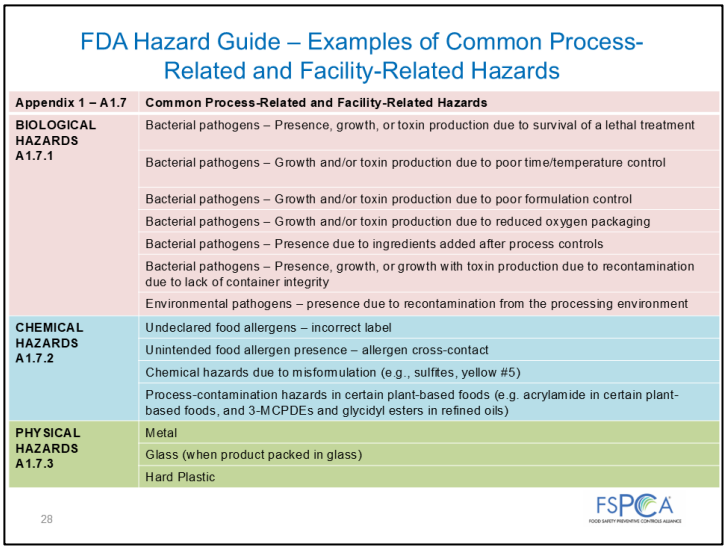


As previously discussed, when conducting the hazard analysis, a facility must consider potential hazards originating from processes (process-related hazards), and the food-production environment (facility-related hazards) (21 CFR 117.130(c)(2)).

Because each facility is unique in its products, operations, processes, and physical plant, process-related hazards and facility-related hazards can be specific to each facility. Therefore, this Appendix 1 no longer identifies potential process-related hazards or facility-related hazards.

Instead, each facility must identify potential process-related hazards or facility-related hazards for its products based on its knowledge, experience, and history of hazards associated with its operations. The Food Safety Team also should consider any personnel practices not managed under GMPs. The information provided in the FDA Hazard Guide, Chapters 2 and 3 is a resource for facilities to do so.

Slide 28: FDA Hazard Guide – Examples of Common Process-Related and Facility-Related Hazards



FDA Hazard Guide – Examples of Common Process-Related and Facility-Related Hazards

Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging
	Bacterial pathogens – Presence due to ingredients added after process controls
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity
	Environmental pathogens – presence due to recontamination from the processing environment
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label
	Unintended food allergen presence – allergen cross-contact
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)
PHYSICAL HAZARDS A1.7.3	Metal
	Glass (when product packed in glass)
	Hard Plastic

28

FSPCA

FSPCA Form 0231 – FDA HAZARD GUIDE APPENDIX 1: COMMON PROCESS-RELATED AND FACILITY-RELATED HAZARDS

In the FDA Hazard Guide, Chapter 3 (sections 3.3.4,3.3.5, 3.4.2, and 3.5) and Appendix 1 (sections A1.7.1, A1.7.2 and A1.7.3), FDA provides background information for the following examples of process-related and facility-related hazards that are most relevant to food safety. The table (FSPCA Form 0231) is also available on FSPCA's Website at the QR Code next to the slide.

Most Relevant Process-Related and Facility-Related Biological Hazards (A1.7.1):

Bacterial Pathogens – Presence/growth/toxin production due to survival of a lethal treatment. (Section 3.3.4.1)

> For example, a heat treatment that is not properly delivered (e.g., the temperature is too low, or the heating time is insufficient) could allow a pathogen to survive; in some cases, the surviving pathogens could subsequently grow and produce toxin.

Bacterial Pathogens – Growth and/or toxin production due to poor time/temperature control. (Sections 3.3.4.2.1 and 3.3.4.2.2)

> For example, a cooling mechanism that does not function as intended could allow a small number of microbial pathogens to increase in number.

Bacterial Pathogens – Growth and/or toxin production due to poor formulation control. (Section 3.3.4.2.3)

> For example, if insufficient acid is added to reduce the pH sufficiently in an acidified food, pathogenic sporeformers could grow and produce toxin.

Bacterial Pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP). (Section 3.3.4.2.4)

> For example, reduced oxygen packaging that is used to increase shelf life could create an environment that supports the growth of *C. botulinum*.

Bacterial pathogens – Presence due to ingredients added after process controls. (Section 3.3.4.3)

Bacterial Pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity. (Section 3.3.4.4)

For example, if a container is not properly sealed and it is cooled in water, water containing pathogens can be drawn into the container.

Environmental Pathogens – Presence due to recontamination from the processing environment. (Section 3.3.5.1)

For example, equipment that is difficult to clean or is prone to damage could increase the risk for environmental pathogens to contaminate the product post-processing.

As another example, facility traffic patterns can transfer environmental pathogens from one process area to another.

Most Relevant Process-Related Chemical Hazards (A1.7.2):
Undeclared food allergens – Incorrect label (Sections 3.4.2.1.2 and 3.4.2.1.3). For example:

An incorrect label can result if you change the product formulation to include a food allergen but do not update the product label to declare that food allergen.

If the product label is pre-printed on the product package, an incorrect label can result if the wrong packaging is brought to the production line.

If you apply the product label to the package after the package has been filled, an incorrect label can result if the wrong label is brought to the production line.

Unintended food allergen presence – allergen cross-contact (Section 3.4.2.1.4). For example:

Allergen cross-contact can result if equipment that is difficult to clean or is prone to damage is used to produce foods that contain ingredients from different food allergen sources.

Allergen cross-contact can result from the unintentional addition of the wrong ingredient [that is or contains an allergen] to a food.

Chemical hazards due to misformulation (e.g., sulfites, yellow #5) (Section 3.4.2.2.2)

For example, misformulation can occur if you manufacture/process some products with added sulfites and other products without sulfites, and if you unintentionally add sulfites to a product that does not include sulfites in the product recipe.

Process-contaminant hazards in certain plant-based foods (Section 3.4.2.3)

For example, some chemical hazards (such as acrylamide in certain plant-based foods and 3-monochloropropane-1,2-diol esters (3-MCPDEs) and glycidyl esters (GEs) (developed in some refined oils)) have the potential to form during food production, particularly at high temperature.

Most Relevant Process-Related Physical Hazards (A1.7.3):
Metal (Section 3.5)

> For example, a process that uses a metal chopping blade could introduce metal fragments if the blade breaks.

Glass (when product is packed in glass) (Section 3.5)

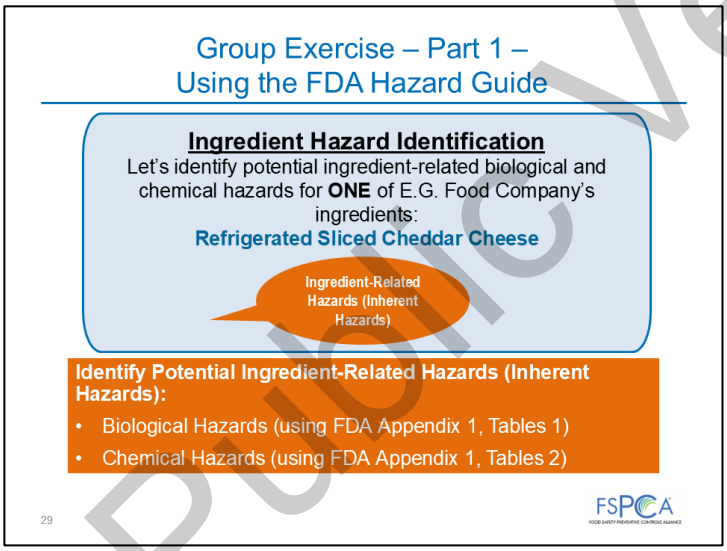
> For example, a product packaged in glass containers could introduce glass fragments if a container breaks.

Hard plastic (Section 3.5)

> For example, hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets, or other containers develop fatigue, crack, and break as they wear, or when plastic sieves and screens deteriorate.

In general, if there is an overlap between facility-related physical hazards and process-related physical hazards and, in evaluating the potential for physical hazards in the food products, it does not matter whether the Food Safety Team considers physical hazards to be facility-related or process-related.

Slide 29: Group Exercise – Part 1 – Using the FDA Hazard Guide (1 of 3)



FDA Hazard Guide Appendix 1

Be prepared to report on which biological and chemical ingredient-related hazards you find applicable in the FDA Hazard Guide, Appendix 1, for refrigerated sliced cheddar cheese.

Respond to the instructor when requested.

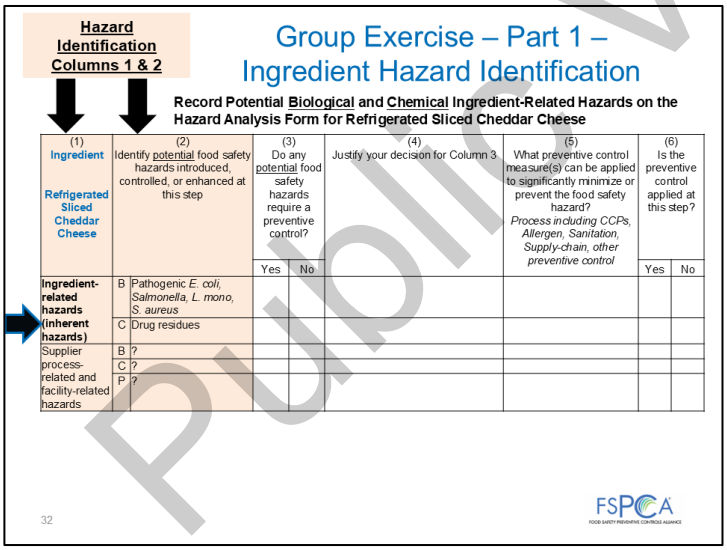
Slide 30: Group Exercise – Part 1 – Using the FDA Hazard Guide (2 of 3)

***Participants do NOT have this slide*.**

Slide 31: Group Exercise – Part 1 – Using the FDA Hazard Guide (3 of 3)

Participants do NOT have this slide.

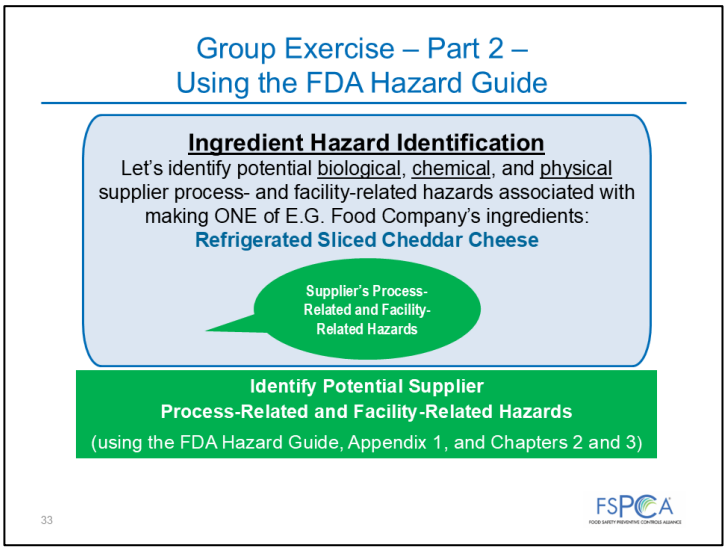
Slide 32: Group Exercise – Part 1 – Ingredient Hazard Identification



The potential ingredient-related biological and chemical hazards that were identified in Part 1 of the group exercise are recorded in Column 2.

Next, complete Part 2 of the group exercise by identifying the cheese supplier's process-related and facility-related hazards associated with manufacturing the cheese.

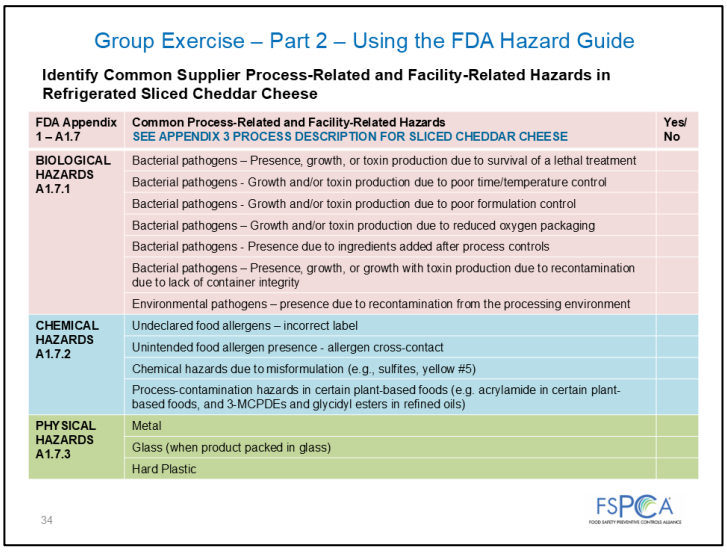
Slide 33: Group Exercise – Part 2 – Using the FDA Hazard Guide (1 of 3)



Be prepared to report on the potential **supplier** process-related and facility-related hazards for making refrigerated sliced cheddar cheese.

Respond to the instructor when requested.

Slide 34: Group Exercise – Part 2 – Using the FDA Hazard Guide (2 of 3)



Group Exercise – Part 2 – Using the FDA Hazard Guide

Identify Common Supplier Process-Related and Facility-Related Hazards in Refrigerated Sliced Cheddar Cheese

FDA Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards SEE APPENDIX 3 PROCESS DESCRIPTION FOR SLICED CHEDDAR CHEESE	Yes/ No
BIOLOGICAL HAZARDS A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment	
	Bacterial pathogens - Growth and/or toxin production due to poor time/temperature control	
	Bacterial pathogens - Growth and/or toxin production due to poor formulation control	
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging	
	Bacterial pathogens - Presence due to ingredients added after process controls	
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	
	Environmental pathogens – presence due to recontamination from the processing environment	
CHEMICAL HAZARDS A1.7.2	Undeclared food allergens – incorrect label	
	Unintended food allergen presence - allergen cross-contact	
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	
	Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)	
PHYSICAL HAZARDS A1.7.3	Metal	
	Glass (when product packed in glass)	
	Hard Plastic	

34

FSPCA

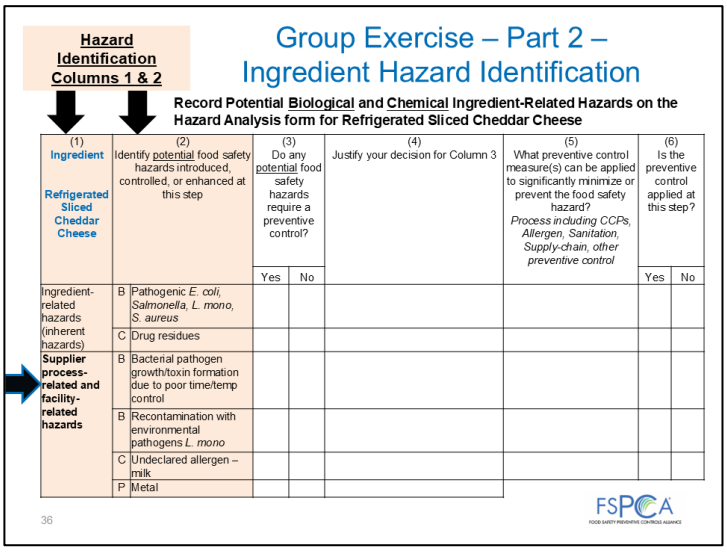
Be prepared to report on potential **supplier** process-related and facility-related hazards for making refrigerated sliced cheddar cheese.

Respond to the instructor when requested.

Slide 35: Group Exercise – Part 2 – Using the FDA Hazard Guide (3 of 3)

***Participants do NOT have this slide*.**

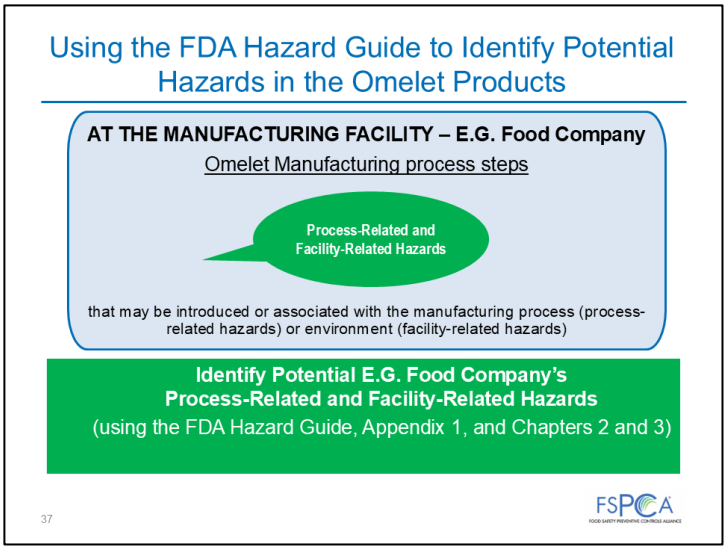
Slide 36: Group Exercise – Part 2 – Ingredient Hazard Identification



The potential supplier process-related and facility-related hazards associated with the manufacturing of the refrigerated sliced cheddar cheese identified in Part 2 of the group exercise, are recorded in Column 2 of the hazard analysis form.

The hazard analysis form now includes all the potential ingredient-related hazards for the refrigerated sliced cheddar cheese (inherent associated with the raw material ingredient (i.e., Pathogenic *E. coli, Salmonella, L. mono, S. aureus* and drug residues), AND the supplier process- and facility-related hazards (bacterial pathogen growth/toxin formation due to poor time/temp control, recontamination with environmental pathogens (*L. mono*), undeclared allergen (milk), and metal).

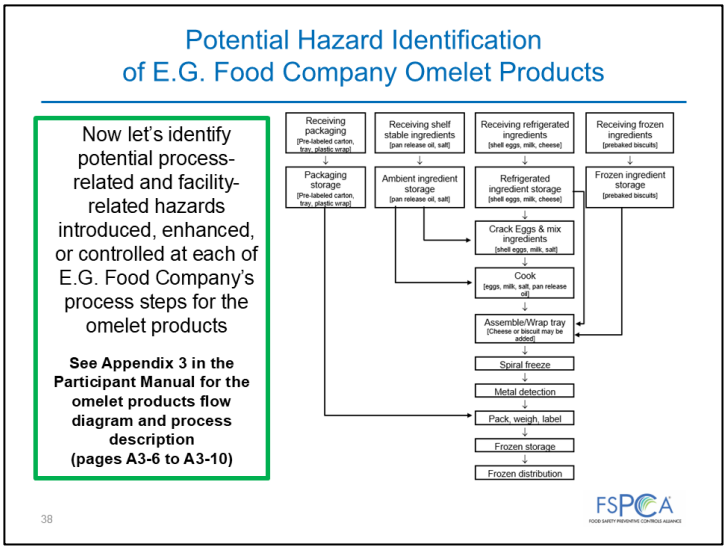
Slide 37: Using the FDA Hazard Guide to Identify Potential Hazards in the Omelet Products



After the ingredient-related potential hazards (including supplier process- and facility-related hazards) are identified, the next step is to identify the potential process-related and facility-related hazards associated with the manufacturing of the food product, in this case the E.G. Food Company's omelet products.

The FDA Hazard Guide, Appendix 1, and Chapters 2 and 3 are helpful tools to use to identify these potential process- and facility-related hazards that may be introduced or associated with the manufacturing process/facility environment.

Slide 38: Potential Hazard Identification of E.G. Food Company Omelet Products



The approach the E.G. Food Company's Food Safety Team would take in identifying the potential process- and facility-related biological, chemical, and physical hazards in the manufacturing of the omelets is to first review the process flow diagram that shows the omelet processing steps identified in Appendix 3, on page A3-6, E.G. Food Company Food Safety Plan Teaching Example.

E.G. Food Company's process steps are detailed in their process description (pages A3-7 to A3-10) which describes the omelets processing including the receiving and storage steps for each raw material or other ingredient, preparation, processing, packaging, storage, and distribution of the product.

Slide 39: Common Process-Related and Facility-Related Hazards in E.G. Food Company's Omelet Products

Common Process-Related and Facility-Related Hazards in E.G. Food Company's Omelet Products

FDA Appendix 1 – A1.7	Common Process-Related and Facility-Related Hazards	Potential? Yes/No (Not applicable – NA)
BIOLOGICAL HAZARDS – A1.7.1	Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment	**Yes** – The omelet mixture with raw egg must be properly cooked
	Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control	**Yes** – Potential
	Bacterial pathogens – Growth and/or toxin production due to poor formulation control	**NA** – Not formulated for safety
	Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP)	**NA** – Not packaged in ROP
	Bacterial pathogens - Presence due to ingredients added after process controls	**Yes** – The sliced cheddar cheese and biscuits added post-process
	Bacterial pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity	**NA** – Not packaged in hermetically sealed container
	Environmental pathogens – presence due to recontamination from the processing environment	**Yes** – The cooked omelet, cheese, and biscuits are ready-to-eat and further handled at assembly before packaging.
CHEMICAL HAZARDS – A1.7.2	Undeclared food allergens – incorrect label	**Yes** – All omelets contain major food allergens egg, milk, and soy; biscuit also contains wheat allergen so correct allergens need to be declared
	Unintended food allergen presence – allergen cross-contact	**Yes** – The biscuits containing wheat could be unintentionally incorporated into the plain and cheese omelet at assembly.
	Chemical hazards due to misformulation (e.g., sulfites, yellow #5)	**NA** – Does not contain ingredients with a maximum use level for safety
	Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils)	**NA** – Not Applicable (the omelet products are not plant-based foods)
PHYSICAL HAZARDS – A1.7.3	Metal	**Yes** – The potential metal from the commercial mixer (wire whip has a history of breaking) and in biscuits and cheese from supplier's slicing process
	Glass (when product packed in glass)	**NA** – Not glass packed
	Hard Plastic	**NA** – Hard plastic not used by E.G. Food Company

E.G. Food Company's process steps will be assessed for common process-related and facility-related biological, chemical, and physical hazards in the manufacturing facility using information in the FDA Hazard Guide specifically Appendix 1 (A1.7), and Chapter 3.

Most Relevant Process-Related and Facility-Related Biological Hazards (A1.7.1):

Bacterial Pathogens – Presence/growth/toxin production due to survival of a lethal treatment. (Section 3.3.4.1)

> E.G. Food Company Example: Yes, a heat treatment that is not properly delivered to cook the omelets could allow a pathogen to survive; in some cases, the surviving pathogens could subsequently grow and produce toxin.

Bacterial Pathogens – Growth and/or toxin production due to poor time/temperature control. (Sections 3.3.4.2.1 and 3.3.4.2.2)

> E.G. Food Company Example: Yes, there is a potential for poor time/temperature control at various process steps, e.g., receiving refrigerated ingredients, storage of refrigerated ingredients, mix ingredients, assemble/wrap, spiral freezer, frozen storage and frozen distribution.

Bacterial Pathogens – Growth and/or toxin production due to poor formulation control. (Section 3.3.4.2.3)

> E.G. Food Company example: Not applicable since omelet products are not formulated for safety.

Bacterial Pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP). (Section 3.3.4.2.4)

> E.G. Food Company Example: Not applicable since omelet products are not packaged in ROP.

Bacterial pathogens – Presence due to ingredients added after process controls. (Section 3.3.4.3)

E.G. Food Company example: Yes, ingredients (cheese and biscuits) are added after E.G. Food Company's process control omelet cook step and bacterial pathogens could be introduced during the ingredient addition steps. Potential biological hazards associated with these ingredients and the supplier's process were already identified during the hazard analysis of the ingredients. Potential introduction of environmental pathogens introduced during addition of the cheese and biscuits at E.G. Food Company are addressed at the assemble/wrap step.

Bacterial Pathogens – Presence, growth, or growth with toxin production due to recontamination due to lack of container integrity. (Section 3.3.4.4)

E.G. Food Company Example: Not applicable since E.G. Food Company does not package omelet products in hermetically sealed containers.

Environmental Pathogens – Presence due to recontamination from the processing environment. (Section 3.3.5.1)

E.G. Food Company Example: Yes, E.G. Food Company's cooked omelet, cheese, and biscuits are ready-to-eat and further handled at assembly before packaging. The omelet products are ready-to-eat and can support pathogens if environmental recontamination occurs.

Most Relevant Process-Related Chemical Hazards (A1.7.2):

Undeclared food allergens – Incorrect label (Sections 3.4.2.1.2 and 3.4.2.1.3).

E.G. Food Company Example: Yes, all omelets contain major food allergens of egg, milk, and soy; biscuit also contains wheat allergen so correct allergens need to be declared on finished omelet product labels.

Unintended food allergen presence – allergen cross-contact (Section 3.4.2.1.4).

E.G. Food Company Example: Yes, biscuits containing wheat used only for the Cheese Biscuit Omelets and could be unintentionally incorporated during assembly into the plain and cheese omelet finished products that do not contain wheat.

Chemical hazards due to misformulation (e.g., sulfites, yellow #5) (Section 3.4.2.2.2)

E.G. Food Company Example: Not applicable since E.G. Food Company does not use ingredients with maximum use levels for safety in their omelet products.

Process-contaminant hazards in certain plant-based foods (Section 3.4.2.3)

E.G. Food Company Example: Not applicable to this food category.

Most Relevant Process-Related Physical Hazards (A.1.7.3):
Metal (Section 3.5)

E.G. Food Company Example: Yes, the E.G. Food Company uses a commercial mixer to mix the eggs, milk and salt, and the mixer's wire whip has a history of

breaking. In addition, metal could be present in the incoming biscuits and cheese from the supplier's slicing process.

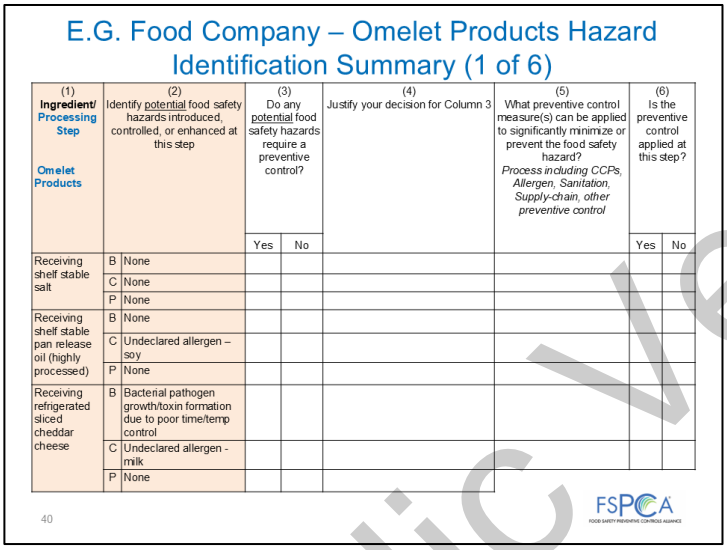
Glass (when product is packed in glass) (Section 3.5)

E.G. Food Company Example: Not applicable since omelet products are not packaged in glass.

Hard plastic (Section 3.5)

E.G. Food Company Example: Not applicable since hard plastic is not used in E.G. Food Company's facility.

Slide 40: E.G. Food Company – Omelet Products Hazard Identification Summary (1 of 6)



The ingredient receiving step is assessed to identify hazards that may be potentially introduced not from the ingredient but from the activity of receiving itself. The ingredient-related hazard identification (hazard associated with the ingredient) was already conducted separately as demonstrated during Slides 29-36. As mentioned earlier, some companies may conduct a separate hazard analysis for all the ingredients. Another common approach is to analyze the ingredient-related hazards while assessing the ingredient receiving step process-related hazards. Either way is acceptable.

Biological Hazards: For the shelf stable ingredients, no biological hazards were identified as known or reasonably foreseeable; however, for the refrigerated sliced cheddar cheese bacterial pathogen growth/toxin formation due to poor time/temperature control was identified as a potential hazard due to the potential temperature abuse at time of receipt.

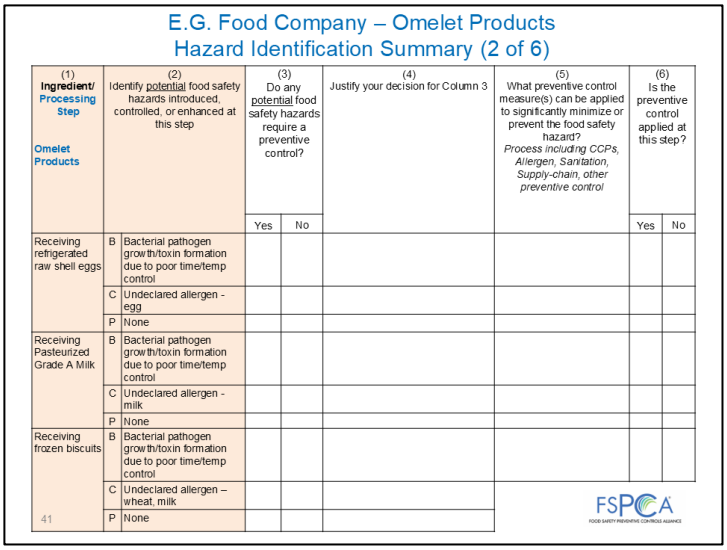
Chemical Hazards: The receiving step for ingredients that contain food allergens is where E.G. Food Company also identifies a potential "undeclared allergen" hazard since this is where the allergenic ingredient is first introduced into the facility. Alternatively, some companies may identify the undeclared allergen (allergenic ingredient) at the ingredient assessment stage (see Slide 36) or at the point of addition

instead of at receipt (e.g., at the mixer, cook step, or assembly where the allergenic ingredient is added). Either way is acceptable as long as the hazard identification and evaluation are conducted.

The shelf stable pan release oil contains soybean oil and soy lecithin with the soy allergen coming from the soy lecithin. The soybean oil used in the pan release oil is highly refined which removes the soy protein rendering the oil non-allergenic. The pan release oil is highly processed (not refined) at temperatures that will not remove the soy protein in the soy lecithin used in the pan release oil; therefore, undeclared soy allergen is identified as a potential chemical hazard. Undeclared milk allergen is identified as a potential chemical hazard in the refrigerated sliced cheddar cheese.

Physical Hazards: Are identified as none for the ingredients receiving steps since these ingredients are received in intact packaging, and therefore, there is no potential for physical hazards to be introduced.

Slide 41: E.G. Food Company – Omelet Products Hazard Identification Summary (2 of 6)



E.G. Food Company – Omelet Products
Hazard Identification Summary (2 of 6)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving refrigerated raw shell eggs	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	Undeclared allergen - egg						
	P	None						
Receiving Pasteurized Grade A Milk	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	Undeclared allergen - milk						
	P	None						
Receiving frozen biscuits	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	Undeclared allergen – wheat, milk						
	P	None						

41

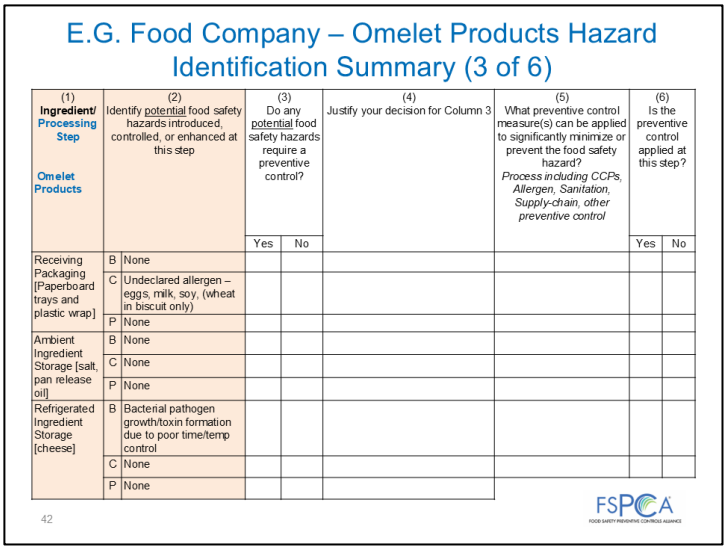
FSPCA

Biological Hazards: For the refrigerated raw shell eggs, pasteurized Grade A milk, and frozen biscuits, bacterial, growth/toxin formation due to poor time/temperature control was identified as a potential due to the potential for temperature abuse at time of receipt.

Chemical Hazards: The receiving step for ingredients that contain food allergens is where E.G. Food Company identifies as potential "undeclared allergen" hazard since this is where the allergenic ingredient is first introduced into the facility.

Physical Hazards: Are identified as none for the ingredients receiving steps since these ingredients are received in intact packaging, and therefore, there is no potential for physical hazards to be introduced.

Slide 42: E.G. Food Company – Omelet Products Hazard Identification Summary (3 of 6)



E.G. Food Company – Omelet Products Hazard Identification Summary (3 of 6)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving Packaging [Paperboard trays and plastic wrap]	B	None						
	C	Undeclared allergen – eggs, milk, soy, (wheat in biscuit only)						
	P	None						
Ambient Ingredient Storage [salt, pan release oil]	B	None						
	C	None						
	P	None						
Refrigerated Ingredient Storage [cheese]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	None						

42

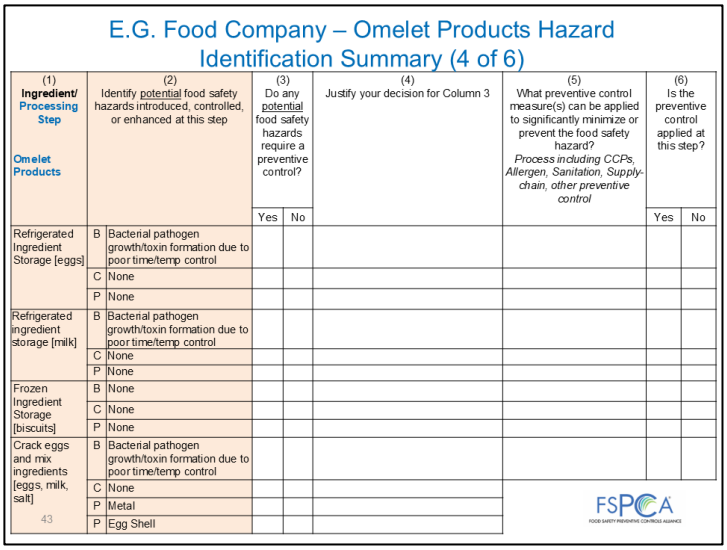
FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

For the receipt of packaging, only chemical hazards, undeclared allergen (eggs, milk, soy, (wheat in biscuit only)), were identified since the packaging for the various omelet products need to list these allergens. Undeclared allergens are a potential hazard if the packaging supplier does not print the labels properly or inadvertently comingles or ships the wrong labels.

For ambient storage of ingredients (salt, pan release oil), no potential hazards were identified.

For the storage of refrigerated ingredients (cheese), only biological hazards were identified namely bacterial pathogen growth/toxin formation due to poor time/temperature control.

Slide 43: E.G. Food Company – Omelet Products Hazard Identification Summary (4 of 6)



E.G. Food Company – Omelet Products Hazard Identification Summary (4 of 6)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Refrigerated Ingredient Storage [eggs]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	None						
Refrigerated ingredient storage [milk]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	None						
Frozen Ingredient Storage [biscuits]	B	None						
	C	None						
	P	None						
Crack eggs and mix ingredients [eggs, milk, salt]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	Metal						
	P	Egg Shell						

43

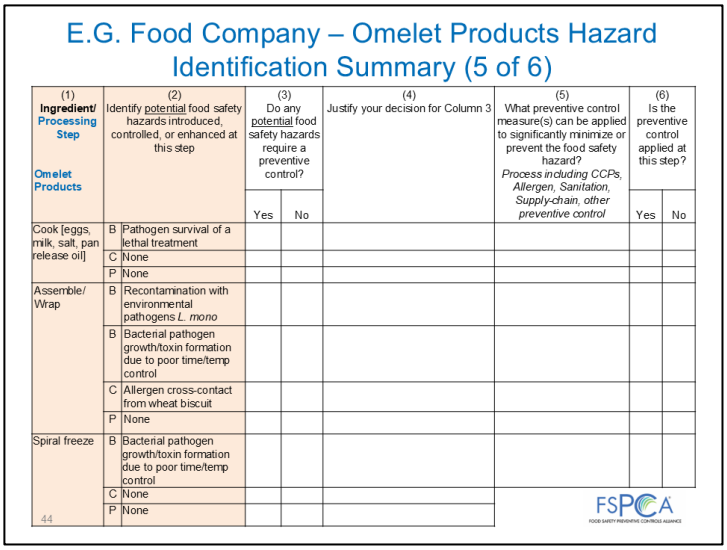
FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

For the storage of refrigerated ingredients (eggs, milk), only biological hazards were identified, namely, bacterial pathogen growth/toxin formation due to poor time/temperature control.

For the frozen storage of biscuits, no potential hazards were identified since the frozen biscuits are intact containers and not exposed to the environment.

For the crack eggs and mix processing step, bacterial pathogen growth/toxin formation due to poor time/temperature control was identified as a potential biological hazard. And for the physical hazards, metal was identified as a potential hazard due to the mixing with a wire whip and egg shell due to the cracking process. Chemical hazards such as allergen cross-contact were not identified as a potential hazard since eggs, milk and salt are the only ingredients used in the mixer.

Slide 44: E.G. Food Company – Omelet Products Hazard Identification Summary (5 of 6)



E.G. Food Company – Omelet Products Hazard Identification Summary (5 of 6)

(1) Ingredient/ Processing Step — Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Cook [eggs, milk, salt, pan release oil]	B	Pathogen survival of a lethal treatment						
	C	None						
	P	None						
Assemble/ Wrap	B	Recontamination with environmental pathogens *L. mono*						
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	Allergen cross-contact from wheat biscuit						
	P	None						
Spiral freeze	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	None						

44

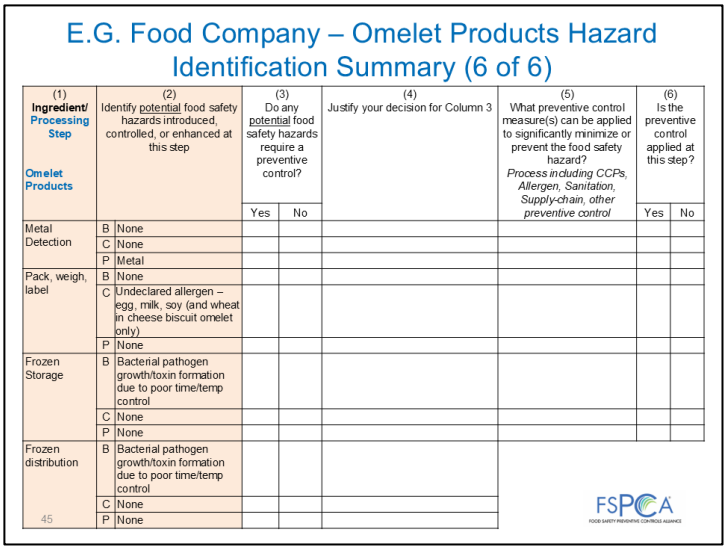
FSPCA

Biological Hazards: At the cooking step, pathogen survival of a lethal treatment was identified as a process-related hazard in the event the omelets are undercooked. No other potential hazards were identified. For the assemble/wrap step, recontamination with environmental pathogens, namely *Listeria monocytogenes* was identified as a potential hazard since the cooked omelets are exposed to the environment prior to packaging. This is not the case during spiral freezing since the omelets are in packaged in trays with plastic overwrap. For both the assemble/wrap and spiral freezer processing steps, bacterial pathogen growth/toxin formation due to poor time/temperature control was identified as a potential biological hazard.

Chemical Hazards: At the assemble/wrap step, allergen cross-contact from the wheat biscuit was identified as a potential hazard for the omelet products that do not contain biscuits because all products are assembled and wrapped on the same table. No chemical hazards (i.e., allergen cross-contact from biscuits), were identified as a potential hazard for the spiral freezing step since the omelets are wrapped in a tray at this point (no exposure to the environment/equipment).

Physical Hazards: No potential physical hazards were identified for the cook, assembly/wrap and spiral freezer steps.

Slide 45: E.G. Food Company – Omelet Products Hazard Identification Summary (6 of 6)



E.G. Food Company – Omelet Products Hazard Identification Summary (6 of 6)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Metal Detection	B	None						
	C	None						
	P	Metal						
Pack, weigh, label	B	None						
	C	Undeclared allergen – egg, milk, soy (and wheat in cheese biscuit omelet only)						
	P	None						
Frozen Storage	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	None						
Frozen distribution	B	Bacterial pathogen growth/toxin formation due to poor time/temp control						
	C	None						
	P	None						

45

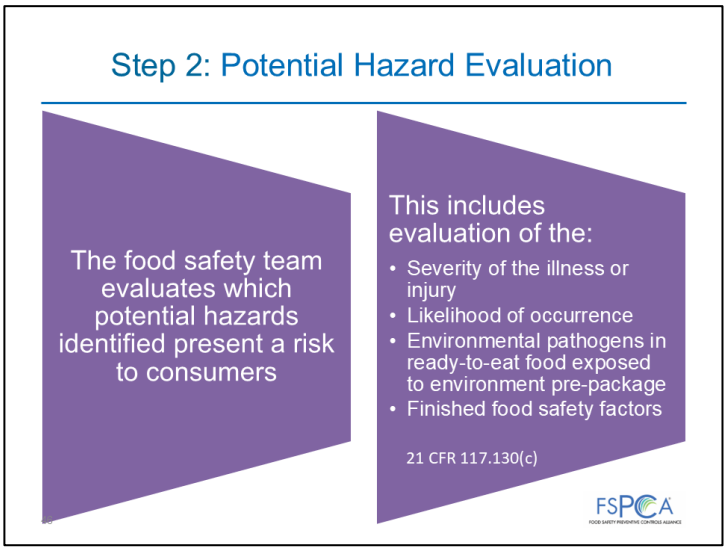
FSPCA

For the metal detection step, metal is identified as a potential hazard because this is where metal originating from ingredients or prior process steps will be controlled.

At the pack, weigh, label step, the undeclared allergens egg, milk, soy (and wheat in cheese biscuit omelets containing the biscuit) will be controlled at this step.

For both the frozen storage and frozen distribution of the assembled omelet products, bacterial pathogen growth/toxin formation due to poor time/temperature control was identified as a potential biological hazard in the event of temperature abuse during storage and distribution.

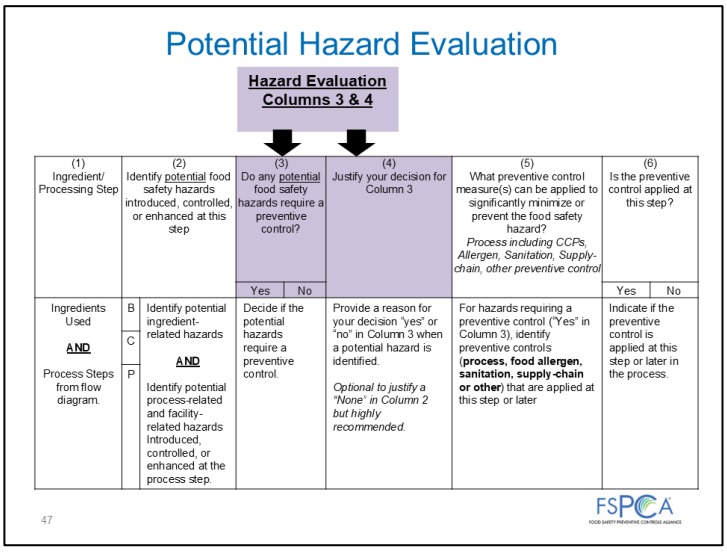
Slide 46: Step 2: Potential Hazard Evaluation



Following identification of all potential hazards, the food safety team needs to evaluate and determine which of the hazards may present risks to consumers. The regulation (21 CFR 117.130(c)) requires the hazard evaluation include:

- an evaluation of the identified potential hazards to assess severity of the illness or injury if the hazard were to occur;
- an evaluation of probability that the hazard will occur in the absence of preventive controls;
- an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure that would significantly minimize the pathogen; and
- consideration of the finished food safety factors including but not limited to formulation of the food, intended or reasonably foreseeable use by the consumer, finished product storage and distribution. See Slide 48 for a full list of factors.

Slide 47: Potential Hazard Evaluation

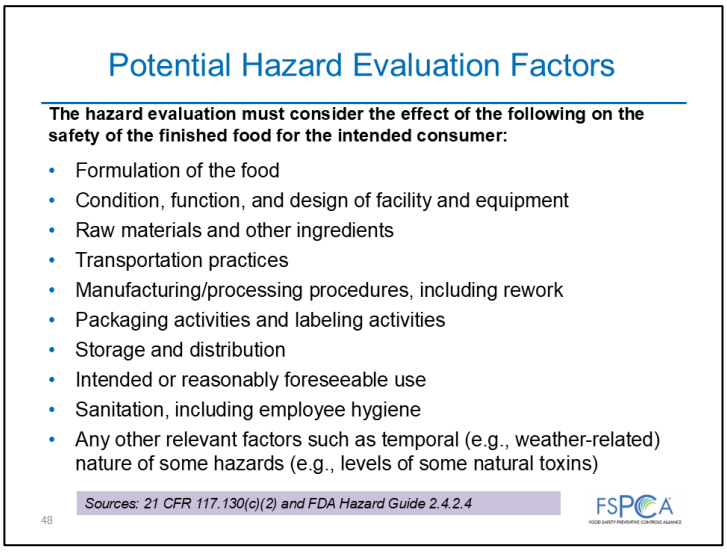


The Food Safety Team will document their hazard evaluation conclusions in Columns 3 and 4.

In Column 3: Record the conclusions of the hazard evaluation (i.e., the determinations of whether each potential food safety hazard listed in Column 2 requires a preventive control (Yes/No)).

In Column 4: Record the reasons that led to the conclusions of the hazard evaluation (i.e., the Yes/No conclusions listed in Column 3). Explaining reasons for a "No" conclusion can be just as important as explaining the reasons for a "Yes" conclusion. Note, it is optional to justify a "none" in Column 2.

Slide 48: Potential Hazard Evaluation Factors



Per the FDA Hazard Guide, Chapter 2, when evaluating hazards, the Food Safety Team must consider the effect of the following on the safety of the finished food for the consumer (21 CFR 117.130(c)(2)):

The formulation of the food: The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food because they may inhibit growth of, or kill, microorganisms of public health significance. This could impact the evaluation at steps during production and storage with respect to the hazard of "pathogen growth." A multicomponent food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or water activity), but when put together there may be an interface where the pH and water activity change (e.g., pies, layered breads). The formulation may contain an ingredient (e.g., a flavoring, coloring, or incidental additive), that is (or contains) an allergen that requires label control and possibly controls to prevent cross-contact.

The condition, function, and design of the facility and equipment: The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling, and conveying equipment), may be more difficult to clean (e.g., because of close fitting components or hollow parts), and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments; in such instances enhanced sanitation controls may be appropriate. Equipment designed such that there is metal-to-metal contact may generate metal fragments; a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs a ready-to-eat product such as fresh soft cheese may have cold, moist conditions that are conducive to the development of a niche where the pathogen *Listeria monocytogenes* can become established and contaminate food-contact surfaces and, eventually, foods; enhanced sanitation controls may be appropriate for such facilities. Facilities with closely spaced equipment

should consider the impact of the close spacing on the potential for allergen cross-contact to be a hazard; targeted food allergen controls may be appropriate.

Raw materials and other ingredients: A food can become contaminated through the use of contaminated food ingredients. Ingredients such as flavorings, colorings, or incidental additives may contain "hidden" allergens. Machinery-harvested produce may be contaminated with physical hazards because the machinery can pick up foreign material from the field.

Transportation practices: The safety of a food can be affected by transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, when a food requires time/temperature control for safety, time/temperature controls would be important during transportation. Distributing a food in bulk without adequate protective packaging makes the product susceptible to contamination during transportation (e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination).

Manufacturing/processing procedures: Hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic sporeforming bacteria such as *Clostridium perfringens* (*C. perfringens*) and *Bacillus cereus* (*B. cereus*) (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of *C. botulinum*, with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria *Staphylococcus aureus* (*S. aureus*) or *B. cereus* in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and *S. aureus* or *B. cereus* is present in the ingredients of the product or is introduced by poor employee hygiene (e.g., *S. aureus*). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives), is used to cut products during manufacturing.

Packaging activities and labeling activities: Preventive controls for glass may be needed for products packed in glass. Preventive controls for *C. botulinum* may be needed when packing certain foods in modified atmosphere packaging. Label controls may be needed to ensure all food allergens are listed on the label of packaged foods that contain allergens.

Storage and distribution: Biological hazards are more likely to require a preventive control during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf stable foods.

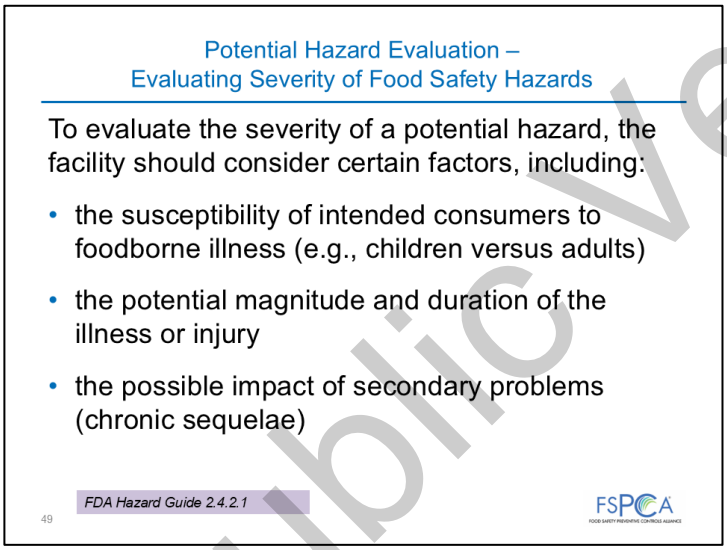
Intended or reasonably foreseeable use: Some foods that are intended to be cooked by the consumer may also have uses that do not include cooking, such as soup mixes used to make dips. Whenever a READY-TO-EAT food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen, hazards such as *Salmonella* spp., *Listeria*

monocytogenes, and *Escherichia coli* O157:H7 (*E. coli* O157:H7) must be considered to determine if they require a preventive control. (See 21 CFR 117.130(c)(1)(ii))

Sanitation, including employee hygiene: Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as *Salmonella* spp., Hepatitis A, and Norovirus.

Any other relevant factors, such as the temporal (e.g., weather-related), nature of some hazards (e.g., levels of some natural toxins): Hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some raw agricultural commodities are more of a problem in some years than in others.

Slide 49: Potential Hazard Evaluation – Evaluating Severity of Food Safety Hazards



Appendix 4: Foodborne Pathogen Supplementary Information provides information on severity of common foodborne pathogens. Consider external assistance if the facility does not have the technical expertise to evaluate the severity of food safety hazards.

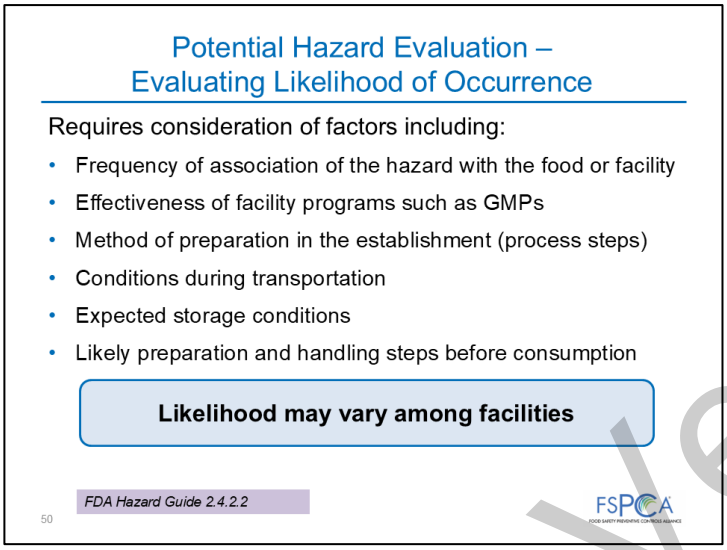
To evaluate the severity of a potential hazard, the Food Safety Team should consider certain factors, including: susceptibility of intended consumers to foodborne illness (e.g., infants, children, and immunocompromised persons may be more susceptible to certain foodborne illnesses); the potential magnitude and duration of the illness or injury (e.g., how long an individual may be sick, and whether hospitalization or death is common); and the possible impact of secondary problems (e.g., chronic sequelae such as kidney damage or reactive arthritis).

Information about vulnerable populations such as infants, children, the elderly, or the immunocompromised is discussed in Chapter 5: Preliminary Steps in Developing a Food Safety Plan. The severity of different hazards is discussed in Chapter 3: Biological Food Safety Hazards, Chapter 4: Chemical, Physical, and Economically Motivated Food

Safety Hazards, and in more detail in Appendix 4: Foodborne Pathogen Supplementary Information.

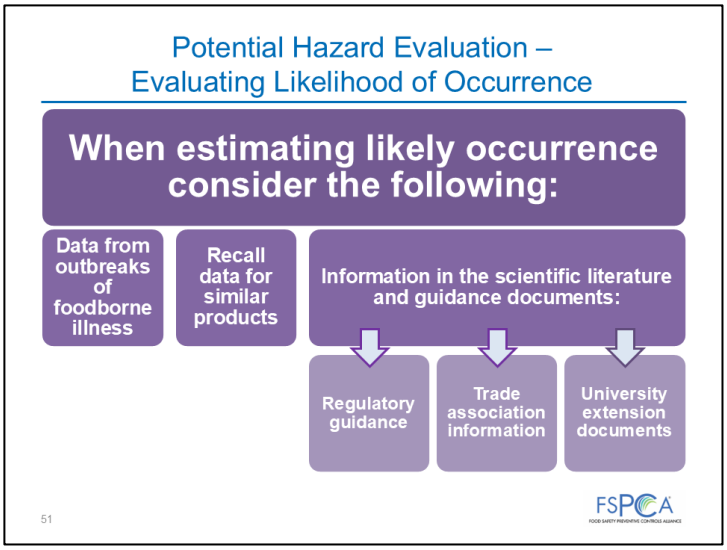
Some facilities may have the expertise necessary to make such evaluations. If a facility's Food Safety Team does not have the expertise to evaluate the severity of a potential hazard, they should consult with outside experts.

Slide 50: Potential Hazard Evaluation – Evaluating Likelihood of Occurrence (1 of 3)



Knowing the food product, ingredients, processes, facility programs such as GMPs, preparation methods, packaging, transportation, distribution, and likely use of the product will be helpful in estimating the likely occurrence of potential hazards. Hazards identified in one operation or facility may not be significant in another operation or facility producing the same or similar products because different equipment and processes may be used, the ingredients and their source may be different, or for other reasons. For example, one facility may package a beverage in glass, and another may package the same product in plastic. The Food Safety Team should consider each operation and facility location individually when estimating the likely occurrence of a food safety hazard.

Slide 51: Potential Hazard Evaluation – Evaluating Likelihood of Occurrence (2 of 3)



FDA has published on their website a list of foodborne illness outbreak investigations by year and a recall data dashboard that can provide useful information when evaluating likelihood of occurrence for a particular hazard in a particular food.

Consider outbreaks in similar products and product recall lists to see if similar products are on the list.

It is important to know how frequently the potential hazard may occur to determine if a preventive control is needed. In addition to food safety reference books, sources of data and information to consider include past foodborne illness outbreaks, recalls from similar products, and information in scientific literature and guidance documents. Guidance documents such as regulatory guidance, trade association information, and university extension documents can be helpful when researching current information on the likely occurrence of hazards in particular foods.

Foodborne Illness Outbreaks: Past outbreaks present a tremendous source of information regarding the hazards that are likely to occur in certain food products. The Food Safety Team should consider lessons learned from these prior events in similar products. The notion that "it has never happened to us" should not be a reason for excluding a hazard if similar products have had an issue with a specific hazard. The FDA provides information for the foods that FDA regulates on their findings related to outbreaks, frequently discussing the factors that contributed to the outbreak at a manufacturing/processing facility. The CDC has a wealth of information on outbreaks that have occurred, not only from processed foods, but also foods prepared in restaurants, retail establishments and other locations. The CDC information covers not only FDA-regulated products, but also products regulated by USDA (e.g., meat and poultry), and those regulated by state and local agencies. Outbreaks that occur in other countries may also be relevant to consider, especially for imported foods.

Food Recalls are a useful source of information on the potential presence of hazards in specific food products. It is important to note that not all recalls are associated with foodborne illness outbreaks. Federal and state government websites post information on food recalls. It may be useful to investigate information on these websites to see if the product the facility is making has been involved in recalls. FDA categorizes recalls as specified in 21 CFR 7.3(m) (see below).

- **Class I** recalls involve products that are likely to cause serious adverse health consequences or death.
- **Class II** recalls involve products that may cause illness or injury, but the probability of serious health consequences is remote; and
- **Class III** recalls involve products that are not likely to cause illness or injury.

When estimating the likely occurrence of a hazard, from recalls and foodborne illness outbreaks the facility should consider information from several sources, such as the following information in the scientific literature and guidance documents:

Food and Drug Administration (FDA):

- Outbreak investigations – reports for FDA regulated foods: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks
- FDA recall data dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm

Centers for Disease Control and Prevention (CDC):

- Foodborne Outbreaks (including links to the List of Selected Multistate Foodborne Outbreak Investigations (see below) and Morbidity and Mortality Weekly Report reports on foodborne outbreaks)
- List of Selected Multistate Foodborne Outbreak Investigations – searchable database for selected
- U.S. outbreaks by year and by pathogen
- Attribution of Foodborne Illness – reports on foods associated with illness

Center for Science in the Public Interest (CSPI):

- Outbreaks and Recalls

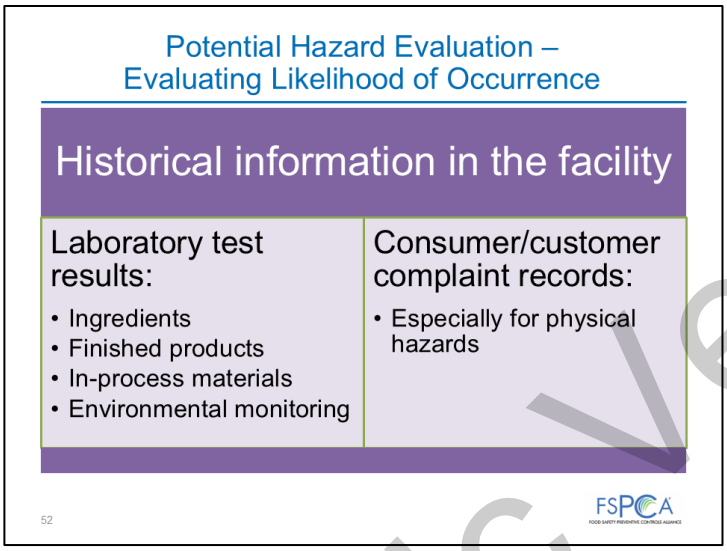
Regulatory Guidance: FDA has published several hazard guides to help manufacturers/processors identify and evaluate food safety hazards in specific food commodities. These include the FDA Hazard Guide; the FDA Fish and Fishery Products Hazards and Controls Guidance (referred to as the Seafood Hazard Guide); and the FDA Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance (referred to as the Juice Hazard Guide). FDA also has numerous guidance documents that contain product-specific food safety information (e.g., on shell eggs, cheese, fruits, vegetables, and milk). These guidance documents, which represent FDA's current thinking on a topic, are available on FDA's website and organized by topic and by year of publication, with recently added guidance documents at the top of the page.

Trade Association Information: Trade associations have also provided guidance targeted to specific types of foods and industry needs. Examples include the American Spice Trade Association's Guide for Hazard Analysis and Risk-Based Preventive Controls for Spices and Seasonings, Consumer Brands Association (former Grocery Manufacturers Association) Control of *Salmonella* in Low Moisture Foods and Industry Handbook for Safe Processing of Nuts, International Dairy Foods Association Allergen

Guidelines and Best Industry Practices, and the International Bottled Water Association Bottled Water Code of Practice. The Innovation Center for U.S. Dairy provides science and research information for dairy products. The International Fresh Produce Association provides food safety information specific to produce. These are just a few of many trade association resources.

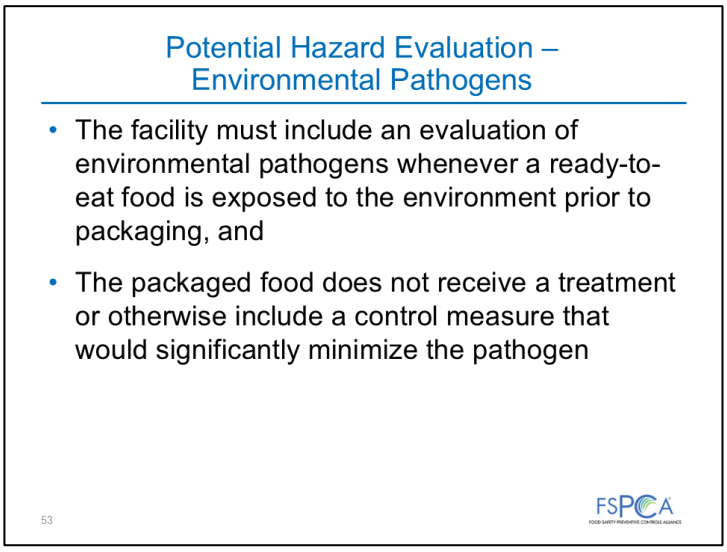
University Extension Documents: many of the university extension offices have resources and outreach centers to provide scientific and technical information to industry, especially small- to medium-sized businesses.

Slide 52: Potential Hazard Evaluation – Evaluating Likelihood of Occurrence (3 of 3)



Facility personnel may already have considerable information on the likelihood of the occurrence of hazards for their food products from various laboratory tests on ingredients, finished products, in-process materials, or environmental monitoring. In addition, they may have consumer complaints about certain hazards, such as physical hazards. This historical facility information will help determine if a hazard at a specific process step is likely to occur.

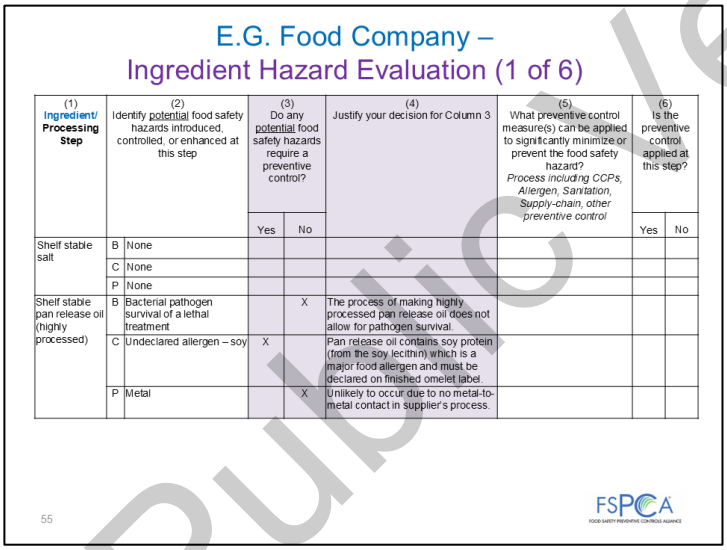
Slide 53: Potential Hazard Evaluation – Environmental Pathogens



If the food facility manufactures a ready-to-eat that is exposed to the environment before packaging, the food could potentially be contaminated with environmental pathogens such as *Listeria monocytogenes* or *Salmonella*. The Preventive Controls for Human Food requirements (21 CFR 117.130(c)(1)(ii)) specify that a facility must consider environmental pathogens in their hazard analysis.

Slide 54: E.G. Food Company Hazard Evaluation Summary – Ingredients – Omelet Products

Slide 55: E.G. Food Company – Ingredient Hazard Evaluation (1 of 6)



(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Shelf stable salt	B	None						
	C	None						
	P	None						
Shelf stable pan release oil (highly processed)	B	Bacterial pathogen survival of a lethal treatment		X	The process of making highly processed pan release oil does not allow for pathogen survival.			
	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label.			
	P	Metal		X	Unlikely to occur due to no metal-to-metal contact in supplier's process.			

The full hazard analysis for the E.G. Food Company's omelets is in Appendix 3: Food Safety Plan Teaching Example. This appendix also includes a description of the process at each step to help visualize how this operation functions.

The hazard evaluation shown here is for the ingredient-related hazards including the supplier process- and facility-related hazards associated with salt and pan release oil.

No potential hazards were identified in Column 2 for the salt. As mentioned before, it is optional to justify a "none" in Column 2.

For the highly processed pan release oil, three potential supplier process- and facility-related identified hazards were evaluated:

- Bacterial pathogen survival of a lethal treatment was deemed not likely to occur because the process of making highly processed pan release oil does not allow for pathogen presence.

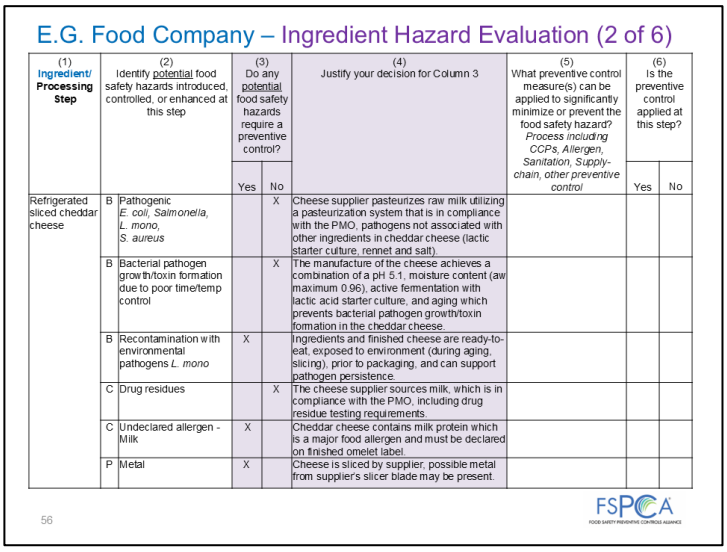
- The undeclared soy allergen in the pan release oil was determined likely to occur since the pan release oil contains soy protein (from soy lecithin) which is a major food allergen and must be declared on finished omelet label.
- Metal was determined not likely to occur due to no metal-to-metal contact in the supplier's process.

The following pan release oil supplier process- and facility-related hazards were determined to be not applicable, and therefore, were not listed in the hazard analysis form:

- Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control is not applicable since oil is shelf stable at ambient temperature.
- Bacterial pathogens – Growth and/or toxin production due to poor formulation control is not applicable as the oil is not formulated for safety.
- Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP) is not applicable because oil is not packaged in ROP.
- Bacterial pathogens – Presence due to ingredients added after process controls is not applicable as no ingredients are added after the highly processed step.
- Bacterial pathogens – Presence, growth, and/or toxin production due to recontamination due to lack of container integrity is not appliable because oil is not packaged in hermetically sealed containers.
- Recontamination with environmental pathogens is not applicable because the pan release oil process is completely enclosed, and oil is not exposed to the environment during processing and packaging.
- Allergen cross-contact is not applicable since the supplier only handles highly refined soy oils with soy lecithin and no other allergens, no possibility for cross-contact.
- Chemical hazards due to mis-formulation (e.g., addition of food/color additives such as sulfites or yellow #5), are not applicable because no ingredients with a maximum use level for safety are used in the pan release oil.
- Process-contamination hazards in certain plant-based foods (e.g. acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils) are not applicable.
- Glass (when product packed in glass) is not applicable because oil is not packaged in glass.
- Hard plastic is not applicable since no hard plastic is used in the supplier's process.

The information for Columns 5 and 6 is discussed later in Chapter 7: Preventive Controls Determination.

Slide 56: E.G. Food Company – Ingredient Hazard Evaluation (2 of 6)



E.G. Food Company – Ingredient Hazard Evaluation (2 of 6)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Refrigerated sliced cheddar cheese	B	Pathogenic *E. coli, Salmonella, L. mono, S. aureus*		X	Cheese supplier pasteurizes raw milk utilizing a pasteurization system that is in compliance with the PMO, pathogens not associated with other ingredients in cheddar cheese (lactic starter culture, rennet and salt).			
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	The manufacture of the cheese achieves a combination of a pH 5.1, moisture content (aw maximum 0.96), active fermentation with lactic acid starter culture, and aging which prevents bacterial pathogen growth/toxin formation in the cheddar cheese.			
	B	Recontamination with environmental pathogens *L. mono*	X		Ingredients and finished cheese are ready-to-eat, exposed to environment (during aging, slicing), prior to packaging, and can support pathogen persistence.			
	C	Drug residues		X	The cheese supplier sources milk, which is in compliance with the PMO, including drug residue testing requirements.			
	C	Undeclared allergen - Milk	X		Cheddar cheese contains milk protein which is a major food allergen and must be declared on finished omelet label.			
	P	Metal	X		Cheese is sliced by supplier, possible metal from supplier's slicer blade may be present.			

56

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

The hazard evaluation shown here is for the ingredient-related (ingredient inherent hazards) and the supplier process- and facility-related hazards for the refrigerated sliced cheddar cheese.

The potential ingredient-related hazards identified from the FDA Hazard Guide were:

- Pathogenic *E. coli*, *Salmonella, L. monocytogenes, S. aureus* which were determined not likely to occur since the cheese supplier pasteurizes raw milk utilizing a pasteurization system that is in compliance with the PMO; pathogens not associated with other ingredients used in cheddar cheese (lactic starter culture, rennet, and salt).
- Drug residues were deemed not likely to occur since the cheese supplier sources milk that is in compliance with the PMO including drug residue testing requirements.

For the cheddar cheese supplier's potential process- and facility-related hazards, the following were identified:

- Bacterial pathogen growth/toxin production due to poor time/temperature control which was deemed unlikely to occur since the manufacture of the cheese achieves a combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture, and aging which prevents bacterial pathogen growth/toxin formation in the cheddar cheese.
- Recontamination with environmental pathogens (*L. mono)* was determined likely since the supplier's ingredients and finished cheese are ready-to-eat, exposed to the environment (e.g. during aging, slicing) prior to packaging, and can support pathogen persistence.
- Undeclared milk allergen was determined likely to occur since the cheddar cheese contains milk protein which is a major food allergen and must be declared on finished omelet label.

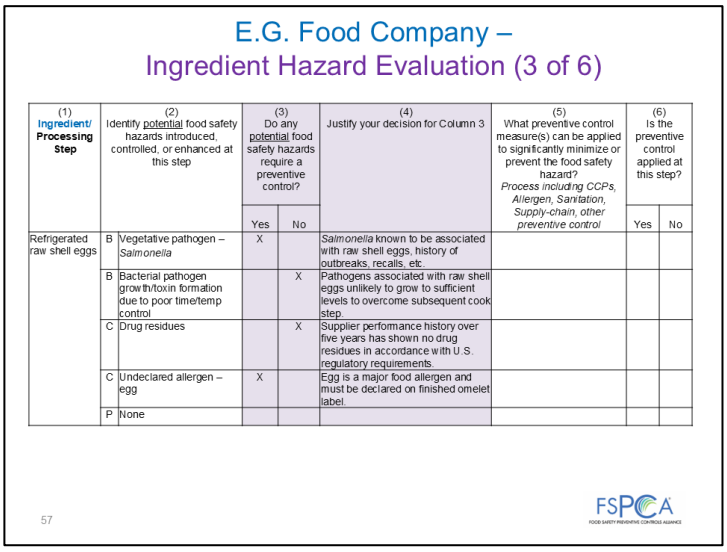
- Metal was determined to be likely since the cheddar cheese is sliced by supplier, possible metal from supplier's slicer blade may be present.

The following cheddar cheese supplier process- and facility-related hazards were determined to be not applicable, and therefore, were not listed in the hazard analysis form:

- Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment since the cheese supplier pasteurizes Grade A milk in compliance with the PMO.
- Bacterial pathogens – Growth and/or toxin production due to poor formulation control is not applicable as the cheese is not formulated for safety.
- Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP) is not appliable because the cheese is not packaged in ROP.
- Bacterial pathogens – Presence due to ingredients added after process controls is not applicable since the ingredients added after the milk pasteurization step (rennet and salt) are unlikely to have bacterial pathogens.
- Bacterial pathogens – Presence, growth, and/or toxin production due to recontamination due to lack of container integrity is not applicable because cheese is not packaged in hermetically sealed containers.
- Allergen cross-contact is not applicable since the cheese supplier only handles milk and no other allergens, no possibility for allergen cross-contact.
- Chemical hazards due to misformulation (e.g., addition of food/color additives such as sulfites or yellow #5), are not applicable because no ingredients with a maximum use level for safety are used in the cheese.
- Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils), are not applicable as cheddar cheese is not a plant-based food.
- Glass (when product packed in glass) is not applicable because cheese is not packaged in glass.
- Hard Plastic is not applicable since hard plastic is not used by supplier.

The information for Columns 5 and 6 is discussed later.

Slide 57: E.G. Food Company – Ingredient Hazard Evaluation (3 of 6)



E.G. Food Company –
Ingredient Hazard Evaluation (3 of 6)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Refrigerated raw shell eggs	B	Vegetative pathogen – *Salmonella*	X		*Salmonella* known to be associated with raw shell eggs, history of outbreaks, recalls, etc.			
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Pathogens associated with raw shell eggs unlikely to grow to sufficient levels to overcome subsequent cook step.			
	C	Drug residues		X	Supplier performance history over five years has shown no drug residues in accordance with U.S. regulatory requirements.			
	C	Undeclared allergen – egg	X		Egg is a major food allergen and must be declared on finished omelet label.			
	P	None						

57

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

For the ingredient refrigerated raw shell eggs, the potential ingredient-related hazards identified from the FDA Hazard Guide were:

- *Salmonella* was determined to be likely to occur based on historical information that *Salmonella* has been known to be associated with raw shell eggs through a history of outbreaks, recalls, etc.
- Drug residues which were deemed not likely to occur due to supplier performance history over five years has shown no drug residues in accordance with U.S. regulatory requirements.

For the raw shell egg potential supplier process- and facility-related hazards, the following were identified:

- Bacterial pathogen growth/toxin production due to poor time/temperature control which was deemed not likely to occur since pathogens that may be associated with raw shell eggs are unlikely to grow to levels that may overcome subsequent cook step.
- Undeclared egg allergen was determined likely to occur since egg is a major food allergen and must be declared on the finished omelet label.

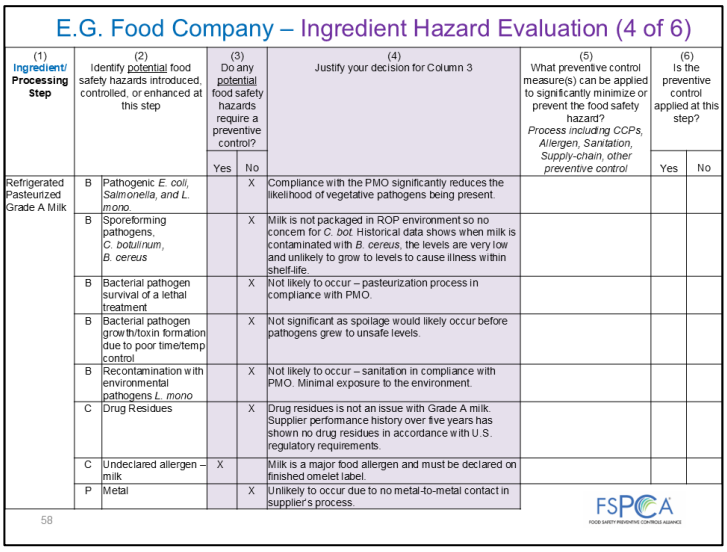
The following raw shell egg supplier process- and facility-related hazards were determined to be not applicable, and therefore, were not listed in the hazard analysis form:

- Bacterial pathogens – Presence, growth, or toxin production due to survival of a lethal treatment is not applicable since the shell eggs are raw.
- Bacterial pathogens – Growth and/or toxin production due to poor formulation control is not applicable as the eggs are not formulated for safety.
- Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP) is not applicable because the eggs are not packaged in ROP.

- Bacterial pathogens – Presence due to ingredients added after process controls is not appliable as no ingredients are added to raw shell eggs.
- Bacterial pathogens – Presence, growth, and/or toxin production due to recontamination due to lack of container integrity is not applicable because eggs are not packaged in hermetically sealed containers.
- Environmental pathogens – presence due to recontamination from the processing environment since environmental pathogens cannot get into intact shell egg.
- Allergen cross-contact is not applicable since the egg supplier only handles eggs and no other allergens, no possibility for allergen cross-contact.
- Chemical hazards due to mis-formulation (e.g., addition of food/color additives such as sulfites or yellow #5), are not applicable because no ingredients with a maximum use level for safety are used in raw shell eggs.
- Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils), are not applicable because shell eggs are not plant-based foods.
- Metal and Hard Plastic are not applicable since neither would get inside an intact shell egg.
- Glass (when product packed in glass) is not applicable because eggs are not packed in glass.

The information for Columns 5 and 6 is discussed later.

Slide 58: E.G. Food Company – Ingredient Hazard Evaluation (4 of 6)



E.G. Food Company – Ingredient Hazard Evaluation (4 of 6)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Refrigerated Pasteurized Grade A Milk	B	Pathogenic *E. coli, Salmonella, and L. mono.*		X	Compliance with the PMO significantly reduces the likelihood of vegetative pathogens being present.			
	B	Sporeforming pathogens, *C. botulinum, B. cereus*		X	Milk is not packaged in ROP environment so no concern for *C. bot.* Historical data shows when milk is contaminated with *B. cereus*, the levels are very low and unlikely to grow to levels to cause illness within shelf-life.			
	B	Bacterial pathogen survival of a lethal treatment		X	Not likely to occur – pasteurization process in compliance with PMO.			
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not significant as spoilage would likely occur before pathogens grew to unsafe levels.			
	B	Recontamination with environmental pathogens *L. mono*		X	Not likely to occur – sanitation in compliance with PMO. Minimal exposure to the environment.			
	C	Drug Residues		X	Drug residues is not an issue with Grade A milk. Supplier performance history over five years has shown no drug residues in accordance with U.S. regulatory requirements.			
	C	Undeclared allergen – milk	X		Milk is a major food allergen and must be declared on finished omelet label.			
	P	Metal		X	Unlikely to occur due to no metal-to-metal contact in supplier's process.			

58

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

The Grade A Pasteurized Milk Ordinance (PMO) is a set of minimum standards and requirements that are established by the Food and Drug Administration (FDA) for regulating the production, processing, and packaging of Grade A milk.

https://www.fda.gov/media/114169/download

For the ingredient, refrigerated pasteurized Grade A milk, the potential ingredient-related hazards identified from the FDA Hazard Guide were:

- Pathogenic *E. coli, Salmonella*, *L. monocytogenes* which were determined not likely since the milk supplier is in compliance with the PMO significantly reduces the likelihood of vegetative pathogens being present.
- Sporeforming pathogens *C. botulinum* and *B. cereus* are not likely to occur since milk is not packaged in Reduced Oxygen Packaging (ROP) environment so no concern for *C. botulinum*; historical data shows when milk is contaminated, with *B. cereus*, the levels are very low and unlikely to grow to levels to cause illness within shelf-life.
- Drug residues which were deemed not likely to occur since drug residues are not an issue with Grade A milk. Supplier performance history over five years has shown no drug residues in accordance with U.S. regulatory requirements.

For the pasteurized milk supplier's potential process- and facility-related hazards, the following were identified:

- Bacterial pathogen growth/toxin production due to poor time/temperature control which was deemed not significant as spoilage would likely occur before pathogens grew to unsafe levels.
- Bacterial pathogen survival of a lethal treatment was deemed not likely to occur since pasteurization process in compliance with PMO.
- Recontamination with environmental pathogens (*L. mono)* was determined not likely to occur since supplier's sanitation controls are in compliance with the PMO.
- Undeclared milk allergen was determined likely to occur since milk is a major food allergen and must be declared on finished omelet label.

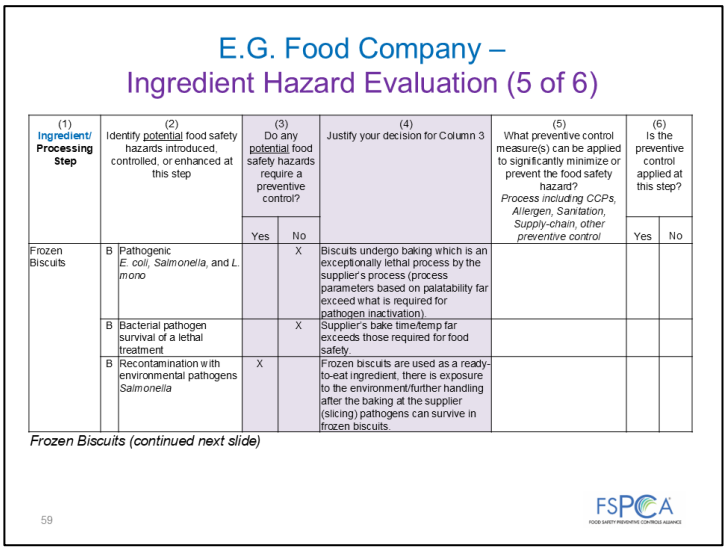
- Metal was determined to be unlikely to occur due to no metal-to-metal contact in supplier's process.

The following pasteurized Grade A milk supplier process- and facility-related hazards were determined to be not applicable, and therefore, were not listed in the hazard analysis form:

- Bacterial pathogens – Growth and/or toxin production due to poor formulation control is not applicable as the milk is not formulated for safety.
- Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP) is not appliable because the milk is not packaged in ROP.
- Bacterial pathogens – Presence due to ingredients added after process controls is not applicable as no ingredients are added to milk post-pasteurization.
- Bacterial pathogens – Presence, growth, and/or toxin production due to recontamination due to lack of container integrity is not appliable because milk is not packaged in hermetically sealed containers.
- Allergen cross-contact is not applicable since the milk supplier only handles milk and no other allergens, no possibility for allergen cross-contact.
- Chemical hazards due to mis-formulation (e.g., addition of food/color additives such as sulfites or yellow #5), are not applicable because no ingredients with a maximum use level for safety are used in the milk.
- Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils), are not applicable because milk is not a plant-based food.
- Hard Plastic is not applicable since it is not used the milk supplier's facility.
- Glass (when product packed in glass) is not applicable because milk is not packaged in glass.

The information for Columns 5 and 6 is discussed later.

Slide 59: E.G. Food Company – Ingredient Hazard Evaluation (5 of 6)



E.G. Food Company –
Ingredient Hazard Evaluation (5 of 6)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Frozen Biscuits	B	Pathogenic *E. coli, Salmonella,* and *L. mono*		X	Biscuits undergo baking which is an exceptionally lethal process by the supplier's process (process parameters based on palatability far exceed what is required for pathogen inactivation).			
	B	Bacterial pathogen survival of a lethal treatment		X	Supplier's bake time/temp far exceeds those required for food safety.			
	B	Recontamination with environmental pathogens *Salmonella*	X		Frozen biscuits are used as a ready-to-eat ingredient, there is exposure to the environment/further handling after the baking at the supplier (slicing) pathogens can survive in frozen biscuits.			

Frozen Biscuits (continued next slide)

59

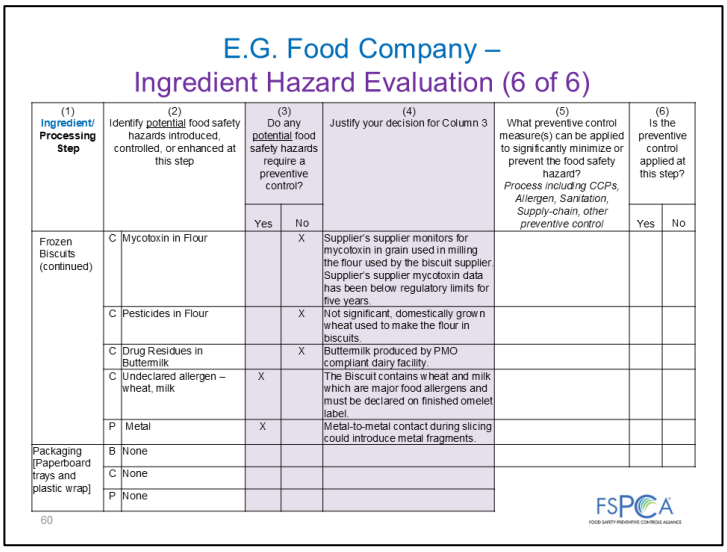
FSPCA

For the ingredient, frozen biscuits, the potential ingredient-related biological hazards identified from the FDA Hazard Guide were:

- Pathogenic *E. coli, Salmonella*, *L. monocytogenes* which were determined not likely since the biscuits undergo baking which is an exceptionally lethal process at the supplier (process parameters based on palatability far exceed what is required for pathogen inactivation).
- For the frozen biscuits supplier's potential process- and facility-related hazards, the following were identified:
    - Bacterial pathogen survival of a lethal treatment was deemed not likely to occur since the supplier's bake time/temp far exceeds those required for food safety.
    - Recontamination with environmental pathogens (*Salmonella)* was determined likely to occur since frozen biscuits are used as a ready-to-eat ingredient, there is exposure to the environment/further handling after baking at the supplier (e.g., slicing), pathogens can survive in frozen biscuits.

The information for Columns 5 and 6 is discussed later.

Slide 60: E.G. Food Company – Ingredient Hazard Evaluation (6 of 6)



E.G. Food Company –
Ingredient Hazard Evaluation (6 of 6)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Frozen Biscuits (continued)	C	Mycotoxin in Flour		X	Supplier's supplier monitors for mycotoxin in grain used in milling the flour used by the biscuit supplier. Supplier's supplier mycotoxin data has been below regulatory limits for five years.			
	C	Pesticides in Flour		X	Not significant, domestically grown wheat used to make the flour in biscuits.			
	C	Drug Residues in Buttermilk		X	Buttermilk produced by PMO compliant dairy facility.			
	C	Undeclared allergen – wheat, milk	X		The Biscuit contains wheat and milk which are major food allergens and must be declared on finished omelet label.			
	P	Metal	X		Metal-to-metal contact during slicing could introduce metal fragments.			
Packaging [Paperboard trays and plastic wrap]	B	None						
	C	None						
	P	None						

60

FSPCA

For the ingredient, frozen biscuits, the potential ingredient-related chemical hazards identified from the FDA Hazard Guide were:

- Mycotoxins in the flour used to make the biscuits was deemed not likely to occur since supplier's supplier monitors for mycotoxins in grain used in milling the flour used by the biscuit supplier. Supplier's supplier mycotoxin data has been below regulatory limits for five years.
- Pesticides in the flour used to make the biscuits was determined not significant since domestically grown wheat used to make the flour in biscuits.
- Drug residues in the buttermilk used to make the biscuits were deemed not significant since the buttermilk used by the biscuit supplier is produced by PMO compliant dairy facility.

For the frozen biscuits supplier's potential process- and facility-related hazards, the following were identified:

- Undeclared wheat allergen was determined likely to occur since the biscuit contains wheat and milk which are major food allergens and must be declared on finished omelet label.
- Metal was determined likely to occur due to metal-to-metal contact during the supplier's slicing which could introduce metal fragments.

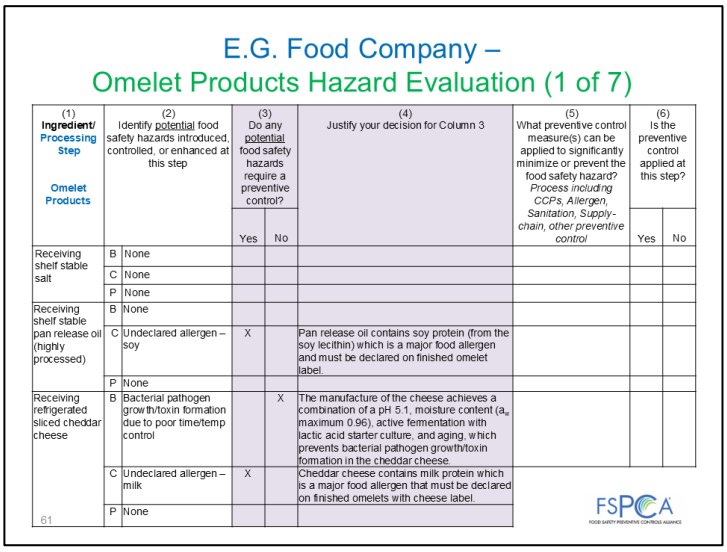
The following frozen biscuit supplier process- and facility-related hazards were determined to be not applicable, and therefore, were not listed in the hazard analysis form:

- Bacterial pathogens – Growth and/or toxin production due to poor time/temperature control is not applicable to frozen biscuits.
- Bacterial pathogens – Growth and/or toxin production due to poor formulation control is not applicable as the biscuits are not formulated for safety.

- Bacterial pathogens – Growth and/or toxin production due to reduced oxygen packaging (ROP) is not applicable because the biscuits are not packaged in ROP.
- Bacterial pathogens – Presence due to ingredients added after process controls is not applicable as no ingredients are added to the biscuits after baking.
- Bacterial pathogens – Presence, growth, and/or toxin production due to recontamination due to lack of container integrity is not applicable because biscuits are not packaged in hermetically sealed containers.
- Allergen cross-contact is not applicable since the biscuit supplier only handles wheat and no other allergens, no possibility for allergen cross-contact.
- Chemical hazards due to mis-formulation (e.g., addition of food/color additives such as sulfites or yellow #5), are not applicable because no ingredients with a maximum use level for safety are used in the biscuits.
- Process-contamination hazards in certain plant-based foods (e.g., acrylamide in certain plant-based foods, and 3-MCPDEs and glycidyl esters in refined oils), are not applicable because the biscuit baking process is unlikely to result in significant acrylamide production.
- Hard Plastic is not applicable since it is not used at the supplier.
- Glass (when product packed in glass) is not applicable because biscuits are not packed in glass.

The information for Columns 5 and 6 is discussed later.

Slide 61: E.G. Food Company – Omelet Products Hazard Evaluation (1 of 7)



E.G. Food Company –
Omelet Products Hazard Evaluation (1 of 7)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving shelf stable salt	B	None						
	C	None						
	P	None						
Receiving shelf stable pan release oil (highly processed)	B	None						
	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label.			
	P	None						
Receiving refrigerated sliced cheddar cheese	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	The manufacture of the cheese achieves a combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture, and aging, which prevents bacterial pathogen growth/toxin formation in the cheddar cheese.			
	C	Undeclared allergen – milk	X		Cheddar cheese contains milk protein which is a major food allergen that must be declared on finished omelets with cheese label.			
	P	None						

61

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

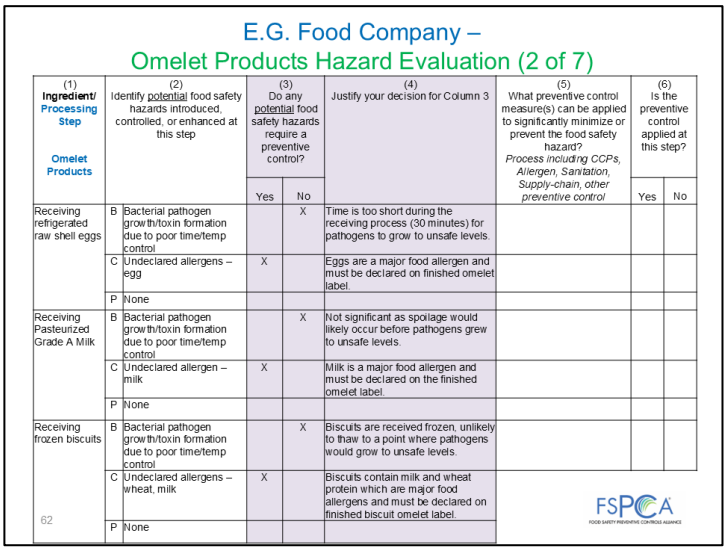
The hazard evaluation shown here is for E.G. Food Company's process steps used to make the omelet products. These hazards are the process- and facility-related hazards associated with E.G. Food Company.

For the shelf stable pan release oil and the sliced, cheddar cheese, the receiving step is where the potential undeclared allergens (soy and milk, respectively), were identified as this is where the allergenic ingredients are introduced into the facility at the point of receipt. As previously mentioned, some companies may identify the undeclared allergen (allergenic ingredient) at the point the ingredient assessment stage (see Slide 36) or at the point of addition instead of at receipt (e.g., at the mixer, cook step, or assembly where the allergenic ingredient is added). Either way is acceptable as long as the hazard identification and evaluation are conducted. The hazard evaluation for both the receipt of the pan release oil and the cheddar cheese deemed the undeclared allergen hazards as likely to occur because the pan release oil and the cheese contain allergens (soy from the soy lecithin and milk, respectively) and must be labeled on the finished omelet products. As noted earlier, the shelf stable pan release oil contains soybean oil and soy lecithin with the soy allergen coming from the soy lecithin. The soybean oil used in the pan release oil is highly refined which removes the soy protein rendering the oil non-allergenic. The pan release oil is highly processed (not refined) at temperatures that will not remove the soy protein in the soy lecithin used in the pan release oil.

For the sliced, refrigerated cheddar cheese receiving step, bacterial pathogen growth/toxin production due to poor time/temperature control was deemed not likely to occur since the manufacture of the cheese achieves a combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture, and aging, which prevents bacterial pathogen growth/toxin formation in the cheddar cheese.

The information for Columns 5 and 6 is discussed later.

Slide 62: E.G. Food Company – Omelet Products Hazard Evaluation (2 of 7)



E.G. Food Company –
Omelet Products Hazard Evaluation (2 of 7)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving refrigerated raw shell eggs	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Time is too short during the receiving process (30 minutes) for pathogens to grow to unsafe levels.			
	C	Undeclared allergens – egg	X		Eggs are a major food allergen and must be declared on finished omelet label.			
	P	None						
Receiving Pasteurized Grade A Milk	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not significant as spoilage would likely occur before pathogens grew to unsafe levels.			
	C	Undeclared allergen – milk	X		Milk is a major food allergen and must be declared on the finished omelet label.			
	P	None						
Receiving frozen biscuits	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Biscuits are received frozen, unlikely to thaw to a point where pathogens would grow to unsafe levels.			
	C	Undeclared allergens – wheat, milk	X		Biscuits contain milk and wheat protein which are major food allergens and must be declared on finished biscuit omelet label.			
	P	None						

62

FSPCA

For the raw shell egg receiving step, bacterial pathogen growth/toxin production due to poor time/temperature control was deemed not likely to occur since the time from receipt to placing shell eggs in the E.G. Food Company's refrigerated storage is too short for pathogens to grow.

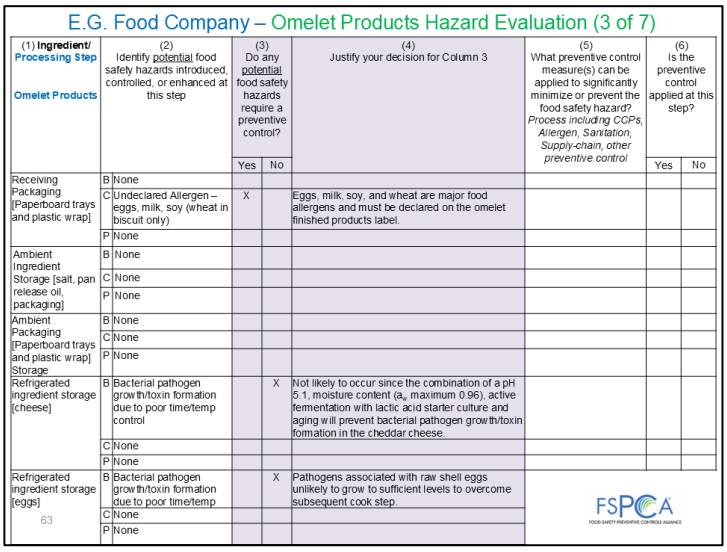
For the pasteurized Grade A milk receiving step, bacterial pathogen growth/toxin production due to poor time/temperature control was evaluated as not significant as spoilage would likely occur before pathogens grew to unsafe levels.

For the frozen biscuits receiving step, bacterial pathogen growth/toxin production due to poor time/temperature control was determined not likely to occur because biscuits are received frozen and are unlikely to thaw to a point where pathogens would grow.

The raw shell egg, pasteurized milk, and frozen biscuits receiving step is where undeclared allergens (egg, milk, and wheat/milk respectively) were identified, as this is where the allergenic ingredients are introduced into the facility at the point of receipt. The hazard evaluation for shell eggs, pasteurized milk and biscuits deemed the potential undeclared allergen hazards as likely to occur because these ingredients contain allergens (egg, milk, and wheat respectively) that must be labeled on the finished omelet products.

The information for Columns 5 and 6 is discussed later.

Slide 63: E.G. Food Company – Omelet Products Hazard Evaluation (3 of 7)



E.G. Food Company – Omelet Products Hazard Evaluation (3 of 7)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving Packaging [Paperboard trays and plastic wrap]	B	None						
	C	Undeclared Allergen – eggs, milk, soy (wheat in biscuit only)	X		Eggs, milk, soy, and wheat are major food allergens and must be declared on the omelet finished products label.			
	P	None						
Ambient Ingredient Storage [salt, pan release oil, packaging]	B	None						
	C	None						
	P	None						
Ambient Packaging [Paperboard trays and plastic wrap] Storage	B	None						
	C	None						
	P	None						
Refrigerated ingredient storage [cheese]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not likely to occur since the combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture and aging will prevent bacterial pathogen growth/toxin formation in the cheddar cheese.			
	C	None						
	P	None						
Refrigerated ingredient storage [eggs]	B	Bacterial pathogen growth/toxin formation due to poor time/temp		X	Pathogens associated with raw shell eggs unlikely to grow to sufficient levels to overcome subsequent cook step.			
	C	None						
	P	None						

63

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

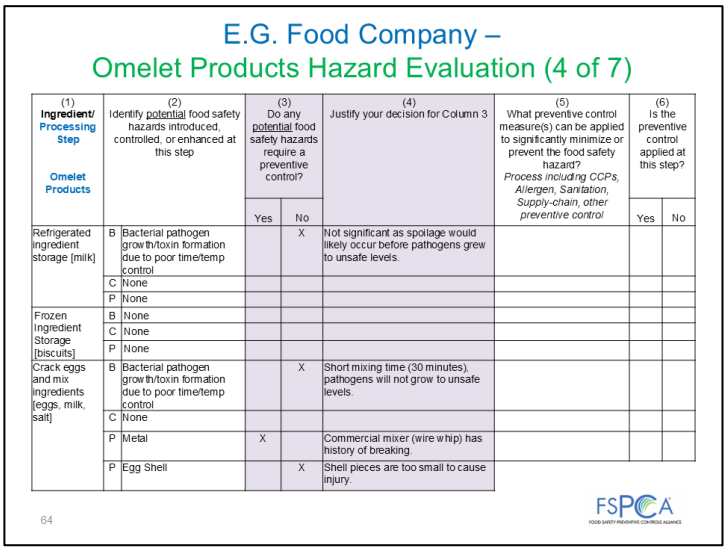
For the packaging receiving step, the potential hazard undeclared allergens (egg, milk, soy, and wheat in the biscuit only) was determined to be likely to occur because eggs, milk, soy, and wheat are recognized allergens and must be labeled on the omelet finished products label.

For the refrigerated ingredient storage step for cheddar cheese, bacterial pathogen growth/toxin production due to poor time/temperature control was evaluated not likely to occur since the combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture and aging will prevent bacterial pathogen growth/toxin formation in the cheddar cheese.

For the refrigerated storage step for raw shell eggs, bacterial pathogen growth/toxin production due to poor time/temperature control was evaluated not likely to occur since pathogens associated with raw shell eggs are unlikely to grow to sufficient levels to overcome the subsequent cook step.

The information for Columns 5 and 6 is discussed later.

Slide 64: E.G. Food Company – Omelet Products Hazard Evaluation (4 of 7)



E.G. Food Company –
Omelet Products Hazard Evaluation (4 of 7)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Refrigerated ingredient storage [milk]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not significant as spoilage would likely occur before pathogens grew to unsafe levels.			
	C	None						
	P	None						
Frozen Ingredient Storage [biscuits]	B	None						
	C	None						
	P	None						
Crack eggs and mix ingredients [eggs, milk, salt]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Short mixing time (30 minutes), pathogens will not grow to unsafe levels.			
	C	None						
	P	Metal	X		Commercial mixer (wire whip) has history of breaking.			
	P	Egg Shell		X	Shell pieces are too small to cause injury.			

64

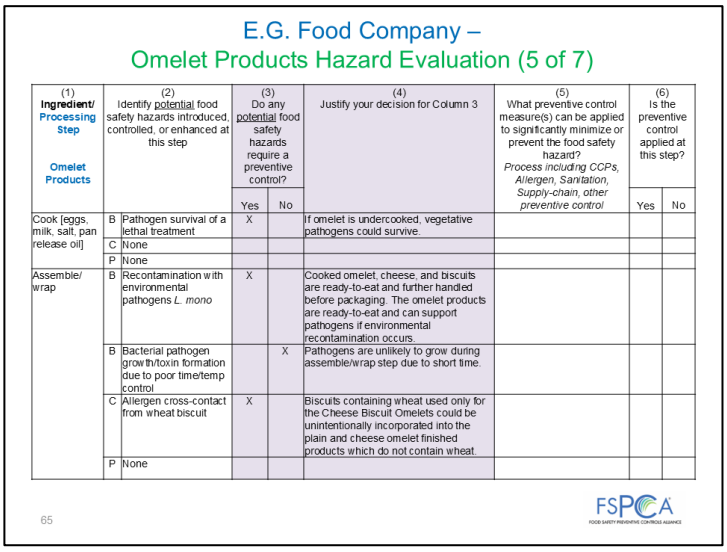
FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

For the pasteurized Grade A milk refrigerated storage step, bacterial pathogen growth/toxin production due to poor time/temperature control was deemed not significant as spoilage would likely occur before pathogens grew to unsafe levels.

For the processing step where eggs are cracked and the ingredients (eggs, milk, salt) are mixed in a commercial mixer, bacterial pathogen growth/toxin production due to poor time/temperature control was evaluated as not likely to occur since the short mixing time (30 minutes) did not provide sufficient time for substantive pathogen growth. Potential metal was determined likely to occur since the commercial mixer (wire whip) has a history of breaking. Egg shells from cracking the eggs at this step were deemed not significant since shell pieces are too small to cause injury.

The information for Columns 5 and 6 is discussed later.

Slide 65: E.G. Food Company – Omelet Products Hazard Evaluation (5 of 7)



E.G. Food Company –
Omelet Products Hazard Evaluation (5 of 7)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Cook [eggs, milk, salt, pan release oil]	B	Pathogen survival of a lethal treatment	X		If omelet is undercooked, vegetative pathogens could survive.			
	C	None						
	P	None						
Assemble/ wrap	B	Recontamination with environmental pathogens *L. mono*	X		Cooked omelet, cheese, and biscuits are ready-to-eat and further handled before packaging. The omelet products are ready-to-eat and can support pathogens if environmental recontamination occurs.			
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Pathogens are unlikely to grow during assemble/wrap step due to short time.			
	C	Allergen cross-contact from wheat biscuit	X		Biscuits containing wheat used only for the Cheese Biscuit Omelets could be unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat.			
	P	None						

65

FSPCA

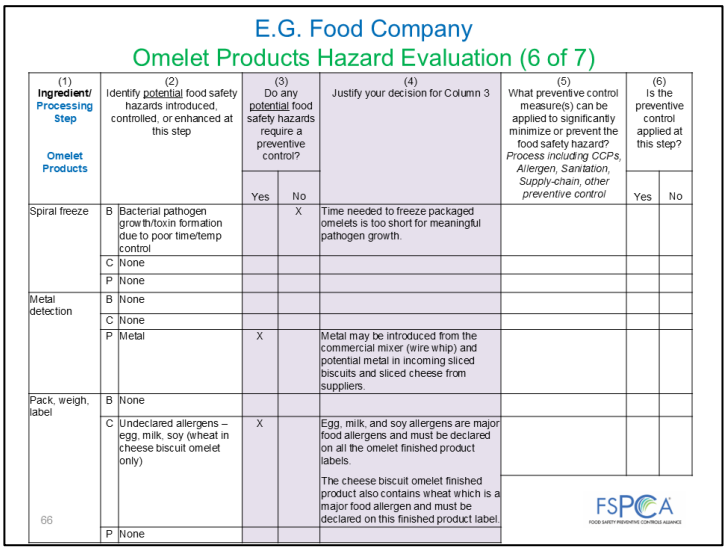
At the cook step, pathogen survival of a lethal treatment was evaluated as likely to occur if the omelets are undercooked, vegetative pathogens associated with the eggs could survive.

For the assemble/wrap step:

- Recontamination with environmental pathogens (*L. mono)* was determined as likely to occur since cooked omelet, cheese, and biscuits are ready-to-eat and further handled before packaging. The omelet products are ready-to-eat and can support pathogens if environmental recontamination occurs.
- Pathogen growth and/or toxin production due to poor time/temperature control was determined to be unlikely since pathogens are unlikely to grow during assemble/wrap step due to short time.
- Allergen cross-contact from the wheat biscuit was evaluated as likely since the biscuits containing wheat, used only for the Cheese Biscuit Omelets, could be unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat.

The information for Columns 5 and 6 is discussed later.

Slide 66: E.G. Food Company – Omelet Products Hazard Evaluation (6 of 7)



E.G. Food Company
Omelet Products Hazard Evaluation (6 of 7)

(1) Ingredient/ Processing Step — Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Spiral freeze	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Time needed to freeze packaged omelets is too short for meaningful pathogen growth.			
	C	None						
	P	None						
Metal detection	B	None						
	C	None						
	P	Metal	X		Metal may be introduced from the commercial mixer (wire whip) and potential metal in incoming sliced biscuits and sliced cheese from suppliers.			
Pack, weigh, label	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit omelet only)	X		Egg, milk, and soy allergens are major food allergens and must be declared on all the omelet finished product labels. The cheese biscuit omelet finished product also contains wheat which is a major food allergen and must be declared on this finished product label.			
	P	None						

66

FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

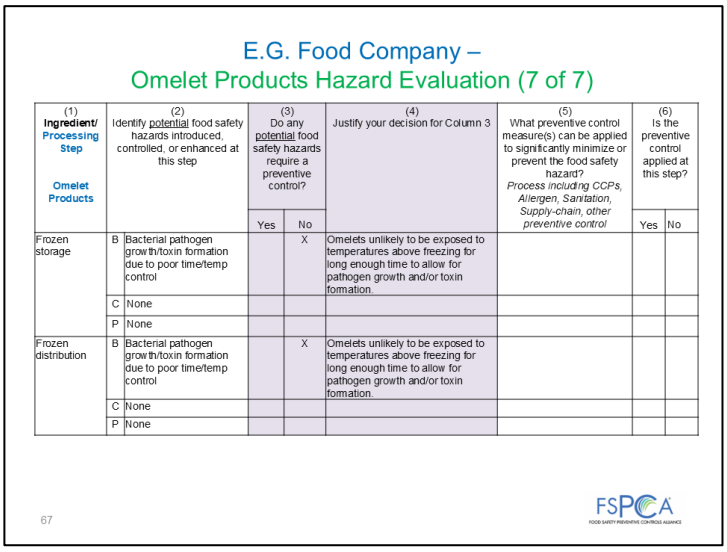
For the spiral freezer process step, bacterial pathogen growth/toxin formation due to poor time/temperature control was deemed not requiring a preventive control because time needed to freeze omelets is too short for meaningful pathogen growth.

Metal was deemed likely to occur because the wire whip has a history of breaking and from the incoming sliced biscuits and sliced cheddar cheese due to the suppliers' slicing operation.

At the pack, weigh, and label step, undeclared allergens (egg, milk, soy, and wheat in cheese biscuit omelet only) are likely to occur at this step if the appropriate finished product label is not applied. Egg, milk, and soy are major food allergens and must be labeled on all the omelet finished products labels. The Cheese Biscuit Omelet finished product also contains wheat which is a major food allergen and must be labeled on this finished product label.

The information for Columns 5 and 6 is discussed later.

Slide 67: E.G. Food Company – Omelet Products Hazard Evaluation (7 of 7)



E.G. Food Company –
Omelet Products Hazard Evaluation (7 of 7)

(1) Ingredient/ Processing Step Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Frozen storage	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Omelets unlikely to be exposed to temperatures above freezing for long enough time to allow for pathogen growth and/or toxin formation.			
	C	None						
	P	None						
Frozen distribution	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Omelets unlikely to be exposed to temperatures above freezing for long enough time to allow for pathogen growth and/or toxin formation.			
	C	None						
	P	None						

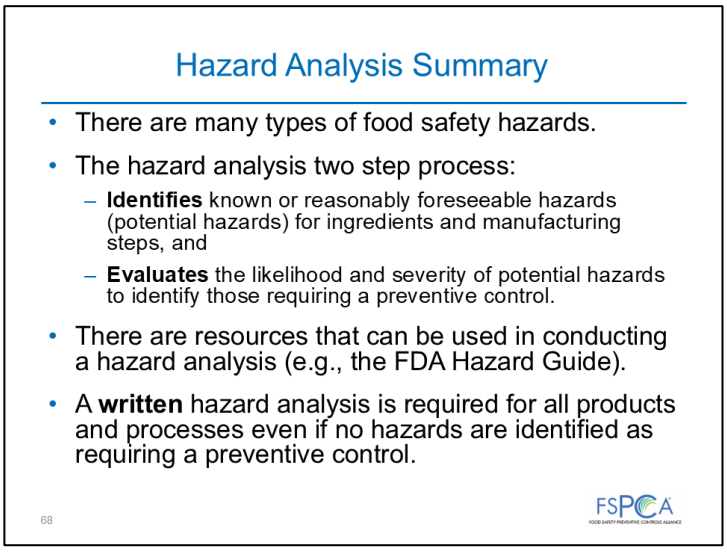
67

FSPCA

For the frozen storage and distribution steps, bacterial pathogen growth/toxin formation due to poor time/temperature control was not evaluated as significant since omelets are unlikely to be exposed to temperatures above freezing for long enough time to allow for pathogen growth and/or toxin formation.

The information for Columns 5 and 6 is discussed later.

Slide 68: Hazard Analysis Summary



There are many types of food safety hazards. Hazards are biological, chemical, or physical agents that have the potential to cause illness or injury.

The hazard analysis two-step process first identifies hazards that are known to be or have the potential to be associated with the facility or food it makes. These potential hazards are then evaluated to assess likelihood and severity to determine, based on risk, those hazards that require a preventive control.

There are numerous resources that can be utilized to conduct a hazard analysis including company specific information such as testing results, consumer complaints, and supplier performance. Other resources include technical experts such as trade associations, U.S. and International government agencies, university extension groups, and the FSPCA Technical Assistance Network. Publications such as FDA guidance documents and trade association guidance can prove to be very valuable to identify and evaluate hazards.

A written hazard analysis is required even when there are no hazards identified as requiring a preventive control. Engaging technical experts may be useful for the hazard analysis to ensure that the hazards requiring a preventive control, and appropriate preventive controls are identified.

Slide 69: Knowledge Check 1

Participants do NOT have this slide.

Slide 70: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Appendix 1: https://www.fda.gov/media/99581/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 2: https://www.fda.gov/media/99554/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 3: https://www.fda.gov/media/99558/download

Fish and Fishery Products Hazards and Controls Guidance https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls

FDA Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-juice-hazard-analysis-critical-control-point-hazards-and-controls-guidance-first

Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food#repo

FDA Information on FSMA: https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma

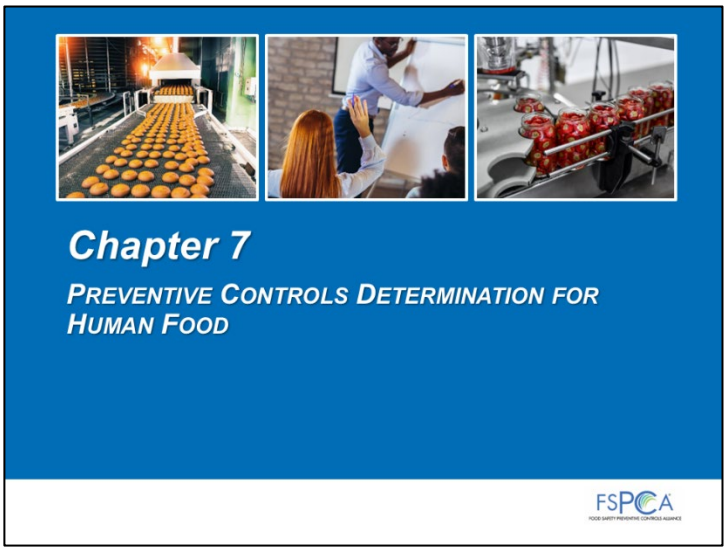
FDA Outbreak Investigations – reports for FDA regulated foods: https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

FDA Recall Data Dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm

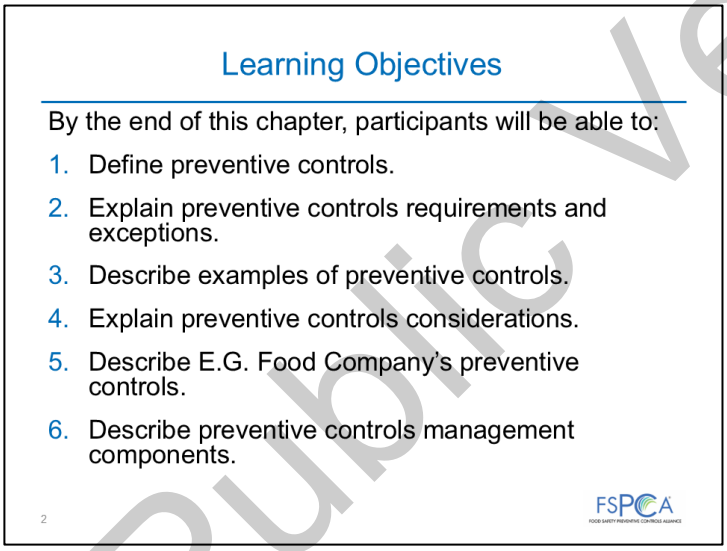
FDA's Bad Bug Book: https://www.fda.gov/food/foodborne-pathogens/bad-bug-book-second-edition

FSPCA Form 0231 – FDA Hazard Guide Appendix 1: Common Process-Related and Facility-Related Hazards: https://www.fspca.net/_files/ugd/38787b_0ff00187a3744334afefbaeb5cf45f4e.pdf

Slide 1: Chapter 7: Preventive Controls Determination For Human Food



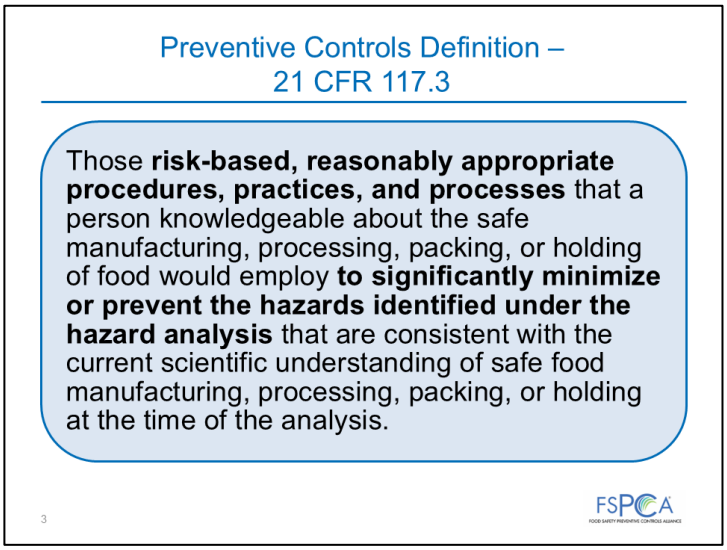
Slide 2: Learning Objectives



Once hazards requiring a preventive control (significant hazards) are determined, preventive controls can be identified to help ensure the safety of the product. Keep in mind that while many different types of controls may be applied when processing a food, "preventive controls" are risk-based and focus on the significant hazards that present the greatest food safety risk to consumers. An overview of preventive controls is the focus of chapter 7.

This slide describes the objectives of this chapter including preventive controls definitions, requirements/exceptions, examples, considerations, E.G. Food Company's preventive controls, and management components.

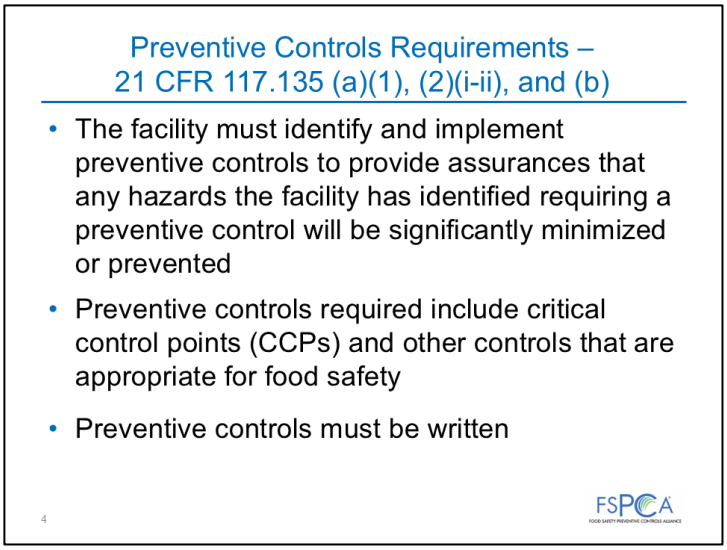
Slide 3: Preventive Controls Definition – 21 CFR 117.3



Hazards evaluated and determined to be significant, based on a hazard analysis for their severity and likelihood of occurrence, will require a preventive control and must be addressed in the Food Safety Plan.

The term "preventive controls" is defined in the Preventive Controls for Human Food regulation 21 CFR 117.3, as indicated above. Note that the determination of a preventive control is risk-based, must be reasonably appropriate and "consistent with the current scientific understanding." Keep in mind that preventive controls are subject to preventive control management components (i.e., monitoring, corrective actions and corrections, and verification) as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system.

Slide 4: Preventive Controls Requirements – 21 CFR 117.135 (a)(1), (2)(i-ii), and (b)



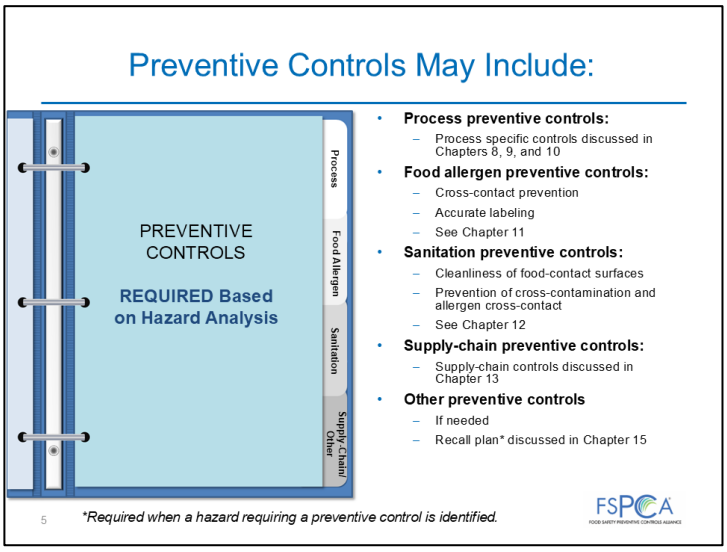
To set the stage and to lay out what is required, this is language directly from the regulation—
21 CFR 117.135(a)(1), (2)(i-ii), and (b) – Preventive controls.

The Food Safety Team "must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the Federal Food, Drug and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act."

Preventive controls include: (1) Controls at critical control points (CCPs), if there are any CCPs; and (2) controls, other than those at CCPs, that are also appropriate for food safety (See 21 CFR 117.135(a)(2)).

The Preventive Controls for Human Food regulation requirements specify that the preventive controls must be written. (See 21 CFR 117.135(b)).

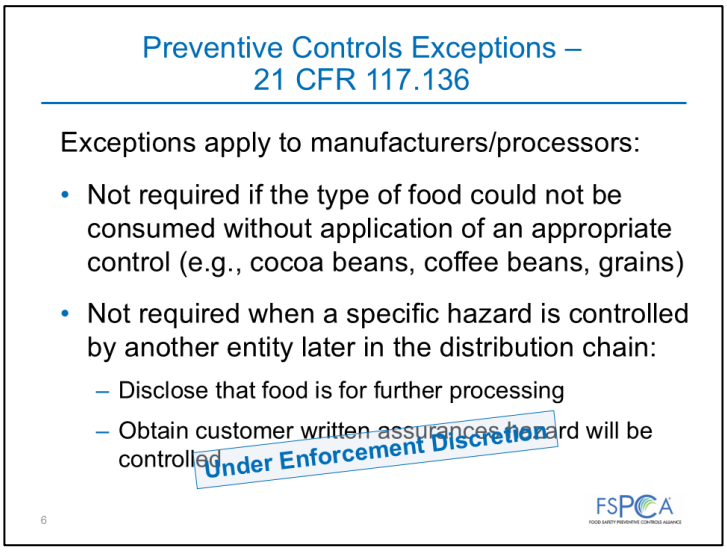
Slide 5: Preventive Controls May Include:



The regulation requirements also specify that preventive controls must include, as appropriate to the facility and the food: (1) Process controls; (2) Food allergen controls; (3) Sanitation controls; (4) Supply-chain controls; (5) Recall plan; and (6) Other controls. (See 21 CFR 117.135(c)).

Process preventive controls are discussed in Chapters 8, 9 and 10; food allergen preventive controls are covered in Chapter 11; sanitation preventive controls are discussed in Chapter 12; supply-chain preventive controls are discussed in Chapter 13; and recall plan is discussed in Chapter 15. In some cases, there may be other controls used by a facility as part of their food safety system, such as transportation controls, which would also be included here.

Slide 6: Preventive Controls Exceptions – 21 CFR 117.136



Preventive controls are not needed when the facility determines and documents that the type of food could not be consumed without processing that would control the hazard (e.g., grains such as raw white rice or steel cut oats that require a cook step before consumption that would control vegetative pathogens).

This slide also shows direct language from the regulation, 21 CFR 117.136(a)(1-4), illustrating the circumstances when a manufacturer/processor is not required to implement a preventive control:

1) A preventive control is not required if the type of food cannot be consumed without the application of an appropriate control (21 CFR 117.136(a)(1)). For example, a manufacturer/processor of raw white rice or steel cut oats could determine that the product will not be consumed without a cooking process that would adequately control vegetative pathogens that may be associated with the rice or oats. Other examples include raw agricultural commodities such as cocoa beans, coffee beans, grains which are cited in 21 CFR 117.136(a)(1).

2) Another circumstance is when the manufacturer/processor relies on their customer (commercial entity, not consumer) to control the identified hazard. For example, a manufacturer of untreated ground black pepper relies on its commercial customer to sterilize the black pepper, which the customer sells as a ready-to-eat product direct to consumers. The manufacturer/processor of the untreated black pepper is not required to implement a preventive control for the hazard of pathogens associated with the black pepper if they comply with the disclosure requirements in 21 CFR 117.136(a)(2-4). The disclosure requirements require the manufacturer/processor to disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]". The disclosure requirement is in effect and enforceable by FDA. The customer written assurance, however, is under enforcement discretion (see definition of enforcement discretion in Appendix 8: Definitions). Note that this could change over time as the FDA adjusts its thinking, so it is particularly important that the Preventive Controls Qualified Individual keeps well-informed of any potential regulatory developments.

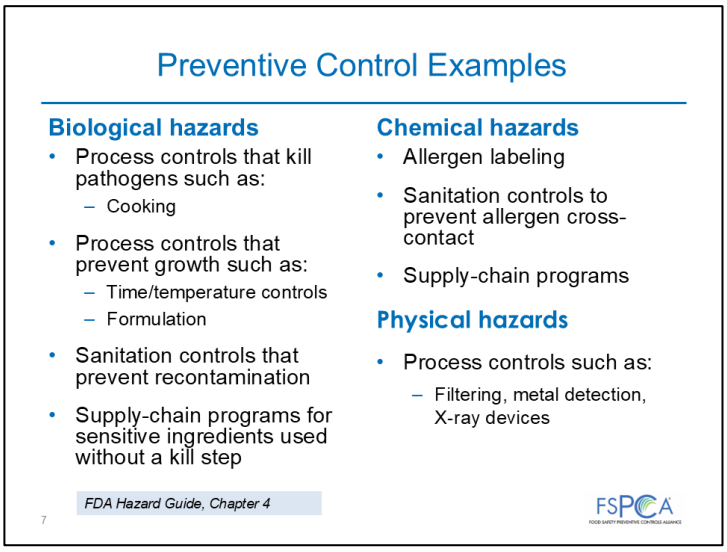
During the enforcement discretion period, the agency does not intend to enforce these provisions as they currently apply to certain entities or activities. In general, the FDA exercises enforcement discretion to allow time to consider changes or other

approaches to address concerns regarding the application of these provisions to certain activities or entities.

FDA issued guidance describing enforcement discretion for customer written assurances:

- FDA intends to initiate a rulemaking that takes into consideration the complex supply-chain relationships and resource requirements.
- To provide sufficient time for FDA to pursue that rulemaking, they are exercising enforcement discretion with regard to the written assurance requirements of 21 CFR Part 117, until completion of that rulemaking process.
- In the meantime, entities with disclosure duties under 21 CFR Part 117, are still required to make necessary disclosures.

Slide 7: Preventive Control Examples



The term "sensitive ingredient," is a term used by industry to refer to an ingredient with a history of association with a pathogen when controls are not in place (FSPCA).

Some examples of preventive controls for biological, chemical (including radiological) and physical food safety hazards are listed in the slide above.

For biological hazards, common control measures include those that 1) significantly minimize or eliminate the pathogen utilizing a lethality process control such as thermal processing, high pressure processing, irradiation; and 2) prevent the germination of spores and/or growth of microbial vegetative cells such as time/temperature process controls (refrigeration, freezing) or through product formulation process controls such as such as water activity, acidification, preservation. Sanitation preventive controls may also be relevant to prevent recontamination of ready-to-eat products that are exposed to the environment before packaging. Supply-chain programs may be relevant, especially if sensitive ingredients are used in ready-to-eat applications and involve verification of the supplier's controls used to control hazards in raw materials or other ingredients before receipt by a manufacturer/processor.

Preventive controls for chemical hazards include:

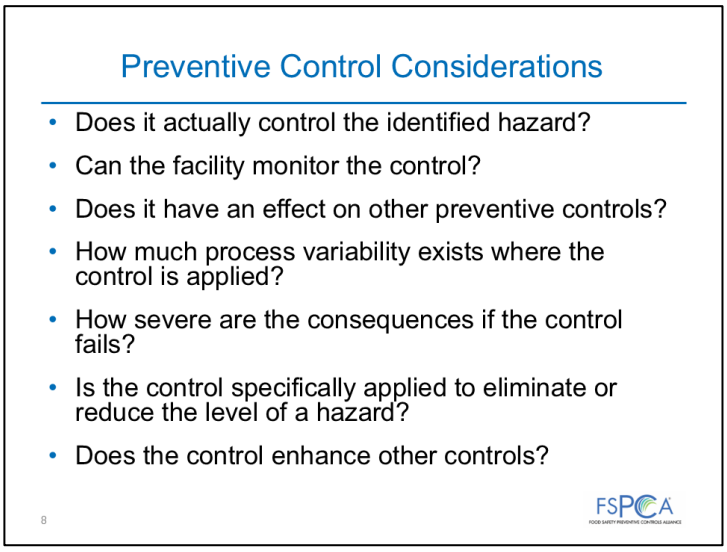
- Allergen controls for undeclared allergen hazards
- Sanitation controls for allergen cross-contact
- Supply-chain programs that include testing for chemical hazards such as mycotoxins and pesticides.

Physical hazards can be controlled by process controls, such as using equipment for straining or aspirating, mechanical separation, metal detection, or x-ray or other detection methods.

For more examples and information about preventive controls, see the FDA Hazard Guide, Chapter 4: Preventive Controls.

Preventive controls for hazards introduced because of economically motivated adulteration may require a supply-chain program or some of the methods above, depending on the specific hazard.

Slide 8: Preventive Control Considerations



The Food Safety Team must consider many factors when identifying preventive controls for the food safety hazards requiring them. In Chapter 2 of the FDA Hazard Guide, FDA describes information related to the selection of preventive controls that the Food Safety Team should consider:

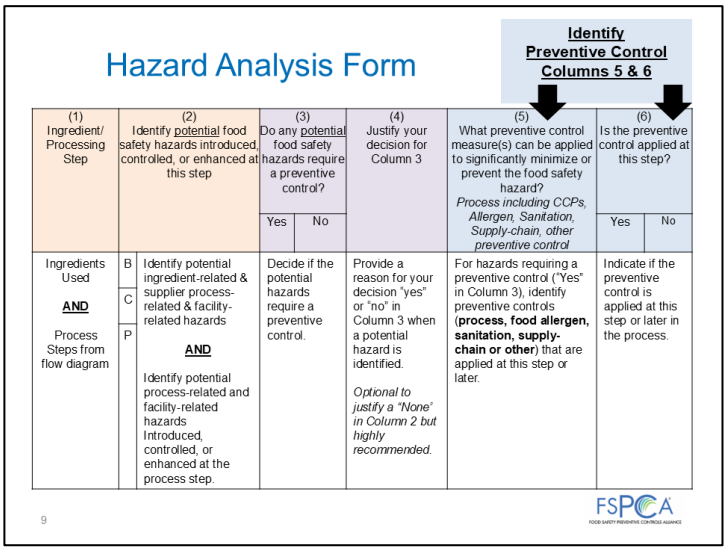
- The effect of the control on identified potential food safety hazards (e.g., Does the preventive control significantly minimize or prevent the potential food safety hazards identified? Is the preventive control hazard-specific or does it control more than one hazard? Does the control effectiveness depend upon other controls? Can the preventive control be validated and verified?)
- The feasibility of monitoring those controls (e.g., Are the critical limits (minimum or maximum values) and, if appropriate, operating limits, for the preventive control measurable and practical? Can facility employees obtain the results of monitoring quickly (i.e., real-time) to determine if the process is in control? Are employees monitoring a batch or continuous process? Is there a mechanism for monitoring continuously or are employees doing spot checks? Can the parameters be monitored in-line, or must the product be sampled? Will the monitored parameters be indirectly linked to the critical limit (i.e., belt speed or pump flow rate for time of process)? Who will perform the monitoring or checks and what are the required qualifications? How is the monitoring verified?)
- The location of the control with respect to other processing control measures (e.g., Is the application of the control measure at the last point in the process to ensure control of the targeted potential food safety hazard? Will the failure of an upstream control result in failure of downstream controls (i.e., acidification failure impacting thermal process efficacy for an acidified food)? Are monitoring activities appropriate to ensure control at this step?)
- Corrective actions that will be needed in the event of a failure of a control measure or a significant processing variability (e.g., Can the process control and critical parameter be brought quickly back into control? How will employees

determine if the control measure is once again under control? Can the implicated product be identified, and its safety evaluated? Can the cause of the loss of control be identified and corrected? What actions would be needed to reduce the likelihood of the failure to recur? Can the product be reprocessed? What actions would be necessary to prevent unsafe product from entering commerce? Can product be diverted to animal food? Does the product need to be destroyed?)

- The severity of the consequences in case of a failure of a control measure (e.g., Is it reasonably likely that unsafe food would be produced as a result of the control measure failure? Is the hazard that could occur reasonably likely to cause serious adverse health consequences or death?)
- Whether the control measure is applied to eliminate or significantly reduce the level of the hazard (e.g., Will the control measure eliminate the hazard, or is the control measure only able to minimize the hazard?)
- Synergistic effects between control measures (e.g., Consider whether one control measure can enhance the efficacy of another control measure. For example, formulation process controls may combine the use of preservatives, acidification, and water activity at levels that individually will not control pathogen growth, but they work together to do so.)

The Food Safety Team uses the written hazard analysis to design the approaches needed to control the hazards. The more thorough the hazard analysis, the more targeted the controls will be to ensure hazards are significantly minimized or prevented, and the more effective the food safety program will be in preventing illness or injury to consumers.

Slide 9: Hazard Analysis Form

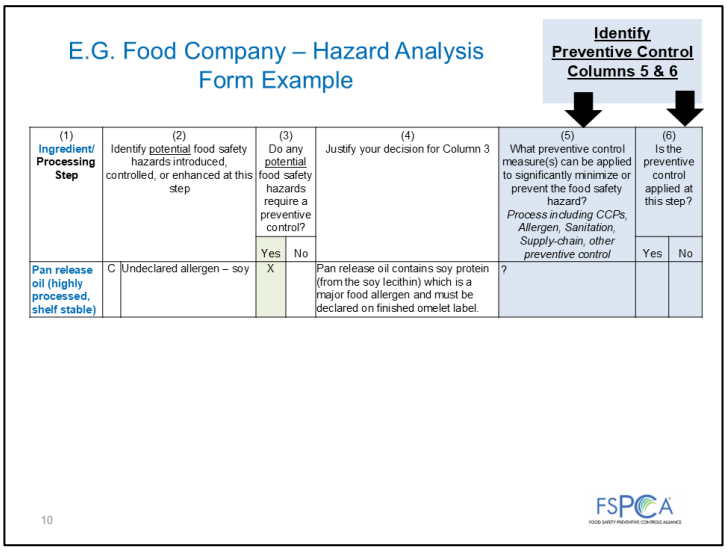


At the completion of the hazard analysis, the Food Safety Team documents the results of the hazard analysis process. The slide above provides the model form with the items to be addressed. Other formats may be used, as long as they clearly identify the potential hazards, evaluate the likelihood and severity of the risk, and identify preventive control measure(s) that are used for all hazards that are reasonably likely to cause illness or injury in the absence of a preventive control.

Column 5: is where the Food Safety Team will identify preventive controls that will significantly minimize or prevent the identified food safety hazard (i.e., a "Yes" in Column 3). As illustrated in the shaded Column 5, hazards requiring a preventive control must be managed through use of process preventive controls, allergen preventive controls, sanitation preventive controls, supply-chain preventive controls, or other preventive controls as appropriate for the food and facility.

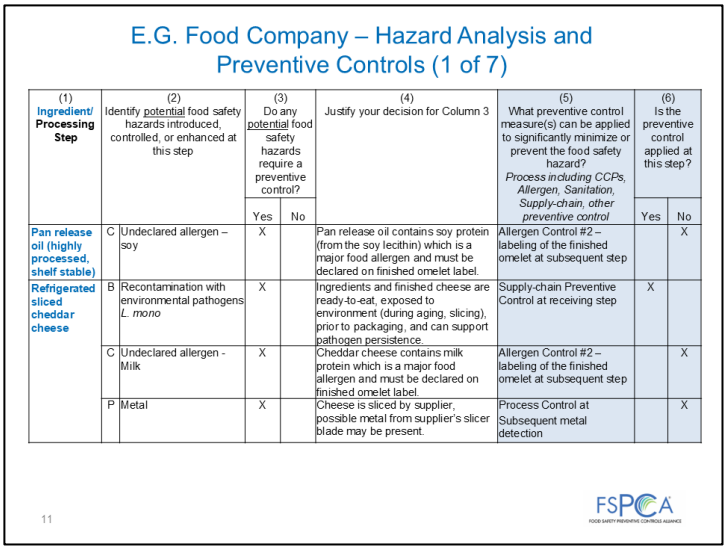
Column 6: because the worksheet breaks the production process into multiple steps, and the preventive control may be applied at a step in the process other than the step where the hazard was listed, the Food Safety Team would specify whether the preventive control will be applied at this particular step (Yes/No). It is important to note that identifying a hazard at a processing step as one that requires a preventive control does not mean that the hazard must be controlled at that processing step.

Slide 10: E.G. Food Company – Hazard Analysis Form Example



As illustrated in this slide, the Food Safety Team will only identify preventive controls if "yes" is marked in Column 3.

Slide 11: E.G. Food Company – Hazard Analysis and Preventive Controls (1 of 7)



E.G. Food Company – Hazard Analysis and Preventive Controls (1 of 7)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Pan release oil (highly processed, shelf stable)	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Refrigerated sliced cheddar cheese	B	Recontamination with environmental pathogens *L. mono*	X		Ingredients and finished cheese are ready-to-eat, exposed to environment (during aging, slicing), prior to packaging, and can support pathogen persistence.	Supply-chain Preventive Control at receiving step	X	
	C	Undeclared allergen - Milk	X		Cheddar cheese contains milk protein which is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	Metal	X		Cheese is sliced by supplier, possible metal from supplier's slicer blade may be present.	Process Control at Subsequent metal detection		X

11

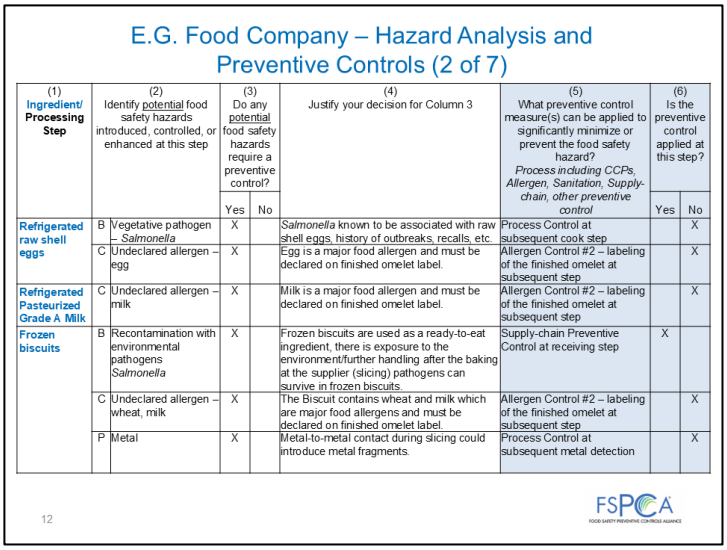
FSPCA

For the pan release oil and the sliced cheddar cheese, the hazard analysis identified undeclared allergens (soy in the oil and milk in the cheese) as significant ingredient-related hazard that will require an allergen preventive control namely proper labeling of the finished omelet at the pack, weigh, label step. More information will be provided about allergen preventive controls in Chapter 11.

For the refrigerated sliced cheddar cheese, the hazard analysis identified two additional significant ingredient-related hazards that will require preventive controls. A supply-chain preventive control was identified as the preventive measure to control the biological hazard recontamination with environmental pathogens (*L. mono*) at the cheese supplier level. The supply-chain preventive controls will involve verification of the supplier's controls they apply to control the identified hazard in the cheddar cheese before receipt by E.G. Food Company. E.G. Food Company would monitor the incoming refrigerated sliced cheddar cheese upon receipt to assure that it is from an approved supplier whose control has been verified. Therefore, the Supplier preventive control would be considered to be applied at the receiving step. More information will be provided about supply-chain preventive controls in Chapter 13.

For the metal hazard identified in the hazard analysis for the sliced cheddar cheese, a Process Control was identified in Column 5 which will be applied at the subsequent metal detection step at E.G. Food Company. Process preventive controls will be discussed in Chapters 8, 9, and 10.

Slide 12: E.G. Food Company – Hazard Analysis and Preventive Controls (2 of 7)



E.G. Food Company – Hazard Analysis and Preventive Controls (2 of 7)

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Refrigerated raw shell eggs	B	Vegetative pathogen – *Salmonella*	X		*Salmonella* known to be associated with raw shell eggs, history of outbreaks, recalls, etc.	Process Control at subsequent cook step		X
	C	Undeclared allergen – egg	X		Egg is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Refrigerated Pasteurized Grade A Milk	C	Undeclared allergen – milk	X		Milk is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Frozen biscuits	B	Recontamination with environmental pathogens *Salmonella*	X		Frozen biscuits are used as a ready-to-eat ingredient, there is exposure to the environment/further handling after the baking at the supplier (slicing) pathogens can survive in frozen biscuits.	Supply-chain Preventive Control at receiving step	X	
	C	Undeclared allergen – wheat, milk	X		The Biscuit contains wheat and milk which are major food allergens and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	Metal	X		Metal-to-metal contact during slicing could introduce metal fragments.	Process Control at subsequent metal detection		X

12

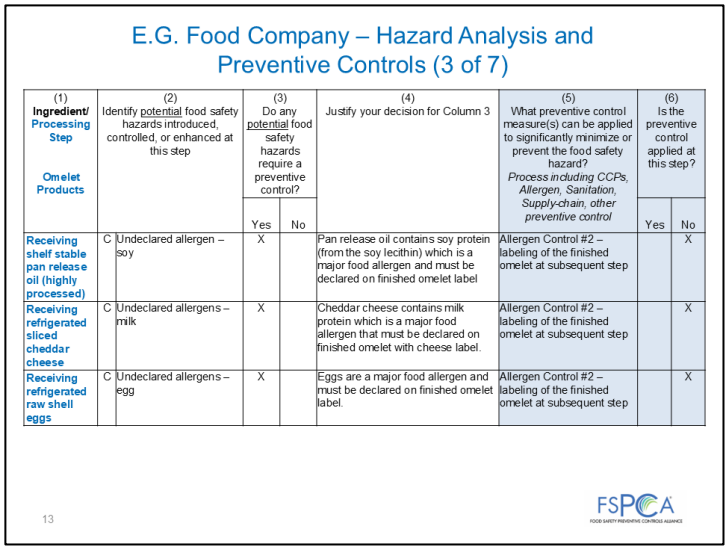
FSPCA

The hazard analysis identified *Salmonella* as a significant biological hazard in refrigerated raw shell eggs. *Salmonella* will be controlled by E.G. Food Company's omelet cook step; a process control applied at a subsequent step.

The hazard analysis identified undeclared allergens (egg in shell eggs, milk in milk and wheat and milk in biscuits) as significant ingredient-related hazards that will require an allergen preventive control namely proper labeling of the finished omelet at the pack, weigh, label step. More information will be provided about allergen preventive controls in Chapter 11.

The hazard analysis identified two additional significant hazards for the frozen biscuits: recontamination with environmental pathogens *(Salmonella)* which will be controlled by a supply-chain preventive control, and metal which will be controlled by E.G. Food Company's metal detection step.

Slide 13: E.G. Food Company – Hazard Analysis and Preventive Controls (3 of 7)



E.G. Food Company – Hazard Analysis and Preventive Controls (3 of 7)

(1) Ingredient/ Processing Step / Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving shelf stable pan release oil (highly processed)	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Receiving refrigerated sliced cheddar cheese	C	Undeclared allergens – milk	X		Cheddar cheese contains milk protein which is a major food allergen that must be declared on finished omelet with cheese label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Receiving refrigerated raw shell eggs	C	Undeclared allergens – egg	X		Eggs are a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X

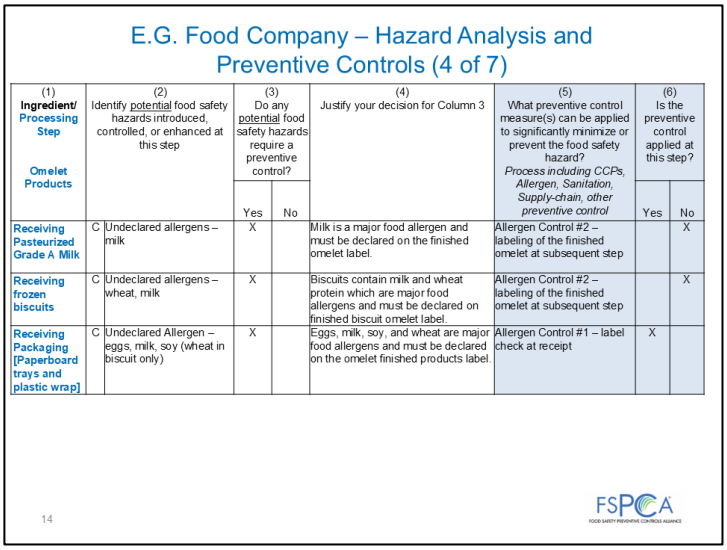
13

FSPCA

At the receiving step, the hazard analysis identified undeclared allergens for the pan release oil (soy from soy lecithin), sliced cheddar cheese (milk), and raw shell eggs (eggs). It is at the receiving step where these allergenic ingredients are first introduced into the facility. All three undeclared allergen hazards will be controlled at E.G. Food Company's subsequent pack, weigh, label step where the appropriate labels are applied to the finished omelet products which is Allergen Control #2. Note, there is another Allergen Control #1 to control undeclared allergens on the incoming packaging to ensure that the labels list the proper allergens and these finished product labels will be controlled upon receipt by checking the allergen label declarations before labels are used in the facility. This is shown on subsequent Slide 14. Allergen Control #1 and #2 work in conjunction with each other.

Food allergen preventive controls will be discussed in Chapter 11.

Slide 14: E.G. Food Company – Hazard Analysis and Preventive Controls (4 of 7)



E.G. Food Company – Hazard Analysis and Preventive Controls (4 of 7)

(1) Ingredient/ Processing Step / Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving Pasteurized Grade A Milk	C	Undeclared allergens – milk	X		Milk is a major food allergen and must be declared on the finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Receiving frozen biscuits	C	Undeclared allergens – wheat, milk	X		Biscuits contain milk and wheat protein which are major food allergens and must be declared on finished biscuit omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
Receiving Packaging [Paperboard trays and plastic wrap]	C	Undeclared Allergen – eggs, milk, soy (wheat in biscuit only)	X		Eggs, milk, soy, and wheat are major food allergens and must be declared on the omelet finished products label.	Allergen Control #1 – label check at receipt	X	

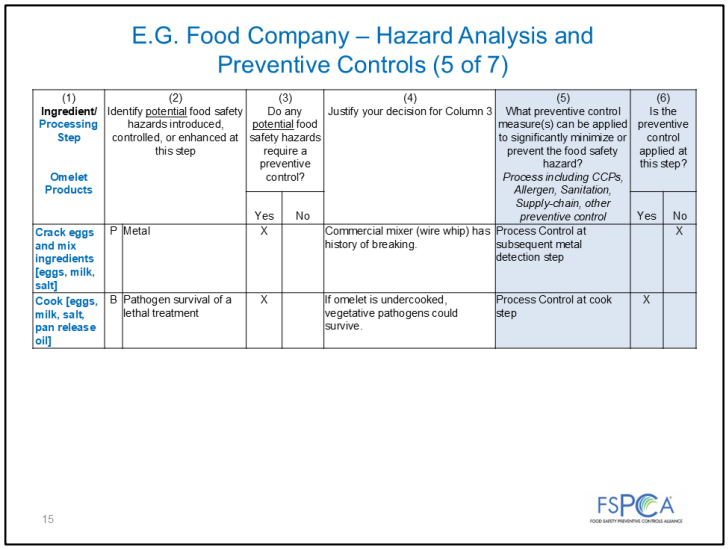
14

FSPCA

The hazard analysis identified undeclared allergens for the pasteurized milk (milk) and frozen biscuit (milk, wheat) at the receiving step since this is where the allergenic ingredients are first introduced into the facility. These undeclared allergen hazards will be controlled by E.G. Food Company at the subsequent pack, weigh, label step where the appropriate labels are applied to the finished omelet products (allergen control #2) and allergen control #1 at packaging receiving.

The hazard analysis also identified undeclared allergens as a significant hazard for the incoming packaging to ensure that the labels list the proper allergens. The finished product labels will be controlled upon receipt by checking the allergen label declarations before labels are used in the facility. Some companies may decide to check the labels at both receipt and application or just at application.

Slide 15: E.G. Food Company – Hazard Analysis and Preventive Controls (5 of 7)

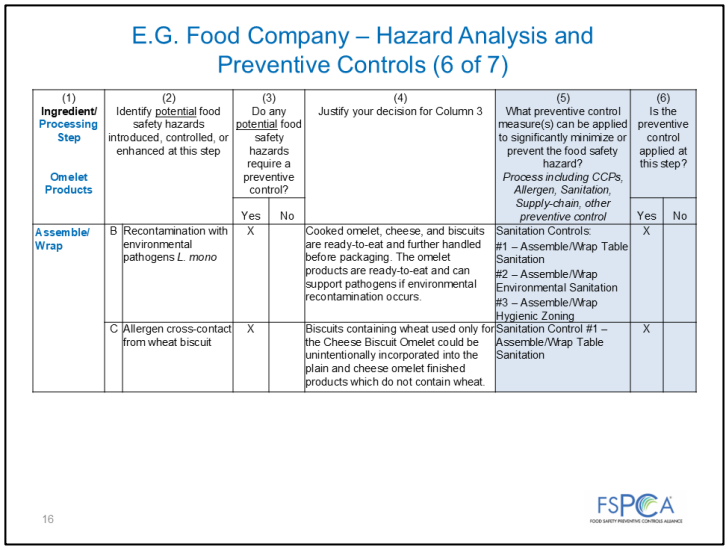


(1) Ingredient/ Processing Step / Omelet Products	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Crack eggs and mix ingredients [eggs, milk, salt]	P	Metal	X		Commercial mixer (wire whip) has history of breaking.	Process Control at subsequent metal detection step		X
Cook [eggs, milk, salt, pan release oil]	B	Pathogen survival of a lethal treatment	X		If omelet is undercooked, vegetative pathogens could survive.	Process Control at cook step	X	

The hazard analysis identified metal as a significant hazard at crack eggs and mix ingredient step since this hazard was deemed significant due to history with the mixer wire whip breaking. The metal hazard will be controlled at E.G. Food Company's subsequent metal detection step.

Pathogen survival of a lethal treatment was identified as a significant hazard at the cook step. Pathogens will be controlled by proper cooking at this step.

Slide 16: E.G. Food Company – Hazard Analysis and Preventive Controls (6 of 7)



E.G. Food Company – Hazard Analysis and Preventive Controls (6 of 7)

(1) Ingredient/ Processing Step / Omelet Products		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Assemble/ Wrap	B	Recontamination with environmental pathogens *L. mono*	X		Cooked omelet, cheese, and biscuits are ready-to-eat and further handled before packaging. The omelet products are ready-to-eat and can support pathogens if environmental recontamination occurs.	Sanitation Controls: #1 – Assemble/Wrap Table Sanitation #2 – Assemble/Wrap Environmental Sanitation #3 – Assemble/Wrap Hygienic Zoning	X	
	C	Allergen cross-contact from wheat biscuit	X		Biscuits containing wheat used only for the Cheese Biscuit Omelet could be unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat.	Sanitation Control #1 – Assemble/Wrap Table Sanitation	X	

16

FSPCA

The hazard analysis identified preventive controls for process- and facility-related hazards that were determined to be significant at the assemble/wrap step.

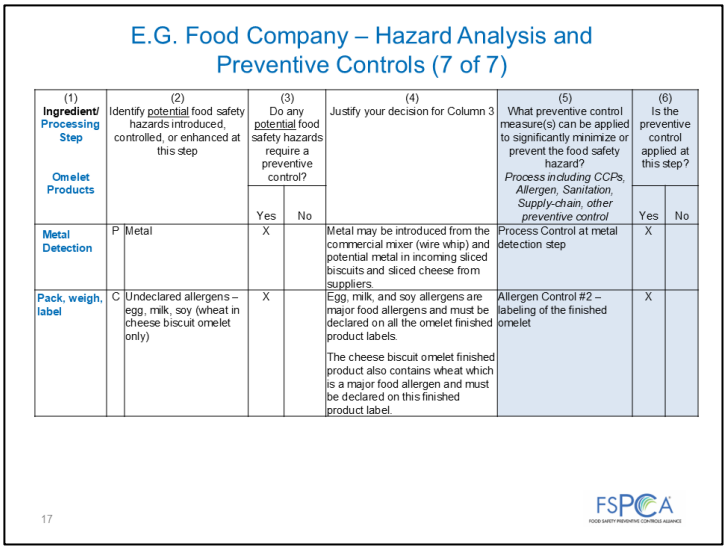
First, sanitation preventive controls were identified at the assemble/wrap step to control recontamination of the finished omelet products with environmental pathogens (*L. mono)*.

Three sanitation preventive controls will be utilized to prevent environmental pathogen recontamination:

1. Sanitation Control #1: Assemble/Wrap Table Sanitation;
2. Sanitation Control #2: Assemble/Wrap Environmental Sanitation (floor and the table support legs); and
3. Sanitation Control #3: Assemble/Wrap Hygienic Zoning (personnel cross-contamination prevention).

Second, Sanitation Control #1 is also used to prevent allergen cross-contact from the wheat biscuit. More information will be provided about sanitation preventive controls in Chapter 12.

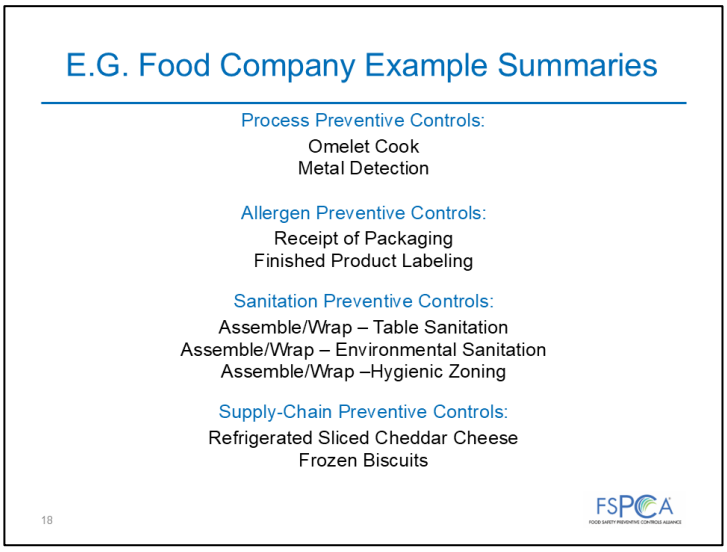
Slide 17: E.G. Food Company – Hazard Analysis and Preventive Controls (7 of 7)



Metal hazards identified in the sliced cheese and biscuit ingredients and at the E.G. Company's mixing step will be controlled by the metal detection step.

The hazard analysis identified food allergens in the pan release oil (soy from soy lecithin), sliced cheddar cheese (milk), raw shell eggs (egg), pasteurized Grade A milk (milk) and biscuits (wheat and milk) which must be declared on the finished omelet product label. The pack, weigh, label step is where the appropriate labels will be applied to the finished omelet products to prevent undeclared allergens.

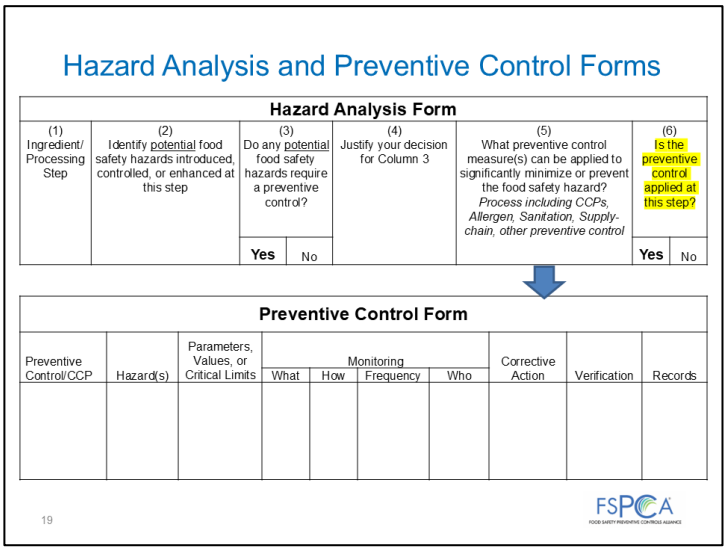
Slide 18: E.G. Food Company Example Summaries



This slide serves as a summary of E.G. Food Company's preventive controls identified in the previous hazard analysis slides.

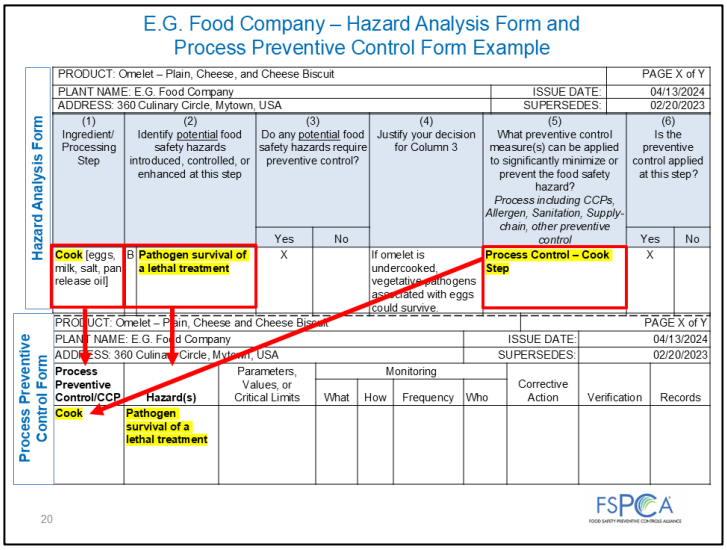
- Process Preventive Controls: Omelet Cook and Metal Detection
- Allergen Preventive Controls: #1 – Label Check at Receipt and #2 – Labeling of the Finished Omelet
- Sanitation Preventive Controls: #1 – Assemble/Wrap Table Sanitation; #2 – Assemble/Wrap Environmental Sanitation; and #3 – Assemble/Wrap Hygienic Zoning.
- Supply-chain Preventive Controls: Refrigerated Sliced Cheddar Cheese and Frozen Biscuits.

Slide 19: Hazard Analysis and Preventive Control Forms



For ease of Food Safety Plan development, information from the hazard analysis can be transferred to the preventive control form as shown on this slide. This is one way to enable this development, and the template example forms are found in Appendix 2 (pages A2-3 to A2-5).

Slide 20: E.G. Food Company – Hazard Analysis Form and Process Preventive Control Form Example



E.G. Food Company – Hazard Analysis Form and Process Preventive Control Form Example

Hazard Analysis Form

PRODUCT: Omelet – Plain, Cheese, and Cheese Biscuit							PAGE X of Y	
PLANT NAME: E.G. Food Company						ISSUE DATE:	04/13/2024	
ADDRESS: 360 Culinary Circle, Mytown, USA						SUPERSEDES:	02/20/2023	
(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?		
		Yes	No			Yes	No	
Cook [eggs, milk, salt, pan release oil]	B **Pathogen survival of a lethal treatment**	X		If omelet is undercooked, vegetative pathogens associated with eggs could survive	**Process Control – Cook Step**	X		

Process Preventive Control Form

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit								PAGE X of Y	
PLANT NAME: E.G. Food Company							ISSUE DATE:	04/13/2024	
ADDRESS: 360 Culinary Circle, Mytown, USA							SUPERSEDES:	02/20/2023	
Process Preventive Control/CCP	**Hazard(s)**	Parameters, Values, or Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	**Pathogen survival of a lethal treatment**								

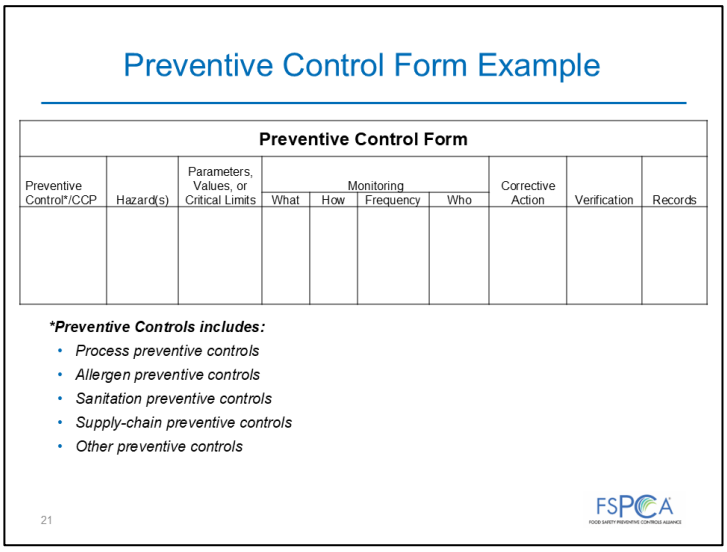
20

FSPCA

As illustrated in this example, the steps identified as requiring a process preventive control, including CCPs, along with the hazards requiring a preventive control are transferred from the Hazard Analysis Form to the first and second columns of the Process Preventive Control Form. This form may be referred to as a HACCP Chart if desired.

The Food Safety Team then lists parameters, values, or critical limits (the minimum or maximum values associated with the parameters) for the controls for each hazard, all elements of monitoring, corrective actions to be taken when deviations from the critical limit occur, verification procedures and records in subsequent columns. Chapter 9 discusses critical limits, monitoring, and corrective action elements of the Process Preventive Control Form. Elements of verification and record - keeping requirements are addressed in separate chapters.

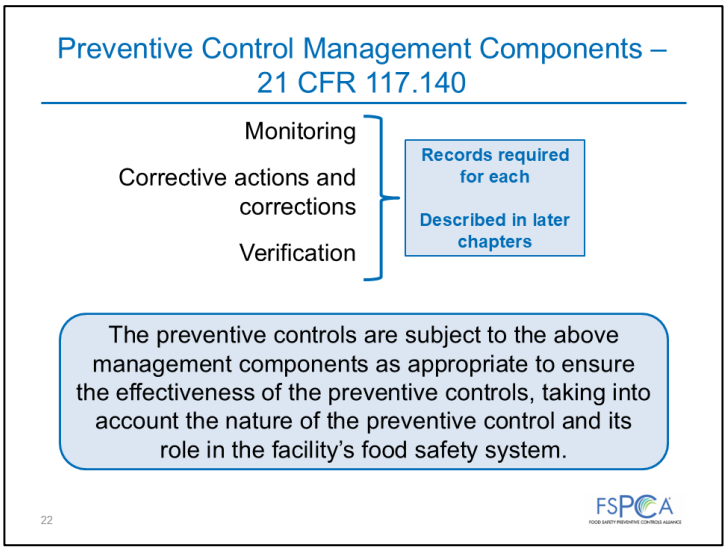
Slide 21: Preventive Control Form Example



A variety of formats can be used to document this information. This course uses the format above, which includes information that must be documented in the Food Safety Plan. Details on information required on Food Safety Plan records are discussed in Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping.

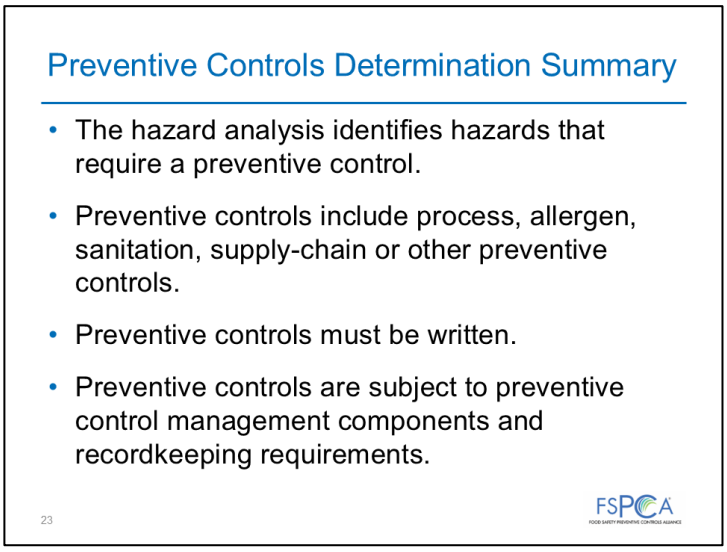
As a reminder, the types of preventive controls are—process preventive controls, food allergen preventive controls, sanitation preventive controls, supply-chain preventive controls, and other preventive controls.

Slide 22: Preventive Control Management Components – 21 CFR 117.140



As a preview of what is to come, this slide outlines what the regulation requires as part of the management components for each preventive control, including monitoring, corrective actions and corrections, and verification. Note that these will be specific to the type of preventive control and how it fits within the food safety system of the facility. More information about the application of preventive controls management components can be found in the FDA Hazard Guide, Chapter 5.

Slide 23: Preventive Controls Determination Summary



This chapter has discussed how to take the information from the hazard analysis and identify preventive controls for those hazards that were determined to be significant. There are four types of preventive controls typically considered – process, allergen, sanitation, and supply-chain, and the Food Safety Team may also identify other types. Preventive controls must be written and include various management components and recordkeeping requirements that will be addressed in subsequent chapters.

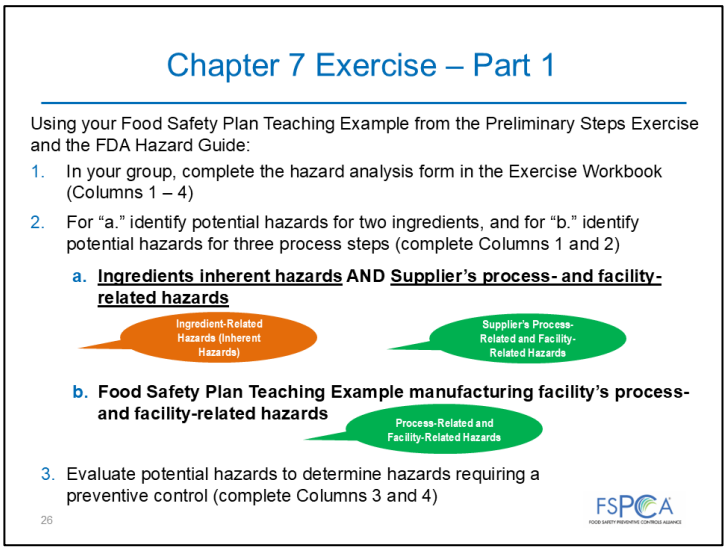
Slide 24: Knowledge Check 1

Participants do NOT have this slide.

Slide 25: Knowledge Check 2

Participants do NOT have this slide.

Slide 26: Chapter 7 Exercise – Part 1

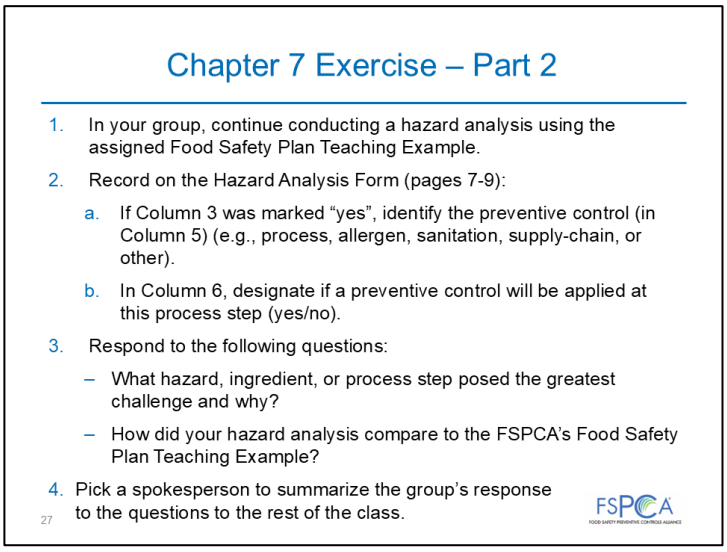


FDA Hazard Guide Appendix 1

Part 1: Using your Food Safety Plan Teaching Example from the Preliminary Steps Exercise and the FDA Hazard Guide, Appendix 1, and Chapters 2 and 3.

1. In your group, complete the hazard analysis form in the Exercise Workbook (Columns 1 – 4).
2. For "a." identify potential hazards for two ingredients, and for "b." identify potential hazards for three process steps (complete Columns 1 and 2):
    a. Identify potential hazards for two (2) ingredients used in the Food Safety Plan Teaching Example in Column 1. (*Note: These two ingredients will be assigned by the Lead Instructor.*)
    b. Identify potential hazards for three (3) process steps from the Food Safety Plan Teaching Example in Column 1. (*Note: These three processing steps will be assigned by the Lead Instructor.*)
    c. In Column 2, for the two ingredients, identify potential ingredient inherent hazards, and supplier process- and facility-related hazards separating into B (biological), C (chemical), and P (physical) hazard types.
    d. Also in Column 2, identify potential hazards that may be introduced, controlled, or enhanced at each process step listed for making the food in your food safety plan teaching example.
3. In Column 3 evaluate all the potential hazards in Column 2 and determine if any of these hazards will require a preventive control by answering yes or no.
4. In Column 4, justify your decision in Column 3.

Slide 27: Chapter 7 Exercise – Part 2



1. In your group, continue conducting your hazard analysis for your Food Safety Plan Teaching Example.
2. Record on the Hazard Analysis Form:
    a. If Column 3 was marked "yes", identify the preventive control in Column 5 (e.g., process, allergen, sanitation, supply-chain, or other).
    b. In Column 6, designate if a preventive control will be applied at this process step (yes/no).
3. Respond to the following questions:
    a. What hazard, ingredient, or process step posed the greatest challenge and why?
    b. How did your hazard analysis compare to the Food Safety Plan Teaching Example?
4. Pick a spokesperson to summarize the group's response to the questions to the rest of the class.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.ifsh.iit.edu/fspca

FSPCA Technical Assistance Network (TAN): https://www.ifsh.iit.edu/fspca/fspca-technical-assistance-network

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/media/100002/download

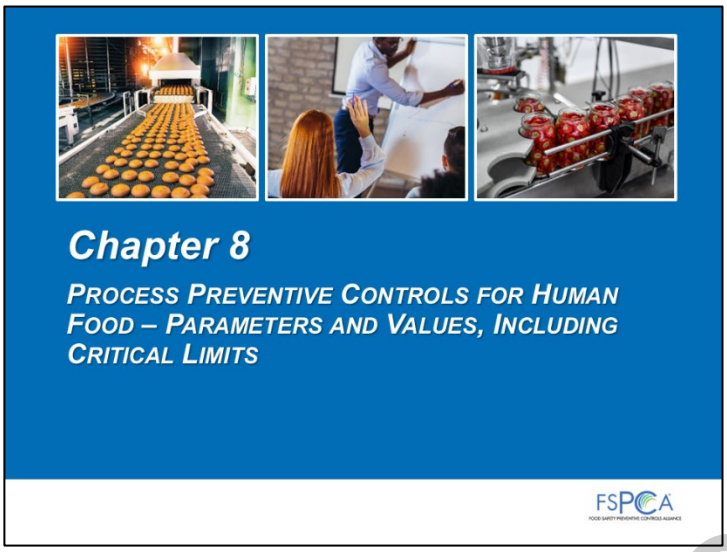
FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 2: https://www.fda.gov/media/99554/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 4: https://www.fda.gov/media/99572/download

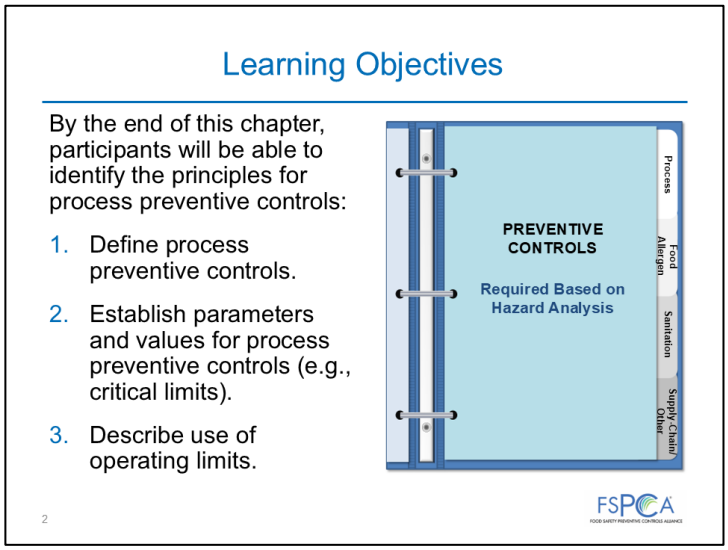
FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 5: https://www.fda.gov/media/99576/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 6: https://www.fda.gov/media/107327/download

Slide 1: Chapter 8: Process Preventive Controls for Human Food – Parameters and Values, Including Critical Limits



Slide 2: Learning Objectives



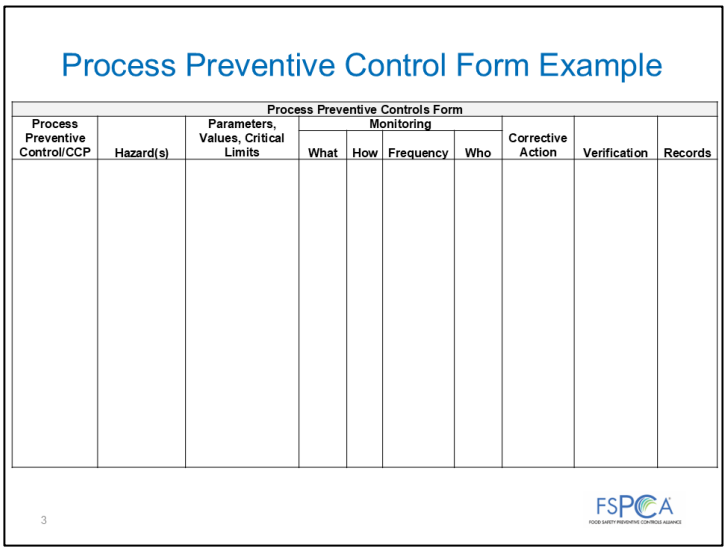
Definition: Critical Control Point (CCP): A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level (21 CFR 117.3).

Hazards requiring a process preventive control are determined and identified during the hazard analysis process.

Per the regulation, 21 CFR 117.135(c)(1), process controls include procedures, practices, and processes to ensure control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (1) Parameters associated with the control of the hazard; and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

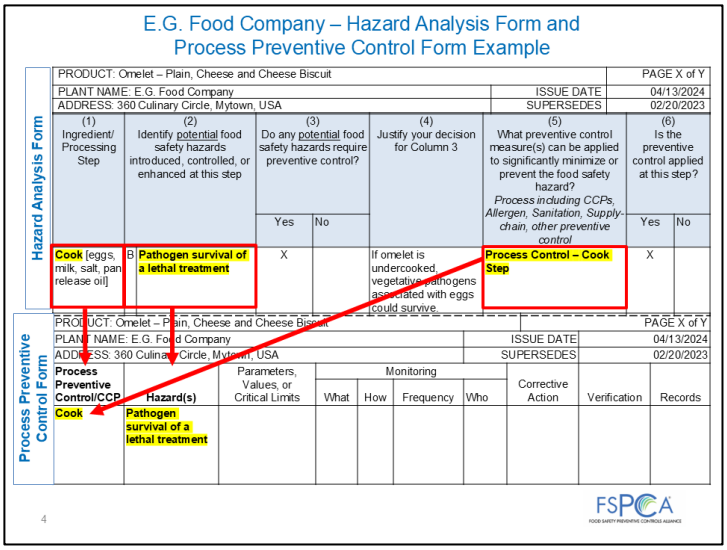
Process preventive controls are frequently called Critical Control Points (CCPs). A CCP is defined in the regulation as a point, step, or procedure, in a food process, at which a control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level (see Appendix 8: Definitions). Once a process preventive control, such as a CCP, is identified for a specific hazard, parameters and values are established to control the hazards identified in the hazard analysis.

Slide 3: Process Preventive Control Form Example



A variety of formats can be used to document process preventive control information. This course uses the format above, which includes information that must be documented in the Food Safety Plan. This chapter focuses on establishing parameters and values, including critical limits. Chapter 9 focuses on determining monitoring and corrective action procedures. Chapter 10 focuses on verification and recordkeeping activities.

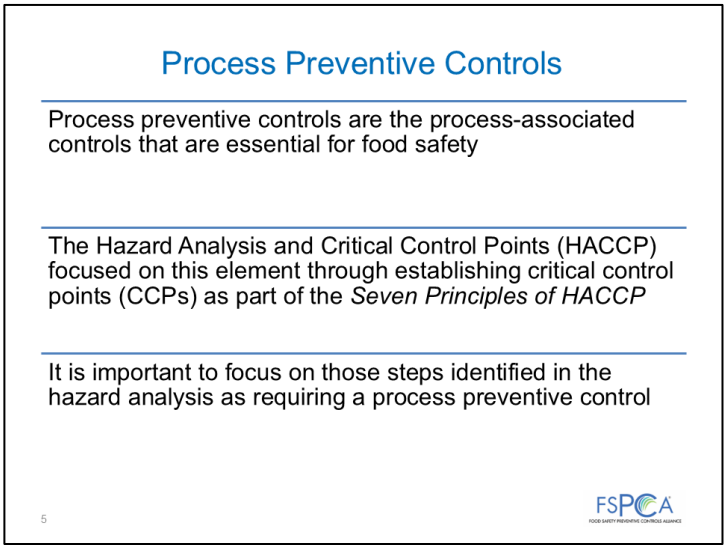
Slide 4: E.G. Food Company Example – Hazard Analysis Form and Process Preventive Control Form Example



As illustrated in this example, the steps identified as requiring a process preventive control, including CCPs, along with the hazards requiring a preventive control, are transferred from the Hazard Analysis Form to the first and second columns of the Process Preventive Control Form. This form may be referred to as a HACCP Chart if desired.

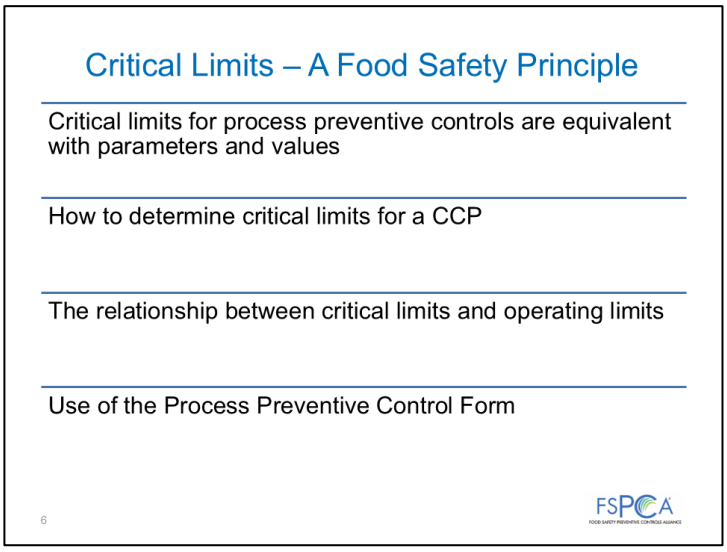
The Food Safety Team determines and lists the parameters, values, or critical limits (the minimum or maximum values associated with the parameters) for the controls for each hazard, all elements of monitoring, any corrective actions to be taken when deviations from the critical limit occur, the verification procedures, and records in subsequent columns. This chapter discusses critical limits on the Process Preventive Control Form. Elements of monitoring, corrective action, verification, and recordkeeping requirements are addressed in separate chapters.

Slide 5: Process Preventive Controls



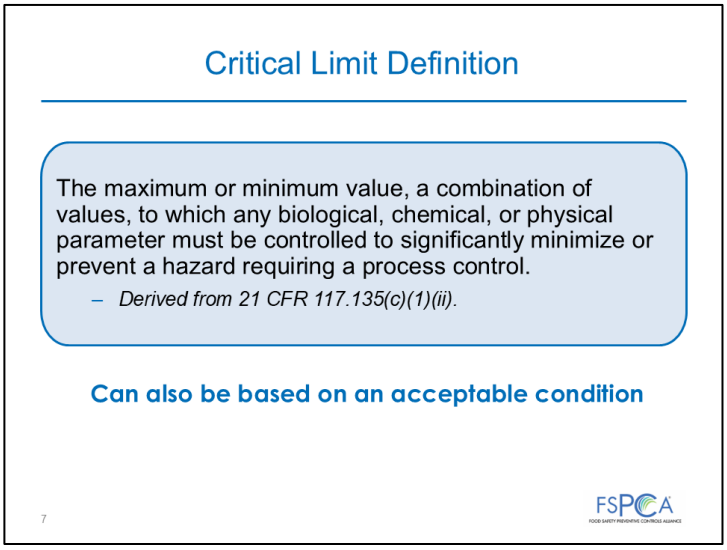
Process preventive controls link back to HACCP Principles that typically result in the identification of Critical Control Points (CCPs). Under 21 CFR Part 117, process preventive controls are identified through a Hazard Analysis when specific hazards will be controlled by the given process step. Under HACCP, these process controls controlling the hazard would have been identified as CCPs. The term "CCP" is used generically for process preventive controls.

Slide 6: Critical Limits – A Food Safety Principle



For simplicity, the term "critical limit" is used in the rest of this chapter instead of "minimum or maximum values associated with the parameters and values to control the hazard." Critical limits play an important role in a preventive control program. If a significant hazard exists, it is important to understand values for the parameters that must be met to control that hazard. This chapter focuses on how to establish science-based critical limits which help to assure process preventive controls are effective. Sources of information on critical limits are readily available, and these will be discussed later in the chapter. The chapter also discusses different approaches used to establish a critical limit, as well as the advantages and disadvantages of these approaches. This chapter also covers "operating limits," a more conservative limit (e.g., higher or lower temperatures than needed for safety), used in production to minimize the risk of not meeting a critical limit. Operating limits are often established for meeting quality standards. Finally, the chapter illustrates how to begin to complete a Process Preventive Control Form.

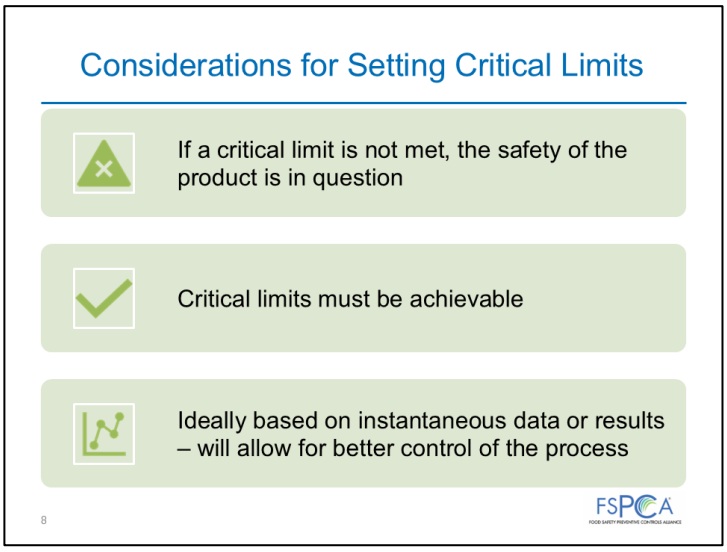
Slide 7: Critical Limit Definition



For most process-related preventive controls, measurable parameters can be identified, and the values established for these parameters are called critical limits, as cited in the regulation in 21 CFR 117.135(c)(1)(ii). The critical limit must be met at the process control step (or CCP) to significantly minimize or prevent the hazard requiring a preventive control. If a critical limit is not met, the process control step is not in control (i.e., a deviation has occurred). When not in control, the potential for producing a product that presents a consumer-health risk exists.

Examples of parameters that may have critical limits established for control include cook time, temperature, flow rate, line speed, product bed depth, weight, viscosity, moisture level, water activity, salt concentration, pH, and others, depending upon the process.

Slide 8: Considerations for Setting Critical Limits (1 of 2)

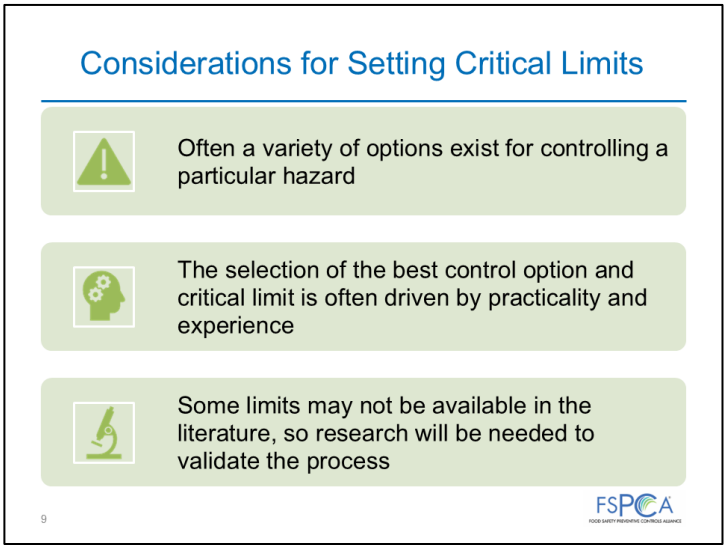


Because of the potential safety implications, meeting critical limits at a process preventive control is essential for the safety of the product. When critical limits are not met, predefined corrective actions must be taken.

Basing the critical limit on instantaneous, real-time data will allow for better control of the process.

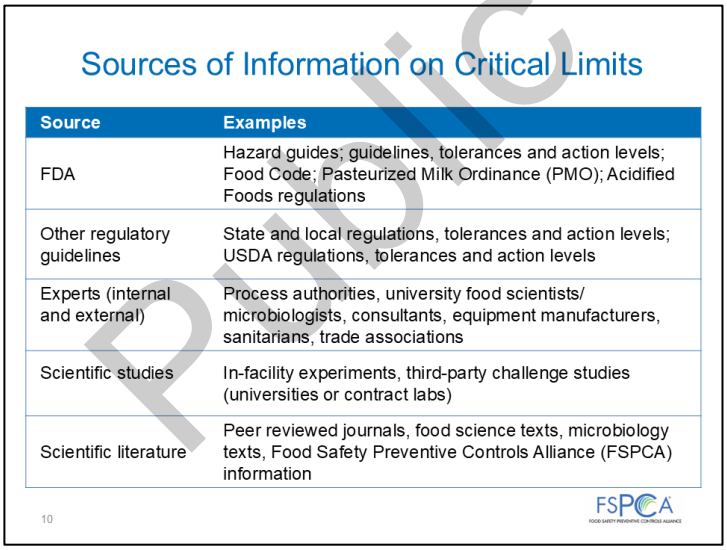
A critical limit is generally expressed as a value equal to or above (or below) a critical value and not at the specific value itself. For example, processing equipment may not easily maintain the exact value of 160°F (71°C) so the critical limit would be set at ≥160°F (71°C). This allows the CCP to be achieved and gives the option of exceeding it, to enable being more conservative or to operate at a higher processing limit.

Slide 9: Considerations for Setting Critical Limits (2 of 2)



There frequently are different ways to control a specific hazard. The Food Safety Team decides the best option for the particular CCP based on practical considerations such as the process capabilities, how measurements can be made, staff capabilities and experience, and other appropriate factors. This may mean the chosen limit may not be available in the literature, but it still needs to be validated following sound research principles.

Slide 10: Sources of Information on Critical Limits



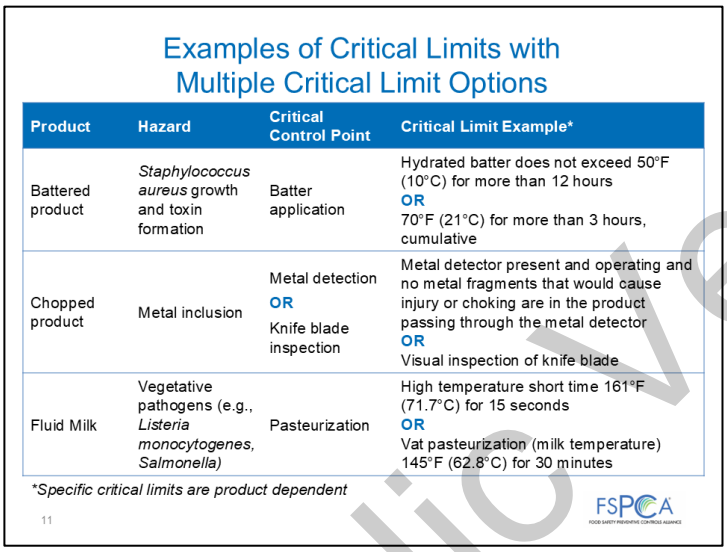
Appendix 4 of this manual has some information that could be used for critical limits for biological hazards.

A number of sources of scientific and technical information can be useful in establishing critical limits. The FDA and other governmental agencies may provide information through technical staff, regulations, guidelines, directives, performance standards, tolerances, and action levels. Trade associations, process authorities, industry scientists, university and extension scientists, and consultants can provide

expertise and guidelines. Scientific studies for specific products can be conducted within a facility, at a contract laboratory, or at a university.

Information can also be obtained from peer-reviewed scientific literature. Care must be taken when applying information from literature sources to critical limits for a specific product and process. There may be important differences between the methods used in a published study and those used for the product and process under consideration. The critical limits may need to be adjusted to account for those differences. For example, higher fat levels in a product may have a protective effect in the microbial lethality of a heat treatment for that product. A higher temperature or a longer time may be required to achieve the same level of lethality compared to a lower fat product.

Slide 11: Examples of Critical Limits with Multiple Critical Limit Options



Examples of Critical Limits with Multiple Critical Limit Options

Product	Hazard	Critical Control Point	Critical Limit Example*
Battered product	*Staphylococcus aureus* growth and toxin formation	Batter application	Hydrated batter does not exceed 50°F (10°C) for more than 12 hours **OR** 70°F (21°C) for more than 3 hours, cumulative
Chopped product	Metal inclusion	Metal detection **OR** Knife blade inspection	Metal detector present and operating and no metal fragments that would cause injury or choking are in the product passing through the metal detector **OR** Visual inspection of knife blade
Fluid Milk	Vegetative pathogens (e.g., *Listeria monocytogenes, Salmonella)*	Pasteurization	High temperature short time 161°F (71.7°C) for 15 seconds **OR** Vat pasteurization (milk temperature) 145°F (62.8°C) for 30 minutes

Specific critical limits are product dependent

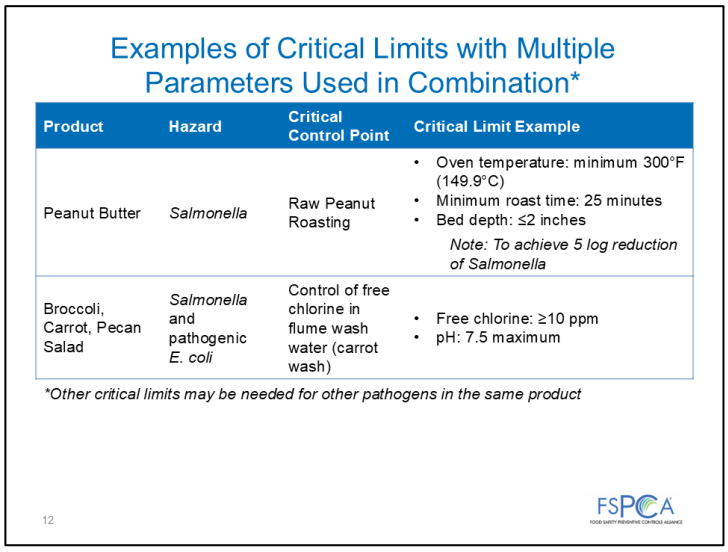
11

FSPCA

There are many different types of critical limits. Critical limits must be specific for the process preventive control step and the hazard that is being controlled. Different critical limits may be needed for ingredient-related hazards and process-related hazards. Each process preventive control must have one (or more) critical limit for each food safety hazard. An effective critical limit defines what can be measured or observed to demonstrate that the hazard is being controlled at that process preventive control step. For example, both time and temperature measurements may be elements of a critical limit to eliminate food safety hazards such as pathogens at a cook step.

There can be multiple critical limits established for a single process preventive control based on different conditions that occur in the process.

Slide 12: Examples of Critical Limits with Multiple Parameters Used in Combination



Examples of Critical Limits with Multiple Parameters Used in Combination*

Product	Hazard	Critical Control Point	Critical Limit Example
Peanut Butter	*Salmonella*	Raw Peanut Roasting	• Oven temperature: minimum 300°F (149.9°C) • Minimum roast time: 25 minutes • Bed depth: ≤2 inches *Note: To achieve 5 log reduction of Salmonella*
Broccoli, Carrot, Pecan Salad	*Salmonella* and pathogenic *E. coli*	Control of free chlorine in flume wash water (carrot wash)	• Free chlorine: ≥10 ppm • pH: 7.5 maximum

**Other critical limits may be needed for other pathogens in the same product*

12

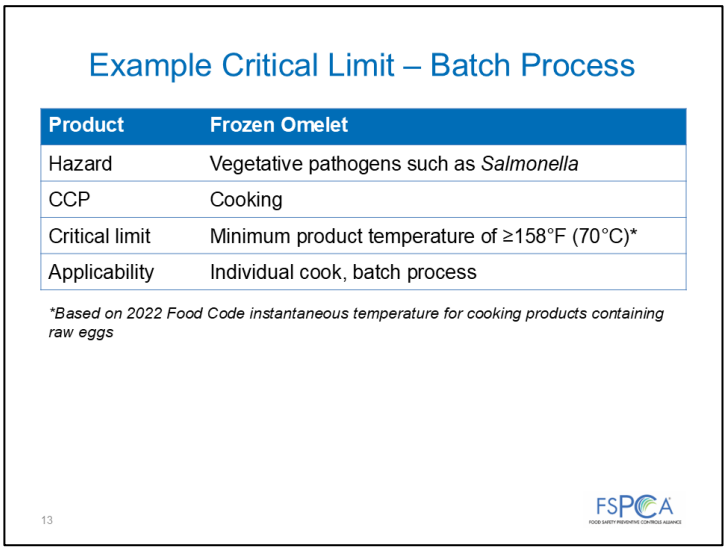
FSPCA

Facilities may have different parameter options for controlling a specific hazard. The selection of the best parameter is often driven by practicality and experience. Critical limits may involve multiple parameters such as time and temperature and bed depth (for a nut roasting process), or free chlorine and pH in a produce flume wash water system. The nature of the product, the specific process, and the hazard being controlled influence what parameters may be used.

Additionally, a facility may have different options for the critical limits to control a specific hazard. For example, a facility may choose to use a higher oven temperature and/or a reduced bed depth in the peanut butter process to achieve the safety level of heat treatment more quickly.

Parameter options and critical limits must be determined on a product- by-product basis and must consider the role of the specific process preventive control in relation to the food safety system.

Slide 13: Example Critical Limit – Batch Process

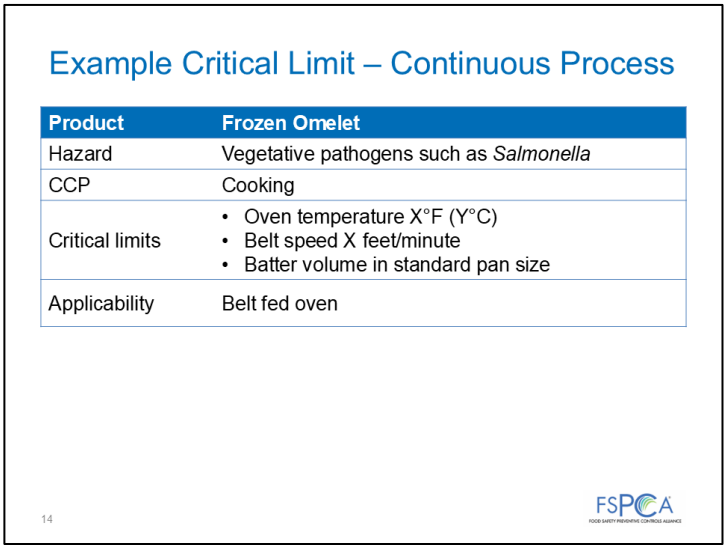


A variety of approaches could be applied to set critical limits for a cooking process preventive control intended to eliminate the hazard of vegetative pathogens in a frozen omelet. In the example on the slide of the frozen omelet, it is a batch process where it is a measurement of product temperature. In this case, the product temperature achieved during cooking is set as the critical limit. However, the product temperature may not be easy to monitor for each individual product cooked. Heat transfer rates during cooking could also vary for several reasons.

For a fluid product like a sauce, measuring the product temperature may be practical because the liquid could be mixed. For a solid product like an omelet, a procedure would need to be developed for consistently measuring the temperature of the omelet. If products are produced using a batch process (e.g., multiple products baked together in a set of pans), then product temperature may be workable as a critical limit. However, if each omelet is individually made, it may be less practical to measure and record temperature because the time needed to capture the data for each unit may be difficult, especially considering that doneness may vary from one omelet to the next.

Batch processes are distinguished from continuous process in how the critical limits are measured.

Slide 14: Example Critical Limit – Continuous Process

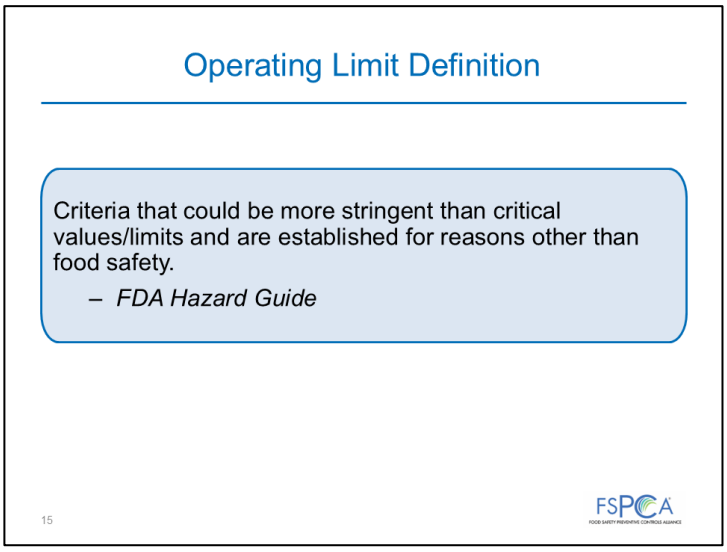


As an alternative to batch process for cooking the omelets, the E.G. Food Company could have used a continuous process, where a critical limit is established for the process parameters. An example of how this could have been done is shown here.

The reality is that except in limited circumstances (e.g., the product is a liquid such as milk in a pipe or a continuously stirred liquid product), it can be unpractical to continually monitor the temperature of each individual food product on a processing line to ensure conformance with a critical limit. As an alternative, the example above establishes process conditions necessary to ensure that the cooking process achieves the minimum product time and temperature. In this approach, the oven temperature, the belt speed going through the oven, and the volume of batter placed into standard pans are all factors that affect the consistency of the product's final temperature. These parameters are easy to monitor, and measurements are obtained quickly to determine that critical limits have been met.

A scientific study (validation, discussed below and in Chapter 10: Verification and Validation Procedures) must be performed to ensure that controlling these process parameters at the specified critical limits will always result in an internal product temperature that will destroy pathogens of concern. Typically, this option provides better assurance and may be easier to perform than the previous option, even though more parameters must be monitored at this step.

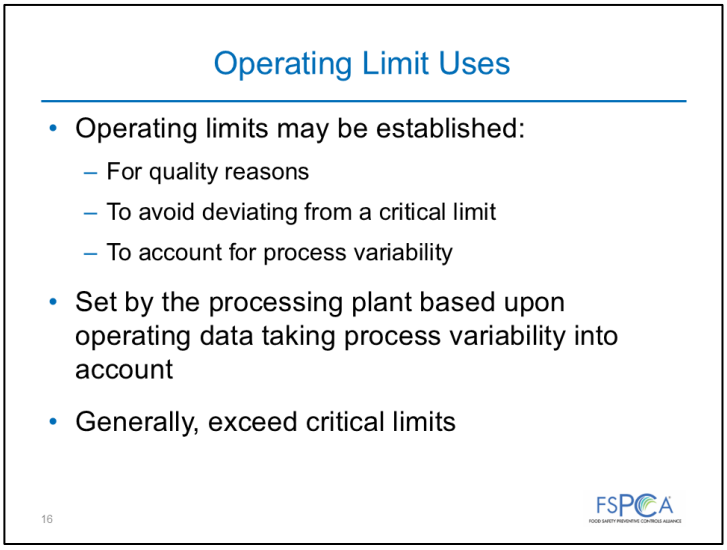
Slide 15: Operating Limit Definition



Use of an operating limit allows the detection of a potential problem before a critical limit is not met. The value for the operating limit parameter is usually more stringent (or conservative) than the critical limit. Operating limits should not be confused with critical limits. Operating limits would be more stringent than the critical limits to ensure that the critical limits are not exceeded.

A process may be adjusted when the operating limit is not met, which avoids deviating from the critical limit. These actions are called "process adjustments." A processor may use these adjustments to avoid loss of a critical limit control resulting in a process deviation and the subsequent requirement to take corrective action. Spotting a processing trend toward loss of control early and acting on it can save product rework or, worse yet, product destruction.

Slide 16: Operating Limit Uses

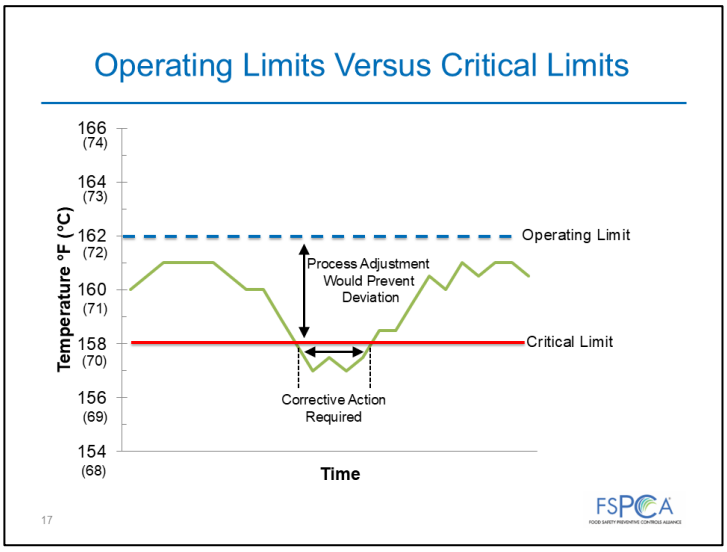


Operating limits may be selected for various reasons:

- For quality reasons: For example, product may be heated to higher temperatures above the critical limit set to eliminate pathogens in order to eliminate spoilage organisms with higher heat resistance.
- To avoid deviating from a critical limit: For example, a product that must be acidified to pH 4.6 for safety may have a more stringent operating limit of 4.4 to reduce the likelihood of exceeding the critical limit.
- To account for normal variability: For example, a fryer with a 5°F (2.8°C) variability should be set at least 5°F (2.8°C) above the critical limit to avoid violating it.

Typically, operating limits are set by the processing plant based upon operating data taking process variability into account and often exceed regulatory requirements and recommendations, generally at values more conservative than the critical limits.

Slide 17: Operating Limits Versus Critical Limits



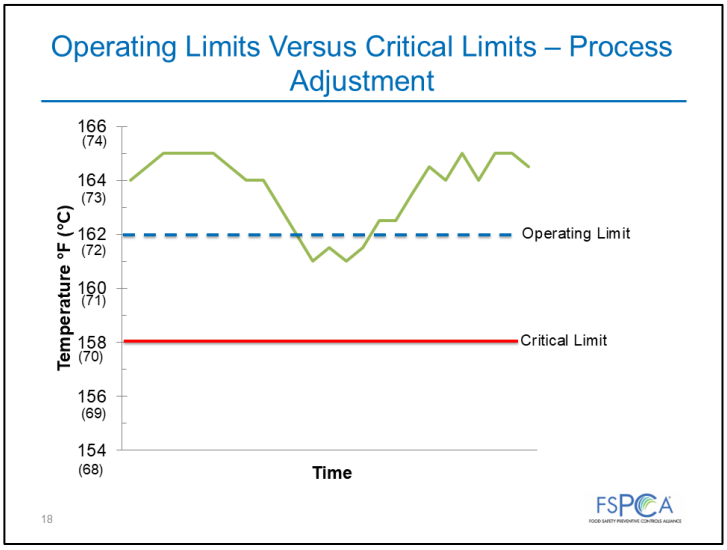
The example on the slide demonstrates two important points:

1. Operating limit deviations and how they relate to process adjustments; and
2. Critical limit deviations and how they relate to corrective actions.

In this example of a cooking process, a critical limit is established at 158°F (70°C) and the temperature fell below that limit. Setting an operating limit above the critical limit could have alerted line personnel to make a process adjustment to bring the cook temperature back above the operating limit. If an adjustment is made before the temperature drops below the critical limit, no corrective action record is required.

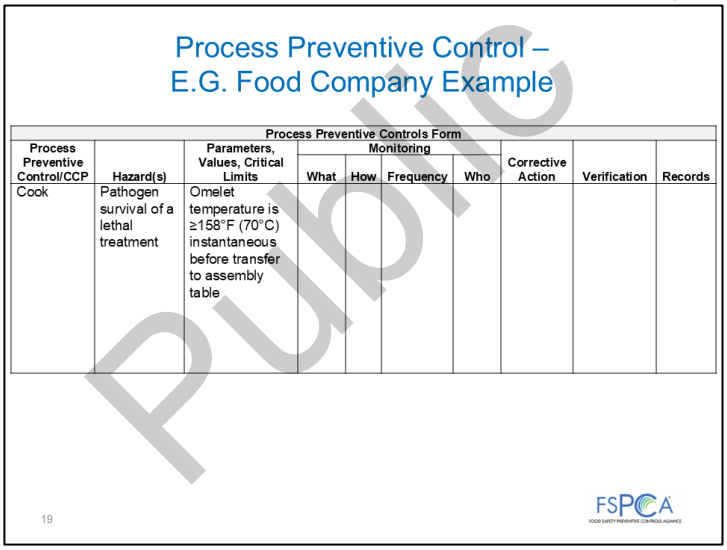
However, in this example, an adjustment was not made until after the temperature dropped below the critical limit of 158°F (70°C), thus appropriate corrective actions must be taken, and a corrective action report must be written and included with preventive controls records.

Slide 18: Operating Limits Versus Critical Limits – Process Adjustment



In this example, setting the operating limit more stringently than the critical limit allows for response by plant personnel before reaching the point at which there is a deviation that requires corrective actions. This example shows that the operating limit was set at 162°F (72°C), which is more than adequate to assure temperatures remain above the critical limit of 158°F (70°C).

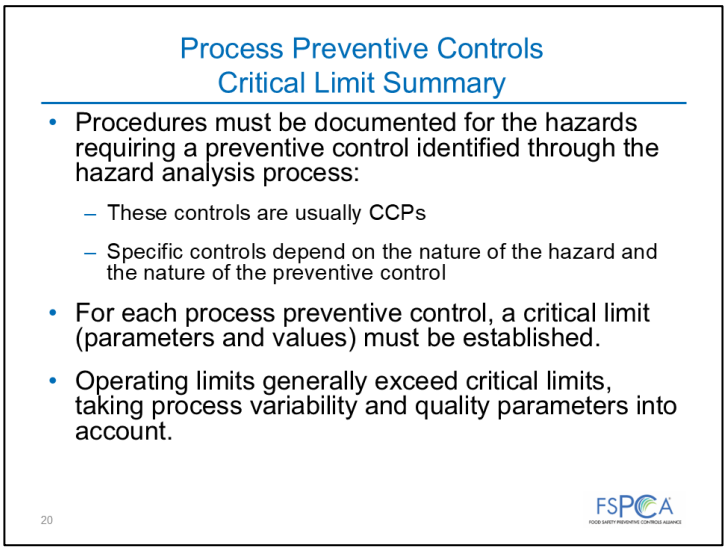
Slide 19: Process Preventive Control – E.G. Food Company Example



As previously discussed, the E.G. Food Company's critical limit for cooking the omelet was determined to be "Omelet surface temperature is ≥158°F (70°C) instantaneous before transfer to assembly table."

This information is recorded in the Food Safety Plan.

Slide 20: Process Preventive Controls Critical Limit Summary



Critical limits (i.e., a maximum and/or minimum value to which a process effectively controls a food safety hazard to an acceptable level), must be determined for each process preventive control (e.g., CCPs), that has been identified in the hazard analysis. Process preventive controls critical limits must be validated to ensure that the values established are effective in controlling the hazard.

Operating limits are set more stringently than the critical limits to ensure that the critical limits are not exceeded, considering specifics related to the process variability and product quality.

Slide 21: Knowledge Check 1

Participants do NOT have this slide.

Slide 22: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

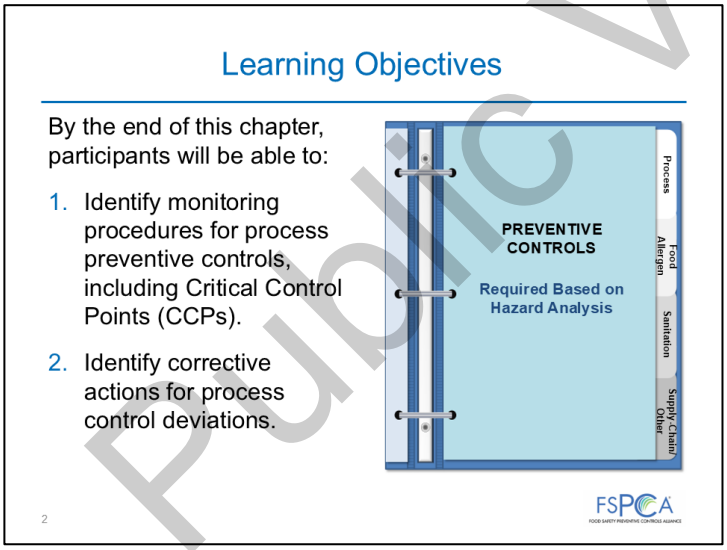
FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/media/100002/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 4: https://www.fda.gov/media/99572/download

Chapter 9: Process Preventive Controls for Human Food – Monitoring and Corrective Action

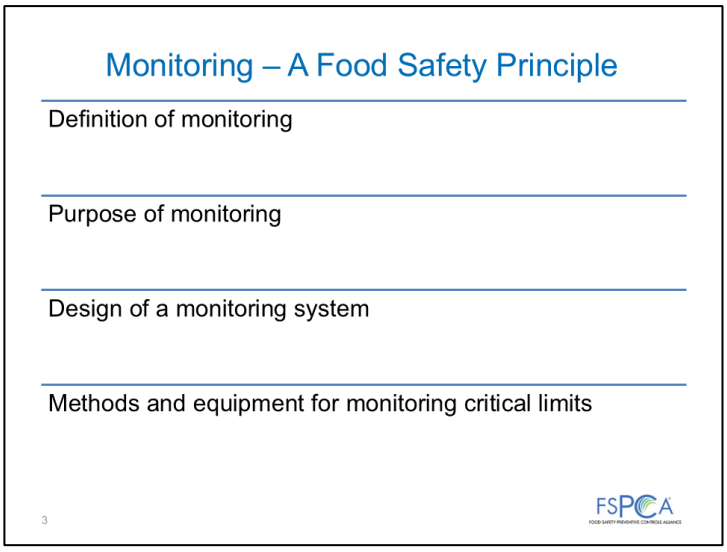
Slide 1: Chapter 9: Process Preventive Controls for Human Food – Monitoring and Corrective Action

Slide 2: Learning Objectives



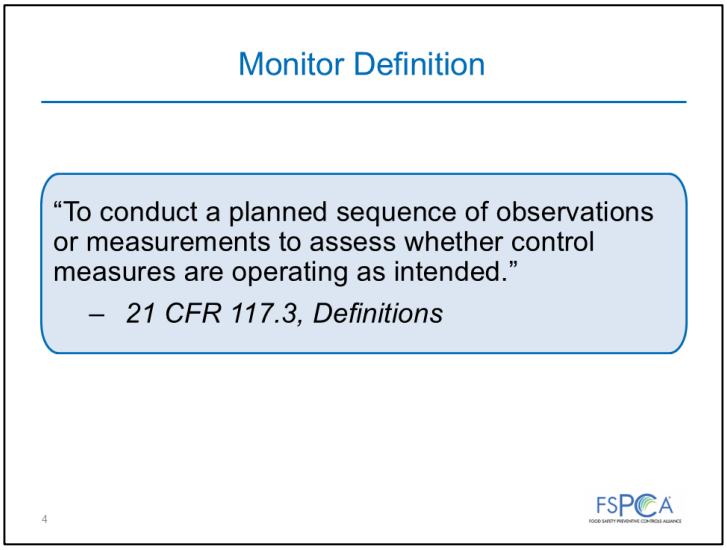
Monitoring and corrective action apply broadly to all preventive controls. This module will review principles for monitoring procedures and corrective actions for process preventive controls.

Slide 3: Monitoring – A Food Safety Principle



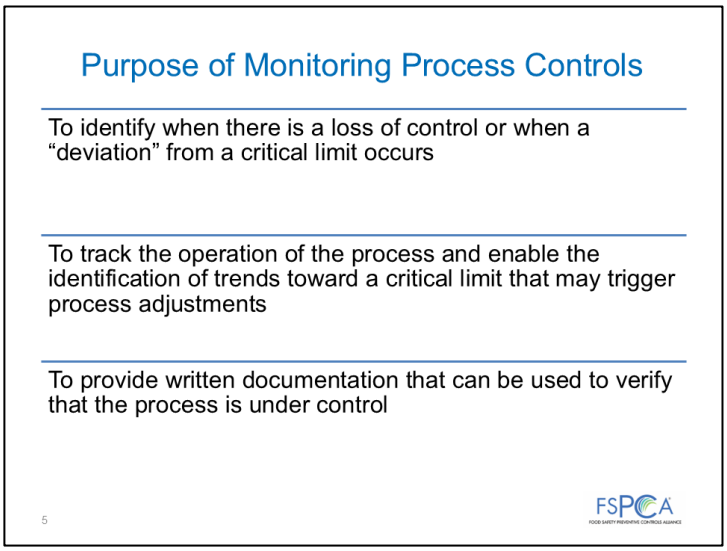
This section covers the definition of monitoring, as well as explaining why it is important. Considerations for designing a process control monitoring system are discussed, as well as different methods that can be used. Monitoring is a preventive controls management component that applies not only to process preventive controls, but also to allergen and sanitation preventive controls, as appropriate to the control and its role in the facility's food safety system.

Slide 4: Monitor Definition



Monitoring involves the selection of appropriate measurements or observations made at a specified frequency to assess whether control measures are operating as intended.

Slide 5: Purpose of Monitoring Process Controls

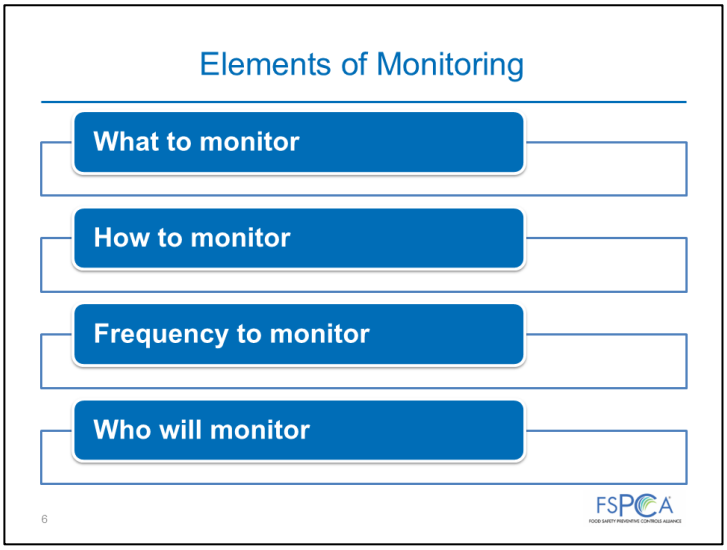


For process preventive controls, as well as for allergen and sanitation preventive controls, the purpose of monitoring is to monitor parameters to ensure the minimum or maximum values, such as a critical limit, are met, thus ensuring the food safety hazard has been controlled. For other preventive controls, monitoring could include the activity to be conducted consistent with a defined procedure.

Monitoring also provides data to document that products were produced over time in accordance with the Food Safety Plan. It is important that what is monitored is directly related to control of the hazard and monitoring procedures are specific for the parameter identified in the Food Safety Plan. When monitoring shows that the minimum or maximum values for a parameter are not met, a corrective action is needed. Corrective actions are discussed in more detail later in the chapter.

Monitoring also provides a written record that demonstrates the process is consistently under control. The regulation (21 CFR 117.145(c)(1)) requires monitoring documentation.

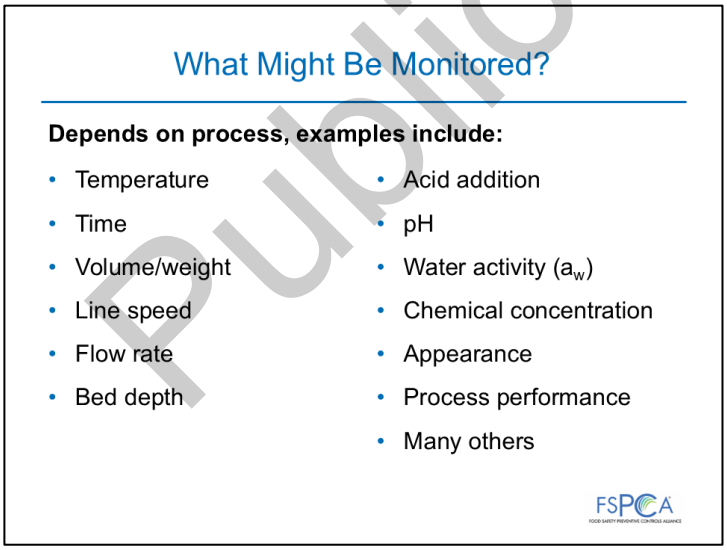
Slide 6: Elements of Monitoring



Monitoring requires four elements that need to be described in the Food Safety Plan:

1) What will be monitored (e.g., what measurements or observations)?
2) How will monitoring be done?
3) How often will monitoring be done (frequency)?
4) Who will do the monitoring?

Slide 7: What Might Be Monitored?

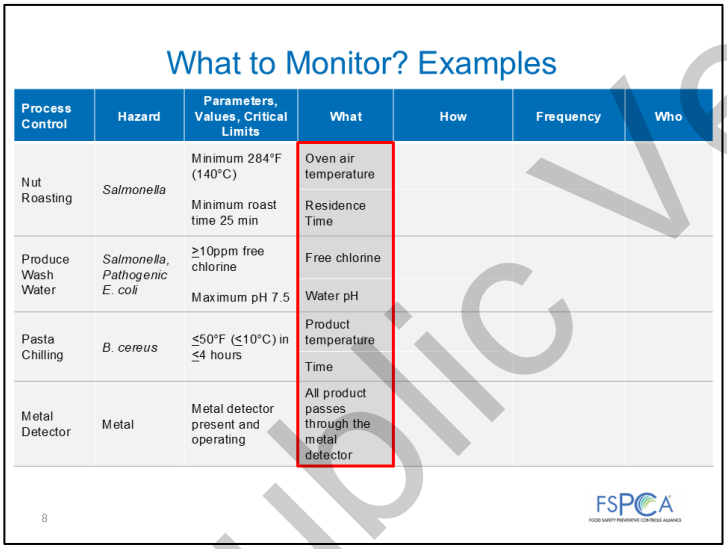


Monitoring process preventive controls depends on the nature of the control and its role in the facility's food safety system as well as the specific parameters. What will be monitored may involve measuring a characteristic of the product or process to

determine if a parameter or value, including a critical limit, is met. Examples of monitoring measurements could include:

- Cold-storage temperature when the refrigeration unit temperature is the parameter for which a critical limit has been established.
- Line speed and cooker temperature when cook time and temperature are parameters for which critical limits have been established.
- The pH resulting from adding an acidifying ingredient when pH is a parameter for which a critical limit has been established.
- Process parameters such as flow rate, bed depth or similar elements if these have been established during validation as critical to control the hazard.
- Observing that the metal detector is on when metal is a hazard of concern.
- Checking that the sizing bar that controls thickness by rejecting oversize units is in place if thickness is a parameter important for heat penetration.

Slide 8: What to Monitor? Examples



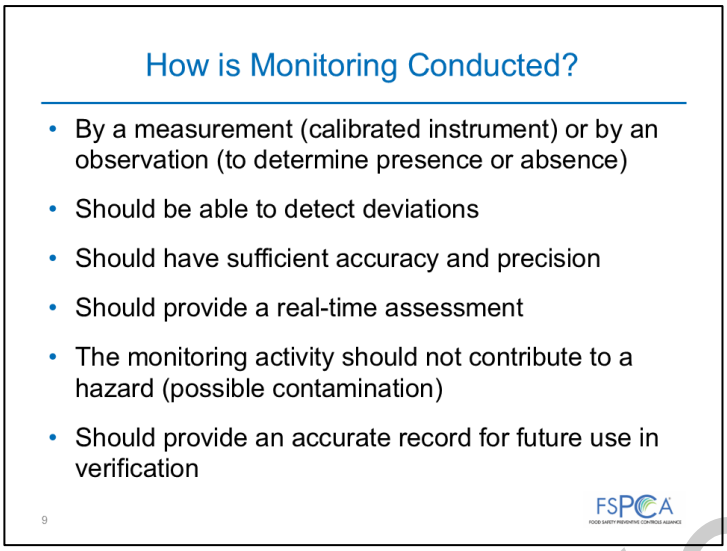
There are many different examples of what might be monitored. Examples highlight the extent of the various factors that need to be monitored based on the specific critical limit to ensure optimal management of the identified hazard.

For example, in the roasting and cooling examples, time and temperature are both monitored. For the cooking CCP, a cooking temperature for a given time is needed to ensure an effective reduction of any vegetative pathogen hazards. For cooling CCP, product must be cooled to a certain temperature in set amount of time to prevent the growth of any spore-forming pathogen hazards.

Similarly, the actual level of free chlorine in a produce wash water system is impacted by pH of the water, so both need to be monitored. Monitoring of the pasta chilling includes product temperature and time to prevent growth of *Bacillus cereus*.

Monitoring the metal detector relates to ensuring that all product passes through the detector.

Slide 9: How is Monitoring Conducted?



The concept of "real time" laboratory methods is evolving. Ideally it provides immediate results such as pH and a_w. Sometimes there is a delay of seconds to minutes. It could also include a longer time if the product remains in process or on hold until results are obtained for decision-making.

Tests that take longer such as microbiological tests, are not useful for real-time monitoring but can play a role through verification procedures. See Chapter 10: Verification and Recordkeeping.

Different methods can be used to monitor critical limits, depending on the nature of the control.

Using calibrated instruments to measure a process control parameter is an effective way to conduct monitoring. Examples of monitoring instruments could include thermometers, pH meters, water activity meters, data loggers, etc. A detailed discussion on calibration of monitoring instruments will occur in Chapter 10. Monitoring methods can also involve observing what is being monitored. When using visual observation as a parameter, it should be clear whether a critical limit has been achieved or not. In our E.G. Food Company's Teaching Example, a production employee observes that the metal detector is on and that the reject device is working.

The methods for monitoring should be sensitive enough to detect when a deviation has occurred to allow for the appropriate action to be taken, as product safety may be compromised. The methods should also account for accuracy, which is "how close a value is to its true value," and precision, which is "how repeatable is a measurement."

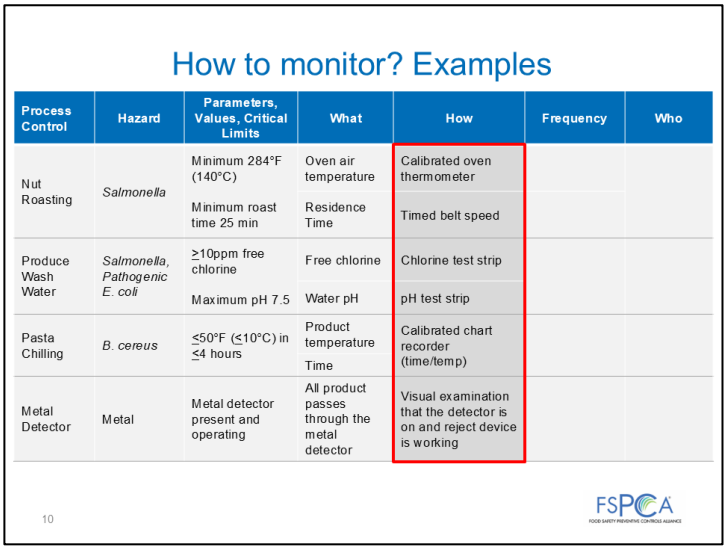
Methods for monitoring also need to reflect what conditions exist at the time the monitoring is done.

Monitoring should be designed to provide rapid, real-time results. Some laboratory methods are relatively quick and can be used for decision-making. For example, pH measurements are useful to monitor fermentation processes. Viscosity measurements may be useful for processes that require specific flow characteristics for an effective heat treatment. Brix measurements, moisture content, water activity, antimicrobial concentration measurements and other types of tests may have application in a Food Safety Plan. However, lengthy analytical tests, such as many microbiological tests, are not useful for real-time monitoring because critical limit failures should be detected quickly, and an appropriate corrective action instituted before product is shipped.

The process of monitoring should be designed so the safety of the product is not impacted. Monitoring methods should be planned so the methods do not introduce additional hazards. For example, collection of data from temperature probe or pH meter electrode which might be placed in a food product should be done in sanitary fashion such that no contaminants from hands or the devices lead to possible cross-contamination.

Monitoring activities result in the creation of a record and documentation that reflects what was measured to allow for verification that critical limits were consistently achieved.

Slide 10: How to monitor? Examples



How to monitor? Examples

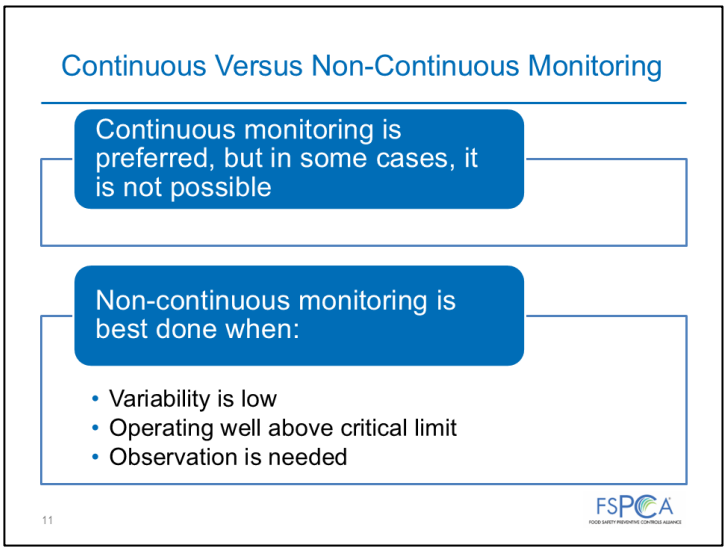
Process Control	Hazard	Parameters, Values, Critical Limits	What	How	Frequency	Who
Nut Roasting	*Salmonella*	Minimum 284°F (140°C)	Oven air temperature	Calibrated oven thermometer		
		Minimum roast time 25 min	Residence Time	Timed belt speed		
Produce Wash Water	*Salmonella, Pathogenic E. coli*	≥10ppm free chlorine	Free chlorine	Chlorine test strip		
		Maximum pH 7.5	Water pH	pH test strip		
Pasta Chilling	*B. cereus*	≤50°F (≤10°C) in ≤4 hours	Product temperature	Calibrated chart recorder (time/temp)		
			Time			
Metal Detector	Metal	Metal detector present and operating	All product passes through the metal detector	Visual examination that the detector is on and reject device is working		

10

FSPCA

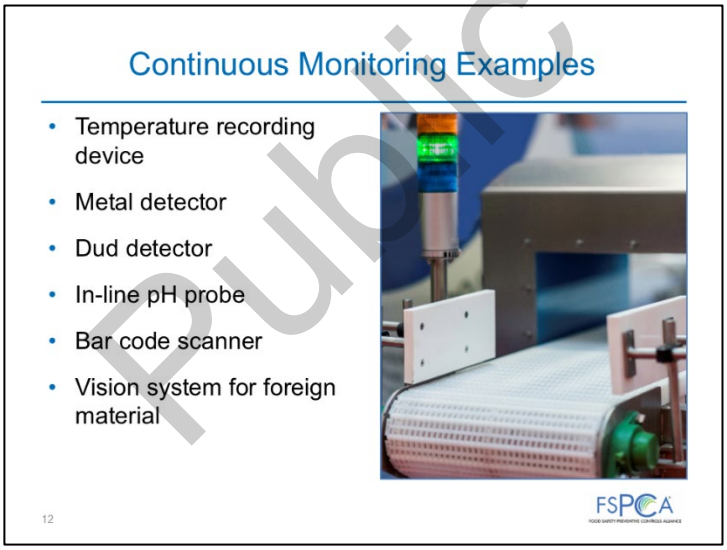
In this slide, more information is added to the previous examples demonstrating how monitoring is to be done. Monitoring activities must reflect each of the specific parameters, values, and critical limits. For example, when a critical limit that includes temperature and time, there needs to be a valid way to ensure that both elements are monitored and recorded.

Slide 11: Continuous Versus Non-Continuous Monitoring



When possible, continuous monitoring procedures should be used. Continuous monitoring is generally performed by an instrument that produces an uninterrupted, also called continuous, record. However, in some situations, non-continuous monitoring systems may be preferable due to low variability or when the process performs well above the critical limit. And in some situations, observation is needed because a continuous monitoring system may not be available or feasible.

Slide 12: Continuous Monitoring Examples



Another example of a continuous monitoring devices is a dud detector used in thermal processing. This is an apparatus for determining the condition of a top panel of a container or of a closure lid on a vacuum-packed container which indicates the vacuum or pressure condition within the container. Each can that passes through the detector is tested. Rejected cans do not have sufficient vacuum.

Image description: Metal detector used in a food processing plant.

Continuous monitoring is generally performed by an instrument that produces a continuous record. These records can be either affirmative records demonstrating temperature is controlled or "exception records" demonstrating loss of temperature control (See discussion below on exception records). When using continuous

monitoring, there should be a periodic check of the paper or electronic record of the continuous monitoring system to determine whether deviations from the control value have occurred. The length of time between checks by an individual directly affects the amount of rework or product loss that may occur when a critical limit deviation is found. The FDA Hazard Guide, Chapter 5 recommends the frequency of this check be done at least daily. Examples of continuous monitoring include:

The time and temperature data for a batch pasteurization process may be continuously monitored and recorded on a temperature-recording chart.

The temperature of a storage cooler may be "continuously" monitored and recorded by an instrument at a predetermined time interval.

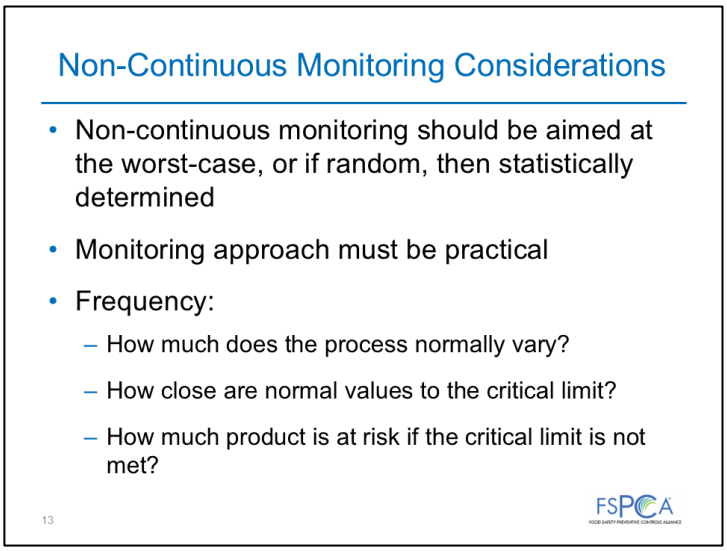
A functioning metal detector automatically monitors all product that passes through it.

Oxidation/reduction potential (ORP) is recorded continuously by a calibrated automated probe in a vegetable flume.

The proper functioning and automated paper or electronic records generated, if any, for each of these types of systems must be monitored or verified, as appropriate, by an individual on a periodic basis to document that the system is performing as specified in the Food Safety Plan. For example, the ORP readings may be read twice a shift by a line operator in addition to the continuous record.

An exception record is only generated when the continuous monitoring system identifies a parameter is not met. An example would be a notification on a cooler that only occurs when the temperature gets too warm. More information will be discussed in the recordkeeping section of Chapter 10.

Slide 13: Non-Continuous Monitoring Considerations



In many situations, continuous monitoring systems are not feasible because the technology does not exist, the cost is prohibitive, or other reasons. It is still necessary to establish a monitoring interval that ensures critical limits are met. Planning for the worst-case situation may help ensure monitoring intervals are effective. Alternately a randomized approach can be used. with statistical considerations incorporated to ensure the intervals consistency of meeting the critical limit.

The approach to monitoring must be practical so that the activity and frequency of monitoring are feasible and achievable (e.g., within the timeframe that's reasonable, accomplished by personnel, etc.).

The frequency of non-continuous monitoring, also referred to as periodic monitoring, could be influenced by historical information of the product and process at the facility. Questions that could help determine the frequency based on information include:

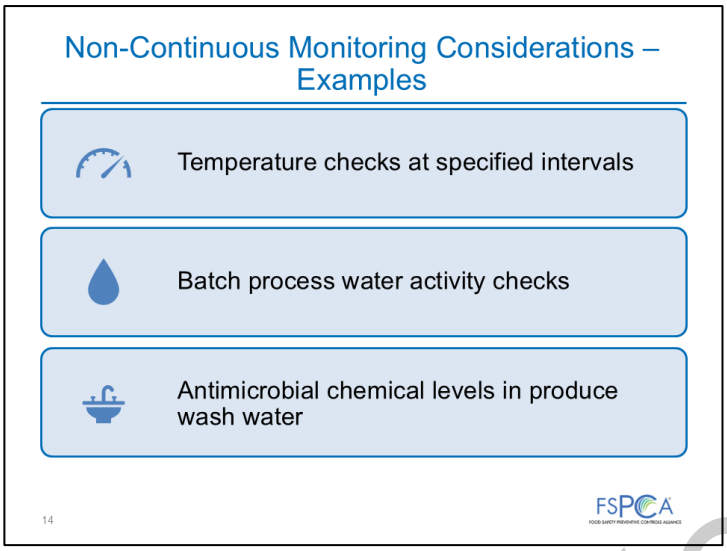
- How much does the process and the parameter normally vary (e.g., how consistent is the data)? If the monitoring data shows a great deal of variation in the parameter, the time between monitoring checks should be short.
- How close are the normal operating values to the critical limit? If the normal values are close to the critical limit, the time between monitoring checks should be short.
- How much of the product is at risk if the critical limit is exceeded (e.g. volume or product flow rate)? If a large amount of product would be impacted and cannot be reworked, for example, more frequent monitoring may be prudent.

Examples of non-continuous monitoring include:

- Temperature checks of batter on a breading line at specified intervals when a continuous monitoring system is not feasible.
- Water activity measurements for batch process operations.

- Antimicrobial chemical levels in a produce wash water flume system when automated monitoring systems are not available.

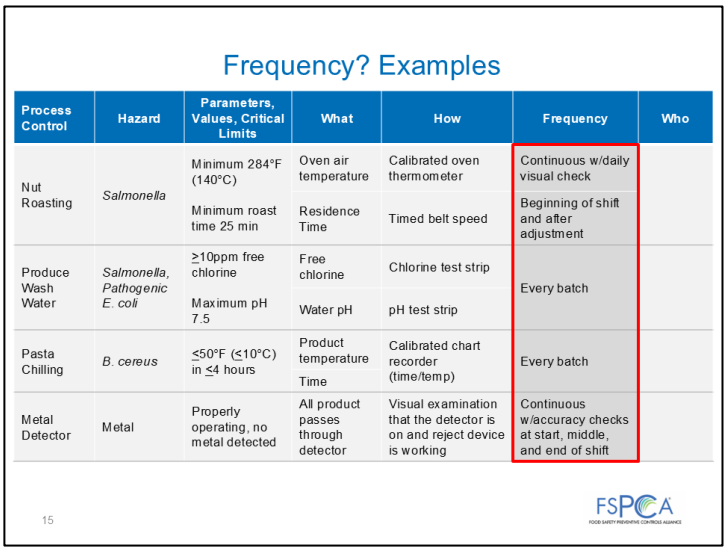
Slide 14: Non-Continuous Monitoring Considerations Examples



Examples of non-continuous monitoring frequency include:

- Temperature checks of batter on a breading line at specified time intervals if a continuous monitoring system is not feasible.
- Water activity measurements for batch process operations with recordings made on a per batch frequency.
- Antimicrobial chemical levels in a vegetable flume monitored at specific intervals through the production run when automated monitoring systems are not available.

Slide 15: Frequency? Examples



Frequency? Examples

Process Control	Hazard	Parameters, Values, Critical Limits	What	How	Frequency	Who
Nut Roasting	*Salmonella*	Minimum 284°F (140°C)	Oven air temperature	Calibrated oven thermometer	Continuous w/daily visual check	
		Minimum roast time 25 min	Residence Time	Timed belt speed	Beginning of shift and after adjustment	
Produce Wash Water	*Salmonella, Pathogenic E. coli*	≥10ppm free chlorine	Free chlorine	Chlorine test strip	Every batch	
		Maximum pH 7.5	Water pH	pH test strip		
Pasta Chilling	*B. cereus*	≤50°F (≤10°C) in ≤4 hours	Product temperature	Calibrated chart recorder (time/temp)	Every batch	
			Time			
Metal Detector	Metal	Properly operating, no metal detected	All product passes through detector	Visual examination that the detector is on and reject device is working	Continuous w/accuracy checks at start, middle, and end of shift	

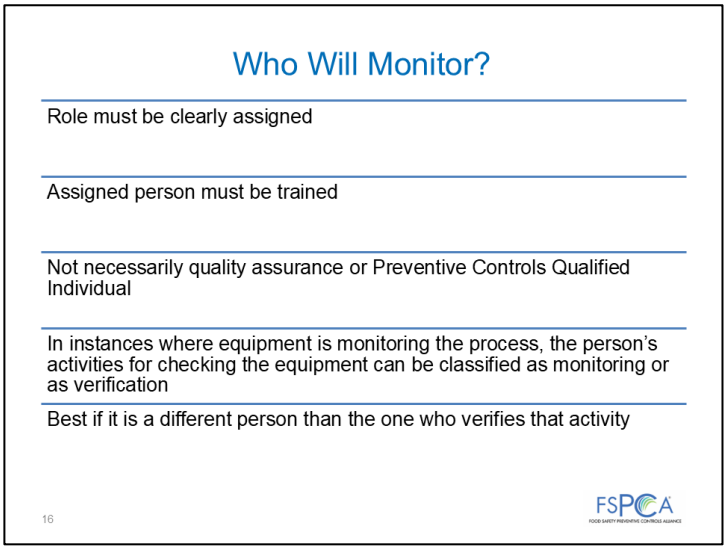
15

FSPCA

This chart shows the "frequency" for specific process controls. Note in the examples for roasting oven air temperature and the metal detector, monitoring is done continuously with a device then verified by a person who verifies nut roasting temperature meets limits and verifies the metal detector's proper operation by conducting accuracy checks.

On the roasting residence time, also described as period of time, the frequency for monitoring is the beginning of the shift and "After adjustment." This is to account for the fact that an operation might need to adjust the belt speed if the belt speed alters during the process. Typically, belt speed is set at the beginning of a shift and is not changed, but if conditions with machines or operations occur during the shift the belt speed might need to be adjusted as a result. This demonstrates tailoring the frequency of monitoring to the specific operation.

Slide 16: Who Will Monitor?



Monitoring personnel (qualified individuals) are not required to be "Preventive Controls Qualified Individuals" but must have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. See definition for "qualified individual" in 21 CFR 117.3

Individuals assigned to preventive controls monitoring activities must receive training appropriate for the tasks assigned. Individuals assigned may be:

- Line personnel
- Equipment operators
- Supervisors
- Maintenance personnel
- Quality assurance personnel

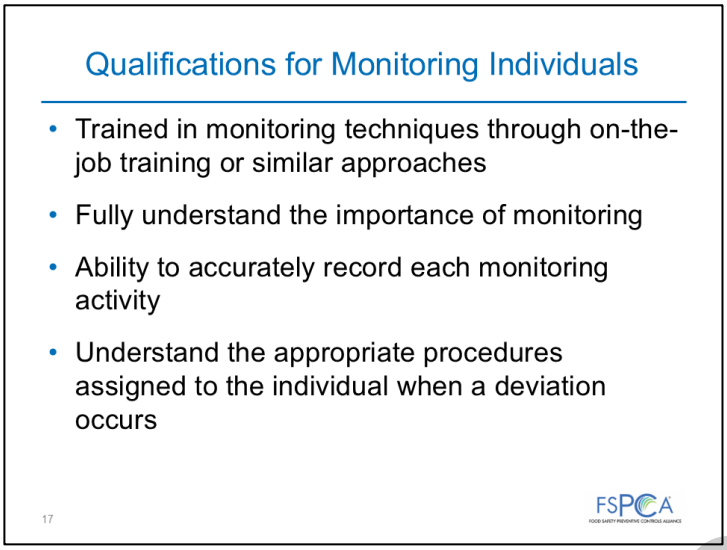
Note that monitoring does not need to be done by the Preventive Controls Qualified Individual or by quality assurance personnel. In fact, monitoring by line personnel and equipment operators can be advantageous since they are actively watching the product or equipment. Including production workers in food safety activities helps build a broad base of understanding and commitment to the Food Safety Plan.

The monitoring individual's duties should require that all deviations from critical limits be acted upon immediately and reported as necessary. Prompt actions ensure that process adjustments and corrective actions are made in a timely manner. As a reminder, rapid response when operating limits are not met can prevent critical limit deviations. All records and documents associated with preventive control (including CCP) monitoring, including corrective actions, must be signed or initialed by the person doing the activity and the date, and, where appropriate, the time of the activity recorded. A more detailed discussion of records occurs in Chapter 10.

Note that monitoring can also be done by automated equipment, with a review of these records by a person denoted as monitoring or verification. Sometimes verification and monitoring activities can appear to be the same thing. For example, a line operator may check the temperature of product at the end of the process and verify processing parameters of the cooker. Equally, the checking of the process parameters could be called the monitoring activity, and the product temperature check could be

designated the verification activity. In the end, what each is called is not as important than that both activities are conducted.

Slide 17: Qualifications for Monitoring Individuals

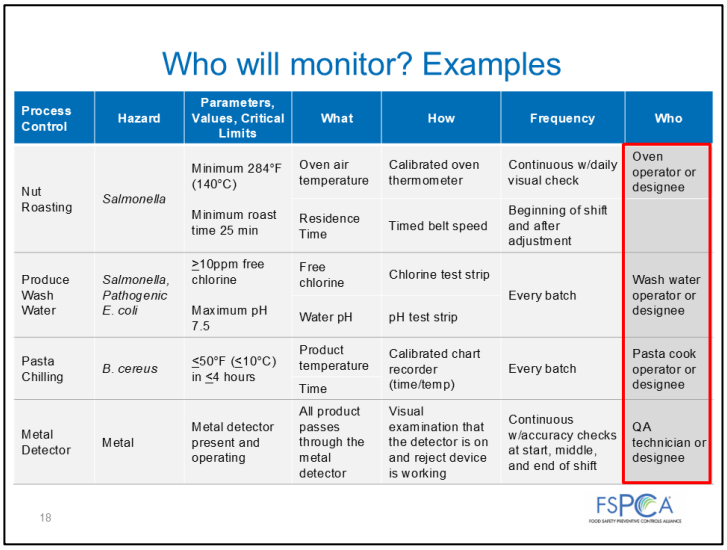


Personnel must be properly trained (become qualified) to conduct the monitoring activity for each determined process preventive control and then be able to accurately perform that task. Process control forms must specify "who" (i.e., the position of the employee), performs monitoring. The person performing this activity must be able to perform that task at the designated frequencies. For example, while this activity may be assigned to a supervisor, is that realistic for a typical operation at the facility? Supervisors are sometimes called away for other activities, such as accompanying an inspector during an inspection and in this case, it would make it difficult for that supervisor to perform the monitoring activities at the same time. If this is the case, it is preferable to identify and adequately train a designee, or a backup person, who can perform the monitoring activity when the primary assigned person is not available. This designee, or backup person, must also be properly trained in the monitoring activity.

An important part of the training of qualified individuals assigned to a monitoring activity is how to conduct any specified corrective actions that is assigned to their role. For example, a QA technician may be trained in monitoring activities at the cooking step. The individual can investigate cook deviations to determine cause, document findings, run calibration checks, etc., without direct involvement from supervisors. This person could even shut the line down if issues are identified and then inform supervisors for more in-depth investigations.

Individuals assigned to preventive controls monitoring activities must also receive food safety training on documentation associated with monitoring activities and corrective actions. Information on documenting monitoring activities is discussed in Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping.

Slide 18: Who will monitor? Examples



Who will monitor? Examples

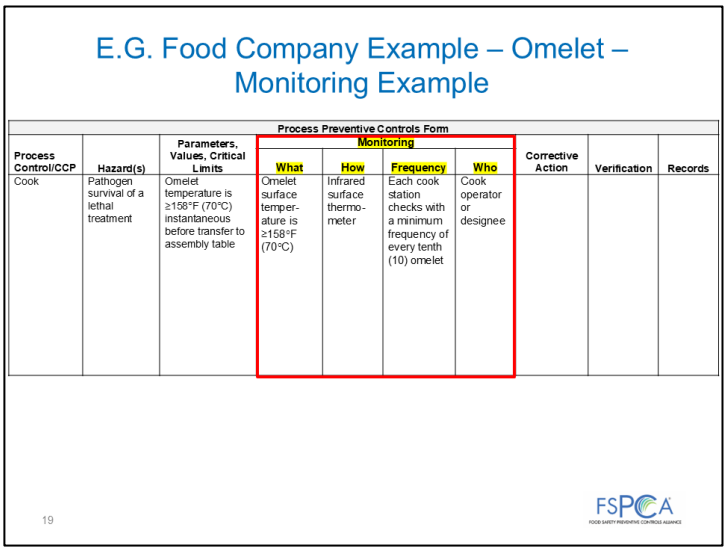
Process Control	Hazard	Parameters, Values, Critical Limits	What	How	Frequency	Who
Nut Roasting	*Salmonella*	Minimum 284°F (140°C)	Oven air temperature	Calibrated oven thermometer	Continuous w/daily visual check	Oven operator or designee
		Minimum roast time 25 min	Residence Time	Timed belt speed	Beginning of shift and after adjustment	
Produce Wash Water	*Salmonella, Pathogenic E. coli*	≥10ppm free chlorine	Free chlorine	Chlorine test strip	Every batch	Wash water operator or designee
		Maximum pH 7.5	Water pH	pH test strip		
Pasta Chilling	*B. cereus*	≤50°F (≤10°C) in ≤4 hours	Product temperature	Calibrated chart recorder (time/temp)	Every batch	Pasta cook operator or designee
			Time			
Metal Detector	Metal	Metal detector present and operating	All product passes through the metal detector	Visual examination that the detector is on and reject device is working	Continuous w/accuracy checks at start, middle, and end of shift	QA technician or designee

18

FSPCA

Building further on the previous examples, these examples of monitoring now include information about who is doing the monitoring. Note that a specific role of someone in the plant is named but there is also the option of a "designee" in the event that the named individual is not available to do the monitoring.

Slide 19: E.G. Food Company Example – Omelet – Monitoring Example



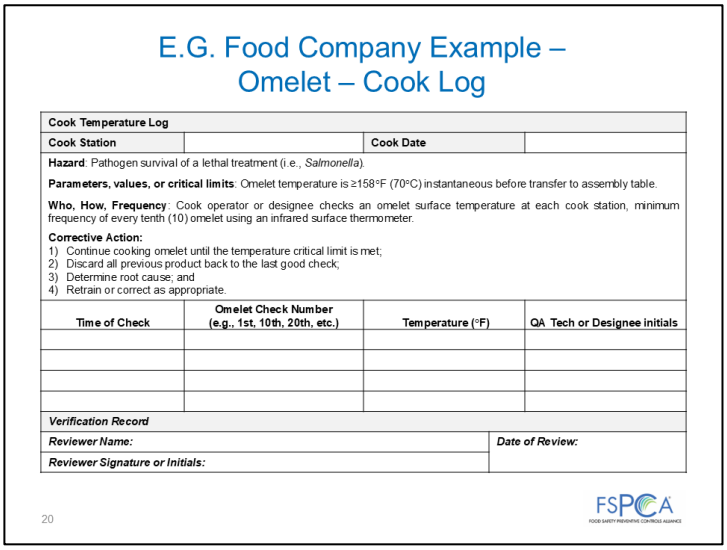
The E.G Food Company's Food Safety Team determined monitoring procedures for each of the two CCPs identified. The cook step is discussed here. Metal detection is available for review in Appendix 3.

As previously discussed, the critical limit for cooking the omelet was determined to be "Omelet surface temperature is ≥158°F (70°C) instantaneous before transfer to assembly/wrap table."

Several elements of monitoring are associated with this CCP:

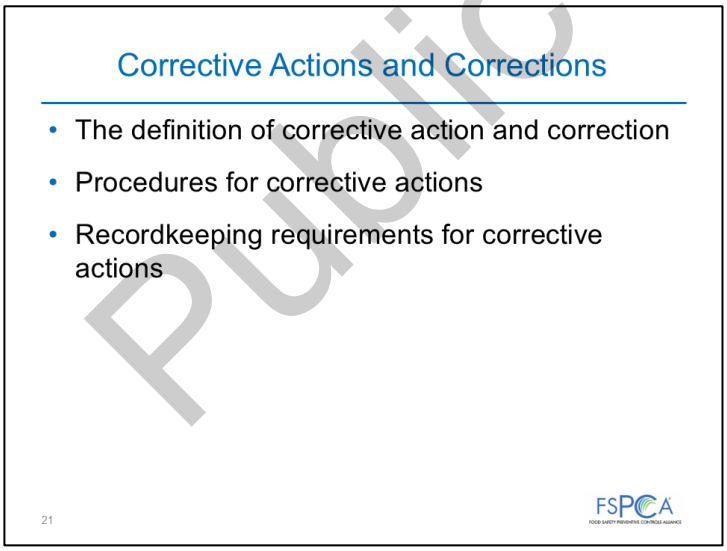
- Each omelet is cooked individually;
- **Who:** A cook operator or designee;
- **What:** Measures the Omelet surface temperature is ≥158°F (70°C);
- **How:** Infrared surface thermometer; and
- **When (or frequency):** Each cook station checks with a minimum frequency of every tenth (10) omelet, documented on the Cook Temperature Log.

Slide 20: E.G. Food Company Example – Omelet – Cook Log



An example of a monitoring record is illustrated above. It provides space to record the data observed during the monitoring activity. While not required, it also includes information from the process control form to ensure that the person who is doing the monitoring activity has the most current information and knows what to do. Recordkeeping requirements for monitoring are covered in Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping.

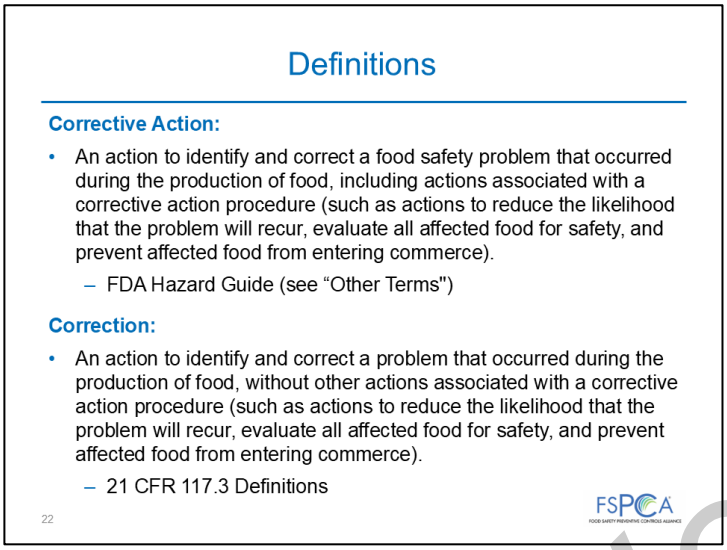
Slide 21: Corrective Actions and Corrections



When parameters, values, or critical limits being monitored are not met, corrective actions or corrections must be performed depending on the hazard and the nature of the preventive control. Requirements vary for process, food allergen, sanitation, and supply-chain program preventive controls. This section covers the definition of corrective action and corrections.

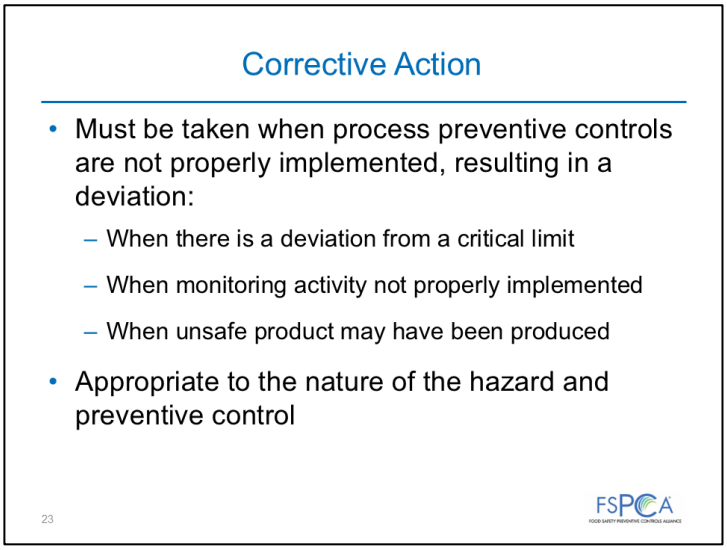
Deviations from process preventive controls frequently require corrective actions, thus corrective actions are addressed in this chapter, including basic information on recordkeeping.

Slide 22: Definitions



Corrective actions and corrections are preventive control management components. Corrective actions are procedures that must be taken if preventive controls are not properly implemented and involve documentation of the specific actions taken. Corrections apply when the facility acts in a timely manner to identify and correct a minor and isolated problem that does not directly impact product safety. The key item to note is that corrective actions are required if product is involved, whereas a correction can be taken if no product has been produced. An example of a situation where a correction is appropriate is where a food-contact surface was observed during monitoring as not properly cleaned, but production had not started and so no product was impacted. A correction for this situation would involve re-cleaning the surface prior to allowing production to begin. Many sanitation preventive control lapses can be effectively managed through use of corrections. Conversely, most process preventive control lapses require corrective action procedures, because in these cases, product is most likely affected.

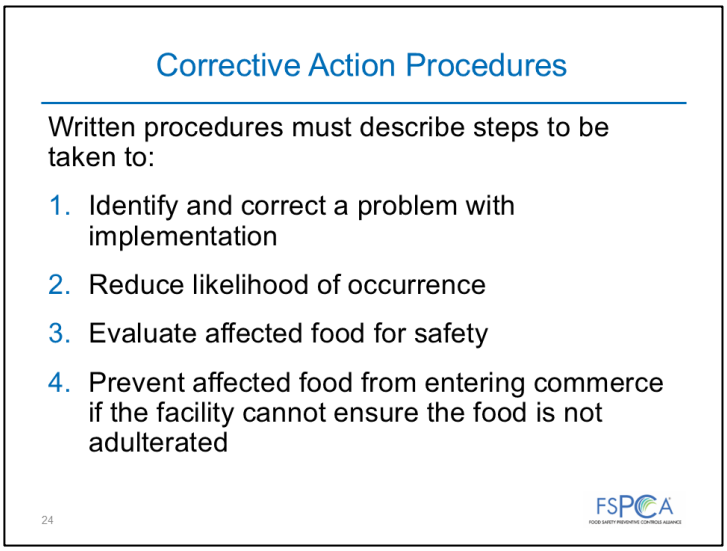
Slide 23: Corrective Action



Corrective actions must be taken when the process preventive control is not properly implemented. Clearly, a deviation from a critical limit will require a corrective action because unsafe product may have been produced. But a corrective action must also be taken when that monitoring activity has not been properly performed, for example, a thermometer used as part of the monitoring activity was not properly calibrated. Corrective action must be taken if it is determined that unsafe product has been produced. For example, product verification testing finds a pathogen in the product.

The corrective actions taken in these situations should be appropriate to the nature of the hazard and the preventive control. In the case of the thermometer out of calibration, if the thermometer was calibrated an hour ago, then only an hour of production may be suspect to corrective action. However, if the thermometer was last calibrated a day ago, then all the product produced from that point in time, where that thermometer was used, may be subject to corrective action.

Slide 24: Corrective Action Procedures



The corrective action procedures must fully describe the steps to be taken to address the preventive control issue. The first requirement of a corrective actions is to take appropriate action to identify and correct the problem with implementation of a preventive control. This could involve failure to meet a critical limit or a verification procedure indicating an issue. Corrective actions may also be required in response to certain verification procedures, such as detection of pathogens.

Process control must be restored in order to continue production. Empowerment of employees to stop the line when they observe a process deviation can enhance food safety and minimize the amount of product that will be subject to corrective action. This requires training and trust but can be very useful to encourage a food safety-minded culture. Predetermined corrective actions in the facility's Food Safety Plan provide a "how-to" guide that describes the steps to take when a preventive control is not properly implemented (e.g., a critical limit deviation occurs).

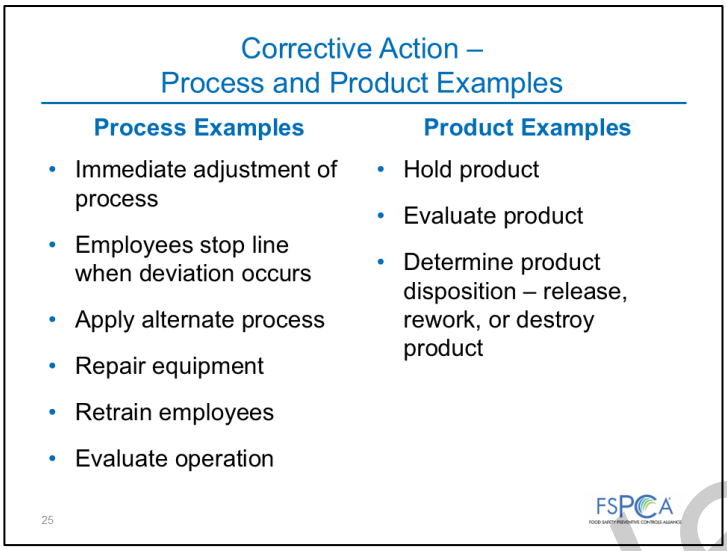
The second requirement of a corrective action is to take action to reduce the likelihood that the problem will recur, when appropriate. Root cause analysis may be useful to determine how to prevent recurrence. Corrective action examples may involve equipment repair, employee training and overall evaluation of the process for improvements. Sometimes this may be a simple readjustment of the process, but other times an alternate process is required. Alternate processes must be validated for effectiveness.

The third requirement of a corrective action is to evaluate all affected food for safety. Implicated product should be segregated and evaluated to determine if a food safety hazard exists. Product testing may or may not be required, depending on the nature of the hazard and the nature of the process.

The fourth requirement of a corrective action is to keep all affected food from entering into commerce unless the facility can ensure that the affected food is not adulterated per section 402 of the Federal Food Drug and Cosmetic Act or misbranded with respect to allergen labeling per section 403(w) of the Federal Food Drug and Cosmetic Act. It

is best to be cautious, but product destruction may not always be necessary. If a hazard exists, the affected product must be reworked or disposed in a manner to ensure it will not cause consumer illness.

Slide 25: Corrective Action – Process and Product Examples



There are two focuses for corrective actions: 1) The process; and 2) The product.

Examples of corrective actions for the process include those listed above and others. Sometimes an immediate adjustment of the process may be possible; however, for many processes, constant "tweaking" can increase process variation, which reduces certainty of the overall effectiveness of the process. If "immediate" adjustments are made frequently, a follow-up study on the impact on the safety of the product overall may be warranted.

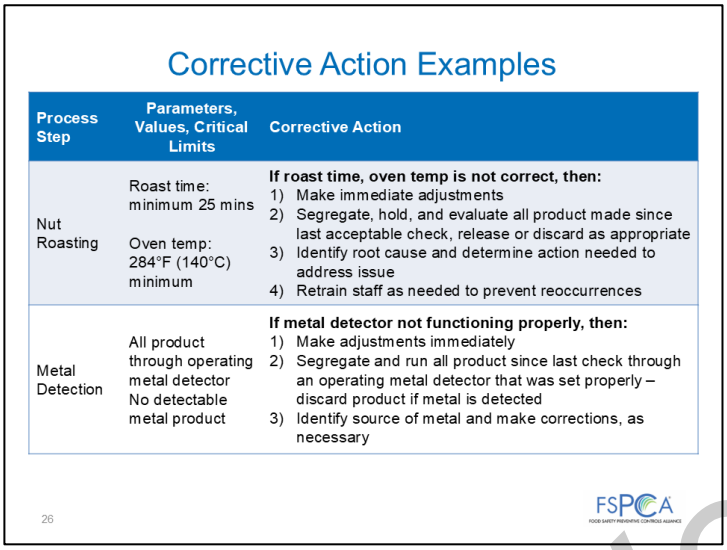
As previously mentioned, it may be appropriate for an employee to stop the line. This requires empowerment of the employee to take this action. In some situations, a validated alternate process may have been identified within the corrective action protocol and can be used to effectively control the hazard. If this is the case, such a process may be used as a corrective action. For example, if a temperature drops below the critical limit, an alternate process that involves longer time at a lower temperature may be applied, provided it has been validated.

Equipment repairs may be required, as well as retraining employees on proper procedures. In some situations, an evaluation of the entire operation may be required to ensure that the product is capable of being produced under conditions that are essential for product safety.

Examples of corrective action for the product include those listed above and others. Isolating and marking product as part of a product hold procedure is an important first action when a deviation occurs at a CCP where product has been produced. The product must be evaluated by those with authority and knowledge to determine the potential risk prior to making the decision to release, rework or destroy the product. This may include diverting the product to a different use where the hazard will be controlled

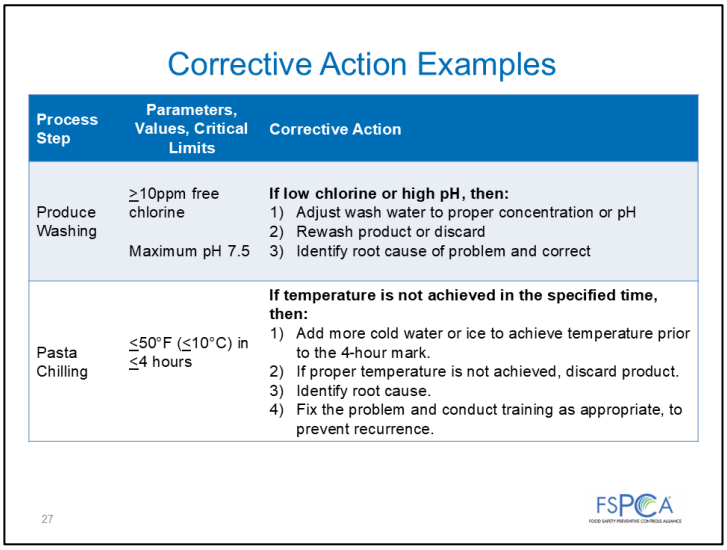
in some way or will not be an issue, such as use as an ingredient that will be further processed or diverting it to animal food. Appropriate regulations must always be followed in diversion situations.

Slide 26: Corrective Action Examples (1 of 2)



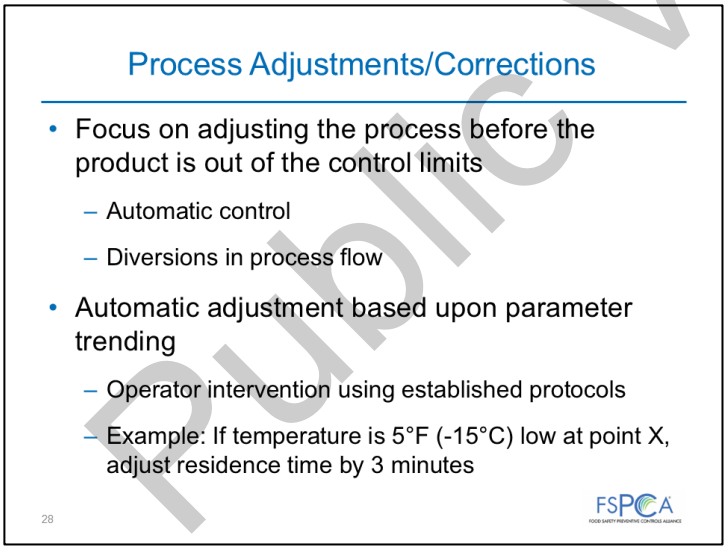
This slide presents some examples of corrective actions that could be applied to roasting and metal detection steps. Included are steps of process correction, root cause analysis, and actions taken against affected product.

Slide 27: Corrective Action Examples (2 of 2)



This slide presents some examples of corrective actions that could be applied to produce washing and pasta chilling steps. Included are steps of process correction, root cause analysis, and actions taken against affected product.

Slide 28: Process Adjustments/Corrections

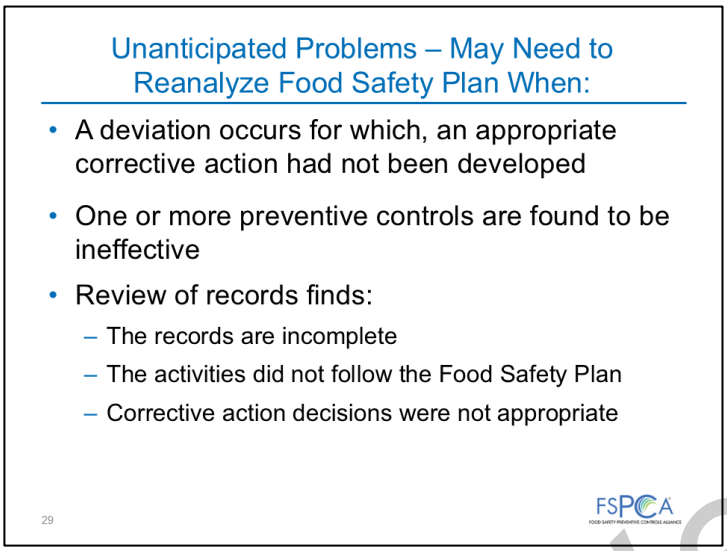


It is common industry practice to keep control of the process before a deviation at a critical limit occurs.

The process may be adjusted when the operating limit is not met, which avoids the critical limit not being met. These actions are called "process adjustments." A processor may use these adjustments to avoid loss of control resulting in a deviation and the need to take corrective action. This may require various adjustments that could be done via an automated process or could result in diverted product.

Spotting a trend toward loss of control early and allowing for the operator to act on and save product rework or, worse yet, product destruction.

Slide 29: Unanticipated Problems – May Need to Reanalyze Food Safety Plan When:



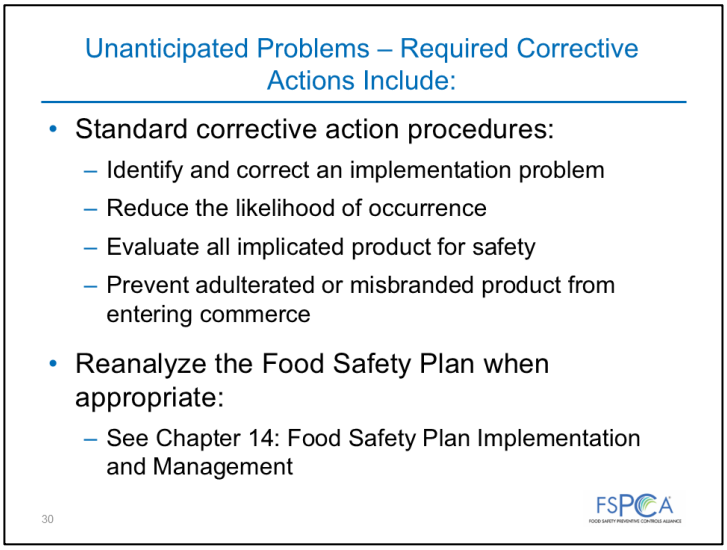
The Food Safety Plan may need to be reanalyzed in the event of unanticipated problems.

Although it may not be possible to anticipate all the deviations that could happen, corrective actions need to be taken and fully documented even when an unanticipated situation occurs. Circumstances considered to be "unanticipated problems" include:

- A preventive control is not properly implemented, and an adequate corrective action procedure for the situation has not been established;
- A preventive control, combination of preventive controls, or the Food Safety Plan as a whole is found to be ineffective; or
- A review of records finds that the records were not complete, activities were not conducted according to procedures in the Food Safety Plan, or appropriate decisions were not made for corrective actions.

In such cases, in addition to taking the corrective actions already described the Food Safety Plan or the applicable portion of the plan must be reanalyzed to determine whether modifications to the plan are required.

Slide 30: Unanticipated Problems – Required Corrective Actions Include:

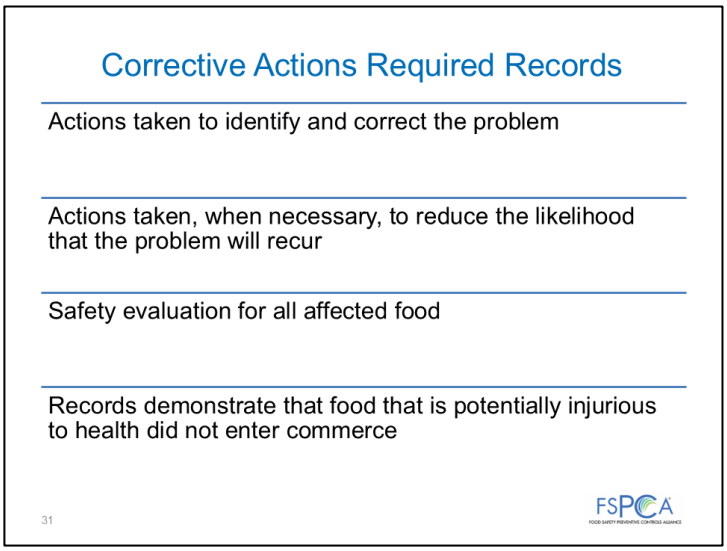


As with other product subject to a deviation, proper and thorough safety evaluation is necessary to determine the disposition of the affected product. Decisions related to the disposition of the affected product must be based on sound evidence. This evidence must be documented to support the decision. Like other corrective actions, if the product is rejected or destroyed, the processor needs to document that this action has been done.

Whether the corrective action was planned or unanticipated, a Preventive Controls Qualified Individual must conduct or oversee a review of records for the appropriateness of the corrective actions. Not every firm has an expert on staff who can evaluate the safety of products involved in a deviation. It may be necessary to identify additional resources including food safety experts to help with product safety evaluations.

When an unanticipated problem arises which results in corrective action, the facility must determine whether this issue impacts the Food Safety Plan. This is done as part of the reanalysis process which will be further discussed in Chapter 14.

Slide 31: Corrective Actions Required Records



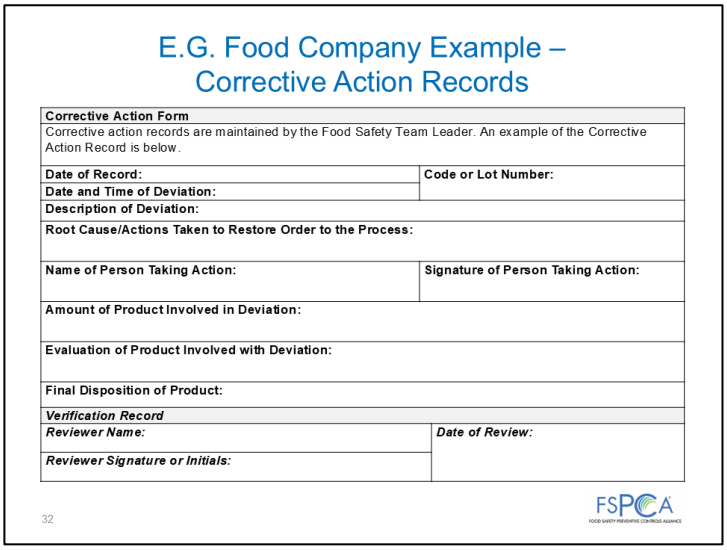
First, records must document the actions taken to identify and correct the problem with implementation of the preventive control in order to reduce the likelihood that the problem will recur. Included in this requirement is a record of the actions taken to fix the problem that caused the deviation and to restore process control. Evaluation of historical corrective action records can help to identify recurring problems. When critical limit deviations frequently reoccur, the process and the Food Safety Plan may need reanalysis and modification. A formal process may be needed to manage major changes that need to be implemented. This may include reissuing forms, retraining employees, phasing in changes, managing label information, informing suppliers and other tasks, depending on the nature of the change.

Second, records must document how the safety of all affected food product was evaluated. Specific technical expertise may be required for the safety evaluation, depending on the nature of the deviation.

Third, records must reflect that all affected product involved in a process deviation was prevented from entering commerce. The records include identifying the amount of product involved in the deviation, as well as records documenting the disposition of the product.

A root cause analysis could be performed to determine the underlying reasons for the problem and clarify steps to correct the cause (see Appendix 8: Definitions).

Slide 32: E.G. Food Company Example – Corrective Action Records



E.G. Food Company Example – Corrective Action Records

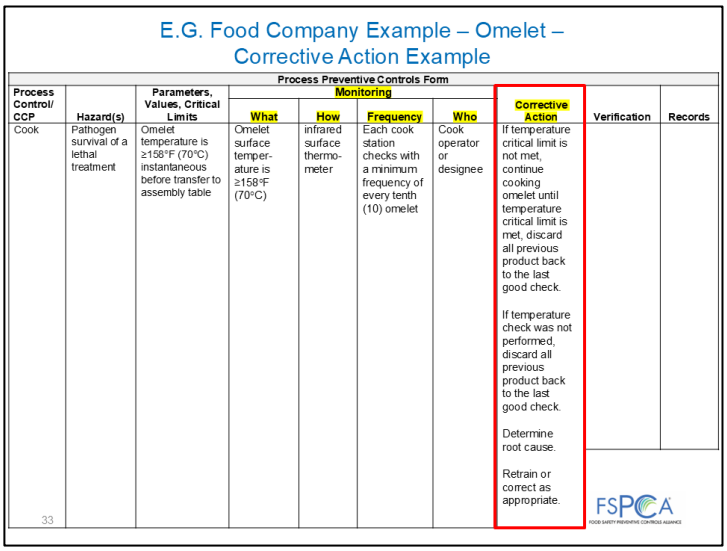
Corrective Action Form	
Corrective action records are maintained by the Food Safety Team Leader. An example of the Corrective Action Record is below.	
Date of Record:	Code or Lot Number:
Date and Time of Deviation:	
Description of Deviation:	
Root Cause/Actions Taken to Restore Order to the Process:	
Name of Person Taking Action:	Signature of Person Taking Action:
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Verification Record	
Reviewer Name:	*Date of Review:*
Reviewer Signature or Initials:	

32

FSPCA

An example of a Corrective Action Record form appears above. In some situations, corrective action activities may take place in a short period of time. In other, more complicated situations, corrective action activities may take place over several days, or possibly longer (e.g., capital improvement projects). It is important to have an accurate record of all corrective actions to protect both the public and the product. For example, failure to provide adequate rationale as to when the incident started and ended can lead to an expanded recall affecting a substantial amount of product.

Slide 33: E.G. Food Company Example – Omelet –Corrective Action Example



E.G. Food Company Example – Omelet – Corrective Action Example

Process Preventive Controls Form

Process Control/ CCP	Hazard(s)	Parameters, Values, Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Pathogen survival of a lethal treatment	Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table	Omelet surface temper-ature is ≥158°F (70°C)	infrared surface thermo-meter	Each cook station checks with a minimum frequency of every tenth (10) omelet	Cook operator or designee	If temperature critical limit is not met, continue cooking omelet until temperature critical limit is met, discard all previous product back to the last good check. If temperature check was not performed, discard all previous product back to the last good check. Determine root cause. Retrain or correct as appropriate.		

33

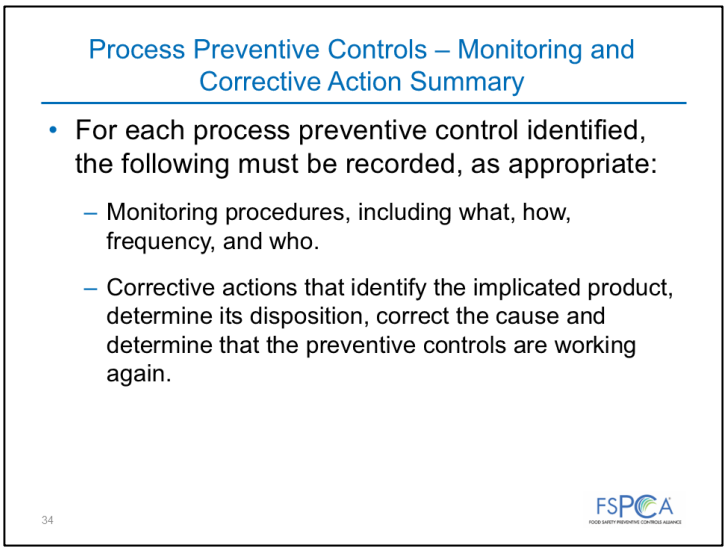
FSPCA

The Cook step for E.G. Food Company's plain, cheese, and cheese biscuit omelets has the following corrective action procedures:

1) If temperature critical limit is not met, continue cooking omelet until temperature critical limit is met, discard all previous product back to the last good check;
2) If temperature check was not performed, discard all previous product back to the last good check;
3) Determine root cause; and
4) Retrain or correct as appropriate.

This information is recorded in the Food Safety Plan.

Slide 34: Process Preventive Controls – Monitoring and Corrective Action Summary



Process preventive controls focus on process steps that are identified in the hazard analysis where control can be applied to significantly minimize or prevent hazards requiring a preventive control. The documented information includes monitoring procedures and corrective actions.

Monitoring procedures are required at each of these steps where a process preventive control is identified to ensure that the process is in control (e.g., that critical limits are met). Such procedures must specify what will be monitored, how the monitoring will be conducted, how often it will be done, and who will do it.

Corrective actions that describe what to do when critical limits are not met must also be determined and documented unless the facility is dealing with a minor and isolated problem that does not directly impact product safety.

Slide 35: Knowledge Check 1

Participants do NOT have this slide.

Slide 36: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

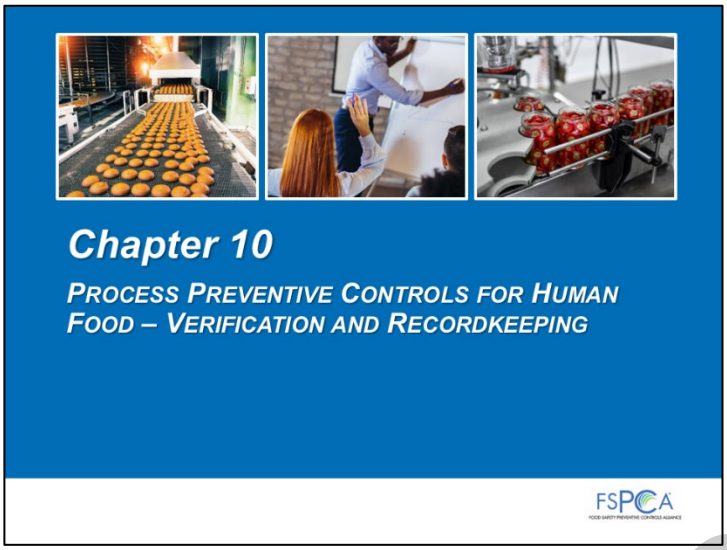
FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/media/100002/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 4: https://www.fda.gov/media/99572/download

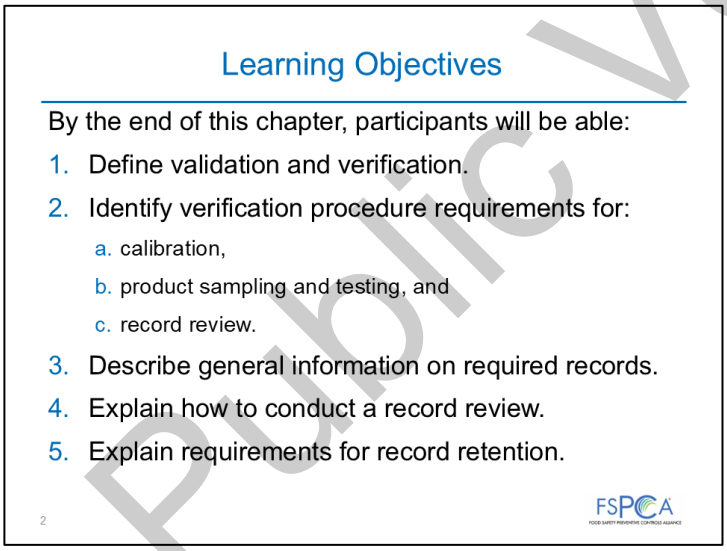
FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 5: https://www.fda.gov/media/99576/download

Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping

Slide 1: Chapter 10: Process Preventive Controls For Human Food – Verification and Recordkeeping



Slide 2: Learning Objectives

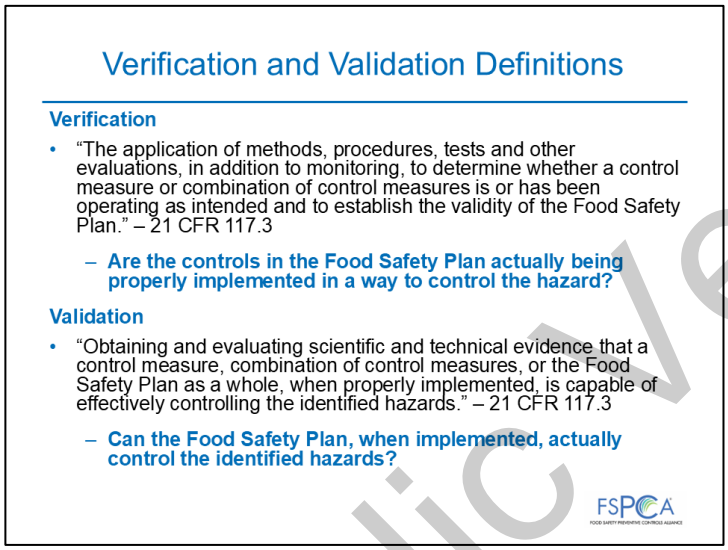


Verification is the next essential element of the Food Safety Plan. Verification is comprised of two elements—verification and validation (which is a verification activity). This chapter explores the concepts of verification and validation, and procedures associated with verification activities. Verification is an important component of process, allergen, sanitation, and supply-chain preventive controls. It confirms that the Food Safety Plan is operating as intended. Validation confirms the effectiveness of the Food Safety Plan in controlling food safety hazards. The purpose of verification is to provide a level of confidence that the Food Safety Plan is: 1) Based on valid scientific principles that are adequate to control the hazards associated with the

product and process; and 2) Being followed correctly during operations. A Preventive Controls Qualified Individual must perform or oversee validation and review of records verification activity. This chapter covers elements of verification, including validation, calibration, product sampling and testing, and record review. All of these are verification activities.

This chapter then covers recordkeeping. Accurate recordkeeping is an essential part of a successful preventive controls system. This chapter details the records that are required under the Preventive Controls for Human Food regulation, general information required on these records, examples of implementation records, requirements for reviewing records and recordkeeping logistics. Regulatory implications related to the use of computerized records are also addressed.

Slide 3: Verification and Validation Definitions



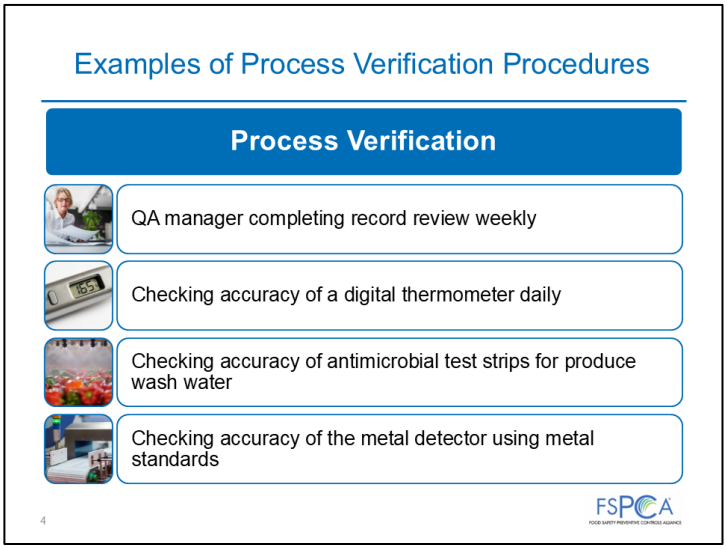
Sometimes verification and monitoring activities can appear to be the same thing. For example, an operator that is cleaning equipment may record observing the equipment is visibly clean as a monitoring activity prior to completing the task. A supervisor may then visually inspect the equipment as a verification activity, confirming that the equipment was cleaned. The important thing is that the activity is done and recorded, rather than what it is called.

Both verification and validation are essential for an effective Food Safety Plan. Routine verification is an ongoing process to provide evidence that the Food Safety Plan is being properly implemented and is operating as intended. Validation is demonstrating that following the plan will actually control the identified hazards.

Routine process verification are those methods, procedures, tests, and other forms of evaluation that provide additional evidence, in addition to monitoring, that the preventive controls are operating as intended. Verification essentially provides a double check of the system for additional assurance, rather than relying on just the monitoring activity.

Validation, which is a verification activity, is obtaining and evaluating the scientific and technical evidence that the preventive control will be able to control the specific hazard. Validation should be done before starting the food process and implementing the Food Safety Plan (initial validation) and whenever a change to a control measure or combination of control measures could impact whether the control measure(s) will effectively control the hazards.

Slide 4: Examples of Process Verification Procedures

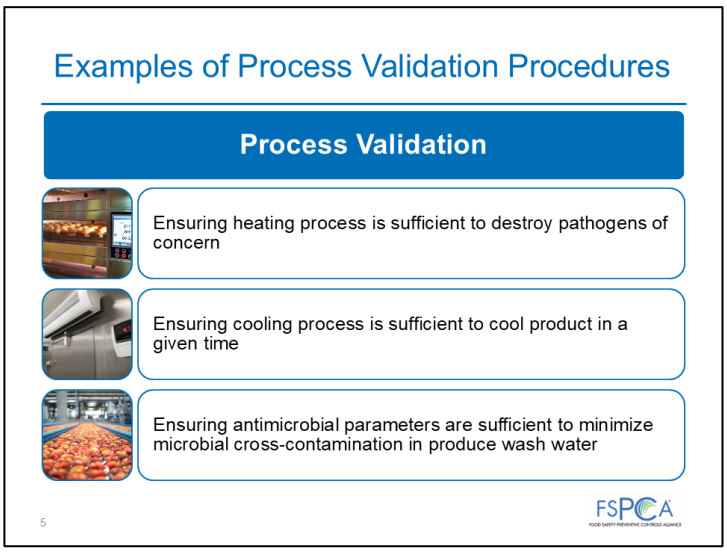


There are different types of verification activities that can be employed, depending upon the food, type of process, and other factors.

Verification procedures typically are ongoing procedures related to monitoring procedures and generally are scheduled activities, such as weekly record reviews (e.g., to show that the oven temperature was at or above the temperature needed to kill the pathogen of concern), a daily accuracy check of a digital thermometer or of antimicrobial test strips for produce wash water and checking the accuracy of the metal detector using metal standards.

Some verification activities are done less frequently, such as periodic in-process or finished product testing, internal audits, or third-party audits. This also includes a reanalysis of the Food Safety Plan when changes are made, or at a given frequency, to ensure the plan still reflects what happens at the facility.

Slide 5: Examples of Process Validation Procedures

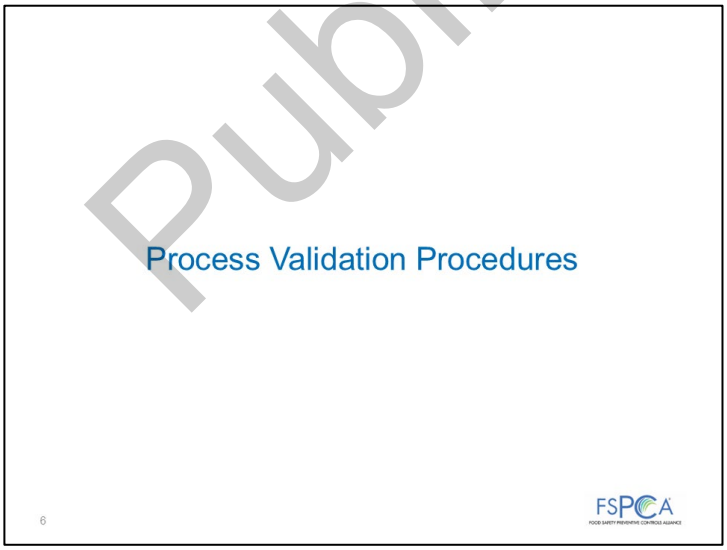


Validation, making sure that the process actually controls the hazard, is required for most process controls when hazards requiring a preventive control are identified.

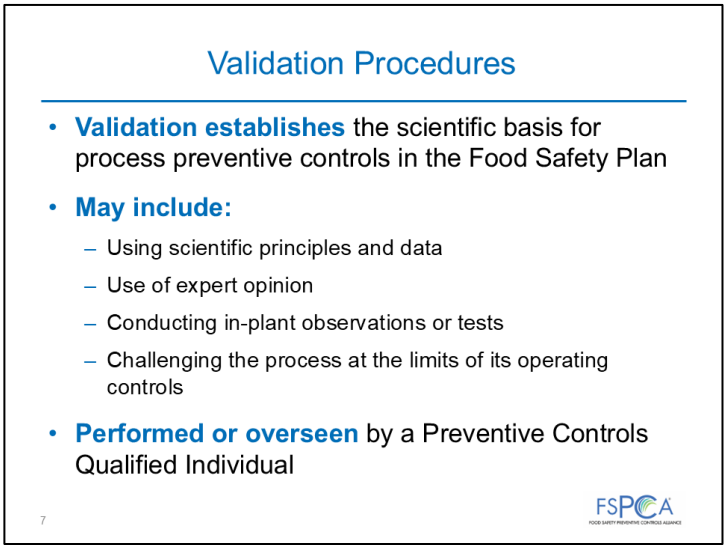
Examples of process preventive controls validation include ensuring that heating or cooling processes are sufficient to destroy pathogens in a given time frame and that the concentration an antimicrobial used in produce wash water will sufficiently minimize microbial cross-contamination in the water.

A formal validation activity may not have to be done by the facility if the parameter is based on a "safe harbor." A safe harbor is when there is a scientifically valid, established, and recognized food safety parameter for control of the hazard. Safe harbor is explained in and discussed in this chapter.

Slide 6: Process Validation Procedures



Slide 7: Validation Procedures



Validation – Does it actually control the hazard?

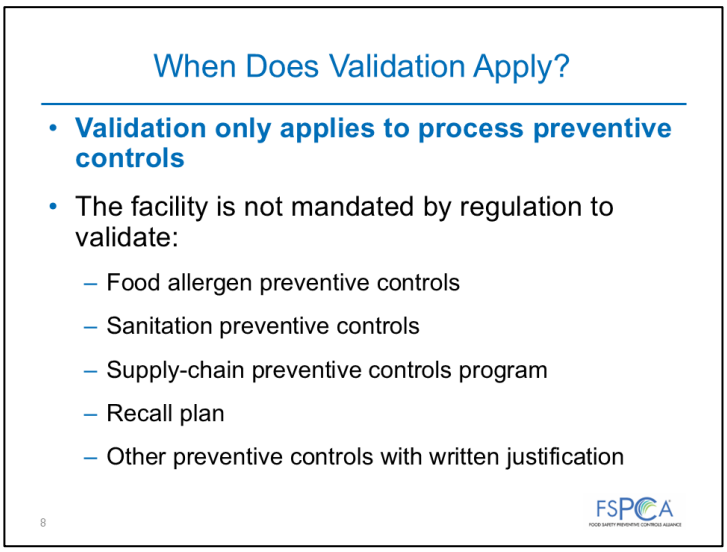
Documentation is needed to demonstrate that procedures in place actually control the hazard.

The purpose of validation is to provide objective evidence that process preventive controls have a scientific basis and represent a valid approach to controlling the hazards associated with a specific product and process. This includes demonstrating that the operational equipment can perform the control as designed and that the design parameters will control the hazard requiring a preventive control. Strategies that can be used to validate the Food Safety Plan include:

- Using scientific principles and data from the literature;
- Relying on expert opinion;
- Conducting in-plant observations or tests at the limits of its operating controls;
- Using mathematical models; and
- Incorporating regulatory guidelines.

Because of the scientific concepts involved in validation, this element of preventive controls must be performed or overseen by a Preventive Controls Qualified Individual. This person does not need to be an employee of the company.

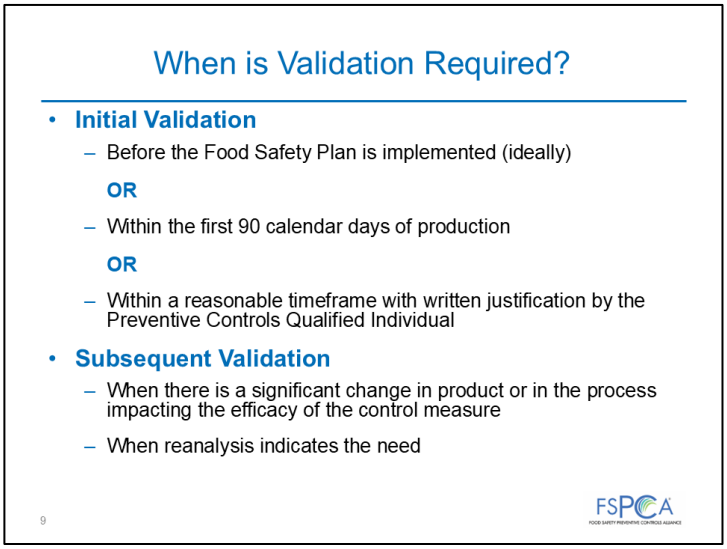
Slide 8: When Does Validation Apply?



The Preventive Controls for Human Food regulation specifies that validation is only required for process preventive controls. The regulation does not mandate validation of food allergen preventive controls, sanitation preventive controls, the supply-chain program, or the recall plan. However, validating some of these other preventive controls may be beneficial, although not specifically required by the regulation. For example, product recalls have been associated with allergen cross-contact in products, so it may be worth considering the validation of cleaning procedures for difficult-to-clean equipment to assure that the cleaning procedures are effective in removing allergen residues, thereby preventing cross-contact.

For other preventive controls, written justification that validation is not applicable to a preventive control may be prepared by the Preventive Controls Qualified Individual. This may be based on factors such as the nature of the hazard, the nature of the preventive control, and the preventive control's role in the food safety system (21 CFR 117.160(c)(5)).

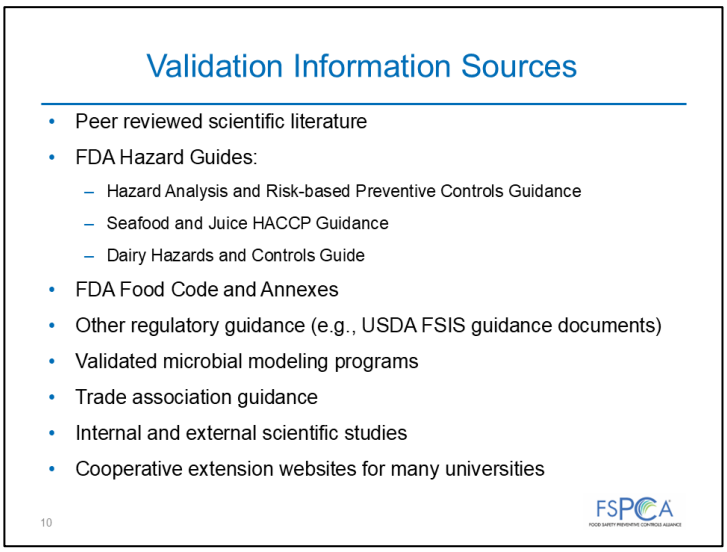
Slide 9: When is Validation Required?



Ideally, an initial validation of process preventive controls should occur before the food process begins. This may not be possible for specific aspects of validation such as cases where process variation must be evaluated. Hence, continued validation activities to assess process capability may be necessary after the process begins. The Preventive Controls for Human Food regulation requires that validation of process preventive control be completed within the first 90 calendar days of production or within a reasonable timeframe provided that a Preventive Controls Qualified Individual overseeing the validation prepares a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins. Processors may want to hold product that is produced before validation data analyses are complete to ensure that the process control is effective in controlling identified hazards.

Revalidation may be required if the process or product is changed in a way that may impact the effectiveness of the process. Reanalysis, as discussed later in the chapter, may also demonstrate the need for revalidation.

Slide 10: Validation Information Sources

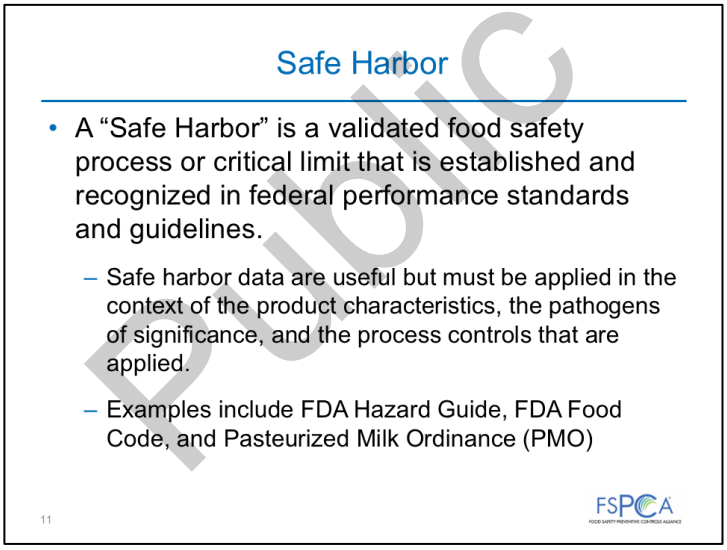


Firms are responsible for confirming the applicability of this information to their specific situation.

There are many sources of information that can be used for process preventive control validation.

It is important that the source of such information be credible and accurate, so reliance on peer-reviewed literature as well as guidance from regulatory agencies is a common practice. Additionally, trade associations and cooperative extension resources from land-grant universities can be helpful.

Slide 11: Safe Harbor



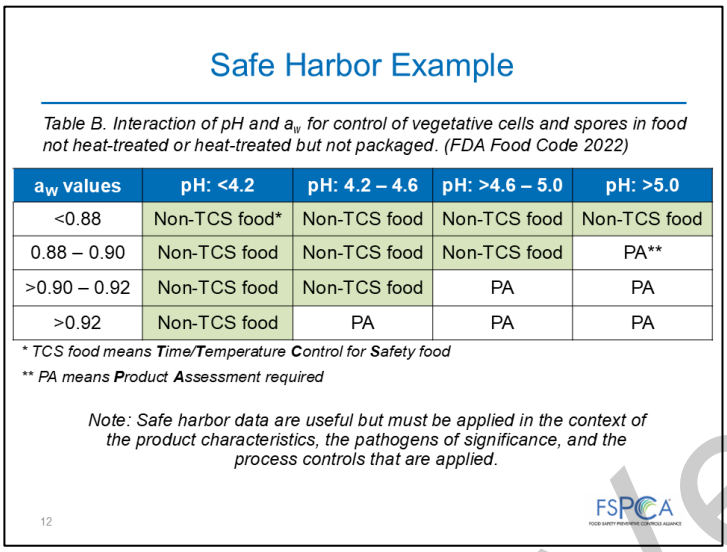
A "safe harbor" critical limit of food process is a scientifically valid, established, and recognized food safety control. In most cases safe harbors are published in federal performance standards, guidelines, or regulations by regulatory authorities such as the FDA or the USDA- FSIS. Other useful safe harbors that can be used to support critical limits or safe food processes include:

- The FDA Food Code;

- The Pasteurized Milk Ordinance (PMO); and
- The Almond Board of California, Nut Processing Guide.

See Additional Reading, Resources, and References at the end of the chapter for links to the above resources.

Slide 12: Safe Harbor Example



Safe Harbor Example

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged. (FDA Food Code 2022)

a_W values	pH: <4.2	pH: 4.2 – 4.6	pH: >4.6 – 5.0	pH: >5.0
<0.88	Non-TCS food*	Non-TCS food	Non-TCS food	Non-TCS food
0.88 – 0.90	Non-TCS food	Non-TCS food	Non-TCS food	PA**
>0.90 – 0.92	Non-TCS food	Non-TCS food	PA	PA
>0.92	Non-TCS food	PA	PA	PA

** TCS food means **T**ime/**T**emperature **C**ontrol for **S**afety food*

*** PA means **P**roduct **A**ssessment required*

Note: Safe harbor data are useful but must be applied in the context of the product characteristics, the pathogens of significance, and the process controls that are applied.

12

FSPCA

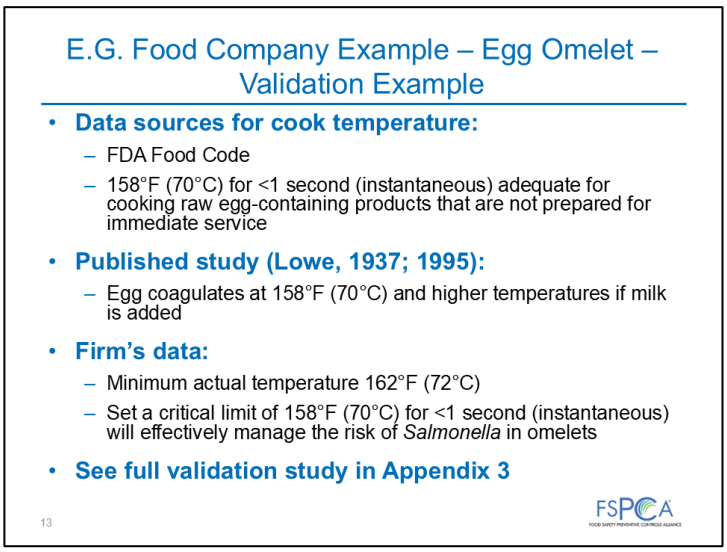
The Institute of Food Technologies (IFT) 2001 report also provides similar information for products that are heat treated and in which only spores must be controlled.

An example of the type of information that may be used to substantiate validation activities is the Slide 12 table sourced from an Institute of Food Technologists report commissioned by FDA (IFT, 2001). This information is also in the FDA Food Code. An accepted data source such as this is sometimes called a "safe harbor." The IFT table is based on a scientific evaluation of the potential for growth of or toxin formation by foodborne pathogens under otherwise ideal conditions. Products with a pH of <4.2 or a water activity (a_W) < 0.88 are not reasonably likely to support foodborne pathogen growth even when products are held at optimum growth temperatures. Various combinations of pH and a_W may also inhibit growth, but combinations, such as a pH >5.0 and a_W >0.92 require further study to preclude pathogen outgrowth, according to the table above.

Safe harbor data are useful but must be applied in the context of the product characteristics, the pathogens of significance and the process controls that are applied. A food establishment could use this table to support their conclusion that pathogen growth in their product is not likely if the product pH and a_W combination falls in the "No growth" area of the table. For some products, the pH and a_W parameters may be preventive controls that would require documentation (e.g., a formulated product). In others where this is a natural characteristic of the product (e.g., salt and sugar have a natural low water activity; vinegar has a naturally low pH), management as a process preventive control is not necessary.

It is also worth noting that in some cases where the product pH and a_W combinations do not support the growth of a pathogen, but the pathogen may still stay viable, should it contaminate the product, and may still cause food safety issues to the product.

Slide 13: E.G. Food Company Example – Egg Omelet – Validation Example



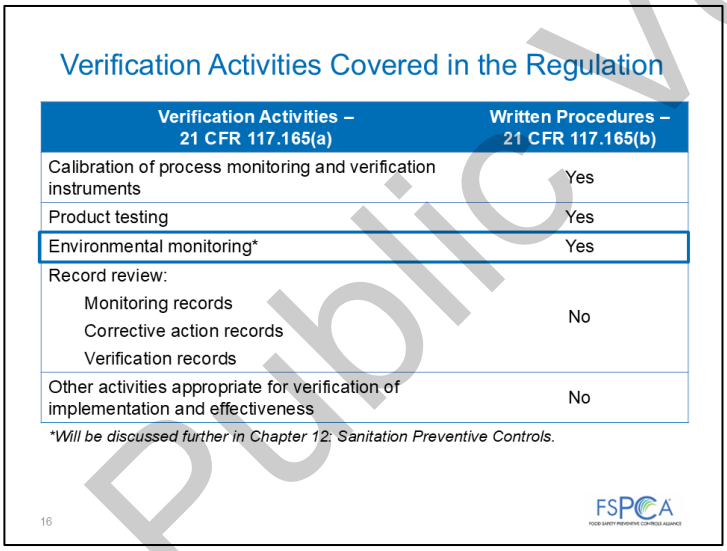
The E.G. Food Company cooks its omelets to a temperature of >160°F (71°C). This is an established operating limit for quality reasons because the omelet batter must be congealed, or set, in order to transfer it to the Assemble/Wrap table where the omelet is folded by hand and placed into a tray. The company worked with a consulting food safety expert to perform a validation study for its cooking procedure. The consultant conducted studies which showed the temperature of the omelet was always above 158°F (70°C), as measured using an infrared thermometer, when the omelet batter was congealed. The consultant wrote a report, which is included in the Food Safety Plan Teaching Example (see Appendix 3).

Slide 14: Process Verification Activities

Slide 15: Verification Activities

Verification provides evidence to demonstrate that the Food Safety Plan is working and being implemented as written. Several types of verification activities may be necessary for each preventive control to ensure that the procedures used are effective.

Slide 16: Verification Activities Covered in the Regulation

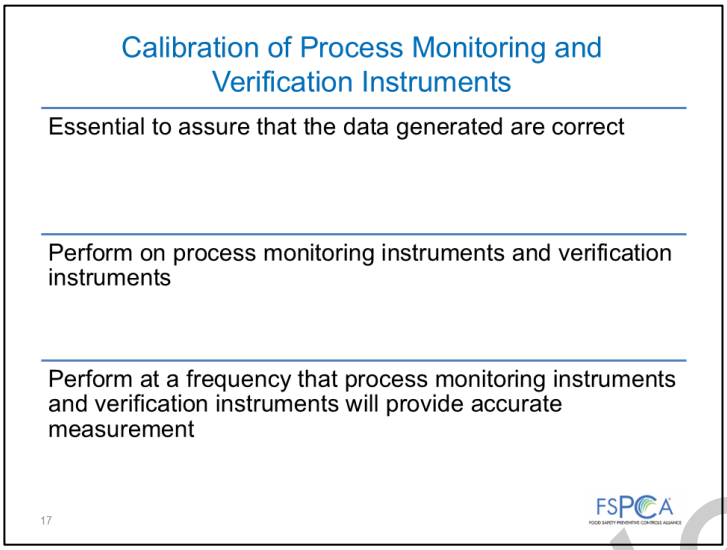


Ongoing verification activities such as calibration of process monitoring instruments and verification instruments to ensure their accuracy, and periodic in-process and finished product testing to verify process control, are important to show that the process preventive control is effective. Environmental monitoring is another verification activity to demonstrate that sanitation preventive controls are effective in facilities that produce ready-to-eat food that is exposed to the environment. This will be discussed further in Chapter 12: Sanitation Preventive Controls.

Supervisory review of monitoring, corrective action, and verification (e.g., calibration and product testing), records is another type of verification used to demonstrate that

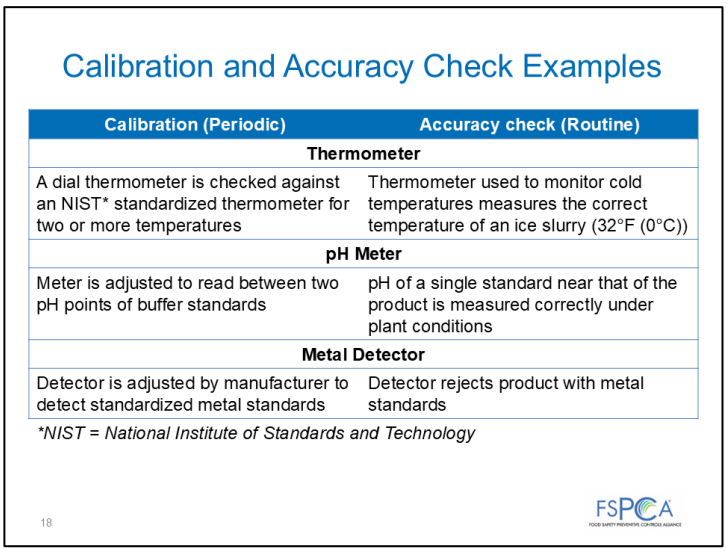
these elements of the Food Safety Plan are being implemented as intended. Verification of supply-chain programs will be discussed in Chapter 13: Supply-Chain Preventive Controls.

Slide 17: Calibration of Process Monitoring and Verification Instruments



Routine accuracy checks and periodic calibration of process monitoring instruments and verification instruments are verification activities used to ensure that the measurements taken by these instruments are accurate and reliable. Accuracy checks and calibration are fundamental to the successful implementation and operation of the Food Safety Plan. If process monitoring instruments and verification instruments do not provide accurate measurements, then monitoring results are unreliable. If a process monitoring instrument or verification instrument is found to be out of calibration, a process preventive control should be considered "out of control" since the last documented acceptable accuracy check and calibration of that instrument. Corrective action should be taken to evaluate the safety of the identified product produced out of control and determine the appropriate disposition of the product (see Chapter 9: Process Controls, Corrective Action section).

Slide 18: Calibration and Accuracy Check Examples



Calibration and Accuracy Check Examples

Calibration (Periodic)	Accuracy check (Routine)
Thermometer	
A dial thermometer is checked against an NIST* standardized thermometer for two or more temperatures	Thermometer used to monitor cold temperatures measures the correct temperature of an ice slurry (32°F (0°C))
pH Meter	
Meter is adjusted to read between two pH points of buffer standards	pH of a single standard near that of the product is measured correctly under plant conditions
Metal Detector	
Detector is adjusted by manufacturer to detect standardized metal standards	Detector rejects product with metal standards

**NIST = National Institute of Standards and Technology*

18

FSPCA

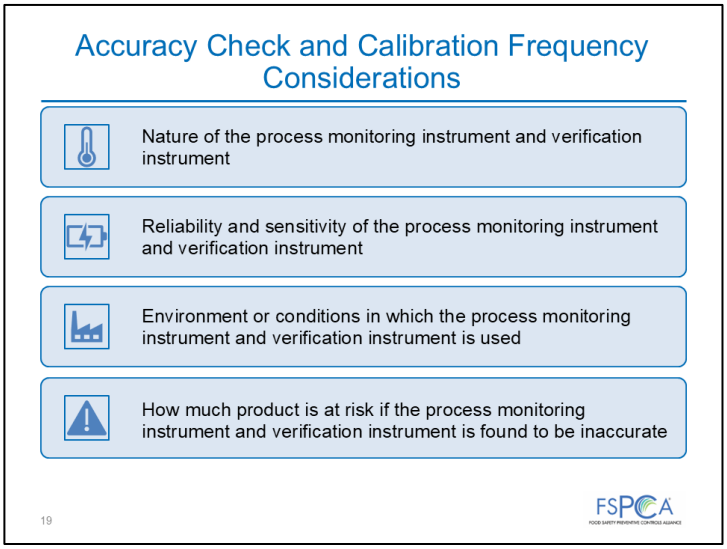
Calibration and accuracy checks are different but related concepts. Ideally a process monitoring instrument used for process control monitoring is both accurate (correct or true), and precise (result is repeatable or reproducible).

The accuracy and precision of a process monitoring instrument, or a verification instrument is usually established by comparing the instrument against a traceable reference standard. Accuracy checks determine if the instrument is reading a true or correct value at a single point. Routine accuracy checks of a thermometer used to measure cold temperatures could involve immersing the probe in an ice-slurry to determine if the thermometer measures a temperature of 32°F (0°C). Boiling water could be used for a thermometer used to measure hot temperatures. Because the boiling point of water varies with altitude, the specific temperature needs to be determined.

Calibration involves determining that the value of multiple measurements from a specific instrument are, in fact, correct, by comparison to a known calibrated instrument or by comparison with two known standards. For example, a thermometer could be calibrated by comparing it to a National Institute of Standards (NIST) traceable thermometer at two different temperatures within the range the instrument will be used. The two temperatures should be above and below the range.

Calibration is typically done less frequently than accuracy checks. Examples of calibration activities and accuracy checks are presented in the slide above.

Slide 19: Accuracy Check and Calibration Frequency Considerations



See Flores & Boyle (2000) in Additional Reading, Resources, and References at the end of the chapter for a reference on thermometer calibration, including forms.

It is important to realize that the accuracy of process monitoring instruments and verification instruments can change. Therefore, it is important to conduct routine accuracy, and periodic calibration checks to assure safety and to minimize the need to detain and evaluate the product.

A number of factors should be considered when determining the frequency of these activities for process monitoring instrument or verification instrument. The design of the process monitoring instrument or verification instrument must ensure that the instrument is capable of making accurate measurements when used within the expected environmental condition over some reasonable period of time. Calibration frequency depends on the type of instrument used, its condition and past performance, as well as the operating environment in which it will be used. For example, some instruments are affected by temperature or humidity.

The reliability and sensitivity of the process monitoring instrument and verification instrument should also be considered when determining the frequency of accuracy checks and calibration. Consistent temperature variations away from the actual value, also referred to as drift, found during accuracy checks or calibrations of an instrument may indicate that more frequent calibration is needed. Drift may also indicate the instrument needs to be replaced, perhaps with a more durable instrument.

Additionally, the amount of product that could be produced and considered out of control if an accuracy or calibration check indicated that the process monitoring instrument was not functioning properly should be considered.

One of the most frequently used process monitoring instruments and verification instruments for food products is a thermometer. Some factors to consider when determining the frequency for thermometer accuracy checks and calibration include:

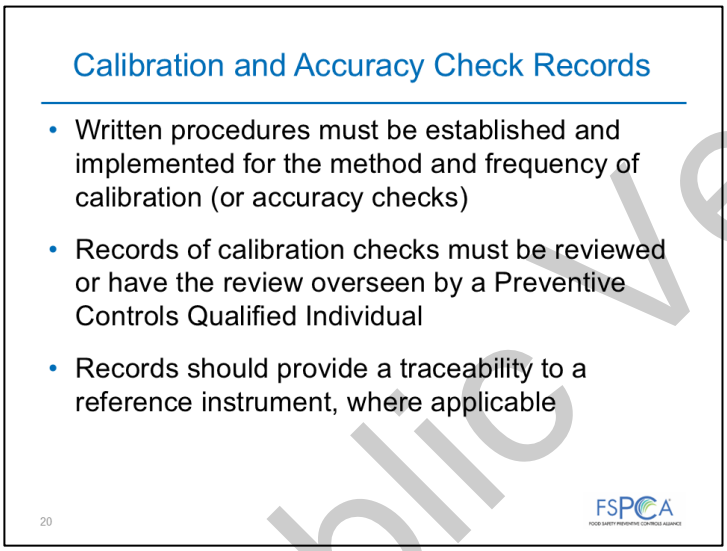
- Inherent reliability of the instrument: Daily accuracy checks may be needed for the least reliable instruments including dial thermometers and bi- metallic types

of thermometers. Periodic checks may be adequate for more reliable instruments such as digital thermometers with a history of reliable performance.

- Manufacturer recommendations for the instrument: The design and expected conditions of use for each individual instrument type is considered when manufacturers make accuracy and calibration recommendations. The manufacturer's information should be used to determine the frequency needed for these activities in the Food Safety Plan.

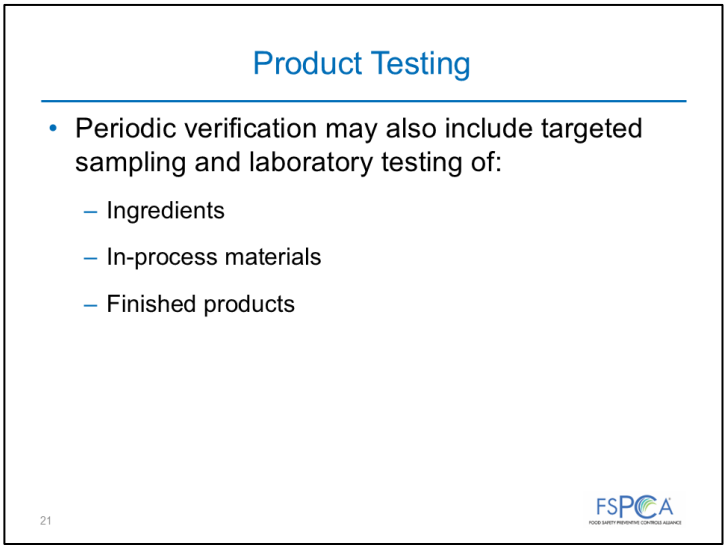
E.G. Food Company uses an infrared surface thermometer to measure the temperature of the cooked omelet as a monitoring activity. Checking the accuracy of the thermometer is therefore important. The Food Safety Team included the following verification activities in the Food Safety Plan to assure that the thermometer was accurate: Daily accuracy check for infrared surface thermometer with annual calibration.

Slide 20: Calibration and Accuracy Check Records



21 CFR 117.165(b)(1) states that a facility must have written procedures for the method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy are required. In addition, records must be kept documenting the results of accuracy checks and calibrations of process monitoring instruments and verification instruments. These records must be reviewed by a person who has the training or experience necessary to evaluate the results and determine that all of these instruments are accurate and properly calibrated. The regulation does not require records to provide traceability to a reference instrument, but this is a useful practice. See the subsequent section on verification records review.

Slide 21: Product Testing



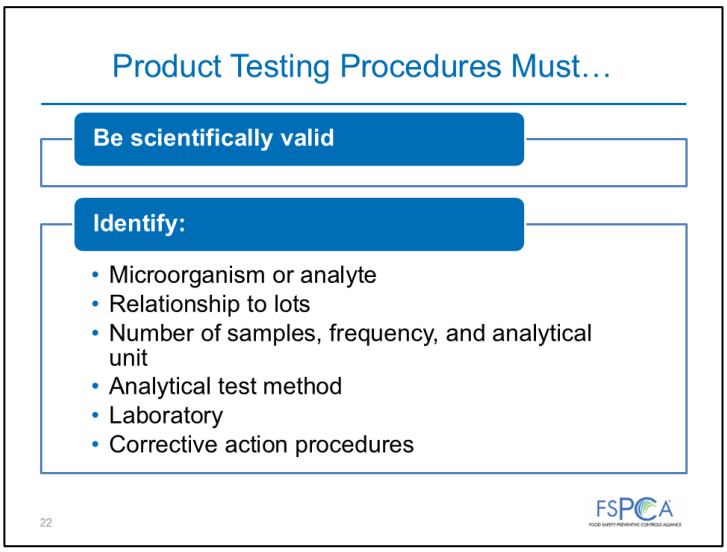
Verification of a preventive control's implementation and effectiveness may also include targeted sampling and testing of ingredients, in-process materials, and/or finished products. For example, supplier compliance with a standard may be verified by targeted periodic sampling and testing when a supply-chain program includes testing of an ingredient or raw material as verification of a supply-chain-applied control.

Like calibration records, verification through testing must be reviewed within a reasonable time after the results are reported. The review or testing reports are part of the facility's verification activities.

Examples of periodic targeted sampling and testing for verification purposes may include:

- Coliform testing for pasteurized milk products to verify that the process meets requirements for safety and that sanitary practice is adequate;
- Testing dry corn for aflatoxin, especially when seasonal conditions increase the risk of aflatoxin production; and
- Pesticide residue testing of raw fruits or vegetables used for further processing, especially from new suppliers.

Slide 22: Product Testing Procedures Must…



The E.G. Food Company Food Safety Plan Teaching Example includes a product testing example (see Appendix 3, page A3-25).

When the Food Safety Plan specifies product testing as a verification activity, the 21 CFR 117.165(b)(2) of the regulation states that procedures for that activity must be documented and followed to identify the parameters listed on the slide. It requires that the testing methods used for a verification activity must be scientifically valid. Resources for testing methods include standard methods published by international, regional, or national standards-writing organizations such as the FDA, AOAC, ISO, etc.

Documented procedures for the testing program must include:

Microorganism or analyte: Identify the specific test microorganism(s) or other analyte(s) to be evaluated. Testing may be for pathogens or for relevant indicator organisms, which may provide quantitative information which is potentially more useful to assess the microbiological status of a lot. For example, the pasteurized milk industry has used coliforms as an indicator in milk products for many years rather than pathogen testing. Adequate pasteurization should destroy coliforms, thus detecting coliforms in a pasteurized milk product suggests post-process contamination or inadequate pasteurization conditions. A facility can act on this information, especially if data are analyzed over time to evaluate trends.

Relationship to lots: Specify the procedures for identifying samples, including their relationship to specific lots of the product. For example, if the sample is an ingredient, preferably the analysis is done before the ingredient is used in a product. If not, then it will be necessary to identify which lot(s) of product contained the ingredient. If it is a line sample, the sample may represent product made since the last clean up.

Number of Samples, Frequency, and Analytical Unit: Include the procedures for sampling, including the number of samples and the sampling frequency. ICMSF (2011) provides considerations and recommendations for microbiological sampling plans for a variety of food products.

Analytical Test Method: Identify the test(s) conducted, including the analytical methods(s) used. The actual test method used must be scientifically valid as discussed

above. Ensure that the method has been validated for the specific food under consideration. Method providers may be of assistance in validating the test method.

Laboratory: Identify the laboratory conducting the testing. The facility may conduct its own testing if it has the appropriate facilities and trained individuals. Often, an outside laboratory is used. Ensure the laboratory has proficiency in working with food samples.

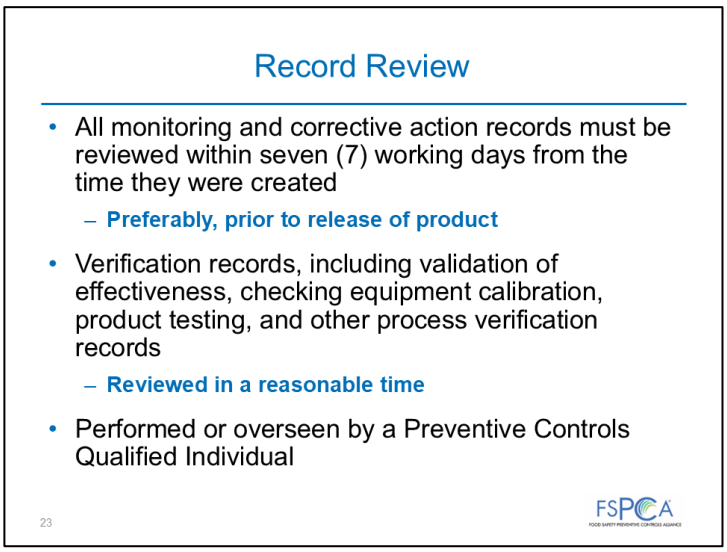
Corrective Action Procedures: Include the corrective action procedures that will be followed if test results do not comply with the standards.

Examples of publications by credible organizations with scientifically valid methods for examination of food:

- American Public Health Association (APHA) Compendium of Methods for the Microbiological Examination of Foods
- APHA Standard methods for the examination of Dairy Products
- FDA Bacteriological Analytical Manual (BAM)
- FDA Macroanalytical Procedures Manual (MPM)
- Food Additives Analytical Manual
- Food Chemicals Codex
- International Standards Organization (ISO) methods
- Official Methods of Analysis of AOAC International
- ORA Laboratory Information Bulletins (LIBs)
- Pesticide Analytical Manual (PAM)

See Additional Reading, Resources, and References at the end of the chapter for more information.

Slide 23: Record Review



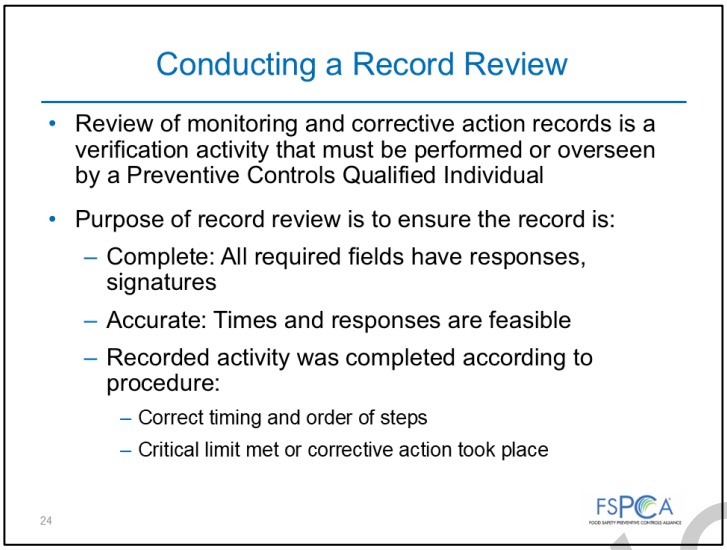
All monitoring and corrective action records must be reviewed by or under the oversight of a Preventive Controls Qualified Individual (21 CFR 117.165(a)(4)). This review is a verification activity. Records are valuable tools that document that the Food Safety Plan is operating within established safety parameters and deviations are handled appropriately. However, records alone are meaningless unless someone reviews them on a periodic basis to verify that the critical limits were achieved, and the Food Safety Plan is being followed. 21 CFR 117.165(a)(4)(i) require that monitoring and corrective action records be reviewed within seven (7) working days after the records are created or within a reasonable timeframe, provided that the Preventive Controls Qualified Individual prepared (or oversees the preparation of) a written justification for a timeframe that exceeds seven (7) working days. When possible, records are reviewed prior to introducing the product into commerce, such as shipping to a customer. This common practice can prevent a potential recall and unintended consequences should a critical limit deviation be discovered during record review. Corrective action must be taken if the record review determines that a deviation has occurred. This is true for sanitation preventive controls records if, for example, the product is no longer in the facility's control and the lack of proper implementation of the preventive control may lead to a hazard being likely to occur in the product.

There is no required time limit to review verification records such as equipment calibration or testing results (product testing, environmental monitoring). 21 CFR 117.165(a)(4)(ii) states these records are to be reviewed within a reasonable time after the records are created. However, it is incumbent on the Preventive Controls Qualified Individual or their designee to ensure these records are reviewed in a timely manner in order to successfully respond to any potential issue signaled in this documentation.

The value of record review is maximized when data are analyzed to look for trends across the food safety system. For example, are the verification results for one supplier the same as another supplier, or are there differences that warrant investigation? Are *Listeria* indicators isolated with greater frequency in one location? Do sanitation verification results indicate higher counts on one line or in one area? If a trend emerges during record review, further investigation or adjustments may be warranted to

minimize the potential for a future deviation. A rigorous verification program can be the basis for continuous improvement of operations and lead to a more effective food safety system, and often more efficient operations.

Slide 24: Conducting a Record Review (1 of 2)

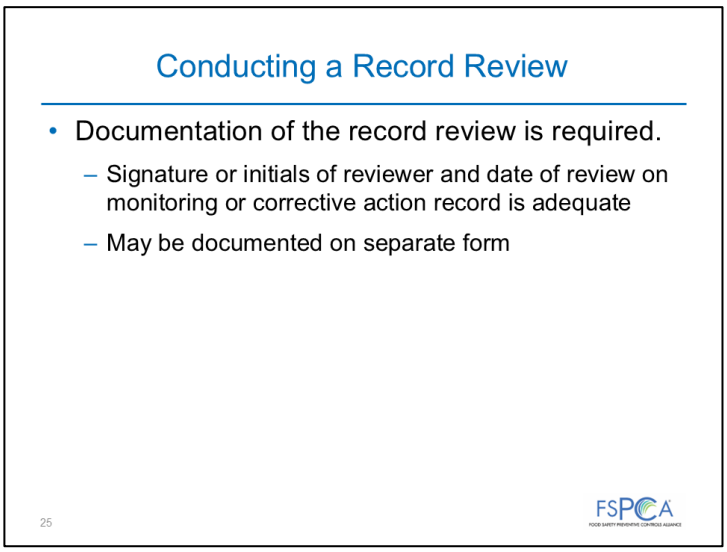


Reviewing monitoring and corrective action records is required to be performed by or overseen by the Preventive Controls Qualified Individual.

The record review verifies that all required monitoring and corrective action information has been documented, including signatures of the individuals performing monitoring and corrective action activities.

The information documented on the record must be accurate and reasonable, meaning that the record reflects the actual events in the facility occurring at times that make sense. Record review must also ensure that the particular activity followed the monitoring and corrective action procedures explicitly. The actions must have been completed in the appropriate sequence and meet the current critical limit and effective corrective actions for the preventive control.

Slide 25: Conducting a Record Review (2 of 2)

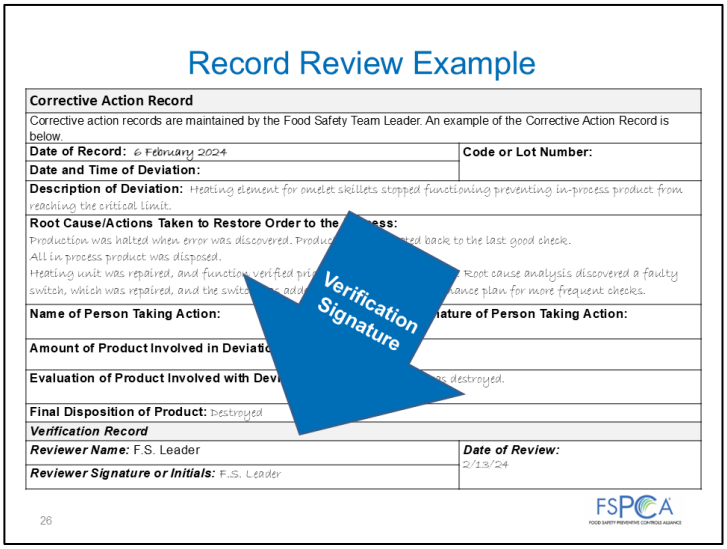


The verification activity of reviewing the monitoring and corrective action records is another element of a Food Safety Plan that requires documentation. Identification of the individual conducting the review and the date the review occurred must be recorded.

Identifying information of the individual conducting the review can be either their signature or initials, provided the initials can be connected to a specific individual.

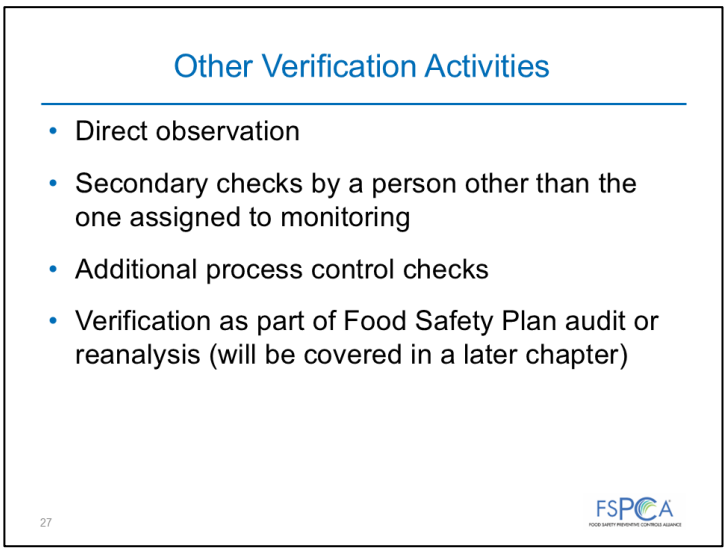
The record review information can be recorded directly on the monitoring or corrective action record or on a separate form, as long as the verification action can be connected to the specific monitoring record. appropriately.

Slide 26: Record Review Example



The example from E.G Food Company uses the corrective action record to document the verification activity of record review. F.S. Leader reviewed the information entered by the packaging line supervisor to ensure that the description of the incident was clear and that the corrective actions taken were consistent with those described in the process preventive control chart. Verification of monitoring records follows the same process. An example of a monitoring record review is discussed on Slide 40.

Slide 27: Other Verification Activities



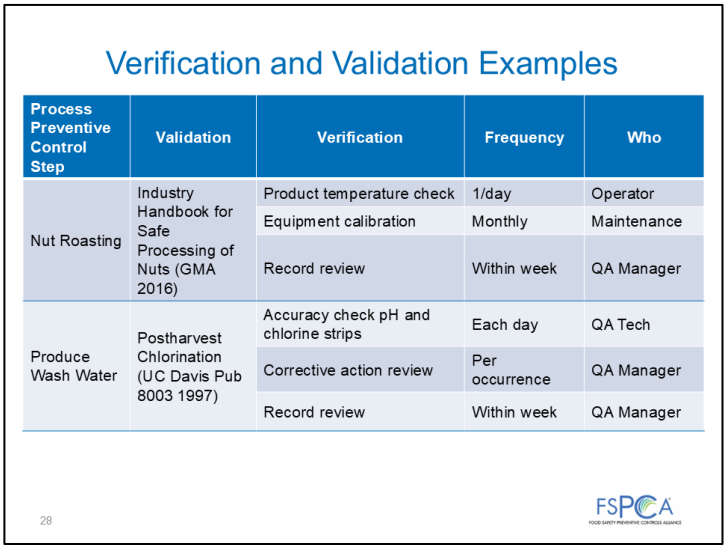
There are other forms of verification that can be performed in addition to the ones already discussed. Direct observation of the preventive control monitoring activities by the supervisor or another designated individual while those activities are being performed verifies that the activity is properly completed.

Process control checks, such as checking that the equipment settings are correct, can help ensure that the process will function correctly.

Verification activities can be completed at a frequency greater than what is required in the Food Safety Plan as an aid to verifying that the process is operating as intended.

Audits of and reanalysis of the Food Safety Plan can also serve as verification activities. More discussion of these concepts is found in Chapter 14.

Slide 28: Verification and Validation Examples (1 of 2)



Verification and Validation Examples

Process Preventive Control Step	Validation	Verification	Frequency	Who
Nut Roasting	Industry Handbook for Safe Processing of Nuts (GMA 2016)	Product temperature check	1/day	Operator
		Equipment calibration	Monthly	Maintenance
		Record review	Within week	QA Manager
Produce Wash Water	Postharvest Chlorination (UC Davis Pub 8003 1997)	Accuracy check pH and chlorine strips	Each day	QA Tech
		Corrective action review	Per occurrence	QA Manager
		Record review	Within week	QA Manager

28

FSPCA

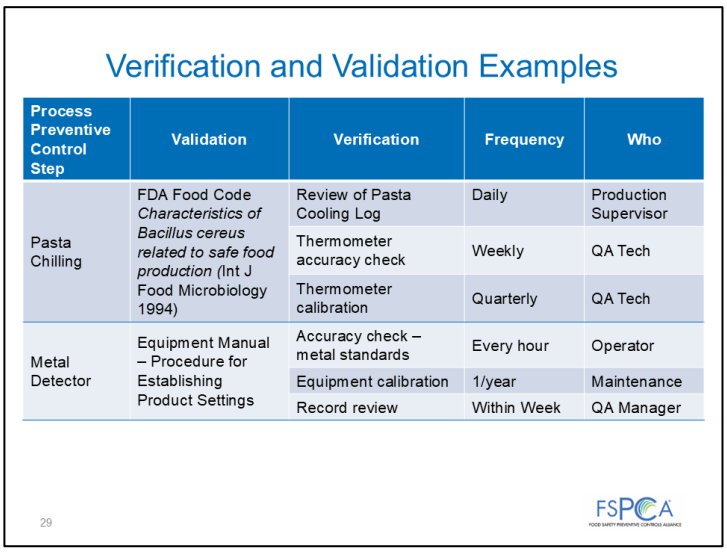
Building upon the examples from previous chapters, verification and validation concepts are applied.

The nut roasting step is validated using a Grocery Manufacturers Association (GMA), 2016 publication on safe processing of nuts which was verified by checking product temperatures, calibrating equipment, and reviewing records.

Wash water chlorination is validated using a U.C. Davis publication and verified via the accuracy checks and review of corrective actions and records.

Frequency and the individuals responsible for these actions are also described.

Slide 29: Verification and Validation Examples (2 of 2)

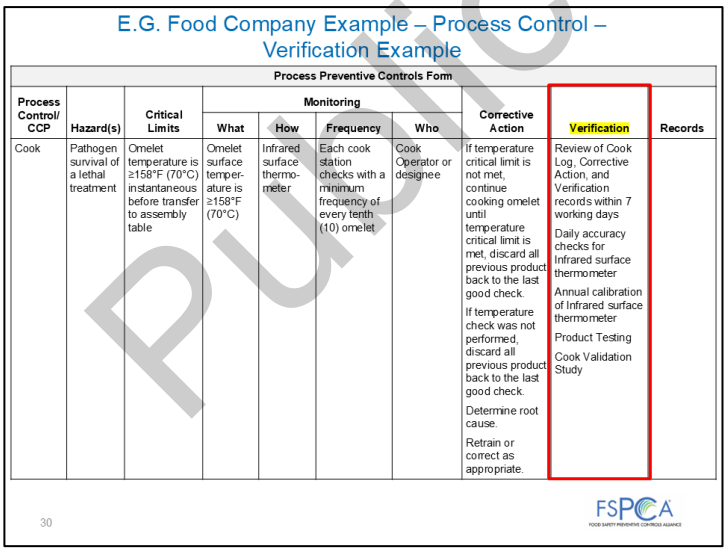


The pasta chilling step is validated using a 1994 FDA publication on *Bacillus cereus* characteristics and verified by reviewing pasta cooling logs along with calibration and accuracy checks of thermometers.

Metal detection is validated using technical information from the manufacturer and verified by accuracy and calibration checks, and by review of records.

The frequency and the persons responsible for these actions are also noted.

Slide 30: E.G. Food Company Example – Process Control – Verification Example



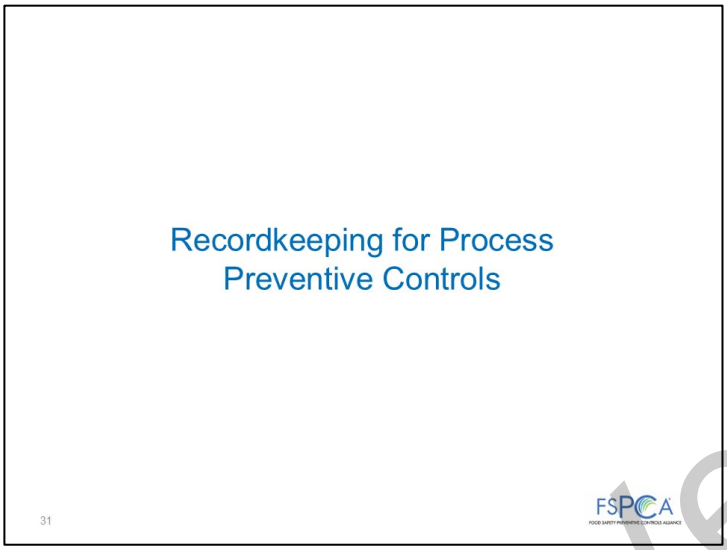
The E.G. Food Company Food Safety Plan Teaching Example also includes other examples of verification for sanitation and allergen preventive controls.

An example of the Process Control verification activities performed by the E.G. Food Company is illustrated above in the Verification column. "Verification activities of the cook step include: 1) Review of the Cook Log, corrective action, and verification records within 7 working days; 2) Daily accuracy checks of the infrared surface

thermometer; 3) Annual calibration of the infrared surface thermometer; 4) Product testing; and 5) Cook validation study.

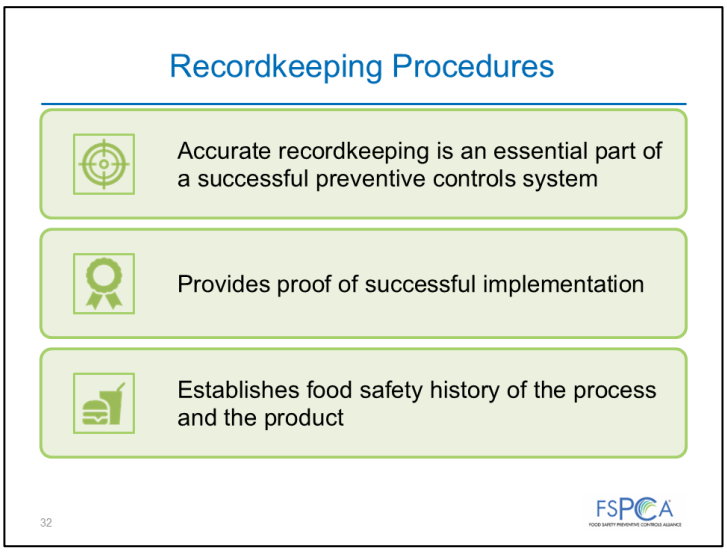
The procedures used to perform these verification activities should be documented and can be found in Appendix 3.

Slide 31: Recordkeeping for Process Preventive Controls



This section focuses on recordkeeping practices and requirements specific to Process Preventive Controls. Many of the concepts covered here will apply to records for the other preventive controls discussed in subsequent chapters.

Slide 32: Recordkeeping Procedures



Accurate recordkeeping is an essential part of a successful preventive controls system, providing proof that the plan was implemented as intended, and establishing a history of the process and product.

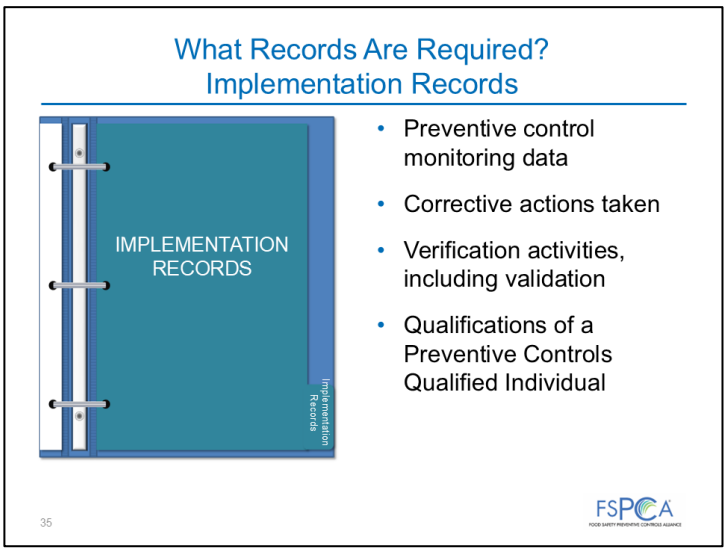
Slide 33: What Records Are Required?

In general, there are two types of required records in the Preventive Controls for Human Food regulation: 1) The Food Safety Plan itself, and 2) Implementation records. All of these documents can be reviewed and copied by regulatory personnel.

Slide 34: What Records Are Required? Food Safety Plan

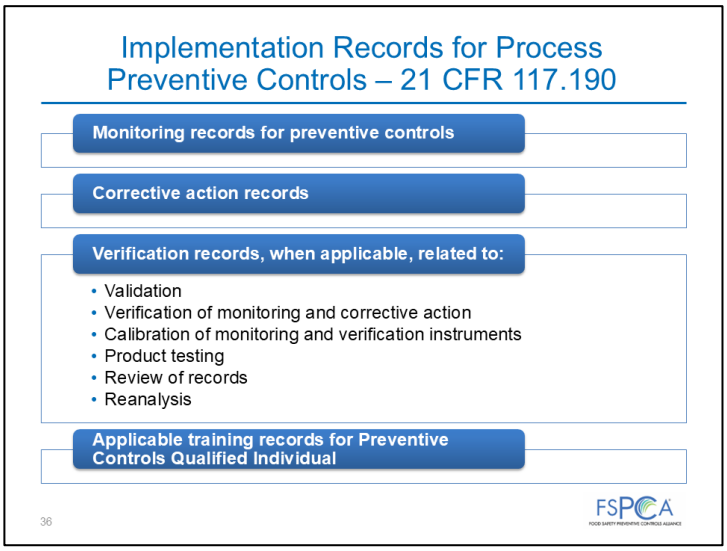
The components of a Food Safety Plan were discussed in earlier chapters. The items listed on the slide are required as part of the Food Safety Plan.

Slide 35: What Records Are Required? Implementation Records



Implementation records document the actual performance of the Food Safety Plan. In other words, implementation records demonstrate that the control steps from the Food Safety Plan were completed.

Slide 36: Implementation Records for Process Preventive Controls – 21 CFR 117.190



Remember in Chapter 2 (Slide 7), we discussed having training records for qualified individuals for food hygiene and food safety training is required as outlined in 21 CFR 117.4(b)(2) and (d).

By regulation, Food Safety Plan implementation records include:

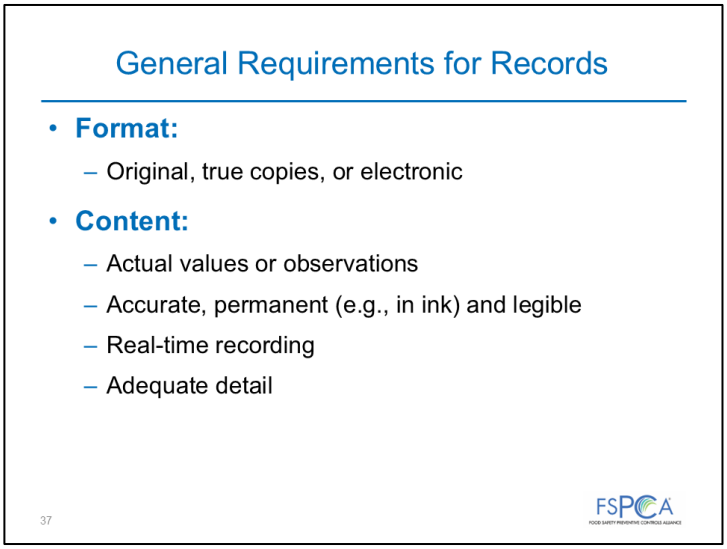
- Monitoring records: All of the data collected from monitoring activity at the given process preventive control;
- Corrective action records: records for each time a corrective action was taken;
- Verification records:
    - Validation which is the documentation that provides support for validity of process preventive control;
    - Verification of monitoring: this will often be a sign off on the monitoring record itself;
    - Verification of corrective actions: this will be a sign off on the corrective action record;
    - Calibration of process monitoring and verification instruments;
    - Product testing;
    - Records review; and
    - Reanalysis (discussed in Chapter 14); and
- Applicable training records for Preventive Controls Qualified Individuals.

Implementation records may include information used for validation and decision-making during hazard analysis, such as published scientific studies, in-facility studies done by technical experts, and data from other experts such as trade associations, equipment manufacturers or sanitation chemical providers.

Documentation of verification activities associated with the supply-chain program, such as ingredient testing or supplier audits, also represent implementation records. This will be discussed in Chapter 13.

Organizing implementation records in a logical manner is recommended to facilitate retrieval during inspection or when an incident requiring investigation occurs.

Slide 37: General Requirements for Records



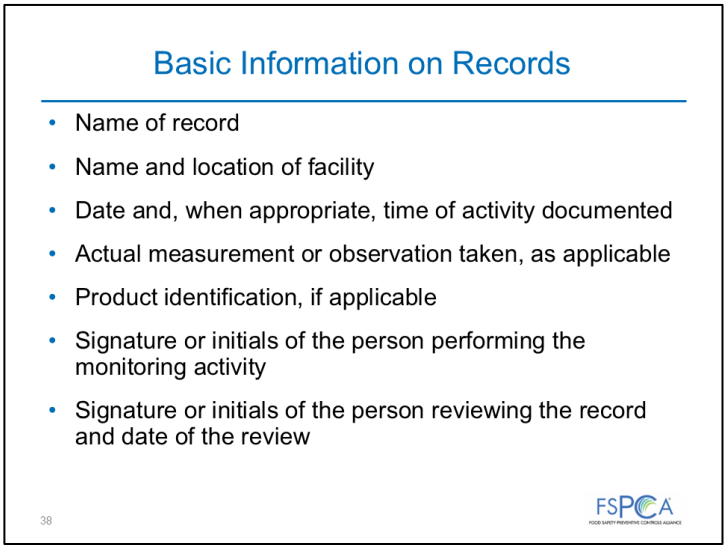
General Requirements are in Subpart F of the Preventive Controls for Human Food regulation.

All records must be kept as originals, true copies, or in an electronic format. True copies include photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of originals.

Monitoring and verification records associated with the Food Safety Plan must include the actual values or observation. For example, if a temperature is being measured, the specific temperature measured must be recorded rather than a checkmark indicating that the temperature complied with the critical limit. All entries must be accurately recorded in a permanent manner that can be read and not easily altered. For example, records cannot be recorded in pencil because they can be easily changed later if recorded in pencil.

The monitoring and verification information must be recorded at the time observed. In other words, it is not acceptable to walk out onto the production area, observe practices and then go back to an office area to record the observations. To comply with the regulations, the information needs to be recorded at the same time the activity is being performed.

Slide 38: Basic Information on Records

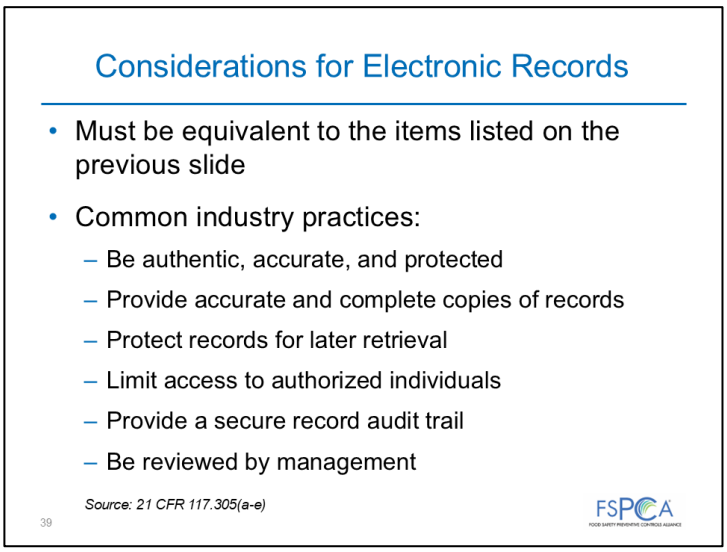


The Food Safety Plan and implementation records must include basic information to provide a history of the actions performed.

Basic information for records includes:

- The name of the record;
- The name and, when necessary, location of the facility;
- The date, and when appropriate, time that the activity was documented;
- The actual measurements or observations made, when applicable.
- Where appropriate, the identity of the product and the lot code, if any. (For many records, product identification and a lot identification code may be relevant, but for some processes, such as pre-operational sanitation records, the time and the date are adequate); and
- Initials or signatures of individuals performing monitoring and verification activities are also required.

Slide 39: Considerations for Electronic Records



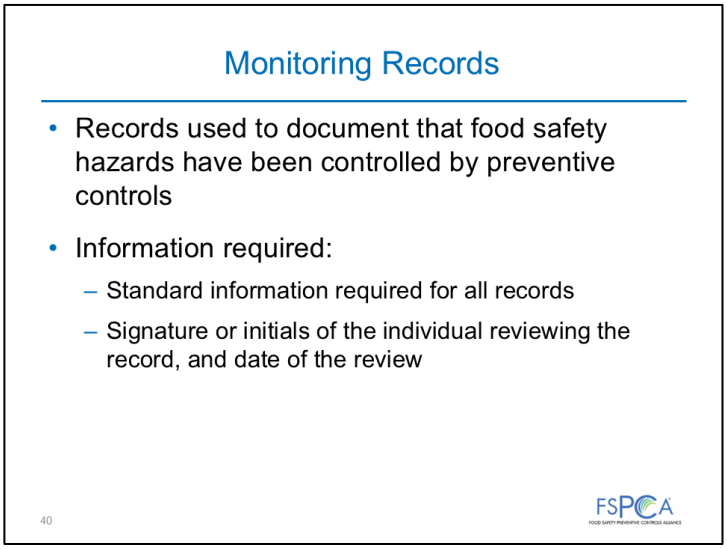
Electronic or computerized records are acceptable in a preventive controls system as long as they are equivalent to paper records and electronic signatures are equivalent to traditional handwritten signatures. Electronic signatures must be unique to each individual user.

Controls are necessary to ensure that electronic records are authentic, accurate and protected from unauthorized changes. If a firm intends to implement an electronic record-keeping system, factors that must be included in the design and implementation of the system include:

- Electronic records must be reviewed by management with adequate frequency to ensure the facility's Food Safety Plan is being followed and
- Electronic records must be available for review and copying by regulatory authorities, upon request.

If a company decides to use an electronic or computerized record- keeping system, the system should be validated just like any other process or piece of equipment. Recent advances in electronic communications make the use of portable electronic instruments beneficial to reduce the amount of paper records that must be kept in a food safety system.

Slide 40: Monitoring Records



Signature or initials of person signing off on the record must be traceable to the person who did the signoff, so they must be legible.

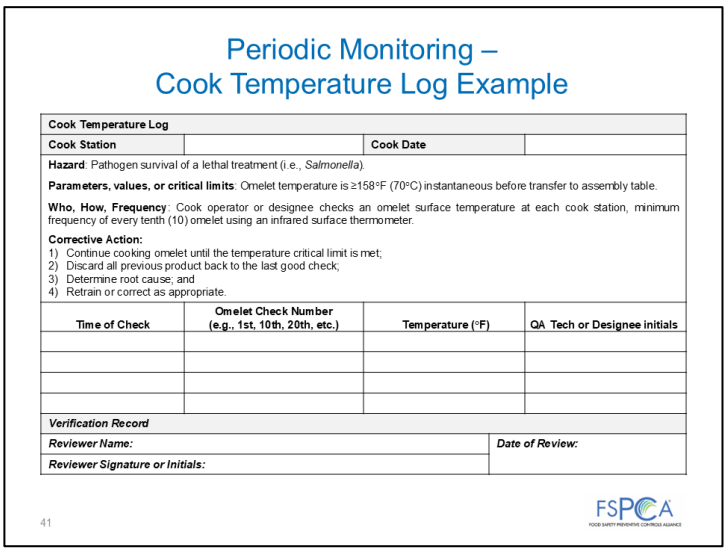
Each monitoring record must be designed to capture the measurements or observations for parameters and associated values, such as critical limits, for the preventive control. The actual measurement or observation must be documented on the record. The date the measurement or observation was made must be documented on the record. The signature or initials of the person who made the monitoring observation must also be recorded.

The record should have a title or other identifier that corresponds to the record described in the Food Safety Plan.

Accurate recordkeeping provides documentation that food safety hazards are being controlled. False or inaccurate records filled out before the actual operation takes place or those that are completed later may lead to regulatory and legal action, especially if found to be fraudulent.

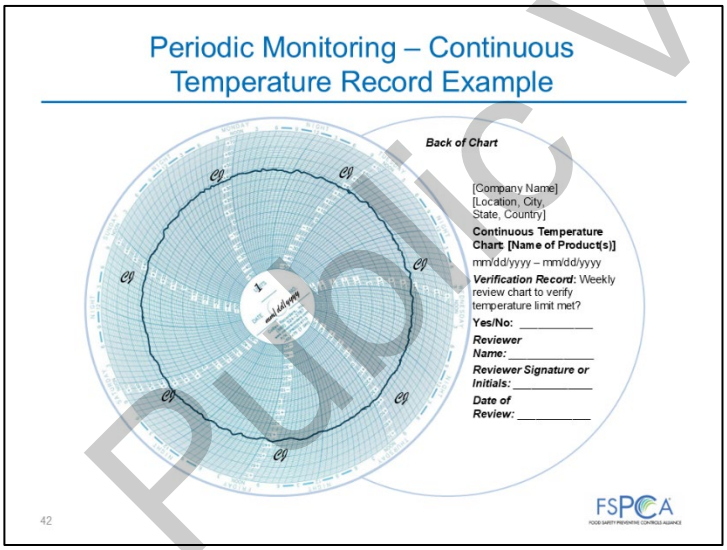
A signature or initials from the individual who verified that the record complied with required parameters and associated values, as well as the date of the verification review was completed must be documented. Record review verification actions can be documented on the monitoring record, or on a separate record that can be connected to the verification action. These verification procedures were discussed in greater detail earlier in this chapter.

Slide 41: Periodic Monitoring – Cook Temperature Log Example



This form, the Cook Temperature Log, documents the periodic monitoring of omelet surface temperature at each omelet cook station to document if the critical limit is met. The initials of the person monitoring the temperature is documented, as well as the name and signature or initial of the person verifying the monitoring record.

Slide 42: Periodic Monitoring – Continuous Temperature Record Example

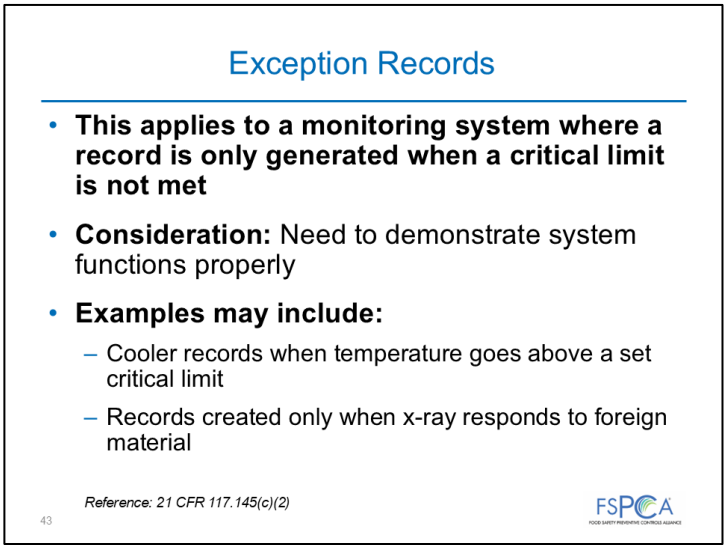


Remember that the verification activity should include more than just signing the chart.

Observation of trends by comparing different days isvery useful for identifying issues BEFORE corrective action is required.

This example record is used to continuously monitor the operations of a refrigerated product(s) storage cooler. The temperature record is periodically checked visually and initialed by the operator to ensure compliance with the critical limit. Notice the back of the chart is used to record the information required on all monitoring records, such as the name and location of the company, the name of the form, and includes the verification information, the record review date and the verifier's name and signature or initials.

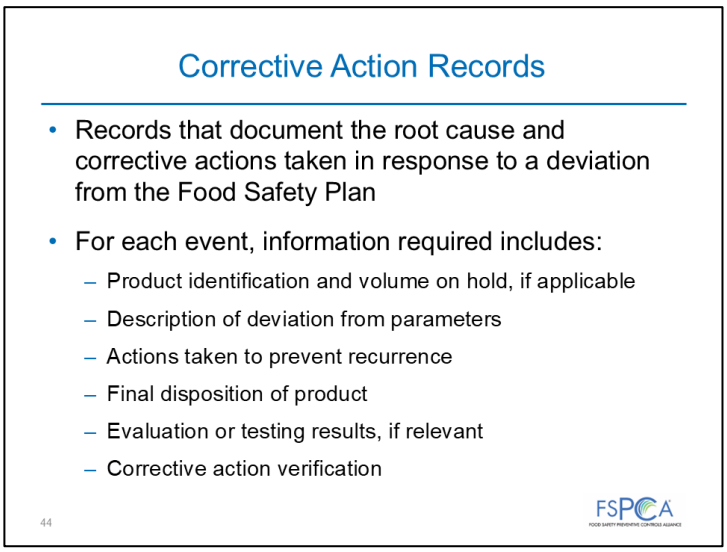
Slide 43: Exception Records



Exception records only provide a record when there is loss of control at a process preventive control. The regulation 21 CRF 117.145(c)(2) allows for records based on an exception in certain circumstances. The regulation states, "Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control." Exception records may be adequate in circumstances other than monitoring refrigeration temperature. Other examples may include the finding of foreign material when an x-ray unit detects it. In this case, the critical limit is not generating a record, but when the critical limit is not met, a record is generated by the equipment, as in the x-ray machine.

It is important to demonstrate that the system designed to generate exception records function properly, so then when an exception occurs it is detected.

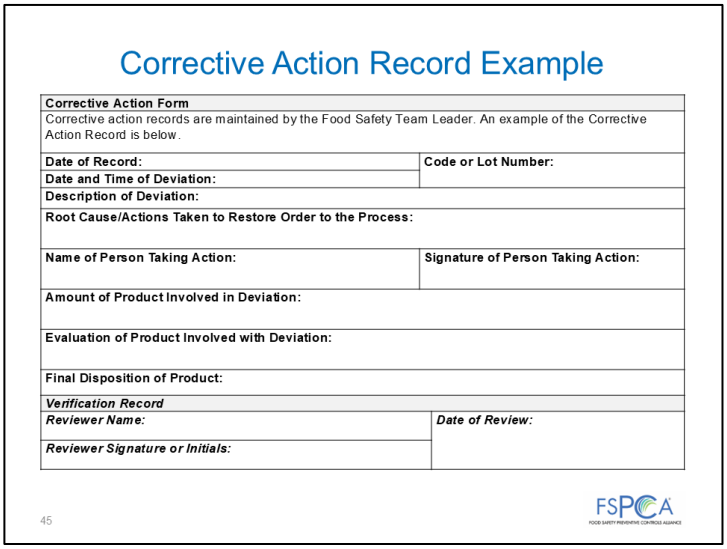
Slide 44: Corrective Action Records



A corrective action record describes the deviation that triggered corrective action and captures the following:

- Product identification such as the product description, lot codes covered and amount of product on hold;
- Summary of the root cause of the deviation and actions taken to prevent further occurrences;
- Results of the evaluation or testing of product placed on hold, if necessary and the final disposition of the product;
- Name and signature of the person responsible for the corrective action(s); and
- Name and signature of the person reviewing the corrective action(s) report.

Slide 45: Corrective Action Record Example



Corrective Action Record Example

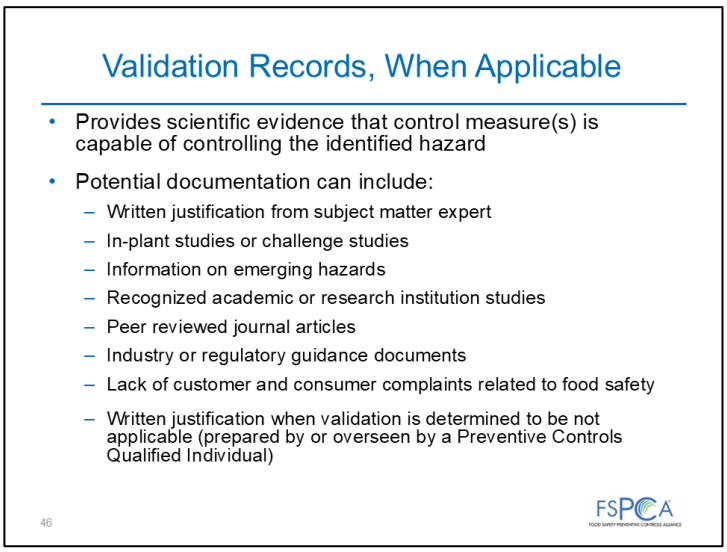
Corrective Action Form	
Corrective action records are maintained by the Food Safety Team Leader. An example of the Corrective Action Record is below.	
Date of Record:	**Code or Lot Number:**
Date and Time of Deviation:	
Description of Deviation:	
Root Cause/Actions Taken to Restore Order to the Process:	
Name of Person Taking Action:	**Signature of Person Taking Action:**
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

45

FSPCA

A sample corrective action record is illustrated above. Some facilities may have a root cause field on the form and have a root cause analysis performed (see Appendix 8 for the definitions of "root cause" and "root cause analysis").

Slide 46: Validation Records, When Applicable



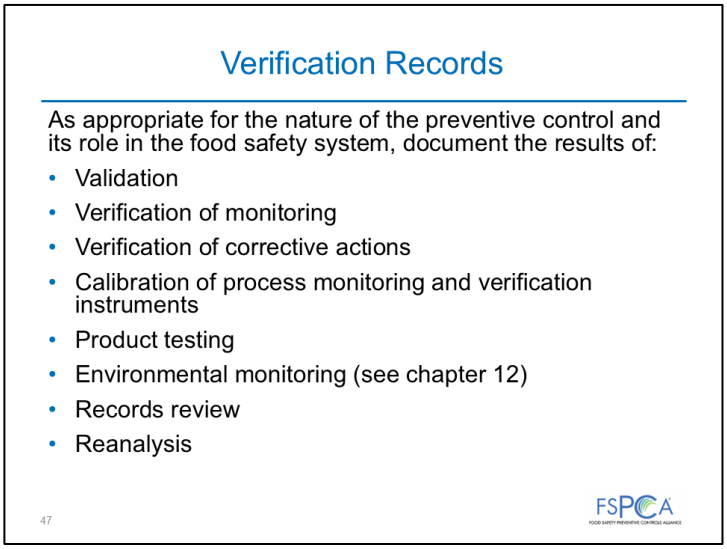
Records generated by third parties also must meet the requirements for records. Examples may include validation studies, calibration records, product testing, and environmental monitoring when conducted by a consultant or outside lab.

The records of validation, discussed earlier in this chapter, provide a scientific basis that the parameters and preventive controls in the Food Safety Plan will control relevant hazards. Validation answers questions such as: Are we doing what we should be doing? Are the preventive controls (and the parameters and values or critical limits at CCPs) adequate to significantly minimize or prevent food safety concerns? Is there new information that should be considered regarding the safety of products, such as emerging hazards? Can the lack of customer or consumer complaints (when the firm has a system to collect them) be used to indicate that there is no history of a food safety concern?

Many sources of information can be used to validate a Food Safety Plan. Some validation options include studies done by process authorities such as a person or institution with expert knowledge and experience to make determinations about the safety of a food process and formulation, in-facility studies or challenge studies conducted on the specific product, trade association summaries on emerging hazards, university or research institution reports and studies, peer reviewed journal articles, and regulatory or other guidance documents. Records supporting validation decisions made by the facility must be maintained.

If a validation of a preventive control is determined to not be applicable, the Preventive Controls Qualified Individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control, and its role in the facility's food safety system.

Slide 47: Verification Records



Records of verification activities must be kept in order to demonstrate that the Food Safety Plan has been implemented properly, the monitoring measurements or observations are accurate and reliable, and the food safety system is working as intended. Different records may be needed to capture the verification information that is specified in the Food Safety Plan.

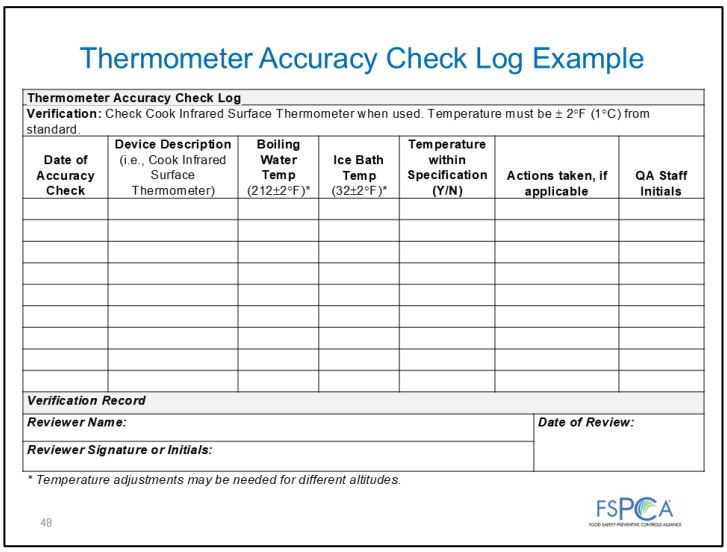
Examples of verification activities requiring frequent records include:

- Logs that document the results of checks to verify the accuracy of thermometers, pH meters or other process monitoring instruments used to monitor critical limits and other parameters.
- Monitoring records by a trained individual under the oversight of a Preventive Controls Qualified Individual to verify that parameters were met, and appropriate corrective actions were taken.

Examples of less frequently used, but also important records for verification activities might include:

- Logs that document calibration activities for the thermometers, pH meters and other process monitoring instruments mentioned above.
- Results of finished product microbiological, chemical, or physical tests.
- Results of equipment evaluation tests, heat penetration or temperature distribution for ovens, fryers, or other equipment.
- Reanalysis activities such as a report describing modifications made to the Food Safety Plan because of a change in products, ingredients, formulations, processes, packaging, or distribution methods.

Slide 48: Thermometer Accuracy Check Log Example



Thermometer Accuracy Check Log Example

Thermometer Accuracy Check Log

Verification: Check Cook Infrared Surface Thermometer when used. Temperature must be ± 2°F (1°C) from standard.

Date of Accuracy Check	Device Description (i.e., Cook Infrared Surface Thermometer)	Boiling Water Temp (212±2°F)*	Ice Bath Temp (32±2°F)*	Temperature within Specification (Y/N)	Actions taken, if applicable	QA Staff Initials

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

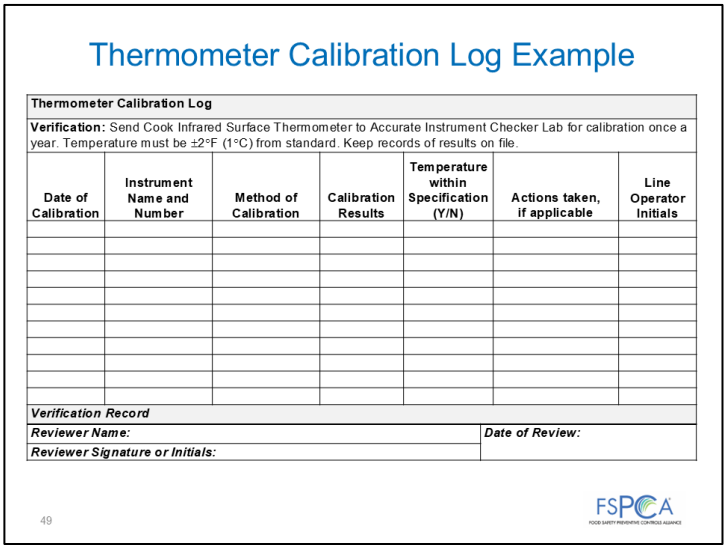
** Temperature adjustments may be needed for different altitudes.*

48

FSPCA

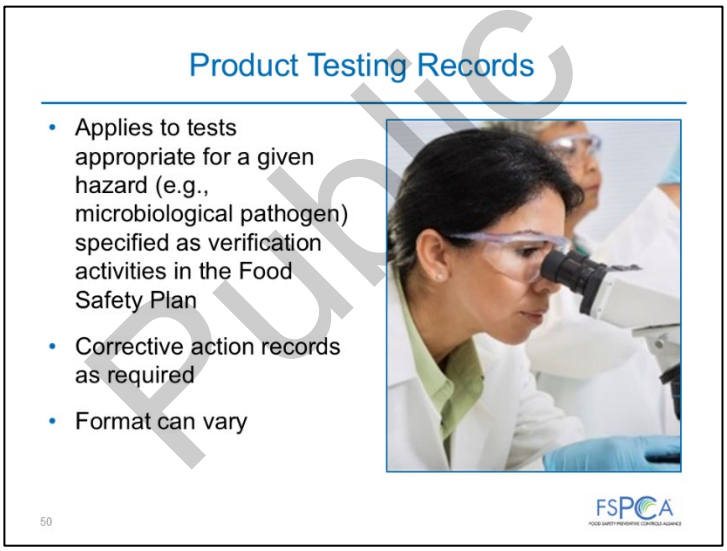
This example form demonstrates how a company may document daily accuracy checks of all thermometers used in the daily process monitoring operations. The form could be modified to include a procedure number for the work instructions directing the daily accuracy check steps. Note that the thermometer sensitivity should be based on the thermometer manufacturer's stated sensitivity. An ice bath would be appropriate to check thermometers used for cold temperatures. If boiling water is used, the temperature for the altitude at the location also should be indicated. Instead of using the heading, "Boiling Water Check," a standard operating procedure could be referenced or other descriptive terminology.

Slide 49: Thermometer Calibration Record Example



This form could be used to document the calibration check of process monitoring instruments and verification instruments such as thermometers on an annual basis. As mentioned previously, the facility needs to determine the frequency with which such activities are conducted. Thermometer calibration may occur on a quarterly basis, a monthly basis, an annual basis, or other frequency deemed appropriate for the type of thermometer and other considerations.

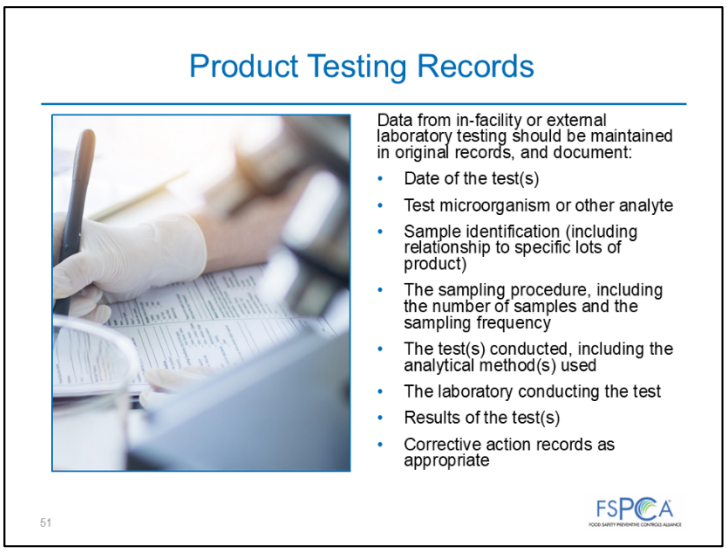
Slide 50: Product Testing Records (1 of 2)



NOTE: A result that says "Negative" or "Not detected" also should include the analytical unit (grams, milliliter, per swab, etc.), in order to determine the sensitivity ofthe test.

Product testing as a verification activity was mentioned earlier in this chapter. The results of those tests are verification records. If appropriate, corrective actions taken in response to the product testing results will be required to be documented in records.

Slide 51: Product Testing Records (2 of 2)

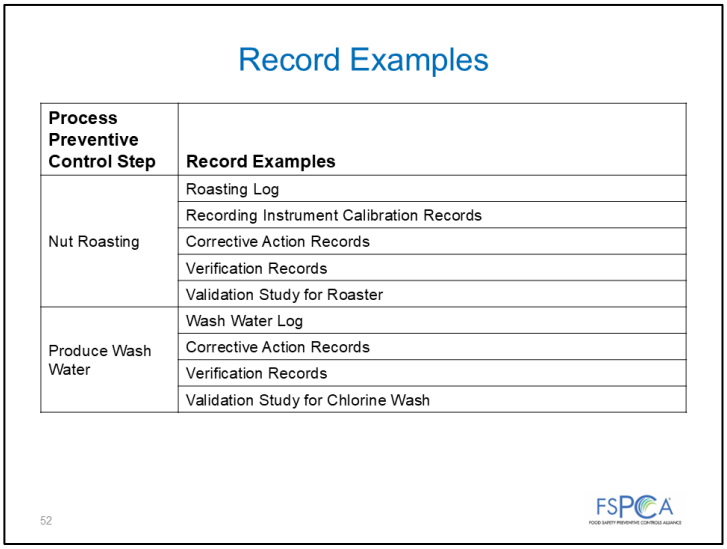


Data from in-facility or external laboratory testing should be maintained in original records and be documented:

- Date of the test(s);
- Test microorganism or other analyte;
- Sample identification (including relationship to specific lots of product);
- The sampling procedure, including the number of samples and the sampling frequency;
- The test(s) conducted, including the analytical method(s) used;
- The laboratory conducting the test;
- Results of the test(s); and
- Corrective action records as appropriate.

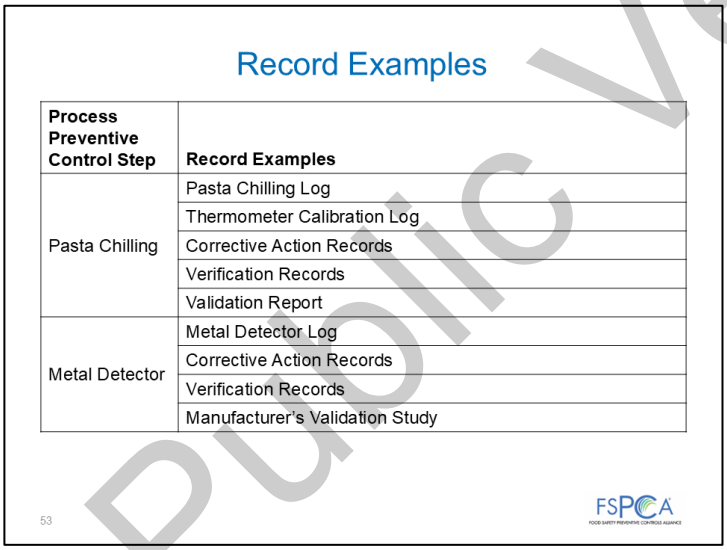
An example of a product testing record is in Appendix 3.

Slide 52: Record Examples (1 of 2)



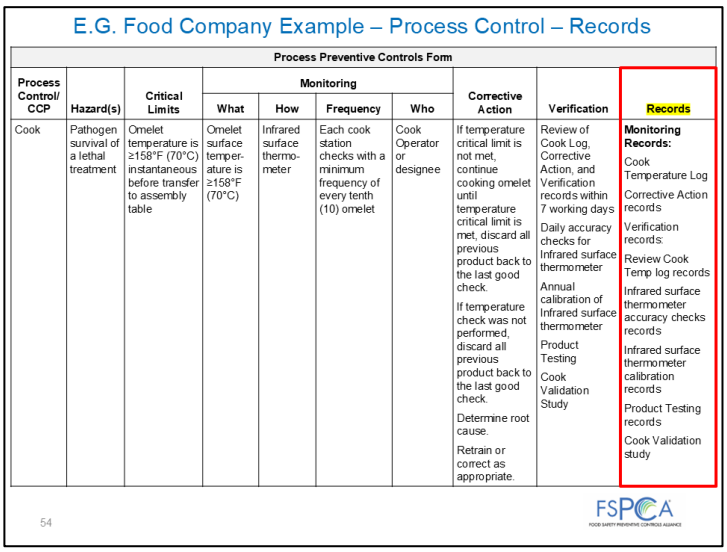
Building on examples of process controls from previous chapters, records from nut roasting and produce wash water steps are included here.

Slide 53: Record Examples (2 of 2)



Continuing to build on examples of process control records from previous chapters, the pasta chilling and metal detection steps are included here.

Slide 54: E.G. Food Company Example – Process Control – Records



The slide above from the E.G. Food Company's Food Safety Plan in Appendix 3: Food Safety Plan Teaching Example, illustrates how implementation records could be referenced in a Food Safety Plan, in the "Records" column. The name of the record for recording monitoring activity is included. Corrective action and verification record titles also are referenced, including the validation study for the cook step.

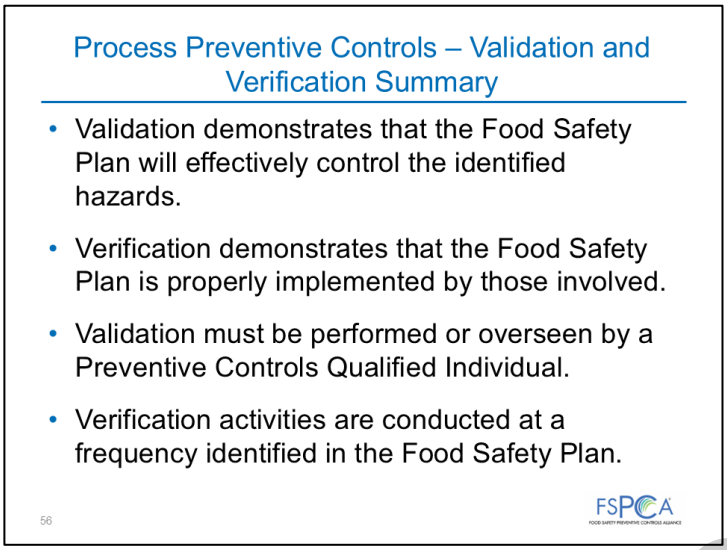
Slide 55: Requirements for Record Retention

The Preventive Controls for Human Food regulation requires that food safety related records must be retained for a minimum of two (2) years from the date the record was created. Records that relate to the general adequacy of the equipment or processes being used, including the scientific studies and evaluations, must be kept at the facility for at least two (2) years after their use is discontinued.

The Food Safety Plan must be retained onsite. Electronic records are considered to be onsite if they are accessible from onsite. Other records, such as monitoring records, may be stored offsite if they are readily available within 24 hours, when requested for

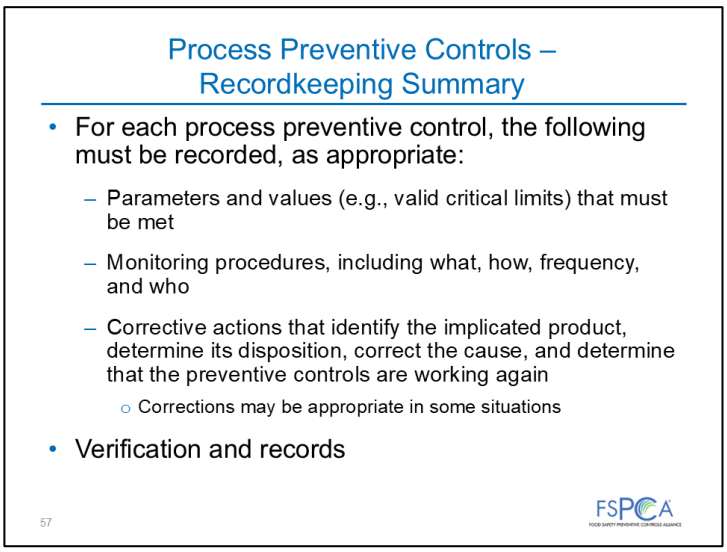
official review (e.g., by the FDA). All records associated with the Food Safety Plan must be available to the FDA regulatory personnel, or their designee for inspection.

Slide 56: Process Preventive Controls –Validation and Verification Summary



Verification and validation are essential elements of an effective Food Safety Plan. The initial and subsequent validation of the Plan must be performed or overseen by a Preventive Controls Qualified Individual to ensure that the controls identified will control the hazards that are likely to be present in the food without such controls. Verification activities are conducted to determine if and document that the Food Safety Plan is being implemented as designed, people are doing what is expected, and records are available to demonstrate ongoing performance. The record review activities must be performed or overseen by a Preventive Controls Qualified Individual.

Slide 57: Process Preventive Controls – Recordkeeping Summary



Records are an essential component of a food safety preventive controls system. Records must be established for each process preventive control and include:

- Required parameters and values;
- Monitoring records, which must be created as the activity takes place, and include information about the procedures (what, how, the frequency, and by whom); and
- Corrective action records identifying the implicated product and how it was dispositioned, correcting the deviation so it is not likely to recur, and ensuring that the process preventive control is functioning properly. Note that corrections may be appropriate in certain instances.

Verification records also are required.

All records must be permanent (e.g., in indelible ink with no erasures), and electronic records can be used if they meet requirements. Required records must be verified by an individual under the oversight of a Preventive Controls Qualified Individual. Upon request all records associated with the Food Safety Plan must be made available for inspection by the FDA or its designee.

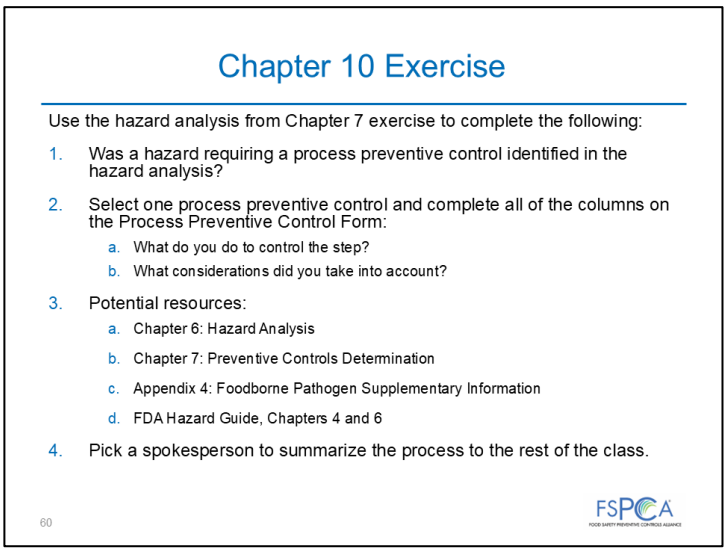
Slide 58: Knowledge Check 1

Participants do NOT have this slide.

Slide 59: Knowledge Check 2

Participants do NOT have this slide.

Slide 60: Chapter 10 Exercise



Use the hazard analysis and preventive controls determination from Chapter 7 exercise to complete the following:

1. Was a hazard requiring a process preventive control identified in the hazard analysis?
2. Select one process preventive control and complete all of the columns on the Process Preventive Control Form:
    a. What do you do to control the step?
    b. What considerations did you take into account?
3. Potential resources:
    a. Chapter 6: Hazard Analysis
    b. Chapter 7: Preventive Controls Determination
    c. Appendix 4: Foodborne Pathogen Supplementary Information.
    d. FDA Hazard Guide, Chapters 4 and 6.
4. Pick a spokesperson to summarize the process to the rest of the class.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan-inquiries-report

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

Almond Board of California. (2007). Guidelines for Validation of Oil Roasting Processes: https://www.almonds.com/sites/default/files/oil-roast-validation-guidelines.pdf

American Public Health Association (APHA) Compendium of Methods for the Microbiological Examination of Foods: https://ajph.aphapublications.org/doi/book/10.2105/MBEF.0222

APHA Standard methods for the examination of Dairy Products: https://ajph.aphapublications.org/doi/book/10.2105/9780875530024

Brackett, R.E. et al. (2014) Validation and Verification: A Practical, Industry-driven Framework Developed to Support the Requirements of the Food Safety Modernization Act (FSMA) of 2011. Food Protection Trends November/December 2014, 410-425.

FDA Bacteriological Analytical Manual (BAM): https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam

FDA. (1983). Food Additives Analytical Manual.

FDA Macroanalytical Procedures Manual (MPM): https://www.fda.gov/food/laboratory-methods-food/macroanalytical-procedures-manual-mpm

FDA Food Code: https://www.fda.gov/food/fda-food-code/food-code-2022

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry (full guidance document): https://www.fda.gov/media/100002/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 4: https://www.fda.gov/media/99572/download

FDA Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry, Chapter 6: https://www.fda.gov/media/107327/download

Flores N.C. and E.A.E. Boyle. (2000). Thermometer Calibration Guide. Kansas State University.

Food Chemicals Codex: https://www.foodchemicalscodex.org/

ICMSF (International Commission on Microbiological Specifications for Foods). (2011). Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance. Springer, New York

IFT (Institute of Food Technologists). (2001). Evaluation and Definition of Potentially Hazardous Foods.

International Standards Organization (ISO) methods: https://www.iso.org/standards.html

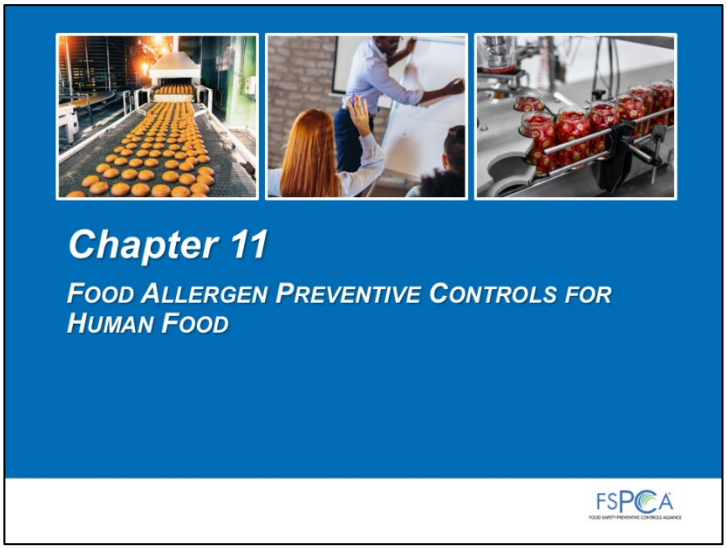
NACMCF (National Advisory Committee on Microbiological Criteria for Foods). (2004). Requisite scientific parameters for establishing the equivalence of alternative methods of pasteurization

ORA Laboratory Information Bulletins (LIBs): https://www.fda.gov/media/73584/download

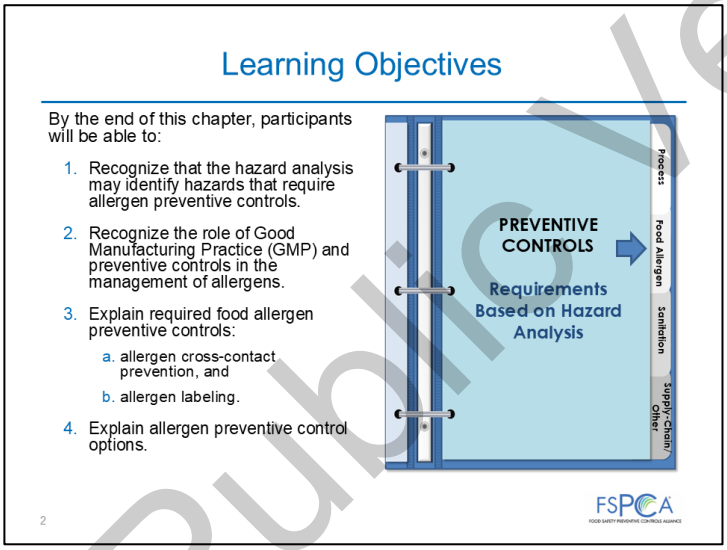
Pasteurized Milk Ordinance: https://www.fda.gov/food/milk-guidance-documents-regulatory-information/national-conference-interstate-milk-shipments-ncims-model-documents

Pesticide Analytical Manual (PAM): https://www.fda.gov/food/laboratory-methods-food/pesticide-analytical-manual-pam

Slide 1: Chapter 11: Food Allergen Preventive Controls for Human Food



Slide 2: Learning Objectives

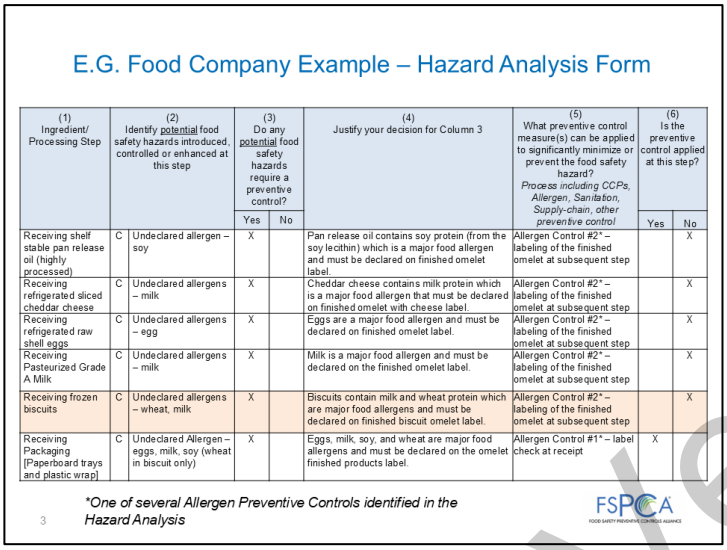


The Preventive Controls for Human Food regulation requires documented food allergen preventive controls to prevent allergen cross-contact and to ensure accurate allergen labeling is on finished food products. The need for specific food allergen controls is determined through the hazard analysis process and this chapter focuses on determining what component(s) of the food allergen program are allergen preventive controls. The specific allergen control practices required to manage food allergens depend on the specific product and manufacturing processes and practices. Common causes for the presence of undeclared food allergens were discussed in Chapter 4: Chemical, Physical, and Economically Motivated Food Safety Hazards. The required elements of allergen controls in a Food Safety Plan (i.e., accurate labeling to inform consumers and prevention of allergen cross-contact, and the associated monitoring procedures), are addressed in this chapter. Allergen testing, which is a

potential verification procedure, is also briefly discussed in the context of allergen cross-contact prevention. As a reminder, other elements of verification were discussed in Chapter 10: Process Preventive Controls – Verification and Recordkeeping.

This is not intended to be a comprehensive training course on allergen management; thus, references are provided for further information at the end of the chapter.

Slide 3: E.G. Food Company Example – Hazard Analysis Form (1 of 2)



E.G. Food Company Example – Hazard Analysis Form

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Receiving shelf stable pan release oil (highly processed)	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label.	Allergen Control #2* – labeling of the finished omelet at subsequent step		X
Receiving refrigerated sliced cheddar cheese	C	Undeclared allergens – milk	X		Cheddar cheese contains milk protein which is a major food allergen that must be declared on finished omelet with cheese label.	Allergen Control #2* – labeling of the finished omelet at subsequent step		X
Receiving refrigerated raw shell eggs	C	Undeclared allergens – egg	X		Eggs are a major food allergen and must be declared on finished omelet label.	Allergen Control #2* – labeling of the finished omelet at subsequent step		X
Receiving Pasteurized Grade A Milk	C	Undeclared allergens – milk	X		Milk is a major food allergen and must be declared on the finished omelet label.	Allergen Control #2* – labeling of the finished omelet at subsequent step		X
Receiving frozen biscuits	C	Undeclared allergens – wheat, milk	X		Biscuits contain milk and wheat protein which are major food allergens and must be declared on finished biscuit omelet label.	Allergen Control #2* – labeling of the finished omelet at subsequent step		X
Receiving Packaging (Paperboard trays and plastic wrap)	C	Undeclared Allergen – eggs, milk, soy (wheat in biscuit only)	X		Eggs, milk, soy, and wheat are major food allergens and must be declared on the omelet finished products label.	Allergen Control #1* – label check at receipt	X	

*One of several Allergen Preventive Controls identified in the Hazard Analysis

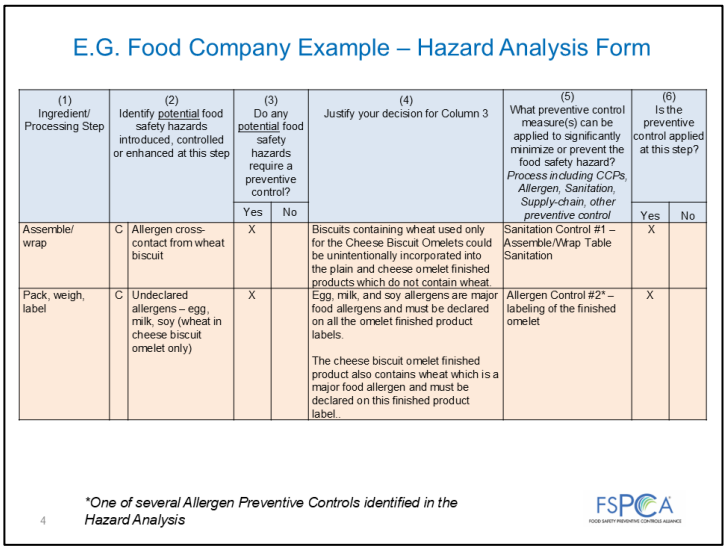
3

FSPCA

Chapter 6: Hazard Analysis, and Chapter 7: Preventive Controls Determination, describe the process of evaluating food allergen hazards to determine the allergen preventive controls that are required to be included in the Food Safety Plan. On the slide above, and on the next slide, several of the steps identified in the E.G. Food Company cheese biscuit omelet example as requiring allergen preventive controls have been illustrated.

Biscuits contain a wheat allergen, which is not present in other E.G. Food Company food products, only in the cheese biscuit omelet product, therefore, we are going to follow the wheat biscuit through the cheese biscuit omelet process. The highlighted step "Receiving frozen biscuits" (Column 1), identifies the specific food allergens (wheat, milk (Column 2)), and concludes that a food safety hazard requiring a preventive control is present (Column 3). The justification (Column 4) identifies one element related to allergen control: The need for allergen labeling to inform consumers. Column 5 identifies the preventive control to address the allergen concern: Allergen Control #2* – labeling of the finished omelet at subsequent step.

Slide 4: E.G. Food Company Example – Hazard Analysis Form (2 of 2)



E.G. Food Company Example – Hazard Analysis Form

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
Assemble/ wrap	C	Allergen cross-contact from wheat biscuit	X		Biscuits containing wheat used only for the Cheese Biscuit Omelets could be unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat.	Sanitation Control #1 – Assemble/Wrap Table Sanitation	X	
Pack, weigh, label	C	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit omelet only)	X		Egg, milk, and soy allergens are major food allergens and must be declared on all the omelet finished product labels. The cheese biscuit omelet finished product also contains wheat which is a major food allergen and must be declared on this finished product label.	Allergen Control #2* – labeling of the finished omelet	X	

*One of several Allergen Preventive Controls identified in the Hazard Analysis

4

The term "sanitation" includes both cleaning and sanitizing activities. Cleaning in this example is also necessary to control allergens. Sanitizing, which is intended to kill microorganisms, has little or no impact on allergens.

The first step illustrated on the slide, "Assemble/Wrap," (Column 1), identifies the potential food safety hazard, "Allergen cross-contact from wheat biscuit," (Column 2) and concludes that a food safety hazard requiring a preventive control is present (Column 3). The justification (Column 4) identifies how the wheat from the biscuit used in the cheese biscuit omelet could be "unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat. Column 5 identifies the preventive control to address the allergen concern, which is Sanitation Control #1 – Assemble/Wrap Table Sanitation, which will be discussed further in Chapter 12: Sanitation Preventive Controls. Whether this is considered an allergen preventive control, or a sanitation preventive control does not matter as long as the activity controls the hazard.

Slide 5: Major Food Allergens in United States

The term "Recognized food allergen" is the same as "major food allergen."

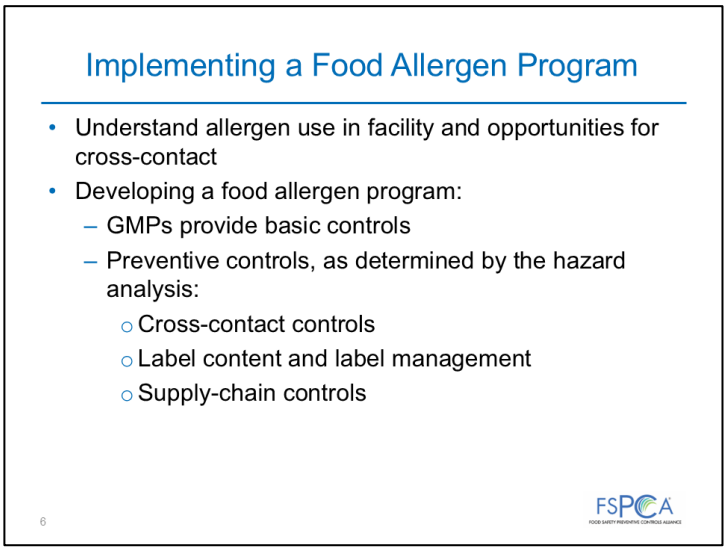
The term "Food allergen profile" is defined by the FDA as "the food allergen sources present or absent in a food. (FDA Hazard Guide)

As discussed in Chapter 4: Chemical, Physical, and Economically Motivated Food Safety Hazards, most of the food allergic reactions in the United States are caused by tree nuts, peanut, fish, milk, eggs, crustacean shellfish, wheat, soy, and sesame. Sesame has been added as the ninth major food allergen requiring labeling as of 2023.

The Food Allergen Labeling and Consumer Protection Act (FALCPA) and the 2021 Food Allergy Safety, Treatment, Education and Research (FASTER) Act mandates labeling of the nine major food allergen groups if they are present in a food product, thus these are the allergens that a facility would identify as hazards requiring a preventive control during the hazard analysis. When labeling a product containing a food allergen or allergens, the label must list the specific allergen(s) to inform the consumer who may have an allergy to that specific item. For example, if tree nuts are present, then the specific tree nut(s) must also be on the label. Similarly, individual species of fish and crustaceans must be labeled. A discussion of labeling is presented later in this chapter.

If all products produced in a given facility have identical food allergen profiles, then the allergen program needs to address only proper labeling because allergen cross-contact is not an issue. Sometimes a supply-chain program may be necessary, depending on the source and complexity of ingredients used in the product. For example, almond ingredients may come from a facility that processes other tree nuts; it will be important that the supplier has controls to address labeling and allergen cross-contact. See Chapter 13: Supply-chain Preventive Controls for more information.

Slide 6: Implementing a Food Allergen Program

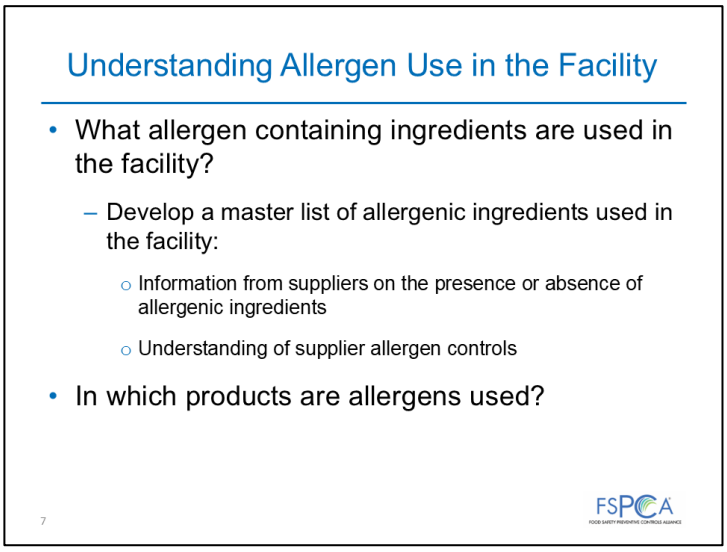


FDA Hazard Guide Chapter 11

Implementing a food allergen program starts with gaining a comprehensive understanding of which food allergens are used in the facility and how these food allergens are received, handled, and processed within the facility. From this understanding, the food allergen program can be developed.

The food allergen program begins with the various Good Manufacturing Procedures (GMPs) and Standard Operating Procedures (SOPs) that support allergen control. However, a food allergen program often goes beyond basic GMPs and SOPs to include the appropriate preventive controls required as an outcome of the company's hazard analysis process. The preventive controls may include controls for cross-contact, development of labels listing allergens, and label management in the facility. These controls could extend to the supply-chain as well.

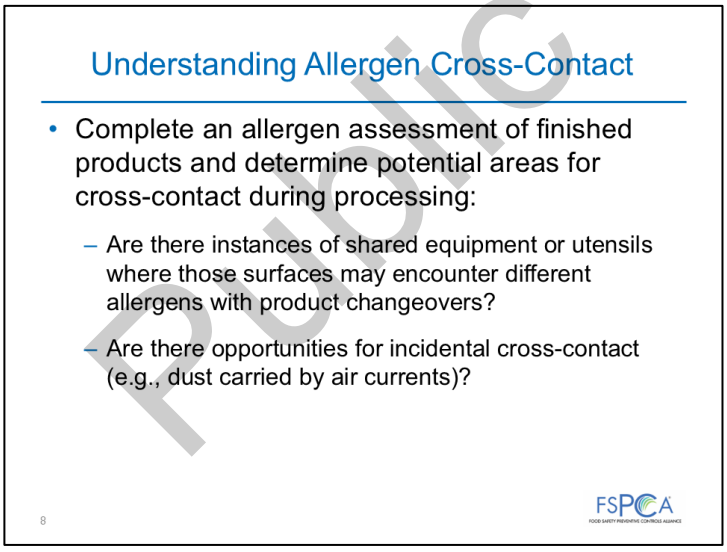
Slide 7: Understanding Allergen Use in the Facility



It is key to be fully aware of all allergens used in the facility. Developing a master list of all ingredients and the allergens they contain is one tool that may be useful. Information from suppliers describing the presence or absence of allergens in the ingredients they provide, and details about how they manage these allergen hazards is also helpful.

After determining which products contain which allergens, this information is used to determine what risks these allergens may present in the manufacturing process.

Slide 8: Understanding Allergen Cross-Contact



Definition: Allergen Cross-Contact: Unintentional incorporation of a food allergen into a food.

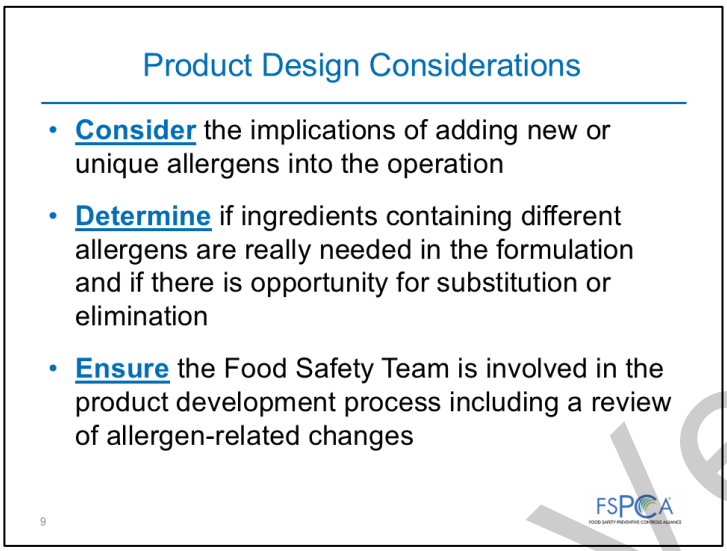
Cross-contact occurs when a residue or trace amount of an allergen unintentionally contaminates a product that doesn't have that allergen. Such occurrences are sporadic.

Managing cross-contact starts with knowledge of what allergens are used in which products and where potential environmental or incidental exposure could occur during food processing or handling. Exposure could happen when multiple foods

containing different allergens are manufactured on the same processing line, or use shared equipment or utensils, or when product is staged or stored closely, such as during changeovers.

If there is the opportunity for incidental cross-contact, such as through dust on air currents, controls to either prevent or at least minimize allergen cross-contact as much as possible must be in place.

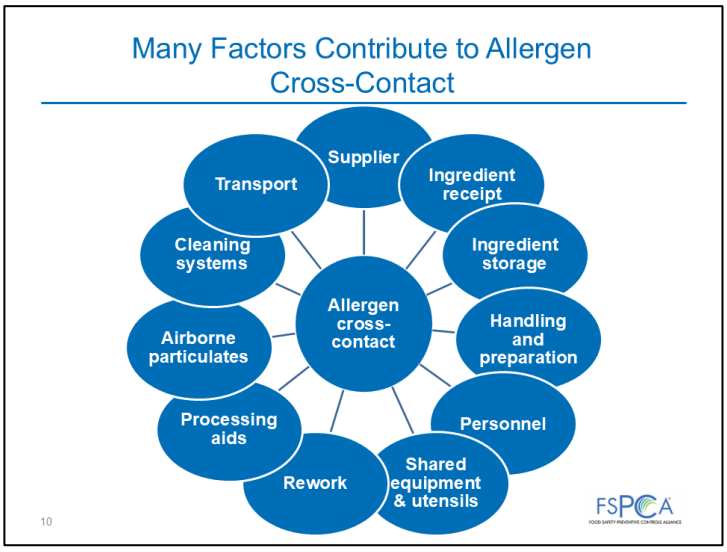
Slide 9: Product Design Considerations



Allergen controls start at the product design phase when the implications of adding new or unique allergens should be considered. Ideally the Food Safety Team should be engaged with research and development (R&D) efforts to review changes and provide input on new formulas. Members of the Food Safety Team may question the design process, including whether introducing the new allergen is necessary, or whether a substitute that will not impact the allergen management programs can be used.

Companies may also need to consider the risk of removing allergens that are present in products with regard to cross-contact. For example, if E.G. Food Company chose to take milk out of their plain omelets, they would need to control dairy hazards between that product and the omelets with cheese. This type of situation could occur with the increased offering of plant-based foods that result in different allergen profiles.

Slide 10: Many Factors Contribute to Allergen Cross-Contact



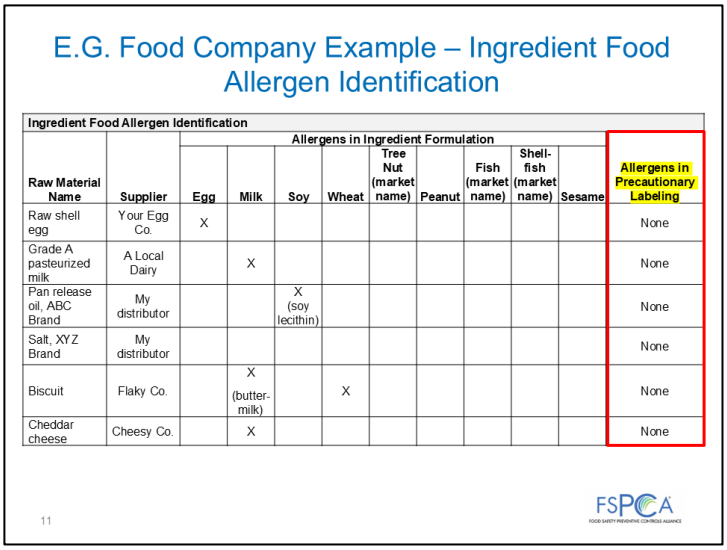
Broad considerations are needed to help prevent cross-contact and include:

- Suppliers, transport, and the receipt of goods;
- Ingredient storage, handling, and processing of allergens, including the use of shared equipment and utensils;
- Personnel practices;
- Possible misuse of rework and processing aids;
- The effectiveness of cleaning;
- Any conveyor or transport systems; and
- The generation of significant dust containing the allergen that may move through the air.

Each of these represents a factor or area where cross-contact needs to be addressed, so it is important to determine the risk of cross-contact and what controls need to be implemented. In some cases, SOPs may be utilized, but in other cases, an allergen preventive control may be needed. The determination of this need was accomplished during the hazard analysis process.

Allergen preventive controls must document those procedures used to prevent allergen cross-contact when the hazard analysis process identifies allergens as hazards requiring a preventive control.

Slide 11: E.G. Food Company Example – Ingredient Food Allergen Identification



E.G. Food Company Example – Ingredient Food Allergen Identification

Ingredient Food Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation									Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shell-fish (market name)	Sesame	
Raw shell egg	Your Egg Co.	X									None
Grade A pasteurized milk	A Local Dairy		X								None
Pan release oil, ABC Brand	My distributor			X (soy lecithin)							None
Salt, XYZ Brand	My distributor										None
Biscuit	Flaky Co.		X (butter-milk)		X						None
Cheddar cheese	Cheesy Co.		X								None

11

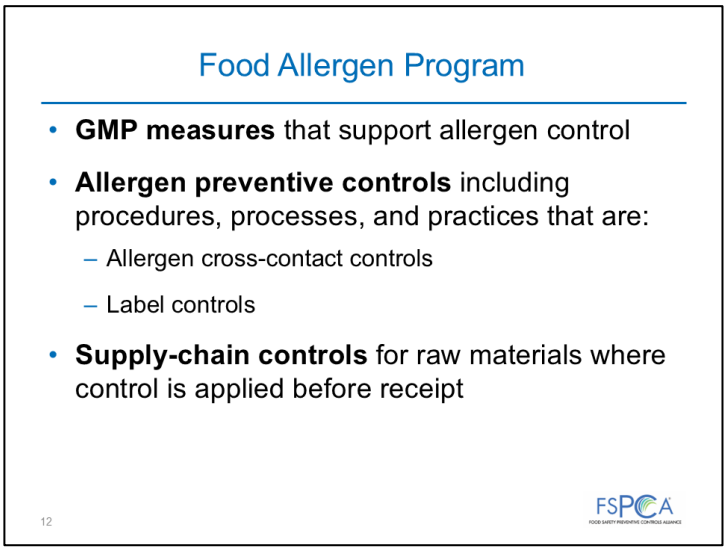
FSPCA

Consider precautionary labeling that comes in on an ingredient and whether it needs to be carried forward to the labels on the finished product.

The E.G. Food Company's Ingredient Food Allergen Assessment lists all of the raw materials used for products, along with the supplier's name.

This information helps E.G. Food Company identify allergens that are in their products, depending on the ingredients used in each product. There is also a column for when precautionary labeling (e.g., "May Contain"), is used by the supplier of a given ingredient. This is important for evaluating the potential risk of cross-contact from that supplier. This concept is discussed further in subsequent slides.

Slide 12: Food Allergen Program

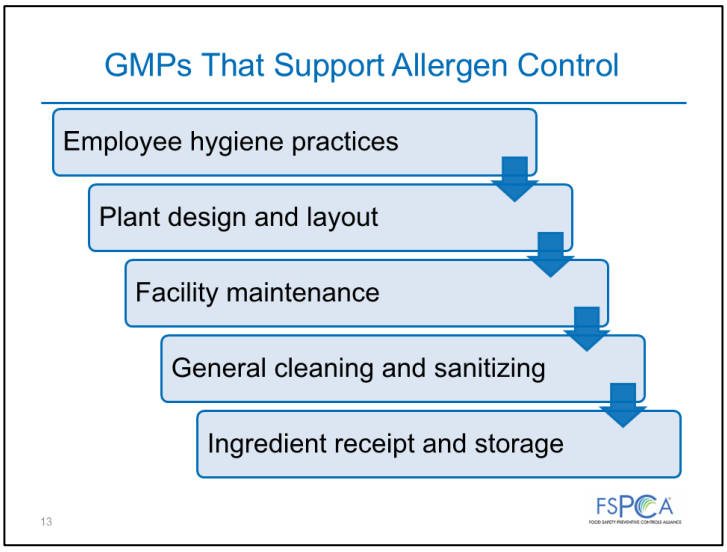


The developed food allergen program can start with various basic GMPs and SOPs that support allergen control, however, a food allergen program typically goes beyond basic GMPs and SOPs to include appropriate allergen preventive controls.

There are two main types of allergen preventive controls within the facility, those that focus on preventing cross-contact, and those that ensure proper labeling. Much of this chapter will be devoted to discussing these two types of controls.

Allergen preventive control of the incoming raw materials is another important aspect of a facility's overall allergen program. This will be discussed in Chapter 13: Supply-Chain Preventive Controls.

Slide 13: GMPs That Support Allergen Control



Many of the GMP procedures used in food facilities are developed to include elements that provide support for the control of allergens. The subsequent slides describe how typical SOPs can also include allergen management.

It is important to note that some aspects of these SOPs could be elevated to the level of preventive controls when the hazard analysis indicates the need.

GMPs for Personnel

Employees can be a vehicle for allergen cross-contact. This can occur as employees move from one product area to another product area, unknowingly carrying allergens on their clothing or their gloves. If they eat food containing allergens in the break area, and fail to wash their hands, they may carry food allergens into the processing area.

Employee movement may have to be restricted from one allergen handling area to another to prevent the risk of their outer clothing carrying residual allergen to the processing area. Approaches to consider include:

- Using color-coded uniforms or hairnets that are specific to a processing area or to a type of allergen-containing food so that these employees can be easily identified if they enter an area with different allergens; and
- Providing dedicated outer clothing (e.g., jacket or smock), that remains in the entrance to the processing area during breaks.

All employees need to be reminded to wash their hands, including maintenance or quality assurance staff members, when moving between areas that handle different allergens to avoid allergen cross-contact issues.

GMPs for Ingredient Receipt and Storage

Inspecting raw materials upon receipt provides an opportunity to identify that the correct materials are received and that all allergens are identified. A documented check will help ensure that the receiver has identified the raw materials allergens and that they are correct for the item being received. This is accomplished by reviewing

the raw material labels and verifying the listed allergens against the ingredient specification. It is common practice to place signage, often in the form of placards, on the incoming materials to designate the allergen or group of allergens contained in the given raw material. Signage can be achieved through use of common wording for allergens, a letter designation, or a color-coding scheme.

This receiving process is often considered a prerequisite program within the food allergen program but may be elevated to a preventive control in a facility that handles many different raw materials with different allergen profiles.

Once received, raw materials are stored based upon allergen content, separating allergen and non-allergen product. Dedicated pallets, combos, or bins for allergenic material can be utilized for the specific raw material. The use of allergen signage, such as placards, can help facilitate the storage process. With signage, consideration should be given to the use of languages other than English. Additionally, if signage is used on pallets, establish a uniform placement protocol so that the allergen label is visible when the pallet is opened, and boxes are removed.

Storage of food products with the same allergens in the same area can simplify management. For example, milk and cheese can be stored together because they both are dairy products containing a milk allergen. However, walnuts and almonds cannot be stored together, even though they are both tree nuts, because they are different allergens. A common practice is that allergen containing materials are not stored above non-allergen materials.

If bags or bins are opened to take test samples upon receipt, dedicated knives should be used to open bags containing specific allergens and then those open bags should be properly sealed after opening. Determine if controls are needed for forklift drivers to prevent damage to packaging. Pierced or dropped bags and cracked or broken bins present allergen cross- contact opportunities that should be avoided and promptly rectified.

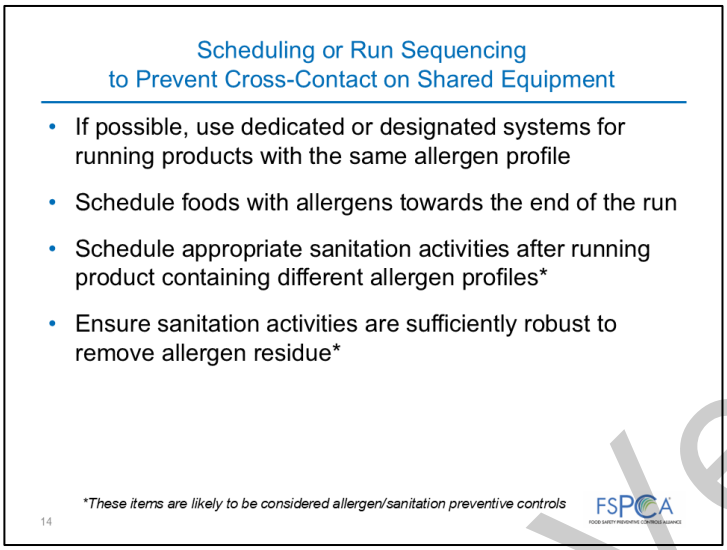
GMP Considerations During Handling and Preparation

Segregation of allergenic foods and ingredients during handling and preparation helps to manage allergen cross-contact in the manufacturing setting. In the processing environment, allergen control considerations must encompass from the time a unique allergen is introduced into the production process and extend through cleanup. For example, powders can easily disperse throughout an area through the air, thus weighing allergenic powders in a different room or dedicated area is useful. Covering totes that contain allergen-containing ingredients during transfer from one room to the next helps to prevent allergen cross-contact. A review of ventilation systems over lines that handle powders may reveal a potential allergen cross-contact issue.

Controlling traffic patterns to reduce allergen cross-contact, such as limiting the movement of people into and out of processing areas with allergen-containing product, can reduce the risk of employees as the source of cross-contact. The use of physical barriers between processing lines may be effective where traffic controls are difficult to implement. The use of dedicated tools for processing lines may also be helpful.

Transfer of allergens through water or oil can also occur. Allergen cross-contact can occur through the reuse of cooking media such as water or frying oil. Consider possible risks from water used to boil eggs or bagel doughs and from oils used to fry seafood. In addition, recirculated sanitation solutions may pose risks if the soil load is heavy; reuse of these solutions is not recommended, especially when allergens are a concern.

Slide 14: Scheduling or Run Sequencing to Prevent Cross-Contact on Shared Equipment



It may not always be possible to implement dedicated systems for processing products with different allergen ingredients. If a line is used to process both allergen-containing and non-allergen-containing food products, the schedule sequence should run unique allergens toward the end. For example, vanilla ice cream might be scheduled first, followed by one with added pecans, followed by one with added pecans and almonds.

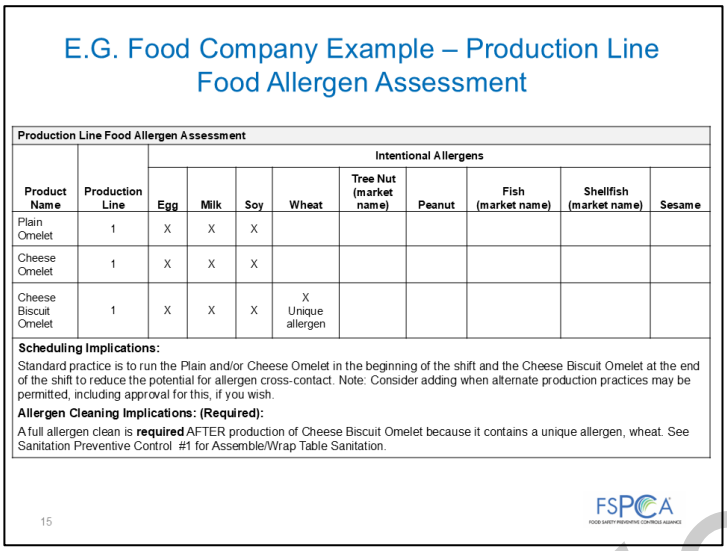
If an allergen present in a current product run is not present in the next scheduled product run, a complete sanitation process must occur. Sanitation activities must be robust enough to remove all visible traces of an allergen residue prior to starting up the next product. If possible, only run products with the same allergen ingredient on the same production line.

Common industry practices for using scheduling to help manage risks from cross-contact have been published by the Food Allergy Research and Resource Program (FARRP), which includes the following:

- Schedule long runs of products containing allergenic ingredients to minimize changeovers;
- Segregate production areas for allergenic and non-allergenic products. If this is not possible, schedule manufacturing of non-allergenic foods before processing foods with allergens;
- Schedule sanitation immediately after production of foods containing allergenic ingredients; and

- When product design permits, add allergenic ingredients as late in the process as possible.

Slide 15: E.G. Food Company Example – Production Line Food Allergen Assessment



E.G. Food Company Example – Production Line Food Allergen Assessment

Production Line Food Allergen Assessment

Product Name	Production Line	Intentional Allergens								
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame
Plain Omelet	1	X	X	X						
Cheese Omelet	1	X	X	X						
Cheese Biscuit Omelet	1	X	X	X	X Unique allergen					

Scheduling Implications:

Standard practice is to run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Biscuit Omelet at the end of the shift to reduce the potential for allergen cross-contact. Note: Consider adding when alternate production practices may be permitted, including approval for this, if you wish.

Allergen Cleaning Implications: (Required):

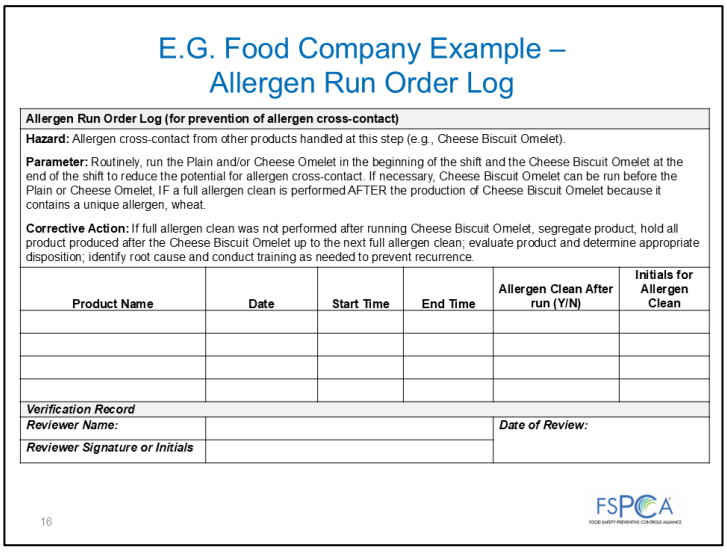
A full allergen clean is **required** AFTER production of Cheese Biscuit Omelet because it contains a unique allergen, wheat. See Sanitation Preventive Control #1 for Assemble/Wrap Table Sanitation.

15

FSPCA

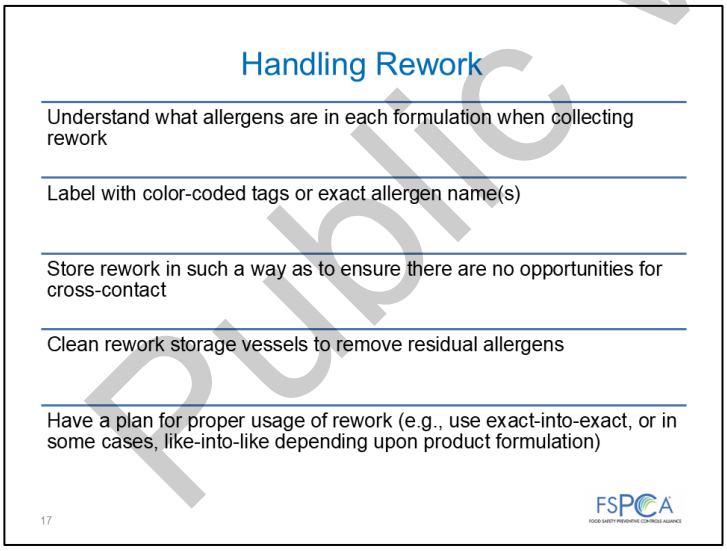
An example of a Production Line Allergen Assessment for the E.G. Food Company appears above. Only one product, the cheese biscuit omelet, has a unique allergen, wheat. Scheduling implications and cleaning implications are noted, illustrating that the cheese biscuit omelet is run at the end.

Slide 16: E.G. Food Company Example – Allergen Run Order Log



E.G. Food Company utilizes the Allergen Run Order Log to capture the sequence of products produced in order to identify that a complete sanitation process will need to be completed after a unique allergen is produced (see the monitor run sequencing as described above and at the bottom of the "Daily Sanitation Log," Appendix 3, page A3-47).

Slide 17: Handling Rework



An awareness of the allergen profile of each formula must extend to rework when considering managing potential cross-contact or misidentification concerns. Considerations for proper handling of rework and work in progress are described on this slide. Mark the rework bin properly with information such as:

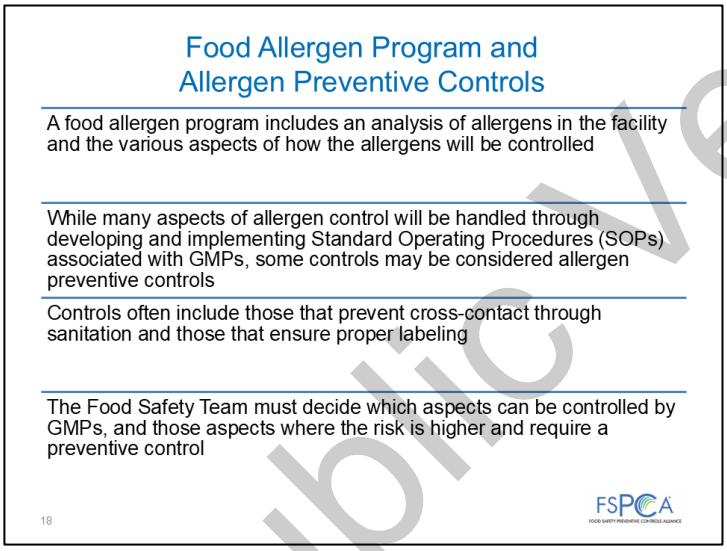
- Name of the rework or QA hold product;
- Exact name of the allergen;

- Date/time of manufacture;
- Date/time put into storage; and
- Date/time for using rework (if known).
- Color-coded labels may be helpful.

To reduce opportunities for cross-contact, use sturdy containers with secure covers, and interior disposable plastic liners where appropriate. Use dedicated containers, lids, and pallets when feasible, or thoroughly wash and sanitize containers before reuse. Using containers that are easily moved without use of equipment to hold allergen-containing materials (e.g., totes on wheels), makes it easier to segregate the material and reduces the potential for damage by forklifts. Containers must be thoroughly cleaned to remove any traces of allergenic material.

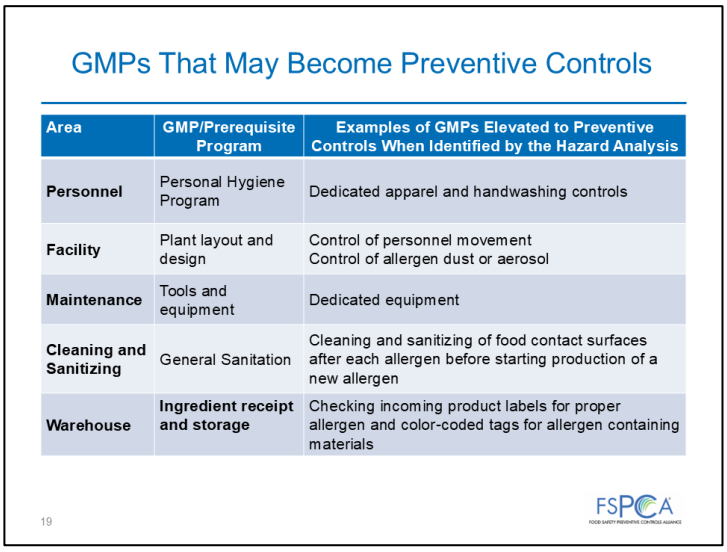
Make sure there are documented procedures for how rework is to be used. Allergen-containing rework is only to be used in a product that contains the same allergens.

Slide 18: Food Allergen Program and Allergen Preventive Controls



A food allergen program is a critical component of a company's food safety system. Food allergen programs start with identifying allergens and how they will be optimally controlled. Many of the controls will include various SOPs related to GMPs, but some will be elevated to be managed as allergen preventive controls. Typically, these will be in areas focused on preventing cross-contact via appropriately targeted sanitation and aspects of product labeling. The Food Safety Team decides how these are to be best managed.

Slide 19: GMPs That May Become Preventive Controls



GMPs That May Become Preventive Controls

Area	GMP/Prerequisite Program	Examples of GMPs Elevated to Preventive Controls When Identified by the Hazard Analysis
Personnel	Personal Hygiene Program	Dedicated apparel and handwashing controls
Facility	Plant layout and design	Control of personnel movement Control of allergen dust or aerosol
Maintenance	Tools and equipment	Dedicated equipment
Cleaning and Sanitizing	General Sanitation	Cleaning and sanitizing of food contact surfaces after each allergen before starting production of a new allergen
Warehouse	**Ingredient receipt and storage**	Checking incoming product labels for proper allergen and color-coded tags for allergen containing materials

19

FSPCA

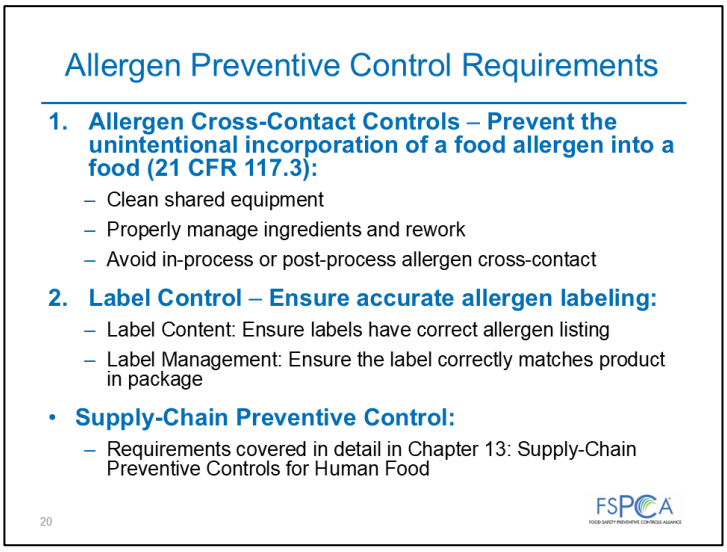
A thorough understanding of where allergenic ingredients exists in the manufacturing environment, how the allergenic ingredients are handled, and where allergenic ingredients are introduced into the process can influence whether practices are managed as GMP, a prerequisite program, or as a preventive control.

Above are examples of GMPs or prerequisite programs that could reasonably elevate to preventive controls in a facility that handles allergens. The allergen preventive controls could focus on preventing cross-contact, with controls directed at personal hygiene such as handwashing, facility layout related to personnel movement and dust management, the use of dedicated tools and equipment, and cleaning of equipment. Additionally, there could be very specific instances where personnel practices or changeovers might need to be considered (e.g., as described in §117.80 (c)(2), related to handwashing, changing garments, etc.), if indicated in the hazard analysis.

Also, at ingredient receipt and storage, there may be a need for a preventive control aimed at assuring that ingredient labeling is accurate, and the allergens listed on the label match what is listed on the specification.

The FDA has detected issues related to allergen control leading to enforcement in the form of Warning Letters (see examples additional reading, resources, and references at the end of this chapter). In these instances, the FDA had identified handwashing as a preventive control practice where there was direct hand manipulation of allergen-containing products or ingredients, and there was inadequate handwashing or glove changing to prevent allergen cross-contact. In other words, situations where the risk for cross-contact occurring from hand hygiene practices are significant. The FDA has identified handwashing as part of allergen preventive control.

Slide 20: Allergen Preventive Control Requirements



In the FDA Hazard Guide, Chapter 11: Food Allergen Program, the FDA discusses the two primary types of allergen preventive controls used within a processing facility. One is how an allergen preventive control can be applied to prevent allergen cross-contact. The other is how an allergen preventive control can be applied to ensure accurate allergen labeling.

Allergen Cross-Contact

An allergen preventive control may be required in circumstances where two different products with different allergen profiles are made using the same equipment. An allergen preventive control can be applied to ensure that allergen residues have been properly removed through sanitation. This can also be viewed as a sanitation preventive control). Other procedures that can become allergen preventive controls include the procedures for handling rework or the control of exposed in-process product to prevent opportunities for cross-contact.

Undeclared Allergens

Preventive controls can be applied to aspects of labeling, and this is especially important in those facilities that may handle a number of different allergen-containing products and/or have a variety of labels with different allergen profiles. Aspects of the labeling process that can become an allergen preventive control include:

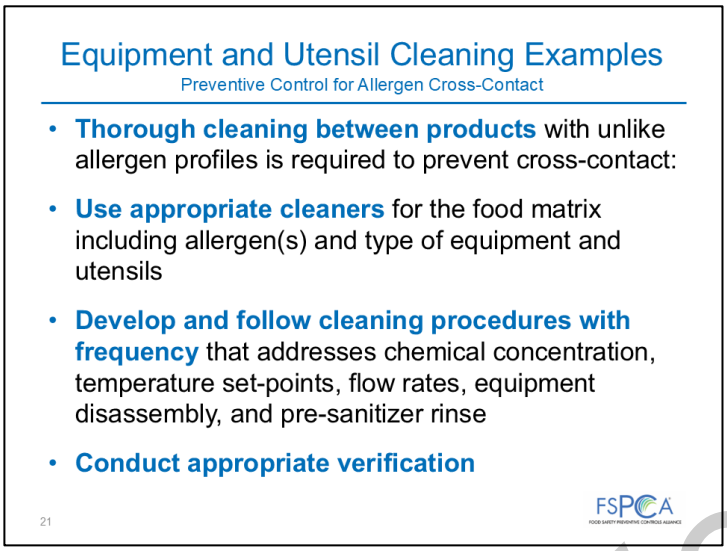
- The design of the label to ensure the proper allergens are listed on the proposed label; and
- The labeling of product to prevent the incorrect label from being placed on the product.

This chapter will go into more detail on these aspects of allergen preventive controls. When a facility decides to designate an aspect of the allergen program as an allergen preventive control, the decision will be driven by the hazard analysis process.

Undeclared allergens may also be present if an ingredient supplier does not manage their allergens effectively or if a label supplier does not print label stock accurately.

Chapter 13: Supply-chain Preventive Controls addresses relevant aspects of allergen control in a supply-chain program.

Slide 21: Equipment and Utensil Cleaning Examples – Preventive Control for Allergen Cross-Contact (1 of 2)



The regulation does not require validation of allergen cleaning, but this is strongly encouraged.

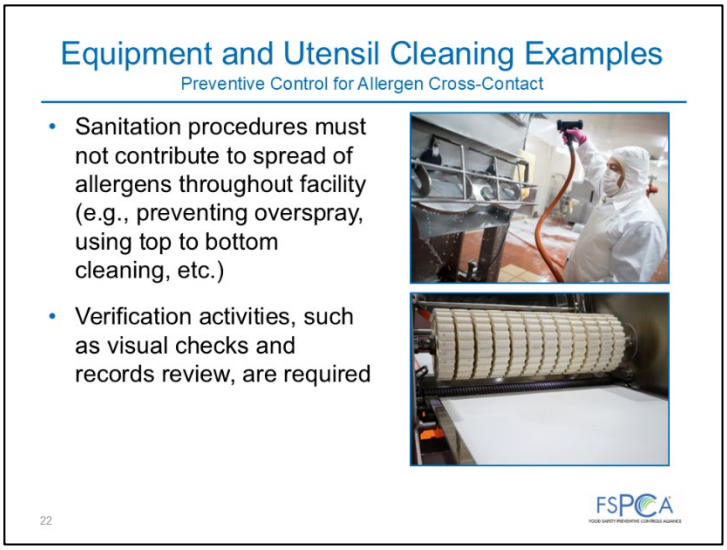
Numerous allergen recalls have occurred because equipment could not be adequately cleaned to remove allergen residues.

Effective cleaning of utensils and equipment at a frequency specific to the hazards in the facility is an essential element in an allergen management program. Food contact surfaces should be clean to the point where there are no residual allergens on that surface prior to the production of food products without the allergen profile of the previous product.

Effective cleaning between products with different allergen profiles is necessary to remove residual allergenic proteins. The cleaning procedures used must be appropriate for the food matrix and the type of equipment. Refer to Chapter 12: Sanitation Preventive Controls, for information on cleaning procedure documentation requirements, and Appendix 5: Sanitation Basics, for more information on cleaning. FARRP has published guidance on components of an effective allergen control plan which also describes recommendations for allergen cleaning.

Cleaners must be effective at removing the type of soil and appropriate for the specific equipment surface. Cleaning activities must follow sanitation SOPs and be consistent with the instructions on the cleaning product's label. The SOPs should include detailed instructions to ensure that the personnel who are cleaning know what steps are required. Key criteria, including required chemical concentration, temperature of mixtures, flow rates, etc., should be specified in the SOPs (as necessary) for consistent results. The SOP should also detail how the equipment must be disassembled, and when rinse steps are required. Verification demonstrating that the procedures are consistently followed is required.

Slide 22: Equipment and Utensil Cleaning Examples – Preventive Control for Allergen Cross-Contact (2 of 2)



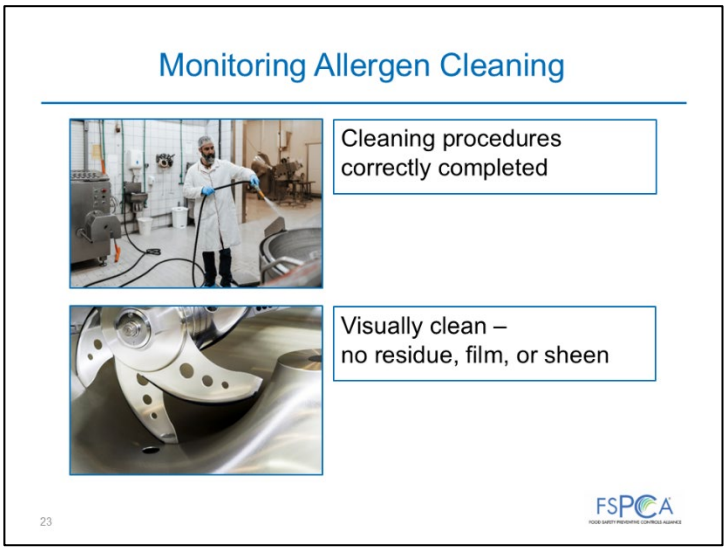
Validation of allergen cleaning procedures is not required but may be beneficial.

The Preventive Controls for Human Food regulation does not require validation of allergen cleaning; however, validation is strongly encouraged when products containing different allergen profiles are run in the facility. Numerous allergen recalls have occurred because equipment could not be adequately cleaned to remove allergen residues, resulting in allergen cross-contact.

Verification demonstrating that the procedures are consistently followed is required. Verification activities can include visual checks that the cleaning process was completed and record checks to ensure the proper levels of cleaner were used.

It is important to ensure that the sanitation procedures themselves do not further contribute to the potential for unintended allergen presence in the facility. For example, spraying an uncleaned production line with a high-pressure hose to remove food solids can cause food allergens to be scattered; carried by water droplets.

Slide 23: Monitoring Allergen Cleaning



Monitoring of the cleaning process to be sure cleaning procedures are correctly completed is an important aspect of verification. Visually observing the cleaning process is one form of verification. This can include checking that the right chemical cleaners are being used at the appropriate concentration and application temperature.

Many companies use a standard of "visually clean" as the primary evidence of allergen cleaning.

This will be discussed next in more detail.

Validation of allergen cleaning is not required. However, validation may be desirable for complex equipment the first time a unique allergen is introduced on a production line, or when major changes are made to product formulation to determine if cleaning procedures need to beadjusted.

Simple-to-clean equipment, such as a stainless-steel tabletop, may not need validation ifthe surface is visibly clean (i.e.,no residue or film), when cleaning procedures are followed.

Slide 24: Verification of Allergen Cleaning

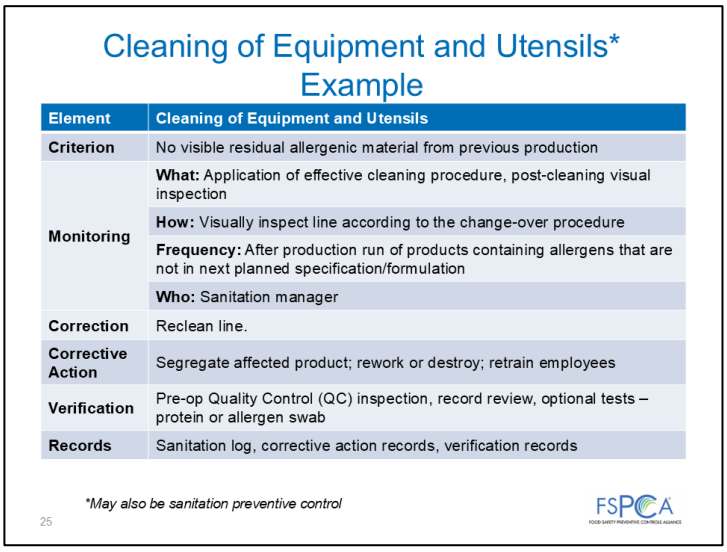
If residue can be seen on the equipment, the equipment is not clean. But if it looks clean, there may still be the presence of films or protein sheen. Chemical test kits can be used to check the cleanliness of the surface and can be an important tool for verifying cleanliness and the absence of allergenic proteins.

Non-specific tests are helpful; however, limitations exist when using tests such as non-specific ATP or protein tests for verifying allergen cleaning. Some of these tests are not sensitive enough to detect levels of protein that could cause an allergic reaction. Validated allergen-specific test kits are available for some food allergens and can be used to detect the presence of food allergens in food products, or on food-contact surfaces using swabs.

When using push-through material as an allergen removal procedure, it is important to establish safe times and/or volumes for such a procedure and so it is important to verify that these procedures work. If a surface cannot be effectively swabbed, final rinse water can be collected and tested, assuming the equipment and environment is suitable for wet cleaning, as discussed in Chapter 12: Sanitation Preventive Controls.

Finished product can also be tested as a verification procedure., Appropriate corrective action is needed if allergens which are not on the label are detected.

Slide 25: Cleaning of Equipment and Utensils Example



Cleaning of Equipment and Utensils* Example

Element	Cleaning of Equipment and Utensils
Criterion	No visible residual allergenic material from previous production
Monitoring	**What:** Application of effective cleaning procedure, post-cleaning visual inspection
	How: Visually inspect line according to the change-over procedure
	Frequency: After production run of products containing allergens that are not in next planned specification/formulation
	Who: Sanitation manager
Correction	Reclean line.
Corrective Action	Segregate affected product; rework or destroy; retrain employees
Verification	Pre-op Quality Control (QC) inspection, record review, optional tests – protein or allergen swab
Records	Sanitation log, corrective action records, verification records

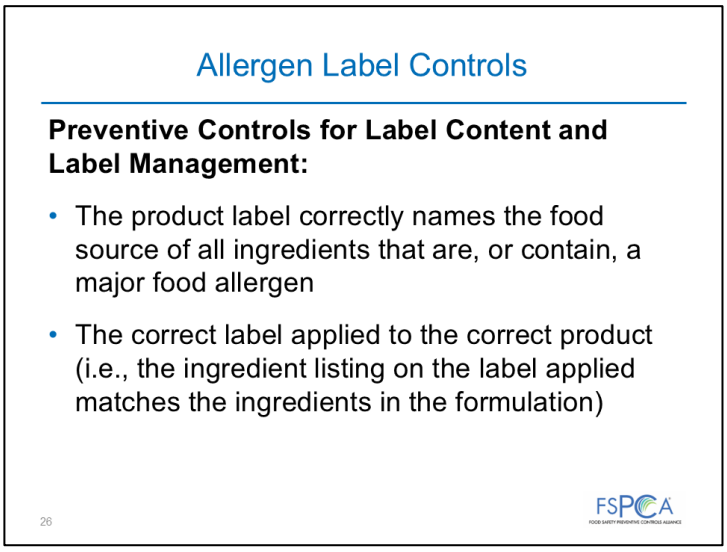
*May also be sanitation preventive control

25

FSPCA

This slide demonstrates an example of equipment cleaning as an allergen preventive control to manage cross-contact hazards including possible parameters and values. Shown are the criterion to which the equipment could be cleaned, all the details of monitoring, corrections, and corrective actions, two different ways that verification can be done and a listing of the relevant records.

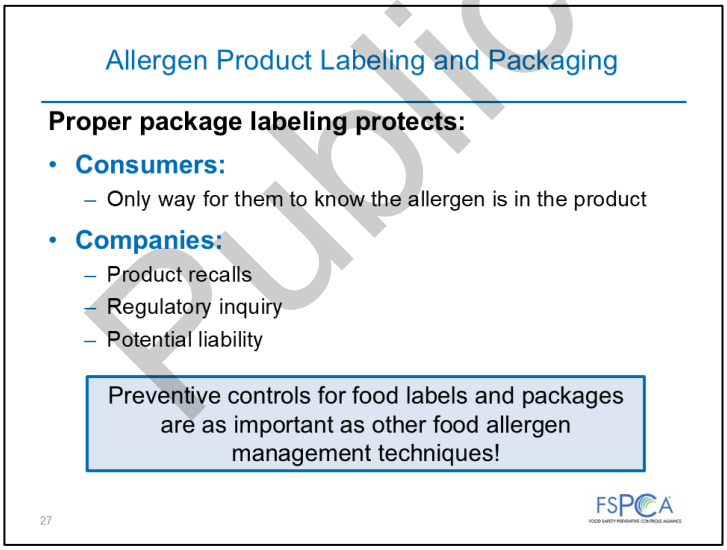
Slide 26: Allergen Label Controls



Allergen label controls must ensure that the label on the product correctly names the food source of all its ingredients which are, or which contain food allergens. Controls must also ensure the ingredient listing on the product label matches the formulation of that product.

Simply put, the label must be correctly designed listing the appropriate allergens in that given food product and then that label is applied to the correct product so that the allergens match the formulated food inside the packaging.

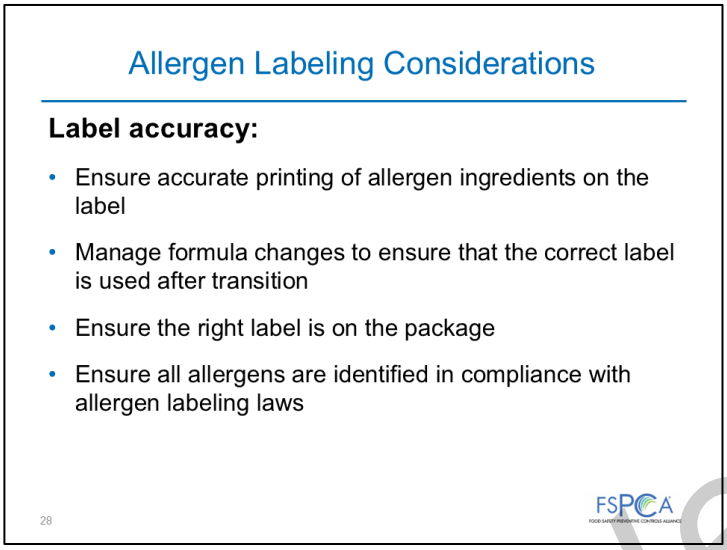
Slide 27: Allergen Product Labeling and Packaging



Allergens listed on food labels are essential to protecting consumers with food allergies. It is the only way for the consumer to know which allergens are in the product they are about to consume. Undeclared allergens, those allergens in the product but not declared on the label, can lead to illness and death of an allergen-sensitive consumer.

Labeling and packaging errors are both leading causes of allergen-related recalls. Not only are these errors an issue for consumer health, but they can also result in brand damage, regulatory action, manufacturing disruption, and potential liability when illness occurs.

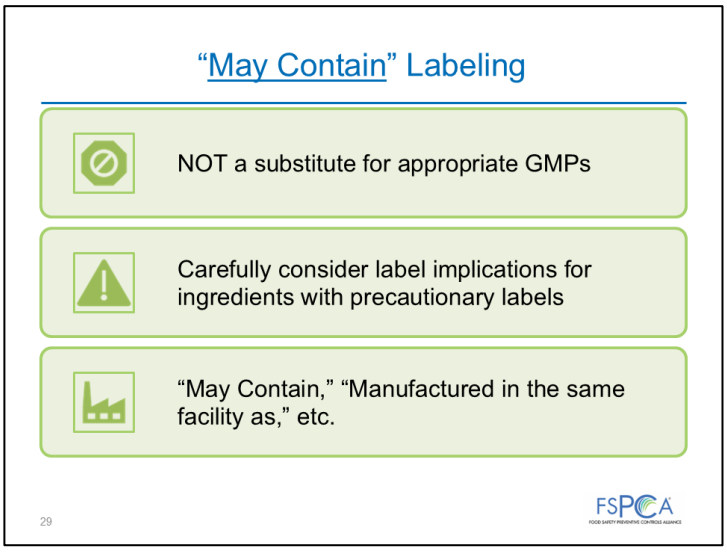
Slide 28: Allergen Labeling Considerations



Procedures that ensure accurate allergen labeling are required in the Food Safety Plan when a food product contains a food allergen. Elements include ensuring that the verbiage is accurate on the label in compliance with the labeling laws and that any formula changes are managed appropriately so that the correct label is used on the new formula. Any out-of-date labels in inventory need to be removed from active inventory. The FALCPA Act and the FASTER Act (see additional reading, resources, and references at the end of this chapter) provide regulatory requirements that apply to ensure proper allergen labeling on FDA-regulated products.

Supply-chain programs are also important to ensure that food ingredient suppliers accurately identify allergens in the food ingredients and food products provided.

Slide 29: "May Contain" Labeling



Potential resources for determining labeling optionswhen an ingredient has a precautionary label are:

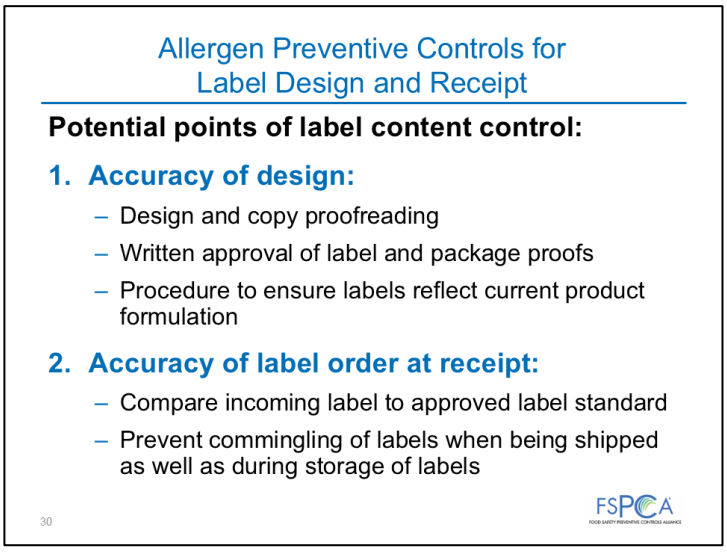
- FDA Guidance for Industry
- The Food Allergy Research and Resource Program (FARRP)

Both resources are available in the Additional Reading, Resources, and References list at the end of the chapter.

Precautionary allergen labeling, such as "May Contain" or "Manufactured in a facility that produces… [a specific allergen]" is not a preventive control. While allergen cross-contact of food products with major food allergens can occur in the manufacturing process when food product is exposed to the environment, precautionary labeling cannot be used to compensate for poor GMPs or inadequate allergen controls.

When an incoming ingredient has a precautionary label, the facility must determine how to address this potential allergen as part of its labeling requirements. Chapter 13: Supply-Chain Preventive Controls, addresses additional requirements for supply-chain programs, which include documentation and verification procedures.

Slide 30: Allergen Preventive Controls for Label Design and Receipt



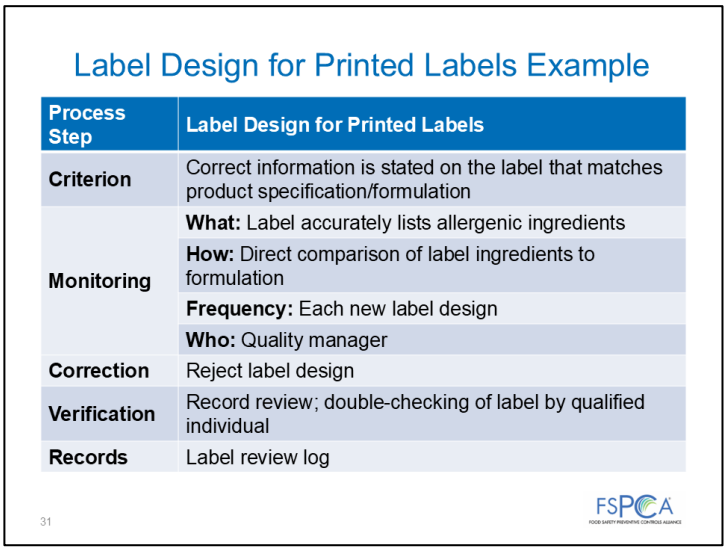
This slide is a lead-in to the subsequent examples outlining specifics of different points where label content controls can be implemented. There are two primary aspects: Designing the label so that it states the appropriate allergens and checking the accuracy of the labels upon receipt or printing.

Proofreading label text is a useful tool to prevent errors, and some organizations consider this a preventive control. If the label is complicated, use more than one person to proofread and consider developing a written approval process to better ensure accuracy. Standard operating procedures should ensure that labels reflect the current formulation being made.

For incoming labels shipped from an external label maker, labels can be checked upon receipt by comparing the new labels to the to a standard label or to a label specification, specifically inspecting for allergens.

Using an identity coding system for printed labels and packages, such as color codes that are easy to visualize, can help with effective label management on the production floor. Procedures that do not allow co-mingling of labels on the same pallet during storage also minimize the potential for the wrong label to be used in production.

Slide 31: Label Design for Printed Labels Example



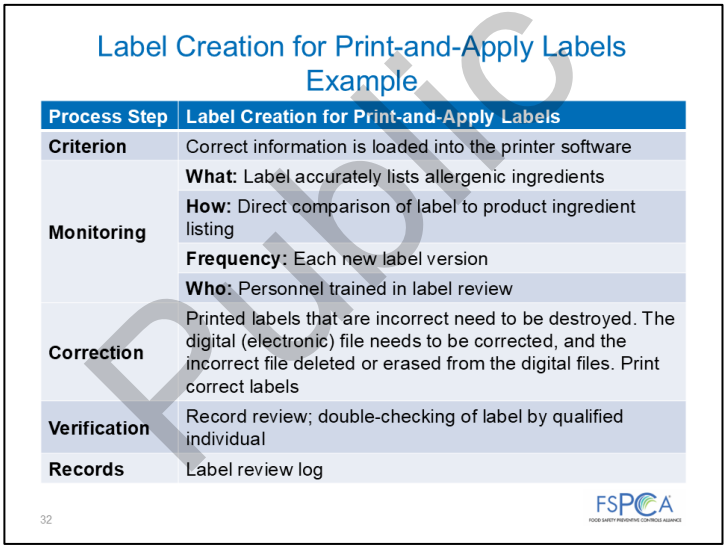
Label Design for Printed Labels Example

Process Step	Label Design for Printed Labels
Criterion	Correct information is stated on the label that matches product specification/formulation
Monitoring	**What:** Label accurately lists allergenic ingredients
	How: Direct comparison of label ingredients to formulation
	Frequency: Each new label design
	Who: Quality manager
Correction	Reject label design
Verification	Record review; double-checking of label by qualified individual
Records	Label review log

31

This slide demonstrates an example of the aspects of label design as an allergen preventive control for labels that are printed by a packaging supplier, received by the plant, and applied to the food item, including possible parameters and values. Shown on the slide are the criterion that the verbiage on the label must match the formula being run, all of the details of monitoring, correction, verification, and a listing of the relevant records.

Slide 32: Label Creation for Print-and-Apply Labels Example



Label Creation for Print-and-Apply Labels Example

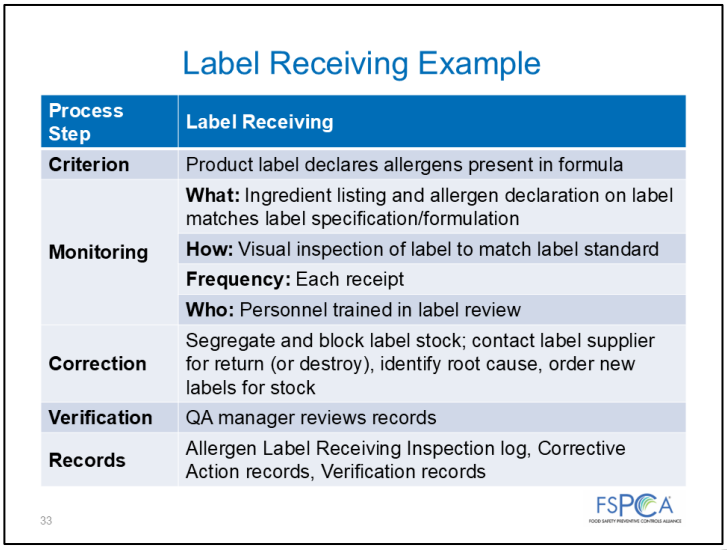
Process Step	Label Creation for Print-and-Apply Labels
Criterion	Correct information is loaded into the printer software
Monitoring	**What:** Label accurately lists allergenic ingredients
	How: Direct comparison of label to product ingredient listing
	Frequency: Each new label version
	Who: Personnel trained in label review
Correction	Printed labels that are incorrect need to be destroyed. The digital (electronic) file needs to be corrected, and the incorrect file deleted or erased from the digital files. Print correct labels
Verification	Record review; double-checking of label by qualified individual
Records	Label review log

32

This slide demonstrates an example of an allergen preventive control for labels that are printed on site by the facility and then applied to the food product. The example includes possible parameters and values for label controls. An example of a type of company that may use this process is a private label bakery manufacturing a wide range of baked goods that may be sold at a grocery store. It is crucial that the information in the printing software (from which the label is printed) accurately reflects the formula being run. Shown are the criterion that the text on the label must match

the formula being run, all of the details of monitoring, correction, verification, and a listing of the relevant records.

Slide 33: Label Receiving Example



Label Receiving Example

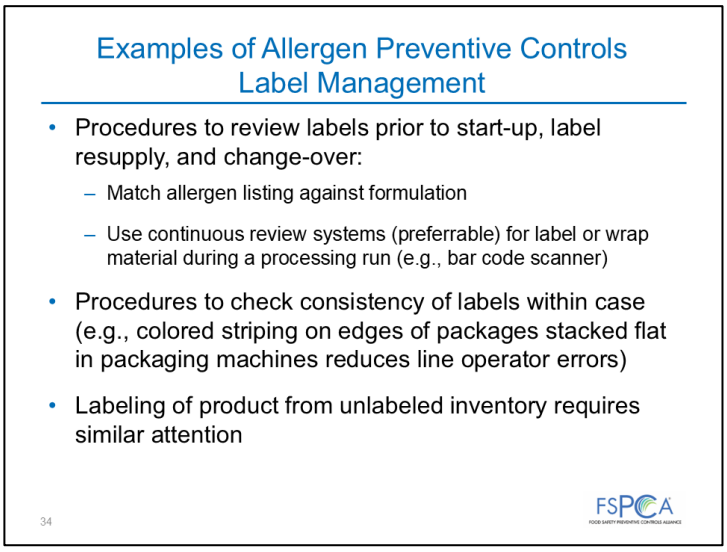
Process Step	Label Receiving
Criterion	Product label declares allergens present in formula
Monitoring	**What:** Ingredient listing and allergen declaration on label matches label specification/formulation
	How: Visual inspection of label to match label standard
	Frequency: Each receipt
	Who: Personnel trained in label review
Correction	Segregate and block label stock; contact label supplier for return (or destroy), identify root cause, order new labels for stock
Verification	QA manager reviews records
Records	Allergen Label Receiving Inspection log, Corrective Action records, Verification records

33

FSPCA

This slide demonstrates an example of an allergen preventive control for label receiving by warehouse staff. The example includes possible parameters and values for label controls to ensure that the incoming label is correct. It is crucial that the information on the received label accurately reflects the formula for the designated product and accurately declares the allergens in the formula. Also shown are the details of monitoring, correction, verification, and a listing of the relevant records.

Slide 34: Examples of Allergen Preventive Controls Label Management



Because applying a label to a package is part of a process, some companies may manage allergen labeling at a process control step and call it a CCP. Other companies may manage it in what they may call an "Allergen Control Plan." Either approach is fine as long as the allergens that are present in the food are declared on the label.

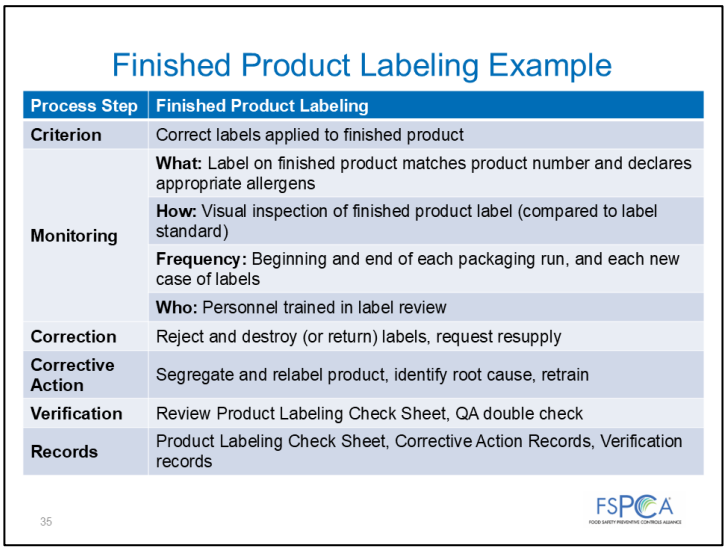
Ensuring that the correct label is applied to a product containing a food allergen is a required allergen preventive control. Shown on the slide are a variety of approaches that could be used to help achieve this, including matching the allergen listing on the label to the formula. These are examples of procedures. Each facility should determine which is best for its operation.

Continuous monitoring, such as a bar code scanner, is the most effective, but may not be affordable for some processors. Colored striping on stacked flat labels in packaging machines is another approach to reduce operator error. This is particularly useful when the label supply runs out mid-production. Returning unused packaging materials to the warehouse, and not mixing them with other packaging materials helps avoid packaging mix-ups. It is best to store packaging (e.g., plastic cups, lids), in boxes that are sealed. Line personnel need to be trained to ensure product labels are switched properly at product changeover. This is especially important when labels are applied to products, such as cans, that are held in unlabeled inventory and labeled well after production.

A variety of other measures can help to reduce mistakes, such as a system to assure that out-of-date labels and packaging are removed and destroyed in a timely manner. Keeping accurate inventory records of labels and packaging can help identify issues. If the numbers do not match, it is likely the wrong label was used on a packaging run. Stage packaging so that only those needed for current product are in the packaging area. Check packaging film labels for accuracy (e.g., by comparing the label to the formulation or recipe of the product being produced), before the label roll is placed on the packaging machine. For onsite computer-generated labels, verify that the correct electronic file is applied for each label, and have a system that lets only authorized personnel edit electronic label files.

Remember that the essential allergen preventive control is that product containers and labels applied during processing are monitored to ensure that allergen information on labels matches ingredient specifications of the food product.

Slide 35: Finished Product Labeling Example



Finished Product Labeling Example

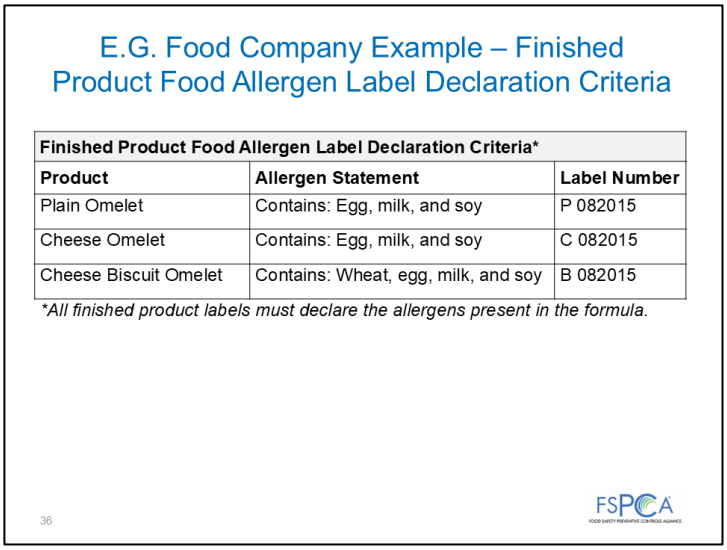
Process Step	Finished Product Labeling
Criterion	Correct labels applied to finished product
Monitoring	**What:** Label on finished product matches product number and declares appropriate allergens
	How: Visual inspection of finished product label (compared to label standard)
	Frequency: Beginning and end of each packaging run, and each new case of labels
	Who: Personnel trained in label review
Correction	Reject and destroy (or return) labels, request resupply
Corrective Action	Segregate and relabel product, identify root cause, retrain
Verification	Review Product Labeling Check Sheet, QA double check
Records	Product Labeling Check Sheet, Corrective Action Records, Verification records

35

FSPCA

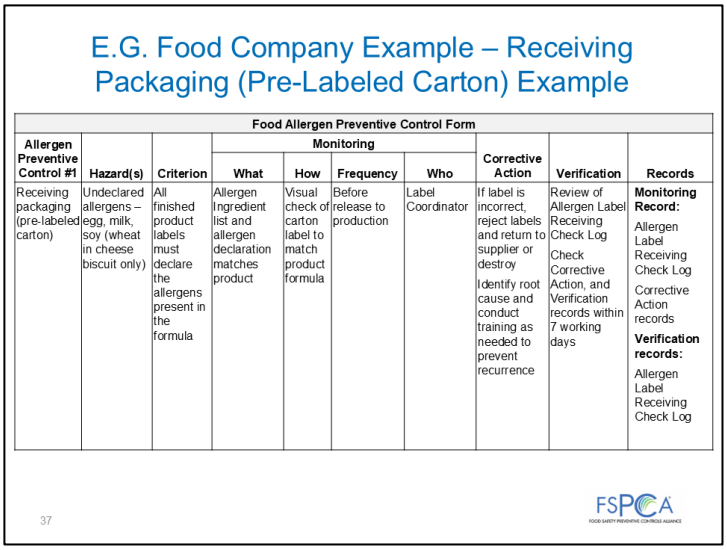
This slide demonstrates an example of finished product labeling as an allergen preventive control including possible parameters and values. It is crucial that the proper label is applied to the finished product matching the formula being made to the label being used and that there is an accurate declaration of the allergens in the formula. Also shown are the details of monitoring, correction, verification, and a listing of the relevant records.

Slide 36: E.G. Food Company Example – Finished Product Food Allergen Label Declaration Criteria



Using their recipe sheets and the Ingredient Allergen Assessment, the E.G. Food Company personnel document the allergen statements that must appear on labels for each product. As an allergen preventive control, they check the label upon receipt from the label manufacturer to prevent potential label errors in case a mistake was made during printing and check the label number when labels are applied to product. Checking the label number when the label is applied involves less detailed review than reading the "contains" statement.

Slide 37: E.G. Food Company Example – Receiving Packaging (Pre-Labeled Carton) Example



E.G. Food Company Example – Receiving Packaging (Pre-Labeled Carton) Example

Food Allergen Preventive Control Form									
Allergen Preventive Control #1	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Receiving packaging (pre-labeled carton)	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit only)	All finished product labels must declare the allergens present in the formula	Allergen Ingredient list and allergen declaration matches product	Visual check of carton label to match product formula	Before release to production	Label Coordinator	If label is incorrect, reject labels and return to supplier or destroy Identify root cause and conduct training as needed to prevent recurrence	Review of Allergen Label Receiving Check Log Check Corrective Action, and Verification records within 7 working days	**Monitoring Record:** Allergen Label Receiving Check Log Corrective Action records **Verification records:** Allergen Label Receiving Check Log

37

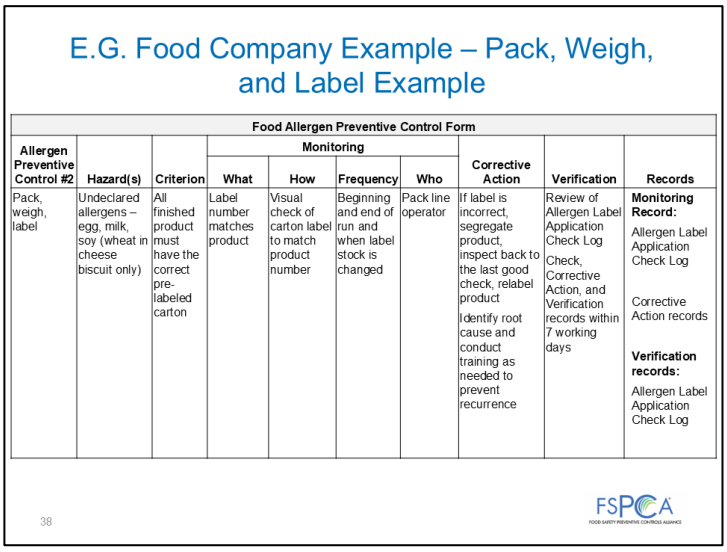
FSPCA

The E.G. Food Company example of an allergen preventive control for reviewing the label upon receipt is shown above and the preventive control for applying the label to the product is shown on the next slide. Upon receipt, the label coordinator matches the information on the label to the product formula information. This includes the allergen declaration, as well as the listing of ingredients (Note: We do not provide a complete listing of ingredients for example).

Label review could be done only at the labeling step, but many organizations perform two label reviews 1) upon receipt and 2) at the labeling step. Complex labels require careful review by people trained in technical label wording requirements. Application of the label on the line may be simply matching a label number to the product formula.

Training may be appropriate for a label developer, for example if a mistake is madeon the copy sent to the printer.

Slide 38: E.G. Food Company Example – Pack, Weigh, and Label Example



E.G. Food Company Example – Pack, Weigh, and Label Example

Food Allergen Preventive Control Form									
Allergen Preventive Control #2	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Pack, weigh, label	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit only)	All finished product must have the correct pre-labeled carton	Label number matches product	Visual check of carton label to match product number	Beginning and end of run and when label stock is changed	Pack line operator	If label is incorrect, segregate product, inspect back to the last good check, relabel product Identify root cause and conduct training as needed to prevent recurrence	Review of Allergen Label Application Check Log Check, Corrective Action, and Verification records within 7 working days	**Monitoring Record:** Allergen Label Application Check Log Corrective Action records **Verification records:** Allergen Label Application Check Log

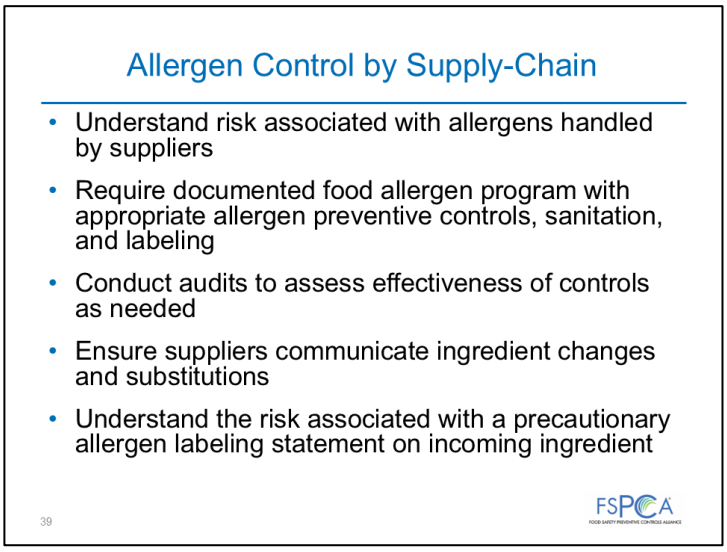
38

FSPCA

At the "Pack, Weigh, Label" step, the E.G. Food Company's Food Safety Plan states that "All finished product must have the correct pre-labeled carton." The monitoring portion of the allergen preventive control uses the same structure as that for process preventive controls—identifying what, how, when, and who. At this step, the pack line operator matches the label to the product number. Pre-determined corrective action addresses what to do with the product, if the label is incorrect, as well as identification of the root cause and taking appropriate action to prevent recurrence.

As with process controls, the records associated with the allergen preventive control procedure are verified, specifically the Label Check Log form and any corrective action or verification records.

Slide 39: Allergen Control by Supply-Chain



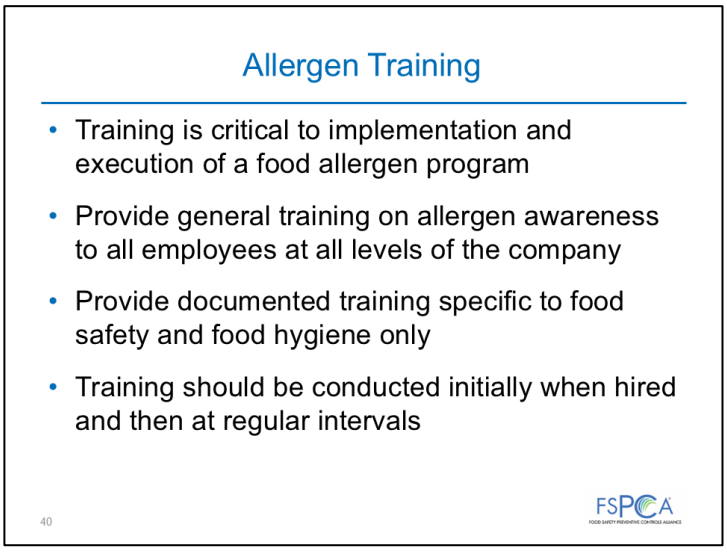
Definition: *Supplier:* The establishment that manufactures/ processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/ processing that consists solely of the addition of labeling or similar activity of a de minimis nature. (21 CFR 117.3)

Whether ingredients are purchased directly from a manufacturer, from a broker, or from a retail store, the manufacturer (or grower) of the ingredient is "the supplier" by regulation (see text box).

It may be important to understand the level of allergen risk associated with an ingredient supplier and the effectiveness of their food allergen program. (e.g., sanitation and labeling). The importance will depend on the nature of the ingredient, the allergen profile of the product, and other products produced by the supplier. Refer to Chapter 13: Supply-Chain Preventive Controls for a discussion of other relevant controls at the supplier level which may include periodic audits to verify effectiveness of controls.

Carefully review the supplier's allergen information related to the raw material including the allergen label. Does the supplier need allergen preventive control? Do they handle other allergens within their operation? If there is a concern, follow up with the ingredient manufacturer to obtain more information. This is especially relevant if "may contain" labeling is used on the ingredient. Ensure that the suppliers communicate any formula or labeling changes promptly.

Slide 40: Allergen Training



The University of Nebraska's Food Allergy Research and Resource Program (FARRP) provides resources and training relevant for food manufacturers (see link at end of this chapter).

Other programs may also be available locally.

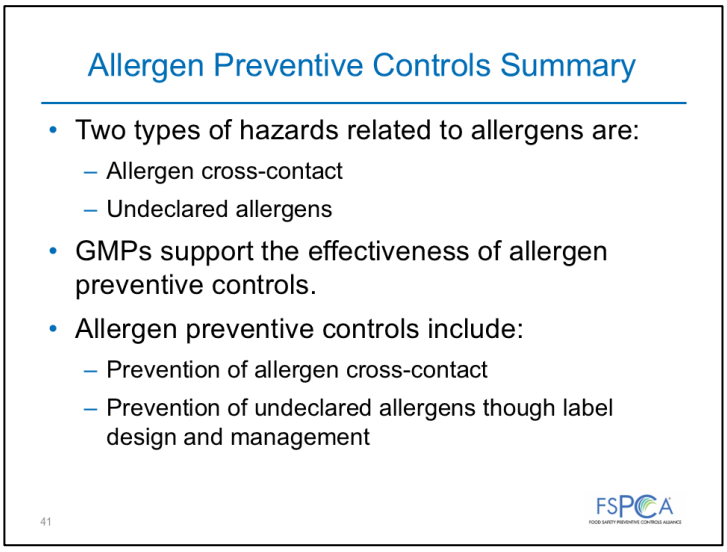
Employee training on allergens is an important factor in implementing an effective food allergen program. This training should include general allergen awareness for all employees, and for those assigned to allergen-related tasks, the importance of allergen preventive control, and proper implementation of the preventive control.

Not all employees in the food facility have or may be aware of others with food allergies, so it is helpful that they are made aware of the health hazards posed to consumers with allergies to certain foods. Training is useful for employees at all levels of the company. It not only provides an opportunity to build knowledge, but also to communicate the importance of each employee's role in allergen management. Overall, training reinforces a commitment to food safety and highlights changes or improvements in production.

Supervisory personnel must be trained in the key areas of allergen preventive control so that they have the knowledge to train and oversee production workers. Food production workers must be trained in each of the areas relevant to their job responsibilities. Food allergen training at the time of initial hire, and then at regular intervals, reinforces proper practices and reminds workers of their importance to food allergic consumers.

The section on allergens in Chapter 4: Chemical, Physical, and Economically Motivated Food Safety Hazards is a good starting point for allergen awareness training. Sanitation chemical suppliers frequently have training materials on allergens as well. It is important to know the culture at the facility to identify the type of training that will work at the location. Budget constraints may limit the options, but good external training is available through recognized resources, such as the Additional Reading list at the end of this chapter.

Slide 41: Allergen Preventive Controls Summary



Food allergens present a risk to consumer health as allergic reactions can be severe to those who are allergic to a given food. Because of ongoing issues facilities have with managing food allergens, allergen issues continue to be a major cause of food safety recalls. Consumers depend on labels to give them accurate information about allergen content.

A facility's food allergen program will utilize GMP procedures and allergen preventive controls to minimize allergen related risk to consumers. GMPs will include elements such as ingredient handling procedures and production scheduling.

Food allergen preventive controls are required when allergens are recognized as a hazard requiring a preventive control in the hazard analysis. Allergen preventive controls prevent allergen cross-contact with food allergenic material and ensure products are accurately labeled. A variety of control methods can be used to accomplish these objectives.

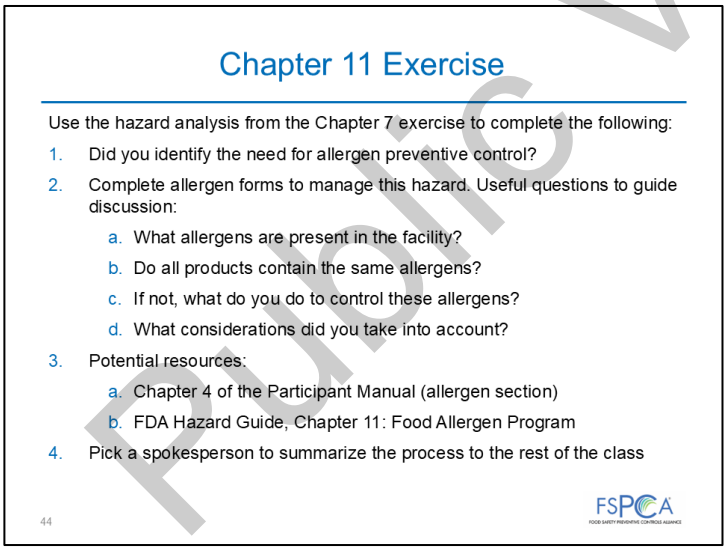
Slide 42: Knowledge Check 1

Participants do NOT have this slide.

Slide 43: Knowledge Check 2

Participants do NOT have this slide.

Slide 44: Chapter 11 Exercise



FDA Hazard Guide
Chapter 11

Use the hazard analysis from the Chapter 7 exercise to complete the following:

1. Did you identify the need for allergen preventive control?
2. Complete allergen forms to manage this hazard. Useful questions to guide discussion:
    a. What allergens are present in the product/facility?
    b. Do all products contain the same allergens?

c. If not, what do you do to control these allergens?

d. What considerations did you take into account?

3. Potential resources:

a. Chapter 4 of the Participant Manual (allergen section)

b. FDA Hazard Guide, Chapter 11: Food Allergen Program

4. Pick a spokesperson to summarize the process for the rest of the class.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Full Guide download): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (Chapter 11: Food Allergen Program download): https://www.fda.gov/media/172318/download?attachment

FDA. (2023). Food Allergies Information: https://www.fda.gov/food/food-labeling-nutrition/food-allergies

FDA Food Allergen Compliance Policy Guide – May 2023 – https://www.fda.gov/media/168000/download

FDA. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA): https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-falcpaFDA. (2022). Guidance for Industry: Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry: https://www.fda.gov/media/117410/download

FDA Seafood List to identify acceptable market names for allergen labeling for fish and crustacean shellfish: https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=SeafoodList

FDA. (May 2023). Sec. 555.250 Major Food Allergen Labeling and Cross-Contact Draft Guidance Policy Guide – Guidance for FDA Staff. https://www.fda.gov/media/168000/download

FDA Warning Letter where violations related to hand contamination and cross-contact were noted: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/m-fierro-sons-llc-641400-01192023

Fish and Fishery Products Hazards and Controls Guidance. June 2022 Edition. https://www.fda.gov/media/80637/download

Food Allergy Research and Resource Program (FARRP). Food Labelling for the Food Allergic Consumer – See Precautionary Labeling Examples: https://farrp.unl.edu/food-labelling-food-allergic-consumer

Food Allergy Research and Resource Program (FARRP) and Food Allergy and Anaphylaxis Network. Components of an Effective Allergen Control Plan – a Framework for Food Processors: https://farrp.unl.edu/3fcc9e7c-9430-4988-99a0-96248e5a28f7.pdf

Food Allergy Research and Resource Program (FARRP) Workshops/Training: https://farrp.unl.edu/farrp-sponsored-workshop-series

Gendel, S.M. & Zhu, J. (2014). (2013). Analysis of U.S. Food and Drug Administration food allergen recalls after implementation of the Food Allergen Labeling and Consumer Protection Act. J. Food Prot. 76(11) 1933-1938.

Gendel, S.M., Zhu, J., Nolan, N., & Gombas, K. (2014). Learning from FDA food allergen recalls and reportable foods. Food Safety Magazine. April-May 2014:46-52, 80.

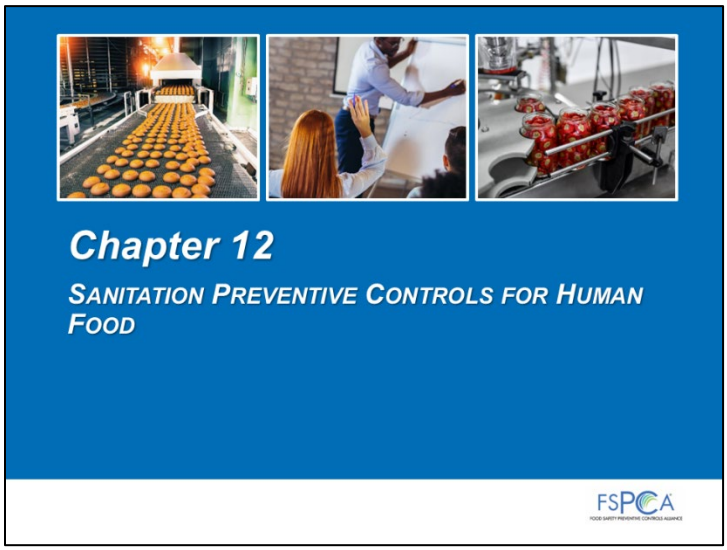
Grocery Manufacturers Association (GMA). (2009). Managing Allergens in Food Processing Establishments.

Jackson et al. (2008). Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. J Food Prot. 71(2):445- 458. https://ofpa.on.ca/wp-content/uploads/2020/10/AllergenProgramValidationReview.pdf

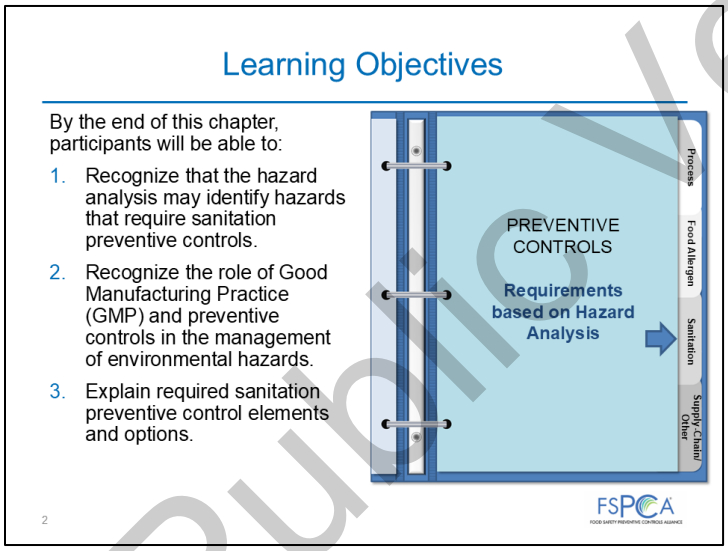
AOAC. (2023). Official Methods of Analysis (OMA). (22nd Ed.): https://www.aoac.org/official-methods-of-analysis/

Pieretti, M.M., Chung, D., Pacenza, R., Slotkin, T., & Sicherer, S.H. (2009). Audit of manufactured products: Use of allergen advisory labels and identification of labeling ambiguities. J Allergy Clin Immunol. 124(2):337-41.

Slide 1: Chapter 12: Sanitation Preventive Controls for Human Food



Slide 2: Learning Objectives



Definition: *Sanitation preventive controls:*
Sanitation preventive controls are procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition to minimize or prevent hazards such as environmental pathogens, hazards from employees handling food, and food allergen hazards. (21 CFR 117.135(3))

Sanitation is the beginning, not the end, of food processing. Sanitation, which includes cleaning and sanitizing steps, establishes the basic hygienic conditions needed to produce safe and wholesome food. Without a clean operation at the beginning of production, equipment and the environment can introduce contamination hazards. Poor sanitation practices can also contribute to loss of food product quality. Refer to Appendix 5: Sanitation Basics for additional detail on basic concepts for food processing sanitation.

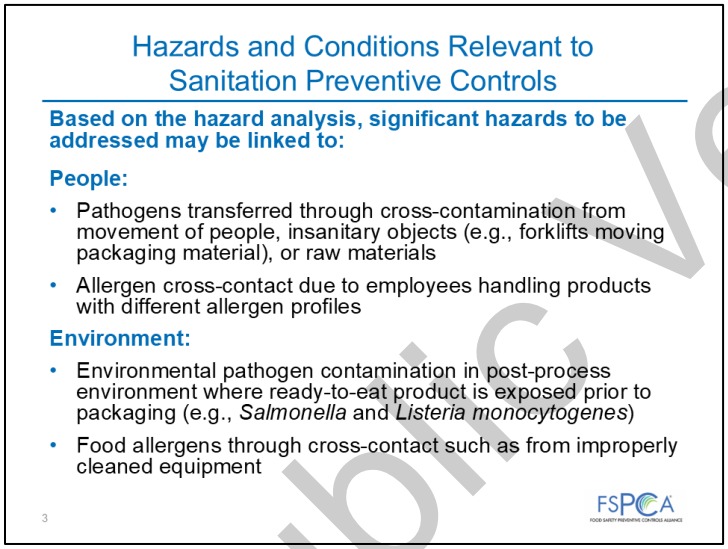
Within the Preventive Controls for Human Food rule, Good Manufacturing Practices (GMPs), emphasizes sanitation practices and controls including general cleaning, washing, and sanitizing of equipment, and the processing room infrastructure such as walls, overhead areas, and floors. Facilities must meet all applicable GMP requirements

to maintain sanitary operations, and documentation of sanitation actions is also required for hazards requiring sanitation preventive controls.

The Preventive Controls for Human Food regulation requires implementation of sanitation preventive controls, as appropriate to the facility and the food, to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. The hazard analysis identifies these types of hazards requiring a sanitation preventive control.

This chapter begins with a review of sanitation-related food safety hazards and hazard analysis examples. Then preventive controls to assure cleanliness of food-contact surfaces, and prevention of allergen cross-contact and biological cross-contamination from objects and personnel in certain facilities are discussed. Monitoring, corrections, and verification requirements for sanitation preventive controls are then addressed. Information about the requirements for environmental monitoring programs are also included.

Slide 3: Hazards and Conditions Relevant to Sanitation Preventive Controls



Definitions (21 CFR 117.3):

Allergen cross-contact: The unintentional incorporation of a food allergen into a food.

Cross-contamination: The unintentional transfer of a foodborne pathogen from a food (where it may occur naturally) or insanitary object to another food (where it may present a hazard).

The hazard analysis process identifies points in the process where sanitation preventive controls are needed to control significant hazards. The sanitation preventive controls work in conjunction with the Sanitation Program as well as other GMPs to prevent contamination to the product during processing.

The equipment and the environment in which the food is processed can become a source of contamination. This contamination enters the facility from raw materials, people, and numerous other vectors. The goal of the sanitation program is to reduce the prevalence of these hazards in the environment and prevent their transfer to food products. The sanitation preventive controls are established at those points where the risk is greatest for cross-contamination or cross-contact.

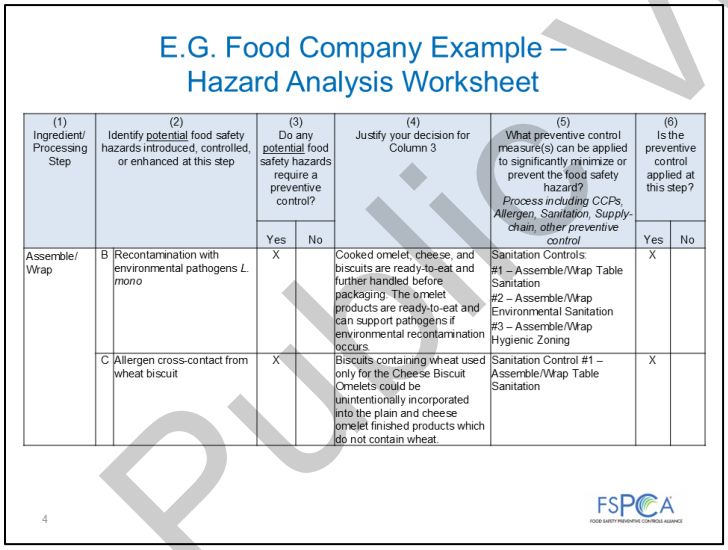
As discussed in Chapter 3: Biological Food Safety Hazards, foodborne pathogens such as *Salmonella* and *Listeria monocytogenes* can enter a facility through a number of different vectors including raw materials. Establishing and implementing programs that

address cross-contamination through the employees' practices and the sanitation of the equipment and the facility, minimizes the prevalence of these pathogens and reduces the risk of their transfer to ready-to-eat products. Environmental pathogens are of particular concern for ready-to-eat foods exposed to the environment prior to packaging. These areas are often best addressed through the implementation of sanitation preventive controls.

As discussed in Chapter 11: Food Allergen Preventive Controls, food allergens can also be transferred from equipment that is not cleaned to remove the food allergens before non - allergen containing products are handled. Establishing and implementing programs to address cross-contact through employees' practices and sanitation of equipment minimizes the prevalence of allergens and reduces the risk of transfer to exposed food. Cross-contact can occur anywhere in the process, but the highest risk is at points in the process where there is equipment that is shared with food items with different allergen profiles. Certainly, in these cases, a sanitation (or allergen) preventive control is needed.

Note that the prevention of allergen cross-contact through sanitation is normally identified as a sanitation preventive control as discussed in the previous chapter. Whether this is considered an allergen preventive control, or a sanitation preventive control does not matter as much as ensuring the activity controls the hazard.

Slide 4: E.G. Food Company Example – Hazard Analysis Worksheet



E.G. Food Company Example – Hazard Analysis Worksheet

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Assemble/ Wrap	B	Recontamination with environmental pathogens *L. mono*	X		Cooked omelet, cheese, and biscuits are ready-to-eat and further handled before packaging. The omelet products are ready-to-eat and can support pathogens if environmental recontamination occurs.	Sanitation Controls: #1 – Assemble/Wrap Table Sanitation #2 – Assemble/Wrap Environmental Sanitation #3 – Assemble/Wrap Hygienic Zoning	X	
	C	Allergen cross-contact from wheat biscuit	X		Biscuits containing wheat used only for the Cheese Biscuit Omelets could be unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat.	Sanitation Control #1 – Assemble/Wrap Table Sanitation	X	

4

FSPCA

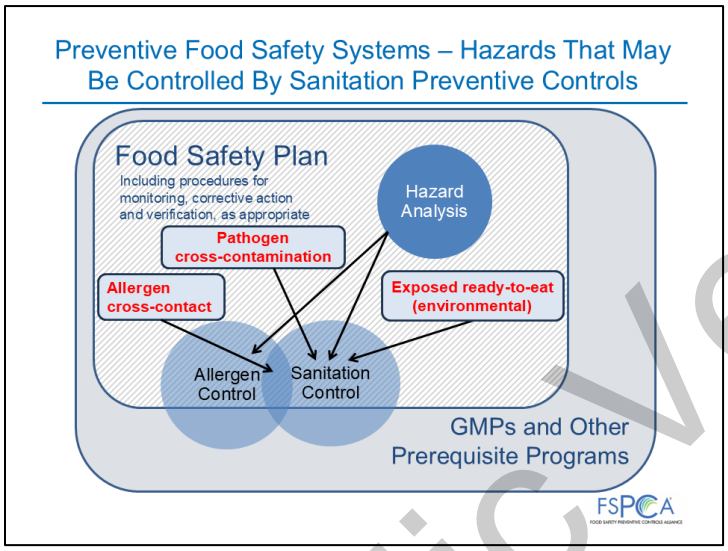
The hazard analysis process determines the hazards requiring a preventive control. Identifying specific hazards and preventive control procedures is required, and the procedures must be performed as designed on a continued basis to prevent the hazard.

The E.G. Food Company's hazard analysis for omelets identified the "Assemble/Wrap" step as requiring a sanitation preventive control to prevent the introduction of environmental pathogens such as *Listeria monocytogenes*. At this step the product has been cooked and then subsequently handled, providing an opportunity for post-cooking cross-contamination. No other step in the process would eliminate

environmental pathogens that might be introduced through handling after the "Cook" step.

The potential for allergen cross-contact from the wheat in the biscuit to non-biscuit containing products was also identified as a hazard requiring a preventive control at the "Assemble/Wrap" step. The potential for allergen cross-contact can be significantly minimized or prevented through sanitation. Thus, E.G. Food Company hazard analysis example documents the sanitation preventive controls that are required to be addressed in the E.G. Food Company's Food Safety Plan. Other sanitation practices are handled through routine GMP procedures at the E.G. Food Company's facility.

Slide 5: Preventive Food Safety Systems – Hazards That May Be Controlled By Sanitation Preventive Controls



Sanitation controls will be utilized within the facility. Many of these procedures will likely be part of the facility's prerequisite program for sanitation and will address GMP requirements. However, there may be components of a facility's sanitation procedures that may elevate to the level of sanitation preventive controls.

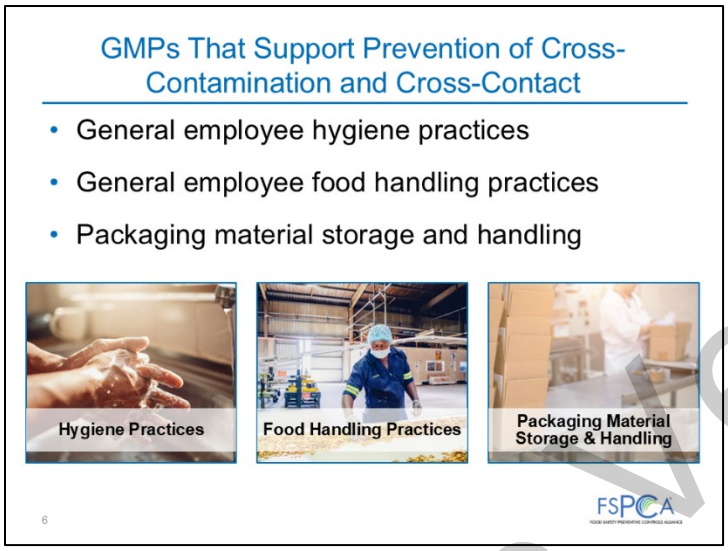
A facility must comply with the CGMPs' required sanitary operations (21 CFR 117.35), and sanitary facilities and controls (21 CFR 117.37). These are the requirements applicable to the cleanliness of equipment and utensils, including food-contact surfaces (21 CFR 117.40), and plant construction and design (21 CFR 117.20(b)). To comply with these CGMP requirements, sanitation procedures, practices, and processes should be developed and implemented. The frequency of most procedures will be performed at least daily, but this frequency will be facility and product specific. The frequency of procedures is commonly addressed in a company's Master Sanitation Schedule.

The goal of sanitation preventive controls is to prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards from cross-contact. Sanitation preventive controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the: (1) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and

(2) prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. (See 21 CFR 117.135(c)(3))

Through the hazard analysis, the facility determines when a hazard requires controls require a sanitation preventive control rather than handling through CGMPs. Thus, some (but not all) of the sanitation procedures, practices, and processes will be sanitation preventive controls.

Slide 6: GMPs that Support Prevention of Cross-Contamination and Cross-Contact (1 of 2)



GMPs related to cleaning and sanitation are addressed in 21 CFR 117.35(d), (e), and (f). These can be managed as prerequisite programs unless the hazard analysis identifies hazards requiring a preventive control to address allergen cross-contact or cross-contamination.

For more information on basic cleaning and sanitation, see Appendix 5: Sanitation Basics.

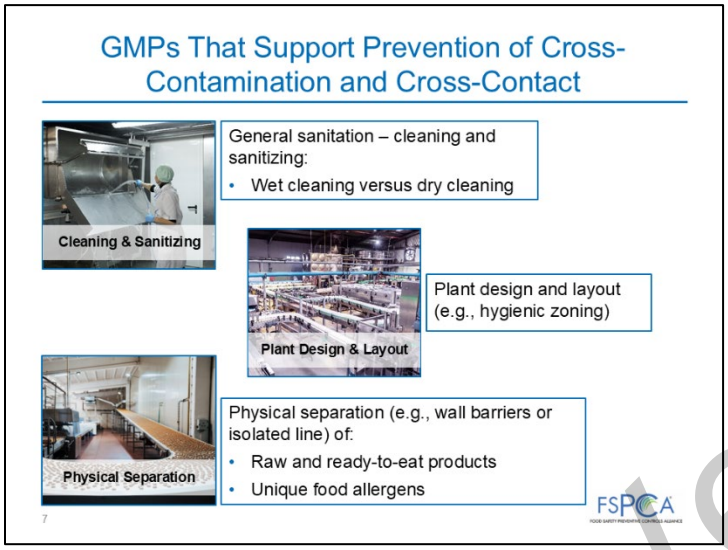
GMPs and other prerequisite programs work together to establish a sound foundation for the facility's food safety system. Employee hygiene practices, employee food handling practices, and packaging material storage and handling are usually managed as GMPs.

Employee hygiene, personnel practices and the design of the facility must prevent cross-contamination and allergen cross-contact. It is important for employees to understand their actions can contribute to product contamination. Employees' hands or gloves and equipment and utensils must be washed and sanitized, when necessary, after being contaminated. For example, employees working in a raw product area should not work with a cooked finished product without first washing and sanitizing their hands or gloves and equipment and utensils to avoid cross-contamination. Similarly, employees handling food allergens should wash their hands before handling another food that does not contain those allergens to prevent allergen cross-contact. Workers must wear clean and appropriate attire and must wash and sanitize their hands at appropriate intervals. In applications where gloves are used, proper protocols must be followed to prevent cross-contact and cross-contamination, including changing gloves when soiled and washing hands before donning new gloves.

Packaging materials must be stored and handled properly by employees, so the materials do not become a source of contamination. If allergens come in contact with packaging and that packaging is then used for a product without that allergen, the

food placed into that package will now have that allergen. With production line changeovers, it is important to control packaging material. Any packaging material that may have been exposed to allergens, must be prevented from being used for other products.

Slide 7: GMPs That Support Prevention of Cross-Contamination and Cross-Contact (2 of 2)



A facility's sanitation program addresses the overall sanitary condition of the facility, including food-contact and non-food-contact surfaces through tailored procedures for equipment, floors, walls, etc. Areas of the facility that do not come in contact with food may be cleaned on a less frequent basis, however, it must be done frequently enough to minimize potential risks. The procedures used within the facility are specific to the facility, the type of equipment, and the type of product produced. For example, in a dry food operation (such as a facility producing cereal), cleaning procedures will often use little to no water, while in a facility processing products with moisture (such as a frozen vegetable facility), water can be used.

Most sanitation procedures used are general Sanitation Standard Operating Procedures (SSOPs). Cleaning the floors and walls in the receiving area or cleaning the incoming product conveyors are examples of general SSOPs. However, when sanitation processes are identified in the hazard analysis for controlling significant hazards, then those cleaning procedures will become part of a sanitation preventive control.

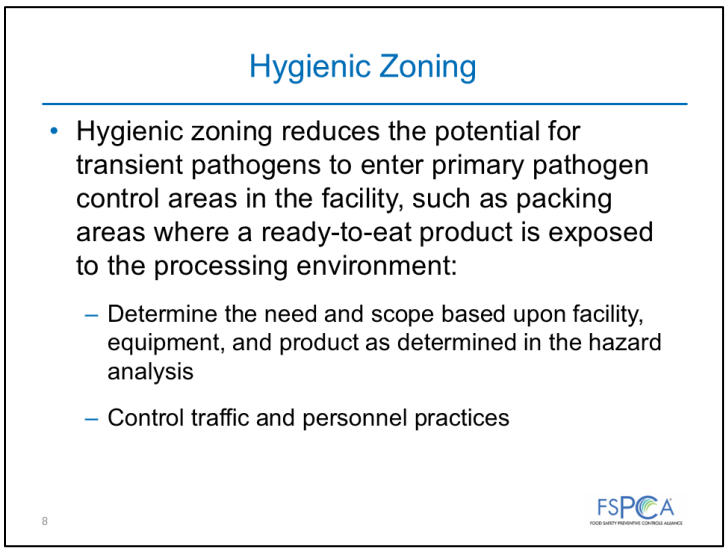
Cleanliness of food-contact surfaces is a primary focus for sanitation preventive controls. However, prevention of allergen cross-contact and microbial cross-contamination requires consideration of sanitation practices for both food-contact and non-food-contact surfaces because of environmental pathogens. For example, when manufacturing low-moisture foods, such as chocolate and confectionary products, dry cleaning procedures facilitate control of environmental pathogens such as *Salmonella*. However, control of allergens may be easier when wet cleaning procedures are used. A facility must carefully consider when to use wet cleaning versus dry cleaning and

beware of possible hazards that could be introduced or enhanced by bringing water into a dry environment.

Food-contact surfaces used for low-moisture food must be in clean, dry, and sanitary condition before use. When the surfaces are wet cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use. Moisture retained in environmental cracks and crevices can support pathogen growth, so the use of wet cleaning in dry environments should be avoided when possible and should not be a routine practice. See Appendix 5: Sanitation Basics for more information on wet versus dry cleaning.

Consideration must be given to preventing contamination of stored ingredients and raw materials, food, and food-contact surfaces. This means separating raw product and unpackaged ready-to-eat product to avoid contamination. Similarly, separating foods that contain food allergens from those that do not contain the same food allergens prevents allergen cross-contact. Food-contact surfaces must be cleaned and sanitized whenever there is the potential for contamination. For example, if the lethality step within the process drops below the critical limit, any sections of the processing line that come in contact with exposed deviated product must be re-cleaned and re-sanitized. A physical separation that prevents cross-contamination (or cross-contact) to a clean area from insanitary objects (such as dirty equipment and environmental sources) is ideal, but not always feasible. In the absence of absolute barriers, hygienic zoning procedures are often implemented to provide this separation. Procedures to designate and identify personnel assigned to finished product areas may be appropriate depending on the operation. Protocols that restrict the movement of raw or unprocessed product or equipment into processed product areas may also be needed.

Slide 8: Hygienic Zoning



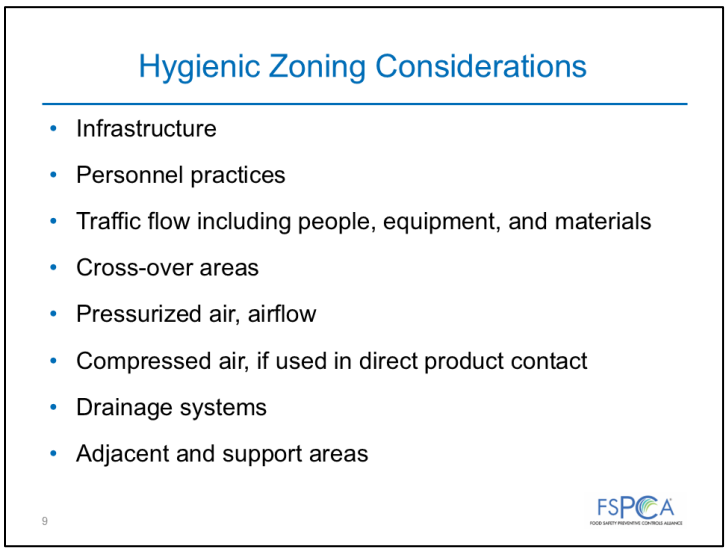
The concept of hygienic zoning is designed to reduce the potential for transient pathogens to move into areas of the facility where they may contaminate foods.

The primary focus of hygienic zoning is protecting exposed ready-to-eat product against potential pathogens from the environment. Some facilities will designate these areas as primary pathogen control areas. These areas are not just packing areas but can also include the storage of packaging material for ready-to-eat products and storage and handling areas for ready-to-eat ingredients.

Hygienic zoning often includes a number of procedures that focus on controlling traffic patterns for materials and employees entering these areas. Through the hazard analysis, some aspects of hygienic zoning may become part of sanitation preventive control.

Bacterial pathogens, including environmental pathogens, are typically introduced into the processing facility through, for example, incoming raw materials, personnel, or pests. It is important to ensure that these microorganisms remain transient and do not become established in the environment where they can grow and multiply. Transient contaminants can, however, result in a diversity of pathogens in the processing environment that can show up in the processing lines and finished product. (FDA Hazard Guide, 3.3.5.2.1)

Slide 9: Hygienic Zoning Considerations



A **support area** is one that supports the facility, such a locker room, lunchroom, or maintenance shop. There may be others in some facilities.

A **crossover or transition area** is an area where there is movement of people, materials, or equipment from one side of the operation to the other side such as the processed/finished product side of the operation. An example could be when one conveyor belt runs over another one.

There are many aspects for consideration when developing a Hygienic Zoning plan.

Infrastructure within the facility: Many facilities were not designed with hygienic zoning principles in mind or were changed over time where there is extensive cross-over areas of raw and finished.

Personnel practices: Hygienic zoning controls must account for personnel movement within the facility and restrict movement into clean areas from those areas that are not controlled.

Traffic flow: People, equipment, and materials must move in the operation. Hygienic zoning controls must take into account movement that is needed, such as moving packaging material into the primary pathogen area and determine appropriate controls for preventing the potential for cross-contamination.

Crossover areas: Crossover areas can be the site for contamination to be deposited and picked up. It is important to have an understanding of where crossover areas exist and what controls can be used

Pressurized air and air flow: Air flow can carry pathogens or allergens from one air to another.

Compressed air: Compressed air can blow contaminants far and wide within a facility. Additionally, the air itself, if not properly filtered can blow particulates or substances such as oil droplets directly onto product.

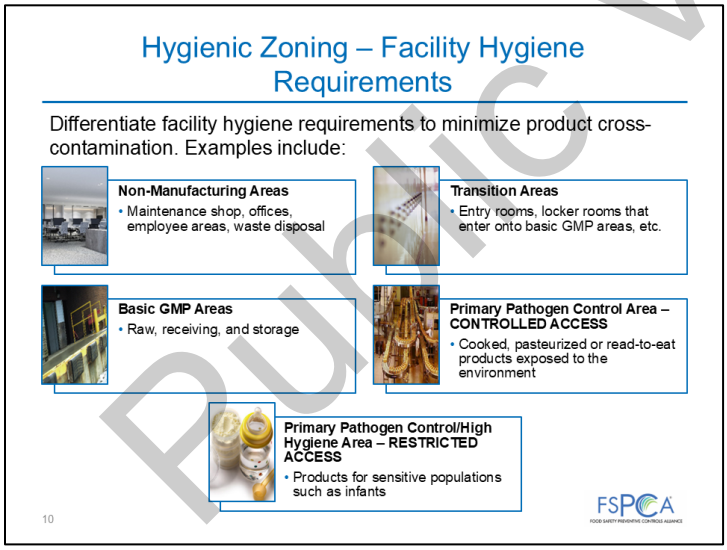
Drainage system: Drains can be a major harborage for pathogens. Drains backing up, and even air flow through a drain can bring that contamination into the processing area. Often times, consideration must extend to the whole drain system that may link drains in raw processing areas to drains in clean areas.

Adjacent areas: Areas adjacent to hygienic areas and support areas. Contamination in areas close to the hygienic area can exert contamination pressure on the hygienic area. For example, if the hygienic area is close to a trash storage area, air flow can carry contaminants into the hygienic area, and the higher the level of contamination, the higher the risk.

The assessment for developing the hygienic zoning program should consider these aspects when developing procedures to minimize or prevent the potential for contamination. Based on the hazard analysis, one or more of these procedures may become part of a sanitation preventive control where that procedure is essential for controlling a significant hazard.

The sanitation preventive controls must address appropriate environmental pathogens if relevant to the product being produced. A facility may choose to use zoning for allergens if this is determined to be a concern through hazard analysis.

Slide 10: Hygienic Zoning – Facility Hygiene Requirements



A facility may choose to use zoning for allergens if this is determined to be a concern through the hazard analysis process.

For more information on Hygienic Zoning, see Appendix 6: Hygienic Zoning and Environmental Monitoring

In developing a hygienic zoning program, a facility will evaluate each area along with the processes and practices to determine the pathogen risk and what requirements are needed for preventing contamination in and around exposed product/high risk processing areas. Non- manufacturing areas do not require the same level of sanitation as food processing areas. Transition areas into a high-risk processing area should be equipped with materials to minimize the potential for transferring potential pathogens. For example, smocks, footwear (if needed), hair covers etc. are typically available in transition areas, as well as hand-washing stations. Sanitation needs in low-risk areas (e.g.

raw material receiving and storage areas where raw product is handled and is physically separated from those areas where a ready-to-eat food is exposed to the environment), are typically managed by GMP requirements and not preventive control requirements. More attention to sanitation and primary pathogen control is needed in high-risk areas that handle ready-to-eat products that are exposed to the environment. Even more diligent efforts are needed in areas that handle products for sensitive populations such as infants.

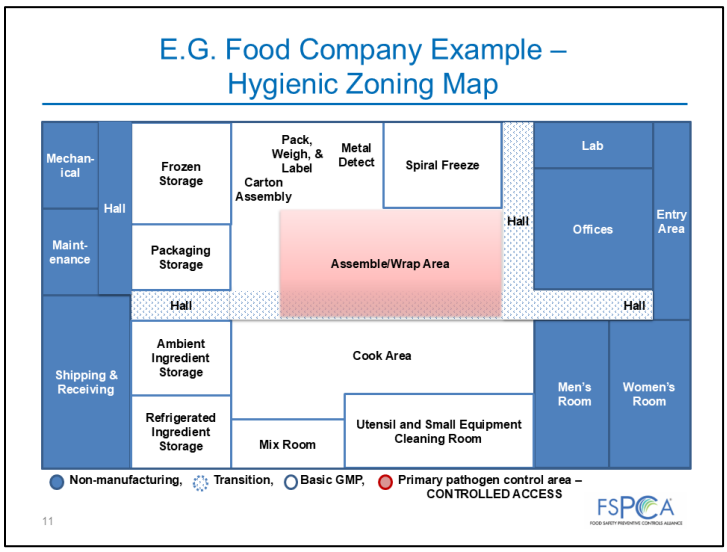
Control of traffic patterns between these areas with different types of hygiene practices can minimize the transfer of hazards. Techniques that may be useful include:

- Dedicated equipment in different areas, especially when it is difficult to clean (e.g., carts, forklifts);
- Use of color-coded uniforms for people who work on the raw side and those who work on the cooked/ready-to-eat side; and
- Linear flow through a facility, such that raw product does not enter the cooked/ready-to-eat product area.

The same analysis should be completed when evaluating allergen risk in a facility. The Food Safety Plan should evaluate the areas that represent a high risk for cross-contact and what types of controls are needed to minimize or prevent the risk of cross-contact.

It is understood that the examples of hygienic zoning may not be practical in all situations. While varying approaches may be used, the requirement is that controls are established to prevent allergen cross-contact and pathogen cross-contamination when hazards requiring a preventive control are identified through hazard analysis. Preventive controls can be addressed through hygienic zoning in combination with other means, as dictated by the individual situation at the specific facility.

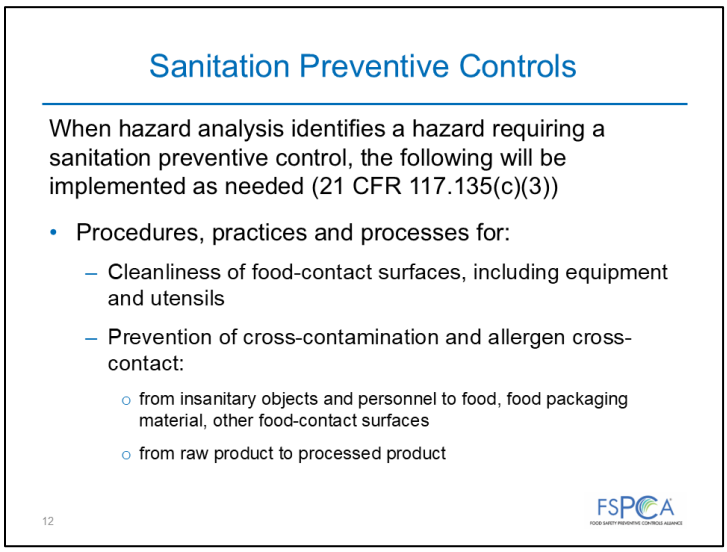
Slide 11: E.G. Food Company Example – Hygienic Zoning Map



The map above is from the hygienic zoning example in Appendix 3: Food Safety Plan Teaching Example (page A3-35). The Assemble/Wrap area is designated as a primary pathogen control area with controlled access because the cooked omelets are exposed to the environment prior to packaging.

Note that this facility has a very open layout because the omelets are cooked by hand and when the omelets leave the cooking process, they are placed on a table between the Cook Area and the Assemble/Wrap area. Envision a kitchen-like environment with no barrier between the areas. This is not ideal for providing separation but may be a reality in a small operation.

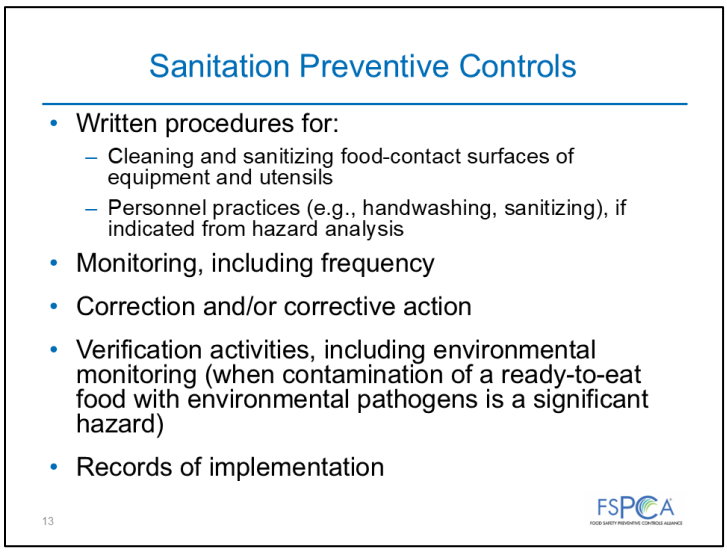
Slide 12: Sanitation Preventive Controls (1 of 2)



If the hazard analysis identifies a hazard requiring a sanitation preventive control, written procedures must be documented in the Food Safety Plan. Sanitation preventive controls will include procedures, practices, and processes needed to ensure the cleanliness of specific food-contact surfaces, including utensils and equipment. For example, the cleaning step comprised of cleaning, rinsing, and sanitizing food-contact surfaces will be monitored, and cleanliness will be verified.

Controls may also include procedures to prevent cross-contamination or allergen cross-contact from insanitary objects, as well as from personnel to food, food packaging material, and other food-contact surfaces. Procedures to prevent cross-contamination from raw product to processed product, and to prevent allergen cross-contact are also included in the Food Safety Plan, when appropriate as identified in the hazard analysis.

Slide 13: Sanitation Preventive Controls (2 of 2)

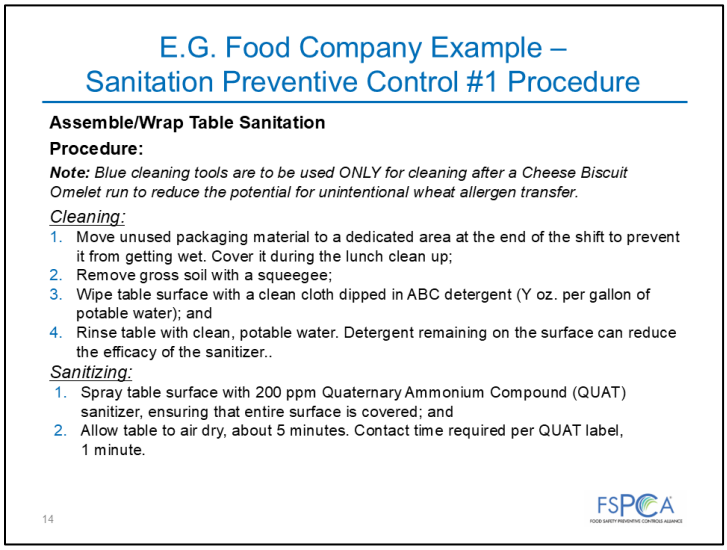


Sanitation preventive controls are needed in areas where ready-to-eat food is exposed to the environment and where allergen cross-contact could occur.

Written sanitation preventive controls contain the following elements:

- Written procedures and instructions to accomplish the task (see Appendix 5 for more information). This could extend to personnel practices such as handwashing if indicated in the hazard analysis;
- Monitoring the frequency or when the procedure needs to be conducted to be effective and who is responsible for performing the procedure and other tasks listed;
- Corrective actions and corrections, or what to do when inspection determines that the procedure was not adequate to produce a sanitary surface or area; and
- Verification procedures which could include monitoring of the environment or other activities.

Slide 14: E.G. Food Company Example – Sanitation Preventive Control #1 Procedure

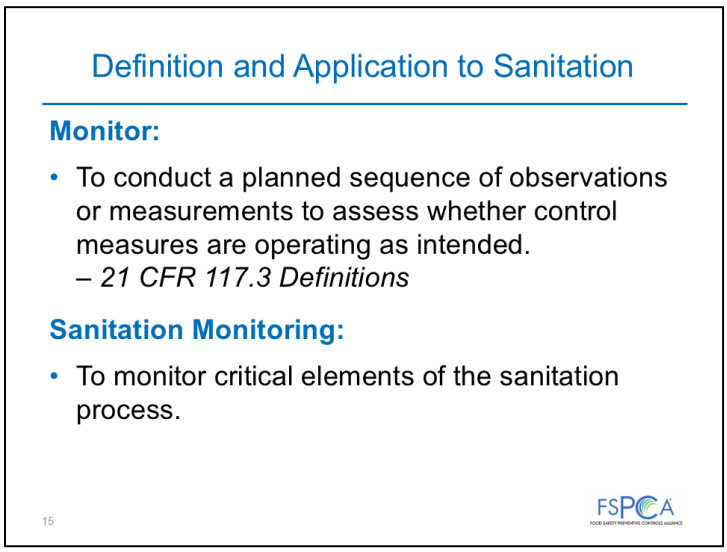


This slide provides an example of the cleaning and sanitizing procedures for the E.G. Food Company's Assemble/Wrap Table Sanitation. For the full written procedures, including monitoring, corrections, records, and verification, see Appendix 3 (pages A3-32 and A3-33).

As an overview of a wet cleaning operation, surfaces are first cleaned and then sanitized. More specifically, solids are removed from the surface, the surface is cleaned with an appropriate cleaner at the correct concentration, the surface is rinsed to remove the cleaner, the surface is sanitized and allowed to air dry.

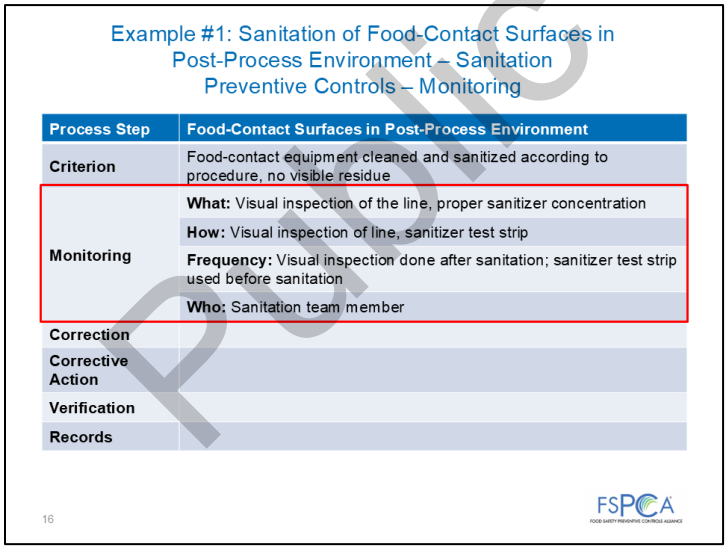
One item to note in this example is that while quaternary ammonium is used as the sanitizer, other registered sanitizing chemicals or recognized hot water sanitizing procedures may be used. For example, the Pasteurized Milk Ordinance specifies hot water sanitizing methods that have been demonstrated to be effective.

Slide 15: Definition and Application to Sanitation



Sanitation preventive controls must be monitored, and results recorded as appropriate. The term "monitor" is defined in the Preventive Controls for Human Food regulation as "to conduct a planned sequence of observations or measurements to assess whether controls are operating as intended." As discussed above, procedures related to the sanitation process, as well as hygienic zoning, if used as a preventive control, require monitoring procedures and records.

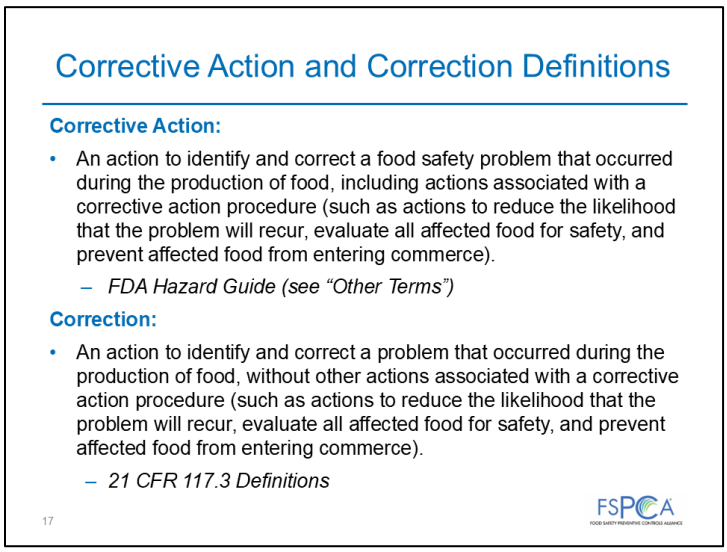
Slide 16: Example #1: Sanitation of Food-Contact Surfaces in Post-Process Environment – Sanitation Preventive Controls – Monitoring



Here is an example of sanitation monitoring procedure used to determine whether cleaning and sanitizing is being conducted according to the written procedure. In this example, the surface is checked to ensure that it is visually clean, and the sanitizer concentration is checked to ensure proper strength.

This example continues in subsequent slides.

Slide 17: Corrective Action and Correction Definitions

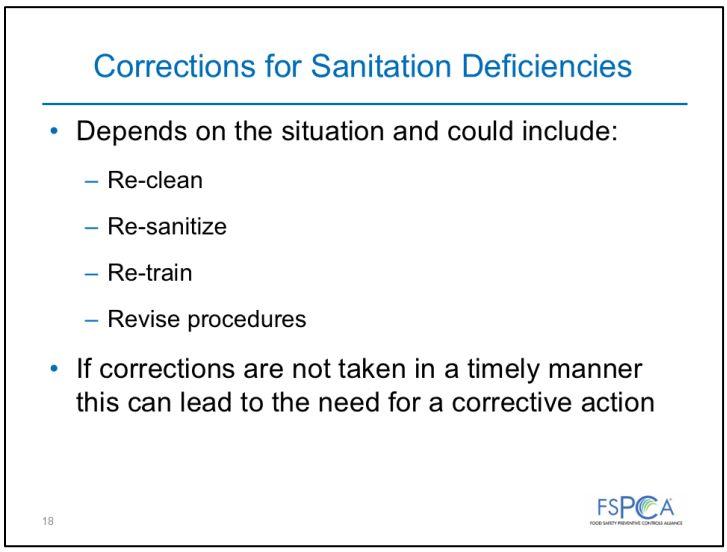


As stated in Chapter 9, when a parameter or value being monitored is not met, corrective actions or corrections must be performed depending on the hazard and the nature of the preventive control. Corrective actions are procedures that must be taken if preventive controls are not properly implemented and involve documentation of the specific actions taken. Corrections apply when the facility acts in a timely manner to identify and correct a minor and isolated problem that does not directly impact product safety.

For sanitation preventive controls, many situations involving sanitation deficiencies will require corrections. That is because product is not affected. For example, a line was not properly cleaned as identified in the pre-operational inspection. In this case, the line is re-cleaned and re-inspected.

Corrective action can be required if the sanitation deficiency impacts product. In the above example, if the production line had started prior to the line being re-cleaned, then corrective action would be needed with the product produced being held and requiring remediation.

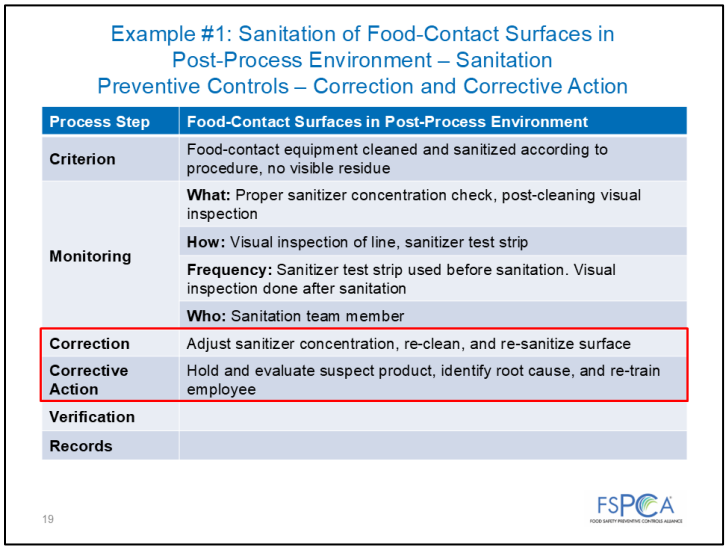
Slide 18: Corrections for Sanitation Deficiencies



When deficiencies at a sanitation preventive control are encountered, corrections must be made in a timely manner. The nature of the corrections depends on the specific situation. Sometimes corrections are relatively easy. For example, if food residue is observed on "clean" equipment, the equipment should be re-cleaned prior to production. If the sanitizer concentration is determined to be incorrect, a new sanitizer solution should be prepared, and the equipment should be re-sanitized. Note that re-sanitizing equipment can be avoided if the sanitizer concentration is checked before it is used and found to be correct! The personnel cleaning the equipment may need to be re-trained.

As mentioned, a correction could elevate to a corrective action if the correction action was not taken in a timely manner and product is impacted. In this case, a root cause analysis process might be needed to determine what led to the need for a corrective action.

Slide 19: Example #1: Sanitation of Food-Contact Surfaces in Post-Process Environment – Sanitation Preventive Controls – Correction and Corrective Action



Example #1: Sanitation of Food-Contact Surfaces in Post-Process Environment – Sanitation Preventive Controls – Correction and Corrective Action

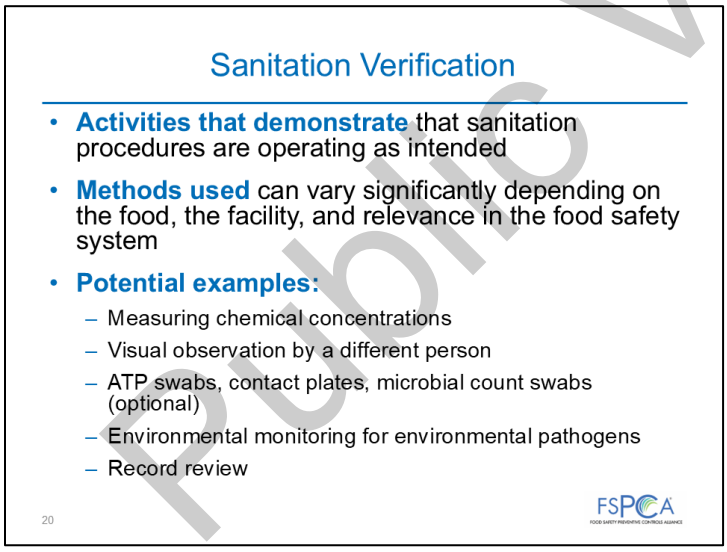
Process Step	Food-Contact Surfaces in Post-Process Environment
Criterion	Food-contact equipment cleaned and sanitized according to procedure, no visible residue
Monitoring	**What:** Proper sanitizer concentration check, post-cleaning visual inspection
	How: Visual inspection of line, sanitizer test strip
	Frequency: Sanitizer test strip used before sanitation. Visual inspection done after sanitation
	Who: Sanitation team member
Correction	Adjust sanitizer concentration, re-clean, and re-sanitize surface
Corrective Action	Hold and evaluate suspect product, identify root cause, and re-train employee
Verification	
Records	

19

The sanitation preventive control example includes details about corrections and corrective actions.

The example continues in subsequent slides.

Slide 20: Sanitation Verification



Sanitation Verification

- **Activities that demonstrate** that sanitation procedures are operating as intended
- **Methods used** can vary significantly depending on the food, the facility, and relevance in the food safety system
- **Potential examples:**
  - Measuring chemical concentrations
  - Visual observation by a different person
  - ATP swabs, contact plates, microbial count swabs (optional)
  - Environmental monitoring for environmental pathogens
  - Record review

20

Verification is conducted to confirm that the sanitation preventive controls are properly implemented, and the system is operating as intended. Review of sanitation preventive control records is a verification activity required by the regulation. Verification activities must be documented.

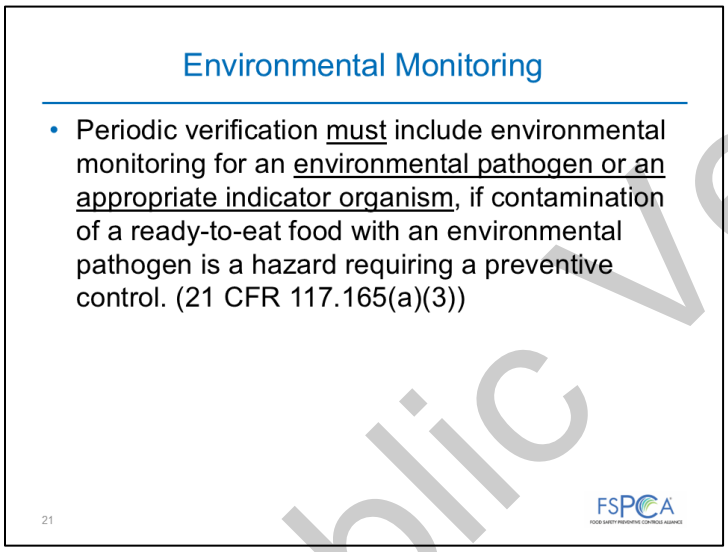
The specific verification activities depend on the facility and how the sanitation activities are conducted. For example, some facilities prepare sanitizing solutions every day. Other facilities use an automated dosing system that includes a monitoring device. In the former example, checking the sanitizer concentration right after making it is a

monitoring activity. However, if the concentration is periodically checked, as part of an automated system, this is a verification activity. In either case, this can be accomplished through the use of a test strip, titration, or other methods frequently provided by the chemical supplier. The action of the chemical concentration being checked and documented is what is important, regardless of the specific operational approach.

Some facilities may use quantitative microbiological swabs (e.g., swabbing a 3 x 3-inch [10 x 10 cm]) area and plating), or indirect methods like Adenosine Triphosphate (ATP) monitoring to provide quantitative verification of the effectiveness of sanitation procedures. This is not a substitute for comprehensive environmental pathogen monitoring.

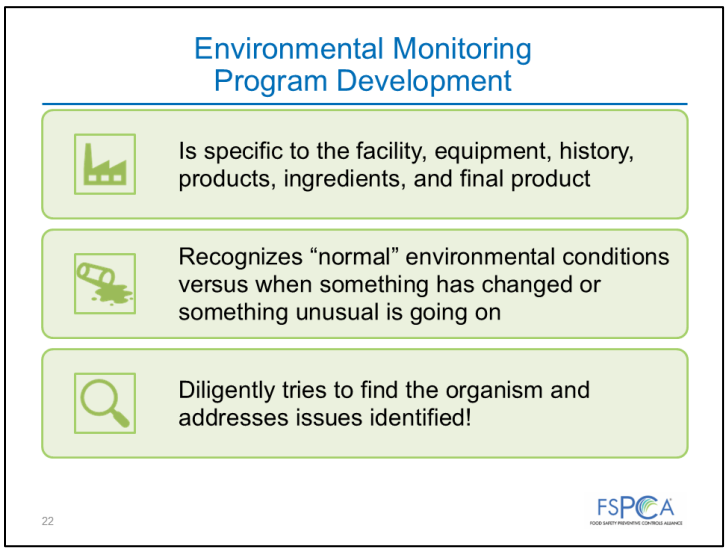
Environmental monitoring will also be used as a verification procedure for sanitation controls, especially in facilities that produce ready-to-eat products that are exposed to the environment.

Slide 21: Environmental Monitoring



Environmental monitoring for pathogens (e.g., *Salmonella, Listeria monocytogenes*), or an appropriate indicator organism (e.g., *Listeria* species), is required when that contamination is identified as a hazard requiring a preventive control for a ready-to-eat food (21 CFR 117.165(a)(3)).

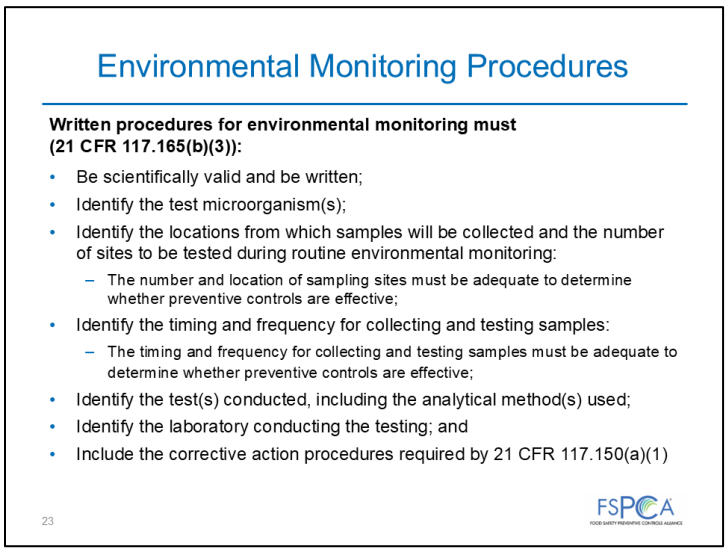
Slide 22: Environmental Monitoring Program Development



An environmental monitoring program must be designed specifically for the facility and must consider the products made, the ingredients used, any history with past environmental pathogens, and other relevant factors. Compiling the routinely collected data to establish a baseline will be helpful to alert the facility when something has changed or is unusual.

An effective environmental monitoring program diligently tries to find the pathogen of concern or appropriate indicator organism so that corrective actions can be taken before product is compromised and the effectiveness of interventions can be evaluated. For example, a robust environmental monitoring program can assist with detection of the presence of niche or resident pathogens and differentiate them from transient strains. This can create a better understanding of how to react to findings. A relentless seek-and-destroy culture as it relates to environmental monitoring is essential.

Slide 23: Environmental Monitoring Procedures



Written environment monitoring procedures must meet requirements identified in 21 CFR 117.165(b)(3). Specifically, the environmental monitoring procedures must be valid and include several elements including the microorganism of concern and sampling locations. The company may want to prepare a map of the facility with all drains and other relevant locations demarcated (marked or identified), to determine a site list for the facility. Samples should also be collected at a frequency that will allow determination of the effectiveness of the preventive controls. The map will list the zones from where the sample is taken. The zone indicates how close that area is to the product.

Sampling frequency and zone concept will be discussed later in this section.

Corrective actions that should be taken in response to positive findings should also be determined and documented, following requirements from 21 CFR 117.150(a)(1).

§117.150 Corrective actions and corrections.

(a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

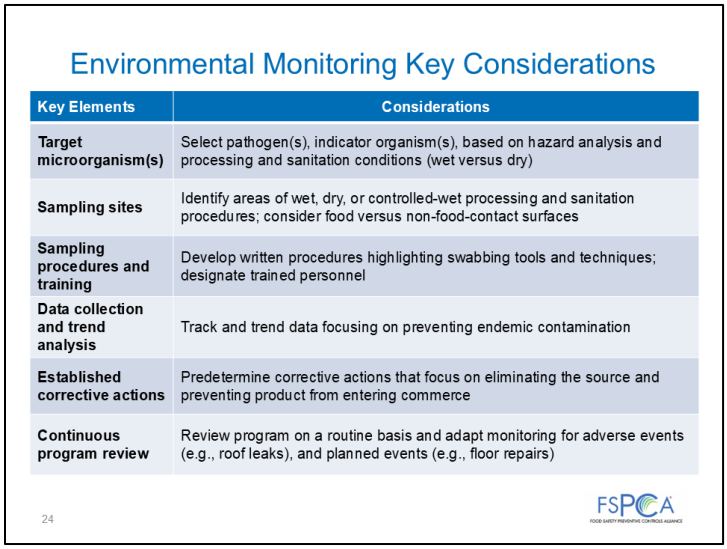
(i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with §117.165(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with §117.165(a)(3).

The Draft Guidance for Industry: Control of *Listeria monocytogenes* in Ready-to-Eat Foods (see Additional Reading, Resources, and References list at the end of this

chapter) includes additional recommendations such as a periodic verification of the written procedures.

Slide 24: Environmental Monitoring Key Considerations



Environmental Monitoring Key Considerations

Key Elements	Considerations
Target microorganism(s)	Select pathogen(s), indicator organism(s), based on hazard analysis and processing and sanitation conditions (wet versus dry)
Sampling sites	Identify areas of wet, dry, or controlled-wet processing and sanitation procedures; consider food versus non-food-contact surfaces
Sampling procedures and training	Develop written procedures highlighting swabbing tools and techniques; designate trained personnel
Data collection and trend analysis	Track and trend data focusing on preventing endemic contamination
Established corrective actions	Predetermine corrective actions that focus on eliminating the source and preventing product from entering commerce
Continuous program review	Review program on a routine basis and adapt monitoring for adverse events (e.g., roof leaks), and planned events (e.g., floor repairs)

24

FSPCA

Draft Guidance for Industry: Control of *Listeria monocytogenes* in Ready-to-Eat Foods

Key considerations for environmental monitoring include:

Target Microorganism: The appropriate target microorganism or analyte could include pathogens, or indicator organisms, as relevant to the specific hazard and operational process. Often *Listeria* and *Salmonella* species are targeted in wet-cleaned operations and *Salmonella*, in dry-cleaned facilities.

Sampling Sites: A common industry practice is to prepare a map of the facility with all targeted locations identified to determine a sample collection site list for the facility. Samples should be collected at a frequency that will allow determination of the effectiveness of preventive controls. Typically, samples from areas on or close to product contact surfaces are prioritized for collection, with a few from areas that are further away.

Sampling Procedures and Training: The procedures used for environmental monitoring must be documented. Personnel must be trained to conduct environmental sampling using consistent techniques and must have a sense for when to make adjustments to the base plan based on observations or special events. Sampling tools should allow collection from cracks, crevices, high areas, large floor areas, and drains, as well as dry scrapings and air.

A three-phased approach to sampling is a recommended practice:

1. Routine samples (focus on high risk);
2. Investigational samples; and
3. Follow-up sampling to confirm the effectiveness of corrective actions.

The frequency of sample collection may be increased or decreased based on a review of the facility's historical data, a determination of traffic patterns and product risk. The laboratory performing the analysis of the samples must be identified.

Data Collection and Trend Analysis: Tracking and trending of environmental monitoring data is a common industry practice. The reporting format for the results will influence the information provided. Maximize the value of the information the sample results provide to protect consumers and the facility by evaluating data in a format that allows for quick decisions and effective intervention actions. For example, spreadsheets help with identification of trends for routine and intensified monitoring activities. Facility mapping can also be used to show where positives results occur and to determine if there are common or related locations, which could indicate an environmental niche. Plotting results compiled from multiple sampling periods on a map (i.e., a heatmap), can be used to demonstrate the effectiveness of preventive controls, and to include corrective actions for environmental pathogens. The goal should be the prevention of an endemic contaminant, an organism that has established itself thoroughly in the facility and becomes extremely difficult to eliminate.

Established Corrective Actions: The facility must take corrective action following the detection of a pathogen or indicator organism within the facility. Specific corrective actions must address removal and prevention of a recurrence of the contamination and address affected product. Detection of a pathogen in a food-contact surface sample location requires immediate action because the safety of the product produced on the line is at risk. Expert consultation is advised to evaluate data collected over time, sanitation practices, and other factors relevant to determining the disposition of specific implicated product lots.

For indicator monitoring, the target and action levels should be established after baselines have been established. It is difficult to interpret results if there is no basis for comparison. Facilities that make the same product can have very different profiles. Baseline data collection typically involves a higher level of sampling over a defined period of time and is an attempt to capture a snapshot of the stable/routine operation. Several sets of data may be collected to cover seasonal variability. If all sites are not sampled at each time of sampling, a rotation system can be used. Because the objective of the program is to proactively identify potential sources of contamination, it is advisable to sample worst-case conditions if they are observed. These could include standing water, drip areas from roof leaks, accumulated product, etc.

Continuous Program Review: As results are gathered and trends emerge, the sanitation control program should be reviewed and adjusted to ensure that any emerging contaminants are detected, evaluated, and aggressively controlled.

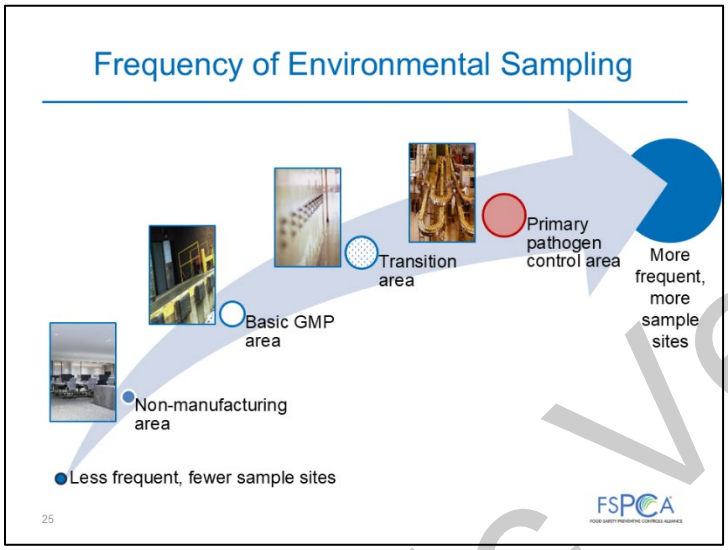
Adaptation of environmental monitoring approaches may be necessary to proactively monitor for adverse impacts in certain circumstances. Some considerations for proactive planning include:

- Roof or water leaks, floor drain back-ups in exposed-product areas, construction or equipment installation, and transition between construction and production areas can increase the prevalence of environmental pathogens. Procedures should be in place to protect processing areas and product during such events.
- For situations involving leaks and entry of water into dry environments, environmental monitoring for *Salmonella* is advisable. Taking these swabs immediately and before cleanup is useful because this likely represents the worst-case situation. If no *Salmonella* is detected in these swabs, the environment may

not be compromised. However, if the organism is detected, immediate action should be taken to sanitize the area without extensive use of water, which is likely to make the situation worse.

- During construction events, traffic patterns should be evaluated so as to minimize a potential source of contamination. Dust and traffic should be controlled in the event of construction. Upon completion of construction activities, the area should be cleaned and sanitized, and swabs should be taken before production begins again. Additional environmental monitoring following these events will help verify restoration of controls.

Slide 25: Frequency of Environmental Sampling

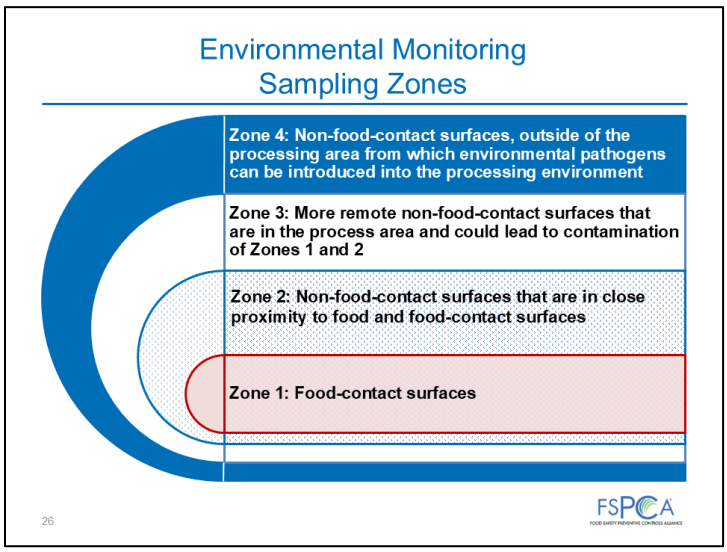


Since the objective of environmental monitoring is to detect potential sources of contamination, sampling typically focuses on the areas of greatest concern. More frequent sampling takes place in primary pathogen control areas. Sampling of non-manufacturing areas is rare.

As part of the procedures, it is important to establish frequency. Typically, sampling frequency during the initial months of the program may be increased to aid in establishing a norm for the facility, considering factors such as seasonality, weather, adjacent establishments, and personnel changes. As a suggestion, take swabs during production, at least three (3) hours in. Samples may be composited to reduce costs by taking individual samples from each site and combining them to form the composite sample. If composite samples are found to contain the target organism, then additional sampling within those areas should be run independently. Do not use the same sponge for multiple sample sites as this could spread potential contamination. Increase sampling when focusing on water, harborage and high traffic areas, as well as sites that are more likely to be a source of contamination based on equipment and plant infrastructure conditions. It is good practice to sanitize the site after sampling.

For more information, refer to the draft *Listeria* guidance referenced earlier or at the end of the chapter.

Slide 26: Environmental Monitoring Sampling Zones



Definitions: *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment." (21 CFR 117.3)

Within each area, the actual sampling location is described in terms of zones.

Zone 1 represents food-contact surfaces, such as vessels, conveyors, utensils, and even hands that come into direct contact with the food. These can include surfaces that could drip or drain onto the food, such as overhead condensate.

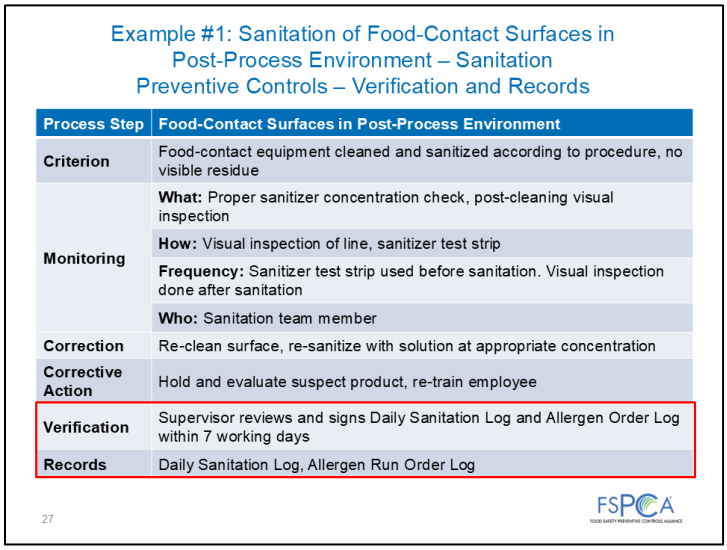
Zone 2 includes areas adjacent to food-contact surfaces, which are sometimes referred to as "indirect product-contact" surfaces. Examples are bearings, equipment panels, or aprons.

Zone 3 includes everything else within the production or processing area such as floors, walls, ceilings, drains, and other equipment.

Zone 4 encompasses all other non-production areas of a facility, such as hallways, maintenance shops and employee welfare areas.

Common industry practices focus on monitoring in Zones 2, 3, and 4 locations. These zones will tend to show signs of contamination in the environment first, thus sampling these zones increases the likelihood that a potential contamination source is detected and acted on before it becomes a contaminant in finished product areas, specifically product-contact surfaces (Zone 1). Early detection and correction will help prevent contamination from making its way to exposed ready-to-eat food product. Zone 1 sampling is infrequent, but when this is done, product may have to be held until results are found to be negative to prevent the potential for a recall situation.

Slide 27: Example #1: Sanitation of Food-Contact Surfaces in Post-Process Environment – Sanitation Preventive Controls – Verification and Records



Example #1: Sanitation of Food-Contact Surfaces in Post-Process Environment – Sanitation Preventive Controls – Verification and Records

Process Step	Food-Contact Surfaces in Post-Process Environment
Criterion	Food-contact equipment cleaned and sanitized according to procedure, no visible residue
Monitoring	**What:** Proper sanitizer concentration check, post-cleaning visual inspection
	How: Visual inspection of line, sanitizer test strip
	Frequency: Sanitizer test strip used before sanitation. Visual inspection done after sanitation
	Who: Sanitation team member
Correction	Re-clean surface, re-sanitize with solution at appropriate concentration
Corrective Action	Hold and evaluate suspect product, re-train employee
Verification	Supervisor reviews and signs Daily Sanitation Log and Allergen Order Log within 7 working days
Records	Daily Sanitation Log, Allergen Run Order Log

27

FSPCA

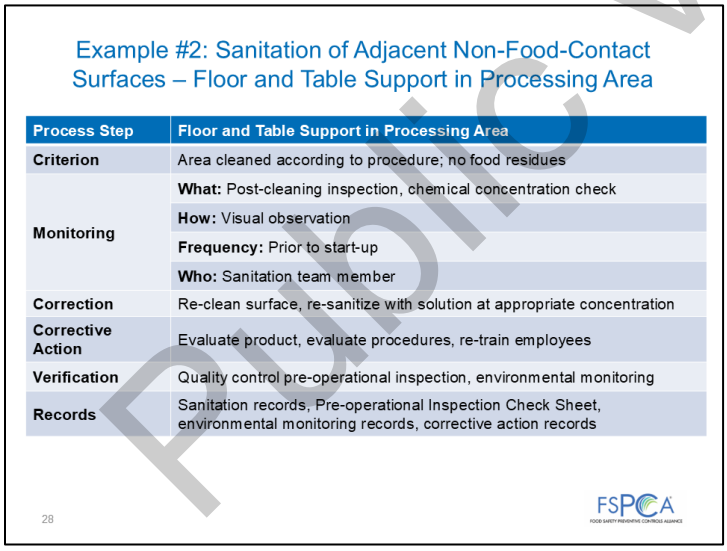
FDA recommends that for sanitation of food-contact surfaces, verification activities should include environmental monitoring of Zone 1 surfaces.

FDA further recommends that this sampling occur during operations, preferably 3 to 4 hours after processes have started, in addition to those samples collected pre-operationally.

When sampling Zone 1 surfaces, there are many important considerations that could include procedures for holding product of the sampled lot and corrective actions following a positive sample.

This slide continues the sanitation preventive control example from earlier. Added here are the details about verification being supervisors review of the Daily Sanitation Log and Allergen Run Order Log.

Slide 28: Example #2: Sanitation of Adjacent Non-Food-Contact Surfaces – Floor and Table Support in Processing Area



Example #2: Sanitation of Adjacent Non-Food-Contact Surfaces – Floor and Table Support in Processing Area

Process Step	Floor and Table Support in Processing Area
Criterion	Area cleaned according to procedure; no food residues
Monitoring	**What:** Post-cleaning inspection, chemical concentration check
	How: Visual observation
	Frequency: Prior to start-up
	Who: Sanitation team member
Correction	Re-clean surface, re-sanitize with solution at appropriate concentration
Corrective Action	Evaluate product, evaluate procedures, re-train employees
Verification	Quality control pre-operational inspection, environmental monitoring
Records	Sanitation records, Pre-operational Inspection Check Sheet, environmental monitoring records, corrective action records

28

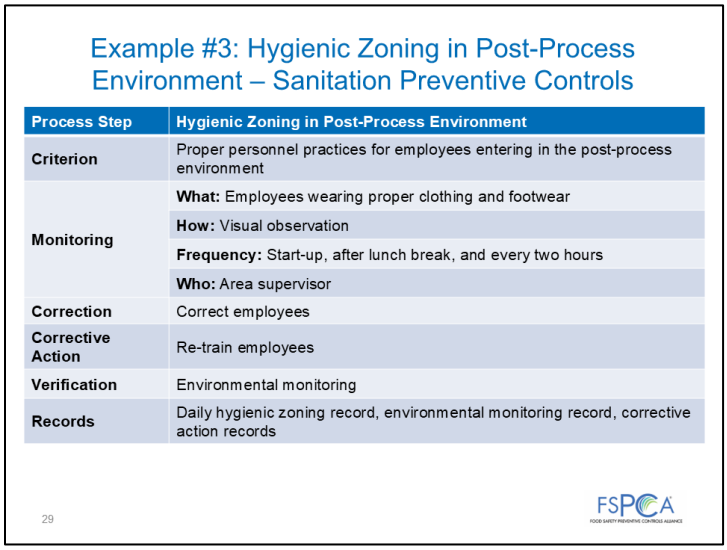
FSPCA

Sanitation of non-food-contact surfaces could become a sanitation preventive control when the hazard analysis identifies a hazard that could occur.

This slide continues the sanitation preventive control example from earlier. Added here are the details about verification using pre-op inspection and environmental monitoring.

This example continues in subsequent slides.

Slide 29: Example #3: Hygienic Zoning in Post-Process Environment – Sanitation Preventive Controls



Example #3: Hygienic Zoning in Post-Process Environment – Sanitation Preventive Controls

Process Step	Hygienic Zoning in Post-Process Environment
Criterion	Proper personnel practices for employees entering in the post-process environment
Monitoring	**What:** Employees wearing proper clothing and footwear
	How: Visual observation
	Frequency: Start-up, after lunch break, and every two hours
	Who: Area supervisor
Correction	Correct employees
Corrective Action	Re-train employees
Verification	Environmental monitoring
Records	Daily hygienic zoning record, environmental monitoring record, corrective action records

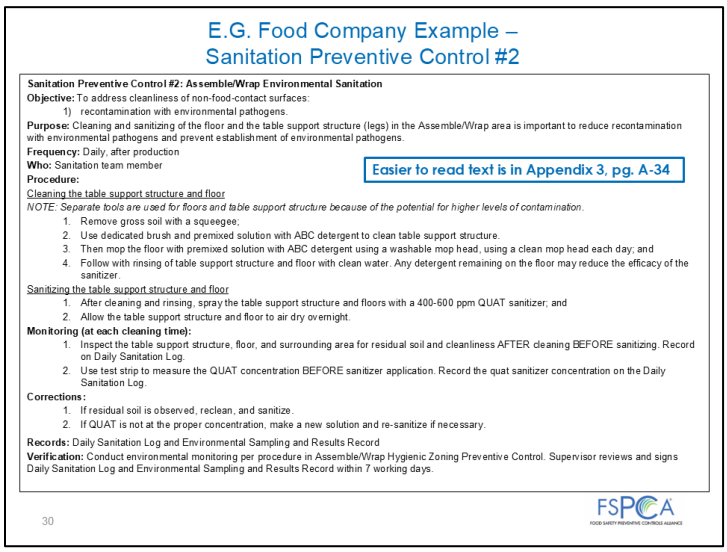
29

FSPCA

This slide continues the sanitation preventive control example from earlier. Added here are the details about verification using environmental monitoring.

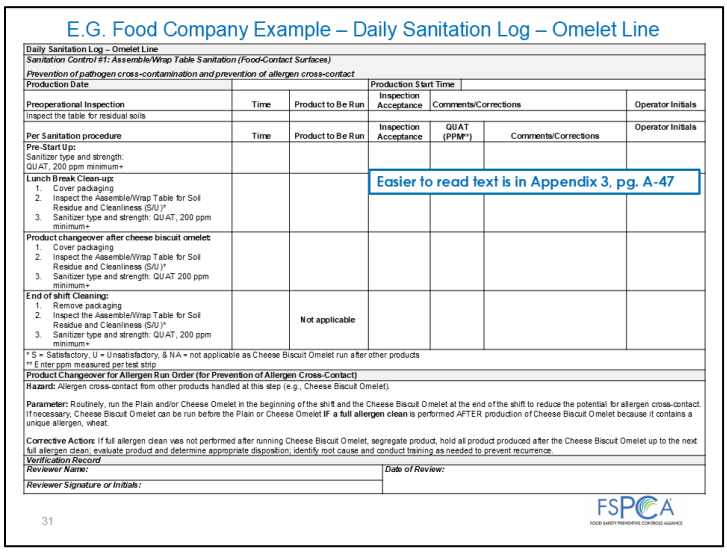
This particular example demonstrates where hygienic zoning will be elevated to a preventive control in areas where ready-to-eat products are exposed to the environment. This will be dictated by the hazard analysis. A possible justification for this decision could be related to the sensitivity of the end consumer (e.g., for an infant or in a medical setting), or prior contamination issues linked to personnel practices.

Slide 30: E.G. Food Company Example – Sanitation Preventive Control #2



An example of the sanitation procedure for the E.G. Food Company's Assemble/Wrap table appears above (Sanitation Preventive Control #2). This is only an example of how a sanitation preventive control could be documented. The format used can vary considerably and may even use photographs instead of words. Two additional sanitation preventive controls are shown in Appendix 3: Sanitation Preventive Control #1: Assemble/Wrap Table Sanitation, and Sanitation Preventive Control #3: Assemble/Wrap Hygienic Zoning.

Slide 31: E.G. Food Company Example – Daily Sanitation Log – Omelet Line



E.G. Food Company Example – Daily Sanitation Log – Omelet Line

Daily Sanitation Log – Omelet Line						
Sanitation Control #1: Assemble/Wrap Table Sanitation (Food-Contact Surfaces)						
Prevention of pathogen cross-contamination and prevention of allergen cross-contact						
Production Date			Production Start Time			
Preoperational Inspection	Time	Product to Be Run	Inspection Acceptance	Comments/Corrections		Operator Initials
Inspect the table for residual soils						
Per Sanitation procedure	Time	Product to Be Run	Inspection Acceptance	QUAT (PPM**)	Comments/Corrections	Operator Initials
Pre-Start Up: Sanitizer type and strength: QUAT, 200 ppm minimum+						
Lunch Break Clean-up: 1. Cover packaging 2. Inspect the Assemble/Wrap Table for Soil Residue and Cleanliness (S/U)* 3. Sanitizer type and strength: QUAT, 200 ppm minimum+			Easier to read text is in Appendix 3, pg. A-47			
Product changeover after cheese biscuit omelet: 1. Cover packaging 2. Inspect the Assemble/Wrap Table for Soil Residue and Cleanliness (S/U)* 3. Sanitizer type and strength: QUAT 200 ppm minimum+						
End of shift Cleaning: 1. Remove packaging 2. Inspect the Assemble/Wrap Table for Soil Residue and Cleanliness (S/U)* 3. Sanitizer type and strength: QUAT, 200 ppm minimum+		Not applicable				
* S = Satisfactory, U = Unsatisfactory, & NA = not applicable as Cheese Biscuit Omelet run after other products ** Enter ppm measured per test strip						
Product Changeover for Allergen Run Order (for Prevention of Allergen Cross-Contact)						
Hazard: Allergen cross-contact from other products handled at this step (e.g., Cheese Biscuit Omelet). **Parameter:** Routinely, run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Biscuit Omelet at the end of the shift to reduce the potential for allergen cross-contact. If necessary, Cheese Biscuit Omelet can be run before the Plain or Cheese Omelet **IF a full allergen clean** is performed AFTER production of Cheese Biscuit Omelet because it contains a unique allergen, wheat. **Corrective Action:** If full allergen clean was not performed after running Cheese Biscuit Omelet, segregate product, hold all product produced after the Cheese Biscuit Omelet up to the next full allergen clean; evaluate product and determine appropriate disposition; identify root cause and conduct training as needed to prevent recurrence.						
Verification Record						
Reviewer Name:			*Date of Review:*			
Reviewer Signature or Initials:						

31

FSPCA

An E.G. Food Company example of a Daily Sanitation Control Record for its omelet line is illustrated above. It includes several monitoring activities on the same form. Visual observation of cleanliness is one type of monitoring activity, recorded as satisfactory or unsatisfactory on the initial observation. Recording the sanitizer concentration is another monitoring activity, which documents the specific concentration of the sanitizer used. Test strips frequently are used for this type of activity. Test strips appropriate for the specific sanitizer must be used.

A facility may use several forms to record the complete sanitation control procedure information in order to ensure efficient recording at the location where the sanitation activity takes place. For example, there could be a monitoring record located in the equipment cleaning room to record the sanitizer concentration in a tank used to submerge cleaned equipment parts (e.g., gaskets, cutter blades,). Other sanitation forms may be located in the production area where the equipment is being cleaned.

An important consideration to minimize the potential for environmental pathogens becoming established and for preventing growth of pathogens on food residues remaining on surfaces, is to establish specific sanitation frequencies. A chemical supplier can help provide guidelines for cleaning frequency in many situations. Note that not all sanitation procedures need to be included in the Food Safety Plan. Sanitation procedures conducted for quality reasons fall under GMPs rather than sanitation preventive controls and, as such, are not required to be documented in the Food Safety Plan.

The date, time (when appropriate), and initials of the operator performing the monitoring task must be included on a monitoring record each time they perform the task.

Slide 32: Sanitation Preventive Controls Summary

Sanitation is an element of GMPs that is required in all facilities. For some products and processes, the hazard analysis will identify specific instances where sanitation preventive controls are essential to protect consumers from contaminated product. Hazards requiring sanitation preventive controls depend on the facility and may include environmental pathogens when ready-to-eat food is exposed to the environment, pathogens transferred through cross-contamination and allergens transferred through allergen cross-contact. Sanitation preventive controls focus on the cleanliness of food-contact surfaces and personnel hygiene practices in order to aid in the prevention of cross-contamination and allergen cross-contact. When identified in the hazard analysis process, these sanitation preventive control procedures must comply with preventive controls requirements and be documented in the Food Safety Plan. Required information includes procedures for cleaning and sanitizing food-contact surfaces and employee hygiene practices, as appropriate, monitoring activities and frequency, corrective actions or corrections, and verification activities.

Slide 33: Knowledge Check 1

Participants do NOT have this slide.

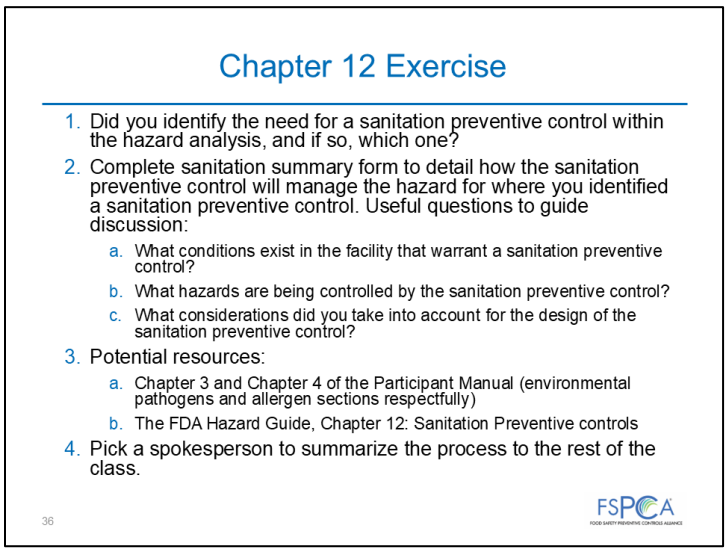
Slide 34: Knowledge Check 2

Participants do NOT have this slide.

Slide 35: Knowledge Check 3

Participants do NOT have this slide.

Slide 36: Chapter 12 Exercise



1. Did you identify the need for a sanitation preventive control within the hazard analysis, and if so, which one?
2. Complete sanitation summary form to detail how the sanitation preventive control will manage the hazard for where you identified a sanitation preventive control. Useful questions to guide discussion:
    a. What conditions exist in the facility that warrant a sanitation preventive control?
    b. What hazards are being controlled by the sanitation preventive control?
    c. What considerations did you take into account for the design of the sanitation preventive control?
3. Potential resources:
    a. Chapter 3 and Chapter 4 of the Participant Manual (environmental pathogens and allergen sections respectfully)
    b. The FDA Hazard Guide, Chapter 12: Sanitation Preventive controls
4. Pick a spokesperson to summarize the process to the rest of the class.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

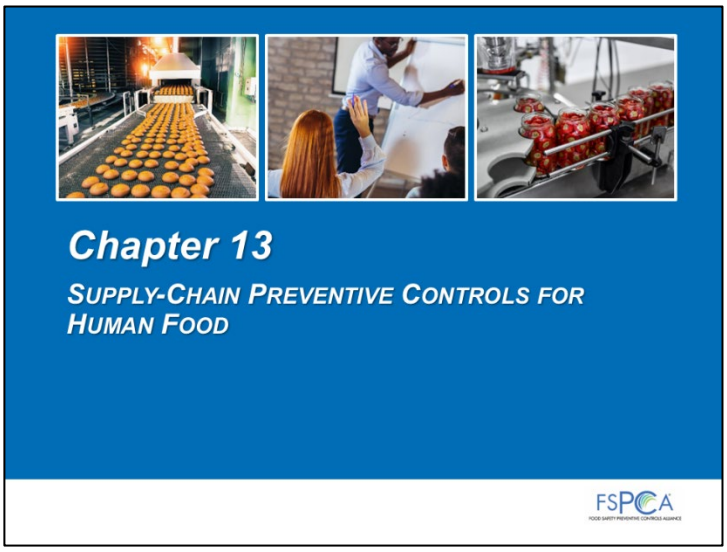
FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

Consumers Brand Association (CBA) (previously Grocery Manufacturers Association [GMA]). (2009). Control of *Salmonella* in Low Moisture Foods Guidance Document: https://forms.consumerbrandsassociation.org/forms/store/ProductFormPublic/SalmonellaControlGuidance

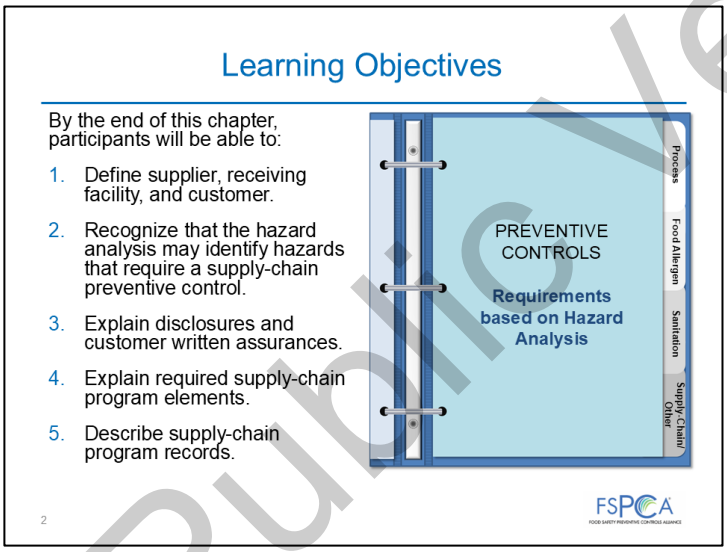
Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-to-Eat Foods: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods

Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

Slide 1: Chapter 13: Supply-Chain Preventive Controls for Human Food



Slide 2: Learning Objectives

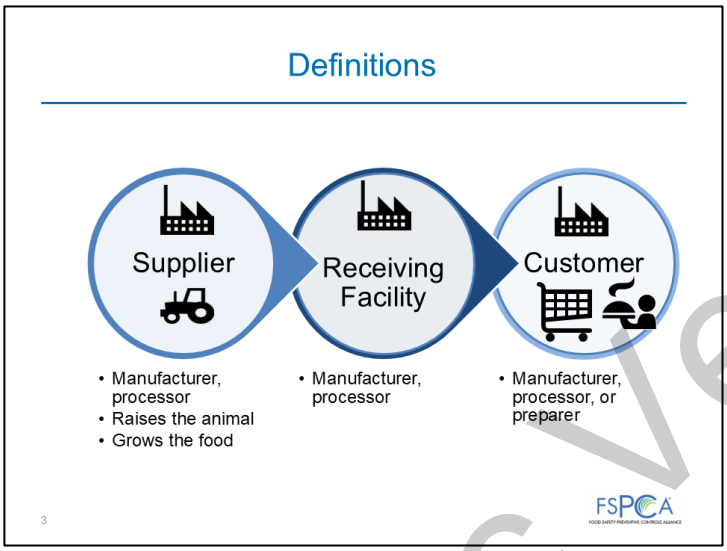


For simplicity, the term "ingredients" may be used in place of the phrase "raw materials and other ingredients" used in the regulation.

The safety of a food product depends on much more than just the hazards controlled within the production facility. Use of raw materials and other ingredients historically associated with a specific hazard may require a supply-chain preventive control for that ingredient. In Subpart G of the Preventive Controls for Human Food (PCHF) regulation, the two terms "supply-chain preventive control" and "supply-chain program" mean the same thing. Companies may have an extensive "supplier program" that encompasses much more than food safety elements (e.g., quality attributes to manage their supplier expectations and performance). This chapter focuses on the regulatory requirements for determining and conducting verification activities to ensure the supplier has implemented controls for the hazards the receiving facility has identified for the given ingredient.

This chapter begins with a review of definitions of supplier, receiving facility, customer, and supply-chain-applied control as they apply to the PCHF regulation. It then discusses the required contents for a supply-chain program under 21 CFR Part 117, Subpart G. This program will include development of supply-chain preventive controls for those ingredients identified in the hazard analysis which have supplier-controlled hazards. As part of the supplier preventive control, the company will implement appropriate supplier verification activities to ensure the adequacy of the supplier's control of the identified hazard. Recordkeeping requirements for supply-chain programs, disclosures, and customer written assurances also are discussed.

Slide 3: Definitions



Definitions:

Supplier: The establishment that manufacturers/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/ processing by another establishment, except for further manufacturing/ processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature. (21 CFR 117.3)

Receiving facility: A facility that is subject to Subparts C [Preventive Controls] and G [Supply-chain Program] of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier. (21 CFR 117.3)

Customer: The commercial entity the receiving facility sells to, who may or may not be subject to the requirements for hazard analysis and risk-based preventive controls. (Based on 21 CFR 117.136) A customer does not include consumer.

Supply-chain-applied control: A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt. (21 CFR 117.3)

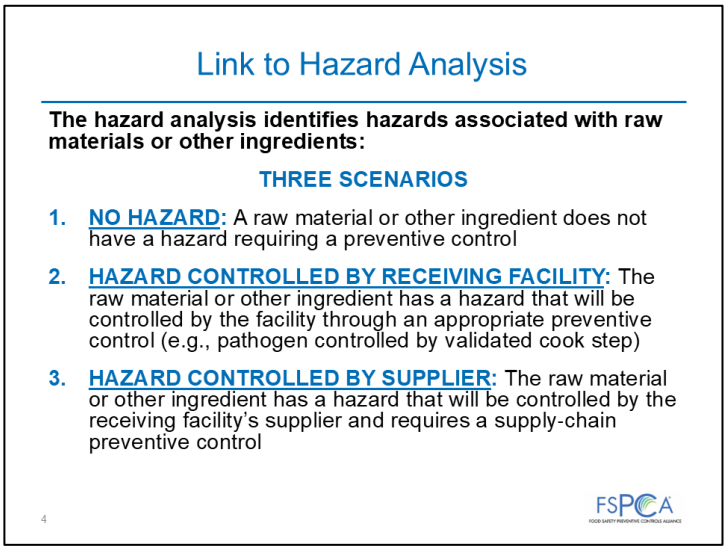
To understand supply-chain program requirements, it is important to understand the definition of supplier, receiving facility, and customer in the context of the regulation. Review the definitions in the textbox and the illustration above.

The manufacturer/processor is the "receiving facility" for the raw material or other ingredient. The "supplier" may be a manufacturer or processor of the food that the facility receives. If the facility receives raw agricultural ingredients, the "supplier" is the entity that grows the food or raises the animal. For example, if a receiving facility receives a crop that is grown by Farmer Green but is harvested and labeled by a regional harvesting organization, Farmer Green is still the supplier.

Also note, the definition of "supplier" in part 117 means that a broker or distributor is not a supplier; the supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food. Thus, if raw materials or other ingredients are purchased from a broker or distributor, a request is made to the broker or distributor to provide the necessary information to allow for the evaluation of the specific supplier that manufactures/processes the specific food, raises the animal, or grows the food as a supplier of the food. Likewise, if raw materials or other ingredients are purchased from a retail establishment (e.g., a warehouse-style establishment that sells to consumers), some applicable information (e.g., name and place of business of the manufacturer, packer, or distributor), would be on the product label as required by food labeling regulations in 21 CFR 101.5. Alternatively, the information may be requested from the retail establishment that allows for the evaluation of the supplier that manufactures/processes the food, raises the animal, or grows the food.

The "customer" can be another manufacturer/processor or an entity which prepares the food, such as a food service or retail establishment, or other type of operation. The customer may or may not be subject to the PCHF regulation.

Slide 4: Link to Hazard Analysis



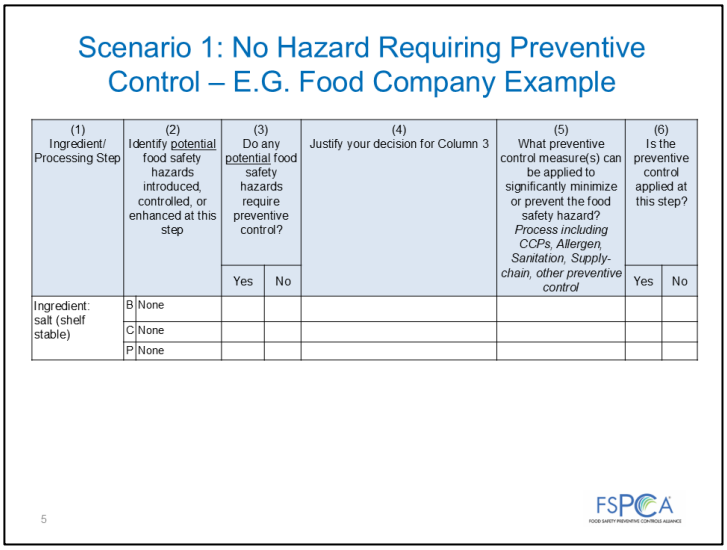
The hazard analysis process discussed in Chapter 6: Hazard Analysis determines when a hazard requiring a supply-chain-applied control exists.

Some raw materials and other ingredients may not have hazards requiring a preventive control. For example, salt has not been associated with significant food safety issues. While a salt processor must operate under GMPs, conduct their own hazard analysis, and implement controls as necessary, a receiver of salt may conclude that a food safety hazard requiring a supply-chain-applied control is not present. The next slide illustrates how this could be documented in the hazard analysis.

Other ingredients, however, do have an association with specific food safety hazards. A supply-chain program is not needed when the receiving facility implements a preventive control for the hazard within the facility. For example, a pathogen is controlled by a validated cook step by the receiving facility.

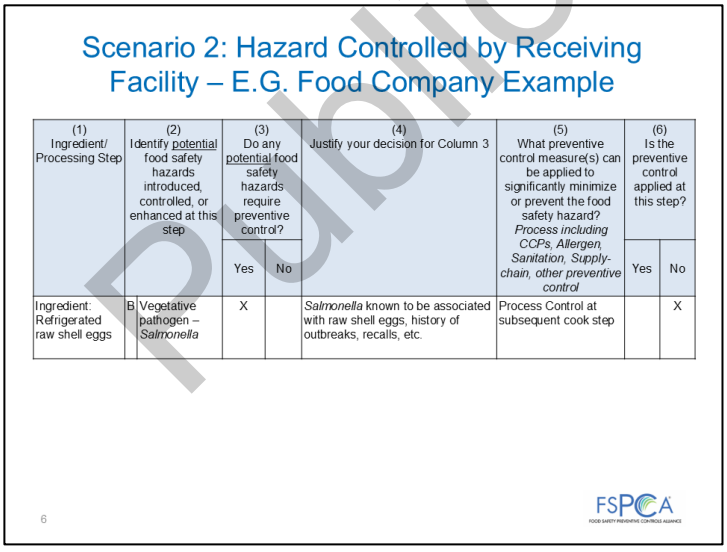
However, in some cases, the receiving facility relies on the supplier to control the hazard because the receiving facility cannot or will not control the hazard through its own manufacturing/processing. In this case, a supply-chain preventive control is required.

Slide 5: Scenario 1: No Hazard Requiring Preventive Control – E.G. Food Company Example



If an ingredient has no identified hazards, that information can be documented in the hazard analysis as shown in the E.G. Food Company example hazard analysis. In the evaluation of the ingredient salt, no hazard exists and therefore no preventive controls would be needed relating to managing the food safety of this ingredient. Sourcing for this ingredient, as for all ingredients, may still be part of a company's overall supplier program.

Slide 6: Scenario 2: Hazard Controlled by Receiving Facility – E.G. Food Company Example



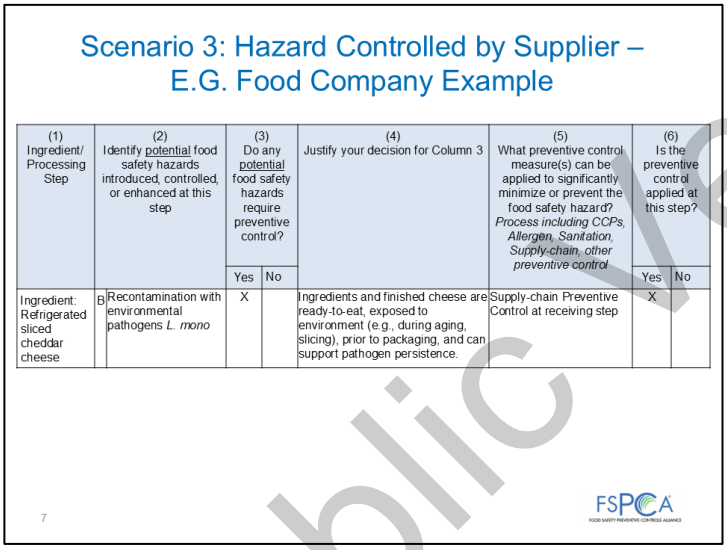
The hazard analysis for the E.G. Food Company identified *Salmonella* as a hazard requiring a preventive control in the raw shell eggs they receive. E.G. Food Company

will control the hazard using a process preventive control within their facility to prevent the hazards from causing illness to the consuming public.

If E.G. Food Company purchased pasteurized in shell eggs instead of raw shell eggs, they could have used a supply-chain preventive control instead of a process preventive control since the supplier performs in-shell pasteurization to control *Salmonella*. This would require E.G. Food Company to verify that the controls at the supplier (for pasteurization of the shell eggs) are adequate to control the hazard on an ongoing basis.

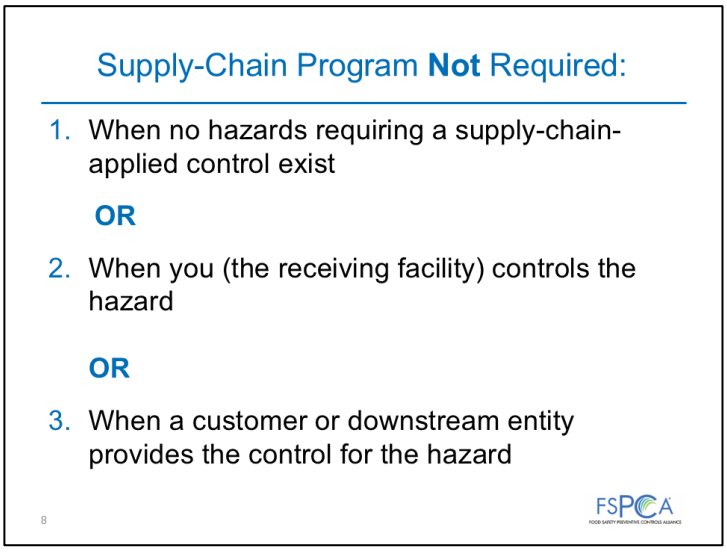
In both approaches described, the *Salmonella* hazard can be effectively controlled to prevent illness. The E.G. Food Company decided to use a process preventive control for the *Salmonella* hazard in raw shell eggs instead of purchasing the more costly pasteurized in shell egg ingredient.

Slide 7: Scenario 3: Hazard Controlled by Supplier – E.G. Food Company Example



For another example, E.G. Food Company chose a supply-chain preventive control for the one biological hazard in sliced cheddar cheese. In this example, the hazard analysis concluded that refrigerated sliced cheddar cheese has the potential for recontamination with environmental pathogen (*L. mono)* at the supplier, so a supply-chain-applied control will be required. The E.G. Food Company does not have processes in place to control pathogens (e.g., cook step because the cheese is placed on the cooked omelet after the validated cooking step). The E.G. Food Company examples illustrate the flexibility that a company can use to ensure that hazards requiring a preventive control are controlled. Sometimes there are options, such as the previous shell egg examples for the omelets. However, sometimes supply-chain control is the best option, such as in the refrigerated sliced cheddar cheese example.

Slide 8: Supply-Chain Program Not Required

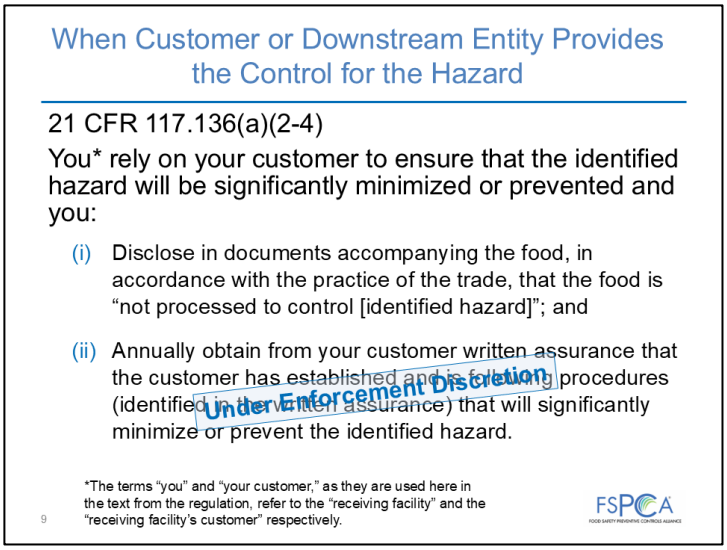


A supply-chain program is not required in the following situations:

- The hazard analysis concludes that there are no hazards requiring a supply-chain-applied control, **or**
- The facility controls the hazards requiring a preventive control within the facility, **or**
- The facility relies on their customer to control the hazard; the facility identifies for their customer that the food has not been processed to control the hazard (reminder: there is enforcement discretion for the provision in the regulation regarding customer written assurances which is discussed during the next slide).

Example: Company A's hazard analysis determines *Salmonella* is a hazard in raw nuts that they receive raw from a farmer (the supplier). Company A sorts and shells the nuts for their customer, who then roasts the nuts using a validated process. Company A is not required to apply a preventive control for *Salmonella* if they disclose in documents accompanying the shipment that the nuts were not processed to control *Salmonella*.

Slide 9: When Customer or Downstream Entity Provides the Control for the Hazard



FDA Guidance for Industry…Enforcement Policy Regarding Certain Provisions

The regulation establishes the requirements for when a receiving facility (manufacturer/processor) elects to:

1) Rely on their customer who is subject to the Preventive Controls regulation to control the identified hazard;
2) Rely on their customer who is not subject to the Preventive Controls regulation to manufacture, process, or prepare the food in accordance with applicable food safety requirements; or
3) Rely on an entity in the distribution chain subsequent to the customer and the receiving facility to control the identified hazard.

In all three situations, the receiving facility is required, by the regulation, to disclosure to the customer in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]."

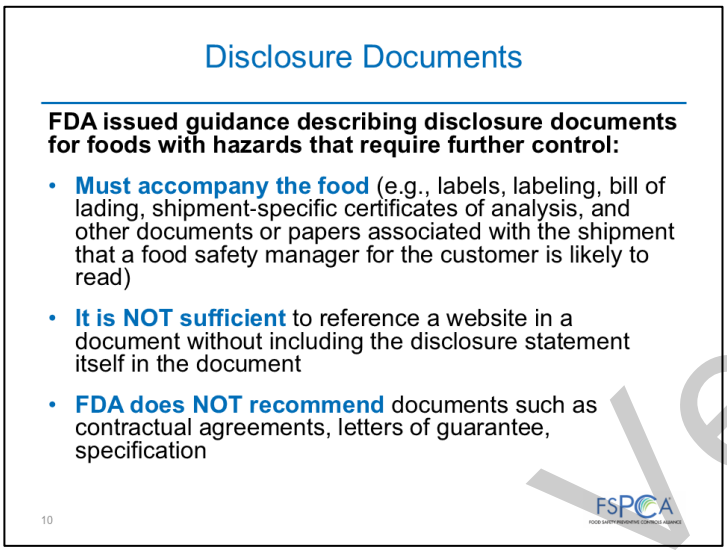
The regulation also contains provisions for the receiving facility in Situation 1, to annually obtain from their customer a written assurance that the customer will control the identified hazard; in Situation 2, to annually obtain a written assurance the customer is manufacturing, processing or preparing food in accordance with applicable food safety requirements; and in Situation 3, to annually obtain from the customer written assurance that the customer will disclose in documents accompanying the food that the food is "not processed to control [identified hazard]", and will only sell to another entity that agrees, in writing, to control the identified hazard (if the entity is subject to the Preventive Controls regulation) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the Preventive Controls regulation).

However, currently all of these customer written assurances are under enforcement discretion. Enforcement discretion occurs when the FDA announces (via guidance to industry), that, based on their current understanding of risks, they do not intend to

enforce certain regulatory requirements as they currently apply to certain entities and/or activities. In general, the FDA exercises enforcement discretion to allow time to consider changes or other approaches to address concerns regarding the application of these provisions to certain activities or entities.

Note that the stated discretion could change over time as FDA monitors the industry, so it is very important that the Preventive Controls Qualified Individual keep well informed of any potential regulatory developments.

Slide 10: Disclosure Documents

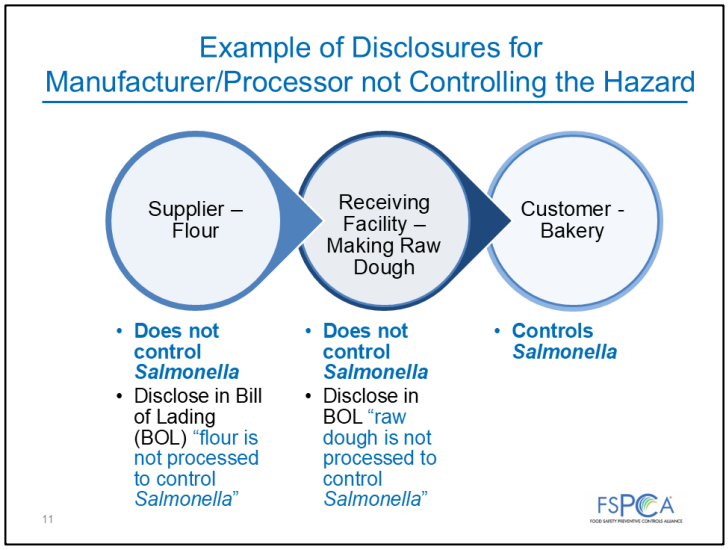


Further information may be found in FDA's guidance, "Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act."

As discussed in the previous slide, when a receiving facility (manufacturer/processor) identifies a hazard requiring a preventive control ("identified hazard"), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard, they must disclose information to their customers about foods that need control downstream to manage the identified hazard. As previously mentioned, the disclosures provision is in effect today and is enforceable by the FDA. The FDA issued guidance describing disclosure documents that must accompany the food. According to FDA, such disclosure needs to be made in documents that accompany the food, in accordance with the practice of the trade, such as labels, bill of lading, shipment-specific certificates of analysis, etc., since it would be expected that the customer is likely to read these documents.

Since it is important that this information be well understood, placing it on a website is not sufficient. The FDA guidance does not recommend other contractual documents since such documents generally are not specific to a particular shipment, and some of these documents may not be available to the customer's food safety manager.

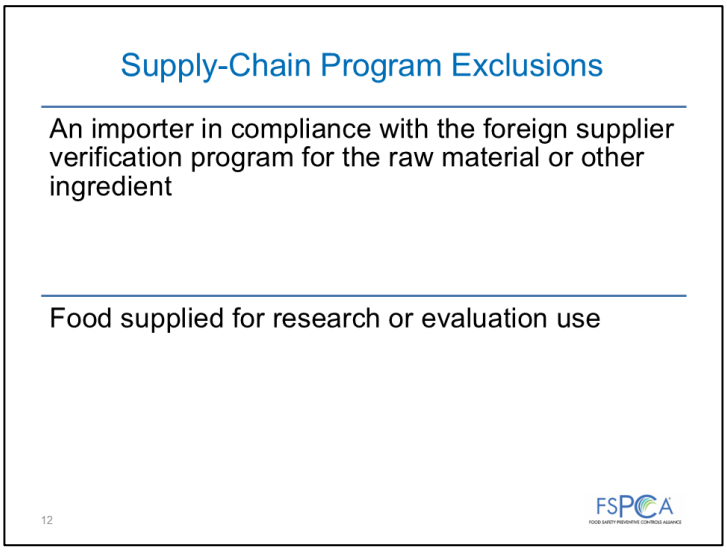
Slide 11: Example of Disclosures for Manufacturer/Processor not Controlling the Hazard



In this diagram, a wheat flour miller supplies raw flour to a facility that manufactures raw dough, who in turn supplies their customer, who is a baker that uses the dough in baked items.

The raw dough manufacturer's hazard analysis determines *Salmonella* is a hazard in raw flour received from a wheat miller (the supplier). The raw dough manufacturer has received the disclosure from the wheat flour miller that accompanies the shipment that the wheat flour has not been processed to control *Salmonella*. The raw dough manufacturer (the receiving facility) combines the flour with other ingredients to make raw dough. The raw dough manufacturer is not required to apply a preventive control for *Salmonella* since they rely on their customer to control the hazard. The raw dough manufacturer discloses in the Bill of Lading documents accompanying the shipment to the bakery customer that the dough was not processed to control *Salmonella*. The bakery customer has been advised of the hazard and controls the hazard in their facility, such as by baking the dough into a baked item.

Slide 12: Supply-Chain Program Exclusions



If applicable to the receiving facility, see the Foreign Supplier Verification Program requirements on FDA's website.

See the FSPCA website for information on the FSPCA Foreign Supplier Verification training.

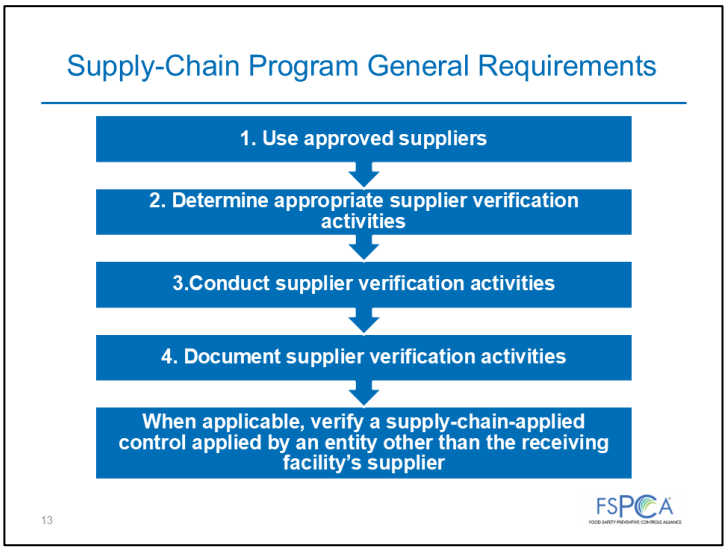
Two additional situations where the supply-chain program requirements do not apply are: 1) when the receiving facility is an importer in compliance with the Foreign Supplier Verification Program (FSVP) regulation requirements; and 2) when the food is supplied for research or evaluation use.

Per Section 117.405(a)(2): A receiving facility that is an importer in compliance with FSVP requirements already has documentation that provides assurance that the hazards requiring a supply-chain- applied control have been significantly minimized or prevented.

Per Section 117.405(a)(3): Food that is supplied for research or evaluation use is not subject to supply-chain program requirements provided that:

- The food is not intended for retail sale and is not sold or distributed to the public;
- The food is labeled "Food for research or evaluation use;"
- The food is supplied in a small quantity consistent with a research, analysis, or quality assurance purpose, it is used only for that purpose and unused food is properly disposed of; and
- The food is accompanied with documents stating that it will be used for research or evaluation purposes and cannot be sold or distributed to the public.

Slide 13: Supply-Chain Program General Requirements



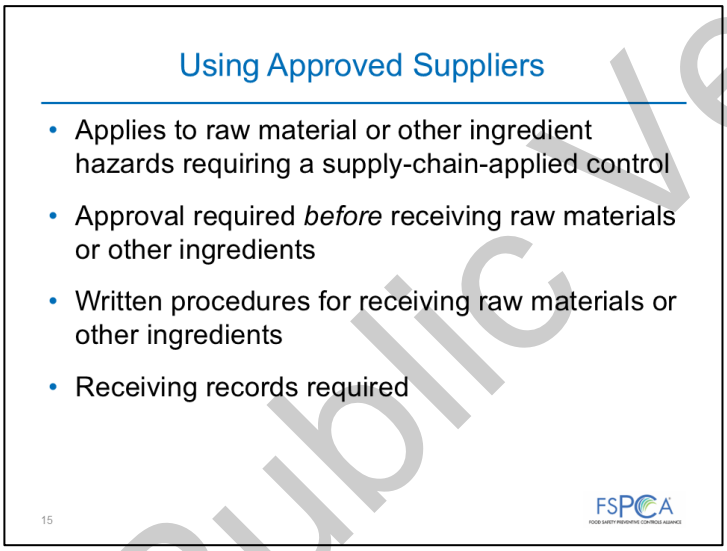
General requirements for the supply-chain program when a hazard requiring a supply-chain-applied control is identified are listed above (1-4). The facility must: 1) approve suppliers for these ingredients for which a supplier has applied the control for a hazard; 2) determine the appropriate supplier verification activities that the facility will use to verify that the supplier is applying appropriate controls for the hazard(s) identified; 3) conduct the supplier verification activities identified in step 2; and 4) ensure that these activities are documented. These activities will vary, depending on the food, the hazard(s), and the facility's food safety system. Each of these requirements will be discussed in more detail in subsequent pages.

In some situations, the supply-chain-applied control may be conducted by an entity other than the facility's direct supplier. For example, aflatoxin is a hazard associated with field corn. A milling company may have an aflatoxin control program for the dried corn they receive. A baking mix company may conduct verification activities at the miller to ensure that aflatoxin is controlled. To receive cornbread muffin mix, the receiving employee may verify the documentation from the baking mix company on their program for the miller. Another example of this situation could be where the farm that grows whole lettuce heads is the supplier (because it's the grower), but a contract harvester is the entity that harvests and then distributes that lettuce to the receiving facility. The receiving facility that is using the whole lettuce as a ready-to-eat ingredient in its fresh-cut salad kit would need to conduct supplier verification activities of the lettuce supplier (the farm that grew the lettuce) to verify that it is controlling the pathogens as well as verify that the contract harvester followed sanitary practices during harvesting to minimize pathogen cross-contamination, even though the harvester is not a supplier as defined in §117.3.

A complete supply-chain program must cover not just the immediate/direct supplier, but also entities that handle the product in ways that may impact the safety of the food.

Slide 14: Using Approved Suppliers

Slide 15: Using Approved Suppliers



The purpose of supplier verification activities is to ensure that hazards that must be controlled before receipt are in fact controlled.

From a regulatory perspective, the use of approved suppliers applies to raw materials or other ingredients where the hazard analysis identifies hazards requiring preventive control and the facility identifies that the hazard will be controlled by the supplier.

The regulation in Section 117.420(a) requires the receiving facility to approve suppliers, and document that approval, before receiving raw material and other ingredient. However, in §117.420(b)(2) sourcing from an unapproved supplier on a temporary basis is permitted provided that adequate supplier verification activities are performed before accepting the food for use (see upcoming Slide 21, Receiving from Approved Suppliers).

Slide 16: Approval of Suppliers – 21 CFR 117.420(a)

FDA Hazard Guide, Chapter 15: Supply-Chain Program

Under Subpart G, suppliers must be approved, and this approval must be documented before receiving raw materials. Section 117.420(a) specifies the receiving facility must approve suppliers in accordance with the requirements of 117.410(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers. Section 117.410(d) states that in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

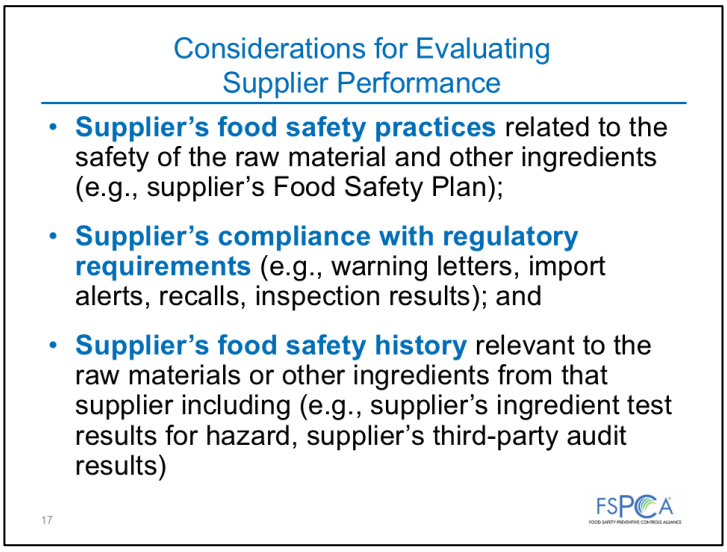
(i) The hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material or other ingredient;

(ii) The entity or entities that will be applying controls for hazards requiring a supply-chain-applied control;

(iii) Supplier performance; and

(iv) Any other factors as appropriate or necessary, such as storage and transportation practices.

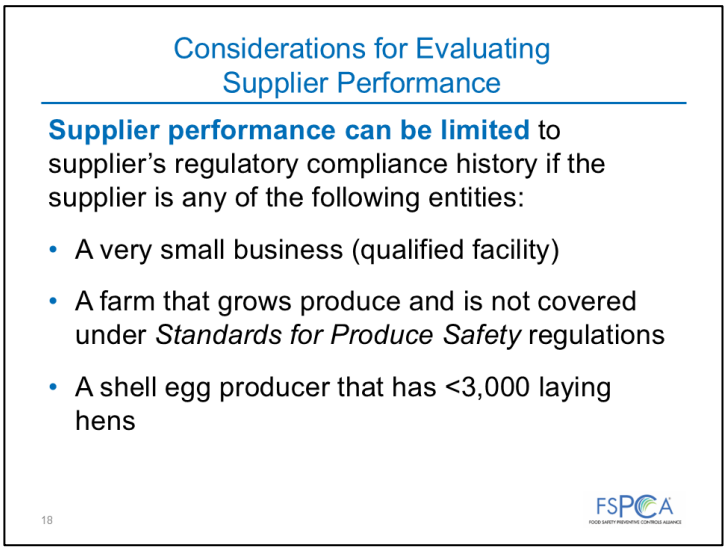
Slide 17: Considerations for Evaluating Supplier Performance (1 of 2)



As stated in the previous slide, considerations for approving a supplier include an evaluation of a supplier's performance. Section 117.410(d)(1)(iii) outlines the supplier performance considerations, including:

- An analysis of the supplier's own procedures, processes and practices related to food safety of the raw material and other ingredients. This can include an adequate review of the supplier's Food Safety Plan and environmental monitoring program especially for a supplier of ready-to-eat ingredients that are exposed to the environment;
- Evaluating the supplier's ongoing compliance with applicable FDA food safety regulations. This can include reviewing inspection results and the supplier's history (if any) of warning letters, import alerts, and recalls; and
- Evaluating the food safety history relevant to the raw material or other ingredients that the receiving facility receives from the supplier, including results from testing raw materials and other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems.

Slide 18: Considerations for Evaluating Supplier Performance (2 of 2)



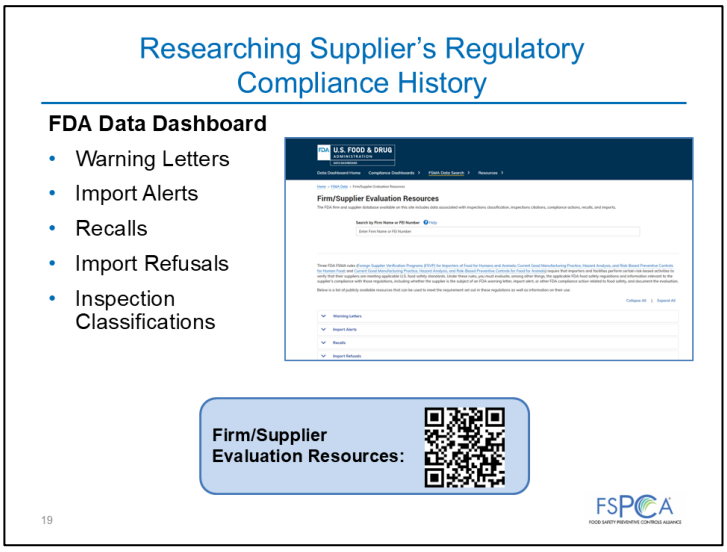
Section 117.410(d)(2) states that supplier performance considerations can be limited to the supplier's regulatory compliance history if the supplier is:

(I) a qualified facility as defined by §117.3;

(II) a farm that grows produce and is not a covered farm under 21 CFR Part 112; or

(III) a shell egg producer that is not subject to the requirements of 21 CFR Part 118, because it has less than 3,000 laying hens.

Slide 19: Researching Supplier's Regulatory Compliance History

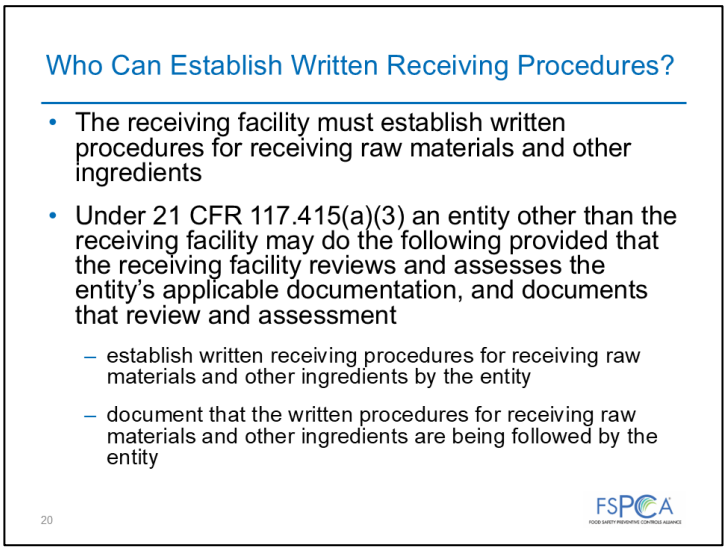


FDA Firm/Supplier Evaluation Resources

The FDA created the Data Dashboard to summarize compliance information for specific firms including information about domestic and foreign inspections (including top 10 citations), compliance actions (e.g., warning letters), recalls, and facts about imports such as summary information, refusals, and entry data. The goal is to increase transparency and accountability by displaying and allowing the analysis of public FDA data through easy-to-use, visually accessible, customizable, and understandable graphics.

The FDA Firm/Supplier Evaluation Resources database can be used to assess a specific supplier's compliance history by searching the supplier's (firm) name or FDA Establishment Identifier (FEI) number if available. This may be helpful information to assess a supplier's regulatory compliance history.

Slide 20: Who Can Establish Written Receiving Procedures?



Written procedures must be established for receiving raw materials and other ingredients, specifically for those ingredients where a supply-chain preventive control was applied. These procedures are generally established by the receiving facility.

The use of written procedures for receiving raw materials and other ingredients is particularly important if an entity other than the receiving facility, such as an entity, is acting as an intermediary. In this circumstance, a written procedure is appropriate to ensure robust and meaningful verification has occurred.

When purchasing from a broker or distributor, approval of the suppliers of the raw materials or other ingredients purchased must still take place. The broker/distributor can provide the documentation demonstrating written procedures are being followed to ensure that the raw materials and other ingredients provided only come from suppliers that have been approved. The broker/distributor would provide this documentation for review and assessment according to the Food Safety Plan. For example, the documentation required may accompany the ingredient shipment. When a broker/distributor has been tasked with ensuring raw materials or other ingredients are only coming from the approved supplier facility, there should be an agreement between parties on what procedures the broker/distributor will use to document this.

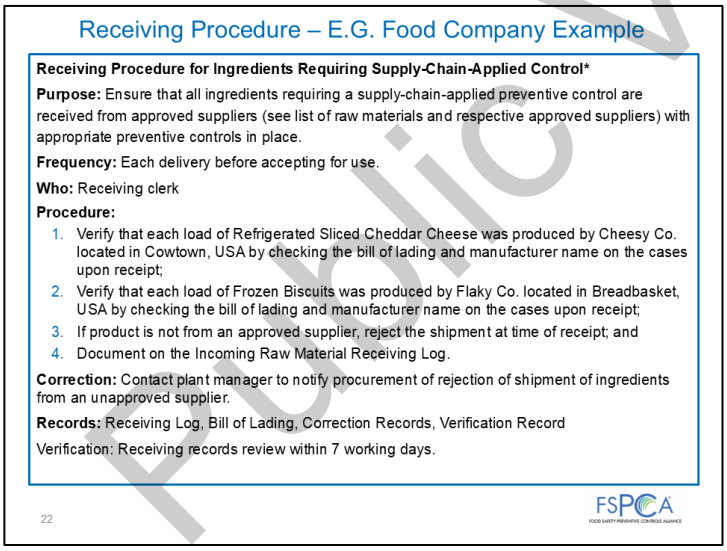
For example, the broker/distributor could have a checklist that an employee dates and initials after reviewing the invoice from the supplier and sends a copy of that dated checklist to the facility, together with the invoice for the raw materials or other ingredients. The facility could use an electronic system or specific supply-chain management software to document receipt of the raw material or other ingredient and review of checklist from the broker/distributor at the time of receipt.

Slide 21: Receiving from Approved Suppliers – 21 CFR 117.420(b)

Receiving procedures must be specific to the producing facility (supplier) and the raw material or other ingredient being purchased.

The regulation specifies the requirements for receiving procedures regarding approved suppliers. Such procedures must be established and followed. The receiving facility must ensure that raw materials are only received from approved suppliers or under certain temporary circumstances, unapproved suppliers; and be documented.

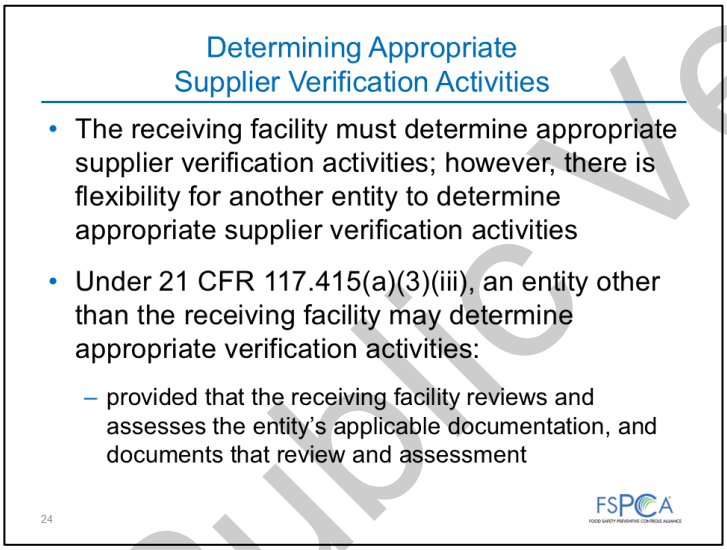
Slide 22: Receiving Procedure – E.G. Food Company Example



Shown here is an example of a receiving procedure for sliced cheddar cheese at E.G. Food Company. In this instance, the supplier controls the hazard, so each delivery of this ingredient needs to be verified to have come from the specifically approved supplier. Note that the approval relates to the specific location of Cheesy Co., located in Cowtown, USA, so that the review procedure must ensure that this cheese is sourced from this specific location.

Slide 23: Determine Appropriate Supplier Verification Activities

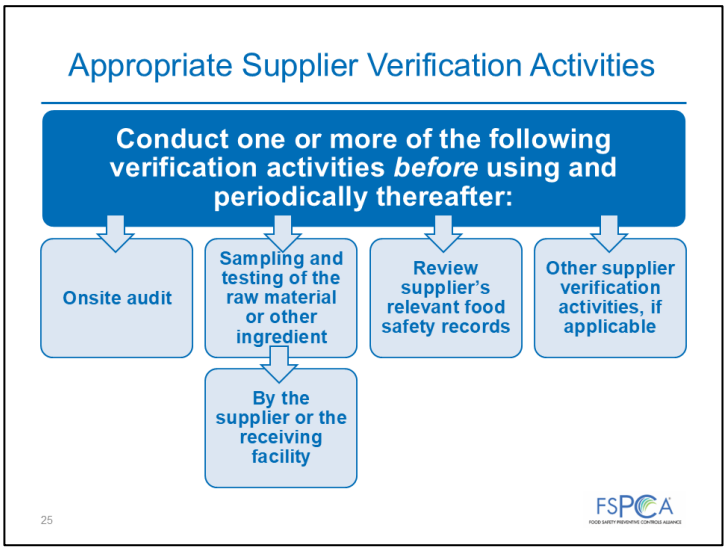
Slide 24: Determining Appropriate Supplier Verification Activities



A receiving facility may not, however, accept a determination by its supplier of the appropriate verification activities for that supplier. (21 CFR 117.415(b)(1))

Under 21 CFR 117.415(a)(3), an entity other than the receiving facility may determine the appropriate supplier verification activities, provided that the receiving facility reviews and assesses the entity's applicable documentation, and then documents the review and assessment. However, 117.415(b)(1) stipulates that a receiving facility may not accept a supplier's own determination of which verification activities are appropriate.

Slide 25: Appropriate Supplier Verification Activities



Definition: *Verification:* The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan. (21 CFR 117.3)

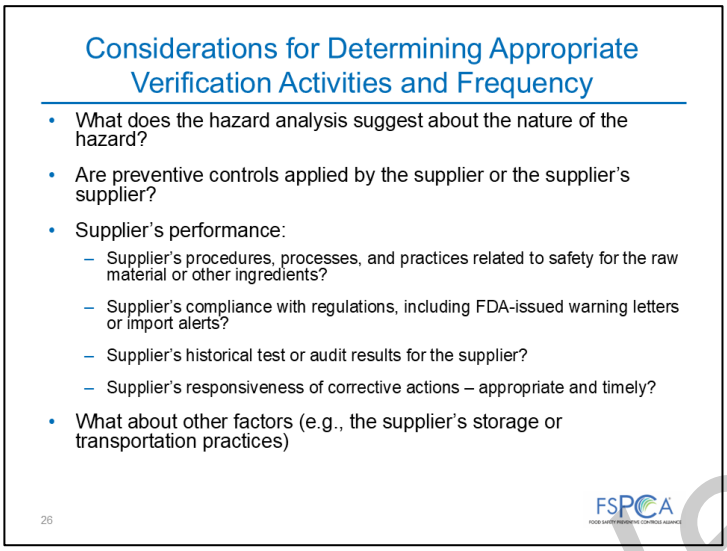
Once approved suppliers are identified, the facility must determine and conduct appropriate verification activities to ensure that the supplier is controlling the hazard requiring a supply-chain-applied control. Verification is usually not conducted at the same frequency as monitoring activities, as discussed in more detail in Chapter 9: Process Preventive Controls – Monitoring and Corrective Action. Typically, verification is conducted after the fact as a check that the system is operating according to the plan. While some verification activities are performed for each lot (e.g., review of supplier's in-house preventive controls monitoring records), other supplier verification activities could be performed annually, such as an audit. When determining the appropriate supplier verification activities and the frequency with which the activities are conducted the following must be considered: the nature of the hazard, who controls the hazard (e.g., supplier's supplier), and supplier performance.

Appropriate supplier verification activities listed are cited in §117.410(b). One or more of the following verification activities must be conducted for each supplier before initial use and periodically thereafter for ingredients that require a supply-chain-applied control:

- Onsite audits. An onsite audit of food safety practices must be performed by a qualified auditor;
- Sampling and testing of the raw material or other ingredient. This means testing the supplier's raw material or other ingredient for the identified hazard of concern;
- A review of the supplier's relevant food safety records (e.g., processing times and temperatures); and
- Other appropriate supplier verification activities based on the risk associated with the ingredient and the supplier (e.g., supplier questionnaires).

The extent to which any of these activities are used must be risk-based and consistent with regulatory requirements. Each of these verification activities will be discussed in more detail later in this chapter.

Slide 26: Considerations for Determining Appropriate Verification Activities and Frequency



Considerations for determining the appropriate supplier verification activities are the same as those for approving suppliers (see Slide 16). (21 CFR 117.410(d)(1))

The verification activities used, and their frequency depends on the specific situation. The PCHF regulation requires consideration of the above in determining relevant verification activities. For example, consider the severity of the hazard. If the hazard is a serious hazard (e.g., Salmonella in a ready-to-eat food), the regulation expects an annual audit. See definition for a serious hazard in Appendix 8: Definitions.

Where a preventive control is applied (e.g., at the supplier or at the supplier's supplier), may also impact verification procedures. For example, aflatoxin may be a hazard requiring a preventive control in cornmeal. The most effective controls for aflatoxin are applied at the farm during production, harvest, and storage of the corn prior to milling. Since the preventive control is applied by the farm (the supplier's supplier), the miller (the supplier) could conduct sampling and testing for aflatoxin of the cornmeal as a verification activity and the results could be reported in a Certificate of Analysis to the receiving facility (company using the cornmeal in food product).

Knowledge of the facility's supplier's procedures, processes and practices related to food safety may also influence verification procedures. For example, a supplier that produces only peanuts would not be a major concern for non-peanut allergens because it only handles peanuts. However, a supplier that makes a variety of nut products with different kinds of nuts may present a higher risk of cross-contact because tree nuts of different varieties have different allergens present. Understanding how such a company controls allergens may be important to the facility's supply-chain program.

Another consideration is a supplier's compliance history with FDA regulations. Warning letters and import alerts for a supplier may warrant taking extra precautions to verify that adequate controls are in place. Country of origin may be a consideration as well.

An ongoing relationship with a supplier is another important consideration. Some suppliers may have demonstrated many years of consistent performance which may reduce the frequency necessary for the verification activity. Conversely, the need to constantly switch suppliers for an ingredient requiring a supply-chain-applied control may warrant heightened verification activity to establish a supplier's ability to consistently meet the facility's food safety requirements. A supplier's response with corrective actions, when necessary, can also impact verification considerations.

There may be other factors to consider, such as transportation and storage methods used by the supplier (e.g., when a food requires refrigeration for safety).

Slide 27: Supplier Verification Activity Exceptions

The receiving facility must obtain written assurance that the supplier retains its regulatory status before approving the supplier for an applicable calendar year; and annually thereafter, by December 31 of each calendar year; AND obtain written assurance, at least every two years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations.

A receiving facility does not need to conduct supplier verification for very small businesses (e.g., qualified facility), farms that grow produce and are not covered under the Standards for Produce Safety regulation 21 CFR Part 112, or shell egg producers not subject to 21 CFR Part 118, because they have less than 3,000 laying hens. However, the receiving facility is still obligated to approve these small suppliers by evaluating the supplier's regulatory compliance history as required by §117.410(d)(1)(iii)(B).

The receiving facility must obtain written assurance that the supplier retains its regulatory status before approving the supplier and annually thereafter, by December 31 of each calendar year, for the following calendar year; AND obtains written assurance, at least every two years, that the supplier is producing the raw materials and other ingredients in compliance with applicable FDA food safety regulations.

Qualified Facility: supplier assurance that they are producing the raw materials and other ingredients in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

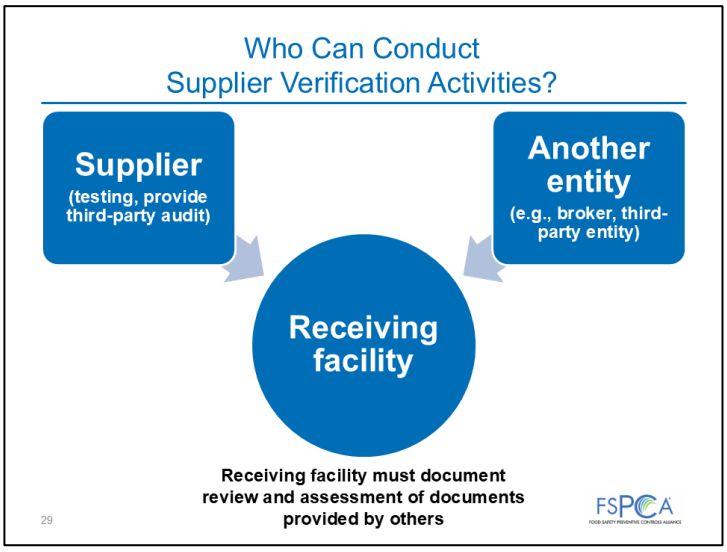
Farms that grow produce and are not a covered farm under Part 112: assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and

regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to the of the United States).

Shell egg producer that is not subject to the requirements of Part 118 (<3,000 laying hens): assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to the of the United States).

Slide 28: Conduct Supplier Verification Activities

Slide 29: Who Can Conduct Supplier Verification Activities?



Only the receiving facility can approve suppliers; however, an entity other than the receiving facility may conduct supplier verification activities, provided that the receiving facility reviews and assesses the entity's applicable documentation, and then documents that review and assessment.

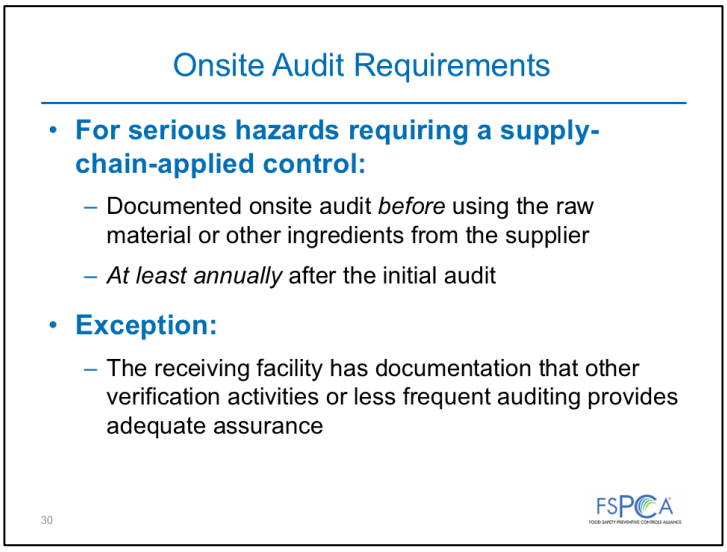
Per 21 CFR 117.415(a)(4), the supplier may conduct and document sampling and testing of raw materials and other ingredients for hazards controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment. However, the facility cannot rely on a supplier's determination of appropriate verification activities for its own product; the facility needs to determine appropriate verification activities that are consistent with the food that the facility is producing. Thus, test results from a supplier are only acceptable if the facility has determined this is an appropriate verification activity for that food.

Per 21 CFR 117.415(b)(2), of the regulation states, a receiving facility may not accept an audit conducted by its supplier. However, the regulation requirements do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §117.430(f), and §117.435.

A supplier's review of their own relevant food safety records cannot be accepted as an appropriate supplier verification activity per §117.415(b)(3).

As noted previously, another entity, such as a broker, may perform supplier verification activities, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment. Remember, the supplier is the entity that manufactures the product, grows the food, or raises the animal; thus, a broker is not a supplier in regulatory terms.

Slide 30: Onsite Audit Requirements



While there is no official list of "serious hazards" (i.e., that will result in serious adverse health consequences or death to humans or animals (SAHCODHA)), The FDA Draft Guidance for Industry: Q&As Regarding the Reportable Food Registry (RFR) identifies some circumstances of Class I recall situations that would be considered a "reportable food," an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. See Appendix 8: Definitions, for more information.

When a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, the appropriate supplier verification activity is an onsite audit of the supplier. The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

A few "serious hazard," examples cited in the FDA Hazard Guide are:

- *Salmonella* in peanut butter;
- *Clostridium botulinum* toxin in under-processed canned chili;
- *Listeria monocytogenes* in smoked salmon;
- Undeclared peanut allergen in ice cream that did not declare peanut-derived ingredients but contained peanut butter as an ingredient; and
- Choking hazards posed by a food for a baby.

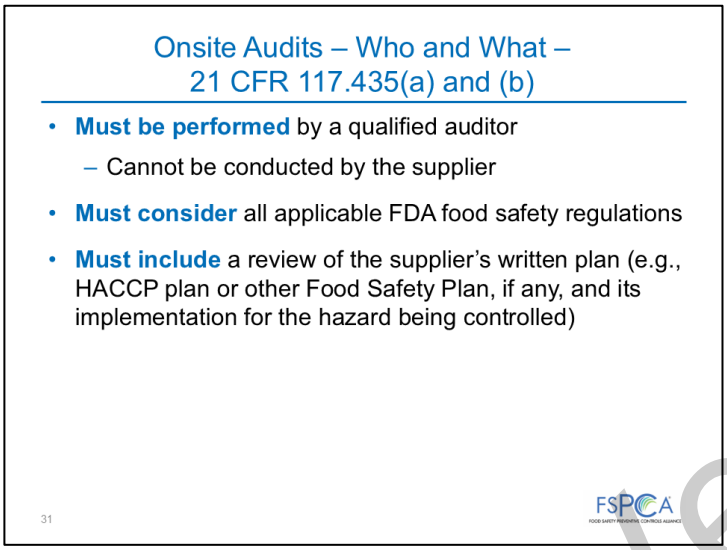
The regulation allows for an exception for annual audits provided there is written determination that other verification activities and/or less frequent onsite auditing of the supplier will provide adequate assurance that the hazards are controlled.

The receiving facility may be able to provide documentation that suggests why less frequent auditing is adequate to assure that controls are in place. For example, based

on the facility's supplier's performance history, the facility may be able to demonstrate that an audit every two years combined with periodic testing provides adequate assurance that the supplier is controlling the hazard.

Audit documentation requirements are outlined in Slide 40.

Slide 31: Onsite Audits – Who and What – 21 CFR 117.435(a) and (b)



The Global Food Safety Initiative is an example of benchmarked auditing programs for food safety standards.

Definition: Qualified auditor: A person who is a qualified individual as defined by this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function required by 117.180(c)(2). Examples of qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations of Part 1, Subpart M of this chapter (21 CFR 117.3 Definitions).

The audit must be performed by a qualified auditor who has technical expertise to adequately review the supplier's Food Safety Plan or HACCP Plan, if any, for the specific raw material or other ingredient, to ensure that the hazard requiring a supply-chain-applied control is being significantly minimized or prevented. The audit would ensure that the appropriate hazards have been identified, the hazards are controlled, and documentation is available to show the hazard was controlled. The audit should include not only a review of the documentation, but also observation of operational practices. The auditor must ensure that the audit focuses on the specific product and the hazard(s) identified by the receiving facility.

A receiving facility may not accept an audit conducted by its supplier per §117.415(b)(2). Note, that §117.415(c) states the requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §117.430(f) and §117.435.

A third-party audit is conducted by someone other than the supplier or the customer. It is important to note that the audited facility is still responsible for the audit outcome and addressing any concerns found during the audit. The supplier may provide a third-party audit to a receiving facility for review.

Some companies use their own qualified employees to audit suppliers (a "second-party audit"). Such audits allow first-hand review of the critical food safety programs and preventive controls in place at the site. The qualified employee can obtain a sense for how effective programs are by diligently reviewing program records, observing activities, and interviewing line workers. While this type of audit allows a company to verify that their specific requirements are being met, it requires internal resources and expertise that may not be feasible for some companies.

Some suppliers are routinely inspected by the FDA or other recognized regulatory agencies. A receiving facility may rely on the results of regulatory inspections instead of a third-party audit. A receiving facility may obtain information on inspections annually from the supplier. Keep in mind that government inspections may not occur annually, and the scope of the inspection may not include the receiving facility's specific raw materials or other ingredients and/or identified hazards.

Section 117.435(c)(1) states that the following may be substituted for an onsite audit, provided that the inspection must be conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local (e.g., county, city, regional), tribal or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or had determined to be equivalent to that of the United States.

§117.435(c)(2) further states for inspections conducted by the food safety authority of a country whose food safety system the FDA has officially recognized as comparable or determined to be equivalent, the food that is subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

Per Section 117.435(b), if the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other Food Safety Plan), if any, and its implementation for the hazard being controlled (or, when appliable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

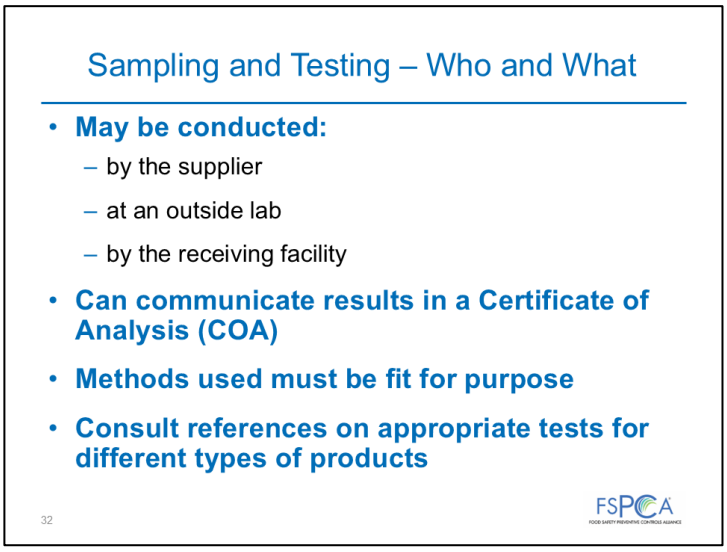
Chapter 15 of the FDA Hazard Guide is a resource that discusses considerations for conducting an onsite audit. Because FDA food safety regulations vary in scope and detail based on the product, the parameters and key components of an onsite audit

conducted under section 21 CFR 117.435(a) would vary depending on what regulations apply to the supplier. A supplier that is subject to the PCHF requirements must have a Food Safety Plan. See 21 CFR 117.126, for more detail. If a supplier is subject to the PCHF requirements, the onsite audit would focus on the supplier's Food Safety Plan and assess the implementation of the preventive controls applied by the supplier to address the known or reasonably foreseeable hazards that the facility has determined to require a supply-chain-applied control. For example, before the facility obtains roasted peanuts for which the facility has identified *Salmonella* as a hazard from a supplier subject to the PCHF requirements, the facility would audit the supplier or obtain documentation of an audit performed by a third-party, to determine whether the supplier's roasting process adequately controlled the *Salmonella* hazard. Because the supplier was subject to the PCHF requirements, the audit should include a review of the supplier's Food Safety Plan. The auditor should review whether the roasting process had been validated to significantly minimize *Salmonella* in peanuts and should examine whether the supplier had implemented the roasting procedures in accordance with its Food Safety Plan (e.g., through observing the establishment's procedures and reviewing records).

A supplier that is not subject to the PCHF requirements, but is subject to HACCP requirements, would have a "HACCP plan" rather than a "Food Safety Plan", and, therefore, an audit of such a supplier would include a review of their HACCP plan or written plan and their implementation of the plan to assure hazards are controlled by the supplier. The produce safety regulation in 21 CFR Part 112, does not require farms that are subject to that regulation to have Food Safety Plans. If the farm does not have a Food Safety Plan, then the audit would be performed to assure compliance with the produce safety regulation provisions. However, in some cases, a supplier (such as a large farming operation) might voluntarily elect to establish a Food Safety Plan. In that case, the onsite audit of the supplier should include a review of the supplier's written plan, and its implementation of the plan, to ensure that identified hazards are being adequately controlled.

An audit of a supplier should include both a records review and observation of practices to obtain a complete picture of the safety of the supplier's operations. Comprehensive systems audits that include records reviews are more likely to reflect conditions throughout the year than an audit focused only on the state of the facility at the time of the audit. An audit of a manufacturing/processing facility subject to the PCHF requirements should address process, allergen, sanitation, and supply-chain-applied controls (if any), as well as GMPs (if applicable) and the specific hazards identified in the receiving facility's hazard analysis of the food.

Slide 32: Sampling and Testing – Who and What



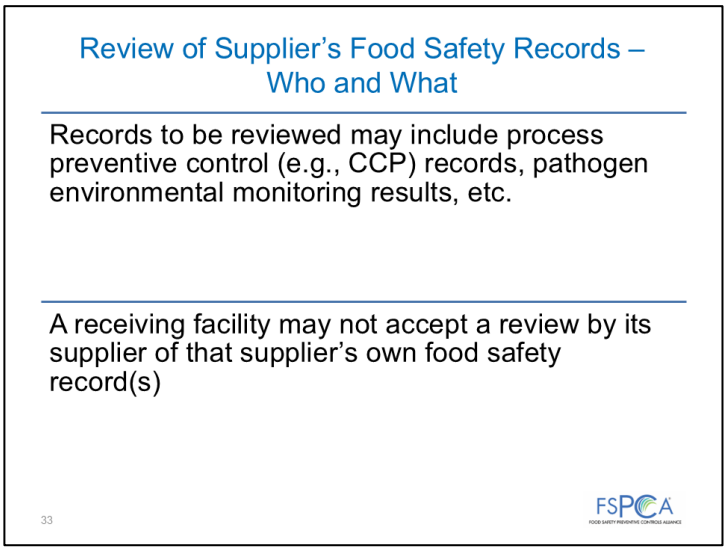
Examples where testing may be an appropriate verification activity include chemical hazards such as pesticides, mycotoxins, and heavy metals.

The regulation states that as part of the receiving facility's verification activity for the supplier, the supplier may conduct and document sampling and testing of raw materials and other ingredients for that supplier-controlled hazard, but the receiving facility must review and assess that documentation. This review and assessment must be documented. Testing of in-process materials, environmental samples or the finished food produced by the supplier, either at the supplier's facility, at an outside laboratory, or in the receiving facility may be appropriate if such testing provides meaningful results related to verifying the control of the given hazard requiring a preventive control. This test information could be captured in a Certificate of Analysis (COA) that would be specific to a lot of the raw material or other ingredient.

It is important to use methods of analysis that are "fit for purpose." The identified hazard(s) and required preventive controls in place for a specific product will influence the type of sampling and testing to be conducted (e.g., testing finished egg omelet products for *Salmonella* to verify the adequacy of the cooking step, testing for mycotoxins to assure proper nut harvesting and storage practices at the farm level). Testing as part of new supplier approval is usually more extensive than for maintenance of approved supplier status. More details about testing and what information needs to be documented will be discussed in subsequent slides.

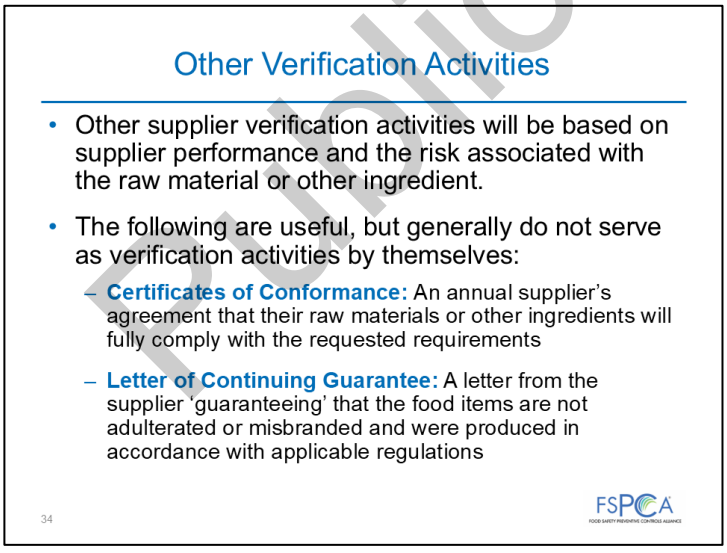
It is advisable to consult a reference book (e.g., ICMSF, 2011; FDA BAM), a technical expert or other credible source (see Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping) to determine appropriate testing and sampling plans for different types of food products.

Slide 33: Review of Supplier's Food Safety Records – Who and What



In addition to audits, and sampling and testing, a review of the supplier's relevant food safety records is another supplier verification activity cited in the regulation. Reviewing the supplier's preventive controls records such as process (CCP) control records, sanitation and allergen preventive control records, and pathogen environmental monitoring records help to assure the identified hazard(s) were controlled by the supplier. Section 117.415(b)(3) states a receiving facility may not accept a review by its supplier of that supplier's own relevant food safety records as a supplier verification activity.

Slide 34: Other Verification Activities



Other activities that may be useful for supplier verification depend on the hazards being managed. Many companies require suppliers to provide a Certificate of Conformance which is typically an annual agreement between a supplier and a receiving facility. In this agreement, the supplier provides a statement that the raw materials or other ingredients will fully comply with the requested receiving facility's

food safety requirements. Letters of Continuing Guarantee are annual guarantees certifying that the supplier's raw materials and other ingredients meet company requirements, including legal, regulatory, and conformance to specifications.

These certificates generally cover multiple shipments or timeframes and should be reviewed and renewed at least annually or when requirements change. These generally do not serve as verification activities in the way that audits or testing (e.g., communicated via Certificates of Analysis (COAs)), do, but may be suitable for certain ingredients, such as those with frequent government inspection. Further, they would not be the sole verification activity for compliance with regulatory requirements.

Slide 35: Corrective Actions Taken for Supplier Non-Conformance

See Appendix 3, A3-58 to A3-60 for an example of documenting corrective actions related to supplier non-conformance.

Per §117.410(e), when an audit, verification testing, or other verification activity, relevant consumer, customer, or other complaint, or other information identifies a gap in supplier performance related to a hazard requiring a preventive control, the receiving facility must ensure that the food manufactured with the supplier's raw materials or other ingredients is not adulterated or misbranded as a result. Corrective actions will vary depending on the specific issue as previously discussed in the other chapters on other preventive controls, but a receiving facility must ensure that the appropriate corrective actions were implemented. Note that §117.475(c)(16) also requires documentation of actions taken with respect to supplier non-conformance.

The FDA Hazard Guide, Chapter 15, recommends that a receiving facility establishes processes and procedures to handle supplier non-conformance situations. The appropriate actions to take in response to non-conformance will depend on the circumstances and the specific root cause of the non-conformance and could include:

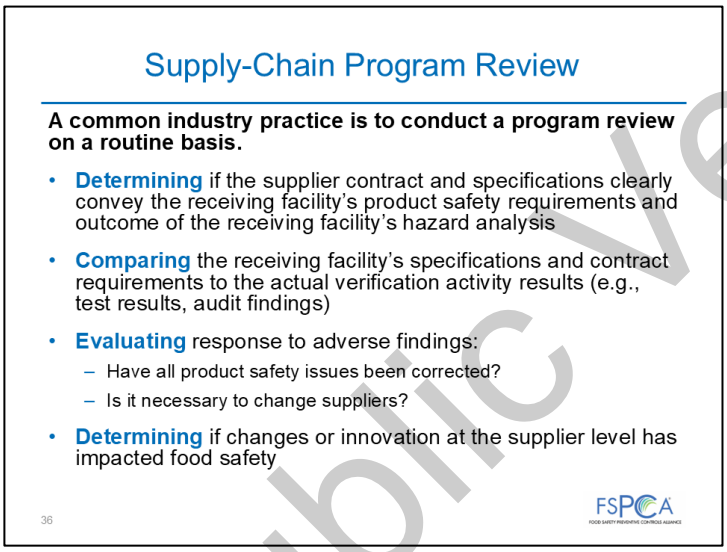
- Discontinuing use of the supplier until the cause or causes of non-conformance, adulteration, or misbranding are adequately addressed;
- Notifying the supplier of the problem and requesting documentation of corrective actions taken by the supplier;

- Assisting the supplier's efforts to correct and prevent recurrence of the problem;
- Revising your supply-chain program; and
- Conducting, or working with your supplier to conduct, a recall of an adulterated or misbranded food.

If a supplier issue resulted in adulterated or misbranded products, and those products did enter commerce, then a recall may be required (see Chapter 15: Recall Plan). Corrective action is discussed in other chapters, including documentation requirements in Chapter 10: Process Preventive Controls for Human Food – Verification and Recordkeeping.

As system failures can occur in the supplier's process or procedures periodically, the supplier must also have a corrective action process for making modifications to prevent reoccurrence of an issue. The receiving facility must ensure that the planned corrective action is actually implemented by the supplier.

Slide 36: Supply-Chain Program Review



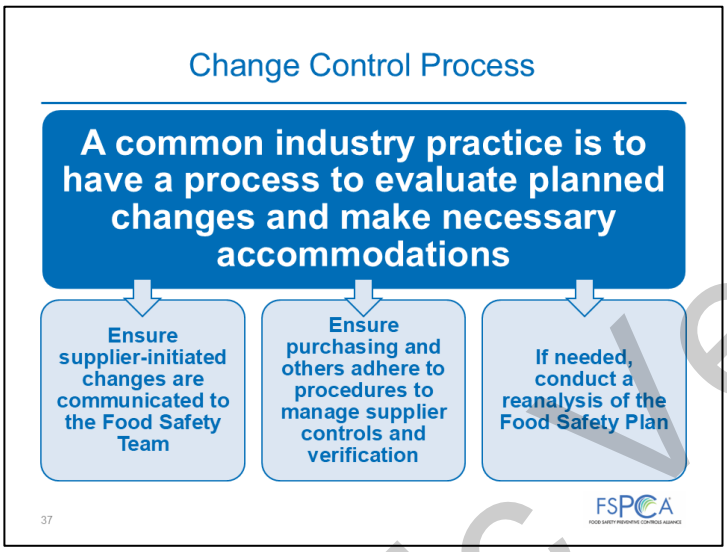
It is common industry practice to evaluate the supply-chain program on a routine basis, typically annually. Comparing findings from supplier approval, verification, and corrective action processes against the safety requirements in the supplier specifications and purchasing contract is a good starting point for evaluation. The results may indicate the need for a change in suppliers. Using the hazard analysis as a basis, purchasing contracts related to raw material and other ingredient specifications should clearly communicate food safety requirements to the supplier as well as identify the hazards for the receiving facility's understanding.

There are other elements for routine evaluation of the facility's supply-chain program. If a food safety issue occurs with a food product, review the supplier program, including verification activities, to ensure that program inadequacy was not the cause. For example, the facility may not have identified a hazard that is associated with an ingredient that needed to be controlled by the supplier. Also verify that the supplier

took steps to prevent recurrence of issues, when applicable. If the facility judges the issues to be serious enough, it could be time to consider changing suppliers.

As a result of innovations, the facility or the facility's supplier may create new formulations or new production processes. Any ingredient change should be reviewed to ensure that food safety requirements are still met by the supplier if the ingredient is associated with a hazard requiring a preventive control. Similarly, new hazards are periodically identified to ensure that the facility's supply-chain program is adequate to address new hazards associated with the raw material or other ingredient that the supplier provides.

Slide 37: Change Control Process



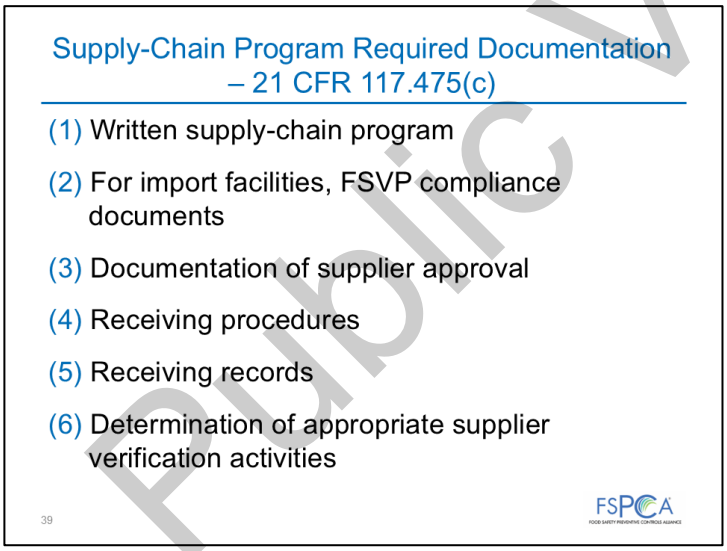
This slide outlines common industry practices related to changes that may need to be made related to suppliers. Change is a necessary part of the business process. Having procedures in place to accommodate changes can help avoid food safety or potentially disruptive supply-chain issues. Two aspects of change should be considered relative to suppliers: 1) Changes made by the supplier; and 2) Changes made by the receiving facility. If suppliers make a change to the ingredients that they provide, the Food Safety Team should be informed so as to allow reanalysis to determine if changes are needed to the Food Safety Plan or supply-chain program. Frequently supplier communications are handled by purchasing; thus, the purchasing team must forward relevant information to the Food Safety Team. The supplier must understand the importance of reporting all changes to customers so they can analyze the change with respect to their use of the ingredient.

Conversely, the purchasing team may identify a new supplier that can provide a similar ingredient. It is essential that purchasing team members do not make a switch in suppliers of an ingredient or raw material associated with a hazard requiring a supply-chain control without the authorization of the Food Safety Team. If new suppliers are necessary, established procedures must be followed. The new supplier must be approved if the ingredient is associated with a hazard requiring a supply-chain-applied control. Again, it is important to consider the resources needed to review supplier programs for new suppliers from a food safety perspective before switching suppliers.

Reanalysis of the Food Safety Plan may also be relevant for supplier changes, especially those for ingredients with hazards requiring a preventive control.

Slide 38: Supply-Chain Program Required Documentation

Slide 39: Supply-Chain Program Required Documentation – 21 CFR 117.475(c) (1 of 5)



Regulators, auditors, and customers view records as the historical method for confirming a program is in place and functional. Without records, one cannot demonstrate supplier programs are implemented as designed and are effective in controlling hazards. The records that document the supply-chain program are subject to the requirements of Subpart F. The receiving facility's Preventive Controls Qualified Individual must perform or oversee the review of the records identified in §117.475(c) within the specified time frame to ensure that the records are complete, the activities reflected in the records occurred in accordance with the Food Safety Plan, the supply-

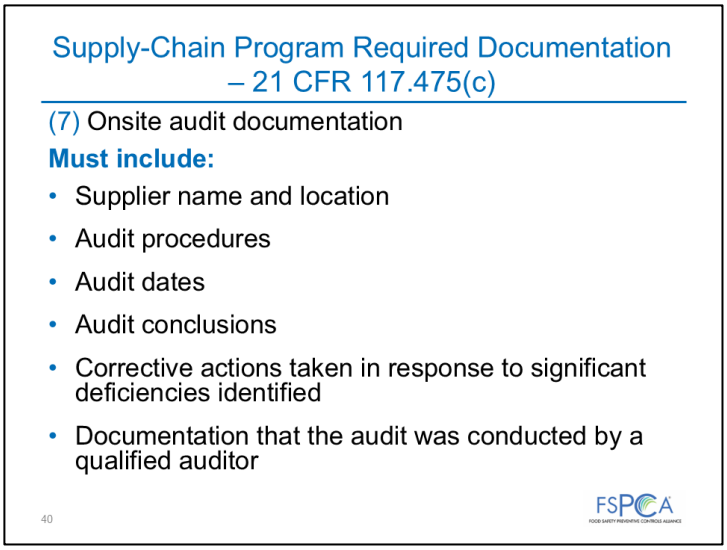
chain preventive controls are effective, and that appropriate decisions were made about corrective actions.

FDA aligned the provisions for supplier verification in the FSVP regulation with the provisions for a supply-chain program in 21 CFR Part 117. A receiving facility that is an importer, is in compliance with the FSVP regulation, and has documentation of verification activities conducted under 21 CFR 1.506(e), does not need to conduct additional supplier verification activities for that raw material or other ingredient. See 21 CFR 117.405(a)(2), for more detail. The receiving facility must:

- Maintain documentation of the approval of the facility's supplier(s) that provide raw materials and other ingredients requiring a supply-chain-applied control;
- Have written procedures for receiving raw materials and other ingredients; and
- Have records demonstrating use of the written procedures for receiving raw material and other ingredients.
- Document the determination of the appropriate supplier verification activities the facility will conduct for raw materials and other ingredients requiring a supply-chain-applied control.

Appropriate supplier verification activities include onsite audits, sampling and testing, review of a supplier's relevant food safety records, or other appropriate supplier verification activities.

Slide 40: Supply-Chain Program Required Documentation – 21 CFR 117.475(c) (2 of 5)

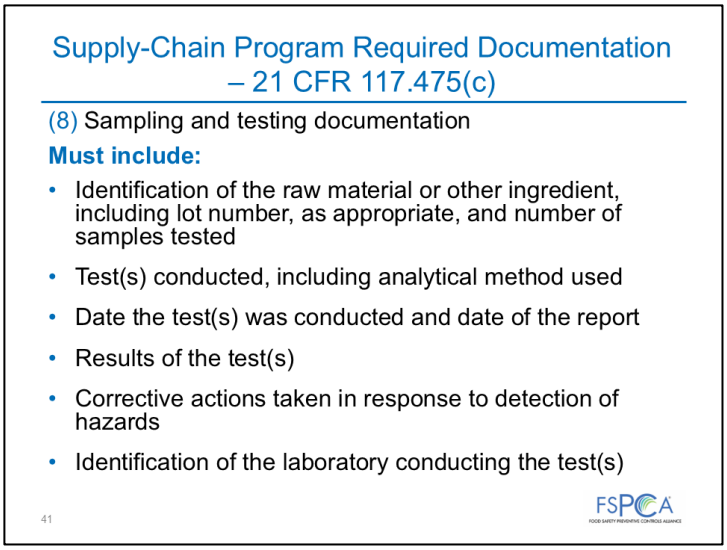


Records of the onsite audits for approved suppliers are required. The audit report must include the supplier's name, audit procedures, the date(s) the audit was conducted, the conclusions of the audit, and corrective actions taken in response to significant deviations identified. Note that the regulation does not require full details of the audit report in its entirety, only the conclusions.

Regarding the audit procedure, remember that regulation §117.435(b) requires that the onsite audit consider applicable food safety regulations and includes a review of the supplier's written plan (e.g., HACCP plan or other Food Safety Plan), if any, and its implementation for the hazard being controlled.

Documentation that demonstrates that the audit was conducted by a qualified auditor is also required, which could be a third-party auditor or a receiving facility's employee, if the employee meets the qualified auditor definition discussed previously.

Slide 41: Supply-Chain Program Required Documentation – 21 CFR 117.475(c) (3 of 5)



Records of sampling and testing must identify the raw material or other ingredient tested (including the lot number, as appropriate, and number of samples tested); identify the test(s) conducted, including the analytical procedures used; the date(s) on which the test(s) were conducted and the date of the report; the results of the testing; corrective actions taken in response to detection of hazards; and information identifying the laboratory conducting the testing.

Slide 42: Supply-Chain Program Required Documentation – 21 CFR 117.475(c) (4 of 5)

If the supplier's relevant food safety records are reviewed as a verification activity, then the review of the supplier's records must be documented. Record review is done to ensure that the supplier is following their food safety procedures and producing safe food. It's important to remember a receiving facility may not accept a review by its supplier of that supplier's own relevant food safety records.

The documentation of the food safety records review must include: the name of the supplier whose records were reviewed; the date(s) of review; the general nature of the records reviewed; the conclusions of the review; and corrective actions taken in response to significant deficiencies identified during the review.

Slide 43: Supply-Chain Program Required Documentation – 21 CFR 117.475(c) (5 of 5)

Additional Supply-Chain Program Required Documentation includes:

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient.

(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

> (i) The written assurance that the supplier is a qualified facility as defined by §117.3, before approving the supplier and on an annual basis thereafter; and
>
> (ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under 21 CFR Part 112, of this chapter:

> (i) The written assurance that supplier is not a covered farm under 21 CFR Part 112, of this chapter in accordance with §112.4(a), or in accordance with §112.4(b) and §112.5, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in 21 CFR Part 118, of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to 21 CFR Part 118, of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local (e.g., county, city, regional), tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit.

(16) Documentation of actions taken with respect to supplier non-conformance.

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier.

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

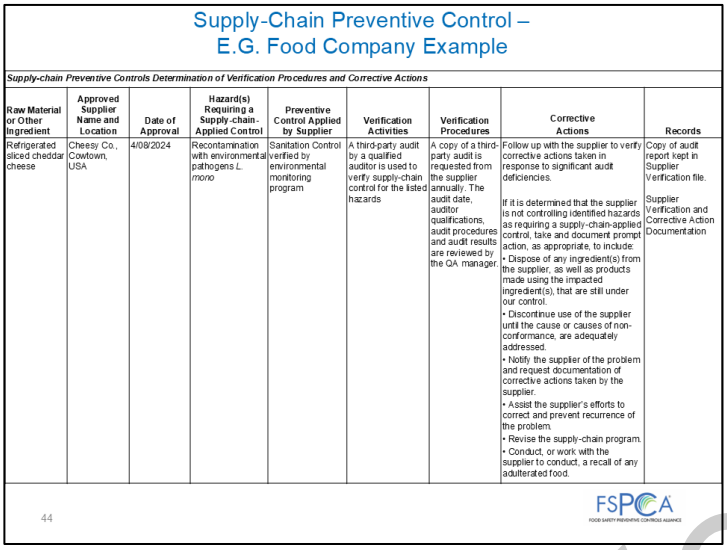
(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §117.430(f) and §117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

Slide 44: Supply-Chain Preventive Control – E.G. Food Company Example



Supply-Chain Preventive Control –
E.G. Food Company Example

Supply-chain Preventive Controls Determination of Verification Procedures and Corrective Actions

Raw Material or Other Ingredient	Approved Supplier Name and Location	Date of Approval	Hazard(s) Requiring a Supply-chain-Applied Control	Preventive Control Applied by Supplier	Verification Activities	Verification Procedures	Corrective Actions	Records
Refrigerated sliced cheddar cheese	Cheesy Co., Cowtown, USA	4/08/2024	Recontamination with environmental pathogens *L. mono*	Sanitation Control verified by environmental monitoring program	A third-party audit by a qualified auditor is used to verify supply-chain control for the listed hazards	A copy of a third-party audit is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by the QA manager.	Follow up with the supplier to verify corrective actions taken in response to significant audit deficiencies. If it is determined that the supplier is not controlling identified hazards as requiring a supply-chain-applied control, take and document prompt action, as appropriate, to include: • Dispose of any ingredient(s) from the supplier, as well as products made using the impacted ingredient(s), that are still under our control. • Discontinue use of the supplier until the cause or causes of non-conformance, are adequately addressed. • Notify the supplier of the problem and request documentation of corrective actions taken by the supplier. • Assist the supplier's efforts to correct and prevent recurrence of the problem. • Revise the supply-chain program. • Conduct, or work with the supplier to conduct, a recall of any adulterated food.	Copy of audit report kept in Supplier Verification file. Supplier Verification and Corrective Action Documentation

44

FSPCA

This is an E.G. Food Company example of a supply-chain preventive control for refrigerated sliced cheddar cheese and frozen biscuit. The following information is identified:

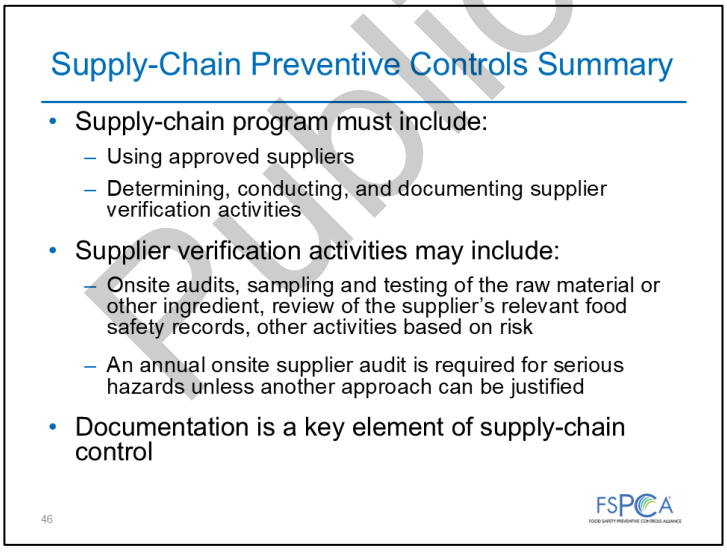
- Name of the raw material or other ingredient
- Approved Suppliers Name and Location
- Date of Approval
- Hazard(s) requiring a supply-chain preventive control
- Preventive control applied by the supplier
- Verification Activities
- Verification Procedures
- Corrective Actions
- Records

Note, the Receiving Procedure was illustrated in Slide 22.

Slide 45: Supply-Chain Preventive Controls Summary (1 of 2)

In summary, a supplier program is an essential element of a food safety system. The supplier is the entity that manufactures, processes, or grows the food, or raises the animal that the receiving facility uses to manufacture/process as a food product. A supply-chain-applied-control is a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled by the supplier before receipt by the receiving facility. The hazard analysis process identifies hazards requiring a supply-chain-applied control for which a supply-chain program must be implemented.

Slide 46: Supply-Chain Preventive Controls Summary (2 of 2)



The supply-chain program must include using approved suppliers, and determining, conducting, and documenting supply-chain verification activities. Verification activities may include onsite audits (required for serious hazards unless another approach is justified), sampling and testing, review of a supplier's relevant food safety records, and other activities based on risk. Records that document all of these activities

must be maintained to demonstrate that the facility's supplier program is operational and effective.

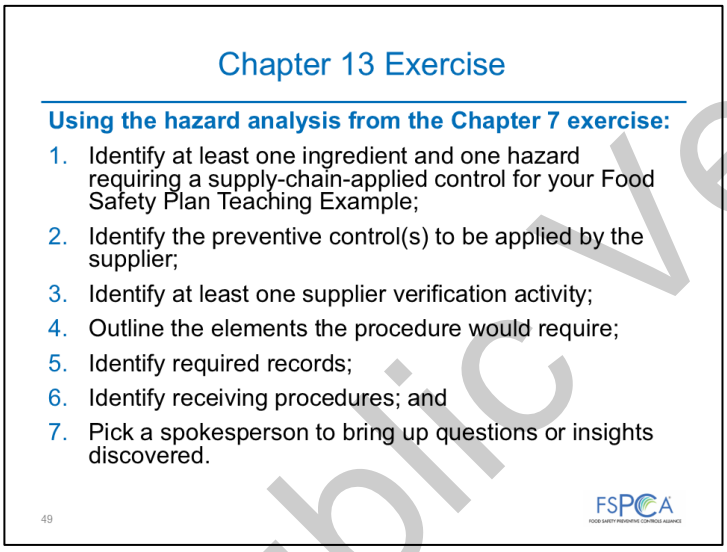
Slide 47: Knowledge Check 1

Participants do NOT have this slide.

Slide 48: Knowledge Check 2

Participants do NOT have this slide.

Slide 49: Chapter 13 Exercise



Using the hazard analysis from the Chapter 7 exercise:

1. Identify at least one ingredient and one hazard requiring a supply-chain-applied control for your Food Safety Plan Teaching Example.
2. Identify the preventive control(s) to be applied by the supplier.
3. Identify at least one supplier verification activity.
4. Outline the elements the procedure would require.
5. Identify required records.
6. Identify receiving procedures.
7. Pick a spokesperson to bring up questions or insights discovered.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FDA Draft Guidance for Industry: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-describing-hazard-needs-control-documents-accompanying-food-required-four

FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, Chapter 15: Supply-Chain Program for Human Food Products: https://www.fda.gov/media/110443/download

FDA Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food#repo

FDA Firm/Supplier Evaluation Resources: https://datadashboard.fda.gov/ora/fd/fser.htm

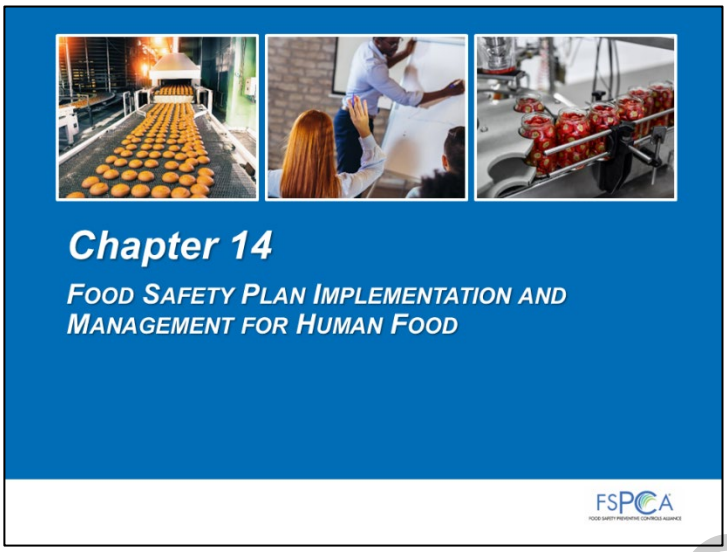
FDA Guidance for Industry: PC, FSVP, IA, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions (including customer written assurances): https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-current-good-manufacturing-practice-and-preventive-controls-foreign-supplier

FDA. (2015). Regulation: Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals: https://www.federalregister.gov/documents/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals

International Commission on Microbiological Specifications for Foods (ICMSF). (2011). Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance. Springer, New York.

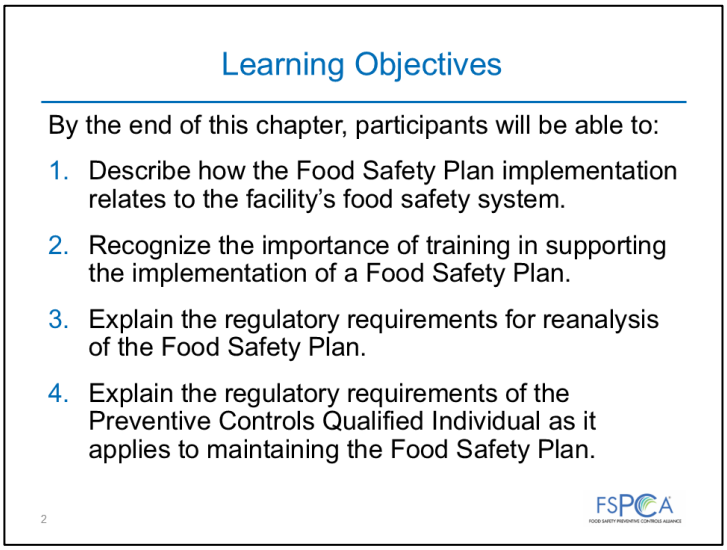
Chapter 14: Food Safety Plan Implementation and Management for Human Food

Slide 1: Chapter 14: Food Safety Plan Implementation and Management for Human Food



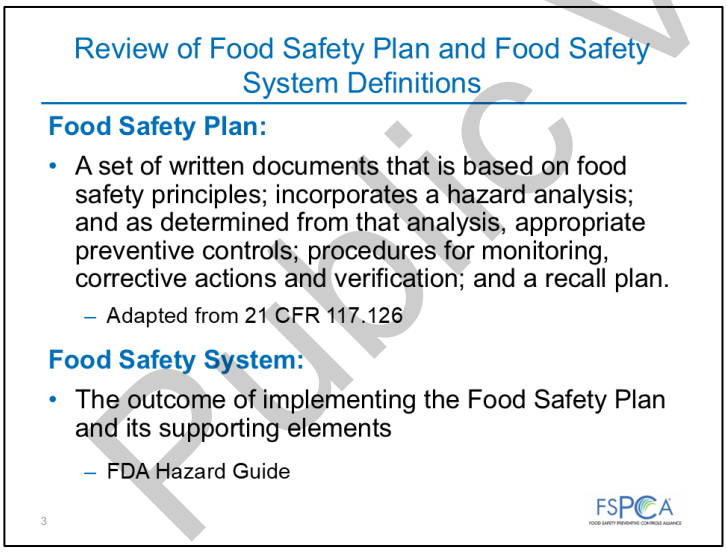
This chapter pulls together what is needed to manage the overall Food Safety Plan. It goes beyond routine verification, which was covered in Chapter 10, and answers the question: Is the facility "living the Food Safety Plan" day by day? It includes information on long-term verification and overall plan review.

Slide 2: Learning Objectives



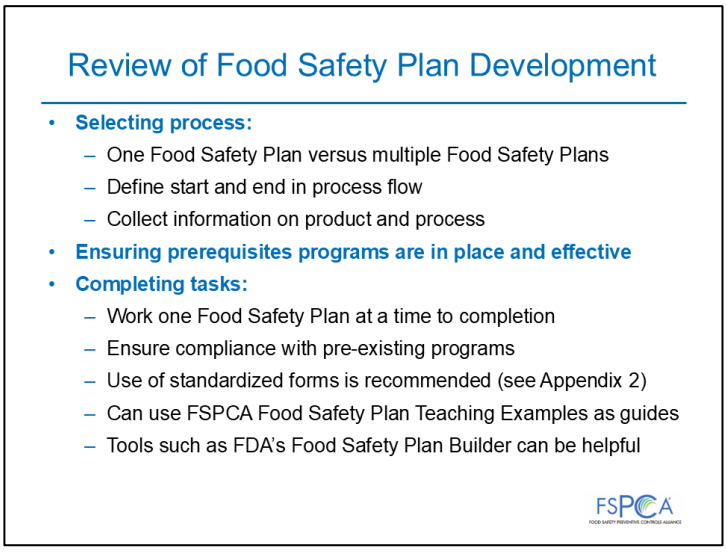
The focus of this chapter is on overall management of the Food Safety Plan. Elements to be covered include training, plan reanalysis, and the requirements that apply to the Preventive Controls Qualified Individual.

Slide 3: Review of Food Safety Plan and Food Safety System Definitions



The definitions for Food Safety Plan and food safety system introduced in Chapter 1: The Food Safety Plan, is a regulatory definition and is different from the definition of the food safety system. Both definitions are necessary to understand how the concepts connect for effective implementation practices.

Slide 4: Review of Food Safety Plan Development



FDA Food Safety Plan Builder

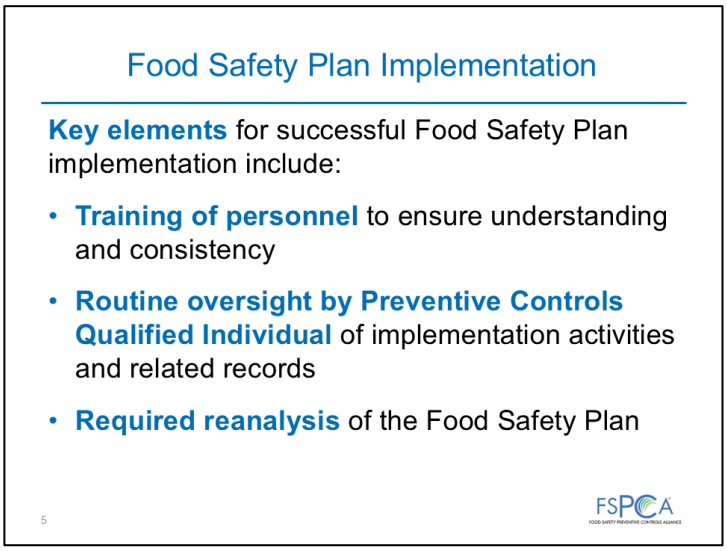
Outlined on this slide are common industry practices that can help to ensure that the Food Safety Plan is to orient participants on the completion of the Food Safety Plan development process and ensure it is effectively developed. This starts with selecting the process for plan development and the decisions that need to be made including, should a facility have just one plan or many plans? And within the plan, what is the defined start and end of the process flow?

Collecting information about the product and process flow will make it easier to extract the information needed for the Food Safety Plan. This needs to extend to any prerequisite programs to ensure that they are in place and effective.

There are many tasks that need to be completed as part of building a Food Safety Plan. It may be more effective to work on one plan at a time and take it all the way to completion and at the same time make sure that the firm follows any pre-existing programs.

There are resources that can be helpful as a guide, but it is important to use the tools properly—they may be helpful, but the facility still needs to make sure that all aspects of the regulation are addressed! Resources include using standardized forms or teaching examples in this course represent one way to manage specific hazards in these Food Safety Plan Teaching Examples, and as a guide only to see how hazards could be addressed. It is highly unlikely that a company's Food Safety Plan will match the FSPCA teaching examples exactly. The Food Safety Plan Builder may be helpful in documenting the Food Safety Plan. Although the content of the Food Safety Plan Builder is consistent with the FDA's existing guidance and regulations, its use does not mean that their Food Safety Plan, preventive controls, good manufacturing practices and other food safety procedures are approved by FDA or comply with FDA requirements. It is crucial that any facility using the Food Safety Plan Builder review the outcome to ensure that it accurately reflects the conditions and operations in their plant.

Slide 5: Food Safety Plan Implementation



For successful implementation, there must be training, oversight, and reanalysis conducted at the appropriate times. When the Food Safety Plan is well organized, the overall management and implementation of the Food Safety Plan are more effective.

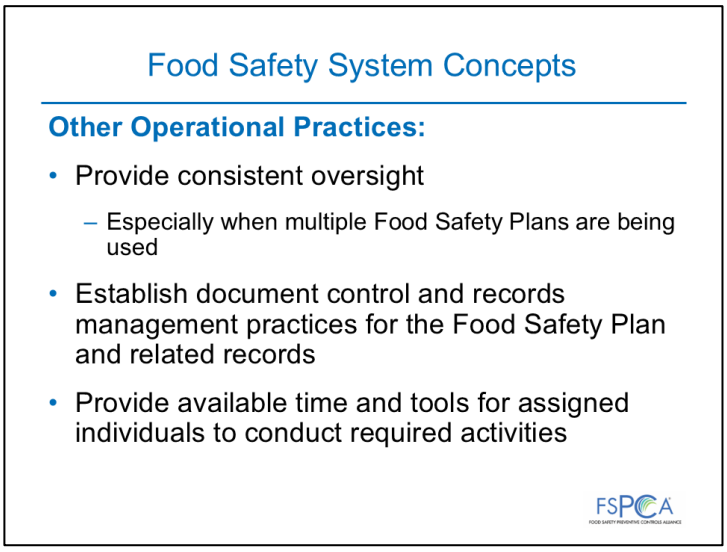
Slide 6: Food Safety System Concepts (1 of 2)

Several approaches are necessary for effective management of the Food Safety Plan. While the regulation does not specify an approach, the common industry practices related to implementation can be used as a guide. For example:

- Management must demonstrate a commitment to producing safe food and ensure that appropriate resources are made available to enable that to occur.
- It is best to have well-defined roles and responsibilities for optimal management and implementation of the Food Safety Plan. There must be an overall coordinator, typically the Preventive Controls Qualified Individual, and a Food Safety Team which provides input and to which various tasks can be delegated. A trainer ensures that proper instructions are given to the appropriate individuals and a consultant may be used to assist with management and implementation.

The goal should be to ensure consistent oversight, document control, and records management. There must be sufficient resources available for proper training of delegated individuals to conduct their assigned activities.

Slide 7: Food Safety System Concepts (2 of 2)



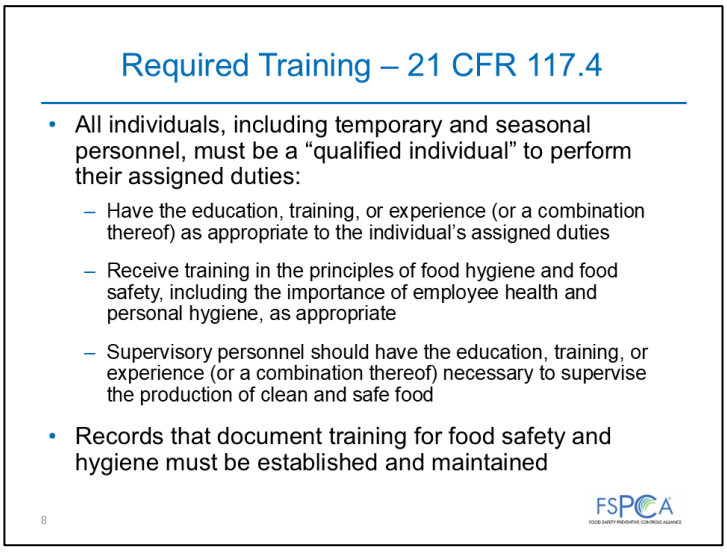
Other common industry practices focus on ensuring that oversight is consistently practiced; establishing document and record controls; and assuring enough time is allotted for required tasks to be fully completed.

Developing and implementing a Food Safety Plan can be difficult, especially when integrating it into an existing system of procedures. It is important to maintain consistency in plans especially related to the control of hazards. For example, if a hazard on an incoming ingredient is to be controlled by an internal process control in one instance, it then cannot be determined that a control is not required for the hazard, or that a hazard does not exist in the ingredient in another plan.

Once implemented, a Food Safety Plan will generate a daily stream of paperwork. There will be different forms for different processes and those forms will need to be reviewed and then filed for easy access. Designing a document control process to ensure the proper forms are being used and that they are being properly reviewed and filed will allow for more efficient handling of documentation and will make inspections easier. Placing titles and control numbers on forms will help staff recognize the appropriate paperwork and version of that paperwork.

It is important that staff have sufficient time to conduct the necessary activities such as performing required calibration, reviewing documentation, and conducting training. It is too easy to miss these activities because production-related needs may pull people away from this work. It is also important to have the proper tools for conducting the required activities. Having accurate and reliable equipment will prevent situations where a measurement is missed because the monitoring equipment failed.

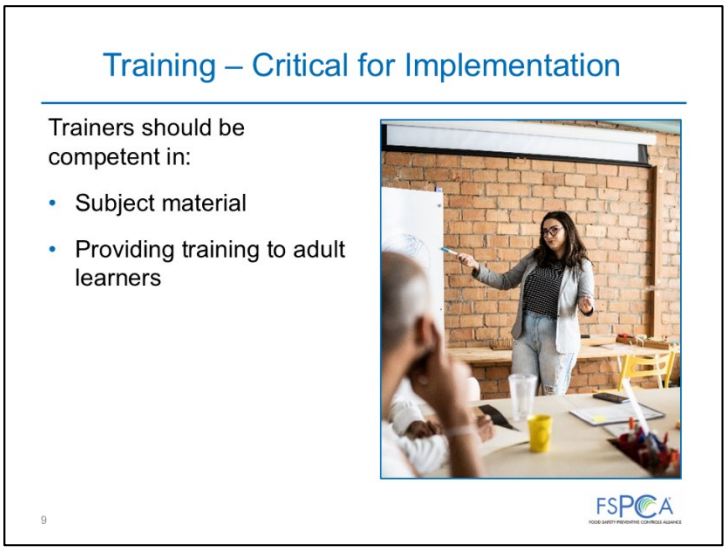
Slide 8: Required Training – 21 CFR 117.4



Definition: *Qualified individual:* A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment. (21 CFR 117.3)

In 21 CFR 117.4, the regulation outlines the qualifications required of individuals who manufacture, process, pack, or hold food. It is essential that individuals are qualified to carry out their specific assigned duties. This qualification can be met through education, training, or experience. These individuals must receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties. Requirements extend to supervisory personnel as well. Supervisors must have the education, training, or experience, or a combination thereof, necessary to supervise the production of clean and safe food. Records documenting this required training must be established and maintained by the facility.

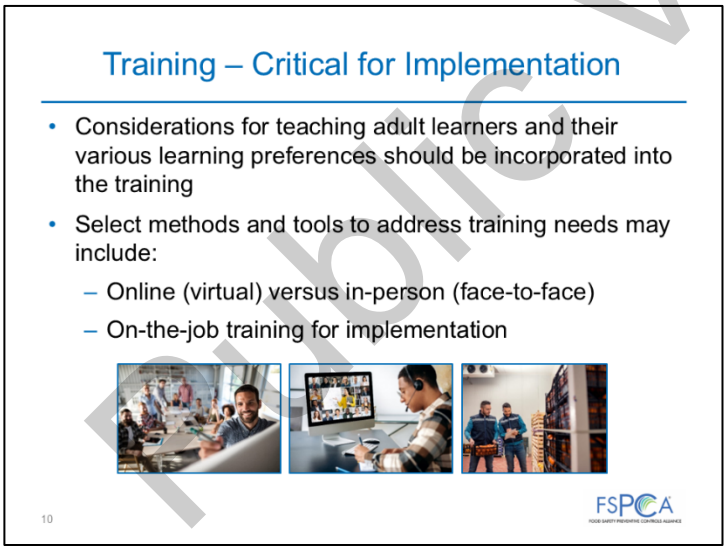
Slide 9: Training – Critical for Implementation (1 of 2)



Training is important for the success of a food safety program.

Those who perform the training of others should be qualified and knowledgeable in the subject matter being taught and be competent in the process of training. This includes understanding the needs of adult learners, so that training will be effective.

Slide 10: Training – Critical for Implementation (2 of 2)



Trainers should be aware of the needs of adult learners and how to best address those needs. Trainers should choose appropriate training methods that align optimally with the training needs. This should include an assessment of online versus face-to-face training methods, and consideration of when on-the-job training would be most effective. Training should be directed towards what is most relevant for the operation, the specific employees, and should be specific to the Food Safety Plan.

Slide 11: Employee Training Records

Employee Training Records

- Records can be kept in individual personnel files
- Record can be summarized in table form for easy tracking, if preferred

Employee Training Record		
Employee Name: F.S. Leader	**Hire Date:** mm/dd/yyyy	
Employee Training Course	**Location**	**Date Completed**
FSPCA Preventive Controls for Human Food course	Local (i.e., regional) University Extension	November 15, 2022
Sanitation in the processing plant, 4-hour course	Chemical supplier in our	February 28, 2022
Good manufacturing practices (GMPs) online course	Cornell University Distance Learning Center	March 15, 2022
Allergen labels and cleaning control procedures	On the job training	March 1, 2022
Date issued: mm/dd/yyyy	**Supersedes:** mm/dd/yyyy	

Example

11

FSPCA

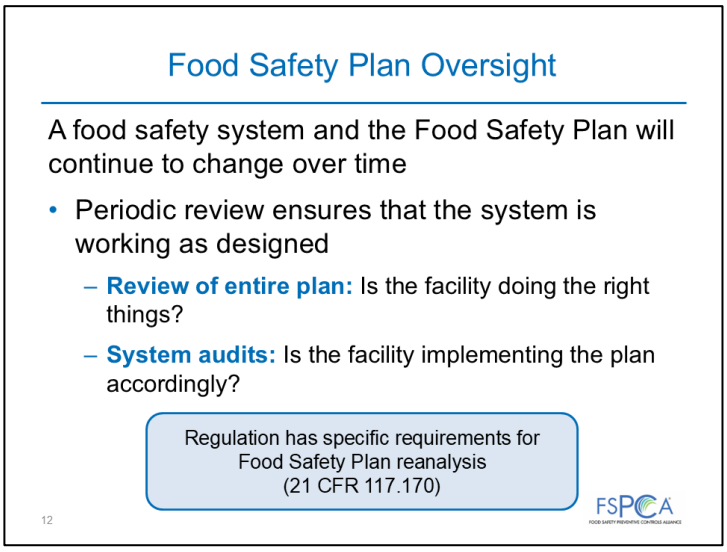
There are many ways to document training activities; examples can be found in Appendix 3.

Training required by the regulation is food safety and hygiene training, including the importance of employee health and personal hygiene (e.g., handwashing). The regulation requires documentation of the food safety and hygiene training as detailed in 21 CFR 117.4(b)(2).

Records of training could include attendance lists or training documents maintained in individual personnel files. The approach is flexible.

Experience, training, or education related to job duties all qualify as methods of training for a "qualified individual."

Slide 12: Food Safety Plan Oversight



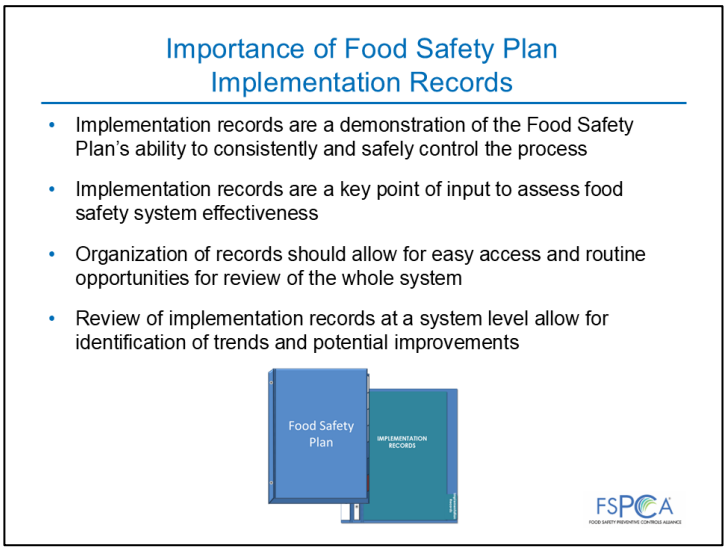
The reality is that a food safety system and Food Safety Plan will continually change over time, and it is important that there is routine oversight to ensure that the system continues to function as designed.

Questions to be addressed in the periodic review should answer:

- Is the facility doing the right thing?
- Is the facility implementing the plan accordingly?

In addition to a periodic review, the regulation requires that reanalysis be done.

Slide 13: Importance of Food Safety Plan Implementation Records



Implementation records are a necessary element of the food safety system. In general, there are two types of required records in the Preventive Controls for Human Food regulation:

1. The Food Safety Plan itself; and
2. The implementation records.

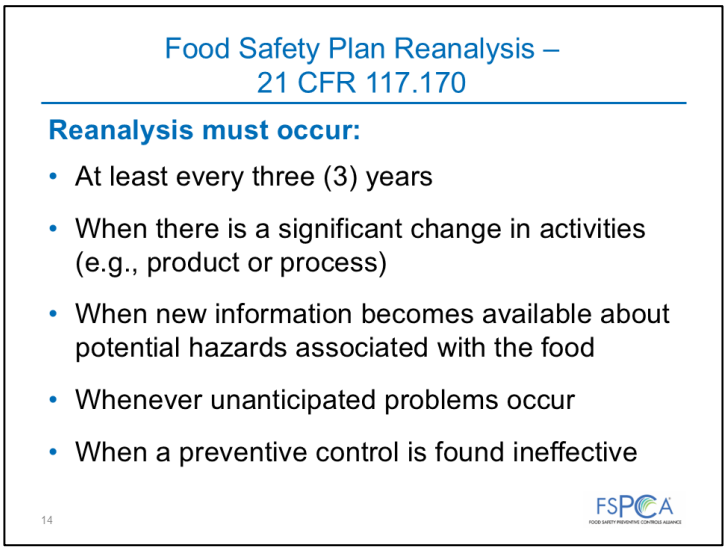
All Food Safety Plan and implementation records are subject to review and copying by regulatory personnel.

Examples of implementation records include (where applicable) records that document the actual monitoring of preventive controls, corrective actions taken, different verification activities performed, validation activities performed (if needed) of all preventive controls, the supply-chain program checks and applicable training records.

There must be a review of implementation records, and the review must be documented. The purpose of the review is to ensure the steps in the Food Safety Plan to control hazards have been performed consistently and safely. In other words, implementation records demonstrate the effectiveness of the food safety system, and that the facility did what the facility was supposed to do.

Records should be organized to enable easy access and review of the entire system. Well-organized records also provide the ability to identify trends and determine where improvements to the system may be needed.

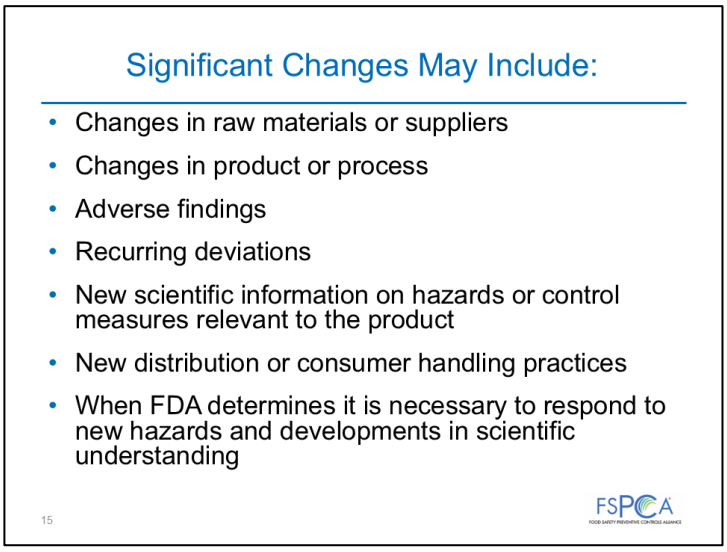
Slide 14: Food Safety Plan Reanalysis – 21 CFR 117.170



Per the regulation, 21 CFR 117.170, in addition to the verification activities for CCPs and other preventive controls, strategies must be developed for scheduled reanalysis of the Food Safety Plan. Reanalysis is required:

- At least every three (3) years or whenever there is a significant change in the product or process;
- If information becomes available about a new hazard associated with the food (e.g., FDA issues an advisory notice), or if there is a failure with the system such as discovering an ineffective preventive control, an outbreak, or similar situation;
- When an unanticipated problem or deviation occurs (i.e., a specific corrective action procedure has not been established); and
- If a preventive control is found to be ineffective in that the hazard was not properly controlled. This can be identified through product testing conducted by a customer, consumer complaints, or other means.

Slide 15: Significant Changes May Include:



"Significant changes" may also include construction events, new equipment installation, etc.

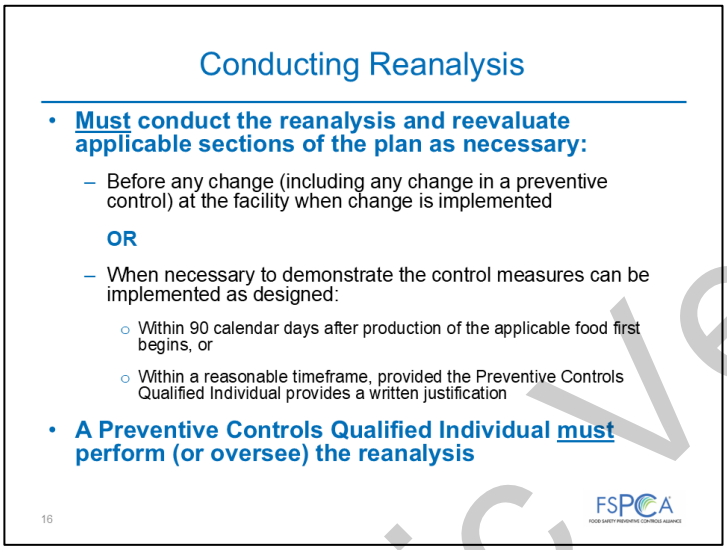
Significant changes in the product or process which may require reanalysis, and sometimes additional validation. include when an event or situation may alter the original conclusions. Examples include the following:

- Raw material changes, including a new supplier, may require reanalysis to determine if there is a potential for food safety related functional properties to be altered. For example, a new thickening agent may change the viscosity of a product, which could have an impact on heating characteristics for some products. Switching suppliers may also warrant a review of the new supplier's allergen controls to assure that a new hazard is not introduced. The process may also require reanalysis.
- Product or process changes may warrant reanalysis. For example, reducing the level of salt, which can alter microbial growth patterns, may require evaluation for some products. Intended shelf-life, process requirements, and other elements of the system may require reanalysis. If a new allergen is introduced on a production line, reanalysis of the procedures used to clean the system may be warranted to validate that surfaces can be adequately cleaned to remove allergens.
- Increasing production volumes that lead to longer run times may provide more time for microbial growth during some processes. The adequacy of sanitation to maintain sanitary conditions during the longer run time may be assessed as part of the reanalysis.
- Implementation issues identified during record reviews or observation of recurring deviations may suggest that the original validation is no longer adequate. This may trigger reanalysis of the full system, including validation of the elements of a process that are not performing in a reliable manner.
- Emerging scientific information on hazards or control measures may also trigger reanalysis activities. For example, when *E. coli* O157:H7 first emerged as a

foodborne pathogen, it was observed that it tolerates higher levels of acid than many other foodborne pathogens. A reanalysis of process lethality was needed.

- New distribution or identification of unanticipated consumer-handling practices may also trigger reanalysis. For example, if an RTE product distributed to the general public though retail sales is subsequently marketed for infants, revalidation of controls to protect this more vulnerable population may be warranted.
- When the FDA judges that a new hazard or new scientific developments warrant a response from regulated firms.

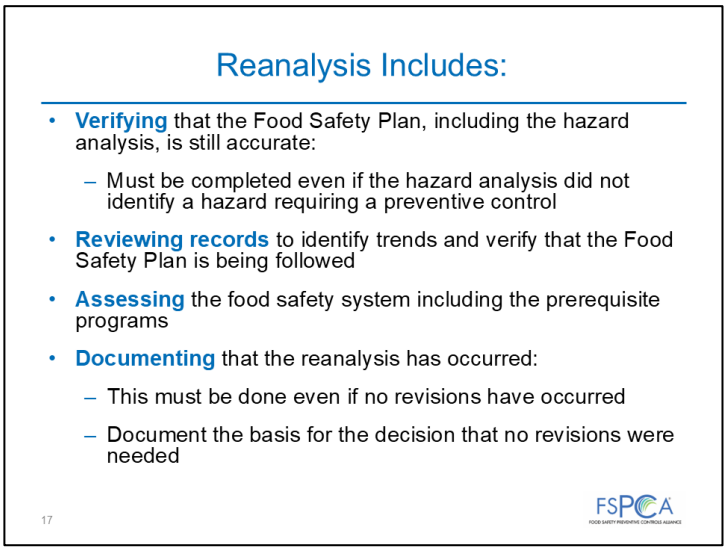
Slide 16: Conducting Reanalysis



Reanalysis should occur at a frequency that ensures the Food Safety Plan is being followed continuously. This frequency depends on several conditions, such as the variability of the process and product. In most cases, when reanalysis is conducted, it must take place before any changes are made to the Food Safety Plan. In specific circumstances it may be necessary to demonstrate control measures can be implemented as designed. In these cases, validation activities that provide support to the reanalysis may take place in the first 90 days of production or within a reasonable timeframe as justified by the Preventive Controls Qualified Individual.

If reanalysis indicates an increased food safety risk, the Food Safety Plan must be revised. If it's determined that no revisions are necessary, the basis for that decision must also be documented. The Preventive Controls Qualified Individual is responsible for ensuring that reanalysis is performed. The Preventive Controls Qualified Individual can do it themselves or oversee the reanalysis process. For example, the facility may contract with an independent consultant to help conduct system-wide verification activities.

Slide 17: Reanalysis Includes:



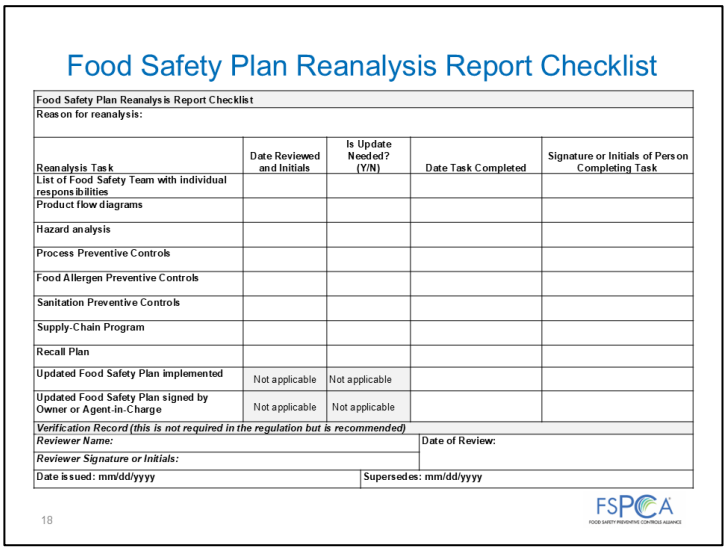
Verifying that the Food Safety Plan is still applicable and relevant is the focus of reanalysis. This includes reanalysis of the hazard analysis. Reanalysis is required even if the hazard analysis did not identify any hazards requiring a preventive control in order to ensure that this is still a valid conclusion.

Reanalysis activities also include onsite observations and record reviews performed by the Food Safety Team or other unbiased individuals not responsible for performing the monitoring activities. This is to verify that the Food Safety Plan is being followed and it may identify trends that need to be addressed.

Reanalysis must also include an assessment of the food safety system including the prerequisite programs.

Results of the reanalysis must be documented, even if no revisions have been made. If that is the case, the rationale for the decision that no revisions were required needs to be documented in the reanalysis record.

Slide 18: Food Safety Plan Reanalysis Report Checklist



Food Safety Plan Reanalysis Report Checklist

Food Safety Plan Reanalysis Report Checklist				
Reason for reanalysis:				
Reanalysis Task	Date Reviewed and Initials	Is Update Needed? (Y/N)	Date Task Completed	Signature or Initials of Person Completing Task
List of Food Safety Team with individual responsibilities				
Product flow diagrams				
Hazard analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-Chain Program				
Recall Plan				
Updated Food Safety Plan implemented	Not applicable	Not applicable		
Updated Food Safety Plan signed by Owner or Agent-in-Charge	Not applicable	Not applicable		
Verification Record (this is not required in the regulation but is recommended)				
Reviewer Name:			Date of Review:	
Reviewer Signature or Initials:				
Date issued: mm/dd/yyyy		Supersedes: mm/dd/yyyy		

18

FSPCA

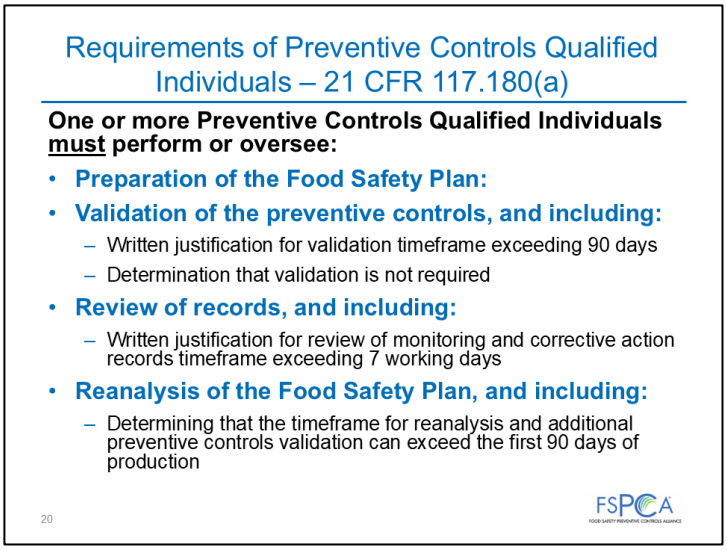
A reanalysis checklist may be helpful to ensure that the reanalysis process is implemented effectively and that the results are documented completely. This checklist should include the date reanalysis activities were performed, the outcome of the reanalysis, and who was responsible for the decision. A reanalysis checklist form is found in Appendix 2.

Slide 19: Owner/Agent-In-Charge Must be Informed

A Food Safety Plan cover sheet that is signed and dated by the responsible individual is sufficient.

It is a regulatory requirement that the Food Safety Plan must be signed and dated by the owner, operator, or agent-in-charge of the facility. The signing must take place when the Food Safety Plan is initially completed and at any time there is a modification to the Food Safety Plan occurs. The signature ensures management is informed of changes and indicates support for implementation.

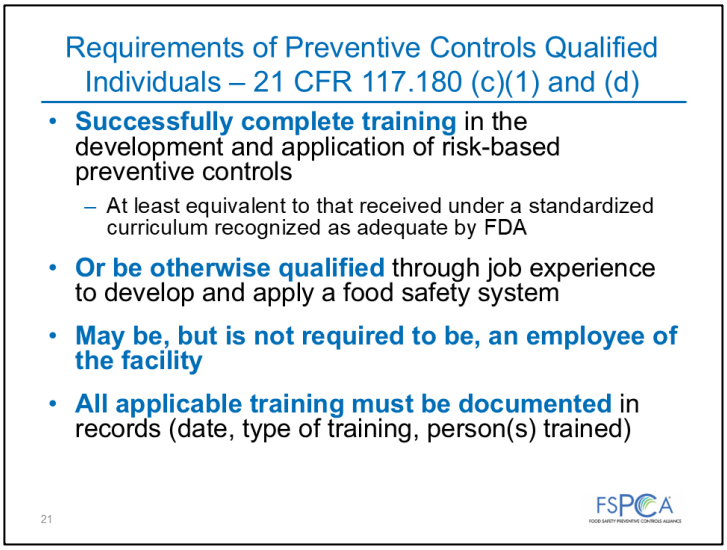
Slide 20: Requirements of Preventive Controls Qualified Individuals – 21 CFR 117.180(a)



A Preventive Controls Qualified Individual is required to, among other things, develop or oversee preparation of the Food Safety Plan, validation of the preventive controls, and review of the records and reanalysis of the Food Safety Plan. Required tasks do not have to be performed by a single Preventive Controls Qualified Individual. The tasks can be shared among multiple Preventive Controls Qualified Individuals.

Additional tasks that must be performed or overseen by a Preventive Controls Qualified Individual involve written justification in situations where expected timeframes for certain activities are not met. These include justification for completing validation activities after 90 days of first production (or determining that validation is not required), justification for review of monitoring and corrective action records exceeding 7 working days and determining that it is appropriate to perform reanalysis and validation of additional preventive controls in a period longer than the first 90 days of production.

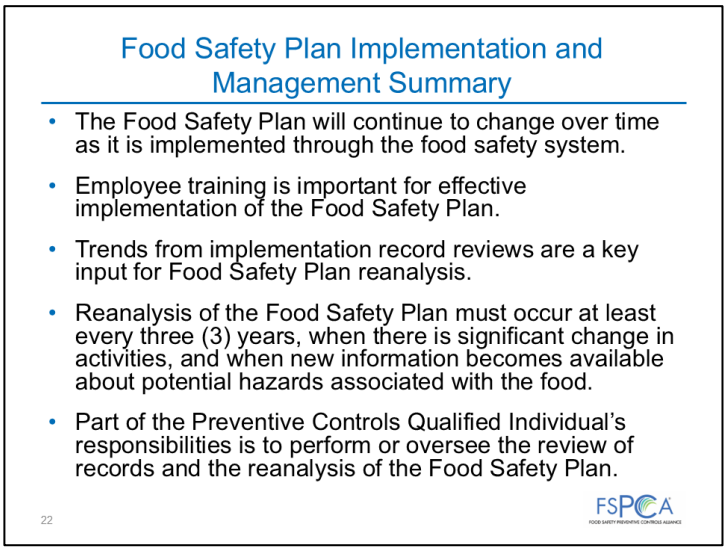
Slide 21: Requirements of Preventive Controls Qualified Individuals – 21 CFR 117.180 (c)(1) and (d)



There are two ways to become a Preventive Controls Qualified Individual. The first way is to successfully complete 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 the FDA, such as attending this FSPCA PCHF training class and successfully completing the exercises. Training must be documented in records, including the date, type of training, person trained etc.

The second way is for an individual to be qualified through job experience to develop and implement a Food Safety Plan. The Preventive Controls Qualified Individual can be an external consultant.

Slide 22: Food Safety Plan Implementation and Management Summary



This chapter has covered what's needed to manage the overall Food Safety plan. This includes proper oversight and management and training of employees. Since a Food Safety Plan will change over time, long term verification and overall review of the Food Safety Plan called "reanalysis" must be done as part of the responsibilities of the Preventive Controls Qualified Individual at least every 3 years or when there are significant changes to the product or process and when new information about hazards becomes available.

Slide 23: Knowledge Check 1

Participants do NOT have this slide.

Slide 24: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

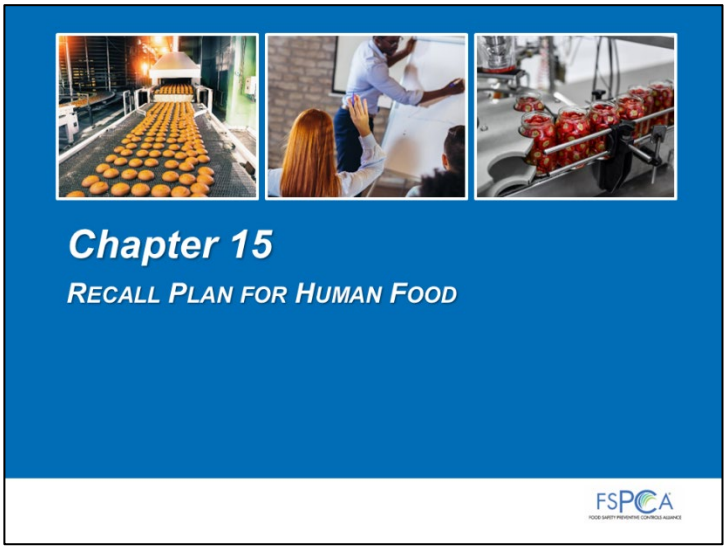
FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

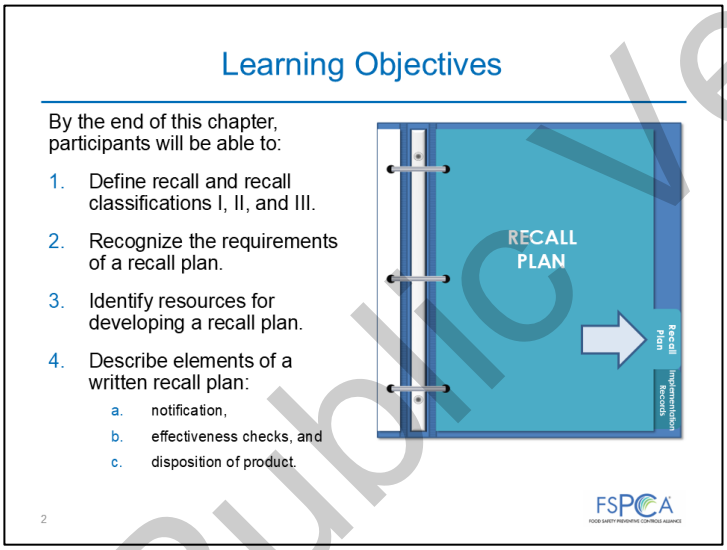
FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FDA's Food Safety Plan Builder: https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder

Slide 1: Chapter 15: Recall Plan for Human Food

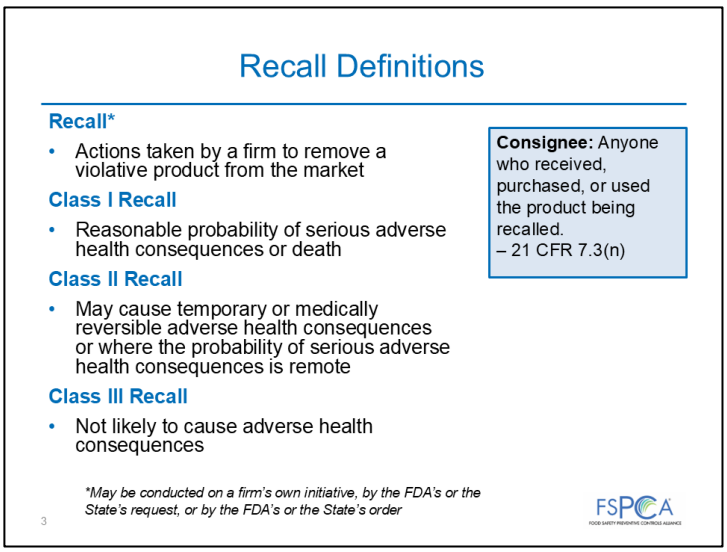


Slide 2: Learning Objectives



The Preventive Controls for Human Food regulation requires the development of a written recall plan when a hazard analysis identifies a hazard requiring a preventive control. This module reviews definitions of recall classes, resources for developing a recall plan, and the required elements of a recall plan (i.e., whom to notify when a recall is necessary, how to conduct effectiveness checks, and methods that can be used to dispose of affected product).

Slide 3: Recall Definitions



Recalls are actions taken by a facility to remove a product from the market that may be adulterated, misbranded, or violate regulations in some way. In other words, a product for which the FDA or a state could take legal action against the facility would be subject to a recall. It is important to note that a recall is different from a market withdrawal and stock recovery. In a market withdrawal, it is the company's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA, or which involves no violation. A stock recovery is when the company corrects or removes a product where that product has not left direct control of the facility.

The numerical designation (i.e., I, II, or III) [is] assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled (FDA Hazard Guide, Chapter 14, 2018).

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1));

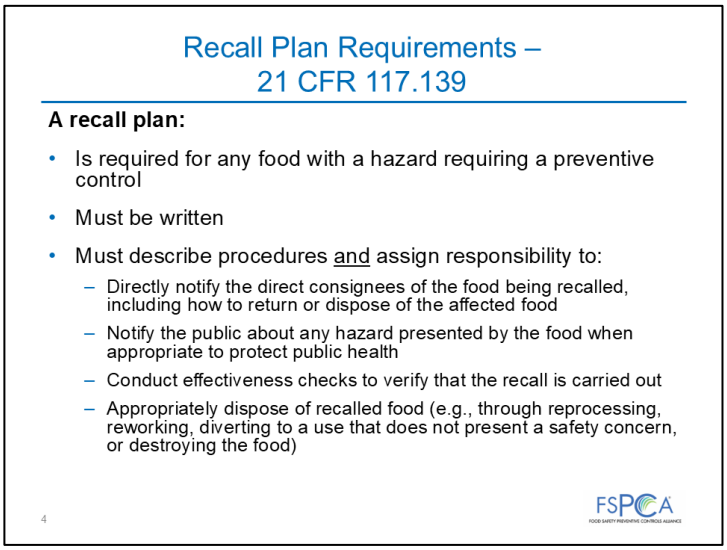
(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2)); and

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause illness or injury (21 CFR 7.3(m)(3)).

(4) (See 21 CFR 7.3(m)).

Typically, a firm voluntarily conducts a product recall, either of their own accord, or at the request of the FDA, or at the request of a State regulatory program. However, the FDA has mandatory recall authority, which is the ability to require a firm to conduct a recall in Class I situations.

Slide 4: Recall Plan Requirements – 21 CFR 117.139



Notification of customers is required for Class I recalls and sometimes for Class II recalls when there is a threat to public health.

Decisions on when notification is necessary can be determined through discussions with the FDA. The FDA has the authority to initiate a recall in Class I situations, but typically a company voluntarily issues the recall notice.

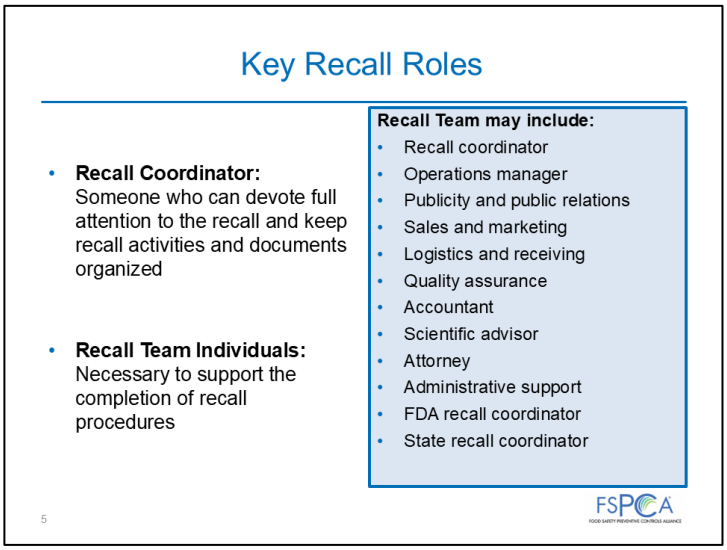
A recall plan is required when a hazard analysis identifies a hazard that requires a preventive control for the specific product. The recall plan must be written and implemented before an adverse event takes place to ensure that actions taken to recall a product are conducted efficiently and quickly. A rapid response is especially important for Class I and Class II recalls for which public health is at risk.

The written recall plan must include procedures that describe the steps to take and assign the responsibility for taking those steps to a specific person or role People can be assigned to multiple tasks, but the roles should be predetermined to support a quick response. The required written procedures are:

1. Direct customer notification, when required (see text box), about the food being recalled, including how to return or dispose of the affected product;
2. Public notification about any hazard presented by the food, when appropriate to protect public health;
3. Effectiveness checks to verify that the recall was carried out; and
4. Appropriate disposition of the food through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

While a recall plan is only required by regulation when the facility has identified through the hazard analysis a hazard requiring a preventive control, common practice is for the firm to have a recall plan regardless.

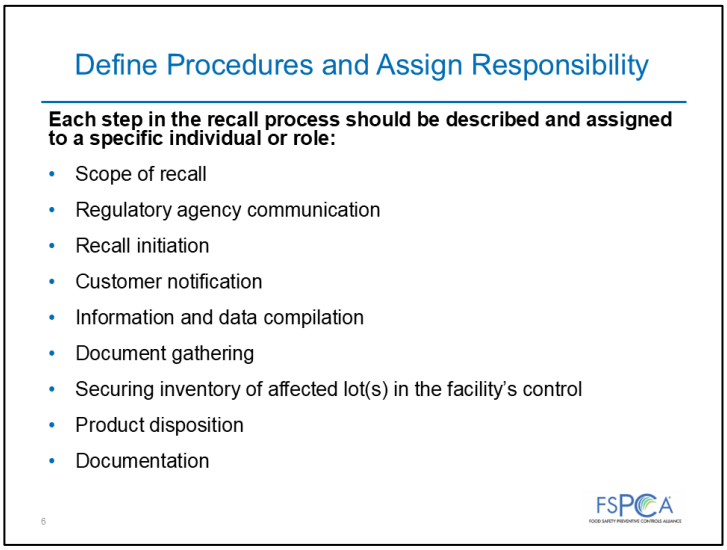
Slide 5: Key Recall Roles



The owner, operator, or agent-in-charge of a facility is accountable for the safety of the food and must ensure that a recall plan is written. The individuals who will function as the recall coordinator and the Recall Team are typically identified prior to a recall occurring. The recall coordinator generally has the duties identified on the slide.

The Recall Team should include all functions necessary to collect accurate and complete information in the event of a recall. For example, production, shipping, quality assurance, sales, and administrative personnel should be considered as members of the Recall Team. If the facility has multiple locations, the team may include corporate team members from different departments (e.g., safety, quality assurance, distribution, etc.). Each Recall Team member should have clearly defined roles.

Slide 6: Define Procedures and Assign Responsibility

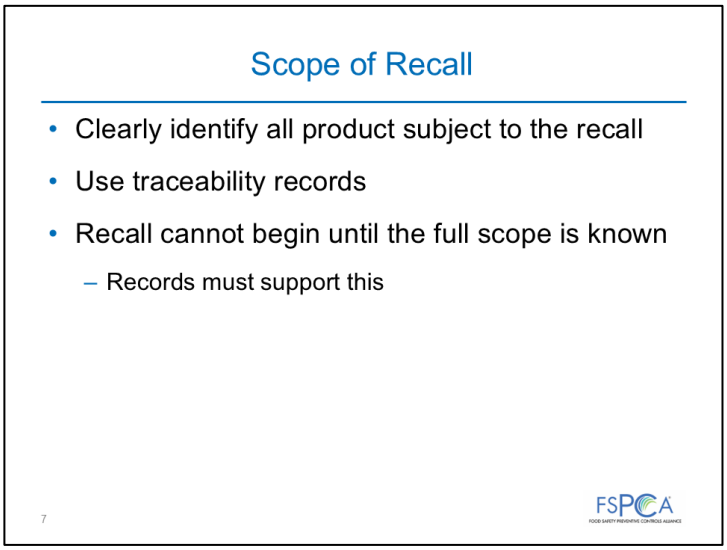


The recall plan should define each step of the recall process, clearly describing what tasks need to be done each step and assigning responsibility for carrying out the step or task. Knowing the recall procedure steps, tasks, and responsible roles ahead of time, and then practicing the procedure reduces potential confusion and helps to support an organized and quick response. Responsibility should clearly define who will initiate the recall and who will notify external customers.

Clear documentation helps define the extent of the recall. While several employees may be involved in gathering different types of documents, one individual should be responsible for compiling the information and data gathered to ensure that a complete picture of the situation is available. Assign responsibility for each of the types of documents needed to ensure that everything is completed.

Frequently, when recalls occur, some of the affected product is still in the company's control, some of the affected product is in the possession of customers, and some of the affected product may be in route to customers. In addition to the responsibility of notifying customers, when a recall occurs, the company should assign responsibility and define procedures for securing inventory that is still within the company's control to avoid contributing to the problem by inadvertently shipping product subject to the recall.

Slide 7: Scope of Recall

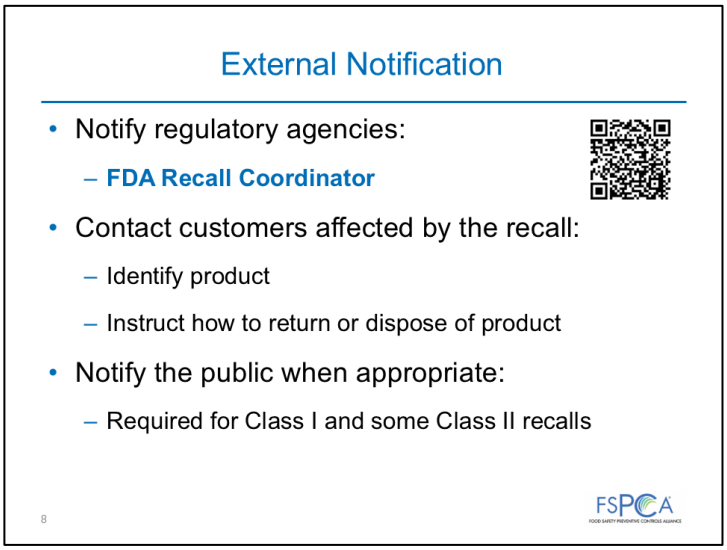


All product lots involved in a recall must be accurately identified.

Specific information on how lots are identified should be easily understood by all the stakeholders that receive this information during a recall investigation. Unclear or poorly identified lots hamper the effectiveness of any recall effort and increase the amount of time and resources needed to complete the recall. It is critical that lot records are clearly identified and stored so that they are rapidly accessible in the event of a recall. Be sure to consider how rework is used in a facility—if rework (from an implicated lot) is used in subsequent lots, the amount of product involved in the recall may expand beyond the originally implicated lot.

All information should be cross-checked against multiple sources and through multiple people so that the accuracy can be verified prior to initiation of the recall. Incomplete or erroneous information causes confusion and delays in transmitting information necessary for product recovery. It cannot be overemphasized that correct information, based on complete and accurate records, is a critical requirement for efficient recall activities. Government agencies will review these records, and a lack of records organization can slow down the process.

Slide 8: External Notification



FDA Recall Coordinators

Useful FDA Website Information

The Reportable Food Registry (RFR) is an electronic portal for industry to report when there is reasonable probability that a food will cause serious adverse health consequences. The facility must report issues that the facility finds.

The RFR is also useful for investigating information on foods that have been reported.

The FDA posts recall notices on their website. Model recall notices are available, which can could use to create a draft recall notice for the facility's recall plan.

The FDA also provides contact information for recall coordinators on the web. Include this information in the recall plan and consider getting to know them prior to a recall situation. For example, several states have Food Safety Task Force meetings that provide access to regulatory officials in an open forum.

See Additional Reading, Resources, and References at the end of the chapter.

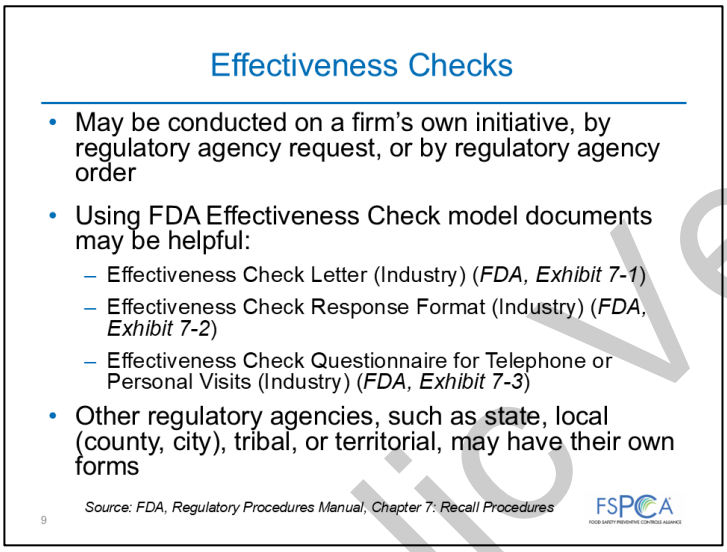
When it is determined that a recall is necessary, notify the appropriate regulatory agencies. In addition to the FDA contacts (see text box and FDA State Recall Coordinators link on the slide), many States have recall coordinators. It is useful to include their contact information in the recall plan. In some cases, an agency may notify the facility/company first, for example if a foodborne illness is traced back to the facility's product. In other cases, the facility may need to initiate contact, such as if the facility/company receives several calls from consumers regarding an allergic reaction to the company's product and the facility/company determines that the product has an allergen that was not listed on the label.

The recall plan must include procedures for notification of outside customers/consignees who received product. Procedures should describe how to inform customers of the type of product, quantities of affected product shipped, dates

product was shipped and the reason for the recall. The procedures should also tell customers to immediately put the product on hold to prevent further distribution. Information regarding recalled product may be requested for customers to report back to the facility. Once information is gathered by the facility, disposition of the product will be determined as well as effectiveness of the recall effort.

A press (or news) release is usually used to inform the public of a recall that has a public health issue. While a detailed press release cannot be developed until an incident occurs, a recall plan can include templates that describe the information that would be inserted and should identify how to distribute a press release if necessary. The **FDA must approve the press release for FDA-ordered recalls** and so the FDA has model press release examples available (see Additional Reading, Resources, and References at the end of the chapter.

Slide 9: Effectiveness Checks



The purpose of an effectiveness check is to verify the recall communication was received by the direct account consignee, and that they understood and followed the recall instructions. The effectiveness check should also verify the recall reached the appropriate level in the distribution chain. An effectiveness check is a means of evaluating the effectiveness of the recall (e.g. the recalled product was removed from the marketplace). If the effectiveness checks indicate that the recall communication was not received and/or its instructions were not followed, then additional steps must be taken to make the recall effective. These steps may involve using alternative means of contacting customers or sending out a follow-up communication that more clearly identifies the product, better explains the problem, and/or provides clearer instructions to the consignees.

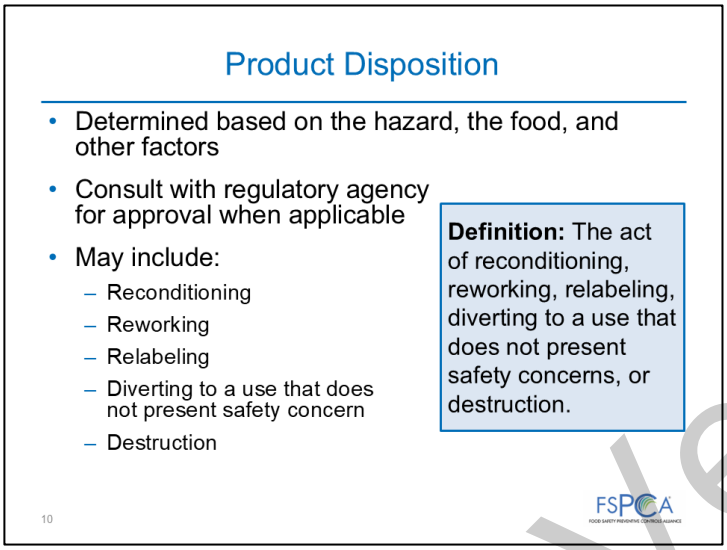
There are model documents available from the FDA:

- Effectiveness Check Letter: https://www.fda.gov/media/79098/download
- Effectiveness Check Response Format: https://www.fda.gov/media/79117/download

- Effectiveness Check Questionnaire: https://www.fda.gov/media/79131/download

If a recalling company's actions do not adequately protect the public from a violative product (i.e., the company fails to initiate a recall effectively), the FDA may consider taking other appropriate actions. Note that some State regulatory programs have their own requirements for recalls.

Slide 10: Product Disposition

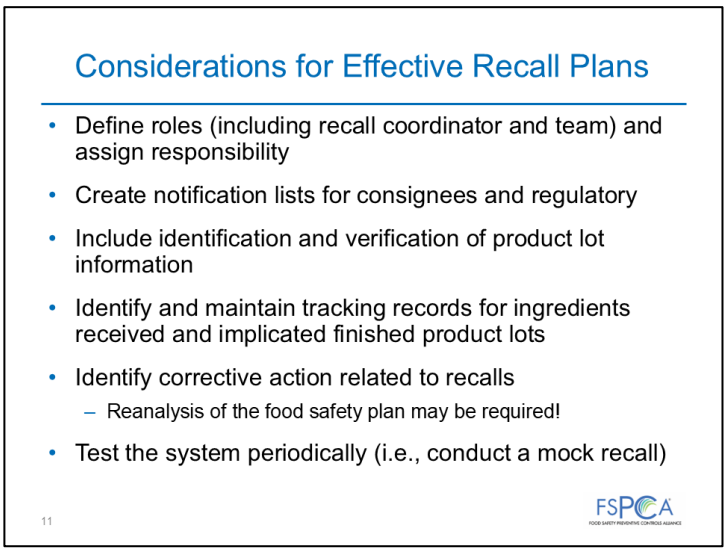


It may be possible to divert product for animal food use. See the discussion on GMPs for animal food use and the Preventive Controls for Animal Food regulation for more information.

The recall plan must include procedures that describe the steps taken to determine the appropriate disposition of the recalled product. Depending on the specific hazard and the product involved, sometimes a product can be reconditioned or reworked to eliminate the hazard. Diverting the product to another use, such as animal food production, may also be an option if it does not present a safety concern to animal health. As discussed in Chapter 2: Current Good Manufacturing Practices and Prerequisite Programs for Human Food, if the facility plans to divert the product to animal food use, the product must comply with the Preventive Controls for Animal Food regulation, so it is recommended that the recall plan address how to meet these requirements if animal food diversion is identified as an option. Destruction of the product is the final option and is sometimes necessary. Consult with the regulatory agency for approval when applicable.

Procedures for product disposition need to consider both the product that is under the facility's control, and product that is returned from customers and consumers. In some cases, a recall plan may direct customers and consumers to destroy the product rather than returning it. Such situations should be described in the facility's recall plan. Regardless of disposition approach, a clear accounting of the amount of recalled product requiring action and its disposition is needed to close out a recall.

Slide 11: Considerations for Effective Recall Plans



The definition of roles for a recall is important. The owner, operator, or agent-in-charge of a facility is accountable for the safety of the food and must ensure that a recall plan is written. A recall coordinator and recall team are typically identified ahead of time. Lists of stakeholders who should be notified (including consignees and regulators) in advance of a recall can be helpful.

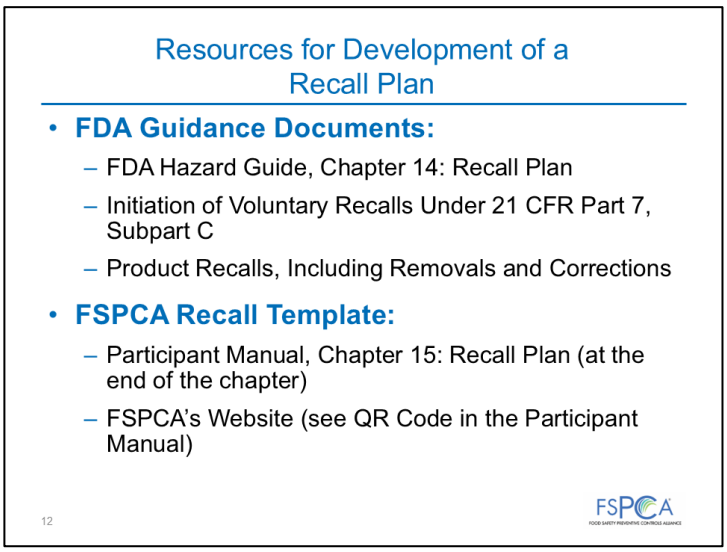
Product lots involved in a recall must be accurately identified. How this is done is dictated by how materials are tracked from incoming goods through the process, and into distribution, as well as how a lot is defined. Recall efforts involve identifying specific lots that might be implicated and then tracing those product lots through the distribution system to ensure that all product that has not already been consumed is recovered. These are critical records.

Examples of records which may support recall plans and activities include:

- Production records determine tracing and tracking of all ingredients from receipt and warehousing through production, and shipment of finished goods. The facility must have documentation to support the decision on which lots are subject to the recall;
- For process-related recall issues, proper identification of the affected production lots;
- A list of consignees who received implicated products and contact records; and
- Reconciliation of what product was recovered, reworked, scrapped, unshipped, etc.

When a recall occurs, reanalysis (see Chapter 14 in your manual) of the Food Safety Plan is required to determine how to prevent a recurring situation. Once the recall plan is developed, it is important to periodically test the system to ensure that it will work if a recall is necessary. This is sometimes referred to a "mock recall."

Slide 12: Resources for Development of a Recall Plan



Recall Plan Template on FSPCA's Website*

(PC Human Food—>Preventive Controls Qualified Individual—>Materials and Resources—>PCHF Workaids)

The FDA has resources for developing a recall plan in its guidance documents. The guidance discusses what preparations facilities in a distribution chain, including manufacturers and distributors, should consider in order to establish recall initiation procedures; to ensure timely identification of, and response to, product problems that might lead to a recall; and to promptly issue recall communications and press releases or other public notices. FDA resources also discuss preparations facilities in the distribution chain should consider making to ensure timely responses to a recall communication. Additionally, it discusses how the FDA assists companies with carrying out their recall responsibilities to protect the public health from distributed products in violation of the FD&C Act and other regulations administered by FDA.

Another document from the FDA provides guidance and recommendations to FDA-regulated industry about what information companies should provide to the FDA and how they should notify their customers about product recalls.

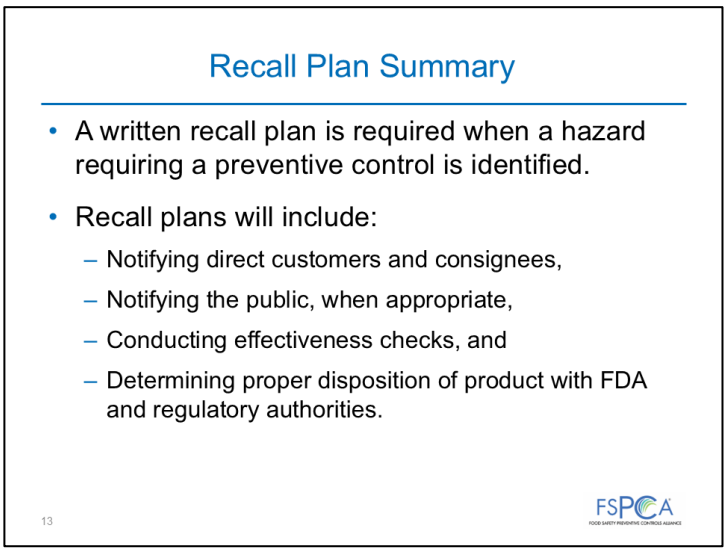
Resources from FDA

Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c

Notifications to the FDA and customers: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections

FSPCA's recall template is available on the FSPCA website (see QR Code next to the slide) and at the end of this chapter.

Slide 13: Recall Plan Summary



A recall plan is needed when a hazard requiring a preventive control is identified. The regulation requires that the recall plan include notification procedures for those affected by the recall, how and when effectiveness checks are to be completed, and that assures proper disposition is carried out under consultation with FDA and other regulatory authorities as appropriate.

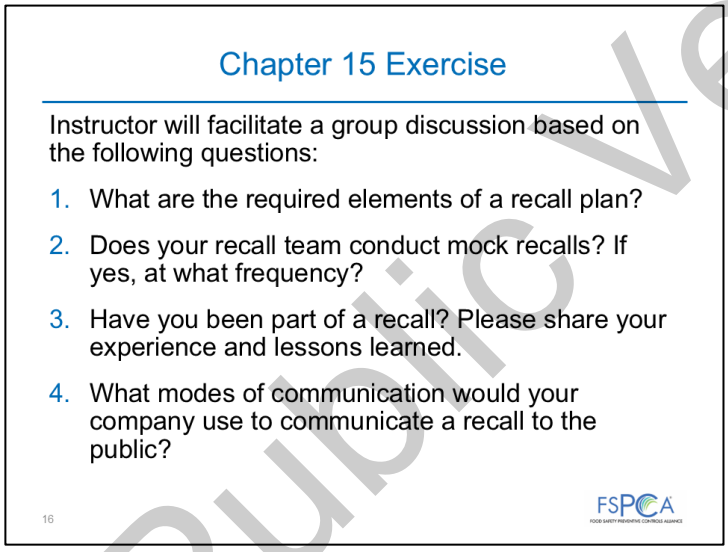
Slide 14: Knowledge Check 1

Participants do NOT have this slide.

Slide 15: Knowledge Check 2

Participants do NOT have this slide.

Slide 16: Chapter 15 Exercise



Participate in the Instructor-led group discussion based on the following questions:

1. What are the required elements of a recall plan?
2. Does your recall team conduct mock recalls? If yes, at what frequency?
3. Have you been part of a recall? Please share your experience and lessons learned.
4. What modes of communication would your company use to communicate a recall to the public?

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FSPCA Recall plan template (click on "Materials and Resources" tab at the top of the webpage): https://www.fspca.net/pc-human-food-preventive-controls-qualified-individual

Association of Food and Drug Officials (AFDO). Directory of state and local officials (DSLO) – a directory of regulatory officials involved with food, animal feed, animal health, and food defense. https://www.afdo.org/directories/dslo/

FDA. (2018). Firm/Supplier Evaluation Resources for FSMA Rules (Recalls): https://www.fda.gov/food/food-safety-modernization-act-fsma/firmsupplier-evaluation-resources-fsma-rules

FDA. (2018). Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: Chapter 14: Recall Plan https://www.fda.gov/media/131287/download

FDA. (2022). Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c

FDA. (2020). Product Recalls, Including Removals and Corrections Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections

FDA. (2014). Recalls Background and Definitions: https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions

FDA. (2021). Regulatory Procedures Manual, Chapter 7 Recall Procedures (Monitoring and Auditing Recall Effectiveness): https://www.fda.gov/media/71814/download

FDA OII Recall Coordinators: https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators

FDA. Recall Data Dashboard: https://datadashboard.fda.gov/ora/cd/recalls.htm

Recall Plan Template and Teaching Example

[Company Name]

Recall Plan

Reviewed by: *Signature*, Title

Date: February 13, 2023

This model recall plan identifies information that is either required or recommended to facilitate an effective and efficient recall. A recall plan is only required by the *Preventive Controls for Human Food* regulation when a hazard requiring a preventive control is determined by the hazard analysis. No specific format and content is required. This model contains questions and templates that can be used to develop an individualized recall plan. A recall plan must be developed as part of the facility's Food Safety Plan records when a hazard requires a preventive control.

Table of Contents

Recall Team

[Add, combine, or delete rows to accommodate your operation]

Assignment	Person	Contact Information
Senior Operations Manager Alternate:		Office: Mobile: Home:
Publicity and Public Relations Alternate:		Office: Mobile: Home:
Sales & Marketing Alternate:		Office: Mobile: Home:
Scientific Advisor Alternate:		Office: Mobile: Home:
Logistics and Receiving Alternate:		Office: Mobile: Home:
Quality Assurance Alternate:		Office: Mobile: Home:
Accountant Alternate:		Office: Mobile: Home:
Attorney Alternate:		Office: Mobile: Home:
Administrative Support		Office: Mobile: Home:
FDA Recall Coordinator		Office:

Determining if a Recall Action Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency believe your product is causing illness	Assemble Recall Team and ask agency if recall is recommended	Evaluate situation; decide if, what, and how much product to recall	**If no recall is needed**: Document why not and action.
News media story on problem with a type of food you produce	Assemble Recall Team, review internal records		**If recall is needed**: • Assign responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble Recall Team and debrief • Prepare for legal issues
Internal QC or customer information suggest a potential problem	Assemble Recall Team and review internal records		
Health Department believes your produce is causing illness	Assemble Recall Team, contact appropriate regulatory agency		

Information Templates for FDA Communication

Product Information

Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

Codes (Lot Identification Numbers):

- UPC code(s) involved: _____
- Lot number(s) involved: _____
- Lot numbers coding system: *Describe how to read your product code:*
  _____

  _____
- Expected shelf life of product: _____

Recalling Firm Contacts

Provide this information to the FDA for clear communication:

Manufacturer name: [Name and address]

Position	Name, Title	Contact Information
Recall coordinator		Office: Mobile: Fax: email:
Most responsible individual		Office: Mobile: Fax: email:
Public contact:	*May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator to focus on retrieving product and resolving the issue.*	Office: Mobile: Fax: email:

Reason for the Recall

Explain in detail how product is defective or violative.	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain the level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved	
If a State agency is involved in this recall, identify Agency and contact.	

Volume of Recalled Product

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace • distributor level	
• customer level	
Provide the status/disposition of marketed product, if known, (e.g., used, used in further manufacturing, or destroyed)	

Distribution Pattern

Number of DIRECT accounts (i.e., customers you sell directly to) by type

Type	Number
• wholesalers/distributors	
• repackers	
• manufacturers	
• retail	
• consumers (internet or catalog sales)	
• federal government consignees	
• foreign consignees (specify whether they are wholesale distributors, retailers or users)	
• Geographic areas of distribution, including foreign countries	

Consignee List

Provide this list to the local District Recall Coordinator. Include U.S. customers, foreign customers, and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)

Commercial customers

Name	Street Address	City	State	Recall contact name	Contact phone number	Recalled product **was** shipped?	Recalled product **was** sold?	Recalled product **may have** been shipped or sold

Was the product sold under Government Contract?

Yes _____ No _____

If yes, include contact name and information above AND complete information below.

Contracting Agency	Contract Number	Contract date	Implementation date

School Lunch Program:

If product was sold to federal, state, or local agency for the school lunch program, complete table and notify "ship to" (so they can retrieve product) and "bill to" customers (so they can initiate the sub-recall).

Consignee	Quantity	Sale date	Shipment date

Recall Strategy

Level in the Distribution Chain

Level	Included		Rationale if "No"
	Yes	No	
Wholesale/distributor			
Retail			

Instructions for Consignee Notification

Write instructions on how consignees will be notified (i.e., by mail, phone, facsimile, email). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g., overnight mail, first class mail, certified mail, facsimile)
- Draft phone script if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to the FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, the FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account (*Note: Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall*.)

Consignee	Recall contact		Date contacted	Method of contact				Date of response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary (to be provided to FDA periodically)

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding, and action taken	Quantity accounted for	Estimated completion date

Product Destruction/Reconditioning

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is strongly recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable regulations.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. The FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by the recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

DRAFT Recall Notice

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity] [--No Other Products Affected--]

Contact
Consumer:
[insert phone number]

Media Contact:
[insert phone number]

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- **[insert lot codes]**

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

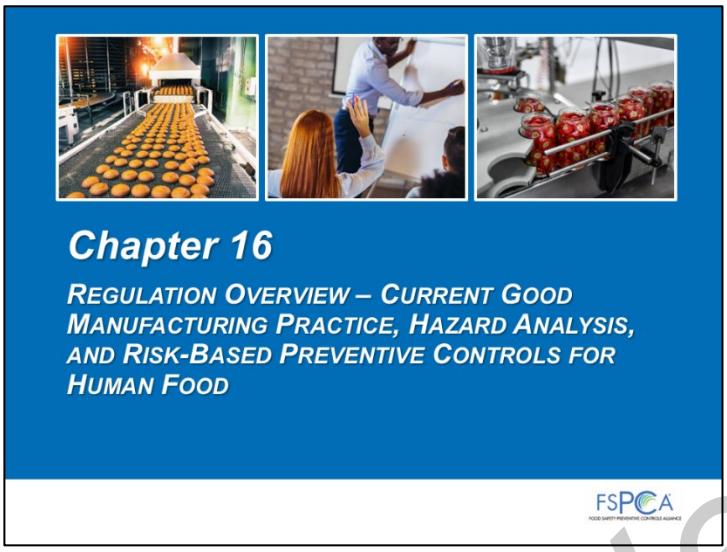
PRODUCT	LOT CODE	ITEM NO.
[Company Name] [insert product name(s)]	[insert product codes(s)]	[insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at [insert phone number] (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at [insert website address].

Chapter 16: Regulation Overview – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

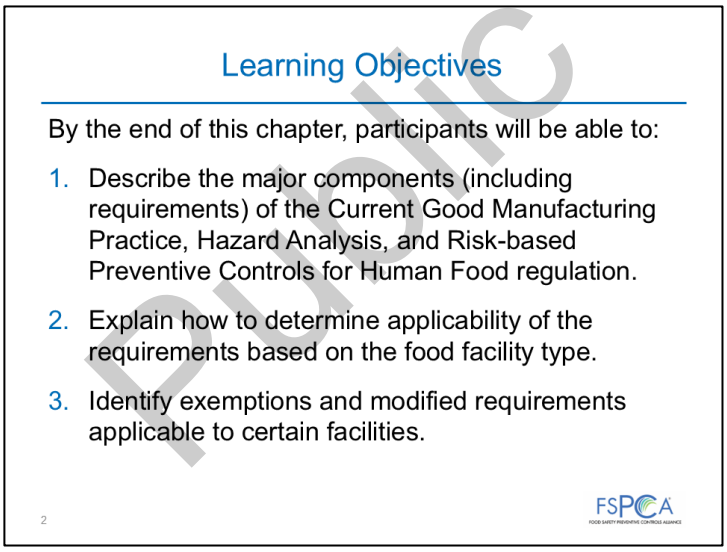
Slide 1: Chapter 16: Regulation Overview – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food



§ = Section: Just a reminder, this symbol refers to a specific section within the regulation and is sometimes used in place of writing out the full reference, (e.g., § 117.4).

This chapter serves as a review of many of the requirements that were covered in previous chapters.

Slide 2: Learning Objectives

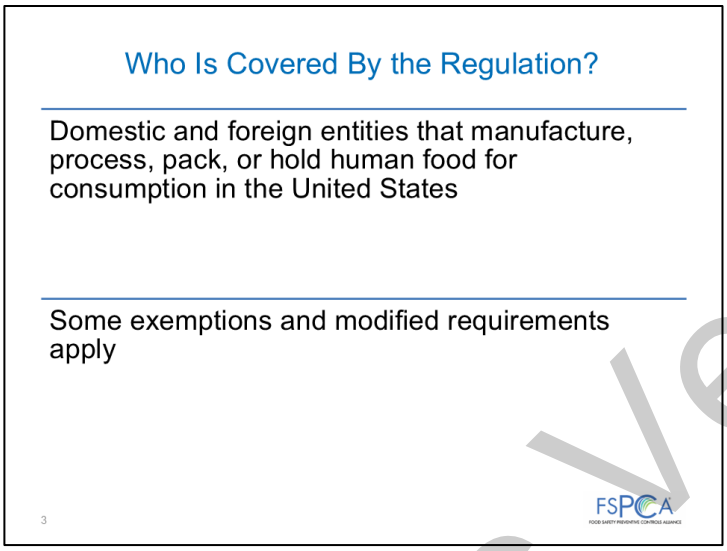


On September 17, 2015, the FDA's final regulation on Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food was published. The regulation focuses on a preventive approach to food safety and is known as the Preventive Controls for Human Food regulation. We refer to it as "the regulation" for the rest of this chapter. A copy of the entire text of the regulation is found in Appendix 1 of this manual.

This course was developed to assist human food establishments with developing and implementing risk-based preventive controls that comply with the regulation. In some sections of the course, the information provided goes beyond what is in the regulation to assist with implementation of a robust Food Safety Plan.

The specific provisions and regulatory citations for the regulatory requirements are included here, in an overview of the regulation. If the facility has specific questions on interpretation, they can use the FDA's Food Safety Modernization Act (FSMA) Technical Assistance Network, which will be reviewed later in this chapter.

Slide 3: Who Is Covered By the Regulation?



"PCHF Food Facility Type and Applicable Regulations Table" (Form_0064): *On FSPCA's website, click on the PC Human Food tab drop down menu, select "Preventive Controls Qualified Individual," scroll over and click on "Materials and Resources, and then click on "PCHF Food Facility Type and Applicable Regulations Table" under "Additional Resources" near the bottom of the web page.*

The regulation generally applies to both domestic facilities and foreign facilities that export food for consumption in the United States.

Facilities required to register with the FDA under Sec. 415 of the FD&C Act are subject to both the GMP and the Hazard Analysis and Preventive Controls for Human Food requirements. Registration is not required for restaurants and retail food establishments, so the PC requirements do not apply to restaurants and retail food establishments.

GMPs generally apply to entities that manufacture, process, pack, or hold human food for consumption in the United States, regardless of whether the entity is a facility required to register.

There are a number of exemptions and modified requirements, mostly with respect to Subpart C on hazard analysis and risk-based preventive controls.

Copied below and on subsequent pages is the FSPCA's Form 0064: Preventive Controls for Human Food: Food Facility Type and Applicable Regulations Table. The purpose of the FSPCA Form 0064 is to show which subparts of 21 CFR Part 117, apply to different food facility types as well as other applicable regulations.

PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE	
FOOD FACILITY TYPE	**APPLICABLE REGULATIONS**
Food facility not qualifying for any exemption under 21 CFR Part 117	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain)
Qualified Facility (QF) – very small business averaging less than $1 million sales of human food per year during three-year period, adjusted for inflation, including subsidiaries and affiliates. <u>Notes</u> Exemptions from 117 subparts C and G • §117.5(a) Must submit attestation to FDA per modified requirements outlined in subpart D §117.201	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart D (§117.201 modified requirements for QF) 117 subpart E (Withdrawal of QF exemption) 117 subpart F (Food safety and food hygiene training records)

PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE	
FOOD FACILITY TYPE	**APPLICABLE REGULATIONS**
Warehouse solely storing unexposed packaged food. Notes Exemptions from 117 subparts C and G • §117.7 If such a warehouse is storing unexposed packaged food that is refrigerated for safety, then subpart D also applies.	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart D (§117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 subpart F (Food safety and food hygiene training records)
Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or processing (e.g., grain elevators). Notes Exemptions from 21 CFR Part 117 • §117.5(k)(1)(iii) Exemption from subpart B (GMPs) • §117.5(j) Exemption from subpart C (preventive controls) and subpart G (supply-chain) if RACs are not fruits or vegetables Not subject to subpart A §117.4 (Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subparts B, C, and G.	FD&C Act
Facility solely engaged in storage of RAC fruits and vegetables (e.g., produce warehouse). Notes Exempt from 117 subpart B • §117.5(k)(1)(iii) Exemption from subpart B (GMPs) Enforcement discretion from PC requirements • Enforcement discretion policy of January 2018 Not subject to §117.4 (Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subpart B and the enforcement discretion from subparts C and G.	FD&C Act

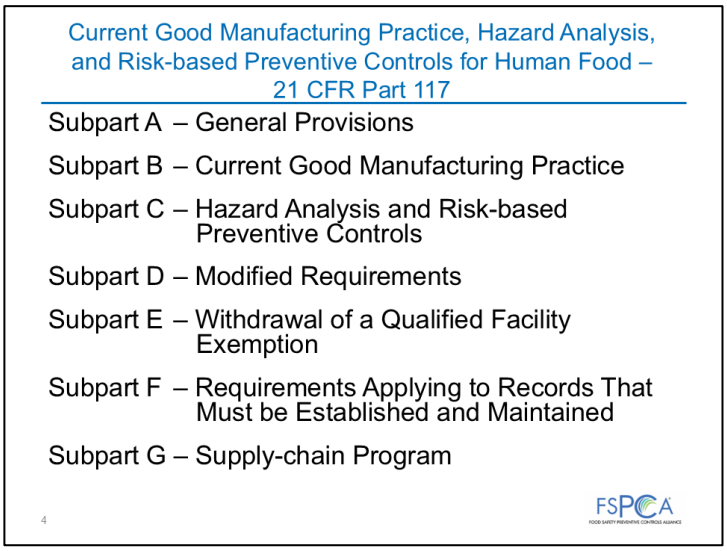
PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE	
FOOD FACILITY TYPE	**APPLICABLE REGULATIONS**
Off-farm packaging, packing, and holding of RAC produce (e.g., packing house) Notes Enforcement discretion from PC requirements • Enforcement discretion policy of January 2018 §117.8 Applicability of subpart B	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs)* 117 subpart F (Recordkeeping) *Either 117 subpart B (GMPs) or applicable requirements for packing and holding RAC produce in 21 CFR Part 112 (produce rule)
Farm mixed-type facility: Establishment that engages in both activities that are exempt from food facility registration (e.g., a farm), and activities that require the establishment to be registered (e.g., a food manufacturer). Notes Small and very small farm mixed-type facility are exempt from subpart C (preventive controls) and subpart G (supply-chain) if they only perform certain activities on certain products. Exemption from 117 subparts C and G for small or very small farm mixed-type facilities: • §117.5(g)(3) lists the 23 low risk packing or holding activity/food combinations • §117.5(h)(3) lists the 27 low-risk manufacturing/processing activity/food combinations	If farm mixed-type facility is a large business OR does any activity/food combination not listed as low-risk under §117.5(g)(3) or (h)(3), then the following apply: 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (preventive controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) If farm mixed-type facility is a small or very small business and does only activity/food combinations listed as low- risk under §117.5(g)(3) or (h)(3), then the following apply: 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records)
Seafood processor Notes Exemption from 117 subparts C and G • §117.5(b)	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records) 21 CFR Part 123 Seafood HACCP Regulation
Juice Processor Notes Exemption from 117 subparts C and G • §117.5(c)	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records) 21 CFR Part 120 Juice HACCP Regulation

PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE	
FOOD FACILITY TYPE	**APPLICABLE REGULATIONS**
Low-Acid Canned Food (LACF) Processor Notes Exemption from 117 subparts C and G • §117.5(d) Control of microbiological hazards such as *C. botulinum* are covered by 21 CFR Part 113 LACF regulation. Control of chemical hazards, physical hazards, and pathogenic heat-stable toxin formation that could occur before LACF thermal process (*S. aureus, B. cereus*) are covered by 21 CFR Part 117.	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (for all hazards except microbiological hazards covered by thermal process) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) §108.35 Thermal Processing of low-acid foods packaged in hermetically sealed containers 21 CFR Part 113 LACF Regulation (for microbiological hazards covered by thermal process)
Acidified Food Processor Notes All hazards, including microbiological hazards, must be controlled as part of the facility's Food Safety Plan subject to 117 subparts C and G.	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) §108.25 Acidified Foods 21 CFR Part 114 Acidified Food Regulation
Bottled Water	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) 129 Bottled Water Regulation §165.110 Bottled Water Standards
Infant Formula	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) 21 CFR Part 106 Infant Formula Requirements 21 CFR Part 107 Infant Formula Regulation

PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE	
FOOD FACILITY TYPE	**APPLICABLE REGULATIONS**
Alcoholic Beverages <u>Notes</u> Exemptions from subparts C and G • §117.5(i)(1) exempts alcoholic beverages if they are at a facility required to register under the BT Act and obtain permits from Department of Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) • §117.5(i)(2) exempts prepackaged food at such a facility if ≤ 5% of the overall sales of the facility	117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records)
Interstate Travel Facilities <u>Notes</u> If an interstate travel facility is required to register as a food facility under the BT Act, then it is subject to 21 CFR Part 117 (e.g., airline caterers). If it meets definition of retail establishment then it does not have to register and is not subject to 21 CFR Part 117.	If an interstate travel facility is required to register as a food facility under the BT Act (e.g., airline caterers, commissaries that also manufacture ice): 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart C (Preventive Controls) 117 subpart F (Recordkeeping) 117 subpart G (Supply-Chain) Commissaries solely engaged in the storage of unexposed packaged food, some of which requires refrigeration for safety: 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart D (§117.206 Modified requirements) 117 subpart F (Recordkeeping) Commissaries solely engaged in the storage of unexposed packaged food that does not require refrigeration for safety: 117 subpart A (§117.4 Qualifications of Individuals) 117 subpart B (GMPs) 117 subpart F (Food safety and food hygiene training records)

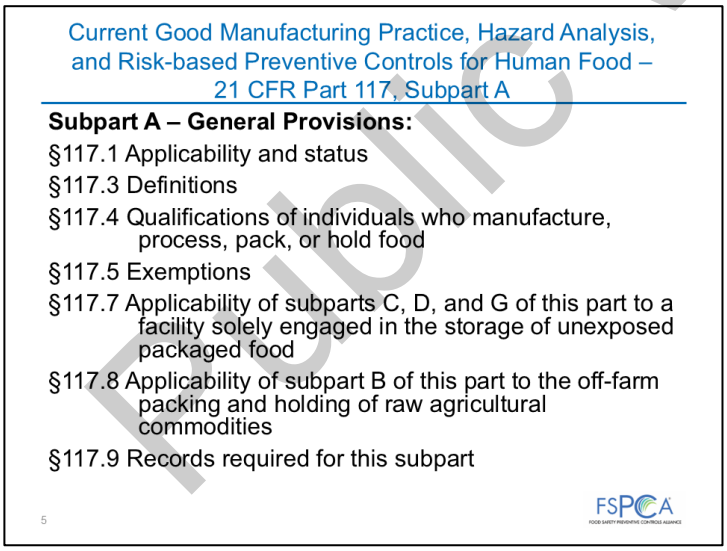
PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE	
FOOD FACILITY TYPE	**APPLICABLE REGULATIONS**
Eggs (Shell eggs are raw agricultural commodity) <u>Notes</u> Farms (e.g., on-farm production of shell eggs and egg packing houses within "farm" definition), are exempt from registration thus exempt from subpart C (preventive controls) and subpart G (supply-chain program) • §117.5(k)(1)(i): Farms are exempt from subpart B GMPs Off-farm egg warehouse • §117.5(k)(1)(iii): Establishments solely engaged in holding or transportation of shell eggs (RAC) are exempt from subpart B GMPs • §117.5(j): Facilities solely engaged in storage of shell eggs (RAC) intended for further distribution or processing are exempt from subpart C (preventive controls) and subpart G (supply- chain) Not subject to subpart A (§117.4 Qualifications of Individuals) and subpart F (Food safety and food hygiene training records) because of the exemptions from subparts B, C, and G.	21 CFR Part 118 Production, Storage, and Transportation of Shell Eggs
Dietary Supplements <u>Notes</u> Exemption from 117 subparts C and G • §117.5(e) exempts facilities manufacturing, processing, packing, or holding dietary supplements in compliance with 21 CFR Part 111 from Part 117 subparts C (preventive controls) and G (supply-chain) Facilities that make <u>dietary ingredients</u> will need to comply with all of 21 CFR Part 117 unless another exemption applies.	117 subpart A (§117.4 Qualifications of Individuals beyond what is in 111 regarding personnel qualification requirements) 117 subpart B (GMPs)* 117 subpart F (Food safety and food hygiene training records) *When a requirement in Part 117 subpart B GMPs is not specified in 21 CFR Part 111 because it is an uncommon occurrence for dietary supplements, then the requirement in 117 subpart B will apply to dietary supplements.

Slide 4: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117



The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food regulation is found in 21 CFR Part 117. It has seven (7) subparts as shown here.

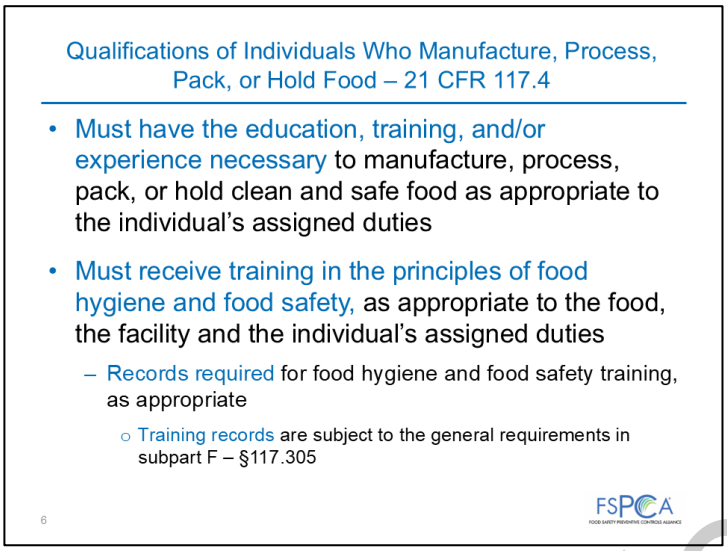
Slide 5: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart A



Subpart A discusses applicability of the regulation to different facilities; defines terms used in the regulation; addresses qualifications for individuals who manufacture, process, pack or hold food; and identifies exemptions from specific regulatory requirements for certain situations. It also updates definitions in other parts of the Code of Federal Regulations such as clarifying what constitutes on-farm manufacturing, packing, and holding of food in 21 CFR Part 1. It also defines a small and very small

business, which have different compliance dates. These updates were required by the Food Safety Modernization Act's Section 103.

Slide 6: Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food – 21 CFR 117.4



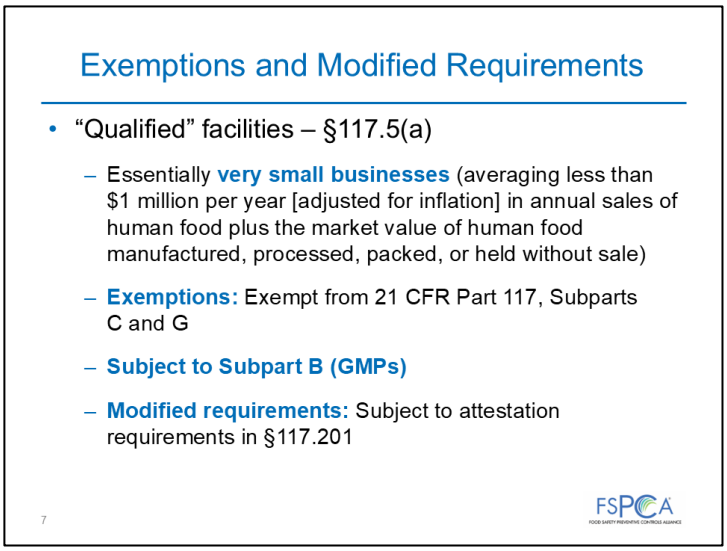
21 CFR Part 117, specifically §117.4, has the requirements for training applicable to all establishments that manufacture, process, pack or hold food.

Individuals must have the education, training, or experience (or combination of these) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties.

Individuals must receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's assigned duties.

Records are required for food hygiene and food safety training. These training records are subject to the general requirements in Subpart F (§117.305).

Slide 7: Exemptions and Modified Requirements (1 of 2)



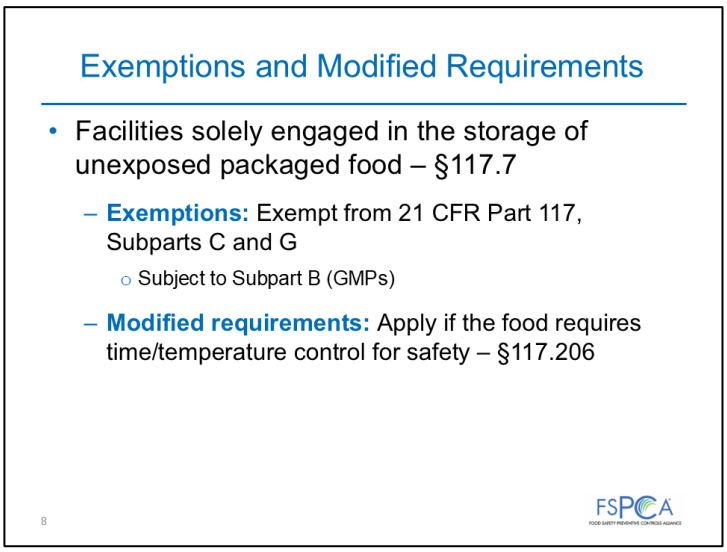
FDA's FSMA Inflation Adjusted Cut Offs

Qualified facilities are exempt from the requirements for hazard analysis and risk-based preventive controls.

These are essentially very small businesses and include a business (including affiliates and subsidiaries) that averages less than $1 million in total annual sales of human food (plus the value of human food held without sale (e.g., for a fee, as is the case for a warehouse), adjusted for inflation. The QR Code to the right of the slide (above) links to FDA's *FSMA Inflation Adjusted Cut Offs* web page.

Qualified facilities are still subject to the GMPs and are subject to attestation requirements in §117.201. This means that they will need to submit a form to FDA, confirming the business' status as a qualified facility (e.g., that they remain under the sales limits), and that the facility is either implementing preventive controls to address hazards associated with its food or is in compliance with non-Federal food safety laws and regulations.

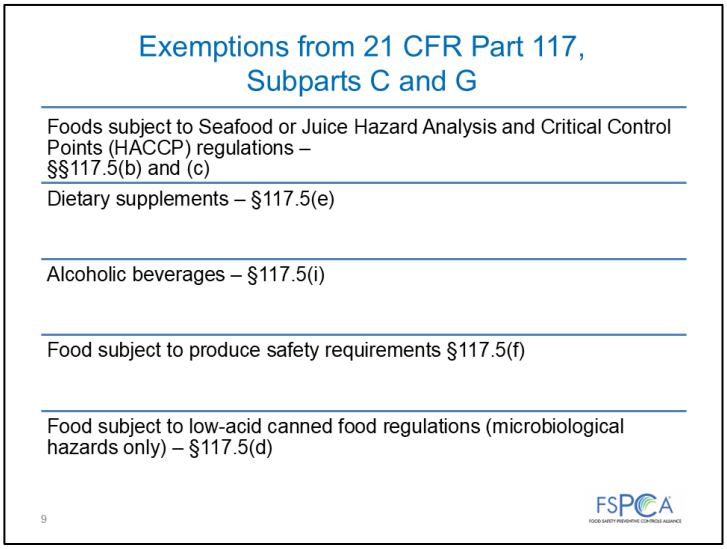
Slide 8: Exemptions and Modified Requirements (2 of 2)



Facilities such as warehouses that store only unexposed packaged food are exempt from the requirements in Subparts C and G. However, certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification, and records. They are subject to Good Manufacturing Practices unless an exemption applies.

See FSPCA's Form 0064: Preventive Controls for Human Food: Food Facility Type and Applicable Regulations Table to identify which subparts of 21 CFR Part 117, apply to facilities solely engaged in the storage of unexposed packaged food.

Slide 9: Exemptions from 21 CFR Part 117, Subparts C and G (1 of 2)

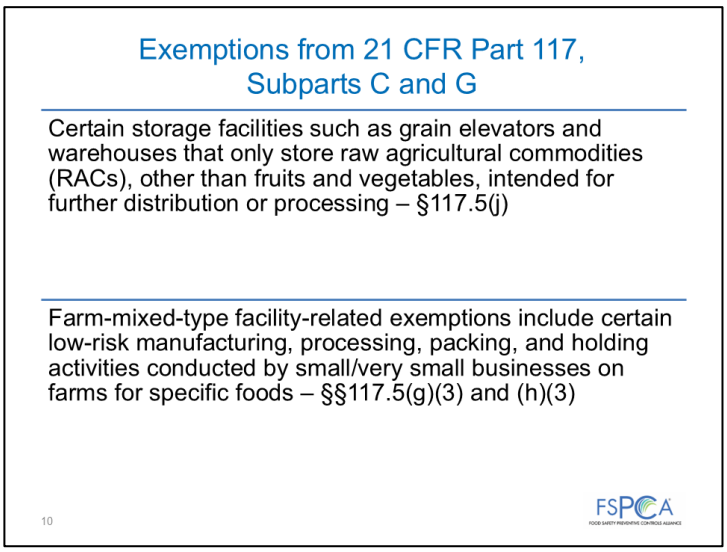


The regulation provides an exemption for the following:

- Food subject to Seafood or Juice HACCP regulations – §117.5(b) and (c)
- Dietary supplements – §117.5(e)
- Alcoholic beverages – §117.5(i)
- Food subject to produce safety requirements – §117.5(f)
- Food subject to low-acid canned food regulations (only with respect to microbiological hazards) – §117.5(d)

See FSPCA's Form 0064: Preventive Controls for Human Food: Food Facility Type and Applicable Regulations Table to identify which subparts of 21 CFR Part 117, apply to these facility types.

Slide 10: Exemptions from 21 CFR Part 117, Subparts C and G (2 of 2)



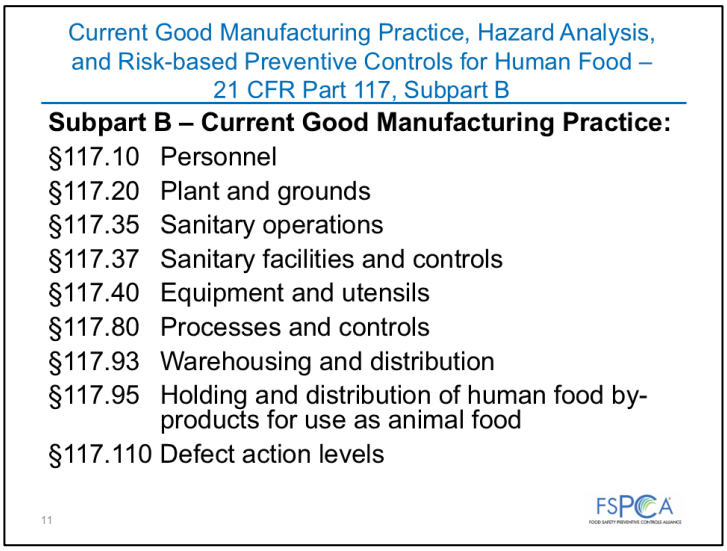
Certain storage facilities such as grain elevators and warehouses that only store raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing are exempt from hazard analysis and risk-based preventive controls.

FSMA provided FDA with authority to exempt or modify requirements for storage of raw agricultural commodities (RACs) intended for further distribution or processing, but specifically excluded storage of fruits and vegetables.

Farm-mixed-type facility-related exemptions include certain low-risk manufacturing, processing, packing, and holding activities conducted by small/very small businesses on farms for specific foods. The regulation includes an exhaustive list, and the exemption only applies if these are the only activities they conduct that were subject to the registration requirement.

See FSPCA's Form 0064: Preventive Controls for Human Food: Food Facility Type and Applicable Regulations Table to identify which subparts of 21 CFR Part 117, apply to these facility types.

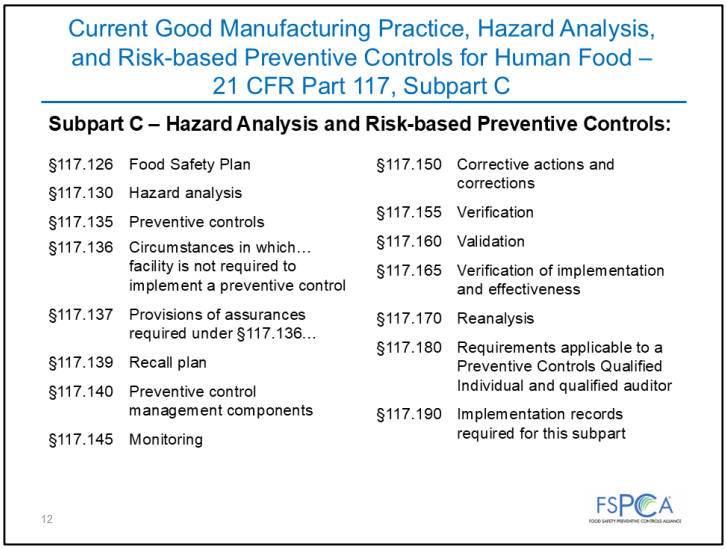
Slide 11: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart B



The different sections of Subpart B (the CGMPs), are shown on this slide. Requirements for personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels are addressed under GMP provisions. In addition, a new provision was added for holding and distribution of human food by-products for use as animal food. GMP provisions are not the focus of this course on hazard analysis and preventive controls.

The new provision in §117.95 pertains to GMPs for holding and distribution of human food by-products for use as animal food. Human food manufacturers that hold and distribute human food by-products without further manufacturing are not subject to the Preventive Controls for Animal Food regulation if the human food is produced in compliance with GMPs and are not further processed, but the by-products must be held in a manner that protects against contamination and identified as human food by-products for use as animal food during holding and distribution.

Slide 12: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart C



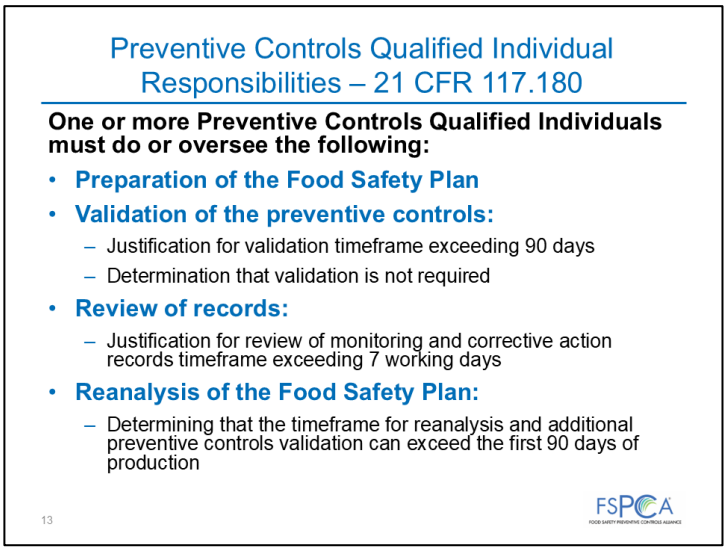
The focus of this training program is on 21 CFR Part 117, Subpart C: Hazard Analysis and Risk-based Preventive Controls for Human Food (referred to as "Preventive Controls for Human Food regulation" in this document) and Subpart G: Supply-Chain Program. Each facility is required to implement a written Food Safety Plan that focuses on significantly minimizing or preventing hazards in foods (21 CFR Part 117, §117.126).

We have covered in more detail the requirements in Subpart C in the individual chapter(s) pertaining to each section.

Here's a high-level summary of the requirements:

- Every facility subject to Subpart C must have a written Food Safety Plan that includes
    - Written hazard analysis
    - Written preventive control procedures, including monitoring, corrective actions, and verification as applicable
        - Written process preventive procedures must include validation
    - Written supply-chain program
    - Written Recall Plan
- Monitoring, corrective actions, and verification (as applicable) must be documented in records
- The facility must have a Preventive Controls Qualified Individual prepare or oversee the preparation of the Food Safety Plan, validation, review of records, and reanalysis.

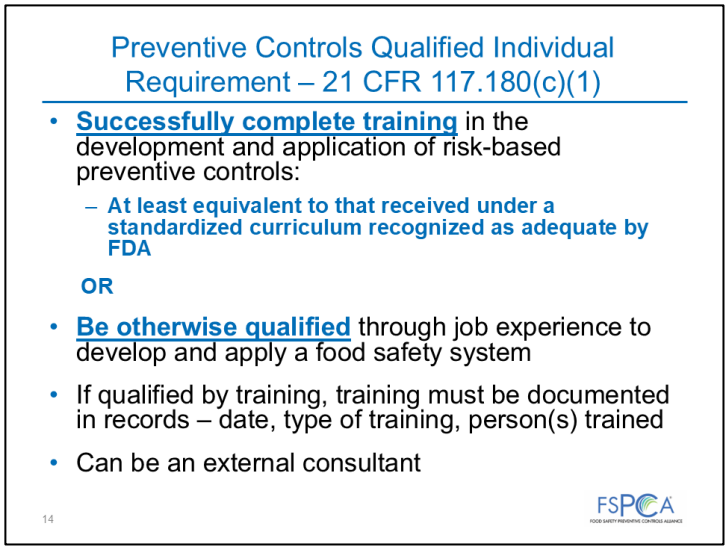
Slide 13: Preventive Controls Qualified Individual Responsibilities – 21 CFR 117.180



A Preventive Controls Qualified Individual is required to, among other things, develop or oversee preparation of the Food Safety Plan, validation of the preventive controls, review of records and reanalysis of the Food Safety Plan.

Additional tasks that must be performed or overseen by a Preventive Controls Qualified Individual involve written justification in situations where expected timeframes for certain activities are not met. These include justification for completing validation activities after 90 days of first production or determining that validation is not required, justification for review of monitoring and corrective action records exceeding 7 working days and determining that it is appropriate to perform reanalysis and validation of additional preventive controls in a period longer than the first 90 days of production.

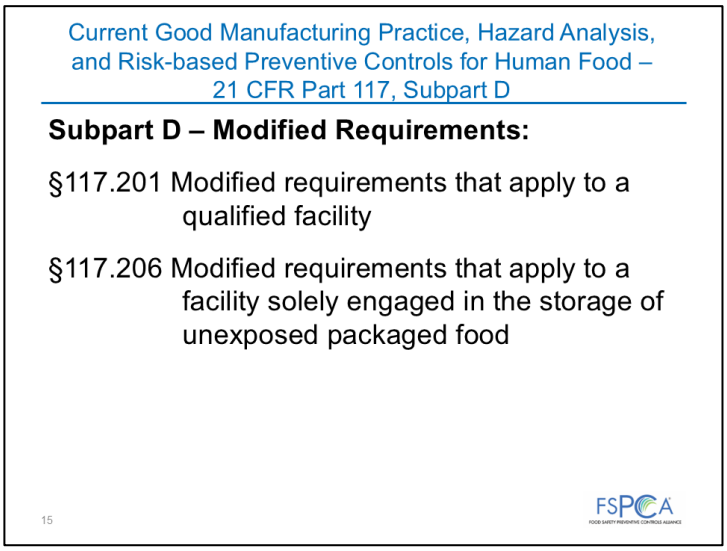
Slide 14: Preventive Controls Qualified Individual Requirement – 21 CFR 117.180(c)(1)



There are two ways to become a Preventive Controls Qualified Individual. The first way is to successfully complete training in the development and application of risk-based preventive controls, such as attending this training class and successfully completing the exercises. The second way is for an individual to be qualified through job experience to develop and implement a Food Safety Plan. If qualified by training, the training must be documented in records, including the date of the training, type of training, and the person(s) trained.

The Preventive Controls Qualified Individual may be, but is not required to be, an employee of the facility. This person can be an external consultant.

Slide 15: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart D



There are modified requirements for certain facilities such as very small businesses (i.e., a qualified facility), or warehouses that solely engage in storage of unexposed packaged food. These modified requirements are addressed in 21 CFR Part 117, Subpart D. Consult this section if the facility is a qualified facility. A brief discussion of requirements that apply to facilities solely engaged in storage of unexposed packaged food follows.

Subpart D contains the provisions for modified requirements that apply to a qualified facility and that apply to a facility solely engaged in the storage of unexposed packaged food that requires time/temperature control for safety.

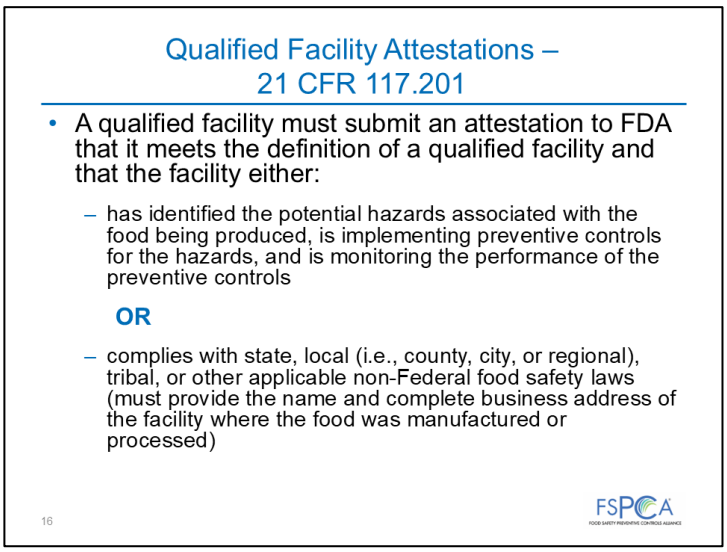
Qualified facilities:

- A very small business is a qualified facility.
- Are exempt from Subparts C and G, but are subject to Subparts A, B, D, E, and F.
- Must submit attestations as described in §117.201.

Facilities solely engaged in the storage of unexposed packaged food (warehouse) that requires time/temperature control for safety:

- Are exempt from Subparts C and G but are subject to Subparts A, B, D, and F (unless another exemption applies).
- Must comply with requirements for temperature control and monitoring as described in §117.206.
- See FSPCA's Form 0064: Preventive Controls for Human Food: Food Facility Type and Applicable Regulations Table to identify which subparts of 21 CFR Part 117, apply to these facility types.

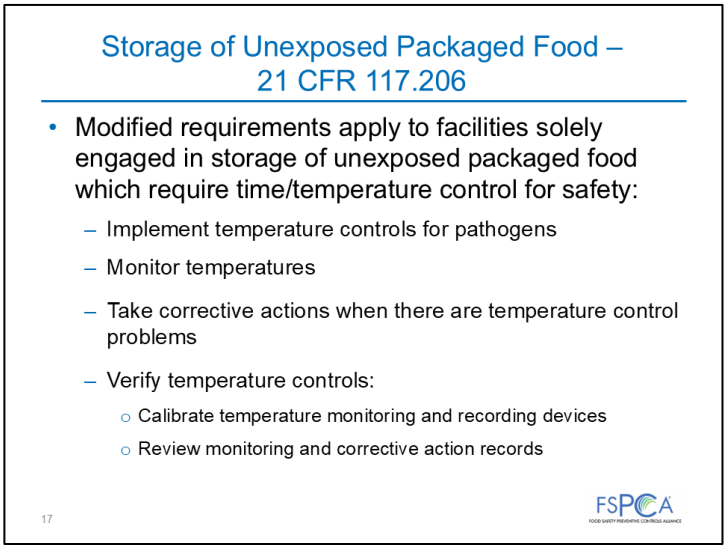
Slide 16: Qualified Facility Attestations – 21 CFR 117.201



A qualified facility must submit the following attestations to FDA as outlined in Subpart D §117.201.

- An attestation that the facility is a qualified facility as defined in §117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011 (see QR Code next to Slide 7); and
- An attestation that the facility has identified the potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or
- An attestation that the facility is in compliance with State, local (county, city, or regional), tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a state department of agriculture), or other evidence of oversight.

Slide 17: Storage of Unexposed Packaged Food – 21 CFR 117.206

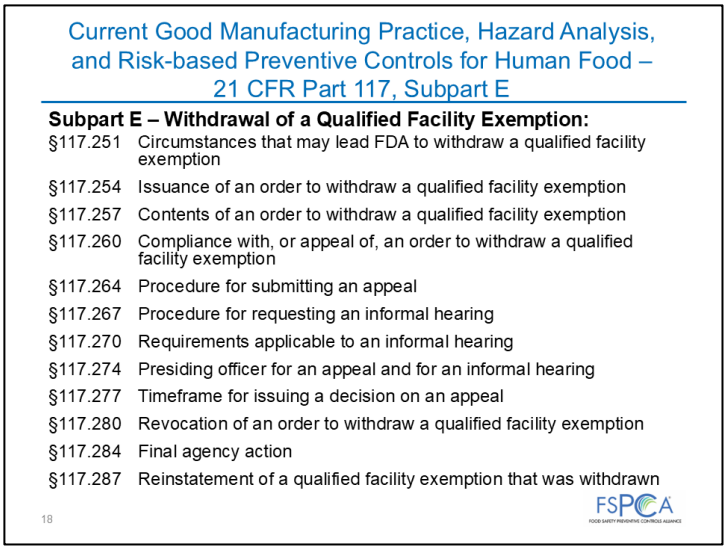


For facilities that are solely engaged in the storage of refrigerated packaged food (e.g., refrigerated storage warehouses), there are requirements for time/temperature control if the product can support pathogen growth or toxin production.

These include monitoring temperatures and taking corrective action when appropriate. Verification activities related to temperature monitoring also apply. In §117.206(a)(4) there is the requirement to verify that temperature controls are consistently implemented by:

> (i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);
>
> (ii) Reviewing records of calibration within a reasonable time after the records are created; and
>
> (iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days.

Slide 18: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart E



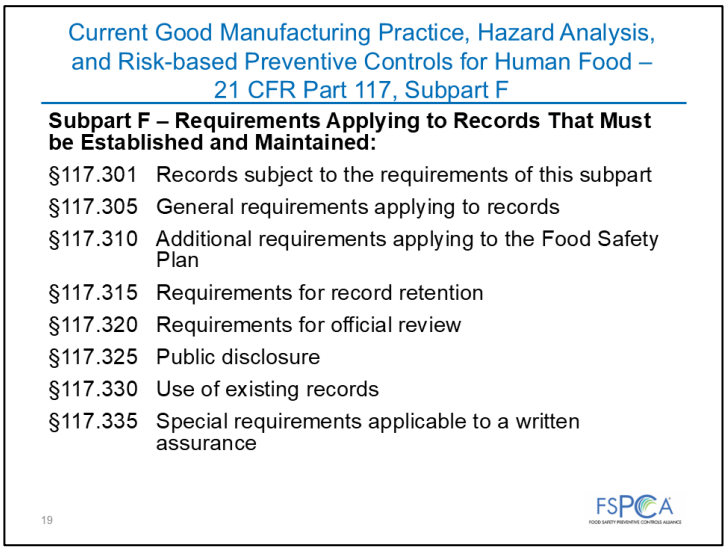
21 CFR Part 117, Subpart E describes the circumstances, procedures, and requirements for withdrawing a qualified facility exemption. If the facility believes that they are a qualified facility, the facility should become familiar with the provisions for withdrawal and reinstatement of the exemption for qualified facilities.

FDA may consider withdrawing the qualified facility exemption when:

- A foodborne illness outbreak is directly linked to the qualified facility.
- FDA determines it is necessary to protect the public health based on conditions and practices associated with a qualified facility.

FDA would only consider pursuing this option in rare circumstances.

Slide 19: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart F



21 CFR Part 117, Subpart F describes requirements for records. Records must be kept as original records, true copies (e.g., photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original), or electronic records. They must contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities. Records must be accurate, indelible, legible, and created concurrently with the activity being documented. Records must be as detailed as necessary to provide a history of the work performed, including:

- adequate information to identify the plant or facility (e.g., the name and when necessary, the location of the facility);
- the date and, when appropriate, time of the activity documented;
- the signature or initials of the person performing the activity; and
- where appropriate, the identity of the product and the lot code, if any.

The Food Safety Plan must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification.

All required records must be retained at the facility for at least 2 years after the date they were prepared. Records related to the general adequacy of the equipment or processes being used by the facility, including scientific studies and evaluations, must be retained for at least 2 years after their use is discontinued. This applies to Food Safety Plans that are no longer used because they have been updated, validation records for processes no longer used, and potentially other records.

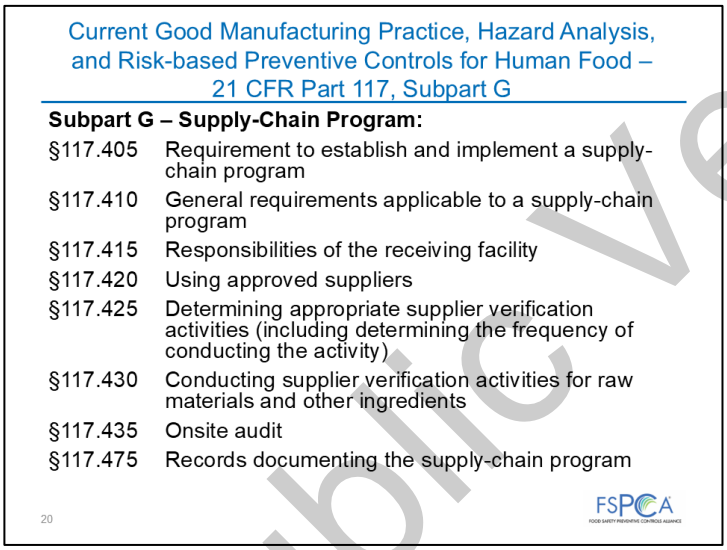
Except for the Food Safety Plan, offsite storage of required records is permitted if they can be retrieved and provided onsite within 24 hours of a request for official review. Electronic records are considered onsite if they can be accessed from an onsite location. All records required must be made promptly available for official review and

copying upon oral or written request. Records required are subject to disclosure requirements under 21 CFR Part 20.

Existing records, such as records kept, to comply with other federal, state or local (county, city, or regional) regulations or any other reason, may be used if they contain all the required information. The facility can supplement existing records if they are missing some of the required elements. The facility does not have to keep their records as one set of records – any new information not on an existing record can be kept separately or combined with the existing records.

Any required written assurance (21 CFR 117.335) related to application of a preventive control elsewhere in the supply-chain (see §117.136 and §117.430) must contain the effective date, printed names and signatures of authorized officials, and relevant information regarding acknowledgement of legal responsibility. Read the section carefully if it applies to the facility.

Slide 20: Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food – 21 CFR Part 117, Subpart G



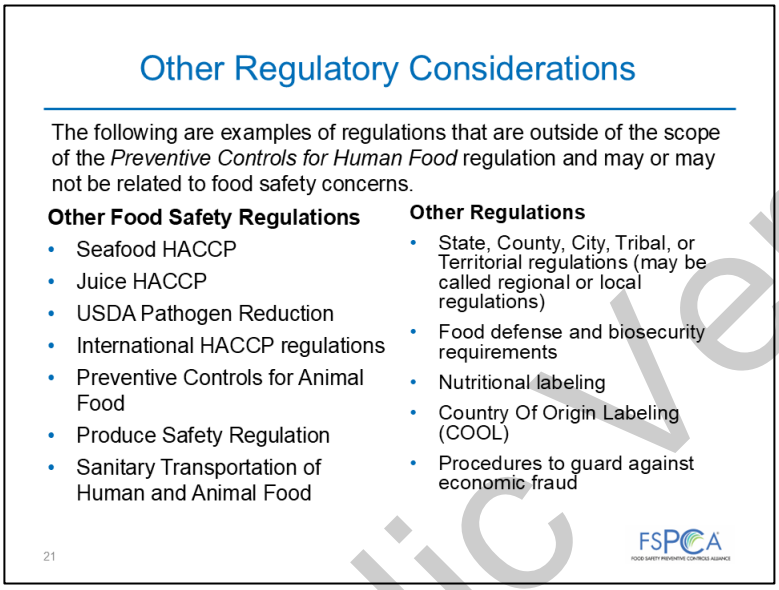
Hazards requiring a preventive control for which the facility relies on supplier controls are managed through the facility's supply-chain program. 21 CFR Part 117, Subpart G covers requirements to establish and implement a supply-chain program, general requirements, responsibilities of the receiving facility, using approved suppliers, determining appropriate verification activities, conducting those activities, onsite audits and records required for the facility's supply-chain program.

In summary:

- Requirements for a supply-chain program only apply to receiving facilities (manufacturer/processor subject to Subparts C and G that have identified a hazard in a raw material or other ingredient that must be controlled before receipt.
- Supply-chain program must include:
    - Approving suppliers

  - Written procedures for receiving from approved suppliers (or temporarily from unapproved suppliers)
  - Written procedures for appropriate supplier verification activities, including frequency
  - Written corrective action procedures
  - Reanalysis of the supply-chain program
- Records documenting the supply-chain program must be established and maintained.

Slide 21: Other Regulatory Considerations



There are a number of food safety regulations in addition to the Preventive Controls for Human Food regulations that may apply to food facilities. Food processors should be aware of these requirements as they may need to be included in a food safety program. For example, seafood and juice products are not subject to certain subparts of the Preventive Controls for Human Food regulation but are subject to GMPs and the seafood and juice HACCP regulations.

The USDA pathogen reduction regulation applicable to meat and poultry establishments is designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, reduce the incidence of foodborne illness associated with the consumption of those products and provide a new framework for modernization of the current system of meat and poultry inspection.

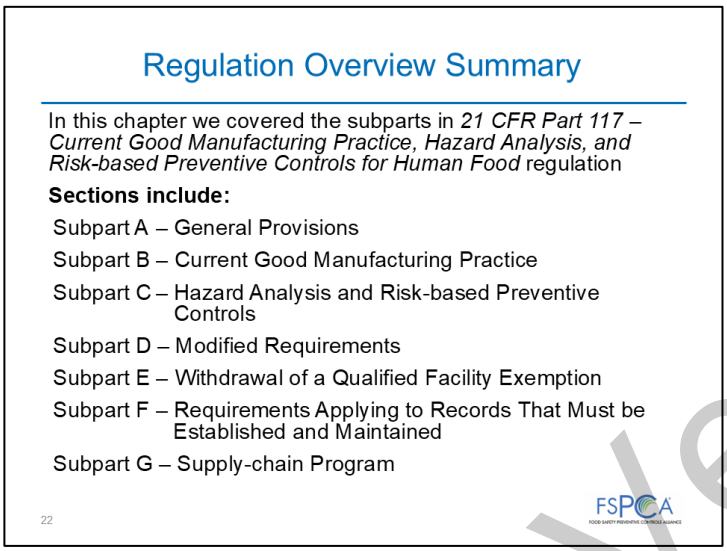
International HACCP regulations apply to food produced in countries outside of the United States. HACCP is an internationally recognized system based on the production of safe food from a preventive approach.

The Preventive Controls for Animal Food regulation requires animal food facilities to have a Food Safety Plan in place that includes an analysis of hazards to determine which ones need control and risk-based preventive controls to minimize or prevent those hazards.

Produce safety regulations establish science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

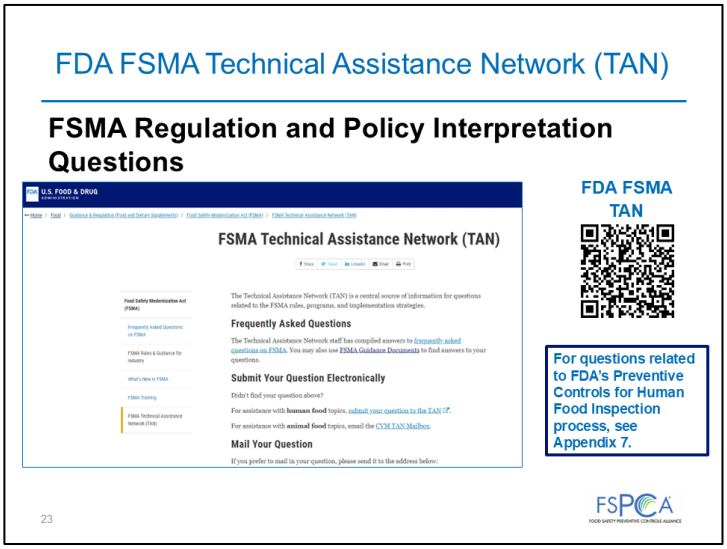
Sanitary food transport regulations establish requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of that food.

Slide 22: Regulation Overview Summary



The Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation is intended to focus preventive controls where they matter most. GMPs are required for all facilities unless an exemption exists. This course focuses on 21 CFR Part 117, Subpart C: Hazard Analysis and Risk-based Preventive Controls for Human Food, and Subpart G: Supply-chain Program. More detailed information on other provisions can be obtained through other means, such as reading the regulation (see Appendix 1) or through other training programs.

Slide 23: FDA FSMA Technical Assistance Network



FDA FSMA TAN

For questions related to FDA's Preventive Controls for Human Food Inspection process, see Appendix 7.

Where to go for help—if the facility has questions regarding regulation and policy interpretation questions, submit questions to FDA's FSMA Technical Assistance Network via the online form. The FDA's subject matter experts will address the questions. Also, the FDA FSMA Technical Assistance Network staff has compiled answers to frequently asked questions on FSMA which may already answer the facility's question (see FSMA FAQ link in the Additional Reading, Resources, and References at the end of the chapter).

If a facility has questions about FDA's Preventive Controls for Human inspection process, what to expect, and how best to prepare for an inspection they can read Appendix 7 which will help in advising on which procedures and records are needed for an FDA inspection, based on their process. In addition, this Appendix 7 will describe FDA's regulatory enforcement actions.

Slide 24: Knowledge Check 1

Participants do NOT have this slide.

Slide 25: Knowledge Check 2

Participants do NOT have this slide.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FSPCA's FORM_0064: PCHF Food Facility Type and Applicable Regulations Table: https://www.fspca.net/pc-human-food-preventive-controls-qualified-individual (click on the "Materials and Resources tab near the top of the web page)

FDA FSMA Inflation Adjusted Cut Offs: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs

Frequently Asked Questions to FDA on FSMA: https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma

Appendix 1: FDA Regulation—Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food

NOTE: NOT an official version. Provided for reference only.
Link to Current 21 CFR Part 117: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117
Includes technical amendments (22 January 2016) and corrections (25 January 2016).

Title 21 of the Code of Federal Regulation Part 117—Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food

Subpart A – General Provisions

§ 117.1 Applicability and status.

(a) The criteria and definitions in this part apply in determining whether a food is:
(1) Adulterated within the meaning of:
(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or
(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and
(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subpart C, D, E, F, or G of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.
(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 117.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:
Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.
Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.
Affiliate means any facility that controls, is controlled by, or is under common control with another facility.
Allergen cross-contact means the unintentional incorporation of a food allergen into a food.
Audit means the systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an entity's food safety processes and procedures.
Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for an adequate time and at an adequate temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
Calendar day means every day shown on the calendar.
Correction means an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
Critical control point means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.
Defect action level means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.
Environmental pathogen means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Facility means a domestic facility or a foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of part 1, subpart H of this chapter.
Farm means farm as defined in § 1.227 of this chapter.
FDA means the Food and Drug Administration.
Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes raw materials and ingredients.
Food allergen means a major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act.
Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
Full-time equivalent employee is a term used to represent the number of employees of a business entity for the purpose of determining whether the business qualifies for the small business exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the business entity and of all of its affiliates and subsidiaries by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks). If the result is not a whole number, round down to the next lowest whole number.
Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.
Hazard means any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
Hazard requiring a preventive control means a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system.
Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.
Known or reasonably foreseeable hazard means a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.
Lot means the food produced during a period of time and identified by an establishment's specific code.
Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating,

freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Packing means placing food into a container other than packaging the food and also includes re-packing and activities performed incidental to packing or re-packing a food (e.g., activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pathogen means a microorganism of public health significance.

Pest refers to any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant means the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive controls qualified individual means 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.

Qualified auditor means a person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter.

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227 of this chapter) that:

(1) Is located:

(i) In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or

(ii) Not more than 275 miles from such facility; and

(2) Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

Qualified facility exemption means an exemption applicable to a qualified facility under § 117.5(a).
Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.
Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated.
Raw agricultural commodity has the meaning given in section 201(r) of the Federal Food, Drug, and Cosmetic Act.
Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
Receiving facility means a facility that is subject to subparts C and G of this part and that manufactures/processes a raw material or other ingredient that it receives from a supplier.
Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.
Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.
Sanitize means to adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
Significantly minimize means to reduce to an acceptable level, including to eliminate.
Small business means, for purposes of this part, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.
Subsidiary means any company which is owned or controlled directly or indirectly by another company.
Supplier means the establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.
Supply-chain-applied control means a preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.
Unexposed packaged food means packaged food that is not exposed to the environment.
Validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.
Verification means the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.
Very small business means, for purposes of this part, a business (including any subsidiaries and affiliates) averaging less than $1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).
Water activity (a_w) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.
Written procedures for receiving raw materials and other ingredients means written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).
You means, for purposes of this part, the owner, operator, or agent in charge of a facility.

§ 117.4 Qualifications of individuals who manufacture, process, pack, or hold food.

(a) Applicability.

(1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.

(2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties.

(b) Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

(1) Be a qualified individual as that term is defined in § 117.3--i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and

(2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

(c) Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

(d) Records. Records that document training required by paragraph (b)(2) of this section must be established and maintained.

§ 117.5 Exemptions.

(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 in §117.201.

(b) Subparts C and G of this part do not apply with respect to activities that are subject to part 123 of this chapter (Fish and Fishery Products) at a facility if you are required to comply with, and are in compliance with, part 123 of this chapter with respect to such activities.

(c) Subparts C and G of this part do not apply with respect to activities that are subject to part 120 of this chapter (Hazard Analysis and Critical Control Point (HACCP) Systems) at a facility if you are required to comply with, and are in compliance with, part 120 of this chapter with respect to such activities.

(d) (1) Subparts C and G of this part do not apply with respect to activities that are subject to part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers) at a facility if you are required to comply with, and are in compliance with, part 113 of this chapter with respect to such activities.

(2) The exemption in paragraph (d)(1) of this section is applicable only with respect to the microbiological hazards that are regulated under part 113 of this chapter.

(e) Subparts C and G do not apply to any facility with regard to the manufacturing, processing, packaging, or holding of a dietary supplement that is in compliance with the requirements of part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and section 761 of the Federal Food, Drug, and Cosmetic Act (Serious Adverse Event Reporting for Dietary Supplements).

(f) Subparts C and G of this part do not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).

(g)(1) The exemption in paragraph (g)(3) of this section applies to packing or holding of processed foods on a farm mixed-type facility, except for processed foods produced by drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), the packing and holding of which are within the "farm" definition in § 1.227 of this chapter. Activities that are within the "farm" definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.

(2) For the purposes of paragraphs (g)(3) and (h)(3) of this section, the following terms describe the foods associated with the activity/food combinations. Several foods that are fruits or vegetables are separately considered for the purposes of these activity/food combinations (i.e., coffee beans, cocoa

beans, fresh herbs, peanuts, sugarcane, sugar beets, tree nuts, seeds for direct consumption) to appropriately address specific hazards associated with these foods and/or processing activities conducted on these foods.

(i) Dried/dehydrated fruit and vegetable products includes only those processed food products such as raisins and dried legumes made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(ii) Other fruit and vegetable products includes those processed food products that have undergone one or more of the following processes: acidification, boiling, canning, coating with things other than wax/oil/resin, cooking, cutting, chopping, grinding, peeling, shredding, slicing, or trimming. Examples include flours made from legumes (such as chickpea flour), pickles, and snack chips made from potatoes or plantains. Examples also include dried fruit and vegetable products made with additional manufacturing/processing (such as dried apple slices; pitted, dried plums, cherries, and apricots; and sulfited raisins). This category does not include dried/dehydrated fruit and vegetable products made without additional manufacturing/processing as described in paragraph (g)(2)(i) of this section. This category also does not include products that require time/temperature control for safety (such as fresh-cut fruits and vegetables).

(iii) Peanut and tree nut products includes processed food products such as roasted peanuts and tree nuts, seasoned peanuts and tree nuts, and peanut and tree nut flours.

(iv) Processed seeds for direct consumption include processed food products such as roasted pumpkin seeds, roasted sunflower seeds, and roasted flax seeds.

(v) Dried/dehydrated herb and spice products includes only processed food products such as dried intact herbs made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling.

(vi) Other herb and spice products includes those processed food products such as chopped fresh herbs, chopped or ground dried herbs (including tea), herbal extracts (e.g., essential oils, extracts containing more than 20 percent ethanol, extracts containing more than 35 percent glycerin), dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars. This category does not include dried/dehydrated herb and spice products made without additional manufacturing/processing beyond drying/dehydrating, packaging, and/or labeling as described in paragraph (g)(2)(v) of this section. This category also does not include products that require time/temperature control for safety, such as fresh herb-infused oils.

(vii) Grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

(viii) Milled grain products include processed food products such as flour, bran, and corn meal.

(ix) Baked goods include processed food products such as breads, brownies, cakes, cookies, and crackers. This category does not include products that require time/temperature control for safety, such as cream-filled pastries.

(x) Other grain products include processed food products such as dried cereal, dried pasta, oat flakes, and popcorn. This category does not include milled grain products as described in paragraph (g)(2)(viii) of this section or baked goods as described in paragraph (g)(2)(ix) of this section.

(3) Subparts C and G of this part do not apply to on-farm packing or holding of food by a small or very small business, and § 117.201 does not apply to on-farm packing or holding of food by a very small business, if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations--i.e., packing (or re-packing) (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

(i) Baked goods (e.g., bread and cookies);

(ii) Candy (e.g., hard candy, fudge, maple candy, maple cream, nut brittles, taffy, and toffee);

(iii) Cocoa beans (roasted);

(iv) Cocoa products;

(v) Coffee beans (roasted);

(vi) Game meat jerky;

(vii) Gums, latexes, and resins that are processed foods;

(viii) Honey (pasteurized);

(ix) Jams, jellies, and preserves;
(x) Milled grain products (e.g., flour, bran, and corn meal);
(xi) Molasses and treacle;
(xii) Oils (e.g., olive oil and sunflower seed oil);
(xiii) Other fruit and vegetable products (e.g., flours made from legumes; pitted, dried fruits; sliced, dried apples; snack chips);
(xiv) Other grain products (e.g., dried pasta, oat flakes, and popcorn);
(xv) Other herb and spice products (e.g., chopped or ground dried herbs, herbal extracts);
(xvi) Peanut and tree nut products (e.g., roasted peanuts and tree nut flours);
(xvii) Processed seeds for direct consumption (e.g., roasted pumpkin seeds);
(xviii) Soft drinks and carbonated water;
(xix) Sugar;
(xx) Syrups (e.g., maple syrup and agave syrup);
(xxi) Trail mix and granola;
(xxii) Vinegar; and
(xxiii) Any other processed food that does not require time/temperature control for safety (e..g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form).

(h)(1) The exemption in paragraph (h)(3) of this section applies to manufacturing/processing of foods on a farm mixed-type facility, except for manufacturing/processing that is within the "farm" definition in § 1.227 of this chapter. Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins, and drying/dehydrating fresh herbs to produce dried herbs), and packaging and labeling such commodities, without additional manufacturing/processing (such as chopping and slicing), are within the "farm" definition in § 1.227 of this chapter. In addition, treatment to manipulate ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling the treated raw agricultural commodities, without additional manufacturing/processing, is within the "farm" definition. In addition, coating intact fruits and vegetables with wax, oil, or resin used for the purpose of storage or transportation is within the "farm" definition. Activities that are within the "farm" definition, when conducted on a farm mixed-type facility, are not subject to the requirements of subparts C and G of this part and therefore do not need to be specified in the exemption.
(2) The terms in paragraph (g)(2) of this section describe certain foods associated with the activity/food combinations in paragraph (h)(3) of this section.
(3) Subparts C and G of this part do not apply to on-farm manufacturing/processing activities conducted by a small or very small business for distribution into commerce, and §117.201 does not apply to on-farm manufacturing/processing activities conducted by a very small business for distribution into commerce, if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk manufacturing/processing activity/food combinations:
(i) Boiling gums, latexes, and resins;
(ii) Chopping, coring, cutting, peeling, pitting, shredding, and slicing acid fruits and vegetables that have a pH less than 4.2 (e.g., cutting lemons and limes), baked goods (e.g., slicing bread), dried/dehydrated fruit and vegetable products (e.g., pitting dried plums), dried herbs and other spices (e.g., chopping intact, dried basil), game meat jerky, gums/latexes/resins, other grain products (e.g., shredding dried cereal), peanuts and tree nuts, and peanut and tree nut products (e.g., chopping roasted peanuts);
(iii) Coating dried/dehydrated fruit and vegetable products (e.g., coating raisins with chocolate), other fruit and vegetable products except for non-dried, non-intact fruits and vegetables (e.g., coating dried plum pieces, dried pitted cherries, and dried pitted apricots with chocolate are low-risk activity/food combinations but coating apples on a stick with caramel is not a low-risk activity/food combination), other grain products (e.g., adding caramel to popcorn or adding seasonings to popcorn provided that the seasonings have been treated to significantly minimize pathogens, peanuts and tree nuts (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens), and peanut and tree nut products (e.g., adding seasonings provided that the seasonings have been treated to significantly minimize pathogens);
(iv) Drying/dehydrating (that includes additional manufacturing or is performed on processed foods) other fruit and vegetable products with pH less than 4.2 (e.g., drying cut fruit and

vegetables with pH less than 4.2), and other herb and spice products (e.g., drying chopped fresh herbs, including tea);
(v) Extracting (including by pressing, by distilling, and by solvent extraction) dried/dehydrated herb and spice products (e.g., dried mint), fresh herbs (e.g., fresh mint), fruits and vegetables (e.g., olives, avocados), grains (e.g., oilseeds), and other herb and spice products (e.g., chopped fresh mint, chopped dried mint);
(vi) Freezing acid fruits and vegetables with pH less than 4.2 and other fruit and vegetable products with pH less than 4.2 (e.g., cut fruits and vegetables);
(vii) Grinding/cracking/crushing/milling baked goods (e.g., crackers), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., raisins and dried legumes), dried/dehydrated herb and spice products (e.g., intact dried basil), grains (e.g., oats, rice, rye, wheat), other fruit and vegetable products (e.g., dried, pitted dates), other grain products (e.g., dried cereal), other herb and spice products (e.g., chopped dried herbs), peanuts and tree nuts, and peanut and tree nut products (e.g., roasted peanuts);
(viii) Labeling baked goods that do not contain food allergens, candy that does not contain food allergens, cocoa beans (roasted), cocoa products that do not contain food allergens), coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products that do not contain food allergens (e.g., corn meal) or that are single-ingredient foods (e.g., wheat flour, wheat bran), molasses and treacle, oils, other fruit and vegetable products that do not contain food allergens (e.g., snack chips made from potatoes or plantains), other grain products that do not contain food allergens (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut or tree nut products,(provided that they are single-ingredient, or are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration, or both (e.g., roasted or seasoned whole nuts, single-ingredient peanut or tree nut flours)), processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola (other than those containing milk chocolate and provided that peanuts and/or tree nuts are in forms in which the consumer can reasonably be expected to recognize the food allergen(s) without label declaration), vinegar, and any other processed food that does not require time/temperature control for safety and that does not contain food allergens (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);
(ix) Making baked goods from milled grain products (e.g., breads and cookies);
(x) Making candy from peanuts and tree nuts (e.g., nut brittles), sugar/syrups (e.g., taffy, toffee), and saps (e.g., maple candy, maple cream);
(xi) Making cocoa products from roasted cocoa beans;
(xii) Making dried pasta from grains;
(xiii) Making jams, jellies, and preserves from acid fruits and vegetables with a pH of 4.6 or below;
(xiv) Making molasses and treacle from sugar beets and sugarcane;
(xv) Making oat flakes from grains;
(xvi) Making popcorn from grains;
(xvii) Making snack chips from fruits and vegetables (e.g., making plantain and potato chips);
(xviii) Making soft drinks and carbonated water from sugar, syrups, and water;
(xix) Making sugars and syrups from fruits and vegetables (e.g., dates), grains (e.g., rice, sorghum), other grain products (e.g., malted grains such as barley), saps (e.g., agave, birch, maple, palm), sugar beets, and sugarcane;
(xx) Making trail mix and granola from cocoa products (e.g., chocolate), dried/dehydrated fruit and vegetable products (e.g., raisins), other fruit and vegetable products (e.g., chopped dried fruits), other grain products (e.g., oat flakes), peanut and tree nut products, and processed seeds for direct consumption, provided that peanuts, tree nuts, and processed seeds are treated to significantly minimize pathogens;
(xxi) Making vinegar from fruits and vegetables, other fruit and vegetable products (e.g., fruit wines, apple cider), and other grain products (e.g., malt);
(xxii) Mixing baked goods (e.g., types of cookies), candy (e.g., varieties of taffy), cocoa beans (roasted), coffee beans (roasted), dried/dehydrated fruit and vegetable products (e.g., dried blueberries, dried currants, and raisins), dried/dehydrated herb and spice products (e.g., dried, intact basil and dried, intact oregano), honey (pasteurized), milled grain products (e.g., flour, bran, and corn meal), other fruit and vegetable products (e.g., dried, sliced apples and dried, sliced

peaches), other grain products (e.g., different types of dried pasta), other herb and spice products (e.g., chopped or ground dried herbs, dried herb- or spice-infused honey, and dried herb- or spice-infused oils and/or vinegars), peanut and tree nut products, sugar, syrups, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

(xxiii) Packaging baked goods (e.g., bread and cookies), candy, cocoa beans (roasted), cocoa products, coffee beans (roasted), game meat jerky, gums/latexes/resins that are processed foods, honey (pasteurized), jams/jellies/preserves, milled grain products (e.g., flour, bran, corn meal), molasses and treacle, oils, other fruit and vegetable products (e.g., pitted, dried fruits; sliced, dried apples; snack chips), other grain products (e.g., popcorn), other herb and spice products (e.g., chopped or ground dried herbs), peanut and tree nut products, processed seeds for direct consumption, soft drinks and carbonated water, sugar, syrups, trail mix and granola, vinegar, and any other processed food that does not require time/temperature control for safety (e.g., vitamins, minerals, and dietary ingredients (e.g., bone meal) in powdered, granular, or other solid form);

(xxiv) Pasteurizing honey;

(xxv) Roasting and toasting baked goods (e.g., toasting bread for croutons);

(xxvi) Salting other grain products (e.g., soy nuts), peanut and tree nut products, and processed seeds for direct consumption; and

(xxvii) Sifting milled grain products (e.g., flour, bran, corn meal), other fruit and vegetable products (e.g., chickpea flour), and peanut and tree nut products (e.g., peanut flour, almond flour).

(i)(1) Subparts C and G of this part do not apply with respect to alcoholic beverages at a facility that meets the following two conditions:

(i) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) the facility is required to obtain a permit from, register with, or obtain approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States, or is a foreign facility of a type that would require such a permit, registration, or approval if it were a domestic facility; and

(ii) Under section 415 of the Federal Food, Drug, and Cosmetic Act the facility is required to register as a facility because it is engaged in manufacturing, processing, packing, or holding one or more alcoholic beverages.

(2) Subparts C and G of this part do not apply with respect to food that is not an alcoholic beverage at a facility described in paragraph (i)(1) of this section, provided such food:

(i) Is in prepackaged form that prevents any direct human contact with such food; and

(ii) Constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.

(j) Subparts C and G of this part do not apply to facilities that are solely engaged in the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing.

(k)(1) Except as provided by paragraph (k)(2) of this section, subpart B of this part does not apply to any of the following:

(i) "Farms" (as defined in § 1.227 of this chapter);

(ii) Fishing vessels that are not subject to the registration requirements of part 1, subpart H of this chapter in accordance with § 1.226(f) of this chapter;

(iii) Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities;

(iv) Activities of "farm mixed-type facilities" (as defined in § 1.227 of this chapter) that fall within the definition of "farm"; or

(v) Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts).

(2) If a "farm" or "farm mixed-type facility" dries/dehydrates raw agricultural commodities that are produce as defined in part 112 of this chapter to create a distinct commodity, subpart B of this part applies to the packaging, packing, and holding of the dried commodities. Compliance with this requirement may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

§ 117.7 Applicability of subparts C, D, and G of this part to a facility solely engaged in the storage of unexposed packaged food.

(a) Applicability of subparts C and G. Subparts C and G of this part do not apply to a facility solely engaged in the storage of unexposed packaged food.

(b) Applicability of subpart D. A facility solely engaged in the storage of unexposed packaged food, including unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 117.206 for any unexposed packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 117.8 Applicability of subpart B of this part to the off-farm packing and holding of raw agricultural commodities.

Except as provided by §117.5(k)(1), subpart B of this part applies to the off- farm packaging, packing, and holding of raw agricultural commodities. Compliance with this requirement for raw agricultural commodities that are produce as defined in part 112 of this chapter may be achieved by complying with subpart B of this part or with the applicable requirements for packing and holding in part 112 of this chapter.

§ 117.9 Records required for this subpart.

(a) Records that document training required by § 117.4(b)(2) must be established and maintained.

(b) The records that must be established and maintained are subject to the requirements of subpart F of this part.

Subpart B – Current Good Manufacturing Practice

§ 117.10 Personnel.

The management of the establishment must take reasonable measures and precautions to ensure the following:

(a) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining cleanliness include:

(1) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

§ 117.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator must be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds must include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(b) Plant construction and design. The plant must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes (i.e., manufacturing, processing, packing, and holding). The plant must:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.

(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means.

(3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food, food-contact surfaces, or food-packaging materials with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 117.35 Sanitary operations.

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use. Compliance with this requirement must be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(c) Pest control. Pests must not be allowed in any area of a food plant. Guard, guide, or pest-detecting dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests. The use of pesticides to control pests in the plant is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials.

(e) Sanitation of non-food-contact surfaces. Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of food, food-contact surfaces, and food-packaging materials.

(f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that protects food-contact surfaces from allergen cross-contact and from contamination.

§ 117.37 Sanitary facilities and controls.

Each plant must be equipped with adequate sanitary facilities and accommodations including:

(a) Water supply. The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing must be of adequate size and design and adequately installed and maintained to:

(1) Carry adequate quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

(e) Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

(f) Rubbish and offal disposal. Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

§ 117.40 Equipment and utensils.

(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(c) Equipment that is in areas where food is manufactured, processed, packed, or held and that does not come into contact with food must be so constructed that it can be kept in a clean and sanitary condition.

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.

§ 117.80 Processes and controls.

(a) General. (1) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable.

(3) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.

(6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) Raw materials and other ingredients.

(1) Raw materials and other ingredients must be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Raw materials must be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause allergen cross-contact or increase the level of contamination of the food.

(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins must comply with FDA regulations for poisonous or deleterious substances before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material must comply with applicable FDA regulations for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food.

(5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

(6) Frozen raw materials and other ingredients must be kept frozen. If thawing is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form must be held in a manner that protects against allergen cross-contact and against contamination.

(8) Raw materials and other ingredients that are food allergens, and rework that contains food allergens, must be identified and held in a manner that prevents allergen cross-contact.

(c) Manufacturing operations.

(1) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning.

(2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food.

(3) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

(5) Work-in-process and rework must be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.
(6) Effective measures must be taken to protect finished food from allergen cross-contact and from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they must not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contaminated food. Food transported by conveyor must be protected against allergen cross-contact and against contamination as necessary.
(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.
(8) Adequate measures must be taken to protect against the inclusion of metal or other extraneous material in food.
(9) Food, raw materials, and other ingredients that are adulterated:
(i) Must be disposed of in a manner that protects against the contamination of other food; or
(ii) If the adulterated food is capable of being reconditioned, it must be:
(A) Reconditioned (if appropriate) using a method that has been proven to be effective; or
(B) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act before being incorporated into other food.
(10) Steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.
(11) Heat blanching, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.
(12) Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.
(13) Filling, assembling, packaging, and other operations must be performed in such a way that the food is protected against allergen cross-contact, contamination and growth of undesirable microorganisms.
(14) Food, such as dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies principally on the control of a_w for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.
(15) Food, such as acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms must be monitored and maintained at a pH of 4.6 or below.
(16) When ice is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with § 117.37(a), and must be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

§ 117.93 Warehousing and distribution.
Storage and transportation of food must be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of food, as well as against deterioration of the food and the container.

§ 117.95 Holding and distribution of human food by-products for use as animal food.
(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor, as identified in § 507.12 of this chapter, must be held under conditions that will protect against contamination, including the following:
(1) Containers and equipment used to convey or hold human food by-products for use as animal food before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of human food by-products for use as animal food;

(2) Human food by-products for use as animal food held for distribution must be held in a way to protect against contamination from sources such as trash; and
(3) During holding, human food by-products for use as animal food must be accurately identified.
(b) Labeling that identifies the by-product by the common or usual name must be affixed to or accompany human food by-products for use as animal food when distributed.
(c) Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against contamination of the human food by-products for use as animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.

§ 117.110 Defect action levels.
(a) The manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
(b) The mixing of a food containing defects at levels that render that food adulterated with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the Defect Levels Handbook, which is accessible at http://www.fda.gov/pchfrule and at http://www.fda.gov.

Subpart C– Hazard Analysis and Risk-Based Preventive Controls
§ 117.126 Food safety plan.
(a) Requirement for a food safety plan.
(1) You must prepare, or have prepared, and implement a written food safety plan.
(2) The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals.
(b) Contents of a food safety plan. The written food safety plan must include:
(1) The written hazard analysis as required by § 117.130(a)(2);
(2) The written preventive controls as required by § 117.135(b);
(3) The written supply-chain program as required by subpart G of this part;
(4) The written recall plan as required by § 117.139(a); and
(5) The written procedures for monitoring the implementation of the preventive controls as required by § 117.145(a)(1);
(6) The written corrective action procedures as required by § 117.150(a)(1); and
(7) The written verification procedures as required by § 117.165(b).
(c) Records. The food safety plan required by this section is a record that is subject to the requirements of subpart F of this part.

§ 117.130 Hazard analysis.
(a) Requirement for a hazard analysis.
(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control.
(2) The hazard analysis must be written regardless of its outcome.
(b) Hazard identification. The hazard identification must consider:
(1) Known or reasonably foreseeable hazards that include:
(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;
(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and
(iii) Physical hazards (such as stones, glass, and metal fragments); and
(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:
(i) The hazard occurs naturally;
(ii) The hazard may be unintentionally introduced; or
(iii) The hazard may be intentionally introduced for purposes of economic gain.
(c) Hazard evaluation.

(1)(i) The hazard analysis must include an evaluation of the hazards identified in paragraph (b) of this section to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.

(ii) The hazard evaluation required by paragraph (c)(1)(i) of this section must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

(2) The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

(i) The formulation of the food;
(ii) The condition, function, and design of the facility and equipment;
(iii) Raw materials and other ingredients;
(iv) Transportation practices;
(v) Manufacturing/processing procedures;
(vi) Packaging activities and labeling activities;
(vii) Storage and distribution;
(viii) Intended or reasonably foreseeable use;
(ix) Sanitation, including employee hygiene; and
(x) Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins).

§ 117.135 Preventive controls.

(a)(1) You must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(2) Preventive controls required by paragraph (a)(1) of this section include:

(i) Controls at critical control points (CCPs), if there are any CCPs; and
(ii) Controls, other than those at CCPs, that are also appropriate for food safety.

(b) Preventive controls must be written.

(c) Preventive controls include, as appropriate to the facility and the food:

(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system:

(i) Parameters associated with the control of the hazard; and
(ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.

(2) Food allergen controls. Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(3) Sanitation controls. Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the:

(i) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment;

(ii) Prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product.

(4) Supply-chain controls. Supply-chain controls include the supply-chain program as required by subpart G of this part.

(5) Recall plan. Recall plan as required by § 117.139.

(6) Other controls. Preventive controls include any other procedures, practices, and processes necessary to satisfy the requirements of paragraph (a) of this section. Examples of other controls include hygiene training and other current good manufacturing practices.

§ 117.136 Circumstances in which the owner, operator, or agent in charge of a manufacturing/processing facility is not required to implement a preventive control.

(a) Circumstances. If you are a manufacturer/processor, you are not required to implement a preventive control when you identify a hazard requiring a preventive control (identified hazard) and any of the following circumstances apply:

(1) You determine and document that the type of food (e.g., raw agricultural commodities such as cocoa beans, coffee beans, and grains) could not be consumed without application of an appropriate control.

(2) You rely on your customer who is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to ensure that the identified hazard will be significantly minimized or prevented and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the identified hazard.

(3) You rely on your customer who is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart to provide assurance it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance that it is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements.

(4) You rely on your customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and you:

(i) Disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(ii) Annually obtain from your customer written assurance, subject to the requirements of § 117.137, that your customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and

(B) Will only sell to another entity that agrees, in writing, it will:

(1) Follow procedures (identified in a written assurance) that will significantly minimize or prevent the identified hazard (if the entity is subject to the requirements for hazard analysis and risk-based preventive controls in this subpart) or manufacture, process, or prepare the food in accordance with applicable food safety requirements (if the entity is not subject to the requirements for hazard analysis and risk-based preventive controls in this subpart); or

(2) Obtain a similar written assurance from the entity's customer, subject to the requirements of § 117.137, as in paragraphs (a)(4)(ii)(A) and (B) of this section, as appropriate; or

(5) You have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food you distribute and you document the implementation of that system.

(b) Records. You must document any circumstance, specified in paragraph (a) of this section, that applies to you, including:

(1) A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;

(2) The annual written assurance from your customer in accordance with paragraph (a)(2) of this section;
(3) The annual written assurance from your customer in accordance with paragraph (a)(3) of this section;
(4) The annual written assurance from your customer in accordance with paragraph (a)(4) of this section; and
(5) Your system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food you distribute.

§ 117.137 Provision of assurances required under § 117.136(a)(2), (3), and (4).
A facility that provides a written assurance under § 117.136(a)(2), (3), or (4) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 117.139 Recall plan.
For food with a hazard requiring a preventive control:
(a) You must establish a written recall plan for the food.
(b) The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:
(1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;
(2) Notify the public about any hazard presented by the food when appropriate to protect public health;
(3) Conduct effectiveness checks to verify that the recall is carried out; and
(4) Appropriately dispose of recalled food--e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

§ 117.140 Preventive control management components.
(a) Except as provided by paragraphs (b) and (c) of this section, the preventive controls required under § 117.135 are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:
(1) Monitoring in accordance with § 117.145;
(2) Corrective actions and corrections in accordance with § 117.150; and
(3) Verification in accordance with § 117.155.
(b) The supply-chain program established in subpart G of this part is subject to the following preventive control management components as appropriate to ensure the effectiveness of the supply-chain program, taking into account the nature of the hazard controlled before receipt of the raw material or other ingredient:
(1) Corrective actions and corrections in accordance with § 117.150, taking into account the nature of any supplier non-conformance;
(2) Review of records in accordance with § 117.165(a)(4); and
(3) Reanalysis in accordance with § 117.170.
(c) The recall plan established in § 117.139 is not subject to the requirements of paragraph (a) of this section.

§ 117.145 Monitoring.
As appropriate to the nature of the preventive control and its role in the facility's food safety system:
(a) Written procedures. You must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control; and
(b) Monitoring. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed.
(c) Records.
(1) Requirement to document monitoring. You must document the monitoring of preventive controls in accordance with this section in records that are subject to verification in accordance with § 117.155(a)(2) and records review in accordance with § 117.165(a)(4)(i).
(2) Exception records.
(i) Records of refrigeration temperature during storage of food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens may be affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control.

(ii) Exception records may be adequate in circumstances other than monitoring of refrigeration temperature.

§ 117.150 Corrective actions and corrections.

(a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:

(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:

(i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and

(ii) The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(2) The corrective action procedures must describe the steps to be taken to ensure that:

(i) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control;

(ii) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur;

(iii) All affected food is evaluated for safety; and

(iv) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

(b) Corrective action in the event of an unanticipated food safety problem.

(1) Except as provided by paragraph (c) of this section, you are subject to the requirements of paragraphs (b)(2) of this section if any of the following circumstances apply:

(i) A preventive control is not properly implemented and a corrective action procedure has not been established;

(ii) A preventive control, combination of preventive controls, or the food safety plan as a whole is found to be ineffective; or

(iii) A review of records in accordance with § 117.165(a)(4) finds that the records are not complete, the activities conducted did not occur in accordance with the food safety plan, or appropriate decisions were not made about corrective actions.

(2) If any of the circumstances listed in paragraph (b)(1) of this section apply, you must:

(i) Take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and, as necessary, prevent affected food from entering commerce as would be done following a corrective action procedure under paragraphs (a)(2)(i) through (iv) of this section; and

(ii) When appropriate, reanalyze the food safety plan in accordance with § 117.170 to determine whether modification of the food safety plan is required.

(c) Corrections. You do not need to comply with the requirements of paragraphs (a) and (b) of this section if:

(1) You take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in § 117.135(c)(2)(i) or the sanitation controls in § 117.135(c)(3)(i) or (ii); or

(2) You take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety.

(d) Records. All corrective actions (and, when appropriate, corrections) taken in accordance with this section must be documented in records. These records are subject to verification in accordance with §117.155(a)(3) and records review in accordance with §117.165(a)(4)(i).

§ 117.155 Verification.

(a) Verification activities. Verification activities must include, as appropriate to the nature of the preventive control and its role in the facility's food safety system:

(1) Validation in accordance with § 117.160.

(2) Verification that monitoring is being conducted as required by § 117.140 (and in accordance with § 117.145).

(3) Verification that appropriate decisions about corrective actions are being made as required by § 117.140 (and in accordance with § 117.150).

(4) Verification of implementation and effectiveness in accordance with § 117.165; and

(5) Reanalysis in accordance with § 117.170.

(b) Documentation. All verification activities conducted in accordance with this section must be documented in records.

§ 117.160 Validation.

(a) You must validate that the preventive controls identified and implemented in accordance with § 117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system.

(b) The validation of the preventive controls:

(1) Must be performed (or overseen) by a preventive controls qualified individual:

(i)(A) Prior to implementation of the food safety plan; or

(B) When necessary to demonstrate the control measures can be implemented as designed:

(1) Within 90 calendar days after production of the applicable food first begins; or

(2) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90 calendar days after production of the applicable food first begins;

(ii) Whenever a change to a control measure or combination of control measures could impact whether the control measure or combination of control measures, when properly implemented, will effectively control the hazards; and

(iii) Whenever a reanalysis of the food safety plan reveals the need to do so;

(2) Must include obtaining and evaluating scientific and technical evidence (or, when such evidence is not available or is inadequate, conducting studies) to determine whether the preventive controls, when properly implemented, will effectively control the hazards; and

(c) You do not need to validate:

(1) The food allergen controls in § 117.135(c)(2);

(2) The sanitation controls in § 117.135(c)(3);

(3) The recall plan in § 117.139;

(4) The supply-chain program in subpart G of this part; and

(5) Other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system.

§ 117.165 Verification of implementation and effectiveness.

(a) Verification activities. You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

(1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy);

(2) Product testing, for a pathogen (or appropriate indicator organism) or other hazard;

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples; and

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and

(ii) Records of calibration, testing (e.g., product testing, environmental monitoring), supplier and supply-chain verification activities, and other verification activities within a reasonable time after the records are created; and

(5) Other activities appropriate for verification of implementation and effectiveness.

(b) Written procedures. As appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, you must establish and implement written procedures for the following activities:

(1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy) as required by paragraph (a)(1) of this section.

(2) Product testing as required by paragraph (a)(2) of this section. Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing; and

(vii) Include the corrective action procedures required by § 117.150(a)(1).

§ 117.170 Reanalysis.

(a) You must conduct a reanalysis of the food safety plan as a whole at least once every 3 years;

(b) You must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan:

(1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard;

(2) Whenever you become aware of new information about potential hazards associated with the food;

(3) Whenever appropriate after an unanticipated food safety problem in accordance with § 117.150(b); and

(4) Whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective.

(c) You must complete the reanalysis required by paragraphs (a) and (b) of this section and validate, as appropriate to the nature of the preventive control and its role in the facility's food safety system, any additional preventive controls needed to address the hazard identified:

(1) Before any change in activities (including any change in preventive control) at the facility is operative; or

(2) When necessary to demonstrate the control measures can be implemented as designed:

(i) Within 90 calendar days after production of the applicable food first begins; or

(ii) Within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 90-calendar days after production of the applicable food first begins.

(d) You must revise the written food safety plan if a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or document the basis for the conclusion that no revisions are needed.

(e) A preventive controls qualified individual must perform (or oversee) the reanalysis.

(f) You must conduct a reanalysis of the food safety plan when FDA determines it is necessary to respond to new hazards and developments in scientific understanding.

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

(a) One or more preventive controls qualified individuals must do or oversee the following:

(1) Preparation of the food safety plan (§ 117.126(a)(2));

(2) Validation of the preventive controls (§ 117.160(b)(1));

(3) Written justification for validation to be performed in a timeframe that exceeds the first 90 calendar days of production of the applicable food;

(4) Determination that validation is not required (§ 117.160(c)(5));

(5) Review of records (§ 117.165(a)(4));

(6) Written justification for review of records of monitoring and corrective actions within a timeframe that exceeds 7 working days;

(7) Reanalysis of the food safety plan (§ 117.170(d)); and

(8) Determination that reanalysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

(b) A qualified auditor must conduct an onsite audit (§ 117.435(a)).

(c)(1) To be a preventive controls qualified individual, the individual must have 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 be otherwise qualified through job experience to develop and apply a food safety system. Job experience may qualify an individual to perform these functions if such experience has provided an individual with knowledge at least equivalent to that provided through the standardized curriculum. This individual may be, but is not required to be, an employee of the facility.

(2) To be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function.

(d) All applicable training in the development and application of risk-based preventive controls must be documented in records, including the date of the training, the type of training, and the person(s) trained.

§ 117.190 Implementation records required for this subpart.

(a) You must establish and maintain the following records documenting implementation of the food safety plan:

(1) Documentation, as required by § 117.136(b), of the basis for not establishing a preventive control in accordance with § 117.136(a);

(2) Records that document the monitoring of preventive controls;

(3) Records that document corrective actions;

(4) Records that document verification, including, as applicable, those related to:

(i) Validation;

(ii) Verification of monitoring;

(iii) Verification of corrective actions;

(iv) Calibration of process monitoring and verification instruments;

(v) Product testing;

(vi) Environmental monitoring;

(vii) Records review; and

(viii) Reanalysis;

(5) Records that document the supply-chain program; and

(6) Records that document applicable training for the preventive controls qualified individual and the qualified auditor.

(b) The records that you must establish and maintain are subject to the requirements of subpart F of this part.

Subpart D – Modified Requirements

§ 117.201 Modified requirements that apply to a qualified facility.

(a) Attestations to be submitted. A qualified facility must submit the following attestations to FDA:

(1) An attestation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and

(2)(i) An attestation that you have identified the potential hazards associated with the food being produced, are implementing preventive controls to address the hazards, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) An attestation that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries, including an attestation based on licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight.

(b) Procedure for submission. The attestations required by paragraph (a) of this section must be submitted to FDA by one of the following means:

(1) Electronic submission. To submit electronically, go to http://www.fda.gov/furls and follow the instructions. This Web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. FDA encourages electronic submission.

(2) Submission by mail.

(i) You must use Form FDA 3942a. You may obtain a copy of this form by any of the following mechanisms:

(A) Download it from http://www.fda.gov/pchfrule;

(B) Write to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20740; or

(C) Request a copy of this form by phone at 1-800-216-7331 or 301-575-0156.

(ii) Send a paper Form FDA 3942a to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Parkway, College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c) Frequency of determination of status and submission.

(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By December 17, 2018, for a facility that begins manufacturing, processing, packing, or holding food before September 17, 2018;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding food after September 17, 2018; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from "not a qualified facility" to "qualified facility" based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from "qualified facility" to "not a qualified facility" based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form 3942a by July 31 of the applicable calendar year.

(d) Timeframe for compliance with subparts C and G of this part when the facility status changes to "not a qualified facility." When the status of a facility changes from "qualified facility" to "not a qualified facility," the facility must comply with subparts C and G of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) Notification to consumers. A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the food was manufactured or processed (including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities), as follows:

(1) If a food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the food.

(2) If a food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f) Records.

(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

§ 117.206 Modified requirements that apply to a facility solely engaged in the storage of unexposed packaged food.

(a) If a facility that is solely engaged in the storage of unexposed packaged food stores any such refrigerated packaged food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by pathogens, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:

(1) Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens;

(2) Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;

(3) If there is a loss of temperature control that may impact the safety of such refrigerated packaged food, take appropriate corrective actions to:

(i) Correct the problem and reduce the likelihood that the problem will recur;

(ii) Evaluate all affected food for safety; and

(iii) Prevent the food from entering commerce, if you cannot ensure the affected food is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act;

(4) Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days;

(5) Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged food; and

(iii) Records documenting verification activities.

(b) The records that a facility must establish and maintain under paragraph (a)(5) of this section are subject to the requirements of subpart F of this part.

Subpart E – Withdrawal of a Qualified Facility Exemption

§ 117.251 Circumstances that may lead FDA to withdraw a qualified facility exemption.

(a) FDA may withdraw a qualified facility exemption under § 117.5(a):

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

(2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conditions or conduct associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(b) Before FDA issues an order to withdraw a qualified facility exemption, FDA:

(1) May consider one or more other actions to protect the public health or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, suspension of registration, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the facility to address the circumstances that may lead FDA to withdraw the exemption.

§ 117.254 Issuance of an order to withdraw a qualified facility exemption.
(a) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.
(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.
(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.
(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 117.257 Contents of an order to withdraw a qualified facility exemption.
An order to withdraw a qualified facility exemption under § 117.5(a) must include the following information:
(a) The date of the order;
(b) The name, address, and location of the qualified facility;
(c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order:
(1) An active investigation of a foodborne illness outbreak that is directly linked to the facility; or
(2) Conditions or conduct associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.
(d) A statement that the facility must either:
(1) Comply with subparts C and G of this part on the date that is 120 calendar days after the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.
(e) A statement that a facility may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 117.287;
(f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart;
(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.270;
(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and
(i) The name and the title of the FDA representative who approved the order.

§ 117.260 Compliance with, or appeal of, an order to withdraw a qualified facility exemption.
(a) If you receive an order under § 117.254 to withdraw a qualified facility exemption, you must either:
(1) Comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or
(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 117.264.
(b) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.
(c) If you appeal the order, and FDA confirms the order:
(1) You must comply with applicable requirements of this part within 120 calendar days of the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and
(2) You are no longer subject to the modified requirements in § 117.201.

§ 117.264 Procedure for submitting an appeal.
(a) To appeal an order to withdraw a qualified facility exemption, you must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of confirmation of the order; and
(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which you rely.

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), you may include a written request for an informal hearing as provided in § 117.267.

§ 117.267 Procedure for requesting an informal hearing.

(a) If you appeal the order, you:
(1) May request an informal hearing; and
(2) Must submit any request for an informal hearing together with your written appeal submitted in accordance with § 117.264 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, written notice of the determination will be given to you explaining the reason for the denial.

§ 117.270 Requirements applicable to an informal hearing.

If you request an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by you and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1-calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:
(1) The order withdrawing an exemption under §§ 117.254 and 117.257, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.
(3) Section 117.274, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.
(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2-calendar days of issuance of the report. The presiding officer will then issue the final decision.
(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.270(c)(4) are part of the administrative record.
(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.
(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) of this chapter does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1) through (3) and (a)(5) of this chapter and 117.270(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 117.274 Presiding officer for an appeal and for an informal hearing.

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 117.277 Timeframe for issuing a decision on an appeal.
(a) If you appeal the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.
(b) If you appeal the order and request an informal hearing:
(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2-calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.270(c)(4), and must issue a final decision within 10-calendar days after the hearing is held; or
(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 117.280 Revocation of an order to withdraw a qualified facility exemption.
An order to withdraw a qualified facility exemption is revoked if:
(a) You appeal the order and request an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10-calendar days after the hearing, or issues a decision revoking the order within that time; or
(b) You appeal the order and request an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10-calendar days after the appeal is filed, or issues a decision revoking the order within that time; or
(c) You appeal the order without requesting an informal hearing, and FDA does not confirm the order within the 10-calendar days after the appeal is filed, or issues a decision revoking the order within that time.

§ 117.284 Final agency action.
Confirmation of a withdrawal order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 117.287 Reinstatement of a qualified facility exemption that was withdrawn.
(a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that a facility has adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at the facility and that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or on the request of a facility, reinstate the exemption.
(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:
(1) Submit a request, in writing, to the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and
(2) Present data and information to demonstrate that you have adequately resolved any problems with the conditions and conduct that are material to the safety of the food manufactured, processed, packed, or held at your facility, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.
(c) If your exemption was withdrawn under § 117.251(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will reinstate your exemption under § 117.5(a), and FDA will notify you in writing that your exempt status has been reinstated.
(d) If your exemption was withdrawn under both § 117.251(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your facility, FDA will inform you of this finding, and you may ask FDA to reinstate your exemption under § 117.5(a) in accordance with the requirements of paragraph (b) of this section.

Subpart F--Requirements Applying to Records That Must Be Established and Maintained
§ 117.301 Records subject to the requirements of this subpart.
(a) Except as provided by paragraphs (b) and (c) of this section, all records required by this part are subject to all requirements of this subpart.

(b) The requirements of § 117.310 apply only to the written food safety plan.
(c) The requirements of § 117.305(b), (d), (e), and (f) do not apply to the records required by § 117.201.

§ 117.305 General requirements applying to records.

Records must:
(a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;
(b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;
(c) Be accurate, indelible, and legible;
(d) Be created concurrently with performance of the activity documented;
(e) Be as detailed as necessary to provide history of work performed; and
(f) Include:
(1) Information adequate to identify the plant or facility (e.g., the name, and when necessary, the location of the plant or facility);
(2) The date and, when appropriate, the time of the activity documented;
(3) The signature or initials of the person performing the activity; and
(4) Where appropriate, the identity of the product and the lot code, if any.
(g) Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 117.310 Additional requirements applying to the food safety plan.

The owner, operator, or agent in charge of the facility must sign and date the food safety plan:
(a) Upon initial completion; and
(b) Upon any modification.

§ 117.315 Requirements for record retention.

(a)(1) All records required by this part must be retained at the plant or facility for at least 2 years after the date they were prepared.
(2) Records that a facility relies on during the 3-year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.
(b) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, must be retained by the facility for at least 2 years after their use is discontinued (e.g., because the facility has updated the written food safety plan (§ 117.126) or records that document validation of the written food safety plan (§ 117.155(b)));
(c) Except for the food safety plan, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. The food safety plan must remain onsite. Electronic records are considered to be onsite if they are accessible from an onsite location.
(d) If the plant or facility is closed for a prolonged period, the food safety plan may be transferred to some other reasonably accessible location but must be returned to the plant or facility within 24 hours for official review upon request.

§ 117.320 Requirements for official review.

All records required by this part must be made promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request.

§ 117.325 Public disclosure.

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

§ 117.330 Use of existing records.

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this subpart. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this subpart.
(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 117.335 Special requirements applicable to a written assurance.

(a) Any written assurance required by this part must contain the following elements:
- (1) Effective date;
- (2) Printed names and signatures of authorized officials;
- (3) The applicable assurance under:
  - (i) Section 117.136(a)(2);
  - (ii) Section 117.136(a)(3);
  - (iii) Section 117.136(a)(4);
  - (iv) Section 117.430(c)(2);
  - (v) Section 117.430(d)(2); or
  - (vi) Section 117.430(e)(2);

(b) A written assurance required under § 117.136(a)(2), (3), or (4) must include:
- (1) Acknowledgement that the facility that provides the written assurance assumes legal responsibility to act consistently with the assurance and document its actions taken to satisfy the written assurance; and
- (2) Provision that if the assurance is terminated in writing by either entity, responsibility for compliance with the applicable provisions of this part reverts to the manufacturer/processor as of the date of termination.

Subpart G--Supply-Chain Program

§ 117.405 Requirement to establish and implement a supply-chain program.

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(2) A receiving facility that is an importer, is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, and has documentation of verification activities conducted under § 1.506(e) of this chapter (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient.

(3) The requirements in this subpart do not apply to food that is supplied for research or evaluation use, provided that such food:
- (i) Is not intended for retail sale and is not sold or distributed to the public;
- (ii) Is labeled with the statement "Food for research or evaluation use";
- (iii) Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of; and
- (iv) Is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:
- (1) Verify the supply-chain-applied control; or
- (2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

§ 117.410 General requirements applicable to a supply-chain program.

(a) The supply-chain program must include:
- (1) Using approved suppliers as required by § 117.420;
- (2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425;
- (3) Conducting supplier verification activities as required by §§ 117.430 and 117.435;
- (4) Documenting supplier verification activities as required by § 117.475; and
- (5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 117.475, or obtaining

documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits;

(2) Sampling and testing of the raw material or other ingredient;

(3) Review of the supplier's relevant food safety records; and

(4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(d)(1) Except as provided by paragraph (d)(2) of this section, in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted, the following must be considered:

(i) The hazard analysis of the food, including the nature of the hazard controlled before receipt of the raw material or other ingredient, applicable to the raw material and other ingredients;

(ii) The entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control;

(iii) Supplier performance, including:

(A) The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients;

(B) Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations); and

(C) The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems; and

(iv) Any other factors as appropriate and necessary, such as storage and transportation practices.

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

(i) A qualified facility as defined by § 117.3;

(ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or

(iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with § 117.150 to ensure that raw materials or other ingredients from the supplier do not cause food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

§ 117.415 Responsibilities of the receiving facility.

(a)(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct the appropriate supplier verification activities, with appropriate documentation.

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of § 117.410(b)(4).

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435.

§ 117.420 Using approved suppliers.

(a) Approval of suppliers. The receiving facility must approve suppliers in accordance with the requirements of § 117.410(d), and document that approval, before receiving raw materials and other ingredients received from those suppliers;

(b) Written procedures for receiving raw materials and other ingredients.

(1) Written procedures for receiving raw materials and other ingredients must be established and followed;

(2) The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use); and

(3) Use of the written procedures for receiving raw materials and other ingredients must be documented.

§ 117.425 Determining appropriate supplier verification activities (including determining the frequency of conducting the activity).

Appropriate supplier verification activities (including the frequency of conducting the activity) must be determined in accordance with the requirements of § 117.410(d).

§ 117.430 Conducting supplier verification activities for raw materials and other ingredients.

(a) Except as provided by paragraph (c), (d), or (e) of this section, one or more of the supplier verification activities specified in § 117.410(b), as determined under § 117.410(d), must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter.

(b)(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans:

(i) The appropriate supplier verification activity is an onsite audit of the supplier; and

(ii) The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.

(2) The requirements of paragraph (b)(1) of this section do not apply if there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

(c) If a supplier is a qualified facility as defined by § 117.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 117.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable,

relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:

(i) A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or

(ii) A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

(d) If a supplier is a farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, the receiving facility does not need to comply with paragraphs (a) and (b) of this section for produce that the receiving facility receives from the farm as a raw material or other ingredient if the receiving facility:

(1) Obtains written assurance that the raw material or other ingredient provided by the supplier is not subject to part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interests that influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity.

§ 117.435 Onsite audit.

(a) An onsite audit of a supplier must be performed by a qualified auditor.

(b) If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., Hazard Analysis and Critical Control Point (HACCP) plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(c)(1) The following may be substituted for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

(i) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives of State, local, tribal, or territorial agencies; or

(ii) For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

§ 117.475 Records documenting the supply-chain program.

(a) The records documenting the supply-chain program are subject to the requirements of subpart F of this part.

(b) The receiving facility must review the records listed in paragraph (c) of this section in accordance with § 117.165(a)(4).

(c) The receiving facility must document the following in records as applicable to its supply-chain program:

(1) The written supply-chain program;

(2) Documentation that a receiving facility that is an importer is in compliance with the foreign supplier verification program requirements under part 1, subpart L of this chapter, including documentation of verification activities conducted under § 1.506(e) of this chapter;

(3) Documentation of the approval of a supplier;

(4) Written procedures for receiving raw materials and other ingredients;

(5) Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients;

(6) Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(7) Documentation of the conduct of an onsite audit. This documentation must include:

(i) The name of the supplier subject to the onsite audit;

(ii) Documentation of audit procedures;

(iii) The dates the audit was conducted;

(iv) The conclusions of the audit;

(v) Corrective actions taken in response to significant deficiencies identified during the audit; and

(vi) Documentation that the audit was conducted by a qualified auditor;

(8) Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include:

(i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested;

(ii) Identification of the test(s) conducted, including the analytical method(s) used;

(iii) The date(s) on which the test(s) were conducted and the date of the report;

(iv) The results of the testing;

(v) Corrective actions taken in response to detection of hazards; and

(vi) Information identifying the laboratory conducting the testing;

(9) Documentation of the review of the supplier's relevant food safety records. This documentation must include:

(i) The name of the supplier whose records were reviewed;

(ii) The date(s) of review;

(iii) The general nature of the records reviewed;

(iv) The conclusions of the review; and

(v) Corrective actions taken in response to significant deficiencies identified during the review;

(10) Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient;

(11) Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans;

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility:

(i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and

regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

(16) Documentation of actions taken with respect to supplier non-conformance;

(17) Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier; and

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third-party qualified auditor in accordance with §§ 117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier.

~~~~~~
~~~~~~

NOTES:

Appendix 2: Food Safety Plan Worksheets

General Information

Worksheets are recommended to document the product description, hazard analysis and preventive controls. The Hazard Analysis form should contain information to justify the identification of the hazards requiring preventive controls and the types of preventive controls applied. The information in the Food Safety Plan must explain the details for each preventive control.

There is no standardized or mandated format for documenting the Food Safety Plan. It is recommended that the information be arranged in the Food Safety Plan in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan. For example, the hazard analysis should contain information to justify the identification of each hazard requiring a preventive control and the types of preventive controls applied. Details should be explained for each preventive control form used for process preventive controls, which may also be adapted for allergen preventive controls. However, other formats are entirely acceptable if the other formats work for the organization and contain all the required information.

The following worksheets are provided as examples. The information is arranged in a similar manner, but the layouts are in either a landscape or a portrait form to suit individual preferences.

Special Note: These worksheets can be used for training purposes as is, but if they are used for official use, they must include details that identify the commercial firm and related information. The additional information must include:

- Firm name and location;
- Date and, when appropriate, the time of the activity documented;
- Where appropriate, product identification and lot code, if any; and
- The signatures or initials of the person performing the activity.

Forms: The following example forms have been provided as samples for use:

- Product Description, Distribution, Consumers, and Intended Use
- Hazard Analysis
- Process Preventive Controls (Landscape Layout)
- Process Preventive Controls (Portrait Layout)
- Food Allergen Preventive Controls
- Ingredient Food Allergen Identification
- Finished Product Food Allergen Label Declaration Criteria
- Production Line Food Allergen Assessment
- Sanitation Preventive Controls
- Corrective Action Form
- Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions
- Ingredient Receiving Procedures
- Food Safety Plan Reanalysis Checklist

All forms can be adapted or modified as needed. There is NO required form.

Form Name: Product Description, Distribution, Consumers, and Intended Use

FACILITY NAME:	**ISSUE DATE:**	**PAGE OF**
ADDRESS:	**SUPERSEDES:**	**PRODUCT CODE:**

Product Name(s)	
Product Description, (including important food safety characteristics)	
Ingredients	
Packaging Used	
Intended Use	
Intended Consumers	
Shelf Life	
Labeling Instructions (related to safety)	
Storage and Distribution	

Approved by*:	***Date Approved:***
Print Name:	
Signature or Initials:	

**Signature or initials may just be on plan or may be on each page.*

Form Name: Hazard Analysis

FACILITY NAME:	ISSUE DATE:	PAGE OF
ADDRESS:	SUPERSEDES:	PRODUCT CODE:

Hazard identification (Column 2) considers those hazards that may be present in the food. Because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain..

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens
C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives
P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury, or other adverse health effects.

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

Appendix 2

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

(1) Ingredient / Processing Step	(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step		(3) Do any <u>potential</u> food safety hazards require a preventive control?		(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							

Form Name: Process Preventive Controls (Landscape Layout)

FACILITY NAME:			ISSUE DATE:	PAGE OF
ADDRESS:			SUPERSEDES:	PRODUCT CODE:
Process Preventive Controls	Process Control/CCP			
	Hazard(s)			
	Parameters, values, or critical limits			
	Monitoring	What		
		How		
		Frequency		
		Who		
	Corrective Action			
	Verification			
	Records			

Form Name: Process Preventive Controls (Portrait Layout)

FACILITY NAME:			**ISSUE DATE:**	**PAGE OF**
ADDRESS:			**SUPERSEDES:**	**PRODUCT CODE:**
Process Preventive Controls *[This is an alternate layout for process preventive controls.]*				
Process Control/CCP Step				
Hazard(s)				
Parameters, values, or critical limits				
Monitoring	**What**			
	How			
	Frequency			
	Who			
Corrective Action				
Verification				
Records				

Form Name: Food Allergen Preventive Controls

FACILITY NAME:			ISSUE DATE:	PAGE OF
ADDRESS:			SUPERSEDES:	PRODUCT CODE:
Food Allergen Preventive Controls	Allergen Controls			
	Hazard(s)			
	Criterion			
	Monitoring	What		
		How		
		Frequency		
		Who		
	Corrective Action			
	Verification			
	Records			

Form Name: Ingredient Food Allergen Identification

FACILITY NAME:	ISSUE DATE:	PAGE OF
ADDRESS:	SUPERSEDES:	PRODUCT CODE:

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation									Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	

How to Use the Ingredient Allergen Identification Chart
List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. **Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.**

Form Name: Finished Product* Food Allergen Label Declaration Criteria

FACILITY NAME:	ISSUE DATE:	PAGE OF
ADDRESS:	SUPERSEDES:	PRODUCT CODE:

Product	Allergen Statement	Label Number
**All finished product labels must declare the allergens present in the formula.*		

Form Name: Production Line Food Allergen Assessment

FACILITY NAME:	ISSUE DATE:	PAGE OF
ADDRESS:	SUPERSEDES:	PRODUCT CODE:

Product Name	Production Line	Intentional Allergens								
		Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame

Scheduling Implications:

Allergen Cleaning Implications: (Required)

How to Use the Production Line Food Allergen Assessment Form
Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product, then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information.

Form Name: Sanitation Preventive Controls

FACILITY NAME:		ISSUE DATE:	PAGE OF
ADDRESS:		SUPERSEDES:	PRODUCT CODE:
Objective			
Purpose			
Frequency			
Who			
Procedure			
Monitoring			
Corrections or Corrective Actions			
Records			

Form Name: Corrective Action Form

FACILITY NAME:	**ISSUE DATE:**	**PAGE OF**
ADDRESS:	**SUPERSEDES:**	**PRODUCT CODE:**

Date of Record:	**Code or Lot Number:**
Date and Time of Deviation:	
Description of Deviation:	
Root Cause/Actions Taken to Restore Order to the Process:	
Name of Person Taking Action:	**Signature of Person Taking Action:**
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Form Name: Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions								
Raw Material or Other Ingredient	Approved Supplier Name and Location	Date of Approval	Hazard(s) Requiring a Supply-Chain-Applied Control	Preventive Control Applied by Supplier	Verification Activities	Verification Procedures	Corrective Actions	Records

Form Name: Ingredient Receiving Procedures

[Document procedures used for receiving ingredients requiring a Supply-chain Preventive Control.]:	
Purpose	
Frequency	
Who	
Procedure	
Corrections	
Records	
Verification	

Example: For each shipment received, the receiving clerk uses the receiving database to identify required documentation then:

- Verifies that the product is from an approved supplier and their specific location;
- Verifies that each lot in the shipment is accompanied by a COA, if appropriate;
- Reviews each COA against acceptance criteria above, as appropriate; and
- Documents the above on the Incoming Raw Material Receiving Log.

Form Name: Food Safety Plan Reanalysis Checklist

FACILITY NAME:	ISSUE DATE:	PAGE OF
ADDRESS:	SUPERSEDES:	PRODUCT CODE:

Reason for reanalysis:

Reanalysis Task	Date Reviewed and Initials	Is Update Needed? (yes/no)	Date Task Completed	Signature or Initials of Person Completing Task
List of Food Safety Team with individual responsibilities				
Product Flow Diagrams				
Hazard Analysis				
Process Preventive Controls				
Food Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-Chain Program				
Recall Plan				
Updated Food Safety Plan Implemented	Not applicable	Not applicable		
Updated Food Safety Plan Signed by Owner or Agent-in-Charge	Not applicable	Not applicable		

Verification Record (this is not required in the regulation but is recommended)

Reviewer Name:	Date of Review:
Reviewer Signature or Initials:	

Date issued: mm/dd/yyyy	Supersedes: mm/dd/yyyy

Appendix 3: Food Safety Plan Teaching Example – Omelet

Food Safety Plan for Frozen Omelets

Reviewed by: *I.N. Charge*, Plant Manager

Date: April 13, 2024

The information in this example is for training purposes only and does not represent any specific operation. Development of a Food Safety Plan is site specific, thus it is highly unlikely that this plan can be adapted to another operation without significant modification.

This teaching model includes required and optional information to illustrate how a Food Safety Plan might be documented. The format may vary significantly for each specific company.

- The **Background Information** section is not required but is highly recommended for organizing the plan and explaining its organization to others. It is essential for a teaching example to clarify underlying assumptions in decisions that are made.
- The **Hazard Analysis** section is required for all Food Safety Plans subject to the *Preventive Controls for Human Food* regulation.
- The Preventive Controls sections (Process, Allergen, Sanitation and Supply-chain) are required ONLY for hazards requiring a preventive control identified by the hazard analysis. Validation is generally only required for process preventive controls, as appropriate.
- A Recall Plan is required ONLY when a hazard requiring a preventive control is identified by the hazard analysis.
- Implementation Records are required only for hazards requiring a preventive control.

Table of Contents

Background Information

Company Overview

E.G. Food Company's approximately 150 employees produce egg-based products, including frozen plain omelets, cheese omelets, and cheese biscuit omelets. E.G. Food Company is not a qualified facility. Product is made 5 days a week in one 8-hour production shift, followed by 4 hours for sanitation. Cleaning and sanitizing of all processing equipment and assemble/wrap environment is conducted per a master sanitation schedule, which also includes cleaning and sanitizing between different products, if needed, for allergen control. Municipal water, which is treated and tested per EPA requirements by the city, is used throughout the facility. The company practices hygienic zoning to prevent cooked product exposure to environmental pathogens and employees working in the high hygiene areas wear color-coded smocks and dedicated footwear. These employees are instructed on proper handwashing procedures, glove use, and the importance of zoning.

Food Safety Team

Name	**Position**	**Training** *(Full training records are in personnel file)*
I.N. Charge	Plant Manager	In plant training
F.S. Leader*	QA manager and Food Safety Team leader	FSPCA course
E.F. Ency	Production supervisor	In plant training
I.M. Clean	Sanitation supervisor	In plant training
P.H. Books*	Consultant, PH Books Consulting Service	M.S. & Ph.D. in Food Science and FSPCA lead instructor

**Preventive Controls Qualified Individual*

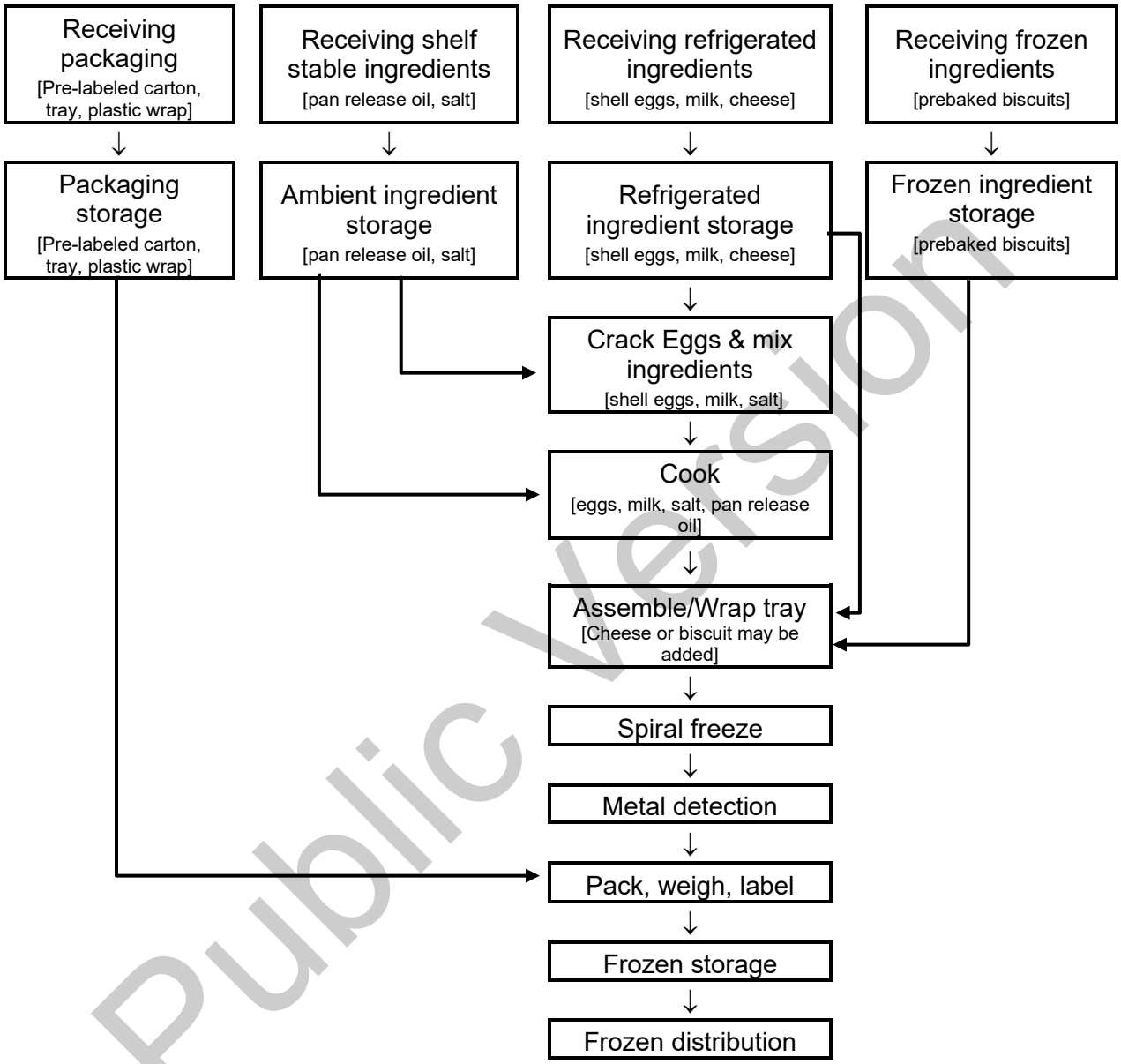
Product Description, Distribution, Consumers, and Intended Use

Product Name(s)	**Omelet – Plain, Cheese, and Cheese Biscuit**
Product Description, including Important Food Safety Characteristics	Frozen, cooked egg omelet, with or without cheese and with or without a wheat biscuit pH 7.1 – 7.9, water activity >0.98, no preservatives
Ingredients	Plain: Eggs, milk, pan release oil, salt Cheese: Eggs, milk, pan release oil, salt, cheese Cheese Biscuit: Eggs, milk, pan release oil, salt, cheese, biscuit
Packaging Used	Paperboard trays wrapped with plastic wrap and inserted in a pre-labeled carton.
Intended Use	The product is considered ready-to-eat but is typically heated to hot holding temperatures (135°F (57°C)) or above for palatability. Heating is typically conducted using microwaves or convection ovens. The end user may thaw at refrigeration temperatures overnight to reduce cooking time. End users may also add toppings or fillings. Sold for foodservice applications. *Potential abuse:* Some establishments may hold thawed product for longer than the recommended 24 hours.
Intended Consumers	General public
Shelf Life	1 year frozen
Labeling Instructions	Keep frozen or thaw under refrigeration (<41°F (5°C)) for <24 hours before cooking.
Storage and Distribution	Frozen

***Approved*:**	***Date Approved:***
Print Name: F.S. Leader	April 11, 2024
Signature or Initials: F.S. Leader	

**Signature may just be on the plan or may be on each page.*

Flow Diagram



Verified by: F.S. Leader **Date Verified:** April 11, 2024

Process Description

This Process Description (or narrative) was developed for teaching purposes to create a common vision of this hypothetical process among course participants. There is no requirement for an establishment to create such a document; however, a Process Description may be useful to guide hazard analysis and to orient auditors. Other company documents outside of the Food Safety Plan may substitute for a Process Description, such as ingredient specifications, product specifications, production instructions, standard operating procedures, etc. This Process Description does not represent any existing process.

Receiving Ingredients and Packaging:

Ingredients and raw materials including packaging are purchased from approved, reputable suppliers that comply with internationally recognized food safety requirements. Ingredients and packaging are stored according to manufacturers' recommendations when specified.

- **Receiving packaging:** Corrugated pre-labeled carton, paperboard trays and plastic wrap are received in bulk. Glass packaging and hard plastic materials are not used. Specifications require food grade material for trays, and plastic wrap that is compatible with frozen storage of food products. Pre-labeled cartons are reviewed for conformance with product allergen requirements and correct ingredients.
- **Receiving shelf stable ingredients:**
    - *Salt*: Received in 10-pound bags from supplier via our distributor. Specifications require food-grade salt.
    - *Pan release oil*: The highly processed pan release oil contains highly refined soybean oil, soy lecithin, and natural flavor. It is received from our supplier via distributor in 10-gallon plastic jugs. The soybean oil used in the pan release oil is highly refined which removes the soy protein, thereby rendering the oil non-allergenic. The pan release oil is highly processed (not refined) at temperatures that will not remove the soy protein in the soy lecithin used in the pan release oil. The pan release oil process is completely enclosed; oil is not exposed to the environment during processing and packaging. The supplier only handles soy-based products. No glass or hard plastic is used in the oil supplier's manufacturing or packaging processes. There is no metal-to-metal contact in the supplier's process.
- **Receiving refrigerated ingredients:** Within 30 minutes from receipt, refrigerated ingredients are transferred into refrigerated storage and required ingredient information is recorded.
    - *Eggs*: Refrigerated raw shell eggs are received in cases of 18 eggs per carton; 12 cartons per case, from our sole source supplier, in refrigerated trucks. The supplier's letter of guarantee states that the eggs are sourced from farms that meet FDA's *Salmonella* criteria of 21 CFR Part 118 and that follow U.S. drug residue requirements. Supplier performance history over five years has shown no drug residues detected. The supplier only handles egg products.
    - *Milk*: Pasteurized Grade A milk is received in refrigerated trucks from a local dairy in bag-in-box containers that hold two 1.5-gallon plastic bags. There is minimal exposure of the milk to the environment prior to packaging. The milk is not packaged in a reduced oxygen packaging. The supplier's letter of guarantee states that production practices are in compliance with U.S. Pasteurized Milk Ordinance (PMO) requirements for pasteurized milk products, including animal drug residue testing and environmental monitoring during packaging. Supplier performance history over five years has shown no drug residues, in accordance with U.S.

regulatory requirements. The milk supplier only handles milk products in its facility. There is no metal-to-metal contact in the supplier's process and no glass or hard plastic is used.

- *Cheddar Cheese:* Sliced cheddar cheese is processed by a local cheese manufacturer who sources raw milk (milk sourced from domestic dairy farms which complies with the PMO drug residue testing requirements) and pasteurizes the milk to be used in the cheddar cheese during the cheese making process. The milk is pasteurized in compliance with the PMO. The cheese contains pasteurized milk, lactic starter culture, rennet, and salt, no flavors or additives are used. The cheese is made in cheese vats in the facility that only handles milk-based products. The cheese is aged for 60 days then sliced and packaged in 5 lb. blocks in an oxygen permeable blue colored plastic wrap (non-hermetically sealed container). The cheese has a pH of 5.1 and a maximum a_w of 0.96. Cheese ingredients and finished cheese are considered ready-to-eat and are exposed to the environment during aging and slicing into single slices prior to packaging. No glass or hard plastic is used for cheese making by the supplier. The only allergen present at the cheese supplier is milk.

- **Receiving frozen ingredients:** Within 30 minutes of receipt, frozen ingredients are transferred into storage and required ingredient information is recorded.
  - *Biscuits*: Pre-sliced wheat biscuits are received frozen in 16-lb. cases (5 trays of 20 biscuits per case) from a supplier via our distributor. The biscuits contain enriched bleached flour (wheat flour, niacin, iron, thiamine mononitrate, riboflavin, folic acid), water, shortening (palm oil, mono and diglycerides, polysorbate 60, citric acid), buttermilk solids, sugar, baking powder (sodium acid pyrophosphate, sodium bicarbonate, cornstarch, calcium sulfate, monocalcium phosphate), and salt. The biscuits do not contain any ingredients with a maximum use level for safety (e.g., preservatives). The biscuits undergo baking which is an exceptionally lethal process at the supplier (process parameters based on palatability far exceed what is required for pathogen inactivation). For the flour used the supplier's supplier monitors for mycotoxins in the domestically grown grain used in milling the flour used by the biscuit supplier; supplier's supplier mycotoxin data has been below regulatory limits for five years. The buttermilk supplier produces the buttermilk in a Grade A facility that only processes milk products all of which comply with the PMO requirements. The biscuit manufacturer only handles allergens wheat and milk. No glass or hard plastic is used by the biscuit supplier.

Storing Ingredients and Packaging:

- **Packaging storage**: Pre-labeled cartons and trays are stored in the dry storage room in the packaging area. Plastic wrap is stored in sealed containers to protect from contamination. Packaging is used First-In-First-Out.
- **Ambient ingredient storage**: Salt and pan release oil are stored in the dry storage room in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid allergen cross-contact and cross-contamination during storage. Ingredients containing food allergens are identified and stored in specific locations with like allergenic ingredients.
- **Refrigerated ingredient storage**: Shell eggs, cheese, and milk are stored in separate designated areas in a cooler that is kept at ≤40°F (≤4.4°C) and are used within code date.

- **Frozen ingredient storage**: Frozen biscuits are stored in a designated area separate from finished goods storage. The freezer is maintained at <0°F (-18°C). A partially used case may be resealed and returned to the freezer after use on the line.

Crack eggs and mix ingredients: Eggs are manually cracked, then combined with milk and salt in pre-cleaned mixing bowls in the mixing room using a commercial mixer with a wire whip. The commercial mixer wire whip occasionally breaks. The batch size is used within 30 minutes. The temperature of the omelet batter is ≤40°F (≤4.4°C) after mixing. Mixing bowls are taken to the cook line for dispensing. Bowls are moved to a separate room for cleaning at the morning break, at lunch break and after the shift. No hard plastic is used during the mix step.

Cook: Pan-release oil is used to grease the omelet pans as needed to prevent sticking. Approximately one cup of omelet batter is deposited manually into omelet pans on a high heat setting. The pan is swirled, and the edges of the omelet are lifted with a spatula to allow uncooked (liquid) batter to flow under the cooked portion. Surface temperatures (the coolest point) are periodically (minimum frequency of every tenth omelet) measured with an infrared thermometer and are typically >162°F (72°C) when the omelet is fully congealed, the surface is not shiny, and thus cooking is complete. A congealed omelet is required to enable assembly. All omelet batter prepared is cooked or discarded—there is no rework. No hard plastic is used during the cook step.

Assemble/Wrap: Cooked omelets are transferred to a table with the cooking spatula. No hard plastic is used during the assemble step. The same table is used to assemble all products. Assembly occurs < 2 hours for each type of omelet product.

- *Plain omelets* are folded by hand to desired shape. Plain omelets are the first product made each day.
- *Cheese omelet* production begins after plain omelet numbers have been prepared. Sliced cheddar cheese is brought to the line just in time for production in sufficient quantity to be used in < 2 hours. Plain omelets are prepared, and a slice of cheese is placed off-center of the omelet prior to folding.
- *Cheese biscuit omelets* are the last item made each day and only prepared when orders require. The required number of biscuits is brought to the line in trays containing 20 biscuits each and placed on assembly tables. A folded plain omelet is placed on the bottom biscuit half, a slice of cheese is placed on the omelet, which is then topped with the biscuit top. All biscuit trays removed from a case are used for production or discarded at the end of the day. A partial case (i.e., 1-4 full trays) may be resealed, dated, returned to the freezer, and used for the next production.

Twelve (12) omelets or six (6) cheese biscuit omelets are placed on a tray and plastic wrap is applied to cover the tray. Packaging does not reduce the oxygen level.

Spiral freeze: Wrapped trays are placed on a belt that carries the omelets though a spiral freezer. Freezing takes place rapidly, with temperatures dropping from >135°F (57°C) to <41°F (5°C) in <1 hour from the time the omelet is placed on the assembly table. Product exiting freezer is frozen solid, with temperatures continuing to drop to <0°F (-18°C) in frozen storage.

Metal detection: Frozen product in trays is passed through a metal detector. All rejected product is examined for the presence of metal. Suspect product is destroyed.

Pack, weigh, and label: Pre-labeled cartons are assembled as needed at the 'Pack, Weigh, Label' step. Four trays of frozen omelets are placed in pre-labeled cartons. Pre-labeled cartons are weighed and sealed, and the lot code is applied. This step takes place in <30 minutes for each case.

Frozen storage: Finished product is stored at <0°F (-18°C).
until distributed.

Frozen shipping: Product is shipped in freezer trucks to customers at <10°F (-12°C).

Hazard Analysis

Hazard identification (Column 2) considers those hazards that may be present in the food. Because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury, or other adverse health effects

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient Hazard Analysis								
Salt (shelf stable)	B	None						
	C	None						
	P	None						
Pan release oil (highly processed, shelf stable)	B	Bacterial pathogen survival of a lethal treatment		X	The process of making highly processed pan release oil does not allow for pathogen survival.			
	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	Metal		X	Unlikely to occur due to no metal-to-metal contact in supplier's process.			
Refrigerated sliced cheddar cheese	B	Pathogenic *E. coli, Salmonella, L. mono, S. aureus*		X	Cheese supplier pasteurizes raw milk utilizing a pasteurization system that is in compliance with the PMO, pathogens not associated with other ingredients in cheddar cheese (lactic starter culture, rennet and salt).			

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient Hazard Analysis								
Refrigerated sliced cheddar cheese (continued)	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	The manufacture of the cheese achieves a combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture, and aging which prevents bacterial pathogen growth/toxin formation in the cheddar cheese.			
	B	Recontamination with environmental pathogens *L. mono*	X		Ingredients and finished cheese are ready-to-eat, exposed to environment (during aging, slicing), prior to packaging, and can support pathogen persistence.	Supply-chain Preventive Control at receiving step	X	
	C	Drug residues		X	The cheese supplier sources milk, which is in compliance with the PMO, including drug residue testing requirements.			
	C	Undeclared allergen - Milk	X		Cheddar cheese contains milk protein which is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	Metal	X		Cheese is sliced by supplier, possible metal from supplier's slicer blade may be present.	Process Control at subsequent metal detection step		X
Refrigerated raw shell eggs	B	Vegetative pathogen – *Salmonella*	X		*Salmonella* known to be associated with raw shell eggs, history of outbreaks, recalls, etc.	Process Control at subsequent cook step		X
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Pathogens associated with raw shell eggs unlikely to grow to levels that may overcome subsequent cook step.			

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient Hazard Analysis								
Refrigerated raw shell eggs (continued)	C	Drug residues		X	Supplier performance history over five years has shown no drug residues in accordance with U.S. regulatory requirements.			
	C	Undeclared allergen – egg	X		Egg is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	None						
Refrigerated Pasteurized Grade A Milk	B	Pathogenic *E. coli, Salmonella, and L. mono.*		X	Compliance with the PMO significantly reduces the likelihood of vegetative pathogens being present.			
	B	Sporeforming pathogens, *C. botulinum, B. cereus*		X	Milk is not packaged in ROP environment so no concern for *C. bot.* Historical data shows when milk is contaminated with *B. cereus*, the levels are very low and unlikely to grow to levels to cause illness within shelf-life.			
	B	Bacterial pathogen survival of a lethal treatment		X	Not likely to occur – pasteurization process in compliance with PMO.			
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not significant as spoilage would likely occur before pathogens grew to unsafe levels.			
	B	Recontamination with environmental pathogens *L. mono*		X	Not likely to occur – sanitation in compliance with PMO. Minimal exposure to the environment.			

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step		(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient Hazard Analysis								
Refrigerated Pasteurized Grade A Milk (continued)	C	Drug Residues		X	Drug residues are not an issue with the Grade A milk. Supplier performance history over five years has shown no drug residues in accordance with U.S. regulatory requirements.			
	C	Undeclared allergen – milk	X		Milk is a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	Metal		X	Unlikely to occur due to no metal-to-metal contact in supplier's process.			
Frozen Biscuits	B	Pathogenic *E. coli, Salmonella,* and *L. mono*		X	Biscuits undergo baking, which is an exceptionally lethal process by the supplier (process parameters based on palatability far exceed what is required for pathogen inactivation).			
	B	Bacterial pathogen survival of a lethal treatment		X	Supplier's bake time/temp far exceeds those required for food safety.			
	B	Recontamination with environmental pathogens *Salmonella*	X		Frozen biscuits are used as a ready-to-eat ingredient; there is exposure to the environment/further handling after the baking at the supplier (slicing) pathogens can survive in frozen biscuits.	Supply-chain Preventive Control at receiving step	X	
	C	Mycotoxin in Flour		X	Supplier's supplier monitors for mycotoxin in grain used in milling the flour used by the biscuit supplier. Supplier's supplier mycotoxin data has been below regulatory limits for five years.			

(1) Ingredient/ Processing Step		(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Ingredient Hazard Analysis								
Frozen Biscuits (continued)	C	Pesticides in Flour		X	Not significant, domestically grown wheat used to make the flour in biscuits.			
	C	Drug Residues in Buttermilk		X	Buttermilk produced by PMO compliant dairy facility			
	C	Undeclared allergen – wheat, milk	X		The Biscuit contains wheat and milk which are major food allergens and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	Metal	X		Metal-to-metal contact during slicing could introduce metal fragments.	Process Control at subsequent metal detection step		X
Packaging [Paperboard trays and plastic wrap]	B	None						
	C	None						
	P	None						

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Processing/Facility Hazard Analysis								
Receiving shelf stable salt	B	None						
	C	None						
	P	None						
Receiving shelf stable pan release oil (highly processed)	B	None						
	C	Undeclared allergen – soy	X		Pan release oil contains soy protein (from the soy lecithin) which is a major food allergen and must be declared on finished omelet label	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	None						
Receiving refrigerated sliced cheddar cheese	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	The manufacture of the cheese achieves a combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture, and aging, which prevents bacterial pathogen growth/toxin formation in the cheddar cheese.			
	C	Undeclared allergens – milk	X		Cheddar cheese contains milk protein which is a major food allergen that must be declared on finished omelet with cheese label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	None						
Receiving refrigerated raw shell eggs	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Time is too short during the receiving process (30 minutes) for pathogens to grow to unsafe levels.			
	C	Undeclared allergens – egg	X		Eggs are a major food allergen and must be declared on finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	None						

(1) Ingredient/ Processing Step		(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Processing/Facility Hazard Analysis								
Receiving Pasteurized Grade A Milk	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not significant as spoilage would likely occur before pathogens grew to unsafe levels.			
	C	Undeclared allergens – milk	X		Milk is a major food allergen and must be declared on the finished omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	None						
Receiving frozen biscuits	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Biscuits are received frozen, unlikely to thaw to a point where pathogens would grow.			
	C	Undeclared allergens – wheat, milk	X		Biscuits contain milk and wheat protein which are major food allergens and must be declared on finished biscuit omelet label.	Allergen Control #2 – labeling of the finished omelet at subsequent step		X
	P	None						
Receiving Packaging [Paperboard trays and plastic wrap]	B	None						
	C	Undeclared Allergen – eggs, milk, soy (wheat in biscuit only)	X		Eggs, milk, soy, and wheat are major food allergens and must be declared on the omelet finished products label.	Allergen Control #1 – label check at receipt	X	
	P	None						
Ambient Ingredient Storage [salt, pan release oil]	B	None						
	C	None						
	P	None						

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Processing/Facility Hazard Analysis								
Ambient Packaging Storage [Paperboard trays and plastic wrap]	B	None						
	C	None						
	P	None						
Refrigerated ingredient storage [cheese]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not likely to occur since the combination of a pH 5.1, moisture content (a_w maximum 0.96), active fermentation with lactic acid starter culture and aging will prevent bacterial pathogen growth/toxin formation in the cheddar cheese.			
	C	None						
	P	None						
Refrigerated ingredient storage [eggs]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Pathogens associated with raw shell eggs unlikely to grow to levels that may overcome subsequent cook step.			
	C	None						
	P	None						
Refrigerated ingredient storage [milk]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Not significant as spoilage would likely occur before pathogens grew to unsafe levels.			
	C	None						
	P	None						
Frozen ingredient storage [biscuits]	B	None						
	C	None						
	P	None						

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Processing/Facility Hazard Analysis								
Crack eggs and mix ingredients [eggs, milk, salt]	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Short mixing time (30 minutes), pathogens will not grow to unsafe levels.			
	C	None						
	P	Metal	X		Commercial mixer (wire whip) has history of breaking.	Process Control at subsequent metal detection step		X
	P	Egg Shell		X	Shell pieces are too small to cause injury.			
Cook [eggs, milk, salt, pan release oil]	B	Pathogen survival of a lethal treatment	X		If omelet is undercooked, vegetative pathogens could survive.	Process Control at cook step	X	
	C	None						
	P	None						
Assemble/ Wrap	B	Recontamination with environmental pathogens *L. mono*	X		Cooked omelet, cheese, and biscuits are ready-to-eat and further handled before packaging. The omelet products are ready-to-eat and can support pathogens if environmental recontamination occurs.	Sanitation Controls: #1 – Assemble/Wrap Table Sanitation #2 – Assemble/Wrap Environmental Sanitation #3 – Assemble/Wrap Hygienic Zoning	X	
	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Pathogens are unlikely to grow during assemble/wrap step due to short time.			
	C	Allergen cross-contact from wheat biscuit	X		Biscuits containing wheat used only for the Cheese Biscuit Omelet could be unintentionally incorporated into the plain and cheese omelet finished products which do not contain wheat.	Sanitation Control #1 – Assemble/Wrap Table Sanitation	X	
	P	None						

(1) Ingredient/ Processing Step		(2) Identify potential food safety hazards introduced, controlled, or enhanced at this step	(3) Do any potential food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Processing/Facility Hazard Analysis								
Spiral freeze	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Time needed to freeze packaged omelet is too short for meaningful pathogen growth.			
	C	None						
	P	None						
Metal detection	B	None						
	C	None						
	P	Metal	X		Metal may be introduced from the commercial mixer (wire whip) and potential metal in incoming sliced biscuits and sliced cheese from suppliers.	Process Control at metal detection step	X	
Pack, weigh, label	B	None						
	C	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit omelet only)	X		Egg, milk, and soy allergens are major food allergens and must be declared on all the omelet finished product labels. The cheese biscuit omelet finished product also contains wheat which is a major food allergen and must be declared on this finished product label.	Allergen Control #2 – labeling of the finished omelet	X	
	P	None						
Frozen storage	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Omelet unlikely to be exposed to temperatures above freezing for long enough time to allow for pathogen growth and/or toxin formation.			
	C	None						
	P	None						

(1) Ingredient/ Processing Step		(2) Identify <u>potential</u> food safety hazards introduced, controlled, or enhanced at this step	(3) Do any <u>potential</u> food safety hazards require a preventive control? Yes	(3) No	(4) Justify your decision for Column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step? Yes	(6) No
Processing/Facility Hazard Analysis								
Frozen distribution	B	Bacterial pathogen growth/toxin formation due to poor time/temp control		X	Omelet unlikely to be exposed to temperatures above freezing for long enough time to allow for pathogen growth and/or toxin formation.			
	C	None						
	P	None						

Process Preventive Controls

Process Preventive Control – Cook

Process Control/ CCP	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Pathogen survival of a lethal treatment	Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table	Omelet surface temperature is ≥158°F (70°C)	Infrared surface thermometer	Each cook station checks with a minimum frequency of every tenth (10) omelet	Cook Operator or designee	If temperature critical limit is not met, continue cooking omelet until temperature critical limit is met, discard all previous product back to the last good check. If temperature check was not performed, discard all previous product back to the last good check. Determine root cause. Retrain or correct as appropriate.	Review of Cook Log, Corrective Action, and Verification records within 7 working days Daily accuracy checks for Infrared surface thermometer Annual calibration of Infrared surface thermometer Product Testing Cook Validation Study	**Monitoring Records:** Cook Temperature Log **Corrective Action records** **Verification records:** Review Cook Temp log records Infrared surface thermometer accuracy checks records Infrared surface thermometer calibration records Product Testing records Cook Validation study

Cook Validation Study

P.H. Books Consulting Services

123 Research Way, Infoville USA

E.G. Food Company Omelet Cook Validation Study

Determination of lethal cook temperatures for *Salmonella* in egg products

Section 3-401.11 (A) (2) of the *Food Code* (a credible source for science-based recommendations) identifies the following time and temperature combinations as adequate for cooking raw egg-containing products:

- 145°F(63°C) for 3 minutes
- 150°F(66°C) for 1 minute
- 155°F(68°C) for 15 seconds
- 158°F(70°C) for <1 second (instantaneous)

Conclusion: A critical limit of ≥158°F (70°C) for <1 second (instantaneous) will effectively manage the risk of *Salmonella* in omelets based on the *Food Code*.

Determination that a congealed omelet is a valid visual cue for achieving a lethal temperature

It is well established that coagulation of eggs protein is a function of temperature. Lowe[1] reported that whole egg coagulates at 158°F (70°C) but commented that addition of milk can elevate the coagulation temperature. Stadelman and Cotterill[2] also discuss the influence of non-egg components on elevation of coagulation temperature. Therefore, a study was conducted to determine temperatures achieved when omelets coagulated under routine operating conditions and to determine the frequency of temperature measurements.

A calibrated infrared thermometer was used to measure the temperature of the surface of omelets when they were cooked to desired doneness by 10 operators – 5 omelets for each of 10 operators on 3 separate days, for a total of 150 measurements. The omelet batter for each of the 3 separate days used different lots of eggs and milk. Omelets were prepared using standard procedures – one cup of omelet batter was deposited into oiled omelet pans on the high heat setting. Each pan was swirled, and edges of the omelet were lifted with a spatula to allow uncooked (liquid) batter to flow under the cooked portion until coagulation was complete, no liquid batter was present, and the surface was no longer shiny.

Conclusion: The minimum temperature observed was 162°F (72°C), which is more than adequate to assure temperatures are above the critical limit of ≥158°F (70°C). The maximum temperature observed was 170°F (77°C).

Signed: P.H. Books Date: March 17, 2024

Title: *Principle Consultant*

[1] Lowe, B. 1937. Experimental Cookery from the Chemical and Physical Standpoint. John Wiley & Sons. Egg section available at http://chestofbooks.com/food/science/Experimental-Cookery/index.html#.UqoI39vnYiR Accessed March 17, 2024

[2] Stadelman, W.J. and O.J. Cotterill (eds). 1995 Egg Science and Technology, 4th Edition, Haworth Press, Inc., Binghamton NY.

Product Testing for Verification

Purpose: To verify the adequacy of process control (cooking) for the hazard of *Salmonella* in raw shell eggs.

Sample identification: Whole cooked omelets at the assembly table prior to packaging and freezing are aseptically sampled. Results from the omelets sampled represent one day of production.

Sampling procedure: Once per month, thirty (30) plain omelets are randomly collected from different cook stations throughout the day. Individual omelets are aseptically collected, placed in sterile, plastic sample bags, which are labeled with the date, time, product type, lot number and operator number. The omelet samples are sent to a contract laboratory identified below in an insulated cooler with an ice pack using overnight express mail. *Note: Product from the sampled lot is held until results are received and confirmed to be in compliance with acceptance criteria identified below.*

Laboratory: *Wee Beasties Laboratory* (987 Critter Drive, Yourtown, USA)

Test conducted: The contract laboratory will sample a 25-gram portion from each omelet and then retain the remaining portion under frozen conditions. The laboratory will composite the 25-gram samples into two (2) 375-gram composites, each composite comprised of 15 of the 25-gram samples. Each composite of 375-grams will be tested for *Salmonella.*

Analytical Method: The FDA's Bacteriological Analytical Methods, Chapter 5 for *Salmonella* and Chapter 1 for Food Sampling Preparation (FDA Food Category II, two (2) 375-grams samples).

Interpretation of results:

Acceptable results: Release product only if all results are negative

Unacceptable results: Apply corrective action when one or more samples are positive for *Salmonella*.

Corrective action for unacceptable results:

1. Destroy the product and implement other corrective actions.
2. Determine root cause:
    a. Test the individual retained samples for *Salmonella* to determine which cook stations resulted in the positive(s).
    b. Increase observation of cooking procedures and temperature verification at the cook step to hourly.
        i. Retrain cooking staff if issues are noted.
    c. Increase routine omelet sampling for *Salmonella* to at least daily until 5 consecutive results are acceptable. Then return to the routine monthly schedule.
3. Provide staff training:
    a. Review the situation with staff to alert them to the issue. Seek input on potential areas of improvement that can help resolve the issue.
4. In the event of a persistent issue, engage experts (e.g., testing lab or consultant P.H. Books) for additional assistance.

Product Testing Results Record

Reference Number:	COA364101
Reporting Date:	25-Jul-23
Sample Origin:	E.G. Food Company 360 Culinary Circle Mytown, USA
Account Number:	**364**
Contact Person:	F.S. Leader
Contact Number:	555.555.5000
E-mail Address:	fsleader@egfood.com

Wee Beasties Laboratory
987 Critter Drive
Yourtown, USA
555.555.5555

Product Testing Results

Product Test Sample			
Date of Collection:	16 Jul 2023	**Test Organism:**	*Salmonella*
Date of Testing	18 Jul 2023	**Test Methodology:**	FDA BAM Chapter 5

Sample Type	**Sample Numbers**	**Lot Number**	**Sampling Date**	**Result Spec: Negative**
Plain Omelet	**1 - 30**	EGF7142380A	7/14/23	Negative

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Process Preventive Control – Metal Detection

Process Control/ CCP	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Metal Detection	Metal inclusion	Metal detector present and operating	All of the product passes through an operating metal detector	Visual examination that the detector is on and reject device is working	Continuous	Production employee	If the product is processed without metal detection, hold it for metal detection. Fix metal detector if found to not be operating properly. Correct operating procedures to ensure that the product is not processed without metal detection If metal is found in product segregate product, evaluate product containing metal and discard product depending on metal type and prevalence. Identify the source of the metal found and fix damaged equipment if relevant	Review of Metal Detector Log and Corrective Action and Verification within 7 working days Accuracy Checks: Pass 3.0 mm ferrous and 3.0 mm non-ferrous and 3.5 mm stainless standard wands through detector at start-up, middle and end of shift to assure equipment is functioning. Calibrate metal detector annually – Note the calibration method is also used for validation. Metal detector validation study	**Monitoring Record:** Metal Detector Log **Corrective action records** **Verification records** Review Metal Detector Log Metal Detector Accuracy Checks Metal detector calibration records (certificate) Validation study
		No metal fragments that would cause injury or choking are in the product passing through the metal detector	Each tray of finished product for presence of metal fragments	Electronic metal detector with reject mechanism to divert product	Each rejection	Metal detector equipment			

Metal Detector Validation Study

From: Metal Detector Validators, Inc.
621 Validator Drive, Ferrousville USA

To: E.G. Food Company
360 Culinary Circle, Mytown, USA

Metal Detector Validation Study

Conduct a validation study to determine the appropriate settings for the metal detector. Place a 3.0 mm Ferrous metal sample into one cheese biscuit omelet and place in paperboard tray with five other cheese biscuit omelets and then wrap with plastic overwrap, freeze, and run frozen omelet tray through operating metal detector. Now perform this testing using the 3.0 mm non-ferrous metal sample and then perform testing using 3.5 mm Stainless Steel sample. Record the results below. Notify Plant and Maintenance Manager if the samples fail the test.

Validator: Jon Jones, Technician **Date:** January 30, 2024

Processing Area Location: After spiral freeze

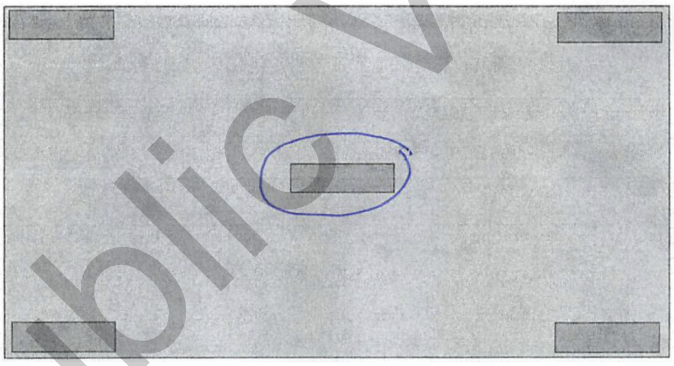
Product Type: Cheese biscuit omelets

Product Temperature at Time of Testing: Frozen 9°F (-12°C)

Block Dimension/Weight: 6 cheese biscuit omelets are placed in a 12" x 6" x 3" plastic tray with plastic overwrap; product/tray/overwrap weight is 24 oz.

Metal Test Piece Used: 3.0 mm Ferrous; 3.0 mm Non-Ferrous; 3.5 mm Stainless Steel

Placement of Metal Test Sample: (Sample placement indicated on the diagram below.)



Did the metal detector alarm go off and/or did the belt stop? (Yes/No): Yes

Validation Result (Pass/Fail): Pass

Comments/Corrective Action (description, time, who was notified): _____

Reviewed by: F. S. Leader **Date:** Jan. 30, 2024

Reviewed by: _____ **Date:** _____

Metal Detector Validation Test
Page I of I

Version I
Supersedes: *N/A*

Annual Metal Detector Calibration Certificate

METAL DETECTOR CALIBRATION CERTIFICATE

This calibration has been carried out using TESTING EQUIPMENT which is traceable to NIST standards.

Contact Details

Company Name: E.G. Food Company
Address: 360 Culinary Circle
City, State: Mytown, USA
Contact Name: I.N. Charge, Plant Manager
Service Report #: L003

Certificate Number: L003c
Date of Calibration: January 30, 2024
Visits Per Year: 1
Next Calibration Date: January 30, 2025

Line	Serial Number	Fe (mm)	Non-Fe (mm)	S/S (mm)	Product	Mode/ Gains/Type	Threshold/ Sensitivity	Packaging	Maximum Weight	Product Temperature
1	KMC242424	3.0	3.0	3.5	Cheese omelet biscuit	Dry	1000	Paperboard tray/ plastic overwrap	24 oz.	9°F (-12°C)
1	KMC242424	3.0	3.0	3.5	Plain omelet	Dry	1000	Paperboard tray/ plastic overwrap	24 oz.	9°F (-12°C)
1	KMC242424	3.0	3.0	3.5	Cheese omelet	Dry	1000	Paperboard tray/ plastic overwrap	24 oz.	9°F (-12°C)

CERTIFIED BY: Jon Jones
POSITION: Service Technician

PRINT NAME: Jon Jones
CERTIFYING COMPANY: Metal Detector Validators, Inc.

Note: Product can determine the performance of the units. For verification use the same product Description and Product Number as above.

Page 1 of 1

Food Allergen Assessment

Ingredient Food Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation									Allergens in Precautionary Labeling
		Egg	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)	**Sesame**	
Raw shell egg	Your Egg Co.	X									None
Grade A pasteurized milk	A Local Dairy		X								None
Pan release oil, ABC Brand	My distributor			X (soy lecithin)							None
Salt, XYZ Brand	My distributor										None
Biscuit	Flaky Co.		X (butter-milk)		X						None
Cheddar cheese	Cheesy Co.		X								None

How to Use the Ingredient Food Allergen Identification Chart

List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. **Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.**

Finished Product Food Allergen Label Declaration Criteria

Product*	Allergen Statement	Label Number
Plain Omelet	Contains: Egg, milk, and soy	P 082015
Cheese Omelet	Contains: Egg, milk, and soy	C 082015
Cheese Biscuit Omelet	Contains: Wheat, egg, milk, and soy	B 082015
**All finished product labels must declare the allergens present in the formula.*		

Food Allergen Preventive Controls

Allergen Controls	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Allergen Preventive Control #1									
Receiving packaging (pre-labeled carton)	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit only)	All finished product labels must declare the allergens present in the formula	Allergen Ingredient list and allergen declaration matches product	Visual check of carton label to match product formula	Before release to production	Label coord-inator	If label is incorrect, reject labels and return to supplier or destroy. Identify root cause and conduct training as needed to prevent recurrence	Review of Allergen Label Receiving Check Log Check Corrective Action, and Verification records within 7 working days	**Monitoring Record:** Allergen Label Receiving Check Log **Corrective Action records** **Verification records:** Allergen Label Receiving Check Log
Allergen Preventive Control #2									
Pack, weigh, label	Undeclared allergens – egg, milk, soy (wheat in cheese biscuit only)	All finished product must have the correct pre-labeled carton	Label number matches product	Visual check of carton label to match product number	Beginning and end of run and when label stock is changed	Pack line operat or	If label is incorrect, segregate product, inspect back to the last good check, relabel product. Identify root cause and conduct training as needed to prevent recurrence	Review of Allergen Label Application Check Log Check, Corrective Action, and Verification records within 7 working days	**Monitoring Record:** Allergen Label Application Check Log **Corrective Action records** **Verification records:** Allergen Label Application Check Log

Sanitation Preventive Controls

Production Line Food Allergen Assessment

Product Name	Production Line	Intentional Allergens								
		Egg	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)	**Sesame**
Plain Omelet	1	X	X	X						
Cheese Omelet	1	X	X	X						
Cheese Biscuit Omelet	1	X	X	X	X Unique allergen					

Scheduling Implications:

Standard practice is to run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Biscuit Omelet at the end of the shift to reduce the potential for allergen cross-contact. *Note: Consider adding when alternate production practices may be permitted, including approval for this, if you wish.*

Allergen Cleaning Implications: (Required):

A full allergen clean is **required** AFTER production of Cheese Biscuit Omelet because it contains a unique allergen, wheat. See **Sanitation Preventive Control #1** for Assemble/Wrap Table Sanitation.

How to Use the Production Line Food Allergen Assessment Form

Complete for each production line. Identify each allergen contained in each product produced on the line. Identify any allergens unique to a specific product, then indicate scheduling information (i.e., run unique allergens last) and allergen cleaning information (i.e., full allergen clean before running cheese or plain omelets after a biscuit run).

Sanitation Preventive Control #1: Assemble/Wrap Table Sanitation

Objective: To address cleanliness of food-contact surfaces:

1. Prevention of allergen cross-contact, and
2. Prevention of recontamination with environmental pathogens.

Purpose: Cleaning and sanitizing of the assembly and wrapping table is important to remove potential wheat allergen and recontamination with environmental pathogens that may impact product safety.

Frequency (based on the following):

1. Prevention of allergen cross-contact:
   - **a. Allergen Scheduling Implications:** Standard practice is to run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Biscuit Omelet at the end of the shift to reduce the potential for allergen cross-contact, and
   - **b. Allergen Cleaning Implications (Required):** A full allergen clean is **required** AFTER production of Cheese Biscuit Omelet because it contains a unique allergen – wheat (see previous page).

2. Prevention of recontamination with environmental pathogens
   - **a. Cleaning:** At lunch break, after Cheese Biscuit Omelet production, and at the end of daily production, and
   - **b. Sanitizing:** Before operations begin, at lunch break, after Cheese Biscuit Omelet production, and at the end of daily production.

Who: Sanitation team member

Procedure:

Note: Blue cleaning tools are to be used ONLY for cleaning after a Cheese Biscuit Omelet run to reduce the potential for unintentional wheat allergen transfer.

Cleaning

1. Move unused packaging material to a dedicated area at the end of the shift to prevent it from getting wet. Cover it during the lunch clean up;
2. Remove gross soil with a squeegee;
3. Wipe table surface with a clean cloth dipped in ABC detergent (Y oz. per gallon of potable water); and
4. Rinse table with clean, potable water. Detergent remaining on the surface can reduce the efficacy of the sanitizer.

Sanitizing

1. Spray table surface with 200 ppm Quaternary Ammonium Compound (QUAT) sanitizer, ensuring that entire surface is covered; and
2. Allow table to air dry, about 5 minutes. Contact time required per QUAT label, 1 minute.

Monitoring (at frequency indicated above)**:**

1. Inspect the table for residual soil and cleanliness. Record on Daily Sanitation Log.
2. Use test strip to measure the QUAT concentration BEFORE application. Record on Daily Sanitation Log.

3. Check the production schedule to document allergen run order. Record on Allergen Run Order Log.

Corrections:

1. If residual soil is observed on the table, reclean and sanitize.
2. If QUAT is not at the proper concentration, make a new solution and re-sanitize, if necessary.

Corrective Actions:

1. If standard allergen run order is not followed and a full allergen clean was not conducted, hold implicated product for further evaluation.
2. Conduct full allergen clean before resuming production.

Records: Daily Sanitation Log, Allergen Run Order Log.

Verification: Supervisor reviews and signs Daily Sanitation Log and Allergen Run Order Log within 7 working days.

Sanitation Preventive Control #2: Assemble/Wrap Environmental Sanitation

Objective: To address cleanliness of non-food-contact surfaces:

1) Recontamination with environmental pathogens.

Purpose: Cleaning and sanitizing of the floor and the table support structure (legs) in the Assemble/Wrap area is important to reduce recontamination with environmental pathogens and prevent establishment of environmental pathogens.

Frequency: Daily, after production

Who: Sanitation team member

Procedure:

Cleaning the table support structure and floor

NOTE: Separate tools are used for floors and table support structure because of the potential for higher levels of contamination.

1. Remove gross soil with a squeegee;
2. Use dedicated brush and premixed solution with ABC detergent to clean table support structure.
3. Then mop the floor with premixed solution with ABC detergent using a washable mop head, using a clean mop head each day; and
4. Follow with rinsing of table support structure and floor with clean water. Any detergent remaining on the floor may reduce the efficacy of the sanitizer.

Sanitizing the table support structure and floor

1. After cleaning and rinsing, spray the table support structure and floors with a 400-600 ppm QUAT sanitizer; and
2. Allow the table support structure and floor to air dry overnight.

Monitoring (at each cleaning time)**:**

1. Inspect the table support structure, floor, and surrounding area for residual soil and cleanliness AFTER cleaning BEFORE sanitizing. Record on Daily Sanitation Log.
2. Use test strip to measure the QUAT concentration BEFORE sanitizer application. Record the quat sanitizer concentration on the Daily Sanitation Log.

Corrections:

1. If residual soil is observed, reclean, and sanitize.
2. If QUAT is not at the proper concentration, make a new solution and re-sanitize if necessary.

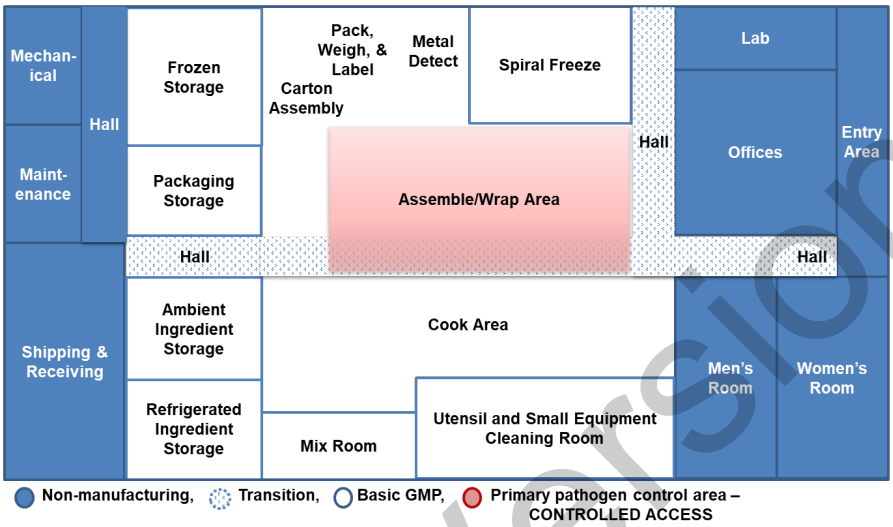
Records: Daily Sanitation Log and Environmental Sampling and Results Record.

Verification: Conduct environmental monitoring per procedure in Assembly/Wrap Hygienic Zoning Preventive Control. Supervisor reviews and signs Daily Sanitation Log and Environmental Sampling and Results Record within 7 working days.

Sanitation Preventive Control #3: Assemble/Wrap Hygienic Zoning

Objective: To address cross-contamination with environmental pathogens from personnel.

Purpose: Hygienic zoning in the assembly and wrapping table area is important to minimize the potential of cross-contamination with environmental pathogens.



Frequency: During production

Who: Employees and other individuals entering the Assemble/Wrap area

Procedure: Employees entering the Assemble/Wrap area must (in the order listed):

1. Take a clean, blue smock from the rack outside the production area and put it on. Smocks must cover outer clothing that would be above the assembly table surface;
2. Take the correct size clean rubber boots from the shelves along the wall outside the Assemble/Wrap area and put them on over shoes;
3. Take a blue hairnet from the box by the entry and put it on. Ensure that all loose hair is captured. Men with facial hair should also apply beard nets;
4. Wash hands just before entering the Assemble/Wrap area following the procedures posted by the sink. Apply a clean pair of gloves and sanitize gloved hands; and
5. When exiting the room dispose of gloves and deposit smocks and rubber boots in the receptacles provided. DO NOT return them to the clean smock and boot receptacle.

Note: Maintenance workers and visitors must follow the same hygienic zone procedures when entering and exiting this area. Traffic in this area is minimized during production.

Monitoring:

1. The sanitation supervisor visually observes employees for proper gowning and handwashing, donning gloves and sanitizing gloves before start-up, after lunch break, and every 2 hours.
2. Record on Daily Hygienic Zoning Log.

Corrections: Employee(s) is instructed to gown properly and wash hands, don gloves, and sanitize gloves.

Corrective Action:

1. In addition to corrections, determine if any product has been impacted.
2. Dispose impacted product.
3. Retrain employee(s).

Records: Daily Hygienic Zoning Log and Environmental Monitoring Sampling and Results Record

Verification: Supervisor reviews and signs Daily Hygienic Zoning Log and Environmental Sampling and Results Record within 7 working days.

Sanitation Preventive Controls #2 and #3: Verification – Environmental Monitoring

Purpose: Environmental monitoring is conducted on non-food contact surfaces to verify the effectiveness of sanitation and hygienic zoning procedures in the Assemble/Wrap area to control environmental pathogens such as *L. mono* from contaminating food contact surfaces and product.

Sample identification: Based on observation when sampling, "worst case" non-food contact surfaces are sampled (e.g., standing water or product residue, around table legs, crevasses, major traffic areas). Record the specific location sampled.

Sampling procedure: Every other week, sponge swabs are collected during production, at least 3 hours after production starts. Sampling time is not uniform to avoid bias of results. Samples are shipped to the laboratory using the sampling kit provided by the laboratory. Samples are refrigerated and shipped in an insulated cooler with a gel pack with next day delivery. Samples are NOT frozen.

Number of samples collected from non-food contact surfaces each time:

- Four (4) samples from the Assemble/Wrap area,
- Two (2) from the Hall between Assemble/Wrap and Cooking,
- One (1) at the employee gowning area, and
- Three (3) other samples based on observed conditions.

Laboratory: *Wee Beasties Laboratory* (987 Critter Drive, Yourtown, USA) conducts the analysis using FDA BAM procedures. Analysis is started within 24 hours of sampling.

Test conducted: For routine samples, the contract lab tests individual sponges following XYZ[1] recommended procedures for *Listeria* species. The test result sheet identifies the specific method number used.

Interpretation of results:

Action for a negative result: Continue routine operations

Corrective action for a positive result:

1. If sample(s) is positive, the positive area(s) is re-sampled (investigation samples) within a day of notification and prior to implementing intensive sanitation procedures. Additional samples (number depends on size of area) are taken in other potential problem areas in an attempt to identify a site of contamination;
2. Intensive sanitation procedures are implemented for the area found to be positive after sampling is complete;
3. If all re-samples are negative, resume the normal sampling frequency; and
4. If one or more re-samples are positive, perform corrective action investigation to resolve the issue. Refer to FDA's Draft Guidance Control of *Listeria monocytogenes* in Ready-to-Eat Foods for more corrective action.

Records: Environmental Monitoring Sampling and Results Record

[1] XYZ would be a scientifically valid method, such as AOAC, ISO, FDA etc.

Environmental Monitoring Sampling and Results Record

Reference Number:	COA364102
Reporting Date:	25-Jul-23
Sample Origin:	E.G. Food Company 360 Culinary Circle Mytown, USA
Account Number:	364
Contact Person:	F.S. Leader
Contact Number:	555.555.5000
E-mail Address:	fsleader@egfood.com

Wee Beasties Laboratory
987 Critter Drive
Yourtown, USA
555.555.5555

Environmental Monitoring Sampling and Results Record

Environmental Sampling

Date of Collection:	16 Jul 2023	**Test Organism:**	*Genus Listeria*
Testing Date:	18 Jul 2023	**Test Methodology:**	FDA BAM

Sample Type	Sample #	Sampling Location	Area Swabbed	Result Pos/Neg
Sponge Swabs	**1**	Assemble/Wrap	Table support legs facing Spiral Freezer side	Neg
Sponge Swabs	**2**	Assemble/Wrap	Table support legs facing cook side	Neg
Sponge Swabs	**3**	Assemble/Wrap	Table undersurface on Spiral Freezer side	Neg
Sponge Swabs	**4**	Assemble/Wrap	Floor surface center under Assemble/Wrap table	Neg
Sponge Swabs	**5**	Hall between Assemble/Cook	Hall flooring centered between Cook & Assemble/Wrap	Neg
Sponge Swabs	**6**	Hall between Assemble/Cook	Hall flooring surface between Cook & Assemble/Wrap & Ambient Ingredient Storage	Neg
Sponge Swabs	**7**	Assemble/Wrap Gown Area	Blue Gown Rack Hook – right side	Neg
Sponge Swabs	**8**	Other	Outside door handle of Refrigerated Storage Cooler	Neg
Sponge Swabs	**9**	Other	Wheels of Tool Cart in Maintenance Room	Neg
Sponge Swabs	**10**	Other	Floor surface at Utensil & Small Equipment Cleaning Room	Neg

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Supply-Chain Preventive Controls

Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions – Refrigerated Sliced Cheddar Cheese

Raw Material or Other Ingredient	Approved Supplier Name and Location	Date of Approval	Hazard(s) Requiring a Supply-Chain-Applied Control	Preventive Control Applied by Supplier	Verification Activities	Verification Procedures	Corrective Actions	Records
Refrigerated sliced cheddar cheese	Cheesy Co., Cowtown, USA	4/08/2024	Recontamination with environmental pathogens *L. mono*	Sanitation Control verified by environ-mental monitoring program	A third-party audit by a qualified auditor is used to verify supply-chain control for the listed hazards	A copy of a third-party audit is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by the QA manager. Follow up with the supplier takes place, as necessary, to verity that any corrective actions mentioned in the report have been completed, with records maintained for this activity.	Follow up with the supplier to verify corrective actions taken in response to significant audit deficiencies. If it is determined that the supplier is not controlling identified hazards as requiring a supply-chain-applied control, take and document prompt action, as appropriate, to include: • Dispose of any ingredient(s) from the supplier, as well as products made using the impacted ingredient(s), that are still under our control. • Discontinue use of the supplier until the cause or causes of non-conformance, are adequately addressed. • Notify the supplier of the problem and request documentation of corrective actions taken by the supplier. • Assist the supplier's efforts to correct and prevent recurrence of the problem. • Revise the supply-chain program. • Conduct, or work with the supplier to conduct, a recall of any adulterated food.	Copy of audit report kept in Supplier Verification file. Supplier Verification and Corrective Action Documentation

Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions – Frozen Biscuit

Raw Material or Other Ingredient	Approved Supplier Name and Location	Date of Approval	Hazard(s) Requiring a Supply-Chain-Applied Control	Preventive Control Applied by Supplier	Verification Activities	Verification Procedures	Corrective Actions	Records
Frozen Biscuit	Flaky Co., Breadbasket, USA	4/10/2024	Recontamination with environmental pathogens *Salmonella*	Sanitation Control verified by environ-mental monitoring program	A third-party audit by a qualified auditor is used to verify supply-chain control for the listed hazards	A copy of a third-party audit is requested from the supplier annually. The audit date, auditor qualifications, audit procedures and audit results are reviewed by the QA manager. Follow-up with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.	Follow up with the supplier to verify corrective actions taken in response to significant audit deficiencies. If it is determined that the supplier is not controlling identified hazards as requiring a supply-chain-applied control, take and document prompt action, as appropriate, to include: • Dispose of any ingredient(s) from the supplier, as well as products made using the impacted ingredient(s), that are still under our control. • Discontinue use of the supplier until the cause or causes of non-conformance, are adequately addressed. • Notify the supplier of the problem and request documentation of corrective actions taken by the supplier. • Assist the supplier's efforts to correct and prevent recurrence of the problem. • Revise the supply-chain program. • Conduct, or work with the supplier to conduct, a recall of any adulterated food.	Copy of audit report kept in Supplier Verification file Supplier Verification and Corrective Action Documentation

Receiving Procedure for Ingredients Requiring a Supply-chain Preventive Control

Purpose: Ensure that all ingredients requiring a supply-chain-applied preventive control are received from approved suppliers (see list of raw materials and respective approved suppliers) with appropriate preventive controls in place.

Frequency: Each delivery before accepting for use.

Who: Receiving clerk

Procedure:

1. Verify that each load of Refrigerated Sliced Cheddar Cheese was produced by Cheesy Co. located in Cowtown, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
2. Verify that each load of Frozen Biscuits was produced by Flaky Co. located in Breadbasket, USA by checking the bill of lading and manufacturer name on the cases upon receipt.
3. If the product is not from an approved supplier, reject the shipment at time of receipt.
4. Document on the Incoming Raw Material Receiving Log.

Correction: Contact plant manager to notify procurement of rejection of shipment of ingredients from an unapproved supplier.

Records: Receiving Log, Bill of Lading, Correction Records, Verification Record

Verification: Receiving records review within 7 working days.

.

Recall Plan

The Recall Plan is maintained by F.S. Leader, with a copy in the Plant Manager's Office.

Implementation Records

Implementation records and forms used for Preventive Controls include the following:

- Monitoring records for preventive controls
  - Process Preventive Control
    - Cook Temperature Log
    - Metal Detector Log
  - Allergen Preventive Control
    - Allergen Label Receiving Check Log
    - Allergen Label Application Check Log
  - Sanitation Preventive Controls
    - Daily Sanitation Log
    - Food Allergen Run Order Log
    - Daily Hygienic Zoning Log
- Corrective Action Records
  - Corrective Action Form
- Verification Records
  - Cook Validation Study (see cook preventive control)
  - Thermometer Accuracy Check Log
  - Thermometer Calibration Log
  - Metal Detector Accuracy Check Log
  - Metal Detector Validation Study
  - Metal Detector Calibration Certificate

Ingredient Receiving Log
Environmental Monitoring Sampling and Results Record
Product Testing Results Record
Supply-Chain Program Records
Food Safety Plan Reanalysis Report
Training records for the Qualified Individuals (in personnel files)

Examples of applicable forms follow.

Monitoring Records Forms – Process Preventive Controls

Cook Temperature Log

Cook Station		**Cook Date**	

Hazard: Pathogen survival of a lethal treatment (i.e., *Salmonella*).

Parameters, values, or critical limits: Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table.

Who, How, Frequency: Cook operator or designee checks an omelet surface temperature at each cook station, minimum frequency of every tenth (10) omelet using an infrared surface thermometer.

Corrective Action:

1) Continue cooking omelet until the temperature critical limit is met,
2) Discard all previous product back to the last good check,
3) Determine root cause, and
4) Retrain or correct as appropriate.

Time of Check	Omelet Check Number (e.g., 1st, 10th, 20th, etc.)	Temperature (°F)	Cook Operator or Designee Initials

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Metal Detector Log

Hazard: Metal inclusion

Parameters, values, or critical limits:

1. All of the product passes through an operating metal detector, and
2. No metal fragments that would cause injury or choking are in the product passing through the metal detector.

Corrective action:

1. If the product is processed without metal detection, hold it for metal detection.
2. Fix metal detector if found to not be operating properly.
3. Correct operating procedures to ensure that the product is not processed without metal detection.
4. If metal is found in product, segregate product, evaluate product containing metal, and discard product depending on metal type and prevalence.
5. Identify the source of the metal found and fix damaged equipment if relevant.

Time	Product	Lot Number	Detector present and on (Y/N)	Metal Detected in Product (Y/N)? If yes, note type of metal found	Line Operator Initials

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Monitoring Records Forms – Allergen Preventive Controls

Allergen Control #1 – Allergen Label Receiving Check Log

Hazard: Undeclared allergens

Parameters: All finished product labels must declare the allergens present in the formula as follows:

Finished Product Allergen Label Declaration Criteria

Product	Allergen Statement	Label Number
Plain Omelet	Contains: Egg, milk, and soy	P 082015
Cheese Omelet	Contains: Egg, milk, and soy	C 082015
Cheese Biscuit Omelet	Contains: Wheat, egg, milk, and soy	B 082015
All finished product labels must declare the allergens present in the formula.		

Corrective Action: If a label is incorrect, place labels on hold, notify label supplier, and return incorrect labels to supplier or destroy.

Date	Time	Product	Allergen Statement	Label Number	Declaration Correct (Y/N) (If no, see Corrective Action above)	Label Coordinator Initials

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or initials:	

Allergen Control #2 – Allergen Label Application Check Log

Hazard: Undeclared allergens

Parameters: All finished omelet labels must declare the allergens present in the formula as follows:

Finished Product Allergen Label Declaration Criteria

Product	Allergen Statement	Label Number
Plain Omelet	Contains: Egg, milk, and soy	P 082015
Cheese Omelet	Contains: Egg, milk, and soy	C 082015
Cheese Biscuit Omelet	Contains: Wheat, egg, milk, and soy	B 082015
All finished product labels must declare the allergens present in the formula.		

Corrective Action: If label is incorrect, segregate product, inspect back to the last good check, repack into properly labeled cartons; identify root cause and conduct training as needed to prevent recurrence.

Date	Time	Product	Lot Number	Proper Label Applied? (Y/N) (If no, see Corrective Action above)	Line Operator Initials

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Monitoring Records Forms – Sanitation Preventive Controls

Daily Sanitation Log – Omelet Line

Sanitation Control #1: Assemble/Wrap Table Sanitation (Food-Contact Surfaces)
Prevention of pathogen cross-contamination and prevention of allergen cross-contact

Production Date			**Production Start Time**			
Preoperational Inspection	**Time**	**Product to Be Run**	**Inspection Acceptance**		**Comments/Corrections**	**Operator Initials**
Inspect the table for residual soils						
Per Sanitation procedure	**Time**	**Product to Be Run**	**Inspection Acceptance**	**QUAT (ppm**)**	**Comments/Corrections**	**Operator Initials**
Pre-Start Up: Sanitizer type and strength: QUAT, 200 ppm minimum+						
Lunch Break Clean-up: 1. Cover packaging 2. Inspect the Assemble/Wrap Table for Soil Residue and Cleanliness (S/U)* 3. Sanitizer type and strength: QUAT, 200 ppm minimum+						
Product changeover after cheese biscuit omelet: 1. Cover packaging 2. Inspect the Assemble/Wrap Table for Soil Residue and Cleanliness (S/U)* 3. Sanitizer type and strength: QUAT 200 ppm minimum+						
End of shift Cleaning: 1. Remove packaging 2. Inspect the Assemble/Wrap Table for Soil Residue and Cleanliness (S/U)* 3. Sanitizer type and strength: QUAT, 200 ppm minimum+		**Not applicable**				

* S = Satisfactory, U = Unsatisfactory, NA = not applicable (Cheese Biscuit Omelet run after other products)
** Enter ppm measured per test strip

Product Changeover for Allergen Run Order (for Prevention of Allergen Cross-Contact)

Hazard: Allergen cross-contact from other products is handled at this step (e.g., Cheese Biscuit Omelet).

Parameter: Routinely, run the Plain and/or Cheese Omelet in the beginning of the shift and the Cheese Biscuit Omelet at the end of the shift to reduce the potential for allergen cross-contact. If necessary, Cheese Biscuit Omelet can be run before the Plain or Cheese Omelet, **IF a full allergen clean** is performed AFTER the production of Cheese Biscuit Omelet because it contains a unique allergen, wheat.

Corrective Action: If full allergen clean was not performed after running Cheese Biscuit Omelet, segregate product, hold all product produced after the Cheese Biscuit Omelet up to the next full allergen clean; evaluate product and determine appropriate disposition; identify root cause and conduct training as needed to prevent recurrence.

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Sanitation Control #2: Assemble/Wrap Environmental Sanitation (Non-Food-Contact Surfaces)
Prevention of recontamination with environmental pathogens

Production Date		**Production Start Time**			
Per Sanitation procedure	**Post-Op Time**	**Inspection Acceptance**	**QUAT (ppm**)**	**Comments/ Corrections**	**Operator Initials**
Prevention of Recontamination with Environmental Pathogens • Floors, table support structure, and surrounding areas cleaned and sanitized (S/U)* • Sanitizer type and strength: QUAT, 400-600 ppm+					

* S = Satisfactory, U = Unsatisfactory
** Enter ppm measured per test strip

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Sanitation Control #3: Assemble/Wrap Hygienic Zoning

Daily Hygienic Zoning Record

Production Date		**Production Start Time**	

The sanitation supervisor visually observes that employees are wearing clean blue smocks, blue hairnets/beardnets, clean, sanitized gloves after washing hands, and clean rubber boots before start-up and after lunch break, and every 2 hours.

Hygienic Zoning Observations (Before each start-up and every two hours)	**Time**	***Clean Blue Smocks**	***Clean and sanitized gloves after handwashing**	***Clean Rubber Boots**	***Hair Covers (blue hairnets/ beard nets**	**Corrections/ Correction Actions**	**Super-visor Initials**
Start Up							
In-Shift Check							
In-Shift Check							
Post-lunch check							
In-Shift Check							
In-Shift Check							

** S = Satisfactory, U = Unsatisfactory*

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Corrective Action Records

Corrective Action Form	
Corrective action records are maintained by the Food Safety Team Leader. An example of the Corrective Action Form is below.	
Date of Record:	**Code or Lot Number:**
Date and Time of Deviation:	
Description of Deviation:	
Root Cause/Actions Taken to Restore Order to the Process:	
Name of Person Taking Action:	**Signature of Person Taking Action:**
Amount of Product Involved in Deviation:	
Evaluation of Product Involved with Deviation:	
Final Disposition of Product:	
Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Verification Records

Verification records are maintained by the Food Safety Team Leader. Examples of verification forms are included as indicated below.

Verification Record	Location
Omelet cook step validation study Metal detection calibration/validation study	Studies are included in process control sections of this plan
Verification of monitoring and corrective action	Documented on the relevant forms, examples of which are in the previous sections
Thermometer Accuracy Checks Metal Detector Accuracy Checks Calibration of monitoring and verification instruments • Thermometer Calibration Log • Metal Detector Calibration/Validation Log	Example forms follow
Product Testing	Procedure included with Cook Process Preventive Control record Results forms provided by testing lab
Environmental Monitoring	Procedure included with Sanitation Preventive Controls Results forms provided by testing lab
Annual Food Safety Plan Reanalysis Report Form	Example form follows
Supply-Chain Program Records	Procedures included with Supply-Chain Preventive Controls in the Food Safety Plan Receiving Log maintained in receiving files Bill of Ladings for each shipment in receiving files Supplier Verification and Corrective Action Documentation

Thermometer Accuracy Check Log

Verification: Check Cook Infrared Surface Thermometer when used. Temperature must be ± 2°F (1°C) from standard.

Date of Accuracy Check	Device Description (i.e., Cook Infrared Surface Thermometer)	Boiling Water Temp (212±2°F)*	Ice Bath Temp (32±2°F)*	Temperature within Specification (Y/N)	Actions taken, if applicable	QA Staff Initials

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

** Temperature adjustments may be needed for different altitudes.*

Thermometer Calibration Log

Verification: Send Cook Infrared Surface Thermometer to Accurate Instrument Checker Lab for calibration once a year. Temperature must be ±2°F (1°C) from standard. Keep records of results on file.

Date of Calibration	Instrument Name and Number	Method of Calibration	Calibration Results	Temperature within Specification (Y/N)	Actions taken, if applicable	Line Operator Initials

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Metal Detector Accuracy Check Log

Verification: Check the accuracy of the metal detector by passing 3.0 mm ferrous, 3.0 mm non-ferrous and 3.5 mm stainless standard wands through detector at start-up, middle and end of shift to assure equipment is functioning

Date/Time of Accuracy Check	Designate Start-up; middle and end of shift	3.0 mm Ferrous (wand detected, Y/N)	3.0 mm Non-Ferrous (wand detected, Y/N)	3.5 mm Stainless Steel (wand detected, Y/N)	QA Staff Initials

Verification Record

Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Annual Metal Detector Calibration Certificate

Annual Metal Detector Calibration Certificate

This calibration has been carried out using TESTING EQUIPMENT which is traceable to NIST standards.

Contact Details

Company Name: _____ Certificate Number: _____

Address: _____ Date of Calibration: _____

City, State: _____ Visits Per Year: _____

Contact Name: _____ Next Calibration Date: _____

Service Report #: _____

Line	Serial Number	Fe (mm)	Non-Fe (mm)	S/S (mm)	Product	Mode/ Gains/Type	Threshold/ Sensitivity	Packaging	Maximum Weight	Product Temperature

CERTIFIED BY: _____ POSITION: _____

PRINT NAME: _____ CERTIFYING COMPANY: _____

Note: Product can determine the performance of the units. For verification use the same product Description and Product Number as above.

Page 1 of 1

Environmental Monitoring Sampling and Results Record

Reference Number:		**[Company Name & Address Providing the Results]**	
Reporting Date:			
Sample Origin:			
Account Number:		**Environmental Monitoring Sampling and Results Record**	
Contact Person:			
Contact Number:			
E-mail Address:			
Environmental Sampling			
Date of Collection:		**Test Organism:**	
Testing Date:		**Test Methodology:**	

Sample Type	Sample #	Sampling Location	Area Swabbed	Result Pos/Neg

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Product Testing Results Record

Reference Number:		**[Company Name & Address Providing the Results]**	
Reporting Date:			
Sample Origin:		**Product Testing Results Record**	
Account Number:			
Contact Person:			
Contact Number:			
E-mail Address:			
Product Test Sample			
Date of Collection:		**Test Organism:**	
Testing Date:		**Test Methodology:**	

Sample Type	**Sample Number**	**Lot Number**	**Sampling Date**	**Result Spec: Negative**

Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Supply-Chain Program Records

Supply-Chain Preventive Controls Determination of Verification Procedures and Corrective Actions									
Raw Material or Other Ingredient	**Approved Supplier Name and Location**	**Date of Approval**	**Hazard(s) Requiring a Supply-Chain-Applied Control**	**Preventive Control Applied by Supplier**	**Verification Activities**	**Verification Procedures**	**Corrective Actions**	**Records**	

Supplier Verification and Corrective Action Documentation		
Verification Activities Conducted (onsite audit, sampling & testing of ingredient, review of supplier's relevant records, and/or other)		
Supplier Name and Address (location):		
Raw Material or Other Ingredient:		
Hazard(s) Requiring a Supply-chain-applied Control:		
Date(s) Verification Activity Conducted:		
Verification Activities Conducted (check all that apply): ☐ **Onsite Audit** ☐ **Sampling & Testing of Ingredient** ☐ **Review of Supplier's Relevant Records** ☐ **Other Verification Activity:** _____		
Onsite Audit	**Audit Procedures Listed in the Report?**	☐ **Yes** ☐ **No**
	Audit Procedures Comments:	
	Audit covered controls for hazard(s) requiring a supply-chain-applied control?	☐ **Yes** ☐ **No**
	Audit performed by Qualified Auditor?	☐ **Yes** ☐ **No**
	Auditor Qualifications (e.g., certification body name):	
	What are the general audit conclusions?	
	List significant deficiencies identified during the audit and corrective actions taken by the supplier:	
	Comments:	
Sampling & Testing of Ingredient	**Date test(s) conducted:**	
	Test microorganism(s) or other analyte(s):	
	Test(s) conducted:	
	Analytical method:	
	Procedures for identifying samples including relationship to specific lot #s of product:	
	Number of samples collected and sampling frequency:	
	Laboratory used:	
	Testing results:	

Supplier Verification and Corrective Action Documentation		
Verification Activities Conducted (onsite audit, sampling & testing of ingredient, review of supplier's relevant records, and/or other)		
	Do the test results meet specifications?	☐ **Yes** ☐ **No**
	Corrective actions taken in response to "out of specification" results:	
	Comments:	
Review of Supplier's Relevant Records	**Were Critical Limits & Parameters Met for the Controls Being Reviewed?**	☐ **Yes** ☐ **No**
	If no, corrective actions taken by supplier:	
	Comments:	
Other Verification Activity:	**Describe Verification Activity:**	
	Were Verification Specifications Met?	☐ **Yes** ☐ **No**
	If no, corrective actions taken by supplier:	
	Comments:	
Additional Corrective Action(s) Taken: *If it is determined that the supplier is not controlling identified hazards as requiring a supply-chain-applied control, document the corrective action(s) taken and date taken, as appropriate:*	**Dispose of any ingredient(s) from the supplier, as well as products made using the impacted ingredient(s), that are still under our control.**	**Action taken:** **Date action taken:**
	Discontinue use of the supplier until the cause or causes of non-conformance, are adequately addressed.	**Action taken:** **Date action taken:**
	Notify the supplier of the problem and request documentation of corrective actions taken by the supplier.	**Action taken:** **Date action taken:**
	Assist the supplier's efforts to correct and prevent recurrence of the problem.	**Action taken:** **Date action taken:**
	Revise the supply-chain program.	**Action taken:** **Date action taken:**
	Conduct, or work with the supplier to conduct, a recall of any adulterated or misbranded food.	**Action taken:** **Date action taken:**

Supplier Verification and Corrective Action Documentation	
Verification Activities Conducted (onsite audit, sampling & testing of ingredient, review of supplier's relevant records, and/or other)	
Verification Record	
Reviewer Name:	***Date of Review:***
Reviewer Signature or Initials:	

Food Safety Plan Reanalysis Report Checklist

Reason for reanalysis:

Reanalysis Task	Date Reviewed and Initials	Is Update Needed? (yes/no)	Date Task Completed	Signature or Initials of Person Completing Task
List of Food Safety Team with individual responsibilities				
Product flow diagrams				
Hazard analysis				
Process Preventive Controls				
Allergen Preventive Controls				
Sanitation Preventive Controls				
Supply-Chain Program				
Recall Plan				
Updated Food Safety Plan Implemented	Not applicable	Not applicable		
Updated Food Safety Plan Signed by Owner or Agent in Charge	Not applicable	Not applicable		

Verification Record (this is not required in the regulation but is recommended)

Reviewer Name:	**Date of Review:**
Reviewer Signature or Initials:	
Date issued: mm/dd/yyyy	**Supersedes: mm/dd/yyyy**

Appendix 4: Foodborne Pathogen Supplementary Information

Microbial growth can be limited when conditions are outside of an organism's growth parameters, and certain time-temperature combinations can inactivate foodborne pathogens in foods. This appendix presents several tables with information on parameters that can be used to inhibit growth or inactivate certain microorganisms.

- **Table A4-1 (FDA Hazard Guide, Appendix 3, Table 3-A):** This table summarizes conditions that limit or prevent foodborne pathogen growth or toxin formation, including temperature, pH, water activity (a_w)), and maximum percent of water phase salt.
- **Table A4-2 (FDA Hazard Guide, Appendix 3, Table 3-B):** This table provides information on time and temperature combinations which, under ordinary circumstances, will prevent growth of foodborne bacterial pathogens. This includes information on maximum cumulative time and internal temperature combinations for exposure of foods that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern. The exposure times are derived from published scientific information. Because bacterial growth is logarithmic, linear interpolation using the time and temperature guidance may not be appropriate. Furthermore, the food matrix affects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth restrictive agents). Consideration of such attributes is needed when using the information in Table A4-2 (FDA Hazard Guide, Appendix 3, Table 3-B).
- **Table A4-3 (FDA Hazard Guide, Appendix 3, Table 3-C):** This table is derived from the FDA Hazard Guide, Appendix 3, Table 3-B. This table is a Quick Reference Guide for time and temperature guidance for controlling pathogen growth and toxin formation in food products (for internal temperatures above 50°F (10°C) but below 135°F (57.2°C)). Because the nature of bacterial growth is logarithmic, linear interpolation using the time and temperature guidance may not be appropriate. Furthermore, the food matrix affects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth-restrictive agents). A facility should consider such attributes when using the information in Tables A4-1, A4-2, and A4-3 (FDA Hazard Guide, Appendix 3, Tables 3-A, 3-B, and 3-C).
- **Table A4-4 (FDA Hazard Guide, Appendix 3, Table 3-D):** This table provides information on time-temperature combinations for destruction of *Listeria monocytogenes*. Lethal rate, as used in this table, is the relative lethality of 1 minute at the reference internal product temperature of 158°F (70°C) (i.e., z=13.5°F (7.5°C)). For example, 1 minute at 145°F (63°C) is 0.117 times as lethal as 1 minute at 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a six logarithm (6D) process for *Listeria* monocytogenes. The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the population of *Listeria monocytogenes* (6D) is, in part, dependent upon the food in which it is being heated. The values in the table are generally conservative and apply to all foods. A facility may be able to establish a shorter process time for the food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in a facility's food if supported by a scientific

study of the typical initial levels in the food. It is also possible that higher levels of destruction may be necessary in some foods, if especially high initial levels are anticipated.

- **Table A4-5 (FDA Hazard Guide, Appendix 3, Table 3-E):** This table contains information on the destruction of *Clostridium botulinum* (*C. botulinum*) type B (the most heat- resistant form of non-proteolytic C. botulinum). (The non-proteolytic strains of *C. botulinum* can grow at refrigeration temperatures and may be a hazard requiring a preventive control in some foods intended to be held refrigerated for extended periods of time.) Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference product internal temperature of 194°F (90°C) (for temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C)). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum*. The values in the table are generally conservative. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies.
- **Table A4-6:** This table lists properties and descriptions of common bacterial foodborne pathogens. Information such as pathogenicity, primary sources, types of foods involved in transmission, contributing factors, atmosphere required for growth, whether the organism is a sporeformer, and other properties are included.

The tables are followed by an alphabetical listing of the organisms (bacteria, viruses, and parasites) identified by Painter et al. (2013) as being relevant for transmission through food. More information on foodborne pathogens is available in FDA's Bad Bug Book (see references).

Table A4-1. Limiting conditions for pathogen growth. (FDA Hazard Guide, Appendix 3, Table 3-A)

Derived from the FDA Hazard Guide (2024) and the International Commission on Microbiological Specifications for Foods (1996).

Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
Bacillus cereus	0.92	4.3	9.3	10	39.2°F (4°C)	131°F[1] (55°C)	facultative anaerobe[4]
Campylo-bacter jejuni	0.987	4.9	9.5	1.7	86°F (30°C)	113°F (45°C)	micro-aerophile[2]
Clostridium botulinum, type A, and proteolytic types B and F	0.935	4.6	9	10	50°F (10°C)	118.4°F (48°C)	anaerobe[3]

Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
Clostridium botulinum, type E, and non-proteolytic types B and F	0.97	5	9	5	37.9°F (3.3°C)	113°F (45°C)	anaerobe[3]
Clostridium perfringens	0.93	5	9	7	50°F (10°C)	125.6°F (52°C)	anaerobe[3]
Pathogenic strains of *Escherichia coli*	0.95	4	10	6.5	43.7°F (6.5°C)	120.9°F (49.4°C)	facultative anaerobe[4]
Listeria mono-cytogenes	0.92	4.4	9.4	10	31.3°F (-0.4°C)	113°F (45°C)	facultative anaerobe[4]
Salmonella spp.	0.94	3.7	9.5	8	41.4°F (5.2°C)	115.2°F (46.2°C)	facultative anaerobe[4]
Shigella spp.	0.96	4.8	9.3	5.2	43°F (6.1°C)	116.8°F (47.1°C)	facultative anaerobe[4]
Staphylo-coccus aureus growth	0.83	4	10	20	44.6°F (7°C)	122°F (50°C)	facultative anaerobe[4]
Staphylo-coccus aureus toxin formation	0.85	4	9.8	10	50°F (10°C)	118°F (48°C)	facultative anaerobe[4]
Streptococcus group A*	–	–	–	6.5	50°F (10°C)	113°F (45°C)	facultative anaerobe[4]
Vibrio cholerae	0.97	5	10	6	50°F (10°C)	109.4°F (43°C)	facultative anaerobe[4]
Vibrio parahaemo-lyticus	0.94	4.8	11	10	41°F (5°C)	113.5°F (45.3°C)	facultative anaerobe[4]

Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
Vibrio vulnificus	0.96	5	10	5	46.4°F (8°C)	109.4°F (43°C)	facultative anaerobe[4]
Yersinia enterocolitica	0.945	4.2	10	7	29.7°F (-1.3°C)	107.6°F (42°C)	facultative anaerobe[4]

*Group A *Strep* is not included in the FDA Hazard Guide but was part of the 2011 Fishery Guidance.
[1]Has significantly delayed growth (>24 hours) at 131°F (55°C).
[2]Requires limited levels of oxygen.
[3]Requires the absence of oxygen.
[4]Grows either with or without oxygen.

Table A4-2. Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products (FDA Hazard Guide, Appendix 3, Table 3-B)

Potentially Hazardous Condition	Product Temperature	Maximum Cumulative Exposure Time
Growth and toxin formation by ***Bacillus cereus***	39.2-43°F (4-6°C) 44-59°F (7-15°C) 60-70°F (16-21°C) Above 70°F (21°C)	5 days 1 day 6 hours 3 hours
Growth of ***Campylobacter jejuni***	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type A, and proteolytic types B and F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 2 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type E, and non-proteolytic types B and F	37.9-41°F (3.3-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	7 days 2 days 11 hours 6 hours
Growth of ***Clostridium perfringens***	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (21°C)	21 days 1 day 6 hours[1] 2 hours
Growth of pathogenic strains of ***Escherichia coli***	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours

Potentially Hazardous Condition	Product Temperature	Maximum Cumulative Exposure Time
Growth of ***Listeria monocytogenes***	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-86°F (22-30°C) Above 86°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
Growth of ***Salmonella*** species	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth of ***Shigella*** species	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth and toxin formation by ***Staphylococcus aureus***	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours[1] 3 hours
Growth of ***Vibrio cholerae***	50°F (10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)	21 days 6 hours 2 hours 1 hour[2]
Growth of ***Vibrio parahaemolyticus***	41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)	21 days 6 hours 2 hours 1 hour[2]
Growth of ***Vibrio vulnificus***	46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80°F (27°C)	21 days 6 hours 2 hours 1 hour[2]
Growth of ***Yersinia enterocolitica***	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	1 day 6 hours 2.5 hours

[1]Additional data needed.
[2]Applies to cooked, ready-to-eat foods only.

Table 4-3. Quick Reference Guide for Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products (for Internal Temperatures above 50°F (10°C) but below 135°F (57.2°C)) (FDA Hazard Guide, Appendix 3, Table 3-C)

If the food is a …	And the food is held at an internal temperature …	Then a facility should limit the exposure time to …	Or, if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern, then a facility should limit the exposure time to …	As long as …
Raw, RTE ingredient or food product	Above 70°F (21.1°C)	2 hours	3 hours	N/A
Raw, RTE ingredient or food product	Above 70°F (21.1°C)	4 hours	N/A	No more than 2 of those hours are between 70°F (21.1°C) and 135°F (57.2°C)
Raw, RTE ingredient or food product	At any time, above 50°F (10°C) but never above 70°F (21.1°C)	5 hours	12 hours	N/A
Raw, RTE ingredient or food product	At internal temperatures (or at ambient air temperatures) below 50°F (10°C) throughout processing	N/A	N/A	N/A
Cooked, RTE ingredient or food product	At any time, above 80°F (26.7°C)	1 hour	3 hours	N/A
Cooked, RTE ingredient or food product	At any time, above 80°F (26.7°C)	4 hours	N/A	No more than 1 of those hours is above 70°F (21.1°C)
Cooked, RTE ingredient or food product	At any time, above 70°F (21.1°C) but never above 80°F (26.7°C)	2 hours	3 hours	N/A

If the food is a …	And the food is held at an internal temperature …	Then a facility should limit the exposure time to …	Or, if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern, then a facility should limit the exposure time to …	As long as …
Cooked, RTE ingredient or food product	Never held above 80°F (26.7°C)	4 hours	N/A	No more than 2 of those hours are above 70°F (21.1°C)
Cooked, RTE ingredient or food product	At any time, above 50°F (10°C) but never above 70°F (21.1°C)	5 hours	12 hours	N/A
Cooked, RTE ingredient or food product	At internal temperatures (or ambient air temperatures) below 50°F (10°C) throughout processing	N/A	N/A	N/A

Note that the preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), which is the recommended maximum storage temperature for refrigerated food products, and 50°F (10°C). This is because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most food processing steps. However, if a facility has processing steps that occur at these temperatures and which approach the maximum cumulative exposure times listed in Table 3-B for the pathogenic bacteria of concern in a facility's product, the facility should consider development of a critical limit for control at these temperatures.

It is not possible to furnish recommendations for each pathogenic bacterium, process, type of food product, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture in its Pathogen Modeling Program (PMP) and by an international consortium of the Institute of Food Research (UK), the USDA Agricultural Research Service (USDA-ARS), and the University of Tasmania Food Safety Centre (CombBase database and Predictor). These programs can provide growth curves for selected pathogens. To use these models, a facility should indicate the conditions, such as pH, temperature, and salt concentration that a facility is interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, and generation time). FDA does not endorse or require the use of such modeling programs but recognizes that the predictive growth information they provide may be helpful to some processors. However, a facility should be aware that significant deviations between actual microbiological data in specific products and the predictions may occur, including those for the lag phase of growth. Therefore, a facility should validate the time and temperature limits derived from such predictive models if growth of pathogens during processing requires a preventive control.

Table A4-4. Inactivation of *Listeria monocytogenes*. (FDA Hazard Guide, Appendix 3, Table 3-D)

Internal Product Temperature (°F)	Internal Product Temperature (°C)	Lethal Rate	Time for 6D Process (Minutes)
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3
151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02
Note: z = 13.5°F (7.5°C)			

Table A4-5. Inactivation of non-proteolytic *Clostridium botulinum* Type B. (FDA Hazard Guide, Appendix 3, Table 3-E)

Internal Product Temperature (°F)	Internal Product Temperature (°C)	Lethal Rate*	Time for 6D Process (minutes)
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2
205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

** Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference product internal temperature of 194°F (90°C) (for temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C))..*

Table A4-6. Properties of common foodborne bacterial pathogens

Organism	Pathogenicity	Common Sources	Transmitted by	Contributing Factors	Atmosphere	Sporeformer/ Non-Sporeformer	Other
Bacillus cereus	Produces two toxins – diarrheal and emetic (vomiting).	Soil.	Rice, starchy foods, meats, vegetables, milk products, sauces.	Temperature abuse.	Facultative Anaerobic – grows with or without oxygen.	Sporeformer	Growth to 10^5 to 10^8 cfu/gr is often associated with illness. Emetic toxin is heat stable
Brucella spp.	Infection causes fever, sweating, weakness, muscle aches, headache. Symptoms can be prolonged.	Unpasteurized milk and undercooked meat.	Uncooked/ unpasteurized milk and meat.	Consumption of infected unpasteurized milk products.	Aerobic.	Non-sporeformer	Survives but proliferates poorly outside of the animal host
Campylobacter spp.	Infection causes diarrhea and potential nerve damage.	Raw poultry, raw milk products, contaminated water	Raw poultry, raw milk products, contaminated water.	Cross contamination and undercooking	Micro-aerophile (3-5% oxygen optimum)	Non-sporeformer	–
Clostridium botulinum	Toxin in food causes blurred or double vision, paralysis of respiratory muscles, and death.	Widespread	Food with anaerobic environment	Temperature abuse.	Anaerobic.	Sporeformer	Mesophilic and psychotropic strains
Clostridium perfringens	Toxin causes diarrhea and abdominal pain.	Soil and intestinal tract of healthy people and animals.	Meats, stews, or gravy, especially those containing spices.	Inadequate hot holding and reheating.	Anaerobic.	Sporeformer	–

Organism	Pathogenicity	Common Sources	Transmitted by	Contributing Factors	Atmosphere	Sporeformer/ Non-Sporeformer	Other
Cronobacter spp. (formerly *Enterobacter sakazakii*)	Infection of bloodstream and central nervous system primarily in infants, especially newborns (<2 months old), and immunocompromised adults	Occurs widely in the environment. Although the bacterium also has been found in a variety of foods, only powdered infant formula has been linked to serious illness.	Contamination thought to occur after spray drying step from environmental contamination or addition of post-process ingredients.	Can survive in dried infant formula and then multiply after reconstitution, especially if the formula is stored at an incorrect temperature. It can also survive in dry milks, herbal teas, and starches	Facultative Anaerobe – grows with or without oxygen	Non-sporeformer	–
Shiga-toxin Producing *Escherichia coli* (STEC)	Infection causes bloody diarrhea and sometimes kidney failure and death.	Intestinal tract of ruminant animals (e.g., cows, sheep).	Raw and undercooked beef, leafy greens, sprouts, and unpasteurized milk and juices.	Poor GAP, inadequate heating, and person-to-person.	Facultative Anaerobe	Non-sporeformer	–
Listeria monocytogenes	Infection causes severe illness in susceptible people – mortality 15-30%.	Occurs widely in agriculture (soil, plants, and water).	Refrigerated RTE foods that support growth.	Environmental pathogen spread by environmental contamination, equipment, people, incoming raw ingredients.	Microaerophile	Non-sporeformer	–
Mycobacterium bovis	Infection causes respiratory symptoms and tuberculosis.	Cattle and raw milk.	Raw milk products.	Lack of milk pasteurization and exposure to aerosols from infected animals.	Microaerophile	Non-sporeformer	–

Organism	Pathogenicity	Common Sources	Transmitted by	Contributing Factors	Atmosphere	Sporeformer/ Non-Sporeformer	Other
Salmonella spp.	Infection causes nausea, vomiting, diarrhea, fever, headache.	Intestinal tract of people and animals.	Meat, poultry, eggs, raw milk, and many other foods (nuts, spices, produce, chocolate, flour).	Cross-contamination, undercooked food, poor agricultural practices, environmental contamination.	Facultative anaerobe	Non-sporeformer	–
Shigella spp.	Infection causes diarrhea, which may be watery to bloody. The infection is called dysentery.	Human intestinal tract.	Fecal contamination from contaminated water or infected food workers.	–	Facultative anaerobe	Non-sporeformer	–
Staphylococcus aureus	Produces heat stable toxins after extensive growth	Boils, nasal passages, and skin	Re-contaminated cooked foods, and foods with high salt or high sugar.	Recontamination and temperature abuse	Facultative anaerobe	Non-sporeformer	Poor competitor
Streptococcus spp. group A	Infection causes sore throat, tonsillitis, and fever.	Infected sites of humans and animals, raw milk	Infected workers handling food and consumption of raw milk or meat products.	–	Facultative anaerobe	Non-sporeformer	–
Vibrio spp.	Infection symptoms vary depending on strain, ranging from diarrhea to high fever.	Salt water environment and seafood	Marine seafood products.	–	Facultative anaerobe	Non-sporeformer	Requires salt to reproduce

Descriptions of Common Foodborne Pathogens

Bacillus cereus (B. cereus) causes either vomiting with short onset (30 minutes to 6 hours), or diarrhea and cramps in 6 to 15 hours. Different strains produce two different toxins – the one responsible for short-onset vomiting is heat resistant. The toxin that causes diarrhea is produced in the intestines. Symptoms, in both forms of illness, last about 24 hours.

Symptoms mimic those of either *S. aureus* (vomiting type) or *C. perfringens* (diarrheal type). Many foods are associated with the diarrheal type of illness, while rice and other grains and starchy foods are associated with the vomiting type. Transmission of illness is caused by the consumption of food containing preformed toxin for the vomiting type of illness, or with high levels of vegetative cells produced during growth under temperature abuse for diarrheal disease. *B. cereus* spores are resistant to normal cooking processes and the vegetative cells grow with or without oxygen ("facultative"). Refrigeration and freezing inhibit *B. cereus* growth but do not kill the bacteria. An estimated 63,400 foodborne cases of *B. cereus* food poisoning occur annually in the United States (Scallan et al., 2011).

***Brucella* spp.** is the bacterium responsible for brucellosis. An estimated 840 foodborne cases of brucellosis occur annually in the United States (Scallan et al., 2011) When sheep, goats, cows, or camels are infected with the pathogen, their milk becomes contaminated with the bacteria. The most common way humans become infected is by eating or drinking unpasteurized/raw dairy products from infected animals. *Brucella* can also enter the body through skin wounds or mucous membranes following contact with infected animals. Symptoms include fever, sweating, malaise, anorexia, headache, pain in muscles, joints, and/or back, and fatigue. Some signs and symptoms may persist for prolonged periods of time or may never go away.

Campylobacter jejuni (C. jejuni) is the bacterium responsible for campylobacteriosis. An estimated 845,000 foodborne cases of campylobacteriosis occur annually in the United States (Scallan et al., 2011). Symptoms include diarrhea, fever, abdominal pain, nausea, headache, and muscle pain. Symptoms start 2 to 5 days after consumption of contaminated food and last 7 to 10 days. A small percentage of patients develop complications that may be severe and last longer than 7 to 10 days. These include bacteremia and infection of various organ systems, such as meningitis, hepatitis, cholecystitis, and pancreatitis. Autoimmune disorders are another potential long-term complication associated with campylobacteriosis (e.g., Guillain-Barré syndrome (GBS)). Everyone is susceptible to infection by *C. jejuni.* Campylobacteriosis occurs more frequently in the summer months than in the winter months.

Clostridium botulinum produces several types of toxins. Types A, B, E, and F toxins are concerns in food and may cause a severe disease called botulism. Blurred or double vision, dry mouth, difficulty swallowing, paralysis of respiratory muscles, vomiting and diarrhea may be present. Symptoms develop 18 to 36 hours (sometimes days) after eating contaminated food and death can occur unless treatment is received. Recovery may be slow (months, even years, on rare occasions,). *C. botulinum* spores may be present in

soil and the intestinal tract of animals and are widespread in nature. The spores are heat resistant and, under the right conditions in the absence of oxygen, can come out of dormancy and produce toxin. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness. Mortality is high; without the antitoxin and respiratory support, death is likely.

Some *C. botulinum* strains (type E and some strains of B and F) can grow at refrigeration temperatures, but most cannot. The spores of strains that grow under refrigeration are not as heat resistant as other spores. The toxin is destroyed by high heat (boiling for 5 min); however, the disease is so severe that heating to destroy toxin is not an appropriate control method. *C. botulinum* can grow in many foods under strict anaerobic (low oxygen) conditions. A pH $\leq$4.6 prevents toxin production by *C. botulinum,* and toxin production for those strains which grow under refrigeration is inhibited at pH<5.0. Sodium nitrite used in cured foods slows toxin production.

Clostridium perfringens causes diarrhea and abdominal pain 6 to 24 (typically 8 to 12) hours after eating food contaminated with large numbers of vegetative cells (>10^6/g), which requires growth in the food. When these viable cells are consumed, they form spores and release toxin in the intestines. *C. perfringens* is found in soil and the intestinal tract of healthy people and animals.

Spores survive normal cooking processes, including boiling. Spices are a potential source for *C. perfringens* as the spores can persist on spices for long periods of time. Inadequate hot holding or cooling of cooked food, particularly meats, pot pies, stew, or gravies, allows bacteria to multiply because the spores can survive the cooking process. *C. perfringens* has one of the most rapid growth rates for foodborne pathogens and can double in less than 10 minutes at optimum temperature.

This pathogen grows best without oxygen. During cooling and holding of food at warm temperatures, the spores germinate, and the resulting vegetative cells of the bacteria grow. An estimated 966,000 cases of foodborne perfringens food poisoning occur annually in the United States (Scallan et al., 2011). Symptoms include abdominal cramps and diarrhea. As noted above, symptoms typically start from 8 to 12 hours after eating contaminated food but can occur as early as 6 hours after exposure, and last for about a day. Everyone is susceptible to perfringens food poisoning, but it is more common in the young and elderly, who may experience more severe symptoms lasting for one to two weeks.

Cronobacter sakazakii* (formerly *Enterobacter sakazakii) is a pathogenic bacterium that can cause illness, primarily among infants younger than two months old, and those who are born prematurely, have weakened immune systems, or are of low birthweight. *Cronobacter* is naturally found in the environment and is particularly good at surviving in low-moisture dry foods, such as powdered infant formula/milk, herbal teas, and starches. Illnesses from *Cronobacter* have been associated with the consumption of powdered infant formula. While *Cronobacter* infections are rare, they can be deadly for young infants and for people with weakened immune systems. As of 2024, *Cronobacter* infections in infants under one year old will be nationally notifiable.

Cryptosporidium parvum is a rarely reported parasite but is notable for its resistance to

chemical agents, including standard levels of chlorine. It is sensitive to drying and ultraviolet light.

Cryptosporidium causes diarrhea, and infection can be fatal for immunocompromised people. Foodborne outbreaks have involved apple cider and unpasteurized milk, as well as contaminated water.

Cyclospora cayetanensis is a parasite that causes prolonged diarrhea. Death rarely occurs. Outbreaks are frequently associated with fruits (berries), leafy greens and other salads, and herbs like basil.

Escherichia coli is a bacterium that is normally present in the intestinal tract of humans and other animals and most strains of *E. coli* are not associated with disease. Certain strains are responsible for four types of illness: 1) Gastroenteritis or infantile diarrhea, caused by enteropathogenic *E. coli* (EPEC); 2) Travelers' diarrhea, caused by enterotoxigenic *E. coli* (ETEC); 3) Bacillary dysentery, caused by enteroinvasive *E. coli* (EIEC); and 4) Hemorrhagic colitis, caused by enterohemorrhagic *E. coli* (EHEC).

E. coli O157:H7 produces a toxin called Shiga-toxin in human intestines, causing severe disease. These disease-causing strains are called enterohemorrhagic, Shiga toxin-producing *E. coli* or STECs, which as a group includes some stains which cause illness, and some strains do not. The Shiga toxins cause diarrhea, which may be bloody, and occasionally, fever. Symptoms start from 8 hours to 9 days after consumption of contaminated food and last from 6 hours to 19 days, with both periods varying significantly between the illness types. Kidney failure and death, especially in children, may result. Very low numbers of some STECs can cause illness. The primary source of STECs is fecal contamination from ruminants, including sheep and deer. These animals typically show no sign of illness. Consumption of raw or undercooked hamburger, contaminated produce, sprouts, and unpasteurized milk and juices has been linked to illness. *E. coli* O157:H7 and other STECs are killed by mild heat treatments. They can grow with or without oxygen. The optimum temperature for growth is around human body temperature, and the organism grows in some moist foods with a pH as low as 4.4.

The O157:H7 strain currently is the predominate strain in the US, causing approximately 75 percent of the EHEC infections worldwide.Other non-O157 EHEC serotypes also cause foodborne illnesses. In the United States O111, O26, O121, O103, O145, and O45 are the most common non-O157:H7 serotypes isolated from clinical infections. However, other EHEC serotypes, such as O113, O91, and others, also can cause severe illness. Thus, public health concerns related to EHEC can change rapidly. Everyone is susceptible to all forms of infection from *E. coli*, but EPEC is most commonly associated with infants, and all types tend to result in more severe symptoms in the very young and elderly.

***Giardia intestinalis* (or *lamblia*),** like other parasites, causes diarrhea and is the most common parasitic cause of diarrhea in the United States. Contaminated water is the primary source of outbreaks, but food and people spread the disease, and as little as only one cyst may be enough to cause illness. Illness occursabout two weeks after eating contaminated food, so tracing the source of illness can be very difficult. Foodborne outbreaks with identified vehicles include ice, lettuce-based salads, chicken salad and unspecified vegetables.

Hepatitis A virus causes the severe disease hepatitis. The health department will be notified if a food worker contracts hepatitis A. Symptoms of hepatitis A include weakness, fever, and abdominal pain. As the illness progresses, the individual usually becomes jaundiced (skin yellows). The severity of the illness ranges from very mild (young children often experience no symptoms) to severe and requiring hospitalization. The fatality rate is low, and deaths primarily occur among the elderly and individuals with underlying diseases. Illness occurs about two weeks after eating contaminated food (but can be much longer), so tracing the source of illness can be very difficult.

Hepatitis A transmission can be prevented by practicing good personal hygiene and exclusion of ill workers, vaccination of food handlers, thorough cooking of food and preventing cross-contamination. Hepatitis A appears to be more heat resistant than other viruses. A laboratory study showed that hepatitis A viruses in infected oysters were inactivated after heating at 140°F (60°C) for 19 minutes.

Listeria monocytogenes is the bacterium responsible for Listeriosis. *Listeria* is a foodborne pathogen of particular concern to the food industry, especially as an environmental pathogen in facilities producing ready-to-eat foods. It can cause meningitis, a severe infection with symptoms including sudden fever, intense headache, nausea, vomiting, delirium, fetal loss in pregnant women, and coma in people with suppressed immune systems. Up to one-third of those who are hospitalized die. Symptoms start from three days to three weeks after consumption of contaminated food. Mortality is high (approximately 25 percent) in those who display more severe symptoms. In a healthy person, infection with *Listeria monocytogenes* may cause no symptoms or a flu-like illness and diarrhea. This organism is a particular problem for pregnant women (causing miscarriage) and the elderly. Illness occurs about two weeks after eating contaminated food (but can be much longer), so tracing the source of illness can be very difficult. Refrigerated ready-to-eat foods are associated with Listeriosis and five key factors influence the risk of contracting Listeriosis from such foods including: 1) the amount and frequency of consumption of the food; 2) the frequency and extent of contamination; 3) the ability of the food to support *Listeria monocytogenes* growth; 4) the temperature of refrigerated storage; and 5) the duration of refrigerated storage. Ready-to-eat meat products, unpasteurized dairy products and other low-acid ready-to-eat foods have been associated with Listeriosis outbreaks. *Listeria monocytogenes* is an environmental pathogen, thus post-heat-processing contamination from the plant environment, including plant personnel, equipment, floors, walls, drains, and condensation from coolers is a primary source of contamination. This non-sporeforming bacterium is killed by pasteurization temperatures, grows with or without air, and can grow at refrigeration temperatures and in higher salt concentrations than some other pathogens. Acid conditions slow growth but may allow survival. *Listeria monocytogenes* is extremely hardy compared to most bacteria, withstands repeated freezing and thawing, and survives for prolonged periods in dry conditions.

Mycobacterium bovis is another foodborne bacterial pathogen that rarely causes foodborne illness in the United States because of the implementation of milk pasteurization requirements and removal of infected cattle. The primary source is cattle and raw milk. The hazard can be easily avoided by using pasteurized milk. Consumption

of raw or undercooked meat, such as venison, of infected animals can also be a source of illness.

Norovirus is highly infectious and can cause illness when as few as 10 to 100 virus particles are consumed. People are the primary source of norovirus and when someone is ill, they can shed millions of viral particles through vomit and feces. Because of this, people with norovirus must be excluded from handling food. If a food worker is diagnosed with norovirus, it is important to clean and disinfect surfaces that they may have contaminated. This is likely to require higher concentrations of sanitizers than those used for food-contact sanitizing. Norovirus causes nausea, vomiting, diarrhea, abdominal cramps and occasionally fever 24-48 hours after initial contact.

Norovirus outbreaks can be prevented by excluding ill workers, by proper personal hygiene, byproperly cooking food, by preventing cross-contamination, and by cleaning and disinfecting surfaces that were contaminated by an infected individual.

Salmonella is among the most common causes of bacterial foodborne illness and can be a risk as an environmental pathogen for operations producing ready-to-eat foods. The infection causes diarrhea, fever, abdominal cramps, and vomiting. Occasionally, *Salmonella* may cause bloodstream infections and death. Severe cases may also result in reactive arthritis. Foodborne illness symptoms generally appear 6 to 48 hours after eating contaminated food and generally last from 4 to 7 days. The intestinal tract of animals is the primary source of *Salmonella*, thus raw animal products (meat, poultry, eggs, milk products) are frequently associated with outbreaks.

Because *Salmonella* survives well in many environments, many other foods have been associated with outbreaks, such as yeast, coconut, sauces, cake mixes, cream-filled desserts, gelatin, peanut products, chocolate and cocoa, and soy ingredients. Fresh fruits, vegetables and nuts can be contaminated during growing if Good Agricultural Practices are not applied.

Salmonella is easily killed at traditional cooking temperatures, grows with or without air, growsbest at human body temperature, grows very poorly at refrigeration temperatures, and does not grow above 115°F (46°C). Unlike most other pathogens, *Salmonella* can grow at a pH as low as 3.7 under otherwise optimum conditions. It survives well in frozen and dry foods, as well as in dry processing environments. Attempts to wet clean dry processing environments have been shown tospread contamination and increase the risk of product contamination because of growth in environmental niches like cracks and crevices that cannot be reached by sanitizers. It is best to keep dry environments dry when *Salmonella* is a potential concern.

Shigella causes diarrhea (often bloody), fever and stomach cramps 12 hours to 2 days after consuming contaminated food or beverages, with symptoms usually lasting 1 to 2 weeks. Symptoms include abdominal pain, cramps, diarrhea, fever, vomiting, blood, pus, or mucus in stools, continuous or frequent urges for bowel movement, and death. *Shigella* is transmitted primarily by people who are infected, thus it is essential for people with diarrhea to be restricted from handling food. *Shigella* is a relatively fragile bacterium that does not survive cooking or in dryenvironments. It can be transmitted by foods such as fresh fruits and vegetables, especially if washed in contaminated water.

Staphylococcus aureus causes a relatively mild illness with vomiting, nausea, abdominal cramps, and diarrhea 1 to 6 hours after eating food contaminated with toxin. The toxin is produced after extensive growth in the product and is very heat stable, even withstanding processing times and temperatures used in canning foods. While the toxin is heat stable, the bacterium is killed by mild heat. Toxin production is favored by the presence of oxygen. The limits for toxin production are more restricted than those for growth. *S. aureus* is a poor competitor; thus, toxin formation may not occur in foods that have many competitive microorganisms, such as raw foods and foods that undergo a controlled fermentation.

From 25 to 50 percent of healthy people and animals can carry *S. aureus* on their skin and in their noses; thus, food may be easily re-contaminated, under poor hygiene or extensive handling conditions. If this occurs along with temperature abuse, rapid growth and subsequent toxin formation is likely in foods with few competing organisms, such as cooked foods or foods with lower water activities that inhibit competing organisms but permit *S. aureus* growth.

Streptococcus group A infections are rare causes of foodborne illness. Transmission through food can be easily avoided by exclusion of ill workers and milk pasteurization.

Toxoplasma gondii is a parasite and a leading cause of death from foodborne illness in the United States, particularly for babies infected in the womb, and for people with suppressed immune systems. People infected with *Toxoplasma* may be asymptomatic, but it can spread to a variety of organs including the brain, eyes, heart, and other muscles. Raw meat products and cat feces are the primary source of this parasite. Freezing food to ≤9°F (-13°C) for 24 hours or more usually prevents infectivity. Cooking meats to recommended temperatures is also an effective control measure.

Trichinella spp. is the parasite that causes trichinosis, which is associated with consumption of raw meat products. In the past, pork was the primary type of meat involved; however, transmission through commercially raised pork is now rare. Trichinellosis is more commonly associated with wild game and exotic meats. As with other parasites, *Trichinella* is susceptible to freezing and cooking.

Vibrio species of concern to food include *V. cholera, V. parahaemolyticus and V. vulnificus*. Because *Vibrio* spp. is a concern for seafood products and generally not other foods, they are not addressed in this training program. Refer to the *Fish and Fishery Products Hazards and Controls Guidance* or Seafood HACCP curriculum for more information on *Vibrio* spp., as well as other regulatory requirements.

Yersinia enterocolitica foodborne illness is primarily associated with cross-contamination from raw pork products. It is a relatively uncommon foodborne illness for other foods.

Additional Reading, Resources, and References

CDC. (n.d.). Estimates of Foodborne Illness in the United States available at: https://www.cdc.gov/foodborneburden/index.html

FDA. 2012. The *Bad Bug Book Foodborne Pathogenic Microorganisms and Natural Toxins,* 2nd Edition.

FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

FDA. 2022. *Fish and Fishery Products Hazards and Controls Guidance*. June 2022 Edition. https://www.fda.gov/food/seafood-guidance-documents-regulatory-information/fish-and-fishery-products-hazards-and-controls

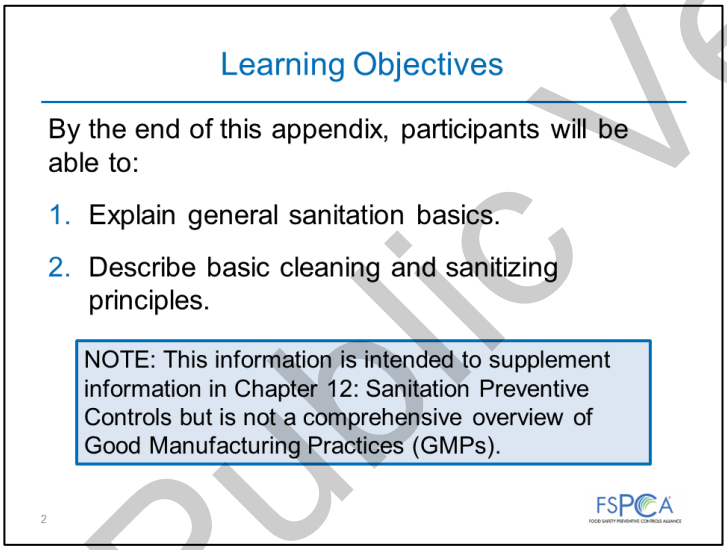
FDA. 2023. Foodborne Pathogens: *Cronobacter sakazakii. https://www.fda.gov/food/foodborne-pathogens/cronobacter-sakazakii*

Painter, JA, RM Hoekstra, T Ayers et al. 2013. Attribution of foodborne illness, hospitalizations, and deaths to food commodities by using outbreak data, United States, 1998-2008. *Emerg. Infect. Dis*. 19(3):407-415.

International Commission on Microbiological Specifications for Foods. 1996. Microorganisms in Foods 5: Characteristics of Microbiological Specifications of Food Pathogens. Blackie Academic and Professional, New York. Scallan.

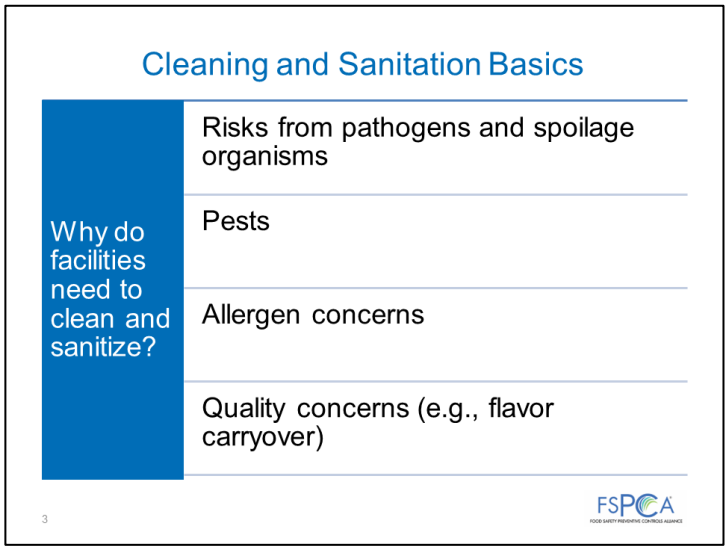
Slide 1: Appendix 5: Sanitation Basics for Human Food

Slide 2: Learning Objectives



Chapter 12: Sanitation Preventive Controls addresses the regulatory requirements for sanitation preventive controls. Sanitation processes are also a GMP requirement. This appendix provides more detail on the basic cleaning and sanitizing process. This appendix includes some text from Chapter 12 because sanitation preventive controls build on the sanitation fundamentals discussed in this appendix.

Slide 3: Cleaning and Sanitation Basics



Definition: *Pest*: Any objectionable animals or insects including birds, rodents, flies, and larvae. (21 CFR 117.3)

The EPA definition of pest includes objectionable microorganisms. Sanitary practices help to keep all of the above under control.

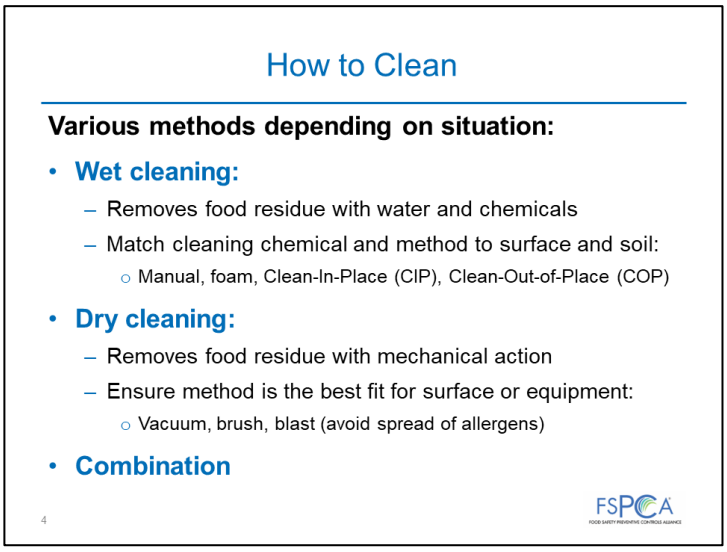
A strong sanitation process is a fundamental prerequisite for a strong food safety program. Without an adequate sanitation process food may become contaminated with microorganisms that could endanger public health or cause spoilage. Major recalls have been caused by sanitation lapses which led to contamination or recontamination of food.

Sanitation removes the food residue that both attracts and supports the growth of pests within and outside of the facility environment. Pests need the same things that people do to live and reproduce—water, air, food, and habitat. Through sanitation, food, habitat and sometimes water are removed so pests are less likely to be attracted.

In addition to pests, very small amounts of food allergens can cause adverse reactions in food-allergen sensitive individuals. An adequate sanitation program is essential to prevent allergen cross-contact between foods that contain allergens and those that do not as well as for foods containing unique allergens.

A strong sanitation program helps assure that the products produced are both safe and wholesome. Additionally, a robust sanitation program may also address quality concerns outside of the food safety program.

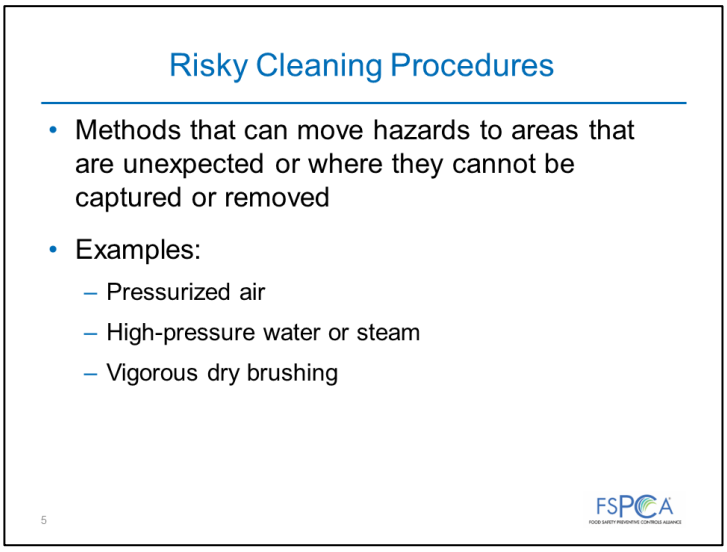
Slide 4: How to Clean



The cleaning method should account for the equipment being cleaned, as well as the hazards that must be controlled. Wet cleaning is frequently the most effective way to remove food residue, especially when the cleaning solution is selected with the particular food residue in mind. Manual, foam/gel, Clean-In-Place (CIP), and Clean-Out of-Place (COP) methods can be effective in wet cleaning situations.

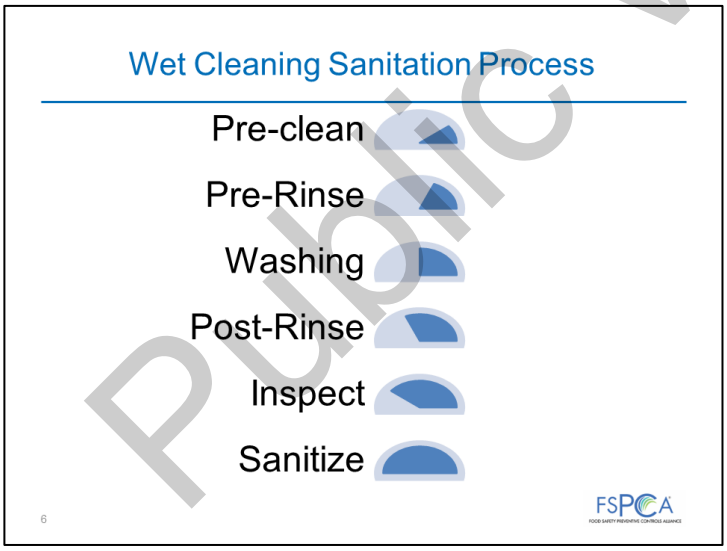
Many types of low-moisture foods and raw materials are handled in the dry environment (e.g., cereal, baking products, dairy powders, nut butters, packaging, etc.). In this environment, dry cleaning methods should be used, and environments should be maintained in a dry condition to prevent the establishment of environmental pathogens. Dry cleaning methods typically use mechanical action and are discussed after wet cleaning.

Slide 5: Risky Cleaning Procedures



Allergens and microbial contamination can be carried as dust by compressed air, or suspended in liquid where high-pressure water or steam is used. The possibility that these hazards will re-enter the processing stream is likely and is very difficult to control. These methods should be avoided unless capture systems, such as vacuums, are available.

Slide 6: Wet Cleaning Sanitation Process



Before work areas and equipment can be sanitized, they must be cleaned. Using sanitizer on a dirty surface can be ineffective because the food residue may bind to the active ingredients. Therefore, sanitation is usually a two-step process; clean and then sanitize. In the food and beverage industry, cleaning consists of several distinct steps, including pre-cleaning, pre-rinsing, washing, post-rinsing, inspecting, and sanitizing.

Pre-cleaning involves the use of a broom, brush, squeegee, or other appropriate tool to sweep up food particles and residue from surfaces prior to pre-rinsing. Pre-clean can decrease the time and chemical requirements for the full cleaning process. Pre-rinsing with potable water to remove any remaining small food particles and residue wets and prepares the surface for detergent application.

Washing involves using the appropriate detergent based on the nature of the soil, the type of surface to be cleaned and the type of cleaning method used (e.g., manual, foam/gel, CIP, COP). Detergent helps to remove residues from surfaces, and then also helps to suspend it so it can be removed during rinsing. The effectiveness of a cleaning process is influenced by four major factors: 1) chemical concentration; 2) mechanical action; 3) time; and 4) temperature. Follow the manufacturer's instructions for ensuring the use of the correct cleaning chemicals with recommended application parameters including concentrations, temperatures, and contact times.

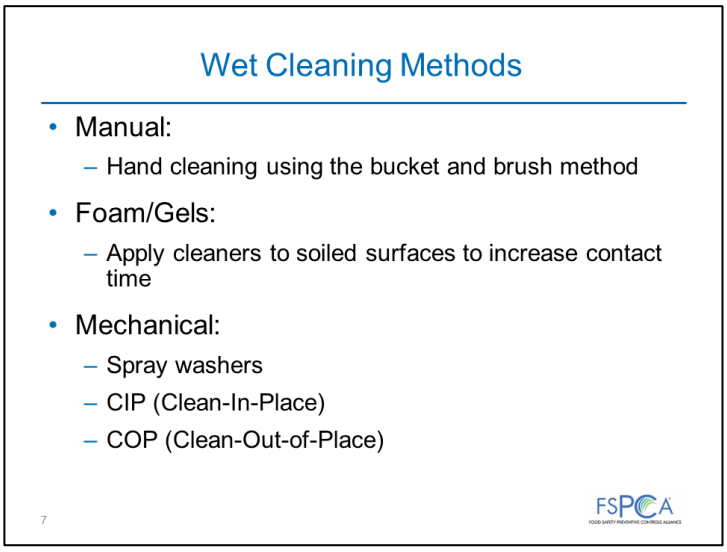
In the post-rinse phase, potable water removes detergent and the remaining loose soil on the surfaces. This process prepares the surfaces for sanitizing. All detergents must be removed because they may inactivate certain sanitizers.

It is important to evaluate the effectiveness of the cleaning procedures. Visual observation of the cleaned surfaces for evidence of residues or how water beads on the surface will indicate whether the surfaces will need to be recleaned. Using tools such as flashlights, black-lights and spotlights can help assist with the visual observation. Microbial evaluation of the surfaces using ATP or microbial plate count methods such as Standard Plate Count (SPC) indicate the degree to which the procedures eliminated microorganisms from the surface. Testing the surfaces for residual proteins will show the degree to which protein residuals have been removed. If a surface is hard-to-reach or hard-to-see, it is also likely to be hard to clean. Dismantling equipment is sometimes necessary to ensure that the cleaning process is effective.

Food-contact surfaces should be sanitized to inactivate pathogens after the surfaces have been cleaned and rinsed. All sanitizers must be used in accordance with the EPA-registered (or similar registration in other countries) label use instructions, including approval for use in food establishments.

A reputable chemical company provider is a good resource for further information on all of these areas.

Slide 7: Wet Cleaning Methods



There are different ways in which food residues can be removed:

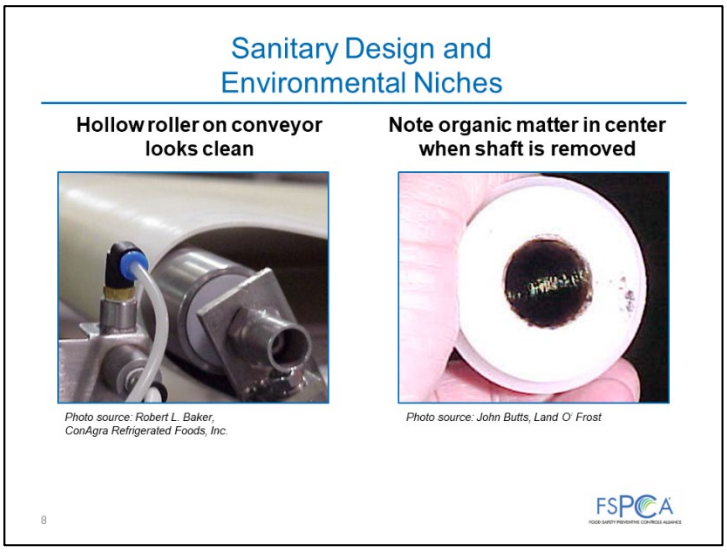
Manual methods involve washing objects by hand using a bucket (or sink) to hold the cleaning solution and a brush or other tool to scrub food-contact surfaces. Items can be left in a soak tank to increase the contact time and reduce the amount of scrubbing needed to remove soils.

Foam/Gel methods involve more concentrated cleaners that can be applied to the surface of soiled equipment. The higher concentration can reduce the time it takes to remove soil. A water spray removes the cleaner and loosened soils.

Mechanical methods include spray washers, CIP systems and COP systems. Spray washers can be conveyor (similar to a car wash) or batch (cabinet washers). CIP systems clean internal surfaces of production equipment without disassembly. Cleaning solutions contact the surfaces by pumped circulation and automatic spraying. COP systems clean disassembled equipment parts that are placed in a tank where the cleaning solution circulates.

For any mechanical process, it is important to follow defined process parameters (e.g., chemical concentration, velocity or flow rate, time and temperature), to assure adequacy of the process.

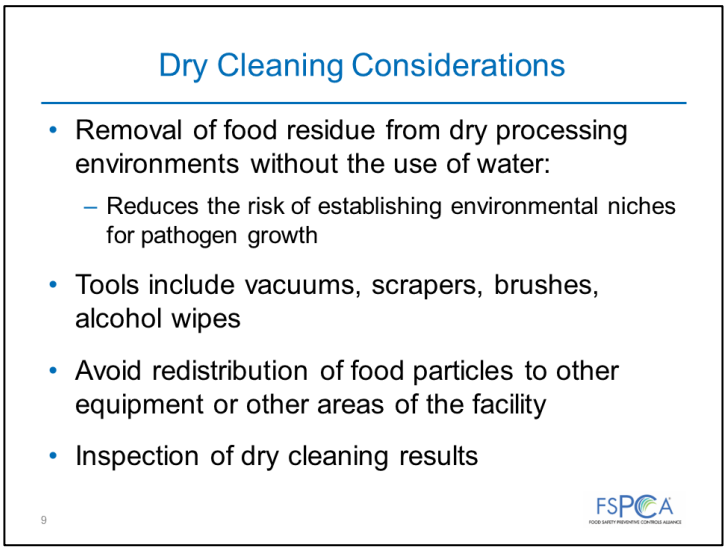
Slide 8: Sanitary Design and Environmental Niches



Sanitary design is an important consideration to prevent product contamination. An example of a potential source of environmental contamination is the hollow roller on a conveyor illustrated on the slide above. The equipment looks clean but when the shaft is removed, organic matter which can support microbial growth is evident in the center of the roller. This type of site may be impossible to clean and sanitize with a normal cleaning procedure.

Re-design of equipment to eliminate hollow rollers is the preferred solution to prevent this type of niche in ready-to-eat facilities that use wet cleaning methods. Cracks and crevices in equipment, floors, and walls present similar cleaning and sanitizing challenges. The required elements for cleaning—time, temperature, mechanical force, and chemical concentration—simply cannot be reliably applied in these tight areas. If such equipment is used, keeping it dry is important to prevent a potential source of contamination. Disassembling equipment for thorough cleaning may be necessary if the equipment cannot be redesigned. References on sanitary design are provided at the end of the chapter.

Slide 9: Dry Cleaning Considerations

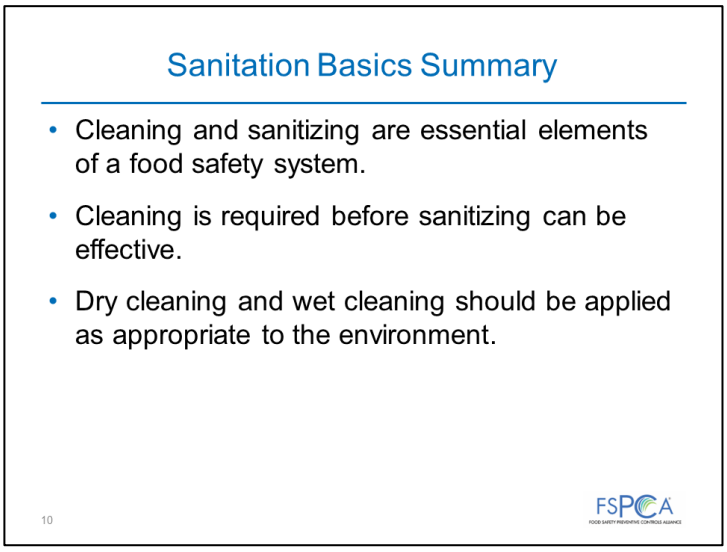


Where wet cleaning increases the risk of environmental pathogens such as *Salmonella*, dry cleaning methods should be used. Tools used for dry cleaning can include vacuums, scrapers, and brushes. The tools must be hygienically designed and in good repair without cracks etc. Hygienic zoning (see Appendix 6) should be present for effective application of dry cleaning. For example, dry cleaning tools should be dedicated to the area or room that is being cleaned.

During dry cleaning, food residue is removed using physical or mechanical actions, such as vacuum systems, brushing, and blasting with high-pressure air. As previously discussed, it is essential that cleaning does not spread hazards (e.g., pathogens or allergenic material) to other surfaces. Capture systems (e.g., vacuums), must be used for some of these techniques. Dry cleaning of enclosed processing lines may use push-through material (e.g., for allergen cleaning). Equipment should be as clean as possible using dry methods before a push-through method is used.

An area that has been dry cleaned should be inspected for effectiveness of the cleaning. The area may not be shiny and completely free of dust, however, there should be very little remaining residue on the equipment. Because some food residues may remain, the effectiveness of dry cleaning procedures to remove food allergens must be considered. Each facility application is different, therefore, this must be evaluated on a case-by-case basis (See Chapter 11: Food Allergen Preventive Controls for Human Food).

Slide 10: Sanitation Basics Summary



Cleaning and sanitizing are required under GMPs, and certain elements of these practices may be a sanitation preventive control. Cleaning is required before sanitizing can be effective. Certain facilities are best cleaned using dry cleaning techniques to prevent formation of environmental niches that can harbor environmental pathogens. Other facilities or locations within facilities require wet cleaning and sanitizing to ensure sanitary operations.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

3-A Sanitary Design Standards: https://www.3-a.org/

American Meat Institute. (2011). Safe Equipment Design Checklist –American Meat Institute. 2003. Sanitary Equipment Design Bakka, R.L. and T. Boufford (ed.). 2004. *Making the Right Choice – Cleaners*. Ecolab Inc., Food and Beverage Division. St. Paul, MN, https://www.meatinstitute.org/sites/default/files/original%20documents/Sanitation%20booklet%202021.pdf

Beuchat, L., et al. (2011). Persistence and Survival of Pathogens in Dry Foods and Dry Food Processing Environments. ILSI Europe Emerging Microbiological Issues Task Force. Boufford, T. (ed.). 2003. *Making the Right Choice – Sanitizers.* Ecolab Inc., Food and Beverage Division. St. Paul, MN

Cramer, M.M. (2006). Food Plant Sanitation: Design, Maintenance, and Good Manufacturing Practices. Taylor & Francis.

Fredell, D. and T. Boufford (ed.). (2007). *Making the Right Choice – Sanitation Process*. Ecolab Inc., Food and Beverage Division. St. Paul, MN

Environmental Protection Agency. *Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions)*. 40 CFR 180.940.

Fresh Produce Association. (2003). Sanitary Equipment Design Buying Guide & Checklist.

Graham DJ. (2006). *Snapshots in Sanitary Equipment: Developing an Eye for Hygiene.* Food Safety Magazine.

Graham, D.J. (2004). *Using Sanitary Design to Avoid HACCP Hazards and Allergen Contamination.* Food Safety Magazine.

Graham, D.J. (2009). *Equipment sanitary design considerations when purchasing.* Food Safety Magazine.

Grocery Manufacturers Association. (2009). *Control of Salmonella in low moisture foods.* Available at Grocery Manufacturers Association. Equipment Design Checklist for Low Moisture Foods.

Imholte, T.J., and Imholte-Tauscher, T.K. (1999). *Engineering for Food Safety and Sanitation. 2nd ed. Technical Institute of Food Safety.*

Marriott, N.G., and Gravani, R.B. (2010). *Principles of Food Sanitation.* 2010. 5th ed. Aspen Publications.

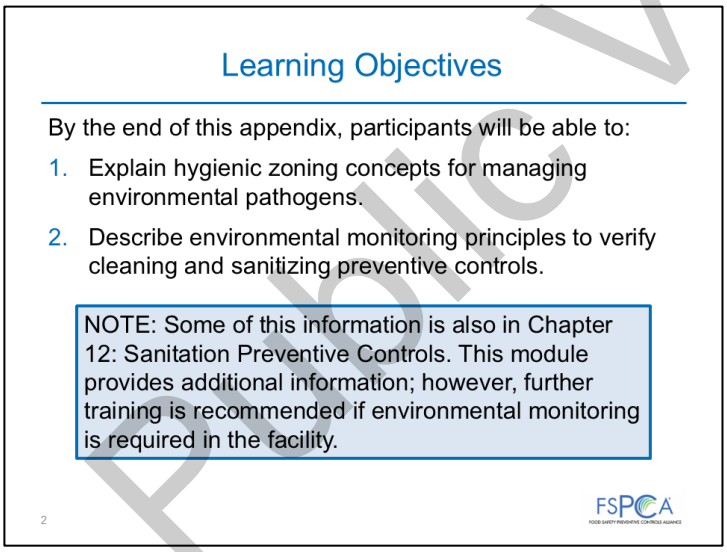
National Seafood HACCP Alliance. (2000). *Sanitation Control Procedures for Processing Fish and Fishery Products.* 1st edition.

Pehanich, M. (2005). *Designing food safety into your plant. Food Processing Sanitary Design. https://www.foodprocessing.com/on-the-plant-floor/plant-safety/article/11372745/food-safety-designing-food-safety-into-your-plant*

Appendix 6: Hygienic Zoning and Environmental Monitoring for Human Food

Slide 1: Appendix 6: Hygienic Zoning and Environmental Monitoring for Human Food

Slide 2: Learning Objectives

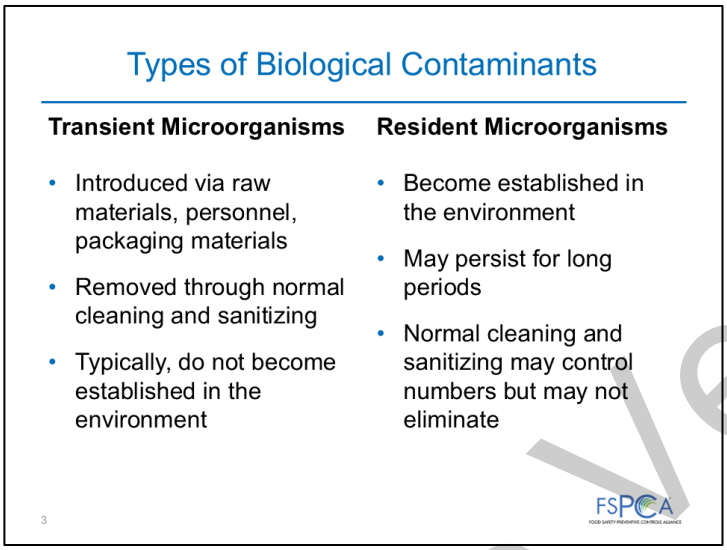


Chapter 12: Sanitation Preventive Controls introduced hygienic zoning as a potential preventive control and environmental monitoring as a verification activity for sanitation and zoning practices. This appendix provides more information on hygienic zoning and environmental monitoring, which may be of interest to participants who have not attended courses on these topics. Some of the information in this appendix includes text from Chapter 12 because sanitation preventive controls build on the fundamentals discussed here in certain facilities.

Environmental monitoring is used to verify the control programs designed to significantly minimize or prevent environmental pathogen contamination of ready-to-eat foods are

working effectively. Sanitation may not be the only control necessary to prevent recontamination of exposed ready-to-eat foods, especially when raw and ready-to-eat products are produced in the same facility. This section discusses different pathways for environmental pathogen contamination, the basic principles for dividing a facility into hygienic zones, the objectives of environmental monitoring, how to implement a program, as well as investigation and corrective actions appropriate when environmental pathogens are detected. Useful records for capturing environmental monitoring results are also discussed.

Slide 3: Types of Biological Contaminants



The first step in understanding environmental pathogens is to understand how microorganisms behave in a food environment. Simplistically, there are two basic types of microbial contaminants—transient and resident microorganisms. Transient microorganisms can enter a food establishment on ingredients, raw materials, personnel, and other incoming items. Essentially, they hitchhike. Normal cleaning and sanitizing should remove transient strains, so they do not persist or become established in a food facility. Even with good sanitation procedures, transient strains will appear from time to time in an establishment and may be detected occasionally through testing. This is to be expected.

Conversely, resident microorganisms become established in the food processing environment. They may find their way into nooks and crannies, referred to as environmental niches or harborages, and persist for long periods of time. These niches are difficult to clean, thus a resident strain may form a colony that periodically contaminates food. The objective of hygienic zoning is to reduce the potential for transient organisms to enter sensitive areas in the facility, such as packing areas where a ready-to-eat product is exposed to the environment. The objectives of an environmental monitoring program are:

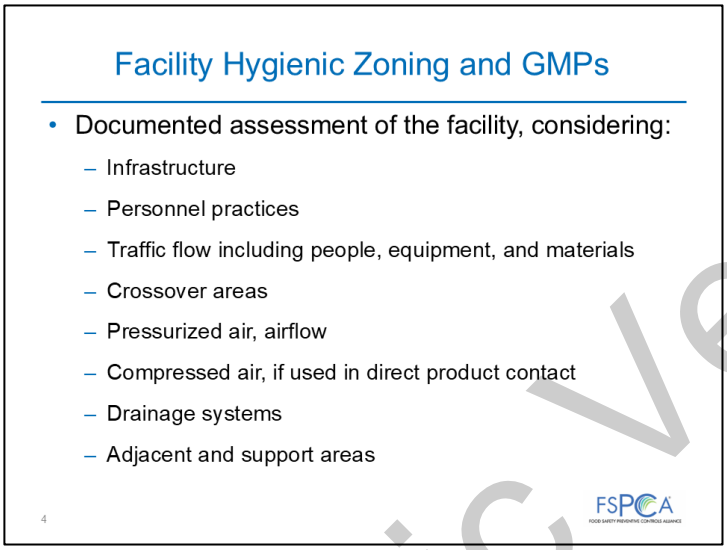
1. To verify that hygienic zoning efforts are effective; and

2. To detect environmental niches and thus target corrective action to remove resident strains.

This requires vigilant sanitation practices and an understanding of the importance of setting up a rigorous program to detect resident strains.

The need and extent of zoning and environmental monitoring depends on the product. Typically, this technique is applied in facilities that make ready-to-eat products. For example, the hygienic zoning and required sanitation preventive controls with associated environmental monitoring will depend on the type of food being produced as well as the food's exposure to the environment.

Slide 4: Facility Hygienic Zoning and GMPs



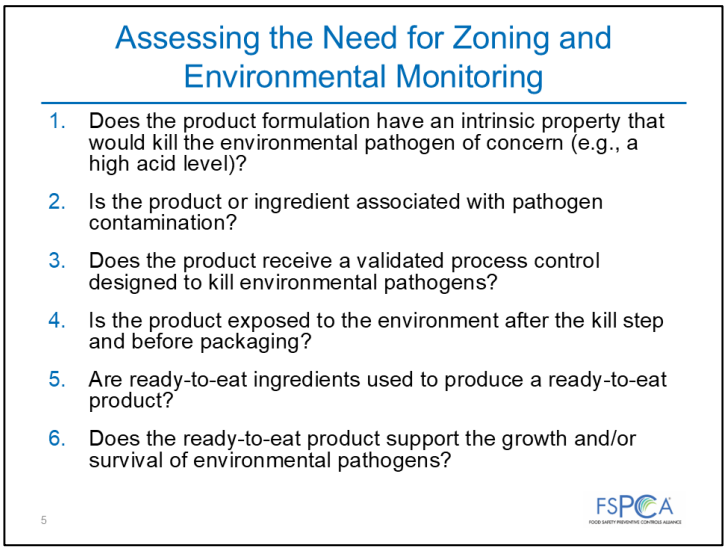
A "support area" is one that supports the facility, such a locker room, lunchroom, or maintenance shop. There may be others in some facilities.

The sanitation preventive controls must address targeted environmental pathogens if relevant to the product being produced. A facility may choose to use hygienic zoning to prevent cross-contamination and prevent allergen cross-contact if this is determined to be a concern through hazard analysis.

Each facility must determine the need for, and the scope of, a sanitation preventive control program based on the potential for product contamination and allergen cross-contact. The assessment should consider the physical structure itself, personnel, packaging, and ingredient traffic flows, and any crossover areas. The assessment should also consider potential contaminants from raw materials, air flow, and/or pressurized air, drainage systems, support areas, and activities taking place in the facility which may include potential allergen and microbiological concerns.

Consider the role of support areas and what sanitation and other practices should optimally be put in place to ensure that they do not contribute to contamination in the production area.

Slide 5: Assessing the Need for Zoning and Environmental Monitoring



Questions that may be considered in determining if zoning and environmental monitoring is useful in a facility include the following:

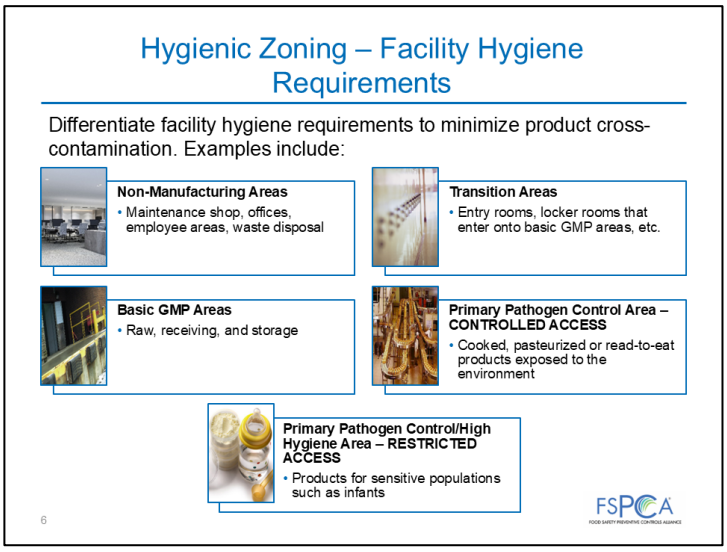
1. Does the product formulation have an intrinsic property that would kill the environmental pathogen of concern?
    - If an intrinsic property kills environmental pathogens (e.g., very high levels of acid as in a vinegar-based sauce), environmental monitoring may not be warranted. Validation (see Chapter 10: Process Preventive Controls For Human Food – Verification and Recordkeeping), of the effectiveness of such intrinsic properties would be needed to ensure that the pathogen is effectively controlled by the intrinsic property.
2. Is the product or ingredient associated with pathogen contamination?
    - The potential for a pathogen to become established in the processing environment increases when an ingredient has a history of pathogen contamination. *Salmonella* has a history of environmental contamination in low-moisture foods such as cereals, peanuts, nuts and nut butters, spices, dried herbs, dairy powders, and chocolate. *Listeria monocytogenes* has a history of association with ready-to-eat food outbreaks, especially for those foods that are refrigerated.
3. Is there a validated process control in place for the product such as a cooking step that will eliminate environmental pathogens, and if so, where in the process does this step take place?
4. Is the product exposed to the environment after a kill step and before packaging?
    - If the unpackaged product is exposed after cooking, the validated process step, which eliminates pathogens, there is an increased risk for recontamination. Exposed ready-to-eat food handling should take place in an environment that has stricter hygiene standards, with periodic environmental monitoring to verify that hygiene controls are adequate to

minimize the potential for product recontamination with environmental pathogens.

5. Are ready-to-eat ingredients used to produce a ready-to-eat product?
    - Sometimes there is no kill step in a process when ready-to-eat ingredients are combined to produce a ready-to-eat product. As with product exposed to the environment after a kill step, enhanced hygiene controls are warranted to reduce the risk of contamination with environmental pathogens.
6. Does the ready-to-eat product support the growth and/or survival of environmental pathogens?
    - If environmental pathogens contaminate foods that are considered ready-to-eat and those foods allow for the survival of the organism, these pathogens will likely be passed to the consumer. Pathogens such as *Salmonella* or *Coronobacter* can survive in dry product conditions for many months and are capable of causing illness at low levels in the food.
    - Foods that allow pathogens not only to survive, but to grow increases this risk of illness to the consumer. This is the case with *Listeria monocytogenes*, a pathogen that is capable of growth at refrigerated temperatures. A low level of *Listeria* contamination on a growth-supporting, refrigerated, ready-to-eat product at the time of packaging becomes a bigger risk if the number of organisms increases.

Contamination of environmental pathogens is a concern not only for ready-to-eat products which will be sold to consumers, but also for ingredients that will be used in ready-to-eat applications. If an ingredient is added to a food matrix likely to support the growth of that pathogen, then there is even a higher risk.

Slide 6: Hygienic Zoning – Facility Hygiene Requirements



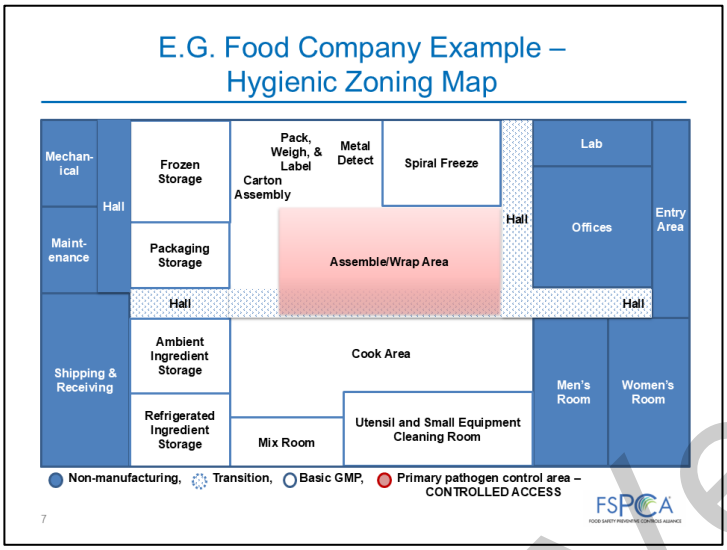
It is useful to define hygiene requirements for different areas based on the risk for contamination from environmental pathogens or from allergen cross-contact:

- Non-manufacturing areas include maintenance areas, offices, and employee areas such as cafeterias. These areas should meet basic sanitation requirements but are not required to meet GMPs. Individuals working in these areas, however, should understand that more strict requirements for sanitation apply in other areas of the facility, and that they must comply with those requirements when they enter other areas;
- Transition areas may include an entry room (or door), locker rooms, and similar areas that enter into basic GMP areas. Smocks, hairnets, footwear, and other personal equipment required for entry into GMP areas should be available in transition areas. Requirements for entry should be listed and the availability of equipment such as hand washing stations, foot foaming stations etc. as relevant to avoid contamination of the facility should be considered;
- Basic GMP areas include raw receiving and storage areas, as well as general food processing areas. These areas must be kept clean to meet basic GMP requirements. Separation of raw ingredient handling areas and tools, from those used for cooked or pasteurized product is necessary to prevent cross-contamination. This includes using linear flow of product and traffic, whether by foot, cart, forklift, or other means, to prevent cross-contamination. If a facility has crossover areas that cannot be engineered out, special attention must be paid to preventive controls in order to avoid accidental cross-contamination;
- Primary pathogen control areas are those where cooked, pasteurized, or ready-to-eat products are exposed to the environment (e.g., packaging areas for such products). More stringent sanitation requirements should apply to these areas to minimize the potential for cross-contamination. Controlling personnel access (e.g., through color coded uniforms, special foot ware etc.), and using dedicated

equipment such as carts and forklifts to hygienic areas may also be useful to keep environmental contaminants from 'hitchhiking' into the more sensitive spaces; and

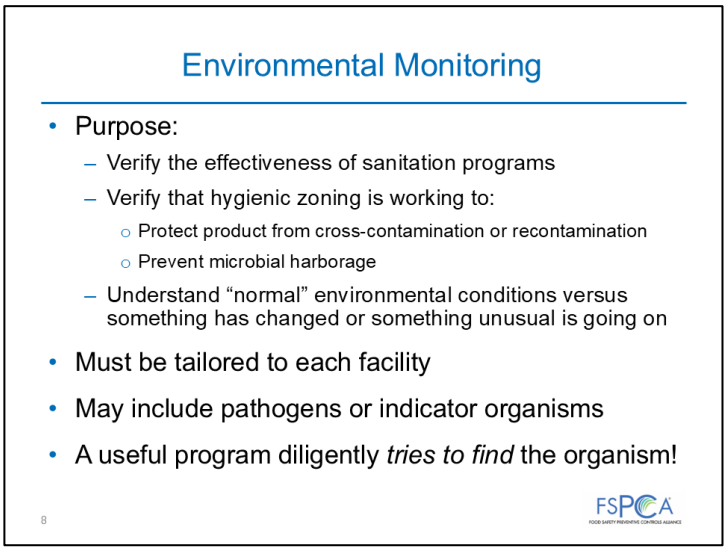
- Sensitive or high-hygiene areas include those areas producing food for sensitive populations such as infants, elderly, and immune-compromised, or producing food dedicated to clinical settings.

Slide 7: E.G. Food Company Example – Hygienic Zoning Map



It is useful to post a color-coded facility map to differentiate hygienic zones to show proper traffic flows to help reinforce zoning and compliance. Such a map can be used to orient new employees and visitors, and to remind everyone about the need to minimize cross-contamination. Implement controls for access and entry into controlled hygiene processing areas. Define and enforce proper attire for each zone of the facility, determine who can go where and the entry requirements. For example, do they have to wear a mask to go into sensitive areas? What about captive (or zoned) footwear? Ideally, transition areas have signs and physical barriers that enforce the proper requirements such as turnstiles, air showers, and handwashing stations at entry points that cannot be bypassed. Pictures on signs are the most effective.

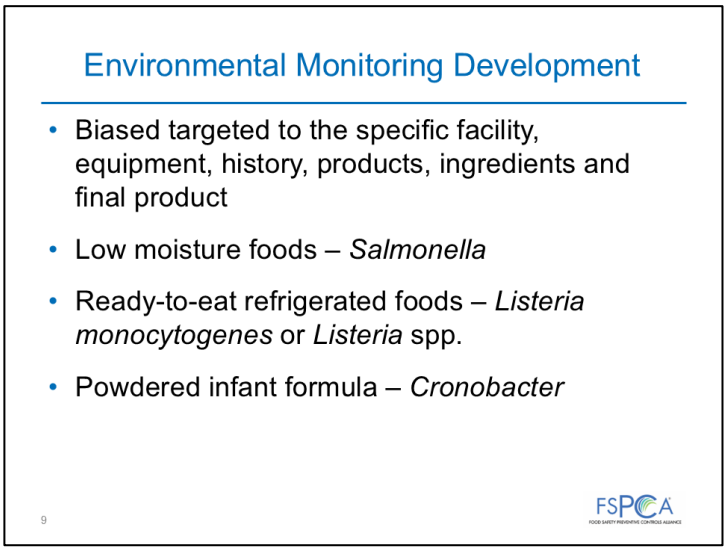
Slide 8: Environmental Monitoring



The primary objective of environmental monitoring is to verify the effectiveness of sanitation controls. Environmental monitoring is useful when the environment needs to be controlled to prevent microbial contamination and when testing will be beneficial to verify control of the pathogen of concern.

An effective environmental monitoring program diligently tries to find the pathogen or indicator of concern so that corrections can be made before product is compromised and the effectiveness of interventions can be evaluated. For example, a robust environmental monitoring program can assist with detection of the presence of niche pathogens and differentiate them from transient strains. This can create a better understanding of how to react to findings. A relentless seek-and-destroy culture (as it relates to environmental monitoring) is essential.

Slide 9: Environmental Monitoring Development



An environmental monitoring program must be designed specifically for the facility and consider the products made, the ingredients used, any history with past environmental pathogens, and other relevant factors. It is a biased sampling in that it looks for worst-case sampling sites and tries to find problem areas, rather than a random sampling program that tries to identify the "average" situation. This may seem risky at first and some may question "Why would I try to find an environmental pathogen in my facility?" The answer is—the facility has a better chance of finding a potential pathogen in the environment before the facility would find it in product, which may prevent a major recall or worse, an outbreak. Investigations of several outbreaks suggest that the facility environment was the source of the outbreak strains

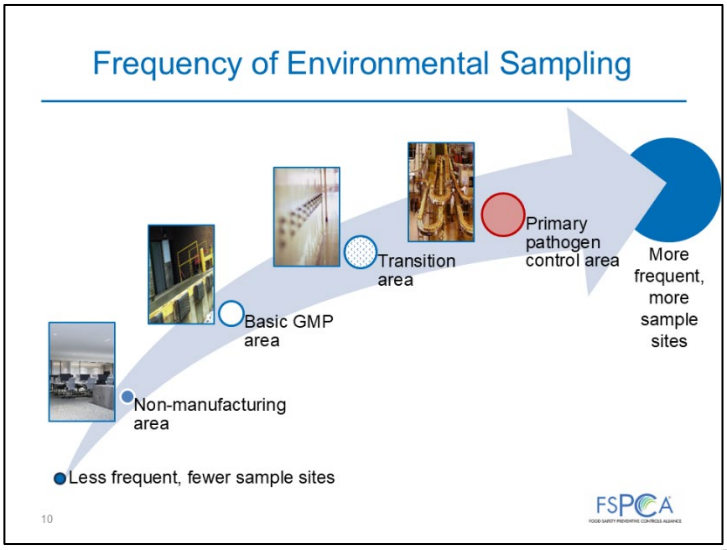
Salmonella survives very well in a dry environment. When water is introduced and nutrients are available (e.g., food dust), *Salmonella* can multiply, which increases the chance of it being transported to another area either by the moisture movement itself, or by contaminating a mobile object or person. *Salmonella* outbreaks thought to involve environmental contamination have been associated with a number of dry food products including bakery mixes, peanut butter, nuts, and breakfast cereals. Therefore, frequent environmental monitoring for *Salmonella* in many ready-to-eat, low-moisture food processing environments is needed.

Listeria monocytogenes outbreaks are associated with refrigerated, ready-to-eat products, thus environmental monitoring frequently is needed to detect the potential for recontamination. *Listeria* spp. monitoring is used as a more general test in some facilities because it is easier to detect a potential problem. However, testing the environment for *Listeria monocytogenes* may be appropriate in some facilities. The decision should be made in consultation with a qualified food microbiologist who understands the microbial ecology of the facility type.

Manufacturers of powdered infant formula are encouraged to conduct the direct testing for *Cronobacter* spp. at some frequency within the processing environment. This program should be designed to cover all stages of processing to ensure that the product does not

become adulterated while focusing the greatest amount of sampling on surfaces from which the risk of contamination to the product is greatest.

Slide 10: Frequency of Environmental Sampling

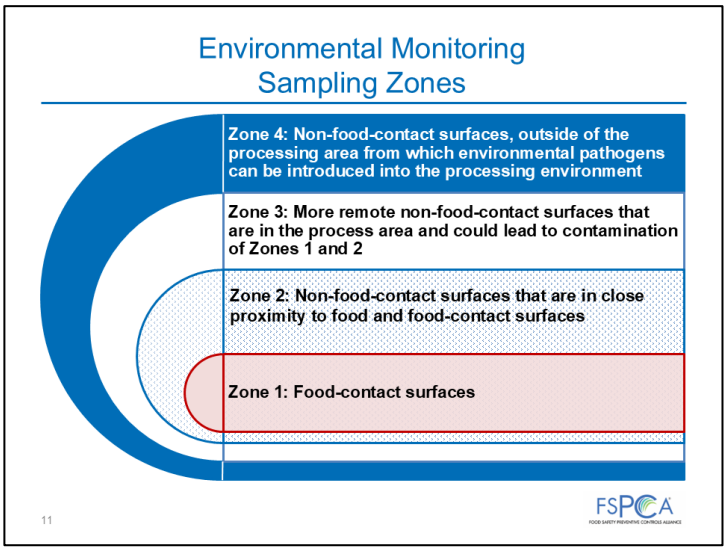


Since the objective of environmental monitoring is to detect potential sources of contamination, sampling typically focuses on the areas of greatest concern. More frequent sampling takes place in primary pathogen control areas. Sampling of non-manufacturing areas is rare but may prove useful during a root cause analysis to determine if the source/niche of an organism is in the non-manufacturing area but is being tracked into the manufacturing area.

As part of the procedures, it is important to establish frequency. Typically, sampling frequency during the initial months of the program may be more frequent to aid in establishing a norm for the facility, and considering factors such as seasonality, weather, adjacent establishments, and personnel changes. As a suggestion, take swabs during production, at least three (3) hours into production. Samples may be composited to reduce costs by taking individual samples from each site and combining them to form the composite sample. If composite samples are found to contain the target organism, then additional sampling within those areas should be run independently. Do not use the same sponge for multiple sample sites as this could spread potential contamination. Increase sampling when focusing on water, harborage, and high traffic areas and sites that are more likely to be a source of contamination based on equipment and plant infrastructure conditions. It is good practice to sanitize the site after sampling.

For more information, refer to the draft *Listeria* guidance referenced at the end of this chapter.

Slide 11: Environmental Monitoring Sampling Zones



Within each area, the actual sampling location is described in terms of zones.

Zone 1 represents food contact surfaces, such as vessels, conveyors, utensils and even hands that come into direct contact with the food. These can include surfaces that could drip or drain onto the food, such as overhead condensate.

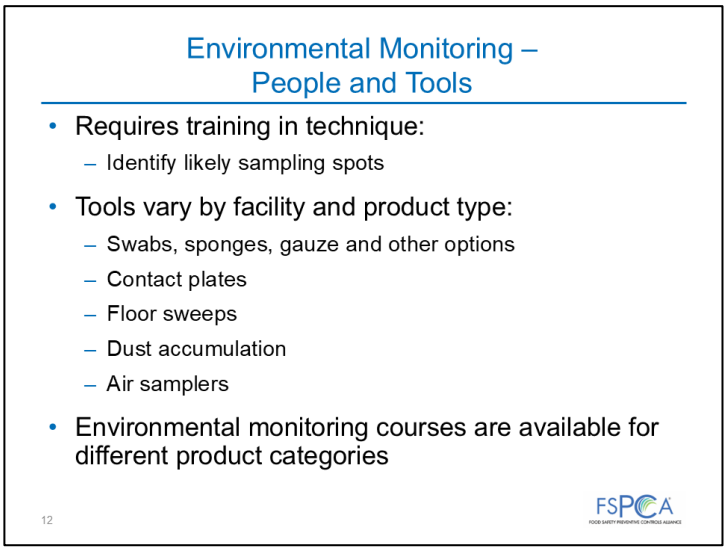
Zone 2 includes areas adjacent to food contact surfaces and are sometimes referred to as "indirect product-contact surfaces." Examples are bearings, equipment panels, or aprons.

Zone 3 includes everything else within the production or processing area such as floors, walls, ceilings, drains and other equipment.

Zone 4 encompasses all other non-production areas of a facility, such as hallways, maintenance shops, and employee welfare areas.

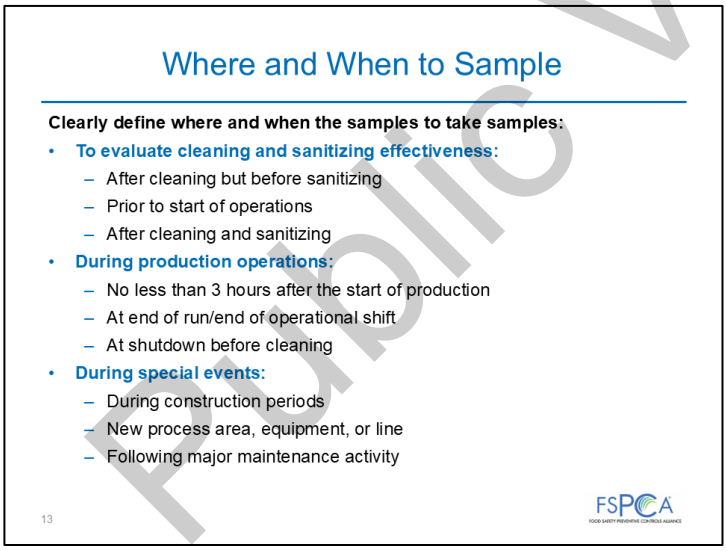
Common industry practices focus monitoring in Zones 2, 3 and 4 locations. These zones will tend to show signs of contamination in the environment first, thus sampling these zones increases the likelihood that a potential contamination source is detected and acted on before it becomes a contaminant in finished product areas, specifically product-contact surfaces (Zone 1). Early detection and correction will help prevent contamination from making its way to exposed ready-to-eat food product. Zone 1 sampling is infrequent, but when this is done, product may have to be held until results are found to be negative to prevent the potential for a recall situation.

Slide 12: Environmental Monitoring – People and Tools



Personnel must be trained to conduct environmental sampling and must have a sense for when to deviate from the plan based on observations or special events. The right tools allow sampling into cracks, crevices, high areas, large floor areas, drains, as well as dry scrapings and air.

Slide 13: Where and When to Sample

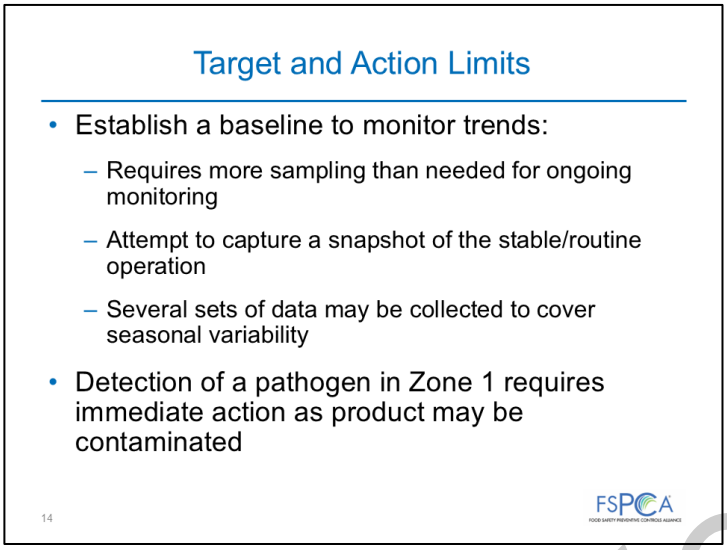


The company may want to prepare a map of the facility with all drains and other relevant locations demarcated (marked or identified), to determine a site list for the facility. Ensure more samples from Zones 2 and 3 are taken each time, with a few from Zone 4.

Take swabs during production, at least three (3) hours after production begins. Samples may be composited to reduce costs by taking individual samples from each site and combining them to form the composite sample. Do not use the same sponge for multiple sample sites as this could spread potential contamination.

Increase sampling when focusing on water, harborage, and high traffic areas, as well as sites that are more likely to be a source of contamination based on equipment and plant infrastructure conditions. It is good practice to sanitize the site after sampling.

Slide 14: Target and Action Limits



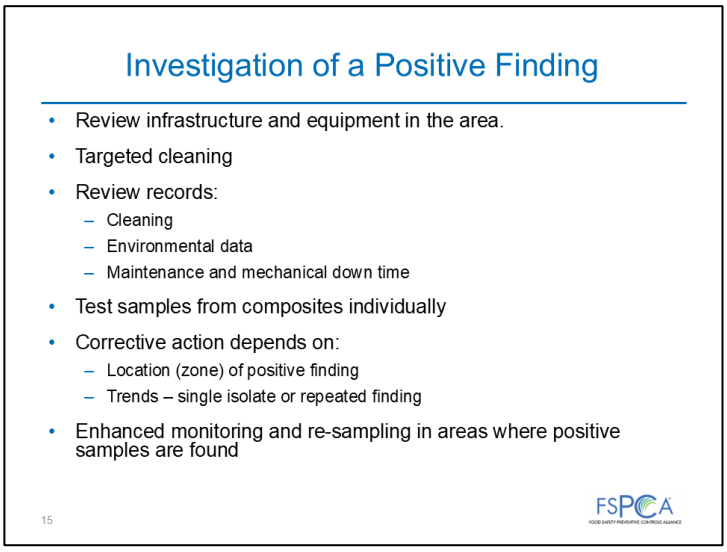
Detection of a pathogen in a Zone 1 sample requires immediate action because the safety of the product produced on the line is in question. Expert consultation is advised when this occurs to evaluate data collected over time, sanitation practices and other factors relevant to determining the disposition of the lot.

For indicator monitoring, the target and action levels should be established after baselines have been established. It is difficult to interpret results if there is no basis for comparison. Facilities that make the same product can have very different profiles. Baseline data collection typically involves a higher level of sampling over a defined period of time and is an attempt to capture a comprehensive snapshot of the stable/routine operations. Several sets of data may be collected to cover seasonal variability. If all sites are not sampled at each sampling time, a rotation system can be used. Because the objective of the program is to proactively identify potential sources of contamination, it is advisable to sample worst-case conditions if they are observed. These could include standing water, drip areas from roof leaks, accumulated product, etc.

Sampling frequency during the initial months of the program may be increased to aid in establishing a norm for the facility, considering factors such as seasonality, weather, adjacent establishments, and personnel changes.

A three-phased approach to sampling is an industry practice: 1) Routine samples (focus on high risk); 2) Investigational samples; and 3) Follow-up sampling to confirm the effectiveness of corrective actions. The frequency of sample collection may be increased or decreased based on a review of the facility's historical data, a determination of traffic patterns and product risk.

Slide 15: Investigation of a Positive Finding



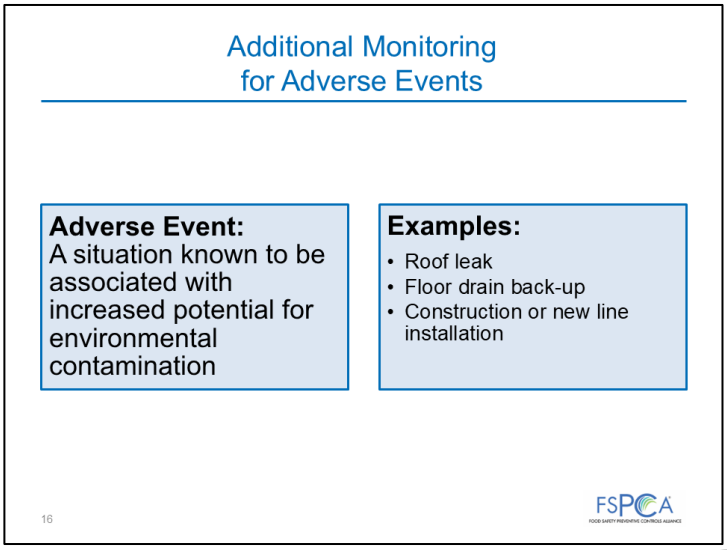
A positive result for an environmental sample necessitates an investigation to determine the source and whether there was a failure within the sanitation program. In some cases, these events may be what is considered less impactful, such as when an organism is found in a less controlled area (e.g., where raw materials are handled). In these cases, this may be what is considered a transient organism, especially if this is a single positive sample, however, a positive finding in a high-risk or high-hygiene area requires robust corrective actions to eliminate these organisms, and to ensure that product contamination has not occurred. Equally important are multiple positives from a given area regardless of the location or zone. This may indicate a resident or persistent organism, something which needs to be eliminated.

A good investigation is a combination of observation, inspection, and intensified sampling. If the positive sample was a composite, then resample the entire area. These samples are then tested individually to help identify and isolate the problem area. In addition to retesting, observe equipment (assessable and disassembled), process, personnel, and cleaning and sanitizing to discover factors that may have contributed to the contamination event. It is also important to look at the flow of materials to determine if crossflows are an issue. Based on the investigation, changes in procedures may be needed. Sometimes corrective action may focus on a niche in the facility or equipment that needs to be removed, corrected, or cleaned. New procedures may be needed, and personnel may need to be trained in these changes. Once the necessary correction is made, a deep cleaning and sanitizing regimen should follow. It is then necessary to confirm effectiveness through repeated intensified sampling for an extended period of time. Re-sample extensively post cleaning and sanitizing, during operations, at change over, and at shutdowns over extended period of time.

If repeated positives results occur after an event, the corrective action taken is not effective. This may be due to a harborage or niche area that was not addressed or discovered. Review facility, equipment, and operational controls to ensure that all possible measures have been taken. Facilities have had to halt production in certain

areas because of contaminated environmental niches that were not possible to eliminate.

Slide 16: Additional Monitoring for Adverse Events



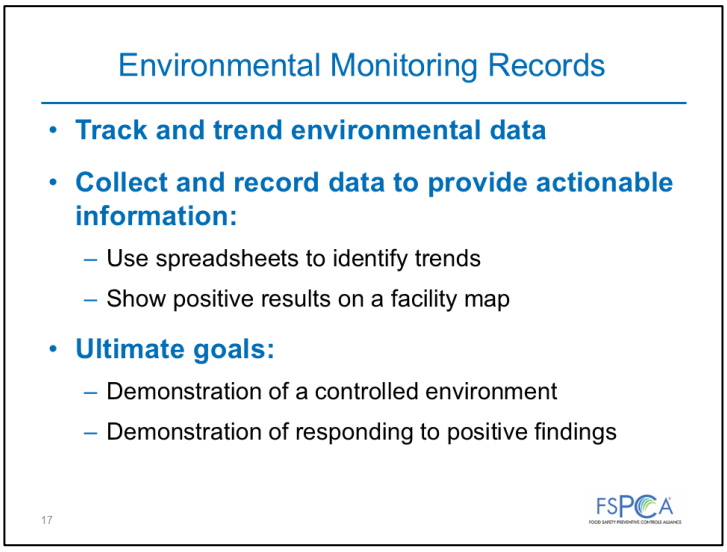
Roof or water leaks, floor drain back-ups in exposed-product areas, construction or equipment installation, and transition between construction and production areas can increase the prevalence of environmental pathogens. Procedures should be put in place to protect processing areas and the product during such events.

For situations involving leaks and entry of water in dry environments, environmental monitoring for *Salmonella* is advisable. Taking these swabs immediately and before cleanup is useful because this likely represents the worst-case scenario. If no *Salmonella* is detected in these swabs, the environment may not be compromised. However, if the organism is detected, immediate action should be taken to sanitize the area without extensive use of water, which is likely to make the situation worse.

For operations where *Listeria monocytogenes* has been identified as a risk, precautionary sampling should be used for situations such as when drain systems back up causing drain water to enter the production area, or when water from spillage, or leaks from raw material wash systems have the potential of getting into finished product areas.

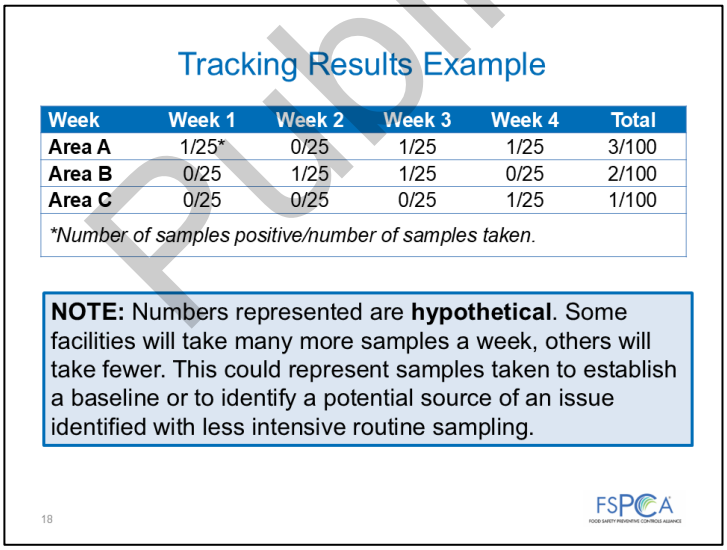
During construction events, traffic patterns should be evaluated to minimize a potential source of contamination. In the event of construction, dust and traffic should be controlled. Upon completion of construction activities, the area should be cleaned and sanitized, and swabs should be taken before production begins again. Additional environmental monitoring following these events will help verify restoration of controls.

Slide 17: Environmental Monitoring Records



Tracking and trending the environment data is a common element of robust environmental monitoring programs. The reporting format for the results will influence the information provided. If the facility is going to put forth the effort to collect environmental monitoring data, it should make sure the facility maximizes the value of the information so that it may be used to protect the product and facility. Results in an actionable format maximize the value of the data. For example, spreadsheets help with identification of trends for routine and intensified monitoring. Facility mapping can also be used to show where positives occur and to determine if the positives are in the same location, which could indicate an environmental niche. Results reported on a map can be used to demonstrate the effectiveness of preventive controls for environmental pathogens.

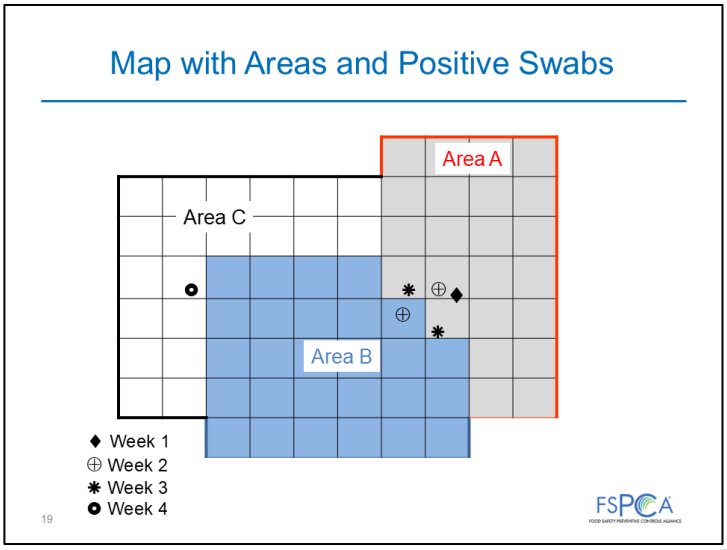
Slide 18: Tracking Results Example



The above slide is an example of using a spreadsheet to report environmental monitoring results over time. The facility has three (3) areas. A total of 25 swabs are taken in each

area on a weekly basis to establish a baseline. Note that the number of samples taken, and the frequency will vary considerably between facilities.

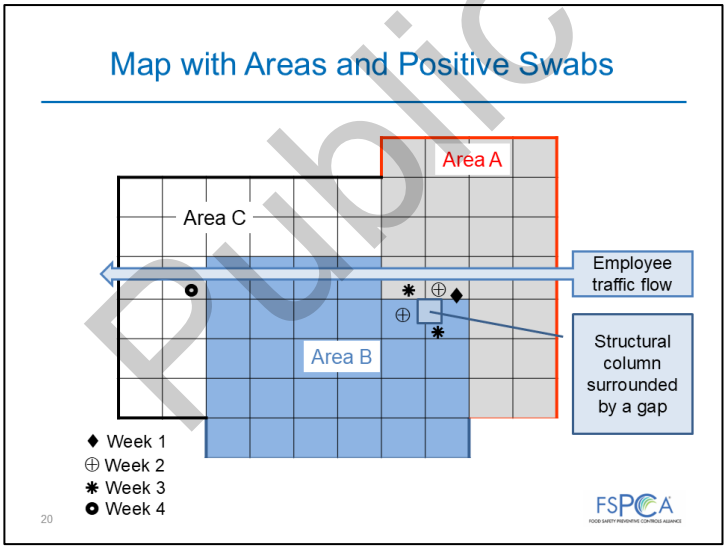
Slide 19: Map with Areas and Positive Swabs (1 of 2)



Participant Manual

Results from environmental sampling are plotted on a grid, indicating different sampling areas. The shapes indicate the location of positive swabs, and the style of the shape represents different weeks.

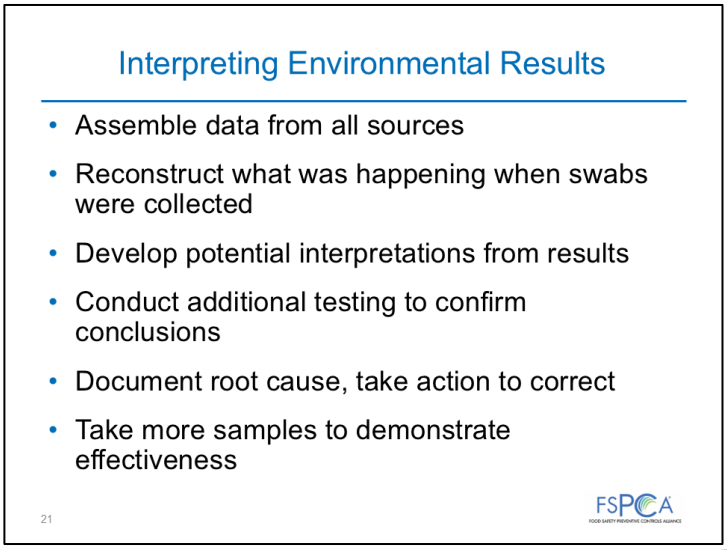
Slide 20: Map with Areas and Positive Swabs (2 of 2)



This enhanced map has the same plotting of the positive results, but also shows infrastructure (e.g., a structural column), and traffic flow. The facility determined there was a likely contamination source above the column and conducted additional investigation to identify and eliminate the source. It was discovered that moisture dripping down along the column transferred contamination through a gap between floors. The

moisture splashed from the column to the floor or other structures in the different area and was then transferred by employee traffic to Area C.

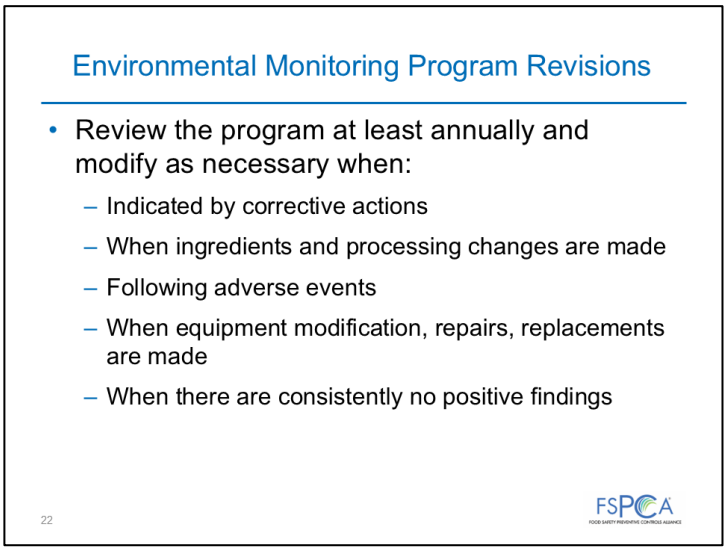
Slide 21: Interpreting Environmental Results



Pull information together from all data sources available, and then reconstruct what was happening when the swabs were collected. This may involve reviewing production schedules, sanitation schedules, visitor logs, and other information sources to determine if something out of the ordinary occurred. Based on the information gathered, identify a potential source of contamination, then confirm what the facility believes was happening through additional observation or data gathering. It is important to document the conclusion of the investigation, document the root cause, and take corrective action to fix the issue. The facility's ultimate goal is to identify a root cause that makes sense based on available information, then take action, and demonstrate that the action taken was effective.

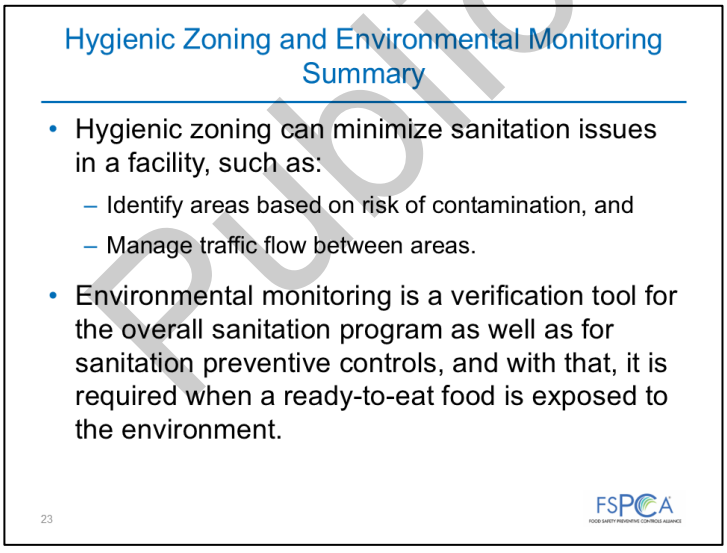
Negative results are good to a point; however, they can provide a false sense of security. Most facilities detect environmental pathogens from time-to-time, and these are usually transient strains. If environmental monitoring results are always negative, ask why the results are always negative. Remember, testing is not a "control." Positive results may also be good to a point because the facility can act on them before a pathogen is detected in a product.

Slide 22: Environmental Monitoring Program Revisions



The environmental monitoring program should be reviewed and refreshed at least annually. With a robust program, modifications take place as needed, such as when indicated by corrective actions and when there are ingredient, process, or equipment changes. If there are consistently no positive findings and this is not what should be expected, this may indicate that the program is not being managed with an aggressive "seek-and-destroy" attitude. Most knowledgeable auditors are going to be skeptical of an environmental monitoring program that never has had a positive finding in the long term.

Slide 23: Hygienic Zoning and Environmental Monitoring Summary



Hygienic zoning can be used to minimize sanitation issues in a facility. Environmental monitoring is a useful technique to verify the effectiveness of sanitation programs, and these are required in facilities that produce ready-to-eat products that are exposed to potential environmental contamination.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

Beuchat, L. et al. (2011). *Persistence and Survival of Pathogens in Dry Foods and Dry Food Processing Environments. ILSI Europe Emerging Microbiological Issues Task Force*. Grocery Manufacturers Association. 2009. Control of Salmonella in low moisture foods.

FDA Draft Guidance for Industry: Control of *Listeria monocytogenes* in Ready-to-Eat Foods: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods

FDA Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food

Innovation Center for US Dairy. (2012). *Pathogen Control Program Tools.*

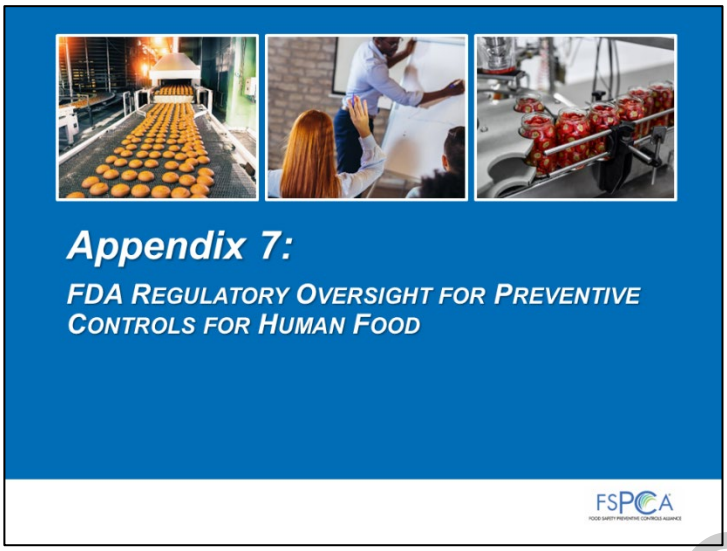
International Commission on Microbiological Specifications for Foods. (2002). *Sampling to assess control of the environment, in Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. Kluwer Academic/Plenum

Kornacki, J.L. (2010). *Principles of Microbiological Troubleshooting in the Industrial Food Processing Environment*. Springer Science + Business Media.

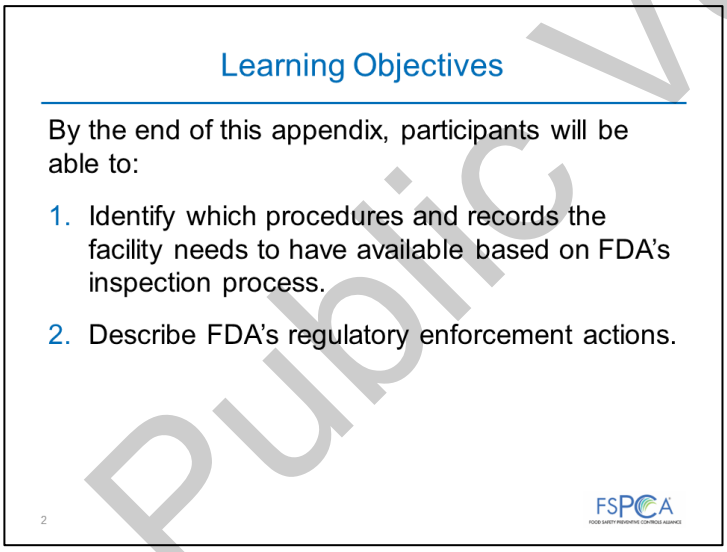
Pehanich, M. (2005). *Designing food safety into your plant*. Food Processing March 7, 2005

Appendix 7: FDA Regulatory Oversight for Preventive Controls for Human Food

Slide 1: Appendix 7: FDA Regulatory Oversight for Preventive Controls for Human Food

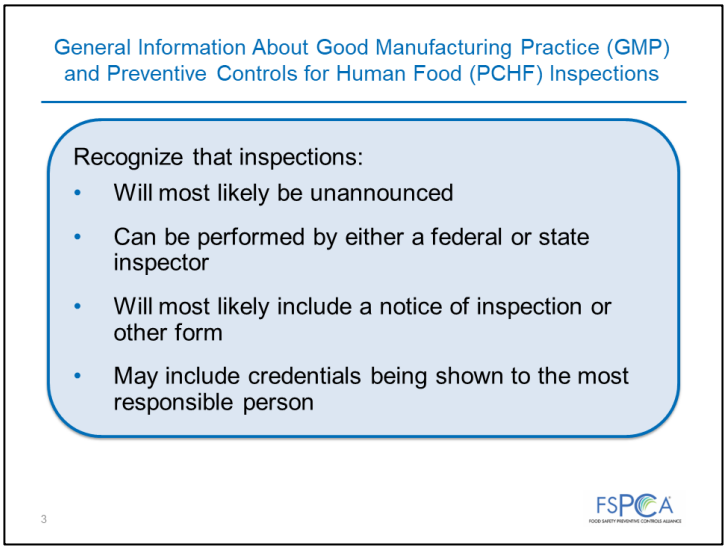


Slide 2: Learning Objectives



This new appendix will help in advising on which procedures and records are needed for an FDA inspection, based on their process. In addition, this appendix will describe FDA's regulatory enforcement actions. These next several slides provide some information about Good Manufacturing Practice (GMP) and Preventive Controls for Human Food (PCHF) inspections, what can be expected, how best to prepare and possible outcomes of inspections.

Slide 3: General Information About Good Manufacturing Practice (GMP) and Preventive Controls for Human Food (PCHF) Inspections (1 of 2)

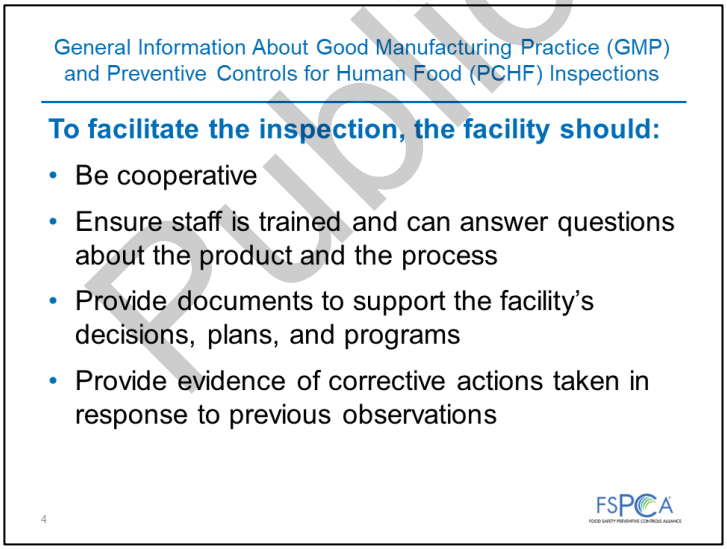


Most inspections are unannounced. Note, however, that foreign inspections are announced and are only performed by federal inspectors.

Domestic inspections may be conducted by FDA or by States under FDA contract.

The inspection will most likely include a notice of inspection, and the most responsible person (or person-in-charge) can view credentials from the inspector.

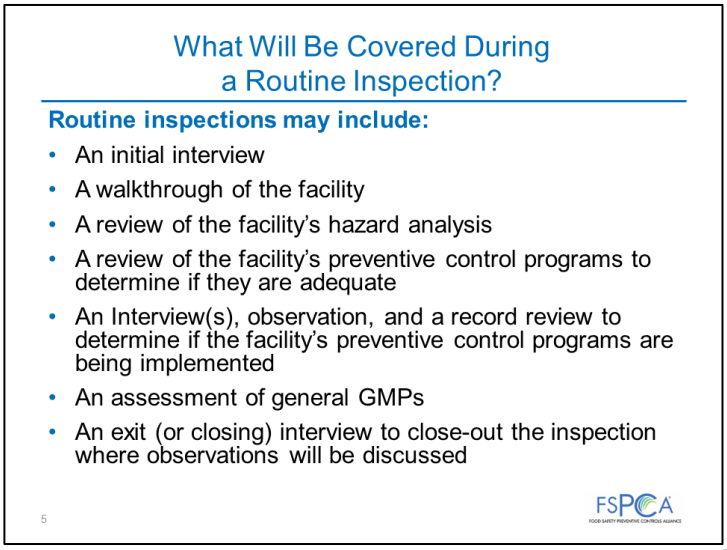
Slide 4: General Information About Good Manufacturing Practice (GMP) and Preventive Controls for Human Food (PCHF) Inspections (2 of 2)



To help ensure that the inspection goes as smoothly as possible, some suggestions have been provided: 1) The staff of the facility needs to be ready to cooperate and to be able to answer questions about the product and process; 2) The facility needs to have documents available in support of the Food Safety Plan, supportive programs, and the

facility's decision-making processes; and 3) The facility will need to have evidence available relating to all corrective actions that were implemented.

Slide 5: What Will be Covered During a Routine Inspection?

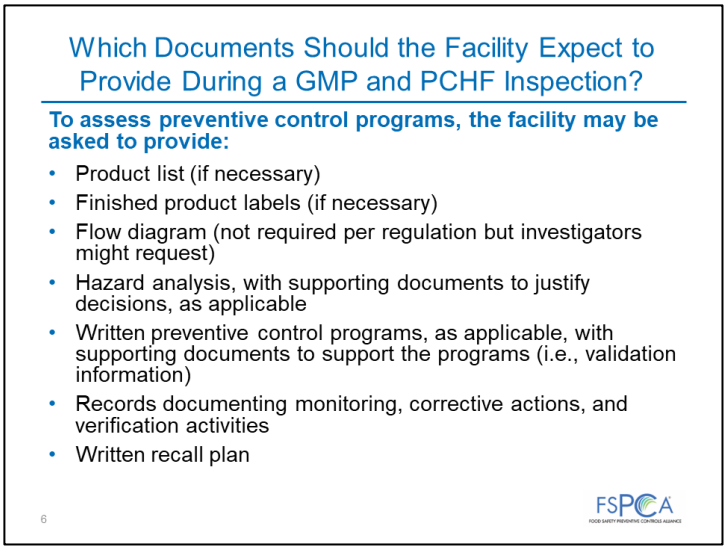


During the initial interview, the inspector will gather information about the facility, its processes, schedules, and product(s) to cover. During the walk-through of the facility, the inspector will be gathering information about the product and the processing, asking employees questions about the processes they are responsible for, and observing employee practices, to inform their hazard analysis.

After the walkthrough, the inspector will conduct his/her own hazard analysis and then compare it with the facility's hazard analysis to ensure that hazards that require a preventive control have been identified. There may be some differences, but all differences should be resolved. Based on the conclusion of the hazard analysis, the inspector will then ask to see the facility's written preventive control programs so they can review them for adequacy. Adequacy means having both monitoring, corrective actions, and verification as appropriate, in place, and that the procedures, if implemented, could control the hazard. For example, monitoring is being done at a frequency sufficient to ensure the hazard is controlled.

Once the inspector reviews the preventive control programs for adequacy, he/she will return to the processing area and interview and observe employees implementing those procedures on the day of the inspection. The inspector will then ask for certain records to assess whether the preventive controls have been implemented consistently over time. The inspector will also do a general assessment of the GMPs, including pest control, water, general sanitation that is outside the sanitation preventive control, etc. The inspector will close the inspection by discussing both written and non-written observations, as applicable.

Slide 6: Which Documents Should the Facility Expect to Provide During a GMP and PCHF Inspection?



1. **Product list (if necessary):** The inspector may ask for a product list to identify the highest risk product(s) that they may want to cover during the inspection.
2. **Finished product labels (if necessary):** The inspector may ask for a finished product label to help them conduct the ingredient hazard analysis.
3. **Flow diagram:** The inspector may ask for the process flow diagram to verify that it covers all steps in the process and to be consistent with the facility's terminology. For example, terminology pertaining to process steps, areas, and equipment.
4. **Hazard analysis:** As previously mentioned, the inspector may ask for the written hazard analysis to compare it with his/hers.
5. **Preventive controls supporting documents:** It is helpful to provide supporting documents to justify the decisions the facility made on whether a hazard requires a preventive control or not, as applicable.
6. **Written preventive control programs, as applicable:** As previously mentioned, the inspector will ask for written preventive control programs to assess adequacy of the programs.
7. **Program supporting documents:** It is helpful if the facility provides any applicable supporting documents to support the facility's programs, for example, a validation study.
8. **Records documenting monitoring, corrective actions, and verification activities:** As previously mentioned, the inspector will ask for certain records to assess whether preventive controls have been consistently implemented over time.
9. **Written recall plan:** The inspector will assess the facility's recall plan against the provisions found in §117.139(b), which includes procedures describing the steps

to be taken, and assigning responsibility for taking those steps, to perform the following actions as appropriate to the facility:

a. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food;

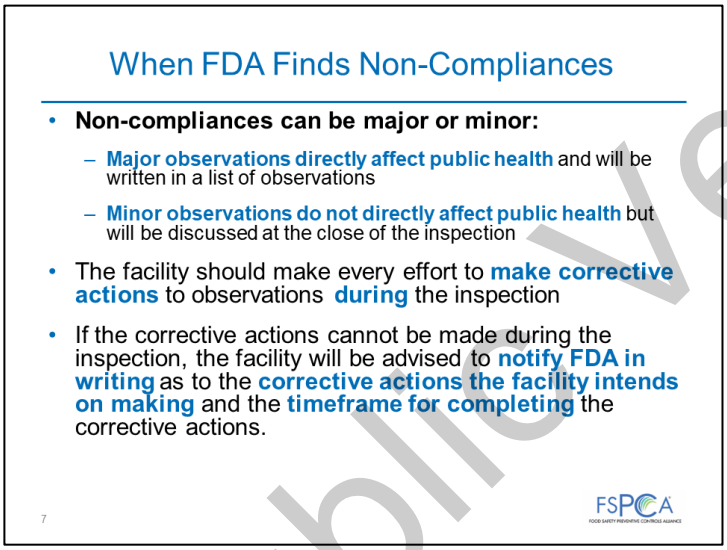
b. Notify the public about any hazard presented by the food when appropriate to protect public health;

c. Conduct effectiveness checks to verify that the recall is carried out; and

d. Appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food); and

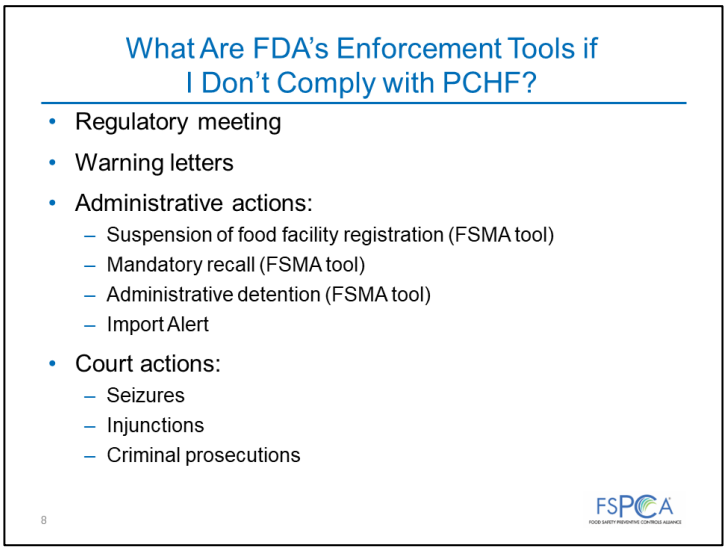
Be prepared to show the inspector where those four elements are in the facility's recall plan.

Slide 7: When FDA Finds Non-Compliances



This slide provides details about non-compliance the FDA inspectors may find. The non-compliances can be major (those affecting public health which will be documented), or minor (not affecting public health which will be discussed). If possible corrective actions addressing the non-compliances should be made during the inspection. If this is not possible, the FDA will expect a written response detailing the corrective actions to be completed and the timeframe for completion of the corrective actions.

Slide 8: What Are FDA's Enforcement Tools if I Don't Comply with PCHF?

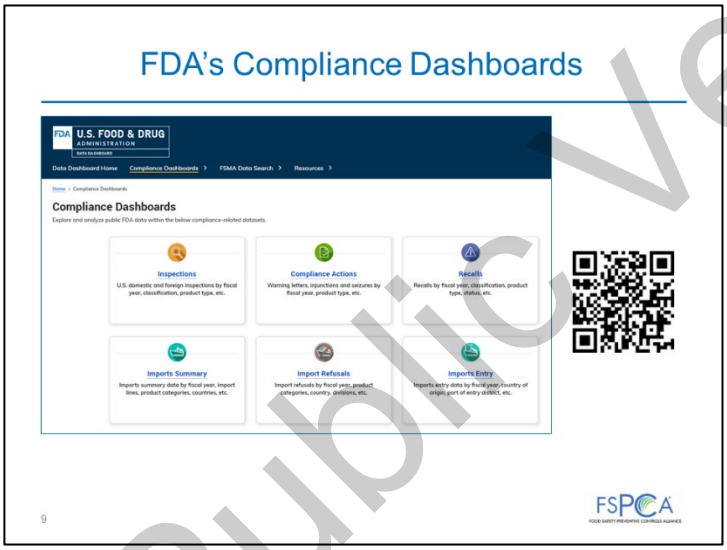


The FDA evaluates many factors when determining appropriate enforcement action. The enforcement tools that the FDA may use include:

- **Regulatory meeting:** The FDA may hold a meeting with facility management to stress the seriousness of deficiencies (typically observed during an inspection) and the importance of corrective actions.
- **Warning letter:** The FDA may issue a warning letter to advise the facility of violations of regulatory significance and to issue a warning of further action if corrections are not made; warning letters are posted on FDA.gov and therefore visible to the public.
- **Court actions,** including seizures, injunctions, and criminal prosecutions.
    - Seizure: Products can be seized if they are adulterated or misbranded while in interstate commerce or afterwards
    - Injunction: Injunctions may be brought when a facility commits a prohibited act; the purpose of an injunction is to stop a violation of the law (e.g., to stop a facility from distributing violative products in interstate commerce), and to correct the violation before resuming distribution
        - Example of a prohibited act: It is a prohibited act if a facility that is subject to the preventive controls requirements of Part 117 does not comply with those requirements,
    - Criminal prosecution: The firm/firm's officials may be prosecuted when they commit a prohibited act; the purpose of criminal prosecution is to punish the firm/firm's officials for prior violations.
- Administrative actions:
    - Suspension of food facility registration: The FDA may suspend a facility's registration if there is reasonable probability that exposure to the food causes serious adverse health consequences or death to humans or

animals; a facility that is under suspension is prohibited from distributing its food in commerce.

- Mandatory recall: The FDA may issue a mandatory recall order if there is reasonable probability that the food is adulterated or misbranded (declaration of allergens per 403(w) only) and that exposure to the food causes serious adverse health consequences or death to humans or animals.
- Administrative detention: The FDA may issue an administrative detention order when there's reason to believe that the food is adulterated or misbranded; foods subject to detention cannot be moved without FDA permission until the order expires (up to 20-30 days).
- Import alert: Informs the FDA staff and the public that the FDA has sufficient evidence to support detention without physical examination (DWPE) of products that appear to be in violation of the law (for example, appearance of adulteration or misbranding); this effectively stops food from entering the United States unless the appearance of the violation is overcome.



The FDA's enforcement actions can be viewed on the FDA Website by using the QR code below this text.

FDA's top ten (10) inspection citations can also be viewed by clicking on the Inspections tab.

The Data Dashboard sources much of its content from FDA compliance and enforcement data that is cleared for public access. It contains data elements from Inspections, Compliance Actions, Recalls, Imports, and Food Safety Modernization Act programs. New dashboards with additional sources will continue to be added.

Where appropriate, a section at the top of each dashboard page includes guidance on the data used, any limitations as well as clarifications regarding what the data represents.

Further information about data sources used is arranged below by topic.

Inspection Classification: The FDA conducts inspections and assessments of regulated facilities to determine a firm's compliance with applicable laws and regulations, such as the Food, Drug, and Cosmetic Act and related Acts.

The Office of Regulatory Affairs (ORA) Freedom of Information Act (FOIA) Electronic Reading Room displays copies of ORA domestic inspection and related records.

The results show final classifications of No Action Indicated (NAI), Voluntary Action Indicated (VAI), and Official Action Indicated (OAI) for each project area within an inspection.

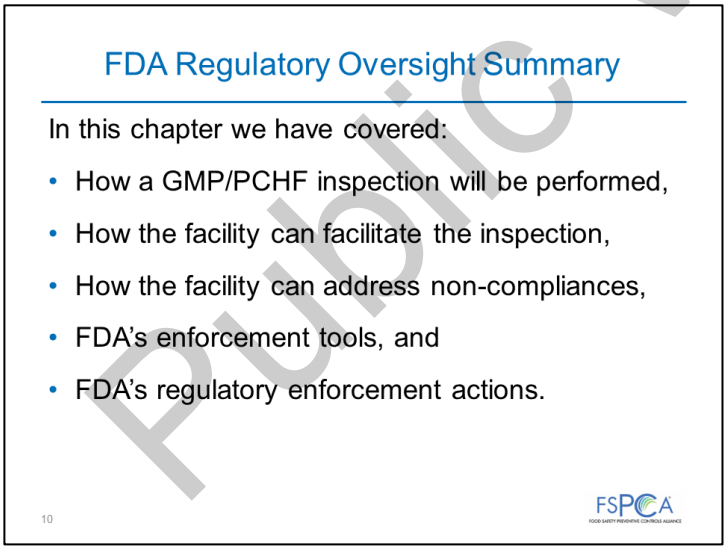
Not all inspections are included in the database. Inspections conducted by States, pre-approval inspections, inspections waiting for a final enforcement action, and inspections of nonclinical labs are not included. Inspections of nonclinical labs are available at Nonclinical Laboratories Inspected under Good Laboratory Practices.

Compliance: Compliance data provides information on a subset of the actions used by the FDA to bring firms into compliance, specifically data pertaining to Warning Letters, Seizures, and Injunctions. The compliance actions disclosed include only *finalized and completed actions* and are primarily used in the domestic arena. Actions pertaining to foreign firms often take the form of import alerts.

Recalls: The recall data included is based on the FDA's Enforcement Reports. For more detailed information about individual recalls, refer to the Enforcement Reports and Recalls, Market Withdrawals & Safety Alerts web pages.

Imports: The Import Program Resources page contains information explaining the import process for FDA-regulated products.

Slide 9: FDA Regulatory Oversight Summary



This Appendix has covered how inspections will be conducted and how the person-in-charge at a facility can best be prepared to facilitate them and address any non-compliances identified. In addition, the FDA enforcement tools, and regulatory enforcement actions have been described.

Additional Reading, Resources, and References

FDA Website: https://www.fda.gov/food

FDA FSMA Technical Assistance Network (TAN): https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

FSPCA Website: https://www.fspca.net/

FSPCA Technical Assistance Network (TAN): https://www.fspca.net/fspca-technical-assistance-network

FDA's Compliance Data Dashboard: https://datadashboard.fda.gov/ora/cd/index.htm

Appendix 8: Definitions

Acid foods or **acidified foods**[3,11]**:** Foods that have an equilibrium pH of 4.6 or below. (NOTE: acid foods have a natural pH of 4.6 or below; acidified foods have acid added to reduce the pH)

Adequate[3,11]**:** That which is needed to accomplish the intended purpose in keeping with good public health practice.

Adulteration[16]**:** A violation of the Federal Food, Drug, and Cosmetic Act which includes products that are defective, unsafe, not shown to be safe, filthy, or produced under insanitary conditions.

Allergen cross-contact[3,11]**:** The unintentional incorporation of a food allergen into a food.

Audit[3]**:** The systematic, independent, and documented examination (through observation, investigation, records review, discussions with employees of the audited entity, and, as appropriate, sampling and laboratory analysis) to assess an entity's food safety processes and procedures.

a_w: See water activity.

CCP: See critical control point.

CGMP (Current Good Manufacturing Practice): See GMPs.

Clean in place (CIP)[11]**:** A system used to clean process piping, bins, tanks, mixing equipment, or larger pieces of equipment without disassembly, where interior product zones are fully exposed, and soil can be readily washed away by the flow of the cleaning solution.

Clean out of place (COP)[11]**:** A system (e.g., cleaning tanks) used to clean equipment parts, piping, etc. after disassembly.

Cleaning[2,11]**:** The removal of soil, food residue, dirt, grease, or other objectionable matter.

Consignee[19]**:** Anyone who received, purchased, or used a product being recalled.

Control point (CP)[11]**:** Any step at which biological, physical, or chemical factors can be controlled.

Correction[3,11]**:** An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Corrective action[11]**:** An action to identify and correct a food safety problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical Control Point (CCP)[3,11]: A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Critical limit[4,11]: The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process preventive control.

Cross-contact: See allergen cross-contact.

Cross-contamination: The unintentional transfer of a foodborne pathogen from a food (where it may occur naturally) or insanitary object to another food (where it may present a hazard).

Customer[17]: The commercial entity the receiving facility sells to, who may or may not be subject to the requirements for hazard analysis and risk-based preventive controls (Based on 21 CFR 117.136). A customer does not include consumers.

Defect action level[3]: means a level of a non-hazardous, naturally occurring, unavoidable defect at which FDA may regard a food product "adulterated" and subject to enforcement action under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act.

Deviation[2,9,11]: Failure to meet a critical limit.

End-Point Internal Product Temperature (EPIPT)[11]: A measurement of the internal temperature of the product at the end of the heat process.

Enforcement discretion[13]: Announced via guidance to industry, the FDA may elect to not enforce certain regulatory requirements, based on their current understanding of risks as they currently apply to certain entities and/or activities. This allows the FDA to take time to consider changes or other approaches to address concerns regarding the application of these provisions to certain activities or entities.

During the enforcement discretion period, the agency does not intend to enforce these provisions as they currently apply to certain entities or activities. "In general, the FDA exercises enforcement discretion to allow time to consider changes or other approaches to address concerns regarding the application of these provisions to certain activities or entities."

Environmental monitoring[15]: A process of sampling and testing to evaluate your facility's overall environment for pathogens, spoilage and indicator organisms, and allergens to identify when and where actions are needed to minimize food safety risks.

Environmental pathogen[3,11]: A pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of

environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.

Environmental sample[11]: A sample that is collected from a surface or area of the plant for the purpose of testing the surface or area for the presence of microorganisms, usually environmental pathogens.

Facility[3]: A domestic facility or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR Part 1, Subpart H.

FDA: U.S. Food and Drug Administration

Food[6,11]: Includes (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article and includes raw materials and ingredients. Examples of food include fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities used for food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods. Does not include pesticides or food contact substances not intended to have any technical effect in the food.

Food allergen[7,11]: Any of the following: (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, sesame, and soybeans. (2) A food ingredient that contains protein derived from a food specified in paragraph (1), except any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

Food-contact surface[3,11]: Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operation. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.

Food Safety Plan[11]: A set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, and delineates the procedures for monitoring, corrective actions, and verification to be followed, including a recall plan.

Food safety system[11]: The outcome of implementing the Food Safety Plan and its supporting elements.

Foodborne infection: Pathogen invades the body after consumption of food contaminated with live harmful microorganisms.

Foodborne intoxication: Pathogen growth in the food produces a toxin that causes illness when the food is consumed.

GMPs (Good Manufacturing Practices): The regulation (21 CFR Part 117, Subpart B) that outlines the conditions and practices the regulated food industry must follow for processing safe food under sanitary conditions, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, and defect action levels considerations.

Guidance: Represents FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Available at: https://www.fda.gov/industry/fda-basics-industry/guidances

HACCP: Hazard Analysis and Critical Control Point (see below).

Hazard[3,11]: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard analysis[11]: The process of identifying potential hazards, evaluating information on those hazards, and determining which hazards require a preventive control" (FSPCA).

Hazard Analysis and Critical Control Point (HACCP)[2]: A system which identifies, evaluates, and controls hazards which are significant for food safety.

Hazard requiring a preventive control[3,11]: A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls), establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification, and records) as appropriate to the food, the facility, and the nature of the preventive control and its role in the facility's food safety system. A hazard requiring a preventive control is also referred to as a significant hazard.

Hygienic zoning[11]: The objective of hygienic zoning is to reduce the potential for transient pathogens to enter sensitive areas in the facility, such as packing areas where a RTE product is exposed to the processing environment. Typically, this type of sanitation control is applied in facilities that make RTE products with consideration of the separation and segregation of process operations such as raw vs. work-in-process versus finished product; wet versus dry; personnel and materials traffic flow; air balance, etc.

Known or reasonably foreseeable hazard[3,11]: A biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food. Also referred to as a potential hazard.

Lot[3]: The food produced during a period of time and identified by an establishment's specific code.

Maximum safety level: A food ingredient can be a chemical hazard if it is added in excess of a regulatory action limit. For example, sodium benzoate is permitted for use in food as an antimicrobial agent with a maximum use level of 0.1% in the food. A chemical

hazard due to mis-formulation could occur if a manufacturer accidentally adds sodium benzoate such that it exceeds 0.1% in the finished food. (FSPCA)

Microorganisms[3]: Includes yeast, molds, bacteria, viruses, protozoa, and microscopic parasites, and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Monitor[3,11]: To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.

NACMCF (National Advisory Committee on Microbiological Criteria for Foods)[10]: Chartered under USDA to provide impartial, scientific advice to U.S. Federal food safety agencies for use in the development of an integrated national food safety systems approach from farm to final consumption to assure the safety of domestic, imported, and exported foods.

Non-food-contact surface: Those surfaces that *do not* contact human food and from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily *does not* occur during the normal course of operation.

Operating limits[11]: Criteria that could be more stringent than critical values/limits and are established for reasons other than food safety.

Operating Prerequisite Program (OPRP)[18]: The concept of the Operational Prerequisite Program (OPRP) was introduced by the ISO in their food safety management standard, ISO 22000. It is defined as a control measure that the hazard analysis identifies as critical to control the likelihood of introducing food safety hazards or the contamination or proliferation of these hazards in the product(s) or the processing environment. In essence, an OPRP controls the likelihood of food safety hazards. It may not necessarily be critical, but they may be essential in reducing the risk of specific hazards.

Parameter: A characteristic, feature or measurable factor that can help in defining a particular system.

Pathogen[3,11]: A microorganism of public health significance.

Pest[3]: Any objectionable animals or insects including birds, rodents, flies, and larvae.

Potable water: Water that meets the standards for drinking purposes of the State or local authority having jurisdiction, or water that meets the standards prescribed by the U.S. Environmental Protection Agency's National Primary Drinking Water Regulations (40 CFR Part 141).

Prerequisite programs[11]: Procedures, including Current Good Manufacturing Practices (CGMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

Preventive controls[3,11]: Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis.

Preventive Controls Qualified Individual (PCQI)[3,11]: 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.

Process preventive controls: Are the process-associated controls that are essential for food safety. Also referred to as Critical Control Points.

Product disposition: The act of reconditioning, reworking, relabeling, diverting to a use that does not present safety concerns, or destruction. Product disposition will be determined based on the hazard, the food, and other factors. Facilities must consult with regulatory authorities for approval, when applicable.

Qualified auditor[3]: A person who is a qualified individual as defined below and has technical expertise obtained through education, training, or experience (or combination thereof) necessary to perform the auditing function as required by §117.180(c)(2). Examples of potential qualified auditors include:

(1) A government employee, including a foreign government employee; and

(2) An audit agent of a certification body that is accredited in accordance with regulations in 21 CFR Part 1, Subpart M of this chapter.

Qualified individual[3,11]: A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

ROP: See Reduced Oxygen Packaging.

RTE (Ready-to-eat) food[3,11]: Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Reanalysis: A verification procedure to assure that the Food Safety Plan remains valid, and the food safety system is operating according to the plan (see Section 117.170).

Recall: Actions taken by a firm to remove a violative product from the market (FDA.gov).

Recall Classification[11]: The numerical designation (i.e., I, II, or III) assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. (1) Class I is a situation in which there is a reasonable probability that

the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1)); (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2)); and (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause illness or injury (21 CFR 7.3(m)(3)). (See 21 CFR 7.3(m)) (see Other Terms)

Recall Coordinator: Someone who can devote full attention to the recall and keep recall activities and documents organized.

Recall Team Members (Individuals): Individuals necessary to support the completion of recall procedures.

Receiving facility[3]: A facility that is subject to Subpart C [*Hazard Analysis and Risk-based Preventive Controls*] and Subpart G [*Supply-Chain Program*] of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.

Reduced Oxygen Packaging (ROP)[12]: (1) Reduced oxygen packaging means: (a) The reduction of the amount of oxygen in a PACKAGE by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21% at sea level); and (b) A process as specified in Subparagraph (1)(a) of this definition that involves a FOOD for which the HAZARDS *Clostridium botulinum* or *Listeria monocytogenes* require control in the final PACKAGED form**.**

(2) Reduced oxygen packaging includes: (a) Vacuum PACKAGING; (b) Modified atmosphere PACKAGING; (c) Controlled atmosphere PACKAGING; (d) Cook chill PACKAGING; or (e) Sous vide PACKAGING

Rework[3]: Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

Risk[1]: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk-Based Preventive Controls: A system that identifies food safety hazards within the food process and designates appropriate controls to minimize the risk of those hazards. Risk-based preventive controls is methodical and systematic, science-based, preventive, not reactive, focuses on the controls that are essential for food safety, and works in conjunction with and is supported by other programs like GMPs.

Root Cause Analysis[11]: A retrospective evaluation of information from a root cause investigation of a contamination event to determine what actions can be taken to eliminate the root cause(s) and prevent a recurrence of the event (see "Other Terms")

Safe Harbor: A validated food safety process or critical limit that is established and recognized in federal performance standards and guidelines.

Safe-Moisture level[3]: A level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a food is related to its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

Sanitize[3,11]: To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sanitary conditions: The result of a combination of cleaning and sanitizing, as appropriate for the environment, that prevents the adulteration of food.

Sanitation Monitoring: To monitor critical elements of the sanitation process.

Section (§): A symbol that refers to a specific section in the regulation and may at times be used in place of spelling out the word "Section."

Sensitive Ingredient: One that is susceptible to contamination by certain microorganisms or their growth. These are then identified as having biological hazards associated with them which need control in a food safety or HACCP plan.

Serious Hazard: a hazard in a food that will result in serious adverse health consequences or death to human or animals (SAHCODHA). Serious hazards in food include those that meet the definition of a Class I recall situation and would also result in a "reportable food" per FDA's Reportable Food Registry which is an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

Serious adverse health consequences or death to humans hazard[11]: A hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.

Severity[8,11]: The seriousness of the effects of a hazard.

Significantly minimize[3, 11]: To reduce to an acceptable level, including to eliminate.

Small business[3]: A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

SOP: Standard Operating Procedure

Supplier[3]: The establishment that manufactures/processes the food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.

Supply-chain-applied control[3]: A preventive control for a hazard in a raw material or other ingredient when the hazard in the raw material or other ingredient is controlled before its receipt.

Temperature Control for Safety (TCS) Food[12]: A food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

Third-party audit: An audit conducted by a qualified auditor that is not an employee of either the receiving facility or the supplier.

Unexposed packaged food[3]: Packaged food that is not exposed to the environment.

Validation[3,11]: Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification[3,11]: The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

Very small business[3]: A business (including any subsidiaries and affiliates) averaging less than $1,000,000, ***adjusted for inflation***, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). Additional information can be retrieved from FDA's Webpage related to adjustments for inflation: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-inflation-adjusted-cut-offs

Water activity (a_w)[3]: A measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Written procedures for receiving raw materials and other ingredients[3]: Written procedures to ensure that raw materials and other ingredients are received only from suppliers approved by the receiving facility (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use).

Reference List

[1] Food and Agriculture Organization/World Health Organization (FAO/WHO). 2014. Section IV. Risk Analysis, *Codex Alimentarius Procedural Manual*, 22nd Edition.

[2] FAO/WHO. 2003. *General Principles on Food Hygiene*. CAC/RCP 1-1969, Rev. 4-2003

[3] Food and Drug Administration (FDA). 21 CFR 117.3 Definitions

[4] FDA. Derived from 21 CFR 117.135(c)(1)(ii)

[5] FDA. Derived from 21 CFR 117.150(a)(1)

[6] FDA. Section 201(f) of the Federal Food, Drug and Cosmetic Act

[7] FDA. Section 201(qq) – Based on requirements in that section.

[8] National Advisory Committee on Microbiological Criteria for Foods. 1998. Hazard Analysis and Critical Control Point Principles and Application Guidelines. *Journal of Food Protection* 61(9):1246-1259.

[9] National Seafood HACCP Alliance. 2020. *Hazard Analysis and Critical Control Point Training Curriculum.* 6th ed.

[10] United States Department of Agriculture, 2014. Advisory Committee Reports.

[11] FDA. 2024, Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food: https://www.fda.gov/media/100002/download

[12] FDA. 2022. Food Code. https://www.fda.gov/food/fda-food-code/food-code-2022

[13] FDA. (2018). FDA Announces Enforcement Discretion Policy for Certain FSMA Regulations. https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-enforcement-discretion-policy-certain-fsma-regulations

[14] American Frozen Food Institute (AFFI). (n.d.). *Hygienic Zoning*. Retrieved from: https://affi.org/lca_categories/hygienic-zoning/

[15] Safe Food Alliance. (n.d.). The Essential Guide to Environmental Monitoring: What is Environmental Monitoring? Retrieved from: https://safefoodalliance.com/food-safety-resources/the-essential-guide-to-environmental-monitoring/

[16] FDA. 2022. Glossary of Terms Related to FDA's Regulation of Animal Products. Retrieved from: https://www.fda.gov/animal-veterinary/resources-you/glossary-terms-related-fdas-regulation-animal-products

[17] 21 CFR 117.136 and FDA Draft Guidance. *Describing a Hazard that Needs Control in Documents Accompanying the Food, as Required by the Four Rules Implementing the FDA Food Safety Modernization Act: Guidance for Industry*.

[18] Safefood 360°. (n.d.). *Understanding the difference between PRP, OPRP & CCP*. Retrieved March 20, 2024 from https://safefood360.com/blog/understanding-the-difference-between-prp-oprp-ccp-an-introduction/

[19] FDA. 21 CFR 7.3 Defintions: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-7/subpart-A/section-7.3