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: http://www.iit.edu/ifsh/alliance/

This publication was developed by the Food Safety Preventive Controls Alliance (FSPCA) and was supported, in part, by a grant from the Food and Drug Administration to the Illinois Institute of Technology’s Institute for Food Safety and Health. The views expressed herein do not necessarily reflect the views of these organizations. Direct all inquiries to the FSPCA at fspca@iit.edu
FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

TRAINING CURRICULUM

First Edition – 2015

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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.

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Developed by the

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE
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Food Safety Preventive Controls Alliance

The Food Safety Preventive Controls Alliance (FSPCA) provides current and cost-effective education and training programs to assist the food industry to achieve compliance with the U.S. Food and Drug Administration (FDA) Hazard Analysis and Risk-based Preventive Controls for Human Food regulation, which is referred to as the Preventive Controls for Human Food regulation throughout this course. The requirements of this regulation are designed to promote safe food production. The structure and the delivery of the FSPCA Preventive Controls for Human Food training course were built on successful examples from two previous alliances – Seafood HACCP and Juice HACCP.

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: Under the Preventive Controls for Human Food regulation, the responsibilities of a “preventive controls qualified individual” include to perform or oversee 1) preparation of the Food Safety Plan, 2) validation of the preventive controls, 3) records review and 4) reanalysis of the Food Safety Plan.

The FSPCA program is based on collaboration among federal and state regulatory officials, academic food safety researchers and educators and U.S. food industry representatives. The program is directed by a voluntary FSPCA Steering Committee, whose members are listed on the inside front cover. Any individual, company, agency or nation can provide input for the FSPCA program through communications with any member of the FSPCA Steering Committee. Participation in working groups is also possible. The FSPCA Steering Committee directs development of the curriculum, all training materials and the
FSPCA Training Protocol for delivering, documenting and updating these materials.

The Association of Food and Drug Officials (AFDO) and the International Food Protection Training Institute (IFPTI) administer certificates for all participants that complete a recognized FSPCA course. Contact IFPTI for questions on certificates or how to become a recognized FSPCA Lead Instructor.

The FSPCA course will be offered in both a formal classroom setting and a self-guided online version that is coupled with a one-day, in person session to develop skills for conducting a hazard analysis and developing a Food Safety Plan. The FSPCA training materials include the standard training manual, slides, explanations of key terms and concepts, an example model Food Safety Plan, abbreviated models for class exercises and reference material. Examples of model Food Safety Plans for processed food products are maintained on the FSPCA website (http://www.iit.edu/ifsh/alliance/). These examples are for reference, and modifications of example plans will be necessary for specific facilities.

The FSPCA training materials are designed to meet the requirements for training under Title 21 Code of Federal Regulations Part 117.180(c)(1) for the preventive controls qualified individual who conducts certain Food Safety Plan activities. Attending an FSPCA course is not mandatory, but it does provide assurances that the course content and resulting knowledge is consistent with regulatory expectations.

The FSPCA course material and information on training for FSPCA Lead Instructors can be found on the FSPCA website.

**History of the Alliance**

The FSPCA was established in 2011 as part of a grant from FDA to the Illinois Institute of Technology’s Institute of Food Safety and Health. 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 and achieving compliance with the Preventive Controls regulation requirements applicable to their facilities. Both human food and animal food regulations are covered in separate courses. FSPCA’s mission is to support safe food production by developing a standardized curriculum and technical educational materials on food safety risk-reduction controls compliant with the Preventive Controls regulations, and providing technical assistance outreach to the food industry, particularly small food companies.
### FSPCA Preventive Controls for Human Food Course Agenda

The agenda is intended to be covered in a 2.5 day (20 hours) course, including frequent opportunities for review and classroom exercises designed to provide learning opportunities for understanding *Preventive Controls for Human Food* regulation requirements. The time allotted to each section will vary based on the audience, level of familiarity and experience with Good Manufacturing Practices and risk-based food safety principles, as well as the food product and processing under consideration. A typical agenda appears below.

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*Wrap Up*
CHAPTER 1. Introduction to Course and Preventive Controls

Introduction to Course and Preventive Controls

Objectives

In this module, you will develop awareness of:

• The objectives of the course
• Format of the course
• How preventive controls build on established food safety principles
• Components of a Food Safety Plan
• The responsibilities of a qualified individual
• Where to find definitions relevant for the course

The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food regulation (hereafter referred to as the Preventive Controls for Human Food regulation) was published on September 17, 2015 and 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.”

This chapter reviews the format for the course and provides a brief overview of how preventive controls build on established food safety principles. It then explores the responsibilities of a preventive controls qualified individual to help you to understand the tasks that you will be expected either to do or to oversee. At the end of the chapter, you will also see a list of definitions to help you understand
the meaning of specific terms used in the course, most of which are from the *Preventive Controls for Human Food* regulation.

**Course Format and Agenda**

The FSPCA course is divided into three parts:

1. The first part defines the contents of the Food Safety Plan, reviews foundational programs such as 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 give a better understanding of how a systematic approach can help to assure the safety of food. As each principle is discussed, the class will progressively develop a Food Safety Plan for a model product produced by a fictional company. This example will help you 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 the participants to the process of developing a Food Safety Plan, including identification of tools and implementation tasks. During this part, the class will be divided into teams to write 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.
Risk-based Preventive Controls

A proactive and systematic 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. 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 and good transportation practices as the basis for food safety management. Successful application of preventive controls approaches not only helps to ensure regulatory compliance, but also minimizes the risk of producing products that can harm consumers!
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 the 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). HACCP implementation expanded voluntarily in the food industry with the understanding that food safety is best assured if each producer and processor understands the significant hazards in their product and operation, and uses scientifically sound preventive controls to significantly minimize or eliminate the hazards.

In the 1970s, FDA used HACCP principles in the development of low-acid canned food regulations. The U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission (Codex) published HACCP principles in the 1990s. FDA has HACCP regulations for seafood and juice products; USDA has HACCP regulations for meat and poultry products; and HACCP is endorsed by many countries, including Australia, Canada, New Zealand and European Union countries.

HACCP principles are illustrated in the slide above. A quick review of these principles is useful to understand how the Preventive Controls for Human Food regulation complements the risk-based HACCP approach.

In a HACCP system, hazard analysis is identifies process-related hazards that, in the absence of control, present a food safety risk. When these hazards are identified, Critical Control Points (CCPs) that are essential to control the process to prevent the hazard from
causing illness or injury are identified. When these CCP process controls are identified, the critical limits define the operating conditions in the process that must be met to effectively manage the hazard. Monitoring of the process is done to provide data to demonstrate that critical limits are met, and corrective actions are predefined to enable swift action when things go wrong, thus preventing expansion of a food safety issue. All of the above is recorded and verified to ensure the system is operating as intended and to provide data to others (e.g., inspectors, auditors, management, new employees) to show that this is the case. More information on each of these principles is discussed in this curriculum, recognizing that a HACCP Plan essentially addresses most of the requirements for preventive controls.

However, the preventive controls process incorporates controls beyond those managed as process-related CCPs in the HACCP framework. These preventive controls address not only CCPs, but also controls for hazards related to food allergens, sanitation, suppliers and others requiring a preventive control. The preventive controls approach also recognizes that critical limits, 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” may not be required for some preventive controls. The broader term, parameters and values, supports identification of a frequency or other metric to assess compliance, rather than setting a precise minimum or maximum value to which a parameter must be controlled. Further, immediate corrections (like re-cleaning a line before start up) may be more appropriate than formal corrective action involving product risk evaluations for some preventive controls. Finally, the extent of validation activities (or demonstrating
the controls actually work) may be less rigorous for some preventive controls than others. Each of these concepts is discussed in greater detail in subsequent chapters.

**Contents of a Food Safety Plan**

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 are added, or new hazards are identified. The schematic above illustrates that the Food Safety Plan includes a number of elements. It starts with hazard analysis, which is used to identify required preventive controls for the process, for sanitation, for food allergens and supply-chain programs, where these are needed to address the hazards requiring a preventive control. These elements, along with a recall plan make up the Food Safety Plan. Many GMPs and other prerequisite programs are managed outside of the Food Safety Plan. While these are separate programs and may not require the same level of documentation as the elements of the Food Safety Plan, they are important. They are generally managed using standard operating procedures with documents and records kept as appropriate. Keep in mind that elements of GMPs that are not covered in the Food Safety Plan are still required by regulations.

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

Preventive Controls Qualified Individual Definition

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

Under the regulation, certain tasks must be performed by a “preventive controls qualified individual.” 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.” Under the Preventive Controls for Human Food regulation, the responsibilities of a “preventive controls qualified individual” include to perform or oversee 1) preparation of the Food Safety Plan, 2) validation of the preventive controls, 3) records review and 4) reanalysis of the Food Safety Plan.

The preventive controls qualified individual may be an employee of the facility but you can also use outside assistance in developing your 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 in this course.

See the 21 CFR 117.3 definitions for “qualified individual” and “preventive controls qualified individual,” as well as the 21 CFR 117.180 requirements applicable to a preventive controls qualified individual in Appendix 1.
What is Expected of the Participant?

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 the discussions can help you and other participants to better understand and apply the concepts. This course includes class participation and exercises. The more you contribute to these exercises, the less complicated the system will seem and the easier it will be to develop and implement an effective Food Safety Plan.

How to Use This Training Manual

This manual is yours. Become familiar with it and use it as a reference. It contains forms that can help you develop a Food Safety Plan and resources to locate other basic information. Make as many notes and marks in the manual as needed to assist you in creating and understanding a Food Safety Plan. This manual does not have a copyright. Make as many copies of the forms as necessary or copy the whole manual to share with others in your company.

As you learn more about developing a Food Safety Plan, there are many definitions that you need to understand. To assist you, the definitions of many commonly used terms are listed at the end of the chapter. Refer to these pages as needed. You may also want to add other terms that you may need in developing and implementing your own Food Safety Plan.
Introduction Summary

- Successful completion of this course is one way to meet the requirements for a “preventive controls qualified individual” to manage a food safety preventive controls program.
- FDA’s Preventive Controls for Human Food rule builds on existing food safety principles.
- Preventive controls reduce risk for the business and for the public.
- Definitions used in the course are at the end of this chapter.
- Participation is vital to successfully completing this course.

By successfully completing this course, you will meet the training requirements for a “preventive controls qualified individual” who can oversee a food safety preventive controls program. You may need assistance from technical experts for certain elements of your food safety program, which will be discussed in chapters later in the course.

Through this course you will learn how to develop a risk-based Food Safety Plan and implement preventive controls to help mitigate and control hazards specific for your product and process. This reduces potential food safety issues for the public and for your business as well.

Participation is vital for understanding the material and your experience and questions can help others in the course as well. Please participate to get as much out of this course as you possibly can.

Definitions and Acronyms

**Acid foods** or **acidified foods**: 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**: That which is needed to accomplish the intended purpose in keeping with good public health practice.

**Allergen cross-contact**: 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 a supplier’s food safety processes and procedures.

**a_w:** Water activity (see below)

**CCP:** Critical Control Point (see below)

**cGMPs:** Current Good Manufacturing Practices (see “GMPs” and Chapter 3)

**Cleaning:** The removal of soil, food residue, dirt, grease or other objectionable matter.

**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).

**Corrective action:** Procedures that must be taken if preventive controls are not properly implemented.

**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.

**Critical limit:** 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:** Unintentional transfer of a pathogen from a food or surface to another food or surface.

**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.

**Deviation:** Failure to meet a critical limit.

**e.g.:** For example (Latin *exempli gratia*)

**Environmental pathogen:** 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**: 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**: Food and Drug Administration

**Food**: 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. 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**: 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 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**: 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**: A set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, supply-chain programs and a recall plan; and delineates the procedures to be followed for monitoring, corrective actions and verification.

**Food safety system**: The outcome of implementing the Food Safety Plan and its supporting elements.

**GMPs (Good Manufacturing Practices)**: The regulation (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.

**HACCP**: Hazard Analysis and Critical Control Point (see below)

**Hazard**: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
**Hazard analysis**: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore must be addressed in the HACCP or Food Safety Plan.

**Hazard Analysis and Critical Control Point**: A system which identifies, evaluates, and controls hazards which are significant for food safety.

**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.

**Known or reasonably foreseeable hazard**: 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**: The food produced during a period of time and identified by an establishment’s specific code.

**Microorganisms**: 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**: 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)**: 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\(^1\): Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.

Parameter\(^1\): a characteristic, feature or measurable factor that can help in defining a particular system.

Pathogen\(^3\): 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 141).

Prerequisite programs: Procedures, including Good Manufacturing Practices (GMPs), that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

Preventive controls\(^3\): 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\(^3\): 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\(^3\): 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 part 1, subpart M of this chapter.

Qualified individual\(^3\): 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.

RTE (Ready-to-eat) food\(^3\): 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).

**Receiving facility**: 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.

**Rework**: 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**: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

**Safe-moisture level**: 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_\text{w}). An a_\text{w} will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_\text{w} will not support the growth of undesirable microorganisms.

**Sanitize**: 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.

**Severity**: The seriousness of the effects of a hazard.

**Significantly minimize**: To reduce to an acceptable level, including to eliminate.

**SOP**: Standard Operating Procedure

**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.

**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.
**Unexposed packaged food**: Packaged food that is not exposed to the environment.

**Validation**: 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**: 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**: 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** ($a_w$): 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**: 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).

**Source of definitions**:

3. Food and Drug Administration (FDA). 21 CFR 117.3 Definitions
4. FDA. Derived from 21 CFR 117.135(c)(i)(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
CHAPTER 2. Food Safety Plan Overview

Food Safety Plan Overview Objectives

In this module you will learn:

• The benefits of using a Food Safety Plan
• The principles applied to build a Food Safety Plan
• A roadmap for building a Food Safety Plan

The Food Safety Plan is the primary document that guides your preventive controls food safety system. The Food Safety Plan is developed using a systematic approach to identify those hazards that require preventive controls to prevent foodborne illness or injury. This chapter provides an overview of the components of a Food Safety Plan that are needed to comply with the Preventive Controls for Human Food regulation.

This module also provides a few examples of outbreaks and recalls that occurred when preventive controls that should be included in a Food Safety Plan were lacking. Learning from past outbreaks and recalls can help protect consumers and your business from similar unfortunate incidents.

As discussed in Chapter 1, the requirements in the Preventive Controls for Human Food regulation are based on well-established food safety principles. This chapter also provides a brief discussion of the systematic process involved in building a Food Safety Plan.

While this chapter provides an overview to help you visualize how you might structure a Food Safety Plan specific to your operation, the details are covered in chapters later in the course.

Definitions:

Food Safety Plan: A set of written documents that is based on food safety principles; incorporates hazard analysis, preventive controls, supply-chain programs and a recall plan; and delineates the procedures to be followed for monitoring, corrective actions and verification.

Food safety system: The outcome of implementing the Food Safety Plan and its supporting elements.
A written hazard analysis is the first required element in a Food Safety Plan. When the hazard analysis process identifies hazards requiring a preventive control, the written preventive controls portion of the plan must address relevant process preventive controls, food allergen preventive controls, sanitation preventive controls, supply-chain or other preventive controls. These are the preventive controls needed to control the hazards identified in the hazard analysis as requiring a preventive control. Monitoring, corrective action and verification procedures for each of the preventive controls identified must also be included in your plan as appropriate to ensure the effectiveness of the controls. A recall plan is also a required element of a Food Safety Plan when a hazard requiring a preventive control is identified. You are also required to maintain implementation records to document that you have implemented your Food Safety Plan.

Because your Food Safety Plan will be used or reviewed by regulators, employees, auditors, customers and potentially consultants, it may also be useful to include a brief description of your facility or company along with a list of your Food Safety Team members, a product description, a process flow diagram and a process description to help people understand the structure of the plan. This course includes these optional elements in the Food Safety Plan example to help class participants visualize the hypothetical operation and resulting documentation examples. The remainder of the course goes into more detail on the elements of an effective Food Safety Plan.
Food Safety Plan Overview

Examples of Outbreaks and Recalls

You may wonder "What’s in it for me?" when you consider what it will take to develop your Food Safety Plan. There are numerous outbreak and recall examples that illustrate the need for controls to prevent illness, as well as the benefit of having an effective and operational plan to avoid being involved in an outbreak or recall. Here are a few examples.

Peanut butter is typically a safe product because effective roasting of peanuts can destroy potential pathogens, such as *Salmonella*. However, an extensive outbreak in the U.S. associated with commercially-used peanut products illustrates the importance of process validation, sanitation controls and supplier controls. The outbreak investigation found that the peanut roasting process had not been validated so it was not known how effective this control measure was. Further, *Salmonella* was found in the processing environment, which suggests the environment was a potential source of product recontamination and that sanitation controls were not adequate. The incident involved hundreds of companies that had used the peanut ingredients in their products without an additional kill step. A supply-chain program, including determining that any pathogen kill step has been validated and that the supplier has controls to prevent recontamination, is another important preventive control to include in a robust food safety system. Together, these preventive controls could have prevented or minimized the size of this incident and associated recalls.

Another example involves a botulism outbreak that occurred in England in 1989. The manufacturer of the hazelnut conserve ingredient for the yogurt used a process that was similar to that used for fruit products. Because fruits have a lower pH than hazelnuts, the
process was not adequate to kill *C. botulinum* spores and the formula was not adequate to control growth of *C. botulinum* when the ingredient was held at room temperature. Process validation or storage of the ingredient at refrigeration temperatures may have prevented the issue. Understanding supplier capabilities is another important lesson from this outbreak – the hazelnut conserve manufacturer did not understand that their new product required more stringent controls. An appropriate supply-chain program could have identified this shortcoming and addressed the issue before the yogurt manufacturer used the hazelnut conserve that had been inadequately processed.

Avoiding or minimizing the potential for a recall is another benefit of having a robust Food Safety Plan. Allergen recalls are responsible for at least a third of food safety recalls for FDA regulated food products (See Additional Reading at the end of the chapter). The root cause for most of these recalls is not declaring the presence of the food allergen on the label. Chapter 10: Food Allergen Preventive Controls provides more information on how to control this food safety hazard.

Contamination of food products typically comes from one of three different sources – 1) ingredients, 2) the processing environment, including equipment or 3) people. This is discussed further in Chapter 4: Biological Food Safety Hazards and Chapter 5: Chemical, Physical and Economically Motivated Hazards.
Principles Applied to Build a Food Safety Plan

Developing a Food Safety Plan, including determining where preventive controls are needed, involves a systematic process based on science to help ensure the safety of the product. It starts with hazard analysis (covered in Chapter 8), which is intended to identify hazards requiring a preventive control – in other words, the ones that matter most for food safety. When these hazards are known, preventive controls that are essential to prevent the hazard from causing illness or injury are identified. As previously discussed, preventive controls may include process preventive controls, allergen preventive controls, sanitation preventive controls, supply-chain preventive controls or other preventive controls that you determine are essential for your product. Once preventive controls are identified, you need to determine relevant parameters that define the conditions that must be met to effectively manage the hazard. Monitoring provides documentation that demonstrates these conditions are met. Corrective actions or corrections are predefined to enable swift action when things go wrong, thus preventing expansion of a food safety issue. When things go wrong, you also have to ask if it was because a hazard was overlooked (in which case you must adjust the hazard analysis), or if a preventive control was not properly identified or implemented. All of the above is recorded and verified to ensure the system is operating as intended and to provide a record for others (e.g., inspectors, auditors, management) to show that this is the case.

Some elements of a preventive controls system also require validation to demonstrate that the controls actually work. This activity may be less rigorous for some preventive controls than others. These differences will become more apparent as we go through the course.

If you currently have a HACCP plan, it likely will be the part of your Food Safety Plan that addresses hazard analysis and process preventive controls (see Chapters 8 and 9). The hazard analysis may need adjustments to identify allergen, sanitation, supply-chain and potentially other preventive controls in addition to those addressed in a traditional HACCP plan.
Food Safety Plans are specific to a facility, with preventive controls specific to a food product and process. It is possible to group products that have the same hazards and controls in one Food Safety Plan provided and differences are clearly identified. Some operations choose to organize Food Safety Plans around unit operations in production (e.g., making a blend that is used in several products) to reduce overlap or avoid inconsistency. The organization of your Food Safety Plan is up to you.

In defining the scope of the Food Safety Plan, you should:

- 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.

The scope of the Food Safety Plan may be influenced by regulatory requirements or specific requirements instituted by a customer.
Food Safety Plan Example

The specific format of a Food Safety Plan is not defined. Each facility can organize the required information in a manner that suits their systems, the needs of their employees, the needs of their customers and the requirements of the regulation. The important thing is to have a plan that is easy to understand, implement and manage; that it is kept up to date; and that it is organized and accessible for inspection. The following is an example of how a Food Safety Plan might be set up, using a notebook. Note that there is no requirement that all components of a Food Safety Plan even be in a notebook – we are just using this as a model.

Main Organizational Sections

1. Background information - optional
2. Hazard analysis
3. Preventive controls
4. Recall plan
5. Implementation procedures
This course is organized around building a Food Safety Plan. In our example, we use the five main sections or tabs for the Food Safety Plan, including background information, hazard analysis, preventive controls, recall plan and implementation records.

The information behind the Background Information tab is covered in Chapter 6: Preliminary Steps in Developing a Food Safety Plan. Background information is not required by regulations, but provides a useful framework for organizing the Food Safety Plan and for explaining the plan to others. 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 required records on training, could be included in this section. Two types of training are required by the regulation: 1) food hygiene and food safety training, as appropriate to an individual’s duties and 2) training, if applicable, for a preventive controls qualified individual.

The product description section helps people understand important elements of the product that may impact food safety. An accurate flow diagram is useful 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 could provide information needed to fully understand how the product is made. This can be helpful to those who are looking at the plan to understand, for example, the types of preventive controls applied. A facility can use other documents to meet these goals, if that works for their system.
The hazard analysis drives decision making on which hazards requiring a preventive control. Thus, the hazard analysis forms the basis for other required elements in the plan. Careful analysis of the hazards that may be relevant for your product will help you to focus the controls on what matters most. See Chapter 8: Hazard Analysis and Preventive Control Determination.

The Preventive Controls section describes the essential controls that ensure safe product is produced. The required preventive controls for a specific product are determined through the hazard analysis process, which considers the nature of the preventive control and its role in your facility's food safety system. Process preventive controls are discussed in Chapter 9. Food allergen preventive controls are covered in Chapter 10, and sanitation preventive controls are...
discussed in Chapter 11. 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 12: 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.

A recall plan describes, ahead of time, what to do when something goes wrong and the product is in commerce. The format that you use can vary considerably. For example, you may want a totally separate recall plan notebook but it would still be considered part of the Food Safety Plan.
The Implementation Procedures tab includes other information required to support your plan. This may include validation studies that demonstrate that the preventive controls you selected are actually effective in controlling the identified hazards. Procedures for and records of monitoring, corrective actions or corrections, and verification activities may also be required to demonstrate that the food safety system was operated as planned on an ongoing basis. Example forms could also be included in a Food Safety Plan notebook. The actual required records could be in a separate notebook, a file cabinet, a computer or whatever format works for your organization.

In summary, the Food Safety Plan is a written document that is specific to the facility. It must contain a 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 through the hazard analysis process. It must also 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 sections, some may separate them. There is no requirement that all parts of the Food Safety Plan be located in one place.

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 implemented. These 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.

Additional Reading
CHAPTER 3. Good Manufacturing Practices and Other Prerequisite Programs

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 are implemented in order to effectively manage risk from foodborne hazards. The Current Good Manufacturing Practice (GMP) regulations address requirements for many prerequisite programs. There are other programs that are likely to apply to most facilities, such as supplier and manufacturing specifications.

In this chapter you will learn the definition of prerequisite programs and their importance in a food safety system. An overview of GMP requirements is provided; however, further reading or training is important to ensure that you understand these foundational programs and the regulatory requirements! You will also learn about other prerequisite programs that may be important for your facility.

Prerequisite programs provide the basic environmental and operating conditions that are 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 required by regulation (e.g., GMPs). The specific prerequisite programs required may vary depending on

Definitions:
Prerequisite program: Procedures, including Good Manufacturing Practices (GMPs) that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

Food safety system: The outcome of implementing the Food Safety Plan and its supporting elements.
the type of food produced and the facility where it is processed or held. Some people use the terms prerequisite program, GMP, cGMP (“c” stands for current), “good hygienic practice” and “sanitation standard operating procedures” 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.

Good Manufacturing Practices

GMPs are federal regulations that apply to all facilities that manufacture, process, pack or hold FDA-regulated food. GMPs are the basis for determining whether food products have been processed under sanitary conditions. They outline the minimum sanitary standards that a food processing facility must meet, including personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, and warehousing and distribution. They also provide for defect action levels for natural or unavoidable defects that at low levels are not hazardous to health. There may be some instances where a specific GMP task is so important to the safety of the product that it is designated as a preventive control in a Food Safety Plan. This is determined during hazard analysis and most likely would occur if there are cross-contamination (in a ready-to-eat food) or allergen cross-contact issues that need to be addressed in written sanitation or allergen preventive controls. Chapter 8: Hazard Analysis and Preventive Control Determination covers this selection process. This chapter focuses on basic GMP requirements.

The GMP regulations do not require written procedures, monitoring or record-keeping (except for training records); however, they are

Components of Good Manufacturing Practices (GMPs)

- The regulation (21 CFR 117 Subpart B) lists these components that establish the conditions and practices the food industry must follow for processing safe food under sanitary conditions:
  - Personnel
  - Plant and grounds
  - Sanitary operations*
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls*
  - Warehousing and distribution, and
  - Defect action levels

*Some components may be preventive controls based on hazard analysis

This is not a comprehensive discussion of GMP requirements. Certain regulatory requirements are addressed in Chapter 16: Regulation Overview – cGMP and Hazard Analysis and Risk-based Preventive Controls for Human Food. Regulations are provided in 21 CFR 117 Subpart B in Appendix 1.
recommended as part of a facility's Standard Operating Procedures (SOPs) to manage the GMPs and document the results of these important programs. This can be very helpful to limit the amount of product that may be subject to corrective actions or recalls when an incident occurs. For example, product made from cleanup to cleanup, as reflected in records, defines impacted product for some recalls. Written SOPs are also helpful for employee training. The rest of this module highlights GMPs that are basic to making sure that products are processed under sanitary conditions.

### Training

- Individuals must be qualified by education, training, or experience to manufacture, process, pack or hold food
- Individuals must receive food hygiene and food safety training
- Supervisors responsible for ensuring compliance must have appropriate by education, training or experience

Employee education and training is an important prerequisite program. Employee training must cover cleanliness, health requirements, how to perform their job and how their work can impact the safety of product. This employee training must be documented. Supervision and setting a good example is also an important part of the system.
Selected GMPs related to personnel practices are listed on the slide above. While we will not go into detail on each of these, a few comments regarding personnel are warranted.

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. Your procedures and practices must make sure that sick people are not around food, and employees must receive training on this.

People can also carry potential contaminants into the processing environment. Clothing must be clean. Uniforms, smocks, dedicated footwear, color coding and other clothing options should be considered depending upon the needs of the operation.

Proper hand washing (and hand sanitizing when handling ready-to-eat foods) is essential to prevent direct contamination, cross-contamination and allergen cross-contact. This should be done each time employees are away from the work station.

### Personnel

- Restricting persons with illness or open wounds
- Proper handwashing and sanitizing
- Adequate personal cleanliness
- Suitable gloves maintained in satisfactory condition
- Suitable outer garments
- Jewelry removed
- Hair restraint
- Personal items stored away from production areas
- No eating, drinking or tobacco use in production area

**Direct contamination** – transfer of human pathogens, e.g. after using the restroom

**Cross-contamination** – Unintentional transfer of a pathogen from a food or surface to another food or surface.

**Allergen cross-contact** – Unintentional incorporation of a food allergen into a food.
GMPs listed above for the plant and grounds help to ensure that the buildings and structures are suitable for food-production purposes, and to reduce the potential for pathogen recontamination. For example, make sure that the grounds outside the food facility are clean, that there is no standing water and that waste is collected and disposed of frequently. Inside the facility provide adequate space and proper separation for operations (e.g., between cooked and raw product and between food with different allergen profiles, if applicable). Also, make sure that walls, floors and ceilings are in good repair. It is also important to ensure that condensate does not drip onto in-process product, that there is adequate light for operations, and that any glass is guarded against breakage.
Sanitary Operations

These GMPs cover specific operations needed to keep a plant in good sanitary condition. Making sure that the food facility is in good condition and that any cleaning or storage of chemicals do not contribute to product contamination are important for all food facilities. As pests can be vectors for contamination, they should be prevented from entering the facility. Food-contact surfaces need to be cleaned and sanitized as often as necessary to ensure they are not a source of contamination. A brief discussion of the bold provisions on the slide for sanitary operations follows.

**Toxic Chemical Storage**

Certain potentially toxic chemicals are essential for effective plant operations. Only cleaning and sanitizing chemicals, laboratory testing chemicals, and chemicals needed for plant and equipment maintenance (e.g., lubricants) may be used or stored in a plant where food is processed or exposed. These chemicals must be properly labeled, used and stored in a manner that protects food, food-contact surfaces and packaging material from contamination. Store toxic chemicals in a secured area with limited access, and separated from food processing areas and areas where food and packaging materials are stored. Follow the label instructions for these chemicals to ensure safe application.

Precautions are necessary for application of insecticides and rodenticides. This frequently requires application by a licensed operator. These toxic compounds are generally used only outside of the processing facility unless special precautions are taken. For example, thorough cleaning of all food-contact surfaces after application 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 overall sanitation of a facility so it is important ensure the effectiveness of pest control. Even if pest control is contracted to an outside company, the facility must assure that there are no pests in the facility. Take measures to exclude pests (e.g., eliminate holes that allow entry), and remove vegetation or structures that attract or provide a harborage for pests. Proper waste removal reduces the availability of a food source or harborage that can attract pests.

Sanitation of Food-contact Surfaces

<table>
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<th>Sanitary Operations</th>
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<tbody>
<tr>
<td><strong>Condition and Cleanliness of Food-contact Surfaces</strong></td>
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<tr>
<td>• Food-contact surfaces must be:</td>
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<tr>
<td>▪ Smooth and easy to clean</td>
</tr>
<tr>
<td>▪ Cleaned and sanitized as necessary to protect against allergen cross-contact and cross-contamination of food</td>
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<tr>
<td>• Potentially hazardous situations that may require Food Safety Plan documentation include:</td>
</tr>
<tr>
<td>▪ Allergen cross-contact</td>
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<tr>
<td>▪ Environmental pathogen harborage sites</td>
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<td>▪ Sanitation frequency to prevent pathogen growth</td>
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The Preventive Controls for Human Food regulation requires documentation of sanitation controls for hazards requiring a preventive control in the Food Safety Plan. Only those sanitation procedures that address hazards requiring a preventive control (e.g., sanitation to address environmental pathogens if relevant) must be documented in a Food Safety Plan. This is discussed further in Chapter 11: Sanitation Preventive Controls. Adequate cleaning and sanitizing procedures and frequencies must be established for all food-contact surfaces, including equipment, utensils and food containers. Gloves and uniforms that contact food may also be included in this category. Suggested frequencies for cleaning and sanitizing include before use, after processing interruptions and as necessary to prevent pathogen growth.

Different methods of cleaning may be relevant in different plant environments. Allergen removal requires cleaning but not use of sanitizers – sanitizing is not intended to have an impact on allergens. Use of water in dry processing areas is discouraged because it can infiltrate cracks, crevices and difficult to clean areas, establishing
potential harborage sites for environmental pathogens. 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. Follow manufacturer's use instructions to ensure efficacy and regulatory compliance.

Sanitation of Non-food-contact Surfaces
As discussed above, sanitation of non-food-contact surfaces is needed in most facilities to eliminate potential food sources for pests. For facilities that make ready-to-eat products that 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 finished product contamination with environmental pathogens. This is discussed further in Chapter 11: 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.

Sanitary Facilities and Controls

<table>
<thead>
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<th>Sanitary Facilities and Controls</th>
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<tbody>
<tr>
<td>• Adequate potable water supply</td>
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<tr>
<td>• Proper plumbing</td>
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<tr>
<td>• Adequate floor drainage</td>
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<tr>
<td>• Proper sewage disposal</td>
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<tr>
<td>• Adequate, accessible, sanitary toilet facilities</td>
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<tr>
<td>• Convenient hand-washing and sanitizing facilities</td>
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<tr>
<td>• Proper trash and waste disposal</td>
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Bold items discussed further

Sanitary facilities and controls include the water supply, plumbing, sewage disposal, toilet facilities, hand-washing facilities, and trash and waste disposal. A brief discussion of the water supply and plumbing, as well as toilet and hand-washing facilities, follows.
Water Supply and Plumbing

Water and ice that contacts food, food-contact surfaces and food-packaging material must be of safe and adequate sanitary quality.

- The source of water and the plumbing system that conveys it to the building must provide a safe supply. In many regions, the water treatment authority is responsible for ascertaining the safety of the water source and conveyance to the building. In these situations, a company’s documentation should include annual water quality tests from the water authority. Facilities using private water systems (e.g., wells) are directly responsible for adequate monitoring and documentation of the safety of the water source. Municipalities in many regions can provide guidance.

- Ice must be made with potable water and protected from contamination with the same care used for food when ice contacts food (or food-contact surfaces).

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

- To ensure water is safe, 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.

Developed regions typically have mature water safety programs, while developing regions may not have uniform delivery of safe drinking water. Potential hazards and controls must be considered for those regions.
Hand Washing, Hand Sanitizing and Toilet Facilities

Potentially hazardous situations include:
- Apparently healthy humans can carry and shed pathogens
- Cross-contamination or allergen cross-contact via employee hands to food, food-contact surfaces or packaging

Must be adequate and readily accessible
Must be kept clean to prevent creation of contamination source
Must maintain an adequate sewage disposal system
Hand washing signs are useful reminders

Employees, even those who are healthy, can carry and shed human pathogens that can be transmitted through food, thus hand washing and sanitary toilet facilities are essential for food safety. Each establishment 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.

Hand washing and, where appropriate, hand sanitizing facilities should be at each location where good sanitary practice requires their use. Effective hand hygiene training should be accompanied by available hand washing supplies that remove food soils from hands; e.g., soap, running water. Hand washing signs are useful reminders. Water at a comfortable temperature must be available and single-use towels or suitable drying devices should be provided to prevent recontamination. Wet hands are more prone to spread contamination than are dry hands.

An adequate sewage disposal system is required. Readily accessible toilet facilities must be maintained in sanitary condition and not be a source of contamination. Toilet facilities should have self-closing doors that do not open into processing areas. Additionally, toilet facilities should be in good repair (e.g., not leaking) and should be properly supplied with personal hygiene products, including hand washing supplies.
Equipment and Utensils

- Cleanable and maintained food-contact and non-food-contact areas
- Preclude adulteration
- Corrosion resistant and nontoxic food-contact surfaces
- Compressed gases properly filtered
- Freezers and coolers have temperature indicating devices and automatic temperature control or alarm
- Properly maintain accurate process control instruments

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 nontoxic materials to prevent adulteration. Seams should have smooth welds to ensure cleanability. Also, compressed air introduced into food must be treated so that it does not contain adulterants and be properly filtered to prevent particles from getting into food.

Cooling equipment, such as freezers and coolers must be equipped with temperature indicating devices, such as thermometers or chart recorders. Automatic temperature control or an alarm system helps to ensure that the proper temperatures are maintained. Thermometers and similar equipment must be accurate (close to the correct measure), precise (appropriately narrow ± range) and maintained.
Processes and controls used for food must ensure that the food remains suitable for human consumption. This provision covers general and more specific requirements for raw materials, ingredients, and manufacturing operations. Take adequate precautions to ensure that procedures do not contribute to allergen cross-contact or contamination from any source, and minimize the potential for microbial growth. When food is adulterated, it usually must be rejected. FDA may allow the food to be treated or processed to eliminate contamination (see 21 CFR 117.80(a)(6)). Appropriate quality control procedures are required to assure success. Some tasks may require special attention. 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.
**Raw Materials and Ingredients**

*Processes and Controls*

**Raw Materials and Ingredients**

- Comply with FDA requirements for pests, extraneous material or undesirable microorganisms, as assured by testing, supplier certification or heat treatment
- Inspect for suitability
- Store and handle to prevent contamination and deterioration
- Properly identify rework and prevent contamination, allergen cross-contact and deterioration

Raw materials must be free from pests, extraneous material (e.g., string, plastic, metal, etc.), and undesirable microorganisms. You are responsible for assuring this using whatever techniques are appropriate for the material and your source of supply. 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). This also applies to thawing. If you use rework, ensure that it is properly identified, stored and handled to prevent contamination, allergen cross-contact and deterioration.

**Manufacturing Operations**

*Processes and Controls*

**Manufacturing Operations**

- Prevent microbial growth through:
  - Cooking, time/temperature control, water activity control (pH) etc.
- Use clean and sanitized equipment, utensils and finished product containers
- Manufacture ice from potable water in a sanitary manner
- Prevent Allergen cross-contact and cross-contamination
All manufacturing operations must be conducted to minimize microbial growth. Pasteurizing, freezing and refrigerating are food processing methods that may be used to prevent spoilage and ensure safety of certain food products. The extent to which these are used depends on the particular product and its distribution. When used, these processes must be done in a manner that ensures the conditions are adequate to maintain product safety and prevent deterioration, including use of time and temperature combinations that kill pathogens of concern (for pasteurization) and that prevent the growth of microorganisms during cooling in refrigeration and freezing processes. 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 hot temperatures. Minimize thermophilic growth through proper temperature and timely cleaning. Certain moist foods such as batters, breading, sauces, gravies, and stuffing can support rapid growth of microorganisms. Protect these from contamination through good 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 (discussed in Chapter 4: Biological Food Safety Hazards) must have parameters (e.g., soluble solids/water ratio or water activity) monitored to assure that growth is controlled, and must be protected from moisture pickup. Factors that influence microbial growth are discussed in Chapter 4: Biological Food Safety Hazards.

Clean and sanitize equipment, utensils and finished product containers as necessary to ensure sanitary conditions. This may require disassembly of equipment to facilitate cleaning. Ice is a common ingredient for many operations. If made in-house, use potable water and produce it in a sanitary manner. Ice machines, like other food processing equipment, must be cleaned and sanitized periodically.

Finished or in-process food must be protected from contamination by raw materials or refuse. This includes exposed food on conveyors in the ambient environment, as well as in freezers and coolers. Use of sieves, traps, magnets and metal detectors can be useful to prevent inclusion of metal and extraneous material, or to detect metal if such contamination does occur. Destruction and reconditioning operations should not serve as sources of contamination and methods used should be shown to be effective.
Sanitary conditions apply not only to manufacturing areas, but also to warehousing and distribution. Microbial growth must be prevented. Allergen cross-contact must 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.

**Human Food or By-products sent to Animal Food**

**GMPs for By-Products Sent to Animal Food**

- Human food by-products sent to animal food use must comply with GMPs during holding and distribution; e.g.
  - Must be held under conditions that will protect against contamination
    - Ensure the safety of containers
    - Avoid contamination from trash or garbage
    - Identify the material through labeling
  - Companies that further process food or by-products for use as animal food must comply with preventive controls for animal food (21 CFR Part 507)

Food companies often send unusable food or 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 or wholesalers; or directly to animal producers that
may feed it directly to animals or, if necessary, process the food to mitigate any hazards.

Human food and 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 animals, but must comply with specific holding and distribution GMPs to keep the by-product safe (21 CFR 117.95 and 21 CFR 507.28). For example, containers used to hold animal food before distribution need to be constructed of appropriate material, cleaned and maintained to prevent them from contaminating the by-products.

By-products must also be held in a way that prevents contamination from trash and garbage (e.g., employee lunches, maintenance department debris). Use of color-coded containers to designate the contents (e.g., for trash versus for human food by-products going to the animal food supply chain) may be useful. Additionally, by-products must be labeled on the container or shipping documents with the common or usual name, such as “cereal food fines” for particles of breakfast cereals obtained as a by-product of their processing (See AAFCO in Additional Reading).

Note that if a human food manufacturer also processes the by-product materials (e.g., drying, pelleting, grinding), they must comply with the Preventive Controls for Animal Food regulation in 21 CFR Part 507. These companies should consider participating in the FSPCA course for animal food.

**Defect Action Levels**

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

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-

![FSPCA](image1.png)
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 under GMPs. Mixing of food containing defects above the defect action level with another lot of food with low levels is not permitted – the entire batch would be considered adulterated regardless of the level present.

**Other Prerequisite Programs**

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<tr>
<td>• Hygienic zoning in ready-to-eat facilities</td>
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<td>• Supplier and product specifications</td>
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<td>• Preventive maintenance</td>
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<tr>
<td>• Signage or color coded equipment</td>
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<td>• Others specific to plant</td>
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In addition to GMPs, other common prerequisite programs include hygienic zoning, supplier and product specifications, preventive maintenance, special signage (e.g., allergen icons) or color coded equipment (e.g., a special color for waste material containers) and other programs specific to the operation.

**Hygienic Zoning**

Hygienic zoning is useful to reduce the potential spread of pathogens in facilities that manufacture ready-to-eat (RTE) products. For example, areas of the facility that handle the raw ingredient (e.g., raw peanuts) may have less stringent expectations for hygiene than those handling the RTE product (e.g., roasted peanuts). Zoning typically involves separation of, for example, cooked product from raw product, and may include different uniforms for “cooked side” and “raw side” employees, dedicated equipment (e.g., carts or fork lifts) for different zones, traffic flow and air flow considerations, etc. Hygienic zoning is discussed further in Appendix 6: Hygienic Zoning and Environmental Monitoring Supplemental Information. Some elements of hygienic zoning may be a preventive control as determined through the hazard analysis process.
Purchasing and Manufacturing Specifications
Written specifications for the products you produce and the processes you use to make them, as well as ingredient and packaging materials, are common in business transactions. Well written specifications help to ensure that expectations are understood by both the customer and the supplier.

This is particularly important for ingredients that have a history of association with foodborne hazards. Efforts should be made to know your suppliers, such as learning about their facilities and practices, and the safety and quality of their products. Buying ingredients on the open market without knowledge of the supplier’s food safety practices or program can add risk to your operation.

Written ingredient and packaging material specifications should be developed for all suppliers, and verification of compliance with those specifications is recommended for ingredient classes that have a history of contamination. Adherence to the specification is commonly confirmed through the use of a letter of continuing guarantee or a certificate of analysis (COA) that verifies the ingredient or product meets specifications. Chapter 4: Biological Food Safety Hazards and Chapter 5: Chemical, Physical and Economically Motivated Food Safety Hazards review some ingredients that have a history of outbreaks associated with specific foodborne hazards.

Periodic reviews of the supplier’s product against ingredient specification requirements should be an element of supply-chain programs. Use of a third-party auditing firm that reviews the supplier’s food safety program is one way to verify that controls are in place at the supplier. The extent to which controls are used should be risk-based and consistent with regulatory requirements. Chapter 12: Supply-chain Programs provides more detail on requirements when hazards requiring a preventive control are addressed by a supplier.

Others Specific to the Operation
Some organizations develop detailed procedures that may also be considered prerequisite programs. These may include receiving, storage and shipping procedures, labeling and label review, ingredient handling practices, glass control, visitor control, etc. The impact of these programs on food safety can be considered during the hazard analysis process. For example, labeling foods that contain food allergens is a preventive control that must be included in the Food Safety Plan, but label review for other information may be a prerequisite program. Similarly, glass control programs may be a prerequisite program for facilities that do not pack in glass containers; however, preventive controls would be required if glass containers are used in a facility.
Other Regulatory Requirements

**Other Regulatory Considerations**

The following are examples of regulations that are outside of the scope of the Preventive Controls for Human Food regulation and may or may not be related to food safety concerns:

**Other Regulations**
- Local regulations
- Food defense and biosecurity requirements
- County of Origin Labeling (COOL)
- Nutritional labeling
- Procedures to guard against economic fraud

**Other Food Safety Regulations**
- Seafood HACCP
- Juice HACCP
- USDA Pathogen Reduction Regulation
- International HACCP regulations
- Preventive Controls for Animal Food
- Produce Safety regulations
- Sanitary Food Transport regulation

Finally, there are a number of requirements that are outside of the scope of the Preventive Controls for Human Food regulation and may not be related to these regulations. These, however, are regulatory requirements under other programs and processors should be aware of these requirements as they may need to be included in their overall food safety program. For example, seafood products are not subject to the Preventive Controls for Human Food regulation but are subject to GMPs and the seafood HACCP regulation.

**GMPs and Other Prerequisite Programs Summary**

**GMP and Prerequisite Programs Summary**

- GMPs and other prerequisite programs provide the foundation necessary for production of safe and wholesome food
- GMPs are required and most are managed as prerequisite programs outside the Food Safety Plan
- Training is needed to understand and effectively implement GMPs

Good Manufacturing Practices and other prerequisite programs must be in place to provide a solid foundation for your Food Safety Plan.
These programs establish the foundation for effectively implementing your food safety system. GMPs are required by regulations, and most elements are managed as prerequisite programs outside of your Food Safety Plan. GMPs are operationalized by workers, frequently through written 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 or business, there may be additional programs to consider and implement.

**Additional Reading**

Links to GMP training and some of the additional references are available on the FSPCA website [http://www.iit.edu/ifsh/alliance/resources/](http://www.iit.edu/ifsh/alliance/resources/).

- AAFCO (Association of American Feed Control Officials) 2015 Official Publication.
- FDA. 21 CFR 117, Subpart B – Current Good Manufacturing Practice
- National Conference on Interstate Milk Shipments. 2013. NCIMS dairy HACCP Questions and Answers – Prerequisite Programs.
CHAPTER 7. Resources for Preparing Food Safety Plans

Resources for Preparing Food Safety Plans

Objective

In this module, you will learn:

• Information sources to help identify food safety hazards and establish preventive controls
• FDA guidance for hazard analysis and preventive controls

A successful Food Safety Plan identifies hazards requiring a preventive controls and procedures to control them to ensure that the food produced is safe to eat. The first part of this chapter introduces numerous resources that can assist in developing and modifying a Food Safety Plan. The second part provides information on FDA guidance to help you to conduct your hazard analysis and develop a Food Safety Plan.

Sources of Information

• Personnel
• Publications
• Reliable internet sites
• FDA guidance documents

The FSPCA website maintains a current list of resource material. Please consult this website for the latest information.
Before implementing a food safety system, you need to perform a hazard analysis to determine which hazards require a preventive control for your products. To conduct a hazard analysis and develop a Food Safety Plan, gather information from a variety of credible sources and use the information that best applies to your situation. Some of the most useful sources of information are described in this chapter. Sources of information include people, publications, reliable internet sites, miscellaneous agencies and the FDA.

**Personnel**

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<tr>
<th>Sources of Information - Personnel</th>
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<tbody>
<tr>
<td>• Your employees</td>
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<tr>
<td>• Consultants and auditors</td>
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<tr>
<td>• Process authorities and subject matter experts</td>
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<tr>
<td>• University specialists</td>
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<tr>
<td>• Government agencies</td>
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<tr>
<td>• Trade associations</td>
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<tr>
<td>• Suppliers, buyers and laboratory analysts</td>
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</table>

**Your Employees**

You and your employees know your operation better than anyone. Experience is an excellent source of information. You may already have knowledge about hazards that can affect your product, and you may already have preventive controls implemented to control those hazards.

In addition to being a source of information, your employees are essential for implementing the plan. This includes everyone, including senior management (who must demonstrate commitment to effective development, implementation and ongoing maintenance of the Food Safety Plan).

**Consultants and Auditors**

Food safety consultants, firms and auditors with expertise in the *Preventive Controls for Human Food* regulation can be a useful resource. Consultants may be helpful in developing and reviewing your Food Safety Plan, particularly if you are just starting a new company or need expertise beyond your company’s abilities in complying with the regulation, sanitation, sampling etc. Auditors that
you hire may identify deficiencies or include recommendations for improvement in the report they provide.

**Process Authorities and Technical Experts**
Some food safety professionals have in-depth expertise related to specific types of foods or processes. These are sometimes called processing authorities. They use scientific methods to determine the proper parameters (e.g., time, temperature, atmosphere, flow rate, $a_W$, oxygen level, pH etc.) to prevent, eliminate or reduce pathogens to acceptable levels. They are a key source for validating the adequacy of a process to ensure that identified controls will actually work to control a hazard. They can also provide technical advice for developing a Food Safety Plan and implementing appropriate corrective action procedures. The FSPCA Technical Assistance Network is discussed in the upcoming section on Reliable Internet Sites.

**University Specialists**
Many, but not all, Land Grant universities have specialists in Cooperative Extension programs. These programs provide outreach, education and technical assistance to industry. Food safety extension specialists and agents can assist in identifying potential hazards and control measures, but their availability may be limited in some areas of the country. University research groups that conduct company-specific research projects also exist.

**Government Agencies**
Federal, state and local agencies may be able to assist you in understanding and meeting regulatory requirements. Some states 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. See the discussion in Reliable Internet Sites.

**Trade Associations**
Trade associations can also provide useful information. Some trade organizations provide services such as consulting, educational programs and publications that can help identify hazards and control measures. While some trade association information is available only to members, others provide technical guidance and resources for sale or in an open format (see Internet Resources section).

**Suppliers, Buyers and Laboratory Analysts**
Suppliers of ingredients, cleaning materials, processing equipment and packaging materials; and analytical laboratories can provide information on potential hazards and control measures. A buyer’s specification may point to a hazard in one of your products. For example, a buyer may require *Salmonella*-free product. It is important to note; however, that not all buyers’ specifications relate to safety.
Analysts at laboratories familiar with food samples are a good source of information in developing validation studies and sampling programs. In seeking recommendations from laboratories, it is important that the laboratory have experience with food because techniques used in food analysis may differ substantially from those used for clinical or environmental analyses.

**Publications**

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<th>Sources of Information – Publications</th>
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<tbody>
<tr>
<td>• <em>Hazard Analysis and Preventive Controls for Human Food</em> training curriculum</td>
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<tr>
<td>• FDA publications</td>
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<tr>
<td>• Peer reviewed literature</td>
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<tr>
<td>• Trade association publications</td>
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<td>• References used to develop this curriculum</td>
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Publications are one type of information source that you may use in developing your Food Safety Plan. It is important that you use credible publications for this purpose. The slide above lists general sources of credible information, and each type is described below.

**FSPCA Basic Course**

One of the best and most accessible food safety resources available to develop and modify a preventive-controls-compliant Food Safety Plan is this book provided in the Food Safety Preventive Controls Alliance basic course – the *Hazard Analysis and Preventive Controls for Human Food* training curriculum. This training curriculum covers steps for developing a Food Safety Plan using a model food designed to be consumed by the general public. 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; elements of process, food allergen, sanitation and supply-chain program preventive controls; and the *Preventive Controls for Human Food* regulation.

**FDA Publications**

FDA’s *Bad Bug Book* (see link on the FSPCA website) provides technical information on foodborne pathogens in everyday language. FDA hazards guides for seafood and juice products are available, and
a comprehensive *Food Safety Preventive Controls for Human Foods Hazards and Controls Guidance* (*Food Hazards Guide*) is under development. The *Food Hazards Guide* will contain information to 1) help identify potential hazards and determine if they require a preventive control, and 2) select approaches to control the hazards. A discussion FDA’s hazard guides is included later in this chapter.

**Peer Reviewed Literature**

Peer reviewed, scientific literature is another useful source of information for developing a Food Safety Plan. As previously mentioned, appropriate expertise is needed to properly apply information to a specific operation. The search tool Google Scholar may be useful to identify peer reviewed literature.

**Trade Association Publications**

Trade associations may be a useful source of information, including model recall plans, generic Food Safety Plans and other information. Trade journals often provide general information on potential hazards and controls. Articles on specific processes or products also can be useful. These trade journals are usually made available to industry at no charge, and many are accessible online. While generic Food Safety Plans may be available for products related to your operations, use these with caution, as your plan should be specific for your particular product and how it is made in your facility.

**References Used in Development of Chapters**

Many references were used in the development of the material in this training curriculum. Refer to the “Additional Reading” section of chapters for references that may be relevant to your operation.

**Reliable Internet Sites**

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<th>Sources of Information – Internet</th>
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<tr>
<td>• FSPCA website</td>
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<td>• FDA website</td>
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<tr>
<td>• Other U.S. agency resources</td>
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<tr>
<td>• Centers for Disease Control and Prevention</td>
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<tr>
<td>• FoodSafety.gov</td>
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<td>• U.S. Department of Agriculture</td>
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<td>• International agency resources, e.g.,</td>
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<tr>
<td>• Canadian Food Inspection Agency</td>
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<td>• Codex Alimentarius Commission</td>
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<td>• European Food Safety Authority</td>
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<td>• Trade association websites</td>
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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 use of inaccurate information! A few websites recommended by FSPCA are discussed below. Because web addresses change and information may be removed if it becomes out of date, check the FSPCA website for updated information and links.

### Food Safety Preventive Controls Alliance (FSPCA) Website
FSPCA maintains links to internet resources on its website and provides periodic updates with new sources of information when they are identified. Access to the FSPCA Technical Assistance Network is available through the FSPCA website. The website also provides updates on FSPCA activities and training courses that are available.

### Food and Drug Administration (FDA) Website
The FDA website ([www.fda.gov](http://www.fda.gov)) provides quick access to industry guidance, bulletins for health professionals, consumer education materials and other documents and data from FDA's centers and offices. Key FDA web resources include:

- FDA's FSMA Technical Assistance Network, which provides answers to policy interpretation questions
- FDA Guidance for Foods
- FDA Outbreak Investigations
- FDA Recalls, Market Withdrawals and Safety Alerts
- FDA Reportable Food Registry
US Agency Resources

- The **Centers for Disease Control and Prevention** is responsible for characterizing risk factors and prevention strategies for diseases that impact public health. The CDC also assists local health agencies in epidemiological investigations of foodborne illness outbreaks. Certain diseases are reported to the CDC by state epidemiologists. CDC information can provide insight into the outbreaks associated with specific food types. Examples of useful CDC websites for Food Safety Plan development include:
  - Multistate Foodborne Outbreak Investigations – Reports investigations of multistate outbreaks involving food and other sources
  - Foodborne Outbreak Online Database (FOOD) – Searchable database for U.S. outbreaks
  - Attribution of Foodborne Illness – Reports on foods associated with illness
  - FoodSafety.gov is a gateway to government food safety information, including links to foodborne pathogens, industry assistance and government agencies.

- The **U.S. Department of Agriculture** (USDA) Food Safety Inspection Service (FSIS) provides food safety information and may be a source of information on process controls, studies and prevalence of pathogens in USDA-regulated products. USDA FSIS also has information on recalls that may be of interest for certain product categories.

International Agency Resources

Many agencies around the world provide science-based information on food safety and potential hazards. A few examples are listed below for easy reference. Keep in mind that specific requirements may be different from one country to another, thus information used from these sites may require adjustments to comply with FDA regulations.

- The **Canadian Food Inspection Agency** provides information on food safety for a variety of food categories, including generic HACCP models for several products.

- The **Codex Alimentarius Commission** is sponsored by the Food and Agriculture Organization and the World Health Organization of the United Nations. Its purpose is to facilitate international trade by establishing uniform standards. The commission has developed many standards and guidelines, including recommended international codes of practice for a wide variety of food products.

- The **European Food Safety Authority** (EFSA) provides European food safety information similar to that for the US agencies
described above. Look for EFSA foodborne disease monitoring and analysis reports.

Trade Association Websites

- **American Frozen Food Institute** provides food safety information related to frozen products.

- **Grocery Manufacturers Association** provides food safety technical guidance on specific topics on their 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.

- The **Innovation Center for U.S. Dairy** provides science and research information for dairy products.

- The **United Fresh Produce Association** provides food safety information specific to produce.

FDA Hazards and Controls Guidance

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<tr>
<td>• Currently available</td>
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<tr>
<td>▪ <em>Seafood HACCP Hazards and Controls Guidance</em></td>
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<td>▪ <em>Juice HACCP Hazards and Controls Guidance</em></td>
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<tr>
<td>• In development</td>
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<tr>
<td>▪ <em>Food Safety Preventive Controls for Human Food Hazards and Controls Guidance</em></td>
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FDA has published hazards and controls guidance for seafood and juice products. These documents represent FDA’s current understanding on hazards and controls for these products. FDA is developing *Food Safety Preventive Controls for Human Food Hazards and Controls Guidance (Food Hazards Guide)* for food subject to the preventive controls regulation.

Although the *Food Hazards Guide* was not available when the 1st edition of the FSPCA training launched, select information in the FDA’s other hazards guides may be applicable to other food products. For example, chapters from the *Seafood Hazards Guide* that may be useful include:
Chapter 12: Pathogenic bacteria growth and toxin formation (other than Clostridium botulinum)
Chapter 13: Clostridium botulinum toxin formation
Chapter 14: Pathogenic bacteria growth and toxin formation as a result of inadequate drying
Chapter 15: Staphylococcus aureus toxin formation in hydrated batter mixes
Chapter 16: Pathogenic bacteria survival through cooking or pasteurization
Chapter 18: Introduction of Pathogenic Bacteria after Pasteurization and Specialized Cooking Processes
Chapter 19: Undeclared Major Food Allergens and Certain Food Intolerance Causing Substances and Prohibited Food and Color Additives
Chapter 20: Metal Inclusion
Chapter 21: Glass Inclusion

Sections of the Juice Hazards Guide may be useful for processors that make fruit or vegetable products, or pack in metal or glass containers. For example, this guide includes discussion of pathogens that may occur in acidic juices (pH ≤4.6) versus those in low-acid juices (pH >4.6), allergens and food intolerance substances added to juice as ingredients, pesticide residues, lead and tin hazards, glass fragments, metal fragments, hazards related to facility sanitation and controls for allergens arising from food contact surfaces.

Keep in mind that the terminology used in both the Seafood Hazards Guide and the Juice Hazards Guide differs from that used for preventive controls regulation. Because the scientific basis for conducting hazard analysis and determining effective controls for those hazards involves the same process, the information provided can be useful. The recommendations included in FDA Hazards Guides are not, for the most part, binding FDA requirements. Use of the hazards 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 than 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.

Subsequent chapters illustrate how information in the Hazards Guides can be used to make decisions and develop a Food Safety Plan.

Additional Reading
See the FSPCA Website for links to many of the referenced listed in this chapter.
CHAPTER 16. Regulation Overview – cGMP, Hazard Analysis, and Risk-based Preventive Controls for Human Food

On September 17, 2015, 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 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. This module focuses on the specific requirements of the regulation. It contains the specific provisions and regulatory citations for the regulatory requirements. This is an overview of the regulation. If you have specific questions on interpretation, you can use the FSMA Technical Assistance Network (see Text Box) or legal counsel.
The regulation is Part 117 in Title 21 of the *Code of Federal Regulations* and contains seven subparts:

A. general provisions such as definitions and exemptions;
B. current Good Manufacturing Practice requirements;
C. hazard analysis and risk-based preventive controls, which is the main focus for this course;
D. modified requirements for certain facilities;
E. withdrawal of a qualified facility exemption;
F. requirements for records that must be established and maintained; and
G. requirements for a supply-chain program.

**Subpart A – General Provisions**

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

Subpart A – General Provisions
Subpart B – Current Good Manufacturing Practice
Subpart C – Hazard Analysis and Risk-based Preventive Controls
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Subpart F – Requirements Applying to Records That Must be Established and Maintained
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The regulation is Part 117 in Title 21 of the *Code of Federal Regulations* and contains seven subparts:
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.

Who is Covered by the Preventive Controls for Human Food Regulation?

- Facilities that manufacture, process, pack or hold human food (§ 117.1)
- In general, facilities required to register with FDA under sec. 415 of the FD&C Act
  - Not farms or retail food establishments
  - Applies to domestic and imported food
  - Some exemptions and modified requirements apply

Facilities covered by the preventive controls requirements in 21 CFR 117 are those that manufacture, process, pack or hold human food. In general, facilities required to register with FDA under current regulations are covered. This applies to both domestic and foreign food processors exporting food covered by 21 CFR 117 to the U.S. Farms and retail food establishments are not covered. There are some exemptions and modified requirements, which are covered later.

The National Sustainable Agriculture Coalition has information designed to help farmers, small food businesses, and the organizations that work with them understand whether the FSMA rules apply to them and, if so, what requirements apply. Look for “Who is Affected” page on their website.  
http://sustainableagriculture.net/fsma/who-is-affected/

Facilities can register on FDA’s website.
The regulation requires that all individuals that manufacture, process, pack or hold food must have the education, training or experience necessary to perform their jobs in a manner to keep the food clean and safe. Individuals need specific training in the principles of food hygiene and food safety as appropriate to the individual's assigned duties. The level of training varies based on duties. For example, training for a fork lift operator may vary from that for an operator handling unpackaged ready-to-eat food. Supervisors must also have the education, training or experience necessary to supervise the production of clean and safe food. Records must be maintained for the food hygiene and food safety training.

### Exemptions and Modified Requirements -1

- “Qualified” facilities (§ 117.5(a))
  - Very small businesses (less than $1 million in total annual sales of human food plus the value of food held without sale)
    - OR
    - Food sales averaging less than $500,000 per year during the last three years AND
    - Sales to qualified end-users must exceed sales to others
- Exempt from hazard analysis and risk-based preventive controls when certain documentation is provided
Most exemptions are with respect to the hazard analysis and risk-based preventive controls provisions. The first example of an exemption is for "qualified facilities," which include:

- Very small businesses (less than $1 million in total annual sales of human food plus the value of food manufactured, processed, packed or held without sale (e.g., for a fee)) or
- Food sales averaging less than $500,000 per year during the last three years and sales to qualified end-users must exceed sales to others.

"Qualified end-users" are consumers in any location, and restaurants and retail food establishments in the same state (or Indian reservation) or within 275 miles of the facility that purchase the food for sale directly to consumers. Qualified facilities are exempt from hazard analysis and preventive controls requirements (including supply-chain programs) but certain documentation is required. They are still subject to the GMP regulations.

The regulation provides an exemption for the following:

- Food subject to HACCP (seafood and juice - 117.5(b) and c))
- Food subject to low-acid canned food regulations (only with respect to microbiological hazards) (117.5(d))
- Dietary supplements (117.5(e))
- Food subject to produce safety requirements (117.5(f))
- Alcoholic beverages (117.5(i))

The types of businesses listed are exempt from Food Safety Plan requirements provided that (with the exception of alcoholic beverages) they are in compliance with the applicable regulations referenced above. These businesses are not exempt from GMP requirements and low-acid canned foods manufacturers must
conduct a hazard analysis to determine if chemical and physical hazards are an issue, and document the analysis.

### Exemptions and Modified Requirements - 3

- Facilities, such as warehouses, that only store unexposed packaged food (§117.7)
  - Certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records (§117.206)
  - GMPs apply

Facilities such as warehouses that store only unexposed packaged food are exempt from the requirements for hazard analysis and risk-based preventive controls, with one exception. That is, certain packaged food for which refrigeration is required for safety must have temperature controls, monitoring, verification and records.

### Exemptions and Modified Requirements - 4 (§117.5(j))

- 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.
- Facilities such as warehouses that store raw agricultural commodities that are fruits and vegetables are NOT exempt from hazard analysis and risk-based preventive controls.

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.

**The “RAC Exemption” (§117.5(k))**

- Subpart B (GMPs) does not apply to holding or transportation of raw agricultural commodities (RACs)
  - This exemption is not new.
- GMPs apply to packaging, packing and holding of certain dried raw agricultural commodities
  - Compliance can be achieved by complying with subpart B or requirements for packing and holding in 21 CFR 112
  - A similar approach can be used for off-farm packaging, packing and holding of produce RACs (§117.8)

21 CFR 117 Subpart B (GMPs) does not apply to farms and activities of farm mixed-type facilities, fishing vessels, establishments solely engaged in holding or transportation of raw agricultural commodities, and establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts without additional processing. This is based on an existing provision in the GMPs (21 CFR 110.19(a)) known as the “RAC exemption.”

GMPs apply to packaging, packing and holding of certain dried raw agricultural commodities such as raisins made from grapes. Compliance may be achieved by complying with Subpart B or the applicable requirements for packing and holding in part 112. Similarly, off-farm packaging, packing and holding of raw agricultural commodities are subject to the GMPs; if these commodities are produce (as defined in 21 CFR part 112) compliance may be achieved by complying with Subpart B or the applicable requirements for packing and holding in part 112.
Farm-related exemptions are activities within the definition of “farm” in 21 CFR 1.227, including farm activities that are covered by the produce regulation, and certain low-risk manufacturing/processing 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.

Subpart B – Current Good Manufacturing Practice

Updated GMPs are part of the regulation (moved from 21 CFR 110 to 21 CFR 117). 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, but an update follows.

### Updated Good Manufacturing Practices

- Protection against allergen cross-contact
- Updated language (e.g., “must” instead of “shall”)
- Certain provisions containing recommendations were deleted
- Requires cleaning of non-food contact surfaces as frequently as necessary to protect against allergen cross-contact and contamination of food, food-contact surfaces and food packaging.
- GMPs for holding and distributing human food by-products for use as animal food are new

The GMPs were modified to clarify that certain provisions requiring protection against contamination of food also require protection against allergen cross-contact. Further, language in the regulation was updated, such as using “must” instead of “shall,” and “manufacturing/processing” in place of “manufacturing” for consistency with definitions. Certain provisions containing recommendations were deleted and may be added to guidance (e.g., previous provisions using “should” or “compliance may be achieved by”).

The GMP regulations now require cleaning of non-food-contact surfaces as frequently as necessary to protect against contamination of food and food-contact surfaces. Additionally, the holding and distribution of human food by-products for use as animal food is not subject to the Preventive Controls for Animal Food regulation if the human food facility complies with the human food GMPs and does not further manufacture the by-products. Facilities that hold and distribute human food by-products for use as animal food must comply with 21 CFR 117.95.
Subpart C – Preventive Controls

The regulation focuses on identifying hazards requiring a preventive control, thus a written hazard analysis is required. The first part of hazard analysis is identification of biological, chemical (including radiological) and physical hazards that may be associated with the facility or the food. These hazards may occur naturally, may be

The focus of this training program is on 21 CFR 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 preventing hazards in foods (21 CFR 117.126).

Hazard Analysis ($\$ 117.130$)

- Must be written regardless of outcome
- Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards.
  - Could occur naturally, be unintentionally introduced or be intentionally introduced for economic gain.

The regulation focuses on identifying hazards requiring a preventive control, thus a written hazard analysis is required. The first part of hazard analysis is identification of biological, chemical (including radiological) and physical hazards that may be associated with the facility or the food. These hazards may occur naturally, may be
unintentionally introduced or may be intentionally introduced for economic gain.

Examples of biological hazards include pathogenic bacteria (including environmental pathogens), viruses, parasites and other pathogens. Chemical hazard examples include radiological hazards, substances such as pesticide and drug residues, natural toxins, certain decomposition products, unapproved food or color additives, and food allergens. Physical hazards examples include stones, glass or metal fragments that could inadvertently be introduced into food. Hazards introduced for economic gain must also be considered.

### Hazard Evaluation

- Determine if the known or reasonably foreseeable hazards require a preventive control
  - Must consider severity of illness/injury and probability of occurrence in absence of a preventive control
- Must include an evaluation of environmental pathogens when:
  - A ready-to-eat food is exposed to the environment prior to packaging and
  - Packaged product is not treated after packaging

During the hazard analysis process, the hazard evaluation is conducted to determine the hazards requiring a preventive control. This evaluation includes an assessment of the severity of the illness or injury that would result if the hazard was in the food. Potential contamination from the food handling environment, as well as from food ingredients, must be considered for ready-to-eat foods that are exposed to the environment prior to packaging if 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.
### Hazard Evaluation Considerations

- Formulation of the food
- Facility and equipment
- Raw materials and ingredients
- Transportation practices
- Manufacturing/processing procedures
- Packaging and labeling activities
- Storage and distribution
- Intended or reasonably foreseeable use
- Sanitation, including employee hygiene
- Other relevant factors

The hazard evaluation must consider the effect of the following on the safety of the finished food for the intended consumer:

- Formulation of the food;
- Condition, function and design of the facility and equipment;
- Raw materials and ingredients;
- Transportation practices;
- Manufacturing/processing procedures;
- Packaging activities and labeling activities;
- Storage and distribution;
- Intended or reasonably foreseeable use;
- Sanitation, including employee hygiene; and
- Any other relevant factors, such as weather-related concerns in regard to formation of some natural toxins.

### Preventive Controls (§ 117.135(c))

Required, if relevant, for hazards requiring a preventive control

- Process controls
- Food allergen controls
- Sanitation controls
- Supply-chain controls
- Recall plan
- Other controls
The preventive controls required depend on which, if any, hazards are determined to require a preventive control. When a hazard requiring a preventive control is associated with the production of the food, an appropriate preventive control for the hazard must be addressed in the Food Safety Plan. Potential preventive controls for the identified hazard may be process controls, food allergen controls, sanitation controls, supply-chain controls, other controls. A recall plan is required whenever a hazard requiring a preventive control is identified.

The preventive controls required include only those appropriate to the facility and the food, as determined by hazard analysis. Preventive controls may or may not be at critical control points (CCPs). Process controls are similar to controls addressed through HACCP CCPs. Required food allergen preventive controls are those determined through hazard analysis as necessary to protect food from allergen cross-contact and to ensure that all food allergens are properly labeled.

Required sanitation preventive controls are those determined through hazard analysis as necessary to significantly minimize or prevent 1) environmental pathogens in a ready-to-eat (RTE) food exposed to the environment prior to packaging where the packaged food does not receive a treatment that would significantly minimize the pathogen; 2) biological hazards in an RTE food due to employee handling; and 3) food allergen hazards. Other aspects of sanitation such as pest control, safety of water and employee health do not need to be in a Food Safety Plan unless they are determined to be hazards requiring a preventive control.

Supply-chain controls, implemented through a supply-chain program, are required for ingredients or raw materials for which the receiving facility’s hazard analysis identified a hazard requiring a supply-chain-applied control. Other preventive controls may be identified as appropriate based on the hazard analysis.
There are certain circumstances in which you are not required to implement a preventive control even when you identify a hazard requiring a preventive control (identified hazard). These include:

- You determine that the type of food made could not be consumed without applying an appropriate control. Examples may include raw agricultural commodities such as cocoa beans, coffee beans and grains. You must document the considerations that lead to this conclusion.
- You rely on a customer to ensure that the identified hazard is significantly minimized or prevented. For this to apply, you must:
  - disclose in documents that accompany the food, in a manner consistent with the practice of trade, that it is “not processed to control [identified hazard].”
  - obtain annual written assurance that the hazard is being controlled.

This can apply whether or not your customer is subject to the preventive controls regulations. If your customer does not control the hazard (e.g., they send it on for further processing), additional assurances are required. Refer to the regulation for specifics.

A facility providing the type of written assurance described above must document the action taken to control the hazard.
A recall plan is required when a hazard requiring a preventive control is identified for a food. It includes written procedures to follow when a recall is needed and assigns responsibilities to do so. These procedures include how you will:

1) inform customers that the food is 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 your customers received notification and removed the recalled product, and
4) appropriately dispose of the recalled food through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.

Preventive Control Management Components
(§ 117.140)

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

- Process, food allergen and sanitation preventive controls
  - Monitoring
  - Corrective actions and corrections
  - Verification (including records review)
- Supplier preventive controls
  - Corrective actions and corrections
  - Records review
  - Reanalysis

Note that reanalysis is also required for other preventive controls in 21 CFR 117.170.
Process, food allergen and sanitation preventive controls all require monitoring, as appropriate, to ensure effectiveness of the preventive control. Predefined corrective actions, or corrections for certain sanitation issues (e.g., observation of unclean equipment before use), and verification are also required, as appropriate, to ensure preventive controls are effective.

Supply-chain programs do not require monitoring; however, corrective actions or corrections (as appropriate) are required as necessary and a review of records of supplier verification activities must be conducted. As with other preventive controls, reanalysis may be needed for supply-chain programs when issues are identified, when a new ingredient is added or when a new supplier replaces a current supplier for the same ingredient.

The recall plan is not subject to these management components.

### Monitoring (§ 117.145)

As appropriate to the nature of the preventive control and its role in the facility’s food safety system:

- Facility must have written procedures, including frequency they are to be performed, for monitoring the preventive controls
- Monitoring must be documented in records subject to verification
- Exception records allowed for refrigeration, and potentially other systems

Written procedures on how you monitor preventive controls are required as appropriate to the preventive control. The procedures must describe the frequency of monitoring.

Refrigeration temperature monitoring records may be either affirmation records (demonstrating that the temperature is controlled in the required limits) or exception records (demonstrating loss of temperature control). An example of an exception record other than refrigeration is x-ray detection for foreign material. No record is generated when no foreign material is present – the record is only generated when foreign material is present, thus it is an exception.

Monitoring records for preventive controls must be verified under the direction of a preventive controls qualified individual.
Corrective action procedures vary depending on the nature of the preventive control and how it fits into the food safety system. For each preventive control requiring a corrective action procedure (typically for a process preventive control), written procedures are required. These corrective actions have four elements:

1) identifying the problem and correcting it,
2) when necessary, reducing the likelihood that the problem will recur,
3) ensuring that affected food is evaluated for safety,
4) ensuring that adulterated food does not enter into commerce.

If it does, a recall is warranted.

All corrective actions taken must be documented in records and the records are subject to verification and record review.

Corrective Actions (§ 117.150(a)(1)) Pathogens

- Establish and implement written procedures to:
  - Respond to detection of a pathogen or appropriate indicator organism in an RTE product subject to verification testing
  - Respond to the presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring
  - Response may vary as appropriate to the nature of the preventive control and its role in the facility’s food safety system

Corrective Actions (§ 117.150(a)(2))

As appropriate to the nature of the preventive control and its role in the facility’s food safety system:

- Facility must establish and implement written corrective action procedures to:
  - Identify and correct a problem with implementation of a preventive control
  - When necessary, reduce the likelihood that the problem will recur
  - Ensure affected food is evaluated for safety
  - Ensure adulterated food is prevented from entering into commerce

- Records of corrective actions taken are required
Corrective action provisions also require written procedures to address the action to take in response to detection of a pathogen or indicator organism in an RTE product that is being tested for verification. Similarly, procedures to respond to detection of an environmental pathogen or indicator organism must be documented. The response to these situations will vary depending on the preventive control itself, the facility, the food and the overall food safety system.

If there is an unanticipated problem and a specific corrective action procedure has not been established, or a preventive control is found to be ineffective (e.g., the process for the product is found to be inadequate), the Food Safety Plan must be reanalyzed to determine whether it should be modified.

If action is taken in a timely manner, full corrective action procedures are not required for:

- Food allergen cross-contact controls (§ 117.135(c)(2)(i))
- Sanitation controls (§ 117.170(c)(3)(i) and (ii))
- A minor and isolated problem that does not directly impact product safety

Keep records of corrections made, as appropriate to the situation.
In some situations you may use corrections in place of corrective action if you take action in a timely manner to identify and correct a minor and isolated problem that does not directly impact product safety. For example, if equipment with a potential food allergen residue is observed before production starts and the surface is cleaned before production begins, a correction is appropriate.

Verification activities are required to ensure that preventive controls are consistently implemented and effective. They include validation, and verification that monitoring is being conducted and that appropriate corrective action decisions are being made. Verification of implementation and effectiveness includes review of calibration, product testing and environmental monitoring records. Reanalysis of the Food Safety Plan is another verification activity.

**Verification (§ 117.155)**

- As appropriate to the nature of the preventive control and its role in the facility’s food safety system, must include:
  - Validation (§ 117.160)
  - Verification that monitoring is being conducted
  - Verification that corrective action decisions are appropriate
  - Verification of implementation and effectiveness (§ 117.165)
    - Calibration, product testing, environmental monitoring, review of records
  - Reanalysis

**Validation (§ 117.160)**

Documented scientific and technical evidence that the preventive control will effectively control the hazard

- Required for process controls
- Performed or overseen by a preventive controls qualified individual
  - Prior to implementation OR
  - Within first 90 days of production OR
  - Reasonable time with written justification

- Not required for:
  - Food allergen controls
  - Sanitation controls
  - Supply-chain program
  - Recall plan
Validation is “the process of 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.” Preferably, validation is conducted before production; however, it is recognized that on-line validation may be necessary, for example to account for process variation. In any case, validation must be complete within the first 90 days of production or a reasonable amount of time with written justification by a preventive controls qualified individual.

Validation is not required for food allergen, sanitation or supply-chain program controls, but may be useful. Validation is not required for the recall plan.

Verification of implementation and effectiveness includes, as appropriate to the facility, the food and the nature of the preventive control

- Calibration
- Product testing for a pathogen or appropriate indicator or other hazard
- Environmental monitoring if an environmental hazard requiring a preventive control is identified
- Review of records

Verification of implementation and effectiveness includes, as appropriate to the facility, the food and the nature of the preventive control, activities such as calibration, product testing, environmental monitoring and records review. These are activities that help you assess whether what you are doing is controlling the hazards.

Calibration is required for instruments used for process monitoring and verification. Product testing for a pathogen (or appropriate indicator) or other hazard is required for hazards requiring a preventive control when appropriate for verification. Environmental monitoring is a required verification activity when an environmental pathogen is identified as a hazard requiring a preventive control.
Review of monitoring and corrective action records is required within seven working days after the record was created unless a preventive controls qualified individual prepares or oversees written justification for a longer “reasonable timeframe.” Calibration records, product testing records and environment monitoring records, when applicable, must be reviewed within a reasonable time after the records were created. Review of relevant supplier and supply-chain verification records is also required in a reasonable timeframe.

Written procedures required for Food Safety Plans vary depending on the facility, the food, the nature of the preventive control and the role of that control in the facility’s food safety system. Written procedures are required for calibrating monitoring and verification equipment in the plan, as well as the frequency of calibration. When product testing
is required, scientifically valid procedures must be used and identified. Written procedures must identify the test microorganisms or analytes, how the samples relate to the lot, the number and frequency of taking samples, the tests conducted and methods used, the laboratory conducting the test, and corrective action procedures to implement for results that do not meet requirements. Similar procedures are required when environmental monitoring is required.

<table>
<thead>
<tr>
<th>Reanalysis (§ 117.170(a) and (b)) – When</th>
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<td>• A verification activity must be conducted for the full plan:</td>
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<td>▪ At least every 3 years</td>
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<td>▪ When FDA determines it is necessary to respond to new hazards</td>
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<td>• Applicable sections of the plan:</td>
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<td>▪ When there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified</td>
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<td>▪ When you become aware of new information about potential hazards associated with a food</td>
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<td>▪ When appropriate after an unanticipated food safety problem (§ 117.150(b))</td>
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<tr>
<td>▪ When you find that a preventive control, combination of preventive controls or the Food Safety Plan as a whole is ineffective</td>
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Reanalysis of the Food Safety Plan is another verification activity. The full plan must be reviewed at least every 3 years to ensure that it still accurately reflects the preventive controls needed. FDA may also determine that reanalysis is necessary in response to new hazards and developments in scientific understanding.

Reanalysis of applicable sections of the plan is also required when there is a significant change in the operation or in current knowledge that may increase concern regarding a new or previously identified hazard. Reanalysis may also be required after an unanticipated food safety problem occurs or when a preventive control, combination of preventive controls or the Food Safety Plan itself is ineffective.
When reanalysis is conducted, in most cases it must take place before any changes are made to the Food Safety Plan. When necessary to demonstrate control measures can be implemented as designed, validation activities needed as a result of the reanalysis may take place in the first 90 days of production. If your reanalysis indicates an increased food safety risk, your Food Safety Plan must be revised. If you determine that no revision is necessary, the basis for that decision must also be documented. A preventive controls qualified individual must perform or oversee the reanalysis.

A preventive controls qualified individual is required to develop or oversee development of the Food Safety Plan, validation of the preventive controls used in the plan, review of records and reanalysis of the Food Safety Plan. Additional tasks that must be performed or
Certain activities for preventive controls must be overseen by a preventive controls qualified individual. There are essentially two ways for an individual to achieve this recognition. 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. 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. These individuals will need to understand the specific regulatory requirements of the Preventive Controls for Human Food regulation, which differ somewhat from requirements in other food safety regulations and standards.

Some organizations may have one or more people on staff that can perform all of the functions that require oversight by a preventive controls qualified individual. Other organizations may choose to engage a technical expert to help with certain aspects, such as development of the hazard analysis, validating preventive controls and other highly technical aspects of this role. This can vary considerably depending on the complexity of the product and the potential food safety hazards for the food and facility.
Auditing may be a required verification activity, for example for a supply-chain program. The auditor must be a qualified individual and be qualified to do the audit through a combination of education, auditing experience (including an understanding of the commodity involved) and auditing training. Records of such experience are required.

**Qualified Auditor (§ 117.180(b) and (c)(2))**

- Must conduct onsite audits, when required
- Must have technical expertise obtained by education, training and experience in the auditing function
- Training must be documented in records — date, type of training, person(s) trained

**Implementation Records (§ 117.190)**

- Records required by 117.136 regarding not implementing a preventive control in your facility
- Records that document monitoring of the preventive controls
- Records that document corrective actions
- Records that document verification
- Records that document the supply-chain program
- Records that document training for the preventive controls qualified individual and the qualified auditor

The *Preventive Controls for Human Food* regulation also has specific requirements for implementation records. You may recall that 21 CFR 117.136 described situations where a preventive control is not required to be implemented, such as when the food could not be consumed without application of an appropriate control or when the processing facility receives assurances that their customer will apply the control. Records documenting these situations are required. Other
records that are more common include those that document monitoring activities of the preventive controls identified in the hazard analysis; records of corrective actions associated with preventive controls; records documenting training in the principles of food hygiene and food safety for individuals engaged in manufacturing, processing, packing or holding food; records for the supply-chain program, records of training for preventive controls qualified individuals and qualified auditors, and several different types of verification activities. Records that document verification include, as applicable:

- validation records that establish the scientific and technical basis of the preventive controls,
- verification of monitoring records to ensure that critical limits and other parameters were met,
- verification of corrective action records to ensure that appropriate actions were carried out and completed,
- calibration of process monitoring and verification instruments to ensure that the data they provide are accurate,
- records of product testing,
- records of environmental monitoring,
- record to document record review, and
- reanalysis of the Food Safety Plan.

**Subpart D – Modified Requirements**

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 117 Subpart D. Consult this section if you are a qualified facility. A brief discussion of
requirements that apply to facilities solely engaged in storage of unexposed packaged food follows.

### Storage of Unexposed Packaged Food (§ 117.206)

- Modified requirements apply to refrigerated foods that require refrigeration for safety
  - Implement temperature controls for pathogens
  - Monitor temperatures
  - Take corrective actions when there are temperature control problems
  - Verify temperature controls
    - Calibrate temperature monitoring and recording devices
    - Review monitoring and corrective action records

For facilities that store *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.

### Subpart E – Withdrawal of a Qualified Facility Exemption

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

Subpart E – Withdrawal of a Qualified Facility Exemption

§ 117.251 Circumstances that may lead FDA to withdraw a qualified facility exemption
§ 117.254 Issuance of an order to withdraw a qualified facility exemption
§ 117.257 Contents of an order to withdraw a qualified facility exemption
§ 117.260 Compliance with, or appeal of, an order to withdraw a qualified facility exemption
§ 117.264 Procedure for submitting an appeal
§ 117.267 Procedure for requesting an informal hearing
§ 117.270 Requirements applicable to an informal hearing
§ 117.274 Presiding officer for an appeal and for an informal hearing
§ 117.277 Timeframe for issuing a decision on an appeal
§ 117.280 Revocation of an order to withdraw a qualified facility exemption
§ 117.284 Final agency action
§ 117.287 Reinstatement of a qualified facility exemption that was withdrawn

21 CFR 117 Subpart E describes the circumstances, procedures and requirements for withdrawing a qualified facility exemption. If you believe that you are a qualified facility, you should become familiar
with the provisions for withdrawal and reinstatement of the exemption for qualified facilities. When such situations arise, other assistance is needed, including from legal counsel, to assure that the legal requirements are fulfilled.

**Subpart F - Records**

21 CFR 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 the 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 regulations or any other reason, may be used if they contain all the required information. You can supplement existing records if they are missing some of the required elements. You do not have to keep your 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 21 CFR 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 your facility.

Subpart G – Supply-chain Program

Hazards requiring a preventive control for which you rely on supplier efforts are managed through your supply-chain program. 21 CFR 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 your supply-chain program.

A supply-chain program is required to address only those ingredients and raw materials that present potential hazards requiring a supply-chain applied control (i.e., the hazard is controlled before receipt). Your supply-chain program must be written and you must have records to demonstrate that the program is implemented.

For these ingredients, you must use approved suppliers. For these suppliers, you must determine the appropriate supplier verification activities, then conduct and document those activities. Sometimes 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 subject to the produce safety rule), 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 verification from another entity (e.g., supplier produce distributor) using one of the verification procedures that is discussed in the next slide.

**Supplier Verification Activities (§ 117.410(b))**

- Onsite audits
- Sampling and testing
- Review of relevant food safety records
- Other as appropriate

The activities listed above are appropriate supplier verification activities for raw materials and other ingredients requiring supply-chain-applied control. In determining which approach to use, consider:

- the results of the hazard analysis including the nature of the hazard requiring a supply-chain-applied control;
- the supplier's procedures, processes and practices related to the safety of the ingredient;
- relevant FDA food safety regulations and information such as warning letters and import alerts related to the food and the supplier's compliance with these;
- the supplier's food safety history including applicable test results, audit results, response to correct problems, etc., and
- storage and transportation practices.

Onsite audits must be performed by a qualified auditor and must include review of the supplier's written plan (e.g., HACCP plan or other Food Safety Plan if the supplier is subject to an FDA food safety regulation). An appropriate inspection conducted by FDA (or other specified agency officials) for compliance with FDA food safety regulations may be substituted for an onsite audit. If this applies to one of your suppliers, refer to the regulation for details.
If you determine through verification activities that the supplier is not controlling the hazard, you must take action and document the action taken to ensure that your food is not adulterated or misbranded.

**Regulation Overview Summary**

- The full regulation, *21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food*, is in Appendix 1
- Sections include
  - Subpart A – General Provisions
  - Subpart B – Current Good Manufacturing Practice
  - Subpart C – Hazard Analysis and Risk-based Preventive Controls
  - Subpart D – Modified Requirements
  - Subpart E – Withdrawal of a Qualified Facility Exemption
  - Subpart F – Requirements Applying to Records That Must be Established and Maintained
  - Subpart G – Supply-chain Program

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 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), through other training programs or through legal counsel.