Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

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Introduction and Purpose

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I. Introduction

In 21 Code of Federal Regulations (CFR) part 117 (part 117), we have established our regulation entitled "*Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food*." We published the final rule establishing part 117 in the *Federal Register* of September 17, 2015 (80 FR 55908). Part 117 establishes requirements for current good manufacturing practice for human food (CGMPs), for hazard analysis and risk-

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft "Introduction and Purpose" that we issued for public comment in August 2016.

based preventive controls for human food (PCHF), and related requirements as shown in Table 1.

Table 1. Subparts Established in 21 CFR Part 117

Subpart	Title
A	General Provisions
B	Current Good Manufacturing Practice
C	Hazard Analysis and Risk-Based Preventive Controls
D	Modified Requirements
E	Withdrawal of a Qualified Facility Exemption
F	Requirements Applying to Records That Must be Established and Maintained
G	Supply-Chain Program

The PCHF requirements implement the provisions of the FDA Food Safety Modernization Act (FSMA), established in section 418 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g). Part 117 includes several complete or partial exemptions from the PCHF requirements. See 21 CFR 117.5 for a list and description of these exemptions.

This document is directed to those persons (you) who are subject to the PCHF requirements of part 117). Establishing risk-based preventive controls enables you to apply a proactive and systematic approach to your food safety program through the establishment of preventive controls designed to protect your food, and the consumer, from biological, chemical (including radiological), and physical hazards. Risk-based preventive controls will not give you a "zero-risk" system for manufacturing, processing, packing, and holding food; rather, risk-based preventive controls are designed to minimize the risk of known or reasonably foreseeable food safety hazards that may cause illness or injury if they are present in the products you produce.

This guidance is intended to help you comply with the following specific PCHF requirements established in subparts C and G of part 117:

- A written food safety plan (FSP);
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions;
- Verification; and
- Associated records.

You only need to apply preventive controls if, after conducting a hazard analysis of the products and processes conducted at your facilities, you identify known or reasonably foreseeable biological, chemical, or physical hazards that require a preventive control. (Known or reasonably foreseeable hazards are the potential hazards to be evaluated by the facility to determine whether any require a preventive control in that facility.) We do not expect that known or reasonably foreseeable hazards for a food require a preventive control in all facilities. We also do not expect that all possible preventive measures and verification procedures apply to all foods produced in your facility. For example, we would not expect you to have sanitation controls to prevent food allergen cross-contact for a processing line that is dedicated to foods containing only that food allergen.

It is important for you to be aware of the potential hazards that may be associated with your food process and products. When you understand the potential hazards, it is easier to design and implement an FSP designed to control all identified food safety hazards that may cause illness or injury if they are present in the products you produce.

This guidance is not directed to persons who are exempt under 21 CFR 117.5. However, such persons may find some of the principles and recommendations in this guidance helpful in manufacturing, processing, packing, and holding human food.

We intend this draft guidance to include the 16 chapters listed in the Table of Contents. We will announce the availability of each draft chapter for public comment as the chapter becomes available, rather than delaying release of individual draft chapters until all the draft chapters are available. Those chapters that you see listed in the Table of Contents as "coming soon" are not yet available.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Purpose of this Guidance

The purpose of this guidance is to help you develop an FSP in accordance with the PCHF requirements. Specifically, this document provides guidance on:

- Understanding the biological, chemical (including radiological) and physical hazards that are commonly of concern in manufacturing, processing, packing, and holding of FDA-regulated food products;
- Understanding the components of an FSP and the importance of each component;
- Understanding how to conduct a hazard analysis and develop an FSP for the products that you process;
- Understanding how to identify control measures for common biological (specifically bacterial pathogens), chemical, and physical hazards associated with many processed foods so you can apply those controls to the hazards identified in your hazard analysis;
- Understanding how to identify and apply the preventive control management components (i.e., monitoring, corrective actions and corrections, and verification); and
- Understanding the recordkeeping requirements associated with the FSP and implementation of the FSP.

We recommend that you consider how this guidance relates to each of your operations and tailor your control strategies to the specific circumstances for the foods you process.

III. Glossary of Terms Used in This Guidance

A. Definitions Established in 21 CFR 117.3

Acid foods or **Acidified foods:** Foods that have an equilibrium pH of 4.6 or below.

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.

Correction: An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical control point (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.

Environmental pathogen: A pathogen capable of surviving and persisting with 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 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.

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 and includes raw materials and ingredients.

Food allergen: A major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act (e.g., 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 surfaces: 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.

Hazard: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control: 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 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 potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

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.

Pathogen: A microorganism of public health significance.

Pest: Any objectionable animals or insects including birds, rodents, flies, and larvae.

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

Preventive controls qualified individual (PCQI): 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 individual: A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

RTE (Ready-to-eat) food: 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.

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.

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

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.

B. Other Terms that FDA Uses in this Guidance

Clean in place (CIP): A system used to clean process piping, bins, tanks, mixing equipment, or larger pieces of equipment without disassembly, where interior product zones are fully exposed and soil can be readily washed away by the flow of the cleaning solution.

Clean out of place (COP): A system (*e.g*. cleaning tanks) used to clean equipment parts, piping, etc. after disassembly.

Control point (CP): Any step at which biological, physical, or chemical factors can be controlled.

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

Control, Control measure: See Preventive controls.

Corrective action: An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical limit (CL): A maximum and/or minimum value to which a biological, chemical, or physical parameter must be controlled to prevent, eliminate or reduce to an acceptable level the occurrence of a food-safety hazard.

Deviation: Failure to meet a critical limit.

End-Point Internal Product Temperature (EPIPT): A measurement of the internal temperature of the product at the end of the heat process.

Environmental sample: A sample that is collected from a surface or area of the plant for the purpose of testing the surface or area for the presence of microorganisms, usually environmental pathogens.

Food safety plan: A set of written documents that is based upon food safety principles and incorporates hazard analysis, preventive controls, and delineates monitoring, corrective action, and verification procedures to be followed, including a recall plan.

Food Safety System: The result of the implementation of the Food Safety Plan.

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

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which should be addressed through a preventive control.

Operating limits: Criteria that may be more stringent than critical limits and are established for reasons other than food safety.

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

Severity: The seriousness of the effects of a hazard.

IV. Table of Abbreviations Used in This Guidance

Abbreviation	What It Means
ABC	Almond Board of California
a_w	Water activity
CCP	Critical control point
CDC	Centers for Disease Control and Prevention
CIP	Clean in place
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
CL	Critical limit
Codex	Codex Alimentarius Commission
COP	Clean out of place

Abbreviation	What It Means
CP	Control point
D-value	Decimal reduction time
EPIPT	End-Point Internal Product Temperature
EPA	U.S. Environmental Protection Agency
FALCPA	Food Allergen Labeling and Consumer Protection Act
FDA	U.S. Food and Drug Administration
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture
FSMA	FDA Food Safety Modernization Act
FSP	Food safety plan
FSPCA	Food Safety Preventive Controls Alliance
HACCP	Hazard Analysis and Critical Control Point
HPP	High Pressure Processing
LACF	Low-acid canned food
NRTE food	Not ready-to-eat food
Part 117	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117)
PCHF	“Preventive Controls for Human Food” (requirements in 21 CFR part 117 for hazard analysis and risk-based preventive controls for human food in accordance with section 418 of the FD&C Act)
PCQI	Preventive controls qualified individual
PPO	Propylene oxide
ROP	Reduced oxygen packaging
RTE food	Ready-to-eat food
TDT	Thermal Death Time
USDA	U.S. Department of Agriculture

Abbreviation	What It Means
WIP	Work-in-process
z-value	The degrees in Fahrenheit required for the thermal destruction curve to cross one log cycle (i.e., for reducing the D value by a factor of 10)

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Chapter 1: The Food Safety Plan

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 1 that we issued for public comment in August 2016.

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1.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you understand what a food safety plan is and how it differs from a HACCP plan. The PCHF requirements specify that a facility must prepare, or have prepared, and implement a written food safety plan. See 21 CFR 117.126.

1.2 What is a Food Safety Plan?

A Food Safety Plan (FSP) consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding. See 21 CFR 117.126.

Below, we describe the written documents that make up the FSP (see 21 CFR 117.126(b)).

- Hazard analysis to identify whether there are hazards requiring a preventive control. This hazard analysis must be written, regardless of whether any hazards requiring a preventive control are identified. (Some facilities may not identify any hazards requiring a preventive control.)
- When the hazard analysis identifies hazards requiring a preventive control, the FSP also includes the following written documents:
    - Preventive controls (see 21 CFR 117.135), as appropriate to the facility and the food, to ensure safe food is produced, including:
        - Process controls
        - Food allergen controls
        - Sanitation controls
        - Supply-chain controls
        - Recall plan
        - Other controls
    - Procedures for monitoring the implementation of the preventive controls, as appropriate to the nature of the preventive control and its role in the facility's food safety system
    - Corrective action procedures, as appropriate to the nature of the hazard and the nature of the preventive control
    - Verification procedures, as appropriate to the nature of the preventive control and its role in the facility's food safety system

This written FSP is a record that you must maintain. See 21 CFR 117.126(c) and 21 CFR part 117, subpart F, particularly 21 CFR 117.310. In addition, you must maintain records to document that you are implementing the FSP. (See 21 CFR 117.190.)

The FSP starts with a hazard analysis of all ingredients and process or manufacturing steps (see Chapter 2 of this guidance). A "hazard" is any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. It is important to understand that for the purposes of food safety, the term "hazard" refers only to the conditions or contaminants in food that are capable of causing illness or injury to people. These include hazards that occur naturally, that are unintentionally added or that may be intentionally added to a food for purposes of economic gain (i.e., economic adulteration). Many conditions are highly undesirable in food, such as the presence of insects, hair, filth or spoilage, and violations of regulatory food standards. All of these defects should be controlled in food processing; often, however, these defects do not directly affect the safety of the product. Unless these conditions directly affect food safety, documents addressing these issues are not included in an FSP. If the hazard analysis does not identify any hazards requiring a preventive control, the only document in the FSP would be the hazard analysis.

1.3 Who Develops the Food Safety Plan for a Facility?

A "preventive controls qualified individual" (PCQI) must develop (or oversee the development of) the FSP. A PCQI is a person with the education, training, or experience (or a combination of these) to develop and apply a food safety system. A PCQI can be qualified through job experience or by completing training equivalent to the standardized curriculum recognized as adequate by FDA (e.g., the Food Safety Preventive Controls Alliance (FSPCA) training). The PCQI does not need to be an employee of the facility. See 21 CFR 117.126(a) and the definition of PCQI in 21 CFR 117.3.

The FSP must be signed and dated by the owner, operator or agent in charge of the facility when it is first completed and whenever the plan is modified (See 21 CFR 117.310.). See section 1.6 of this document for information on signing an FSP that consists of multiple components such as HACCP plans, prerequisite programs, a recall plan and a variety of procedures.

1.4 What are the Differences Between a HACCP Plan and a Food Safety Plan?

Hazard Analysis and Critical Control Points (HACCP) is a preventive food safety strategy that is a systematic approach to the identification and assessment of the risk of hazards from a particular food or food production process or practice and the control of those hazards that are reasonably likely to occur. HACCP systems have been mandated by U.S. Federal regulations issued by the Food and Drug Administration (FDA) for seafood and juice and by the Food Safety and Inspection Service (FSIS) for meat and poultry.

The preventive controls approach to controlling hazards used in an FSP incorporates the use of risk-based HACCP principles in its development. (See the HACCP principles and their application as described by the National Advisory Committee on Microbiological Criteria for Foods.) Although an FSP and a HACCP plan are similar, they are not identical. Table 1-1 compares what is required for the elements of each type of plan. In the following paragraphs, we briefly discuss each of these elements.

Table 1-1 Comparison of Elements of a HACCP Plan and a Food Safety Plan

Element	HACCP Plan	Different in Food Safety Plan
Hazard Analysis	Biological, chemical, physical hazards	Chemical hazards include radiological hazards, consideration of economically motivated adulteration (21 CFR 117.130(b)(1)(ii))
Preventive Controls	CCPs for processes	Process CCPs + controls at other points that are not CCPs (21 CFR 117.135(a)(2))
Parameters and values	Critical limits at CCPs	Parameters and minimum/maximum values (equivalent to critical limits for process controls) (21 CFR 117.135(c)(1))
Monitoring	Required for CCPs	Required as appropriate for preventive controls (21 CFR 117.145)
Corrective actions and Corrections	Corrective actions	Corrective actions or corrections as appropriate (21 CFR 117.150(a))
Verification (including validation)	For process controls	Verification as appropriate for all preventive controls; validation for process controls; supplier verification required when supplier controls a hazard (21 CFR 117.155, 117.160)
Records	For process controls	As appropriate for all preventive controls (21 CFR 117.190)
Recall plan	Not required in the plan	Required when a hazard requiring a preventive control is identified (21 CFR 117.139)

1.4.1 Hazard Analysis and Controls to Address the Hazards

In developing a HACCP plan, the hazard analysis leads to the identification of critical control points (CCPs) where essential process controls are needed to prevent a foodborne hazard from causing illness or injury. Once CCPs are identified, critical limits are established that define the operating conditions in the process that must be effectively managed and monitored to control the hazard. When critical limits are not met, predefined corrective actions are taken. All of the steps in a HACCP plan are recorded and verified to ensure the system is operating as intended.

The FSP also begins with a hazard analysis, which includes consideration of radiological hazards as chemical hazards, as well as hazards due to economically motivated adulteration, such as addition of dyes containing lead to spices to enhance color. The outcome of the hazard

analysis is the facility's determination of whether there are any known or reasonably foreseeable hazards that require a preventive control. In an FSP, preventive controls may be applied at CCPs, but also at points other than at CCPs. The FSP includes control measures that, under the HACCP approach, may have been included in prerequisite programs or CGMPs. For example, supplier controls and food allergen controls have often been addressed through prerequisite programs, and sanitation controls have often been addressed through CGMPs. Process controls in an FSP will have parameters with minimum or maximum values, which are equivalent to the critical limits for HACCP CCPs. The use of preventive controls in an FSP may expand beyond CCPs by identifying and providing controls that may not be process-related, but are still important in the control of a hazard. Critical limits (minimum or maximum values) may not be practical or needed for non-process-related preventive controls, such as using hygienic zoning controls to prevent cross-contact and cross-contamination or ensuring that suppliers have adequately controlled hazards in the foods they are providing a manufacturer/processor.

1.4.2 Monitoring

In a HACCP plan, the CCPs are always monitored. In an FSP, preventive controls are only monitored as appropriate to the nature of the preventive control and its role in the facility's food safety system, and some preventive controls that are not applied at CCPs may not be monitored.

1.4.3 Corrective Actions and Corrections

In a HACCP plan, corrective actions are taken for deviations from a critical limit at a CCP. An FSP also provides for facilities to take corrective actions. However, immediate corrections (e.g., re-cleaning and sanitizing a line before start-up of production when food residue remains after cleaning) may be more appropriate for some preventive controls than a specific corrective action involving product risk evaluations of product safety for some preventive controls. The requirements for an FSP provide this flexibility.

1.4.4 Verification

In a HACCP plan, verification activities take place for process controls to ensure the process can control the hazards and the HACCP plan is being followed. In an FSP, verification activities will also be applied to preventive controls, but because preventive controls are not just process controls, there is flexibility to conduct verification activities as appropriate to the food, the facility and the nature of the preventive control and its role in the food safety system.

1.4.5 Validation

Some HACCP systems (e.g., for juice, and for meat and poultry products) require validation of the HACCP plan as a whole. In an FSP, validation means obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards. The extent of validation activities may be less rigorous for some preventive controls than others, or may not be required (e.g., sanitation controls).

1.4.6 Recall plan

In a HACCP plan, recall plans have not been included. In an FSP, a Recall Plan must be prepared for each product for which a hazard requiring a preventive control has been identified.

1.5 What if a Facility Already Has a HACCP Plan?

If you have an existing HACCP plan, you should determine if it satisfies all the PCHF requirements in part 117. You can use existing programs, procedures, and records and supplement these with any additional information required, such as a supply-chain program.

1.6 What Format Is Required for a Food Safety Plan?

There is no standardized or required format for an FSP. This guidance provides flexibility in its approach to guide you in identifying and establishing preventive controls for different types of hazards identified in your hazard analysis. You can use whatever format works best for your facility, provided that the FSP includes all the required information. The formats shown in this guidance are for illustrative purposes only and may not be complete. The FSPCA training materials have FSP worksheets and teaching example model FSPs that may be helpful.

The FSP may consist of one or more existing HACCP plans, one or more prerequisite programs that include food safety controls, a recall plan, a written supply-chain program, written verification procedures such as environmental monitoring, and any other components specified in the PCHF requirements. You have flexibility in how to organize these documents within your FSP. One approach for organizing the FSP to allow for signing and dating it is to collect all these documents in a single location (e.g., a binder or folder) with a cover page containing the signature of the owner, operator, or agent in charge of the facility and the date on which the cover page was signed. However, because the FSP also could be a set of documents kept in different locations within the facility, another approach is for the owner, operator, or agent in charge of the facility to sign and date a list of the relevant documents (e.g., as in a Table of Contents).

1.7 When Are Changes Needed for a Food Safety Plan?

The FSP is a dynamic document that reflects your current hazard analysis, preventive controls, and applicable procedures. The FSP as a whole must be reanalyzed at least every 3 years. The reanalysis may be limited to the applicable portion of the FSP when you make changes to your system or equipment, when you become aware of new information about potential hazards associated with the food or your facility, when there is an unanticipated food safety problem, or when you find that a preventive control, combination of preventive controls, or the FSP itself is ineffective. See 21 CFR 117.170.

1.8 References

National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1998. “Hazard Analysis and Critical Control Point Principles and Application Guidelines.” *J Food Protect* 61: 1246-1259.

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Chapter 2: Conducting a Hazard Analysis

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2.4.2.3. Evaluating environmental pathogens whenever a ready-to-eat food is exposed to the environment

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 2 that we issued for public comment in August 2016.

2.4.2.4. Evaluation factors
2.5 Identify Preventive Control Measures
2.6 References

2.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you conduct a hazard analysis in accordance with the PCHF requirements. The hazard analysis must be written, regardless of the results of the analysis, and must include two elements: (1) a hazard identification and (2) a hazard evaluation. You conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are hazards requiring preventive controls. See 21 CFR 117.130.

2.2 Overview of a Hazard Analysis

Part 117 does not define the term "hazard analysis." See Box 2-1 for a definition of "hazard analysis" that was developed by the Food Safety Preventive Controls Alliance (FSPCA).

Box 2-1. A Definition for "Hazard Analysis"

Hazard Analysis

The process of collecting and evaluating information on hazards and the conditions leading to their presence to determine which hazards are significant for food safety and therefore should be addressed in a HACCP plan or food safety plan (FSP).

Food Safety Preventive Controls Alliance

This section will guide you through the steps involved in conducting a hazard analysis. The PCHF requirements do not specify that you must use a "Hazard Analysis Worksheet" to conduct your hazard analysis. However, you may find it useful to use such a worksheet. See Form 2-B in Appendix 2 of this guidance and Box 2-3 in this chapter.

The PCHF requirements do not specify that you must use a certain format for conducting a hazard analysis. You may use formats other than the Hazard Analysis Worksheet that we provide in this guidance (including the use of a written narrative) as long as your hazard analysis contains the elements of hazard identification and hazard evaluation.

You use the hazard analysis to determine appropriate preventive controls. Your hazard analysis should provide justification for your decisions. You may group products together in a single hazard analysis worksheet if the food safety hazards and controls are essentially the same for all products in the group, but you should clearly identify any product or process differences. Keep in mind that you will need to refer to your written hazard analysis when you reanalyze or

modify your FSP and that it can be a resource for you when you are asked by inspectors or auditors to justify why certain hazards were or were not included in your FSP.

The hazard analysis helps you to focus resources on the most important controls applied to provide safe food. If you do not conduct the hazard analysis correctly, and do not identify all hazards warranting preventive controls within the food safety plan, the food safety plan will not be effective in protecting consumers and preventing food safety issues, no matter how well your facility follows the plan. A proper analysis of biological, chemical (including radiological), and physical hazards associated with food ingredients, finished products, and the processes used calls for good judgment, detailed knowledge of the properties of the raw materials/other ingredients and manufacturing processes, and access to appropriate scientific expertise.

2.3 Recommended Activities Prior to Conducting a Hazard Analysis

Although the PCHF requirements do not specify that you must do so, we recommend that you conduct certain preliminary steps, and set up a Hazard Analysis Worksheet, as a useful framework for organizing and documenting your hazard analysis.

2.3.1 Conduct Preliminary Steps

Box 1-2. Preliminary Steps

1. Assemble a Food Safety Team
2. Describe the product, its distribution, intended use, and consumer or end user of the product
3. Develop a process flow diagram and verify it on site
4. Describe the process

Your written hazard analysis is part of your food safety plan, which must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals (21 CFR 117.126(a)(2)). Although the PCHF requirements do not specify that you must do so, we recommend that a Food Safety Team of individuals with expertise in the day-to-day operations of your facility conduct your hazard analysis under the oversight of a Preventive Controls Qualified Individual. The individuals may include personnel from production, sanitation, quality control, laboratory, and maintenance. Using people from different functions within the facility can help provide a complete understanding of the process and things that can go wrong. You can supplement the expertise of the Food Safety Team by competent technical experts from other off-site functions within the firm (where applicable), such as research and development (R&D), technical applications groups, and quality management, as well as from outside experts from universities, cooperative extension services, trade associations, private consulting firms, or other sources.

The effectiveness of your Food Safety Team will be impacted by the quality and completeness of the information provided to them about the facility and food product(s) to be evaluated. Therefore, in order for your Food Safety Team to conduct the hazard analysis, we recommend that you define and document the following details for the facility:

- Product description, including its distribution, intended use, and identification of consumer or end user;
- Process flow diagram; and
- Detailed process description to supplement the process flow diagram.

A product description and how the product will be distributed helps team members understand elements of the product that may impact food safety, such as whether temperature controls are needed during distribution. The description should include the full name of the finished product, including descriptors such as ready-to-eat (RTE), frozen; the packaging type and material; and storage and distribution details. Understanding how the product will be used by the consumer (e.g., consumed with or without further processing, such as cooking) and knowing the intended consumer of the product (e.g., whether the food is intended for general public or specifically intended for a more susceptible population such as infants and young children (e.g., infant formula), the elderly (e.g., foods manufactured for nursing homes), or immunocompromised persons (e.g., foods manufactured for hospitals) helps to identify hazards of particular concern and the need for more stringent controls or verification activities.

The purpose of a process flow diagram is to provide a clear, simple description of the steps involved in the processing of your food product and its associated ingredients as they "flow" from receipt to distribution. The process flow diagram should cover all steps in the process that the facility performs, including receiving and storage steps for each raw material or other ingredient, preparation, processing, packaging, storage and distribution of the product. Additionally the process flow diagram should identify the equipment (e.g., pumps, surge tanks, hoppers, fillers) used in the operations. An accurate process flow diagram serves as a useful organizational format for elements of the food safety plan, because it identifies each of the steps that must be evaluated in the hazard analysis. You should verify the process flow diagram on-site in order to ensure no steps have been overlooked.

The purpose of a detailed process description is to explain what happens at each of the process steps. Information such as the maximum length of time a food is exposed to ambient temperature during processing, whether a food is handled manually, and whether rework is incorporated into product can be important for an accurate hazard analysis.

2.3.2 Set Up the Hazard Analysis Worksheet

Once you have assembled the Food Safety Team and started gathering the information you will use in your hazard analysis, we recommend that you set up a document that you will use to organize the hazard analysis. In this guidance, we describe how to set up an adaptation of the "Hazard Analysis Worksheet" used in HACCP systems to organize your hazard analysis. In this section of this chapter, we discuss how to set-up this worksheet (see Box 2-3, which shows a form adapted from a form used by the FSPCA). In the next section of this chapter, we provide details that will help you use the worksheet to conduct your analysis.

- Column 1: Here, you will list (1) receipt of ingredients used in the process as a means of identifying hazards associated with an ingredient (you may group some ingredients, e.g., "spices"); and (2) processing steps. The process flow diagram recommended as a preliminary step (see Box 1-2) can help you to identify the processing steps that are included in the hazard analysis.
- Column 2: Here, you will list the results of your hazard identification – i.e., the food safety hazards that potentially could be introduced, controlled, or enhanced at this step (known or reasonably foreseeable hazards). Include all ingredient-related hazards, process-related hazards, and hazards that may be introduced from the environment.

- Column 3: Here, you will record the conclusions of your hazard evaluation – i.e., the determinations you make of whether each listed food safety hazard requires a preventive control (Yes or No).
- Column 4: Here, you will record the reasons that led to the conclusions of your hazard evaluation (i.e., the Yes/No conclusions listed in column 3). Explaining your reasons for a "No" conclusion can be just as important as explaining your reasons for a "Yes" conclusion. To be thorough and to have readily available answers to questions about your hazard analysis, you may find it useful to take a conservative approach by listing in Column 2 several potential hazards even though they clearly do not require a preventive control (especially when there has been significant debate over whether something is actually a potential hazard for the facility), and explain the reasons for your "No" conclusion. This can be useful both during your own review of your food safety plan and during review of your food safety plan by others – e.g., if an inspector or auditor questions whether a particular hazard was considered.
- Column 5: Here, you will identify preventive controls that will significantly minimize or prevent the food safety hazard (e.g., process, allergen, sanitation, supply-chain or other) for those hazards you identified as requiring a preventive control (i.e., a "Yes" in column 3).
- Column 6: Because the worksheet breaks your production process into multiple steps, and the preventive control may be applied at a step in the process other than the step where you listed the hazard, you specify whether the preventive control will be applied at this particular step (Yes/No). It is important to note that identifying a hazard at a processing step as one that requires a preventive control does not mean that the hazard must be controlled at that processing step.

Box 2-3. Example Hazard Analysis Work Sheet (Also see Form 2-B, Appendix 2)[2]

(1) Ingredient / Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step B = biological C = chemical, including radiological P = physical	(3) Are any potential food safety hazards requiring preventive control? (Yes/No)	(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supplier, other preventive control*	(6) Is the preventive control applied at this step? (Yes/No)

2.4 Conducting a Hazard Analysis

2.4.1 Identify Potential Hazards (Ingredient-Related Hazards, Process-Related Hazards, and Hazards that May Be Introduced from the Environment (Hazard Identification)

See 21 CFR 117.130(b).

We recommend that you start your identification of hazards potentially associated with a food or process (the "known or reasonably foreseeable hazards") with a brainstorming session to generate a list of biological, chemical, and physical hazards. Consider the following as you work through this process:

- Information about the product description, intended use, and distribution.
- In-plant experience regarding the likelihood of hazards being associated with the finished products. This may include information from product testing results, consumer complaints, or knowledge of

[2] Adapted from a form available from the FSPCA in "FSPCA Preventive Controls for Human Food Training Curriculum, First Edition – 2016." The 2016 FSPCA form includes some additional features, such as a separate column for "Yes" and "No" responses and a separate row at each step for biological, chemical, and physical hazards (labeled B, C, and P, respectively). You can obtain the FSPCA form, including any later version if the form changes, from the FSPCA website (https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSPCA_Ap2_Worksheets__V1.1_Fillable.pdf)

facility personnel about the condition, function, and design of the facility that may be relevant to contamination.

- Raw materials and ingredients used in the product. Hazards, such as food allergen hazards or pathogens known to be associated with specific types of foods, may be introduced during product formulation. For example, mayonnaise is formulated with egg, which is a food allergen; "egg" must be included on the label and the mayonnaise may be a source of allergen cross-contact in your facility.
- Activities conducted at each step in the manufacturing process. Some processes may introduce hazards (e.g., a broken chopping blade can introduce metal fragments; a broken glass container can introduce glass fragments; improper cooling can allow low numbers of microbial pathogens to increase).
- Equipment used to make the product. Some types of equipment are more difficult to clean than others or are more prone to damage, which may increase the risk of hazards (e.g., biological or physical) being introduced into the product.
- Types of packaging and packaging materials. Reduced oxygen packaging, used to increase shelf life (e.g., potato salad packaged in a plastic container with a snap lid), may create an environment that supports the growth of *Clostridium botulinum (C. botulinum)*.
- Sanitary practices. You should consider the sanitary conditions within the processing facility (e.g., cleanliness of equipment and processing environment) and employee hygiene when identifying hazards. Hard-to-clean equipment may result in pathogen harborage sites. Producing foods with different food allergens on the same line may result in allergen cross-contact.
- External information. Sources may include scientific papers, epidemiological studies (e.g., data from previous outbreaks associated with ingredients or processes relevant to a product), information from applicable government or industry food safety guidance documents, and historical data for similar products, if available.

After reviewing all the relevant information, the Food Safety Team can then develop a list of biological, chemical, and physical hazards that may be introduced, increased (e.g., due to pathogen growth), or controlled at each step described on the flow diagram. Enter those in column 2 of the Hazard Analysis Worksheet.

We recommend that you consult Chapter 3 and Appendix 1 of this guidance to help you identify potential hazards. Chapter 3 of this guidance provides a review of biological, chemical, and physical hazards and Appendix 1 of this guidance provides tables describing potential ingredient-related hazards and process-related hazards. The hazards identified in Chapter 3 and in Appendix 1 do not represent an exhaustive list of hazards potentially associated with a food facility or food. You are responsible for identifying any hazard that may be associated with your process or product, even if it is not listed in Chapter 3.

You may find the following list of questions helpful during the hazard identification process. We adapted this list from Hazard Analysis and Critical Control Point Principles and Application Guidelines published by the National Advisory Committee on Microbiological Criteria for Foods.

<u>Examples of questions to be considered when identifying potential hazards</u>

1. Ingredients

    a. Does the food contain any ingredients that may present microbiological hazards, chemical hazards, or physical hazards?

b. Is all the water used at any point in the manufacturing process of the appropriate quality standard?

c. What are the sources of the ingredients (geographical regions, specific supplier details)?

2. Intrinsic Factors – physical characteristics and composition of the product during and after processing

    a. What hazards may result if the food composition is not controlled?

    b. Does the food permit survival or promote pathogen growth and/or toxin formation during subsequent steps in the manufacturing process or distribution/storage?

    c. Are there similar products already in the marketplace, and if so, which hazards have been associated with those products? What is the food safety record of those products?

3. Processing procedures

    a. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider not only vegetative cells but also spores, which are typically more resistant to inactivation treatments compared to their vegetative counterparts.

    b. Is the product susceptible to recontamination between processing and packaging? If so, what are the biological, chemical (including radiological), or physical hazards potentially associated with the process environment?

4. Microbial content of the food

    a. What is the baseline microbial content of the food?

    b. Does the microbial population change during the normal storage time of the food prior to consumption?

    c. Do changes in the microbial population affect the safety of the food?

    d. Based on the answers to the above questions, is there a significant likelihood of any biological hazards?

5. Facility design

    a. Does the layout of the facility provide an adequate separation of raw materials from RTE foods when this is necessary for food safety? If not, what are the hazards that could contaminate the RTE product?

b. Is positive air pressure maintained in product packaging areas? Is this required for product safety?

c. Is the traffic pattern for people and moving equipment a significant source of contamination?

6. Equipment design and use

a. Will the equipment provide the necessary time-temperature control to ensure a safe product?

b. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe product?

c. Is the equipment reliable and maintained in good repair?

d. Is the equipment easy to clean and sanitize?

e. Can parts of the equipment contaminate the product and thereby introduce physical hazards?

f. What product safety devices are used to control the potential for physical hazards to contaminate the product? Examples include: metal detectors, magnets, sifters, filters, screens, thermometers, bone removal devices, dud detectors

g. Are allergen protocols needed for using the same equipment for different products?

7. Packaging

a. Does the method of packaging affect the rate of growth of microbial pathogens and/or the formation of toxins?

b. Is the package clearly labeled with the appropriate storage instructions, e.g., “Keep refrigerated,” if required for safety?

c. Does the package include instructions for the safe handling and preparation of the food by the end user?

d. Is the packaging material resistant to damage and effective in preventing post-packaging microbial contamination?

e. Are tamper-evident packaging features used?

f. Is each package and case legibly and accurately coded?

g. Does each package contain the proper label?

h. Are allergenic ingredients included in the list of ingredients on the label?

8. Employee health, hygiene, and education

    a. Can employee health or personal hygiene practices impact the safety of the food being processed, and in what way(s)?

    b. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?

    c. Will the employees inform management of a problem that could impact food safety?

9. Storage conditions between packaging and the end user

    a. What is the likelihood that the food will be improperly stored at the wrong temperature?

    b. Would an error in storage lead to a microbiologically unsafe food?

10. Intended use and user

    a. Will the food be heated by the consumer?

    b. Will there likely be leftovers? If so, how and maximally for how long should they be stored? How should they be re-heated?

    c. Is the food intended for the general public?

    d. Is the food intended for consumption by a population with increased susceptibility to illness or a particular hazard (e.g., Infants, the elderly, the immuno-compromised, or pregnant women)?

    e. Is the food intended to be used for institutional feeding (e.g., in school cafeterias, hospitals) or in private homes?

2.4.2 Evaluate Potential Hazards to Determine Whether the Hazard Requires a Preventive Control (Hazard Evaluation)

See 21 CFR 117.130(c).

- Under 21 CFR 117.130(c)(1)(i), you must assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls.
- Under 21 CFR 117.130(c)(1)(ii), you must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does

not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen.

- Under 21 CFR 117.130(c)(2), you must consider the effect of certain factors on the safety of the finished food for the intended consumer.

We discuss each of these points in the remainder of this section.

Consult the hazards in Chapter 3 and controls in Chapters 4 and 5 of this guidance document for each of the potential hazards that you entered in Column 2 of the Hazard Analysis Worksheet. These chapters offer guidance for completing your hazard analysis and developing your FSP. Chapters 6-13 each contain a section "Understand the Potential Hazard" that provides information about the significance of the hazard, the conditions under which it may develop in a processed product, and methods available to control the hazard.

Once you have identified all potential hazards, the next step is to evaluate each hazard and determine whether the hazard poses a significant risk to the end user or consumers in the absence of a preventive control. Narrow the list of potential hazards that you entered in column 2 to those that require a preventive control.

For example, at the receiving step for ingredients, you may identify soy as an allergen in your product because soy protein is one of the ingredients. Because it is an allergen, you would mark "Yes" in column 3 and explain that soy may cause allergic reactions in some consumers in column 4.

For each hazard also consider the following:

- Seriousness of the potential illness or injury resulting from exposure to the hazard, and
- The likelihood of occurrence in the absence of a preventive control.

2.4.2.1 Evaluating severity

To evaluate the severity of a potential hazard, you should consider certain factors, including

- susceptibility of intended consumers to foodborne illness (e.g., infants, children, and immunocompromised persons may be more susceptible to certain foodborne illnesses),
- the potential magnitude and duration of the illness or injury (e.g., how long an individual may be sick, and whether hospitalization or death is common), and
- the possible impact of secondary problems (e.g., chronic sequelae such as kidney damage or reactive arthritis).

If your facility does not have the expertise to evaluate the severity of a potential hazard, you should consult with outside experts.

2.4.2.2 Estimating the likely occurrence

The likelihood of occurrence of a particular food hazard in the food when consumed can be influenced by:

- Frequency of association of the hazard with the food or facility
- Effectiveness of facility programs such as CGMPs
- Method of preparation in the establishment

- Conditions during transportation
- Expected storage conditions
- Likely preparation and handling steps before consumption

Knowing your product, ingredients, processes, preparation methods, packaging, transportation, distribution, and likely use of the product will be helpful in estimating the likely occurrence of potential hazards. Hazards identified in one operation or facility may not be significant in another operation or facility producing the same or similar products because different equipment and processes may be used, the ingredients and their source may be different, or for other reasons. For example, one facility may package a beverage in glass and another may package the same product in plastic. You should consider each operation and facility location individually when estimating the likely occurrence of a food safety hazard.

When estimating likely occurrence, you should consider information from several sources, such as the following:

- Data from outbreaks of foodborne illness,
- Data from recalls,
- Information in the scientific literature, and
- Experience and historical information gathered by your facility.

2.4.2.2.1 Data from outbreaks

Your Food Safety Team should consider foodborne illness outbreaks in the same or similar products, as well as data on foodborne illness outbreaks provided from other product types that may be relevant, or from foods prepared in retail food establishments rather than in manufacturing facilities. Several publicly available resources can provide such information. For example, we provide information on our findings related to outbreaks, including a discussion, whenever possible, of factors that would have contributed to the outbreak at the processing or production site for the foods we regulate. Moreover, the Centers for Disease Control and Prevention (CDC) provides considerable information on outbreaks that occurred from processed foods, as well as from foods prepared in restaurants, retail establishments, and other locations. See Box 2-4 for a list of useful reports and the list of references in section 2.6 of this chapter for how to access these reports. Information may also be available on outbreaks from similar foods that occur in other countries. For example, the European Food Safety Authority (EFSA) publishes summaries of foodborne disease outbreaks in European countries.

Box 2-4. Sources of Data about Outbreaks [3]

Food and Drug Administration (FDA)

- Outbreak investigations – reports for FDA regulated foods

Centers for Disease Control and Prevention (CDC)

- Foodborne Outbreaks (including links to the List of Selected Multistate Foodborne Outbreak Investigations (see below) and Morbidity and Mortality Weekly Report reports on foodborne outbreaks)
- List of Selected Multistate Foodborne Outbreak Investigations - searchable database for selected U.S. outbreaks by year and by pathogen
- Attribution of Foodborne Illness – reports on foods associated with illness

Center for Science in the Public Interest (CSPI)

- Outbreaks & Recalls

2.4.2.2.2 Data from recalls

Recalls provide useful information in understanding the likely occurrence of potential hazards and the foods in which they occur. We categorize recalls as specified in 21 CFR 7.3(m):

Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

- Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1);
- Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2); and
- Class III is a situation in which use of, or exposure to, a violative product is not likely to cause illness or injury (21 CFR 7.3(m)(3).

Federal and state websites post information on food recalls. See Box 2-5 for a list of some helpful federal websites that provide data about recalls. See the list of references in section 2.6 of this chapter for the links to access this information.

[3] See section 2.6 of this chapter for information on how to access these sources of data about outbreaks.

Box 2-5. Sources of Data About Recalls[4]

- **Food and Drug Administration (FDA) Recalls, Market Withdrawals, & Safety Alerts**
- **U.S. Department of Agriculture (USDA) Food Safety and Inspection Service Recall Archive**
- **Foodsafety.gov (Gateway to Federal Food Safety Information), Recalls & Alerts**

2.4.2.2.3 Information in the scientific literature

Peer-reviewed scientific journals and other sources of technical literature (e.g., Codex Alimentarius Commission (Codex), the Food and Agriculture Organization and the World Health Organization) provide considerable information on foodborne hazards, including their occurrence, their potential growth in foods (e.g., for biological hazards), and their control. A useful search engine is Google Scholar. USDA provides a microbial modeling program that is available online and can be used to evaluate potential growth of pathogens under a variety of conditions. ComBase is an online tool for quantitative food microbiology. It contains the ComBase database of microbial growth and survival curves and the ComBase Predictor that uses the data to predict growth or inactivation of microorganisms. Keep in mind that modeling programs may not reflect exactly what will occur in a particular food, but they can provide an estimate of relative risk of different scenarios. Codex maintains internationally recognized codes of practice that are based on scientific literature and are available in several languages. Trade associations also provide food safety recommendations for specific types of foods and industry needs.

We provide other guidance documents that contain product-specific food safety information (e.g., on shell eggs, cheese, fruits, vegetables, and milk). These guidance documents, which represent FDA's current thinking on a topic, are organized by topic and by year of publication, with recently added guidance documents at the top of the page.

2.4.2.2.4 Establishment's historical information

You may already have considerable information on your products from various laboratory tests on finished products, ingredients, in-process materials, or environmental monitoring. In addition, you may have experienced a contamination problem in the past that suggests a hazard is reasonably foreseeable, or received consumer complaints about certain hazards, such as physical hazards.

You should evaluate the potential hazards independently at each processing step to determine whether you should identify that hazard as one requiring a preventive control. For example, you would identify a hazard as one requiring a preventive control if:

- it is reasonably likely that the hazard can be introduced at an unsafe level at that processing step; or
- it is reasonably likely that the hazard can increase to an unsafe level at that processing step; or

[4] See section 2.6 of this chapter for information on how to access these sources of data about recalls.

- the hazard was identified in an ingredient or at another processing or handling step and it can be controlled (i.e., significantly minimized or prevented) at the current processing step.

When evaluating whether a hazard requires a preventive control, you should consider the method of distribution and storage and the intended use and consumer of the product (information which you developed as part of your preliminary steps in conducting a hazard analysis).

If you determine that a potential hazard requires a preventive control, you should answer "Yes" in column 3 of the Hazard Analysis Worksheet. If you determine that it does not require a preventive control, you should answer "No" in that column. In column 4, record your reason for your "Yes" or "No" answer. If the hazard does not require a preventive control, you would not complete columns 5 and 6.

2.4.2.3. Evaluating environmental pathogens whenever a ready-to-eat food is exposed to the environment

If the food you make is ready-to-eat (see the definition in 21 CFR 117.3, which we included in the Glossary in section III of the Introduction of this guidance), the food could be contaminated with environmental pathogens such as *Listeria monocytogenes* (*L. monocytogenes*) or *Salmonella*. See 21 CFR 117.130(c)(1)(ii) for when the PCHF requirements specify that you must consider environmental pathogens in your hazard analysis.

2.4.2.4. Evaluation factors

When evaluating hazards, you must consider the effect of the following on the safety of the finished food for the consumer (21 CFR 117.130(c)(2)):

- The formulation of the food: The addition of certain ingredients such as acids and preservatives may be critical to the safety of the food, because they may inhibit growth of, or kill, microorganisms of public health significance. This could impact the evaluation at steps during production and storage with respect to the hazard of ''pathogen growth.'' A multicomponent food may have individual ingredients that do not support growth of undesirable microorganisms (e.g., because of pH or a_w), but when put together there may be an interface where the pH and a_w change (e.g., pies, layered breads). The formulation may contain an ingredient (e.g., a flavoring, coloring, or incidental additive) that is (or contains) an allergen that requires label control and possibly controls to prevent cross-contact.
- The condition, function, and design of the facility and equipment: The condition, function, or design of a facility or its equipment could potentially result in the introduction of hazards into foods. For example, older equipment (e.g., older slicing, rolling and conveying equipment) may be more difficult to clean (e.g., because of close fitting components or hollow parts) and, thus, provide more opportunities for pathogens to become established in a niche environment than modern equipment designed to address the problem of pathogen harborage in niche environments; in such instances enhanced sanitation controls may be appropriate. Equipment designed such that there is metal-to-metal contact may generate metal fragments; a preventive control such as metal detectors may be appropriate. A facility that manufactures, processes, or packs an RTE product such as fresh soft cheese may have cold, moist conditions that are conducive to the development of a niche where the pathogen *L. monocytogenes* can become established and contaminate food-contact surfaces and, eventually, foods; enhanced sanitation controls may be appropriate for such facilities. Facilities with closely spaced equipment should consider the impact of the close spacing on the potential for allergen cross-contact to be a hazard; targeted food allergen controls may be appropriate.
- Raw materials and other ingredients: A food can become contaminated through the use of contaminated food ingredients. Ingredients such as flavorings, colorings, or incidental additives may

contain ‘‘hidden’’ allergens. Machinery-harvested produce may be contaminated with physical hazards, because the machinery can pick up foreign material from the field.

- Transportation practices: The safety of a food can be affected by transportation practices for incoming raw materials and ingredients or for outgoing finished product. For example, when a food requires time/temperature control for safety, time/temperature controls would be important during transportation. Distributing a food in bulk without adequate protective packaging makes the product susceptible to contamination during transportation—e.g., from pathogens or chemicals present in an inadequately cleaned vehicle or from other inadequately protected foods that are being co-transported and are potential sources of contamination.
- Manufacturing/processing procedures: Hazards may arise from manufacturing/processing processes such as cooling or holding of certain foods due to the potential for germination of pathogenic sporeforming bacteria such as *Clostridium perfringens (C. perfringens)* and *Bacillus cereus (B. cereus)* (which may be present in food ingredients) as a cooked product is cooled and reaches a temperature that will allow germination of the spores and outgrowth. Hazards also may arise from manufacturing/processing processes such as acidification due to the potential for germination of spores of *C. botulinum*, with subsequent production of botulinum toxin, if the acidification is not done correctly. Toxins can be produced by the bacteria *Staphylococcus aureus (S. aureus)* or *B. cereus* in a product that has been heated and held at room temperature during the manufacturing process if the product formulation supports growth and toxin formation by the bacteria and *S. aureus* or *B. cereus* is present in the ingredients of the product or is introduced by poor employee hygiene (e.g., *S. aureus*). Physical hazards may occur from metal fragments generated during the manufacture of food on equipment in which metal (e.g., wires, saw blades or knives) is used to cut products during manufacturing.
- Packaging activities and labeling activities: Preventive controls for glass may be needed for products packed in glass. Preventive controls for *C. botulinum* may be needed when packing certain foods in modified atmosphere packaging. Label controls may be needed to ensure all food allergens are listed on the label of packaged foods that contain allergens.
- Storage and distribution: Biological hazards are more likely to require a preventive control during storage and distribution in foods that require refrigerated storage to maintain safety than in shelf-stable foods.
- Intended or reasonably foreseeable use: Some foods that are intended to be cooked by the consumer may also have uses that do not include cooking, such as soup mixes used to make dips. Whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen, hazards such as *Salmonella* spp., *L. monocytogenes*, and *Escherichia coli* O157:H7 (*E. coli* O157:H7) must be considered to determine if they require a preventive control. (See 21 CFR 117.130(c)(1)(ii).)
- Sanitation, including employee hygiene: Sanitation measures and practices can impact the likelihood of a hazard being introduced into a food. For example, the frequency with which a production line is shut down for a complete cleaning can impact the potential for food residues to transfer pathogens from equipment to foods (e.g., pathogens present on raw produce that could carry over into the next production cycle on a line). Practices directed at worker health and hygiene can reduce the potential for transfer of pathogens such as *Salmonella* spp., hepatitis A, and norovirus.
- Any other relevant factors, such as the temporal (e.g., weather-related) nature of some hazards (e.g., levels of some natural toxins): Hazards such as aflatoxin are subject to a weather-dependent effect in that aflatoxin levels in some raw agricultural commodities are more of a problem in some years than in others.

As noted earlier, identifying a hazard at a processing step as one that requires a preventive control does not mean that the hazard must be controlled at that processing step. Once you determine that a hazard requires a preventive control, the next step is to identify control measures to control the hazard.

2.5 Identify Preventive Control Measures

Box 2-6. Definition of "Preventive Controls" in Part 117

Preventive Controls

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.

21 CFR 117.3

For each hazard that your Food Safety Team first identified in Column 2 as potentially associated with an ingredient, processing step, or the environment, and then identified in Column 3 as requiring a preventive control, you must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented. See 21 CFR 117.135. If a process control can be applied at a point or step in the food production process to prevent or eliminate the food safety hazard, or reduce it to an acceptable level, you should classify the point or step as a Critical Control Point (CCP). There are several control approaches, which may or may not include CCPs, that you can consider, depending on the potential hazard and where in the process flow diagram you determine the control measure should be applied. These include:

- Supply-chain controls
- Food allergen controls
- Sanitation controls
- Process controls

Supply-chain controls involve verification of controls used by suppliers to control hazards in raw materials or other ingredients before receipt by a manufacturer/processor. Food allergen controls include labeling and controls to prevent cross-contact, such as product sequencing, in addition to sanitation controls (i.e., to prevent cross-contact with allergens from other foods produced on the same line). Sanitation controls may be important to prevent contamination with microbial pathogens, especially for RTE foods that are exposed to the environment. Process controls are applied at specific processing steps, where critical parameters such as time and temperature may be identified to control the hazard of concern. See Box 2-7 for some examples of in-process controls.

Box 2-7. Examples of In-Process Controls

Examples of In-Process Controls
• Acidification • Cooking • Drying • Fermentation • Filtering • Freezing • High pressure processing • Irradiation • Metal detection • Pasteurization • Refrigeration • Retort processing • Use of x-ray area

For every hazard you identify as requiring a preventive control, you must identify and implement at least one preventive control measure. See 21 CFR 117.135. Importantly, remember that more than one hazard may be addressed by a specific control measure. For example, several vegetative pathogens, such as *Salmonella*, *L. monocytogenes*, and *E. coli* O157:H7, are killed by cooking. Several chapters in this guidance provide one or more control strategy examples for how one or more hazards can be controlled, because there are often more ways than one to control a hazard. The control strategy examples also contain control measure information. Record the control measure(s) that you choose in column 5 of the Hazard Analysis Worksheet for each "Yes" answer in column 3.

When identifying preventive controls for your food process, your Food Safety Team should also consider

- The effect of the control on identified potential food safety hazards (e.g., Does the preventive control significantly minimize or prevent the potential food safety hazards identified? Is the preventive control hazard-specific or does it control more than one hazard? Does the control effectiveness depend upon other controls? Can the preventive control be validated and verified?)
- The feasibility of monitoring those controls (e.g., Are the critical limits (minimum or maximum values) and, if appropriate, operating limits, for the preventive control measureable and practical? Can you obtain the results of monitoring quickly (i.e., real-time) to determine if the process is in control? Are you monitoring a batch or continuous process? Are you monitoring continuously or doing spot checks? Can the parameters be monitored in-line or must the product be sampled? Will the monitored parameters be indirectly linked to the critical limit (i.e., belt speed or pump flow rate for time of process)? Who will perform the monitoring or checks and what are the required qualifications? How is the monitoring to be verified?)

- The location of the control with respect to other processing control measures (e.g., Is the application of the control measure at the last point in the process to ensure control of the targeted potential food safety hazard? Will the failure of an upstream control result in failure of downstream controls (i.e., acidification failure impacting thermal process efficacy for an acidified food)? Are monitoring activities appropriate to ensure control at this step?)
- Corrective actions that will be needed in the event of a failure of a control measure or a significant processing variability (e.g., Can the process control and critical parameter be brought quickly back into control? How will you determine if the control measure is once again under control? Can the implicated product be identified and its safety evaluated? Can the cause of the loss of control be identified and corrected? What actions would be needed to reduce the likelihood of the failure to recur? Can the product be reprocessed? What actions would be necessary to prevent unsafe product from entering commerce (e.g., can product be diverted to animal food or does the product need to be destroyed)?)
- The severity of the consequences in case of a failure of a control measure (e.g., Is it reasonably likely that unsafe food would be produced as a result of the control measure failure? Is the hazard that could occur reasonably likely to cause serious adverse health consequences or death?)
- Whether the control measure is applied to eliminate or significantly reduce the level of the hazard (e.g., Will the control measure eliminate the hazard, or is the control measure only able to minimize the hazard?)
- Synergistic effects between control measures (e.g., Consider whether one control measure can enhance the efficacy of another control measure. For example, formulation process controls may combine the use of preservatives, acidification, and water activity at levels that individually will not control pathogen growth, but they work together to do so.)

You use your written hazard analysis to design the approaches you will use to control the hazards. The more thorough the hazard analysis, the more targeted your controls will be to ensure hazards are significantly minimized or prevented, and the more effective your food safety program will be in preventing illness or injury to consumers.

In the chapters that follow we address managing food safety hazards through heat treatments, time/temperature control, product formulation, sanitation controls, and food allergen controls. We address supply-chain controls in "Chapter 15 – Supply-Chain Program for Human Food Products."

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 3: Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 3 that we issued for public comment in August 2016.

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3.1 Purpose of this Chapter

The guidance in this chapter is intended to help you consider the biological, chemical, and physical hazards that are commonly of concern in food plants and that should be addressed in a hazard analysis. It addresses ingredient-related hazards, process-related hazards, and hazards that may be introduced from the food-production environment (facility-related hazards). It does not provide an exhaustive compendium of hazards or details about each hazard. Where possible, we cite scientific literature, regulations, and/or guidance (issued by FDA or our food safety regulatory partners) that may provide useful detailed discussion or analysis of hazards of concern. See the definition of “hazard” in 21 CFR 117.3.

It is important for you to understand the potential hazards that may be associated with your products using the raw materials and other ingredients, processes, and equipment specific for those products, as well as the environment of your specific facility. If you identify hazards requiring a preventive control, you will then have to determine what preventive controls are needed to reduce food safety risks and ensure the safety of your products for human consumption. See 21 CFR 117.130 and 117.135. Although this chapter briefly describes the types of preventive controls that may be appropriate for you to implement to control certain hazards, see Chapter 4 and Chapters 6 through 13 of this guidance for more detailed discussion of applicable preventive controls.

3.2 Potential Hazards

Food products can become contaminated with biological, chemical (including radiological), or physical hazards. Table 3-1 provides examples of potential hazards and is not exhaustive.

Table 3-1 Examples of Potential Hazards

Hazard Category	Hazard Sub-category	Examples
Biological	Bacteria	• *Bacillus cereus* (*B. cereus*) • *Campylobacter jejuni* (*C. jejuni*) • *Clostridium botulinum* (*C. botulinum*) • *Clostridium perfringens* (*C. perfringens*) • Shiga-toxin producing *Escherichia coli* such as O157:H7 (*E. coli* O157:H7) • *Listeria monocytogenes* (*L. monocytogenes*) • *Salmonella* spp. • *Shigella* spp. • *Staphylococcus aureus* (*S. aureus*)
Biological	Protozoa and Parasites	• *Cryptosporidium parvum* • *Cyclospora cayetanensis* • *Giardia lamblia (G. intestinalis)* • *Trichinella spiralis*
Biological	Viruses	• Norovirus • Hepatitis A • Rotavirus
Chemical	Pesticide residues	• Organophosphates • Carbamates • Chlorinated hydrocarbons • Pyrethroids
Chemical	Heavy Metals	• Lead • Arsenic • Cadmium • Mercury
Chemical	Drug residues (veterinary antibiotics)	• Chloramphenicol • Beta- Lactams

Hazard Category	Hazard Sub-category	Examples
Chemical	Industrial chemicals	• Ammonia
Chemical	Environmental contaminants	• Dioxins
Chemical	Mycotoxins	• Aflatoxin • Patulin • Ochratoxin • Fumonisin • Deoxynivalenol
Chemical	Allergens	• Milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans (commonly called "the Big 8")
Chemical	Unapproved colors and additives	• FD&C Red #4 • Melamine
Chemical	Substances associated with a food intolerance or food disorder	• Lactose • Yellow #5 • Sulfites • Carmine and Cochineal • Gluten
Chemical	Radionuclides	• Radium 226 and 228 • Uranium 235 and 238 • Strontium 90 • Cesium 137 • Iodine 131
Physical	N/A	• Metal • Glass • Hard plastic

As discussed in Chapter 2 of this guidance, when conducting your hazard analysis you must consider the potential for biological, chemical, and physical hazards to be related to raw materials and other ingredients (ingredient-related hazards), processes (process-related hazards), and the food-production environment (facility-related hazards) (21 CFR 117.130). In Chapter 2 we also provide examples of questions to be considered when identifying potential hazards in the following areas:

- Ingredients;
- Intrinsic factors;
- Processing procedures;
- Microbial content of the food;
- Facility design;
- Equipment design and use;
- Packaging;

- Employee health, hygiene, and education; and
- Storage conditions between packaging and the end user.

Throughout this chapter, we discuss potential biological, chemical, and physical hazards from the perspective of ingredient-related hazards, process-related hazards, and facility-related hazards, considering the issues and factors listed immediately above.

3.3 Biological Hazards

You must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens. See 21 CFR 117.130(b)(1)(i). When your hazard analysis identifies a known or reasonably foreseeable biological hazard that requires a preventive control, you must identify and implement a preventive control for the biological hazard. See 21 CFR 117.135(a)(1).

The biological hazards that are the focus of this guidance are bacterial pathogens (e.g., *Salmonella* spp., *Listeria monocytogenes*, *Clostridium botulinum*, and Shiga-toxin producing *Escherichia coli* (STEC) such as O157:H7) that may be associated with foods or food processing operations and can cause consumer illness or disease. The other biological hazards, viruses (e.g., norovirus and hepatitis A) and parasites (e.g., *Cryptosporidium* spp. and *Giardia intestinalis*), are also known to cause illness or disease, but these would generally be addressed by following Current Good Manufacturing Practice (e.g., worker hygiene and disease control) in facilities and our regulation entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (21 CFR part 112) (e.g., worker hygiene and disease control, water safety) on farms that supply raw agricultural commodities to facilities.

Food products can become contaminated with bacterial pathogens that can be:

- Ingredient-related hazards - i.e., introduced from raw materials and other ingredients;
- Process-related hazards - e.g., if the pathogens:
    - Survive processing that was intended to significantly minimize the pathogen;
    - Increase in number due to lack of time/temperature control or due to the food's formulation; or
    - Selectively grow, and/or produce toxin, in a food as a result of using reduced oxygen packaging;
- Facility-related hazards – e.g., if the pathogens are introduced from:
    - Food processing equipment (e.g., insanitary equipment and utensils);
    - Cross-contamination between raw and cooked products;
    - Air; or
    - Contaminated water or sewage; or
- People-related hazards – e.g., due to people handling the product during packing or processing. (Such people-related hazards are sometimes controlled by following Current Good Manufacturing Practice (e.g., worker hygiene and disease control)).

For further details on the sources of biological hazards that can be introduced into food products, see Tables 1A through1Q and Tables 3A through 3Q of Appendix 1 of this guidance.

Bacterial pathogens can be classified based on whether they form spores ("sporeformers") or whether they only exist as vegetative cells and do not form spores ("non-sporeformers"). Spores are not hazardous as long as they remain in the spore state. Unfortunately, spores are very resistant to heat, chemicals, and other treatments that would normally kill vegetative cells of both sporeformers and non-sporeformers. As a result, when spores are a concern, the process steps used to kill them are often much more severe than those necessary to kill vegetative cells. When spores survive a processing step designed to kill vegetative bacteria, they may become a hazard in the food if they are exposed to conditions that allow germination and growth as vegetative cells. This can be particularly serious when a processing step has removed most of their competition. Thus, other controls such as reduced pH or water activity (a_w) or temperature control (refrigeration or freezing) may be needed to control sporeformers that remain after a kill step.

Because the characteristics of foodborne pathogens differ, the preventive controls that you identify and implement to control specific pathogens should be based on the characteristics of those specific pathogens. In the remainder of this section on biological hazards, we briefly review characteristics of common vegetative and sporeforming foodborne pathogens. For more detailed information, see FDA's *Bad Bug Book* (FDA 2012c).

Table 3-2 is a Quick Reference Guide to help you identify potential pathogens by biological classification and potential sources or entry points in your facility. The potential hazards listed in Table 3-2 will not apply to all facilities.

Table 3-2 Quick Reference Guide for Common Sources of Biological Hazards

Primary Source	Bacteria	Parasites	Viruses
Ingredient-related (e.g., contamination of raw materials and other ingredients)	• *Salmonella* spp. (e.g., poultry, produce, nuts) • *E. coli* O157:H7 & similar STEC (e.g., ruminant animals, dropped fruit, sprouts) • *Campylobacter* spp. (e.g., poultry and raw milk) • *B. cereus* (e.g., rice and other grains) • *C. botulinum* (spores may be found in soil and on certain root crops.) • *C. perfringens* (e.g., spices, may come in soil on produce) • *L. monocytogenes* (e.g., raw agricultural commodities, other contaminated products used as ingredients)	• *Cryptosporidium parvum* (contaminated water used as an ingredient) • *Cyclospora cayetanensis* (berries) • *Toxoplasma gondii* (meat)	• Norovirus (produce, shellfish) • Hepatitis A virus (produce, fruits)

Primary Source	Bacteria	Parasites	Viruses
Process-related (e.g., poor or ineffective process controls, including by a supplier)	• *Salmonella* spp. survive inadequate heat treatment • *C. perfringens* (improperly cooled cooked foods) • *L. monocytogenes* (raw agricultural commodities, contaminated products)	*Cryptosporidium parvum* (contaminated water source)	N/A
Facility-related (may be caused by poor sanitation practices (e.g., inadequate cleaning and sanitizing of potential harborage sites), poor plant and equipment design, and poor pest management practices)	• *L. monocytogenes* (e.g., reservoirs include floors, cold wet areas, equipment, drains, condensate, coolers, and soil) • *Salmonella* spp. (pests)	N/A	Norovirus (only when active shedding occurs in facility through vomiting and diarrhea)
People-related (individuals who are carriers, showing no signs of disease, who are shedding the hazard, or who are infected and are actively ill)	• *S. aureus* • *Shigella* spp. • *Salmonella* spp.	*Cryptosporidium parvum*	• Hepatitis A virus • Norovirus • Rotavirus

3.3.1 Characteristics of Vegetative Foodborne Pathogens

Table 3-A in Appendix 3 of this guidance contains information on the physical conditions (i.e., a_w, acidity (pH), temperature, and oxygen requirements) that will limit growth for most of the vegetative pathogens that are of greatest concern in food processing. Data shown are the minimum or maximum values - i.e., the extreme limits reported among the references cited. These values may have been obtained in laboratory media, which may be more favorable to growth than many foods. These values may not apply to your specific processing conditions.

***Brucella* spp.** is the bacterium responsible for brucellosis. An estimated 840 foodborne cases of brucellosis occur annually in the United States (Scallan et al., 2011) When sheep, goats, cows, or camels are infected with the pathogen, their milk becomes contaminated with the bacteria. The most common way for humans to be infected is by eating or drinking unpasteurized/raw dairy products from infected animals. *Brucella* can also enter the body through skin wounds or mucous membranes following contact with infected animals. Symptoms include: fever; sweats; malaise; anorexia; headache; pain in muscles, joints and/or back; and fatigue. Some signs and symptoms may persist for prolonged periods of time or may never go away.

***Campylobacter jejuni* (*C. jejuni*)** is the bacterium responsible for campylobacteriosis. An estimated 845,000 foodborne cases of campylobacteriosis occur annually in the United States (Scallan et al., 2011). Symptoms include diarrhea, fever, abdominal pain, nausea, headache, and muscle pain. Symptoms start from 2 to 5 days after consumption of contaminated food and last from 7 to 10 days. A small percentage of patients develop complications that may be

severe. These include bacteremia and infection of various organ systems, such as meningitis, hepatitis, cholecystitis, and pancreatitis. Autoimmune disorders are another potential long-term complication associated with campylobacteriosis; for example, Guillain-Barré syndrome (GBS). Everyone is susceptible to infection by *C. jejuni.* Campylobacteriosis occurs more frequently in the summer months than in the winter.

Pathogenic strains of *Escherichia coli* (*E. coli*) are responsible for four types of illness: gastroenteritis or infantile diarrhea, caused by enteropathogenic *E. coli* (EPEC); travelers' diarrhea, caused by enterotoxigenic *E. coli* (ETEC); bacillary dysentery, caused by enteroinvasive *E. coli* (EIEC); and hemorrhagic colitis, caused by enterohemorrhagic *E. coli* (EHEC). EHEC is the most severe, with potential for serious consequences such as hemolytic uremic syndrome, particularly in young children. An estimated 205,800 foodborne cases from all four types of *E. coli* occur annually in the United States (Scallan et al., 2011). Symptoms vary for the different forms of illness, but include abdominal pain, diarrhea, vomiting, fever, chills, dehydration, electrolyte imbalance, high body fluid acidity, and general discomfort. Symptoms start from 8 hours to 9 days after consumption of contaminated food and last from 6 hours to 19 days, with both periods varying significantly between the illness types. Everyone is susceptible to all forms of infection from *E. coli*, but EPEC is most commonly associated with infants, and all types tend to result in more severe symptoms in the very young and elderly.

***Listeria monocytogenes* (*L. monocytogenes*)** is the bacterium responsible for listeriosis. An estimated 1,600 foodborne cases of listeriosis occur annually in the United States (Scallan et al., 2011). *L. monocytogenes* produces mild flu-like symptoms in many individuals. However, in susceptible individuals, including pregnant women, newborns, and the immunocompromised, it can result in more severe symptoms, including septicemia, meningitis, encephalitis, spontaneous abortion, and stillbirth. Symptoms start from 3 days to 3 weeks after consumption of contaminated food. Mortality is high (approximately 25%) in those that display the more severe symptoms.

***Salmonella* spp.** is the bacterium responsible for salmonellosis. An estimated 1,029,000 cases of foodborne salmonellosis occur annually in the United States (Scallan et al., 2011). Symptoms include: nausea, vomiting, abdominal cramps, diarrhea, fever, and headache. Symptoms start from 6 hours to 2 days after consumption of contaminated food and generally last from 4 to 7 days. The most severe form, typhoid fever, is caused by *Salmonella* Typhi. Everyone is susceptible to infection by *Salmonella* spp*.,* but symptoms are most severe in the elderly, infants, and the infirmed. Infections by *Salmonella* spp*.* and other closely related bacterial pathogens, such as *Shigella* spp*., E. coli*, and *Yersinia enterocolitica,* can lead to chronic reactive arthritic symptoms in pre-disposed individuals.

Shigella spp. is the bacterium responsible for shigellosis. Shigella infections may be acquired from eating contaminated food. Foods may become contaminated by infected food handlers who do not wash their hands before handling food. An estimated 131,000 foodborne cases of shigellosis occur annually in the United States (Scallan et al., 2011). Symptoms include: abdominal pain; cramps; diarrhea; fever; vomiting; blood, pus, or mucus in stools; continuous or frequent urges for bowel movement; and death. Symptoms start from 12 hours to 2 days after consumption of contaminated food and last from 1 to 2 weeks. Everyone is susceptible to infection by *Shigella* spp*.*

***Staphylococcus aureus* (*S. aureus*)** is a common bacterium found on the skin and in the noses of many healthy people and animals. The bacterium is responsible for producing toxins as it grows in foods, causing staphylococcal food poisoning. An estimated 241,000 foodborne

cases of staphylococcal food poisoning occur annually in the United States (Scallan et al., 2011). Symptoms include: nausea, vomiting, diarrhea, abdominal pain, and weakness. Staphylococcal toxins are fast acting and can cause illness in as little as 30 minutes. Symptoms usually start within one to six hours after eating contaminated food. Everyone is susceptible to intoxication by *S. aureus* toxin, with more severe symptoms, including occasional death, occurring in infants, the elderly and debilitated persons.

3.3.2 Characteristics of Spore-Forming Foodborne Pathogens

Table 3-A in Appendix 3 contains information on the conditions that will limit growth for most of the spore-forming pathogens that are of greatest concern in food processing. Data shown are the minimum or maximum values – i.e., the extreme limits reported among the references cited. These values may have been obtained in laboratory media, which may be more favorable to growth than many foods. These values may not apply to your processing conditions.

***Bacillus cereus* (*B. cereus*)** is the bacterium responsible for *B. cereus* food poisoning. An estimated 63,400 foodborne cases of *B. cereus* food poisoning occur annually in the United States (Scallan et al., 2011). There are two forms of illness, associated with two different toxins. In one form of illness, *B. cereus* produces an emetic toxin in the contaminated food; the emetic toxin causes nausea and vomiting, starting from 30 minutes to 6 hours after consumption of the food. In the other form of illness, associated with an infection due to high numbers of *B. cereus* in the contaminated food, *B. cereus* produces a diarrheal toxin in the intestines of the affected consumer after the consumer ingests food; the diarrheal toxin causes diarrhea, starting from 6 to 15 hours after consumption. Symptoms in both forms of illness last about 24 hours. Everyone is susceptible to *B. cereus* food poisoning.

***Clostridium botulinum* (*C. botulinum*)** toxin is the toxin responsible for a severe paralytic illness called botulism. *C. botulinum* is found in soil and grows best in low oxygen conditions. The bacteria form spores that can survive in a dormant state until exposed to conditions that support their germination and growth, such as in inadequately processed low-acid canned foods. Foodborne botulism is caused by eating foods that contain the botulinum toxin, which is formed during growth of *C. botulinum*. There are seven types of botulism toxin designated by letters A through G; only types A, B, E and F have caused botulism in humans. An estimated 55 foodborne cases of botulism occur annually in the United States (Scallan et al., 2011). Symptoms include: weakness; vertigo; double vision; difficulty in speaking, swallowing, and breathing; abdominal swelling; constipation; paralysis; and, possibly, death. Symptoms start from 18 to 36 hours after eating a contaminated food, but can occur as early as 6 hours or as late as 10 days after exposure. Everyone is susceptible to intoxication by *C. botulinum* toxin; only a few micrograms of the toxin can cause illness. Mortality is high; without the antitoxin and respiratory support, death is likely.

***Clostridium perfringens* (*C. perfringens*)** is the bacterium responsible for perfringens food poisoning. *C. perfringens* causes illness when large numbers of the bacteria are consumed in contaminated food. The bacterium then produces enough toxin in the intestines to cause illness. *C. perfringens* spores can survive high temperatures. During cooling and holding of food at warm temperatures, the spores germinate and the resulting vegetative cells of the bacteria grow. An estimated 966,000 foodborne cases of perfringens food poisoning occur annually in the United States (Scallan et al., 2011). Symptoms include: abdominal cramps and diarrhea. Symptoms typically start from 8 to 12 hours after eating a contaminated food, but can occur as early as 6 hours after exposure and last for about a day. Everyone is susceptible to perfringens

food poisoning, but it is more common in the young and elderly, who may experience more severe symptoms lasting for one to two weeks.

3.3.3 Potential Ingredient-Related Biological Hazards

See Table 3-2 in this chapter and Tables 1A through 1Q in Appendix 1 of this guidance for information that can help you identify potential ingredient-related biological hazards that may be associated with specific food products. See Chapter 4 – Preventive Controls, as well as Chapters 6 through 13, for recommendations on control of some specific ingredient-related biological hazards.

3.3.4 Potential Process-Related Biological Hazards

The purpose of this section is to help you identify potential process-related biological hazards for the foods that you produce. See Chapter 4 – Preventive Controls, as well as Chapters 6 through 13, for recommendations on control of some specific process-related biological hazards.

Some process-related biological hazards can occur if something goes wrong with a process control. For example, pathogens that you intend to control by cooking could survive if your product is undercooked during application of a heat treatment; pathogens that you intend to control by refrigeration could multiply and/or produce toxin if there is a lack of proper refrigerated holding during product assembly; and pathogens that you intend to control by a_w could multiply and/or produce toxin if the product is not properly formulated (e.g., too little sugar is used, resulting in an increase in the a_w). Other process-related biological hazards are not related to something going wrong with a process control. For example, if you plan to use reduced oxygen packaging (ROP) to prevent the growth of spoilage organisms and extend the shelf life of the product, the extended shelf life provides more time for toxin production or pathogen growth if pathogens are present and temperatures are suitable for growth. As another example, if you manufacture a product by adding spices after a process control that would significantly minimize pathogens, pathogens in the added spices could introduce pathogens to the treated product. As yet another example, pathogens could be introduced to a treated product after packaging if there is a lack of container integrity.

In the following sections on process-related biological hazards, we describe examples of these kinds of process-related biological hazards.

3.3.4.1 Bacterial pathogens (vegetative and sporeforming) that survive after treatment

If a process that you design to kill bacterial pathogens and/or their spores does not work as intended, the bacterial pathogens and/or their spores that you intended to control can be present in your food product. The primary pathogens of concern are *L. monocytogenes*, *Salmonella* spp., *S. aureus* and *C. jejuni*, pathogenic strains of *E. coli*, *Yersinia enterocolitica* (*Y. enterocolitica), B. cereus C. perfringens, and C. botulinum*. See Appendix 3 of this guidance for limiting conditions for growth of bacterial pathogens.

See Chapter 4 of this guidance for an overview of recognized and established processing conditions to control pathogens and for factors to consider when designing your process to prevent problems. For example:

- Some foods heat faster than others. Bacterial pathogens in the cold spot of the food will be inactivated more slowly than those at the surface because those in the cold spot are subjected to less heat. If the minimum process for lethality is not achieved at the cold spot, pathogens may survive the treatment.
- Certain characteristics of food make it either easier or harder to destroy bacterial pathogens, if present. For example, pathogens are more easily destroyed in foods with an acidic pH; sugars and oils tend to shield pathogens from the effects of heat; and the presence of moisture, both in and surrounding the food, make destruction easier. If these have not been taken into account in designing the process, pathogens may survive the treatment.
- Spores of bacterial pathogens are more heat tolerant than the vegetative cells of the same pathogen and different bacterial pathogens have different heat resistances (see Appendix 3 of this guidance). If the process is not designed to control the most resistant pathogen of concern in the food, pathogens may survive the treatment.

See also Chapter 6 – Use of Heat Treatments as a Preventive Control for more detailed recommendations to control process-related biological hazards through heat treatments.

3.3.4.2 Bacterial pathogens that grow and/or produce toxin

3.3.4.2.1 Due to lack of proper time/temperature control

Bacterial pathogens that are introduced from contaminated ingredients into a product that does not undergo a lethality process, or that survive a lethality process as a result of a problem with a process control, can multiply ("grow") and, depending on the pathogen, produce toxin as a result of time and temperature abuse of food products. Certain bacterial pathogens (e.g., *E. coli* O157:H7, *S. aureus,* and *L. monocytogenes)* grow well in time- and temperature-abused food. Time and temperature abuse occurs when a product is allowed to remain at temperatures favorable to bacterial pathogen growth for sufficient time to result in unsafe levels of the pathogens or their toxins in the product. Most bacterial pathogens will grow well in cooked foods that are temperature-abused if their growth is not otherwise controlled by means such as drying, salting, or acidification, because competing bacteria are significantly reduced by the cooking process. Uncooked foods that have high water activities and pH, such as batters, which are subjected to time/temperature abuse (e.g., using room-temperature batter for several hours), can support growth and toxin production by pathogens such as *S. aureus*.

Vegetative pathogens may grow in products during processing steps and may be ultimately destroyed by a lethal step such as cooking. However, too much bacterial growth before the lethal step may render the lethal process inadequate. Moreover, if the time and temperature abuse allows production of toxin, such as toxin production from *S. aureus* in temperature-abused custard pies, this toxin will not be destroyed by a heat step later in the process.

In evaluating the potential for bacterial pathogens to grow and/or produce toxin in your food products, you should consider the following factors:

- The types of pathogenic bacteria that are known or reasonably likely to be present;
- Whether those pathogens can grow in the food;
- The infective dose of the pathogenic bacteria;
- The expected initial level of the pathogenic bacteria in the food.

See Chapter 4 of this guidance for an overview of processing conditions to minimize pathogen growth by controlling temperatures to prevent pathogen growth and time of exposure to temperatures at which growth can occur. See also Chapter 7 – Use of Time/Temperature Control as a Process Control for more detailed recommendations to control process-related biological hazards through time/temperature controls. Tables 3-A and 3-B (Appendix 3 of this guidance) provide the limiting temperature conditions for growth of vegetative and sporeforming bacterial pathogens.

3.3.4.2.2 Due to lack of proper cooling after heat treatments

Depending upon the food and ingredients, heat treated foods can still possibly have viable forms (i.e., spores) of pathogenic bacteria present. Sometimes, vegetative cells that are particularly heat tolerant, (like *Listeria monocytogenes*) survive the cooking process; however, this should not be the case if the appropriate target pathogen was selected to be controlled by the applied process. More often, it is spores that survive the cooking process if they are present, and they begin to germinate when the product temperature begins to drop below 140°F. In addition, they will be present in the food during storage. Some spores such as those from pathogens such as non-proteolytic *C. botulinum* and some strains of *B. cereus* have the ability to germinate and grow at refrigeration temperatures, although long times are required. Other spores that remain in the food remain dormant until the product is temperature abused. In such an event, pathogenic spores that may be present are able to germinate, grow and possibly produce toxin due to the fact that most spoilage bacteria have been eliminated by the reduction step.

See Chapter 4 of this guidance for an overview of processing conditions to minimize pathogen growth by controlling temperatures during cooling after cooking. See also Chapter 7 – Use of Time/Temperature Control as a Process Control for more detailed recommendations to control process-related biological hazards through time/temperature controls.

3.3.4.2.3 Due to poor formulation control

Products most susceptible to biological hazards due to problems with formulation are RTE products that either do not receive a kill step in their process or that receive a kill step for vegetative pathogens but not spores and that may require refrigeration for safety during their manufacture and shelf life. For this category of products, product formulation can play a significant role in significantly minimizing or preventing hazards. For example, a naturally acidic product with a pH below 4.6 may rule out *C. botulinum* as a hazard requiring a preventive control, since this pH will prevent spore germination, growth, and toxin production. Formulation parameters such as pH, a_w, use of preservatives, and oxygen availability, can work in concert to establish an ecosystem that is designed to inhibit the growth of the pathogens that may be present. If not, just as described for foods that have been time and temperature abused, bacterial pathogen growth and toxin formation can result due to this lack of inhibition and control.

In determining the potential for a process-related hazard due to poor formulation control, we recommend that you know the formulations or ingredient lists of your incoming products, as well as the equilibrated pH, titratable acidity, a_w, percent moisture, percent sodium and percent sugar, as appropriate, of the finished combined product. Many of the products susceptible to biological hazards due to problems with formulation are made up of multiple ingredients, each with their own specific set of formulation parameters. Any one individual component not meeting the required formulation criteria to ensure that the designed preventive control system

is achieved may result in a food that does not inhibit the growth or toxin formation of a pathogen that may be present in the food.

In determining the potential for a process-related biological hazard due to poor formulation control, we also recommend that you consider the interactions that may occur among the various products, raw materials, and other ingredients when combined. Layering product components of significantly different pH or a_w values alters the microenvironments at the interfaces of the components. A simple example is an éclair filled with a cream filling. The pH and a_w at the interface of the pastry and the filling will be affected by the difference between the higher pH and lower a_w of the pastry and the potentially lower pH and higher moisture content of the filling, potentially resulting in an environment favorable to microbial growth. A microorganism that is in the filling may not grow due to the pH, but the pH of the pastry may favor growth of a microorganism at the interface during the product's shelf life. Characteristics such as oxygen-reduction (redox) potential and the effectiveness of antimicrobials are also likely to differ at component interfaces and may impact pathogen survival and growth.

In determining the potential for a process-related hazard due to poor formulation control, we also recommend that you consider how the equilibrium pH and a_w of the finished product compares to that of the individual components. If a finished formulated product is a more homogeneous mixture of the components, then the resulting final equilibrium pH and a_w may be significantly different from that of the individual components. A good example is hummus, which is typically made from chick peas (garbanzo beans), which may be rehydrated from a dry state, blended with acidifying agents, oils and spices and then pureed. The final product with a smooth texture will have an equilibrium pH, and possibly a_w, different from the original ingredients. If a topping of pine nuts, or oil, or diced red peppers is added to the top in the container as "decoration" then those additions could then significantly change the microenvironment at the interface and may require a control (such as acidification).

See Chapter 4 of this guidance for an overview of formulation-based controls. See Chapter 8 – Use of Formulation as a Preventive Control for more detailed recommendations to control process-related biological hazards through product formulation.

3.3.4.2.4 Due to reduced oxygen packaging (ROP)

From a food safety standpoint, packaging serves two functions: (1) It prevents contamination of the food; and (2) it makes possible, or extends the effectiveness of, food preservation methods. For example, packaging can maintain the atmosphere in a controlled or modified atmosphere package or a vacuum package, or it can prevent rehydration of a dried food. All of these different packaging methods are grouped into a category that we call ROP. ROP is used to prevent the growth of spoilage organisms, thereby extending the shelf life of the product. There are some other product quality benefits as well, such as reductions in rancidity, shrinkage, and color loss.

However, ROP does not control the growth of all bacterial pathogens and can create a process-related biological hazard. The extended shelf life provides more time for toxin production or pathogen growth if pathogens are present and temperatures are suitable for growth. Lower oxygen levels favor pathogens that can grow in the absence of oxygen over the aerobic spoilage organisms that require oxygen for growth. For this reason, you may get toxin production before you get spoilage - something that is less likely to happen in traditional packaging.

The major concern with ROP is *C. botulinum,* although there may also be concerns with other pathogens such as *L. monocytogenes*, particularly in refrigerated RTE foods. You should not use ROP unless barriers for *C. botulinum* are present. These barriers include: a_w below 0.93; pH below 4.6; salt above 10%; thermal processing in the final container; and freezing with frozen storage and distribution. Each of these barriers by itself can be effective in the control of *C. botulinum* growth. Refrigeration below 38°F (3.33°C) can prevent growth of all strains of *C. botulinum,* but because temperatures above this are commonly employed for refrigeration, temperature should not be relied on as the only control. Combinations of barriers that individually would not control growth of *C. botulinum* can work together to prevent growth.

For a further discussion on the potential for ROP to create a process-related biological hazard, see Annex 6 of the 2013 Food Code (FDA, 2013b).

3.3.4.3 Bacterial pathogens in ingredients added after process controls

The manufacture of certain RTE products involves, by design, the addition of ingredients after any process controls are applied. For example, the production of some fresh vegetable salad kits includes the addition to the final product, prior to packaging, of various ingredients such as nuts, dried berries, and seeds. The process control for the salad components (e.g., chlorine wash) is applied to the various fresh cut vegetables that are mixed in preparation for packaging, while the nuts, berries, and seeds are added just prior to packaging. As another example, the production of some fresh-baked pastry products includes the addition of toppings, such as frostings, nuts, dried fruit, confections (e.g., sprinkles). A facility that produces products containing ingredients added after a process control should consider the potential for the added components to be a process-related biological hazard as part of its hazard analysis.

3.3.4.4 Bacterial pathogens introduced after packaging due to lack of container integrity

Food manufactured and processed (e.g., heat treated) in a container and/or clean-filled after treatment can become contaminated if its container forms a leak or loses seal integrity, thereby exposing the processed food to a variety of biological hazards. The primary pathogens of concern include *C. botulinum*, *L. monocytogenes*, pathogenic strains of *E. coli*, *Salmonella* spp*.*, *S. aureus*, and *B. cereus*.

The primary causes of recontamination of foods after a process control step and packaging are defective container closures and contaminated cooling water. Poorly formed or defective container closures can increase the risk of bacterial pathogens entering the container through container handling that occurs after the product has been filled and the container has been sealed. This risk is a particular concern during container cooling performed in a water bath. As the product cools, a vacuum is drawn in the container. Contaminated cooling water can enter through the container closure, especially if the closure is defective.

3.3.5 Potential Facility-Related Biological Hazards

Foodborne illnesses due to commercially produced foods have been traced to post-process contamination due to the poor implementation of CGMPs, such as by exposure or contact with contaminated equipment during processing such as conveying, holding, chilling or packaging. Examples of events and foodborne illness outbreaks due to contamination of RTE foods are quite extensive and readily available in scientific literature. Typically in these events, foods that were processed by some means (e.g., cooked, pasteurized, dried) to reduce the presence of

microorganisms, in particular pathogens identified as hazards requiring a preventive control, were subsequently exposed to the environment where they were recontaminated with pathogens. As discussed in the following sections on facility-related biological hazards, there are challenges to prevent this from happening.

Table 3-3 provides a list of examples, adapted in part from ICMSF Book 7, Chapter 11 (ICMSF, 2002) and from FDA documents that highlight the public health impact of contamination of RTE foods with environmental pathogens.

Table 3-3. Examples of Pathogens Identified from Outbreaks Attributed to Contamination with Environmental Pathogens

Product	Environmental Pathogen	Details	Reference
Chocolate	*S.* Napoli	Possibly contaminated water used in double-walled pipes, tanks and other equipment	Gill, *et. al.* (1983)
Chocolate	*S.* Eastbourne	From processing environment	Craven, *et. al.* (1975)
Butter (from pasteurized cream)	*L. monocytogenes*	From processing environment	Lyytikainen *et. al.* (2000)
Peanut butter	*S.* Tennessee	From processing environment	FDA (2007a, 2007b)
Peanut butter	*Salmonella* spp.	From processing environment	Cavallaro et al. (2011); FDA (2009b, 2009c)
Whole white pepper	*S.* Rissen	From processing environment	FDA (2009d)
Cantaloupes	*L. monocytogenes*	From processing environment	FDA (2012a)
Peanut butter	*S.* Bredeney	From processing environment	FDA (2012b)
Soft cheeses (from pasteurized milk)	*L. monocytogenes*	From processing environment	FDA (2013c)
Soft cheese (from pasteurized milk)	*L. monocytogenes*	From processing environment	FDA (2014a)

The PCHF requirements specify that your hazard evaluation must include an evaluation of environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. (See 21 CFR 117.130(c)(1)(ii).) Effectively designed and implemented CGMPs are key to keeping biological hazards out of your food products. However, experience has shown that application of CGMPs – even in combination with a HACCP plan - cannot guarantee that

contamination of a processed food from the environment will not occur. This is one reason why the PCHF requirements specify that sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens (21 CFR 117.135(c)(3)). In addition, the PCHF requirements specify that, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system, you must conduct activities that include environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples.

In the following sections, we provide information to help you determine whether an environmental pathogen is a hazard requiring a preventive control in your facility. Although Table 3-3 includes some examples of outbreaks of foodborne illness caused by facility-related biological hazards other than environmental pathogens, we do not discuss those other facility-related biological hazards in this chapter.

3.3.5.1 Sources of facility-related biological hazards

The likelihood of product contamination with a facility-related environmental pathogen increases as the prevalence of the environmental pathogens in the processing environment increases. The prevalence of the environmental pathogens in the processing environment can be influenced by the raw materials used in the process, the type of process, and the hygienic practices applied to keep to keep the processing area clean and hygienic. Table 3-4 is a quick reference guide to help you identify some of the most common sources for facility-related hazards that can contaminate the food processing environment; Table 3-4 does not provide an exhaustive list of such pathogens.

Table 3-4. Quick Reference Guide for Common Sources of Facility-Related Biological Hazards

Source	Examples
Raw agricultural commodities	• Raw milk • Cocoa beans • Fruits and vegetables • Nuts • Unprocessed spices
Food handlers and maintenance personnel	• Transfer of biological hazards from one point to another on, for example, shoes and other clothing • Improper hand washing • Transfer of biological hazards to foods through improper handling or maintenance practices
Air and water	• Lack of appropriate air filtration for cooling, drying, air conveying • Improper air flow from "raw" to RTE areas • Aerosols from improper cleaning practices
Insects and pests	• Flies • Cockroaches • Rodents

Source	Examples
Transport equipment	• Forklifts • Trolleys • Racks • Carts

With these varied sources for potential contamination, it is easy to understand how a failure of one or more steps in your CGMPs can lead to contamination of the processing environment and, ultimately, your food products with facility-related biological hazards.

3.3.5.2 Transient vs. resident facility-related environmental pathogens

Once bacterial pathogens have been introduced into the processing environment, experience has shown that pathogens may be present as "transient" contamination or "resident" contamination within the facility.

3.3.5.2.1 Transient contamination

Bacterial pathogens, including environmental pathogens, are typically introduced into the processing facility through, for example, incoming raw materials, personnel, or pests. It is important to ensure that these microorganisms remain transient and do not become established in the environment where they can grow and multiply. Transient contaminants can, however, result in a diversity of pathogens in the processing environment that can show up in the processing lines and finished product. This phenomenon is typical for food operations using a wide variety of ingredients, in particular raw commodities, because these materials can contain very diverse microflora. Generally though, the proper application of cleaning and sanitizing in accordance with CGMPs is adequate to control the transient bacteria in the processing facility. So, contamination detected from day-to-day may be found to be quite diverse.

3.3.5.2.2 Resident contamination

Bacterial pathogens causing resident contamination can also be introduced into the processing facility, where the pathogens then become established in a harborage site, multiply, and persist for extended periods of time, even years. A harborage site, or niche, is a site in the environment or on equipment (e.g., junctions, cracks, holes, and dead-end areas) that enables the accumulation of residues (food debris, dust, and water) and permits the growth of microorganisms such as *L. monocytogenes* and *Salmonella*. These sites may be difficult to inspect or access and therefore can protect environmental pathogens during routine cleaning and sanitizing. Thus, while common cleaning and sanitation practices are adequate to control the presence of transient contaminants, such practices do not control the presence of resident contaminants once they have become established. Sanitation controls, including proper personnel practices and equipment and facility design, are key to preventing transient bacterial pathogens from becoming resident strains. Once an environmental pathogen has become established as a "resident strain," there is a persistent contamination risk for foods processed in that facility. The facility will need to use intensified sanitation procedures to eliminate the contamination. Of all the bacterial pathogens, *Salmonella* and *L. monocytogenes* have the most extensive history of being able to set up residence in a processing facility. Although not as likely, the potential exists for the other pathogens discussed previously in this chapter to become established as resident contaminants.

Key determinants for the pathogens to become established in a food processing environment are: 1) The temperature at which the food processing environment is maintained; 2) the available moisture in the food processing environment; and 3) the availability of nutrients for growth. For processed foods, this typically translates into two primary categories of food processing environments by the nature of the products that are manufactured and packaged in a facility:

- Frozen/refrigerated and wet
- Warm/ambient and dry

In both cases, proper cleaning is needed to minimize nutrient availability. The pathogen most often associated with cold and wet processing environments is *L. monocytogenes,* and the pathogen most often associated with warm and dry processing environments is *Salmonella* (Scott et. al., 2009; ICMSF, 2005).

3.3.5.3 Facility-related environmental pathogens associated with wet vs. dry processing environments

Food processing operations can typically be classified into one of two simple categories – wet processing environments or dry processing environments (Table 3-5). This very simple distinction has significant implications for the strategy that must be applied to control food contamination from environmental pathogens.

Table 3-5. Some Examples of Foods Processed in Wet and Dry Processing Environments

Processing Environment Conditions	Examples of Foods
Wet	• Ice Cream • Refrigerated Dairy Products • Refrigerated Deli Salads • Refrigerated and Frozen Meals • Refrigerated Beverages (non-juice)
Dry	• Chocolate and Confections • Milk Powders • Baked Goods • Dehydrated Soups • Powdered Beverages • Nut/nut products

3.3.5.3.1 Wet process environments

The most effective strategy to prevent the contamination of finished products with *L. monocytogenes* is to maintain an environment as dry as possible. Wet environments have some very obvious characteristics that lead to problems with contamination by *L. monocytogenes*, such as:

- Wet floors due to constant wet cleaning will facilitate the transfer of *Listeria* spp., including *L. monocytogenes,* from an environmental source to food contact surfaces;
- Wet floors can create harborage sites if they are not well maintained and have broken/cracked grout or tiles. These structures may provide protected harborage to environmental pathogens even when the floors are cleaned and sanitized.
- Condensation on overhead structures as a result of air temperature and humidity control issues and from use of water in cooking and cooling operations creates a means of transfer of *Listeria* spp., including *L. monocytogenes,* from non-food-contact surfaces to exposed product and equipment food-contact surfaces.
- Frost formation due to condensation at freezer entry and exit points provides an opportunity for moisture accumulation and a constant source of water for *Listeria* spp. to multiply.
- Inadequate sanitation practices on floor freezer and cooler units may provide the moisture to support *Listeria* spp., including *L. monocytogenes,* if water sources are not properly plumbed to hygienically designed drains.

Wet floors can serve as vectors for spreading *Listeria* spp. via the movement of people and equipment and material handling items such as totes and pallets. Wet floors can also serve as vectors for pathogen transfer when personnel walk through standing water on poorly designed floors and drains and during cleaning. *L. monocytogenes* does not spread alone through the air; however, in wet environments, aerosols from high pressure water hoses used during cleaning operations help spread *L. monocytogenes* throughout the environment and from one surface (e.g., floors) to another surface (e.g., food contact surfaces, such as conveyors, tables, and product containers). In many facilities, certain processing operations are inherently wet, such as product debagging, raw material preparation, mixing and formulation of liquid product components, cooking, and blanching. In these cases, the best that can be done is to control the personnel, equipment traffic, and cleaning practices that are involved with the specific operation. The intent is to minimize water accumulation and aerosol formation to prevent in-process and finished product recontamination.

We recommend that wet processing areas be dried out as much as possible. This continues to be an ongoing challenge for the food industry that has for many years depended upon the unlimited use of water for equipment and facility cleaning practices.

3.3.5.3.2 Dry process environments

Moisture control is critically important in preventing *Salmonella* contamination in low-moisture products (ICMSF, 2005). Water in the dry processing environment is one of the most significant risk factors (perhaps the single most important factor) for *Salmonella* contamination, because water allows for pathogen growth, significantly increasing the risk for product contamination. Water, present even in very small amounts for short, sporadic time periods, may allow *Salmonella* to grow in the environment. At times, moisture is obvious in the form of water droplets or puddles from wet cleaning or from other not-so-apparent sources such as high relative humidity or moisture accumulating inside of equipment.

Salmonella can, to varying degrees, be introduced into low-moisture product manufacturing facilities and become established in those environments. Harborage sites may develop and become a source of product contamination, unless the sites are identified and eliminated (CAC, 2008).

Growth of *Salmonella* is only possible in the presence of water. Because food particles and dust are normally expected to be present in processing areas, adequate nutrients are always available to microorganisms. Growth cannot occur, however, if the plant environment is sufficiently dry. The potential *Salmonella* harborage sites become more important when water is present for a sufficient period of time. The presence of water in the dry processing environment can result from improper use of water during cleaning, which has been linked to the occurrence and spread of *Salmonella* (CAC, 2008). Other events resulting in the presence of water in a dry area include condensate formation, leaking water or steam valves, infiltration of water following heavy rains (e.g., leaky roofs) and the use of water showers in the case of fire emergencies. (CAC, 2008). We recommend that you remove water immediately from the primary *Salmonella*-controlled hygiene areas (areas where RTE food is exposed to the environment) following such events in order to keep the plant environment as dry as possible.

You should maintain dry conditions at all times in primary *Salmonella*-controlled hygiene areas, except for the occasions when you have determined that controlled wet cleaning is necessary. Potential problems arise when there is visible water present in the dry areas or when there are areas in which standing water has dried out. *Salmonella* may be found both in wet spots and in spots where standing water has dried (Zink, 2007). The latter situation may present an additional risk of spread via the generation of airborne contaminated dust.

3.4 Chemical Hazards

You must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable chemical hazards. See 21 CFR 117.130(b)(1)(ii). When your hazard analysis identifies a known or reasonably foreseeable chemical hazard that requires a preventive control, you must identify and implement a preventive control for the chemical hazard. See 21 CFR 117.135(a)(1).

The chemical hazards that are the focus of this section of this chapter include ingredient-related chemical hazards (i.e., pesticide and drug residues, heavy metals, environmental contaminants, histamine due to decomposition, natural toxins (e.g., mycotoxins), radiological hazards, unapproved food and color additives, food allergens, and substances associated with a food intolerance or food disorder) and process-related chemical hazards (i.e., food allergens, substances introduced by misformulation and the introduction of industrial chemicals or other contaminants from the food processing environment).

Food products can become contaminated with chemical hazards that are introduced at any stage in food production and processing. Some ingredient-related chemical hazards are natural components of food, such as food allergens, or are produced in the natural environment, such as mycotoxins, whereas other ingredient-related hazards (e.g., pesticides, drug residues, heavy metals, environmental contaminants) are contaminants of raw materials and other ingredients. Some process-related chemical hazards may be included in product formulation (e.g., sulfites that are a hazard for those consumers who are sensitive to them), whereas other process-related chemical hazards may be unintentionally introduced into food, such as industrial chemicals that are used in a facility for purposes other than food production. Process contaminants may also form during heating (e.g., acrylamide).[2] For further details on the

[2] Some processing contaminants are formed during the heating of certain ingredients or finished foods (e.g., acrylamide). We have not included such contaminants in Table 3-6 as potential process-related chemical hazards that may require a preventive control as part of a food safety plan under part 117 because we believe that more information is needed regarding appropriate levels and effective controls. As stated in our "Guidance for Industry: Acrylamide in Foods" (FDA, 2016a), we recommend that

sources of ingredient-related and process-related chemical hazards, see Tables 2A through 2Q and Tables 3A through 3Q of Appendix 1 of this guidance.

A chemical hazard may cause immediate effects, or may be associated with potential long-term effects after chronic exposure to the chemical. One example of an immediate effect is gastrointestinal illness such as nausea, which can be caused by elevated levels of industrial chemicals (such as caustic cleaning compounds). Caustic cleaning compounds can also cause burning of the mouth and esophagus. Ammonia in food contaminated by a refrigerant leak has caused gastrointestinal illness (stomachache and nausea) and headaches (Dworkin, et al. 2004). Sulfites have resulted in diarrhea, headache, difficulty breathing, vomiting, nausea, abdominal pain and cramps in sulfite-sensitive individuals (Timbo et al. 2004). Examples of long-term effects include impaired cognitive development in children chronically exposed to relatively low levels of lead (e.g., in contaminated candy) (FDA, 2006a) and liver cancer resulting from chronic exposure to the mycotoxin, aflatoxin (Williams et. al, 2004 and Shephard, 2008).

FDA has set action levels and tolerances for some contaminants (FDA, 2015f). They represent limits at or above which FDA will take legal action to remove products from the market. Where no established action level or tolerance exists, FDA may take legal action against the product at the minimal detectable level of the contaminant. Action levels and tolerances are established based on the unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. For example, FDA has established an action level of 3 ppm polychlorinated biphenyl (PCB) residues in red meat on a fat basis (FDA, 1987). FDA also has issued for public comment a draft guidance for industry that would, when finalized, establish an action level of 100 ppb for inorganic arsenic in infant rice cereal (FDA 2016). FDA has established tolerances for polychlorinated biphenyls (PCB's) in foods such as milk and other dairy products, poultry, eggs, and infant and junior foods (see 21 CFR 109.30).

Further, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), certain substances, such as food additives, color additives, new animal drugs, and pesticides require premarket approval before they may be legally used.

FDA also has issued guidances to provide information to industry on methods to reduce levels of specific chemicals in foods. For example, FDA has issued guidance providing information to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods (FDA, 2016a). Similarly, the Codex Alimentarius Commission has established a number of codes of practice for controlling mycotoxins, heavy metals, and other chemicals in foods (CAC, 2012).

Chemical residues in a food are not always considered hazards and their occurrence may be unavoidable. Because the particular chemical and its levels in the food determine whether it is a hazard, and because mechanisms whereby a chemical hazard can be introduced into a food product are both varied and dependent on the nature of the chemical, the preventive controls that you identify and implement to control specific chemical hazards should be based on the characteristics of those chemicals and the mechanisms whereby they could be introduced into your food product. In the following sections on chemical hazards, we describe some common preventive controls for controlling chemical hazards. For additional information on the control of

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manufacturers evaluate approaches to acrylamide reduction that may be relevant to their particular processes and consider adopting approaches, if feasible, that reduce acrylamide levels in their products.

chemical hazards, see Chapter 4 – Preventive Controls and Chapter 12 – Preventive Controls for Chemical Hazards.

In the remainder of this section on chemical hazards, we briefly describe characteristics of some chemical hazards that are of concern in foods and processing environments, including mechanisms whereby they can be introduced into a food product. We do not discuss seafood toxins in this guidance because seafood is exempt from the PCHF requirements; for a discussion of seafood toxins see our *Fish and Fishery Products Hazards and Controls Guidance* (FDA, 2011).

Table 3-6 is a quick reference guide to help you identify some of the most common sources of chemical hazards; Table 3-6 does not provide an exhaustive list of such hazards

Table 3-6. Quick Reference Guide for Common Sources of Chemical Hazards

Source	Examples
Ingredient-related chemical hazards	• Pesticide residues on produce raw agricultural commodities • Drug residues in milk • Heavy metals in or on produce raw agricultural commodities • Environmental contaminants (e.g., dioxins) • Mycotoxins in grains • Histamine in some aged cheeses • Radiological hazards in foods from areas after a nuclear accident • Unapproved food or color additives • Food allergens and substances associated with a food intolerance or food disorder (e.g., sulfites, gluten)
Process-related chemical hazards	• Undeclared food allergens due to mislabeling or cross-contact • Improper addition of substances associated with a food intolerance (e.g., sulfites) • Improper use of a color additive such as Yellow No. 5 • Contamination with industrial chemicals such as cleaners or sanitizers • Radiological hazards from use of contaminated water supply
Facility-related chemical hazards	• Heavy metals due to leaching from equipment, containers, or utensils

3.4.1 Ingredient-Related Chemical Hazards

3.4.1.1 Pesticides

Pesticide residues may be of concern in food crops and in foods of animal origin (as a result of pesticide residues in animal food). The term pesticide is used for products such as insecticides, fungicides, rodenticides, insect repellants, herbicides or weed killers, and some antimicrobials that are designed to prevent, destroy, repel, or reduce all types of pests (See EPA “Setting

Tolerances for Pesticide Residues in Foods") (EPA, 2015). Three federal government agencies share responsibility for the regulation of pesticides. Pesticides that have been registered (i.e., approved) with the U.S. Environmental Protection Agency (EPA) may be applied according to label directions directly to raw agricultural commodities or food (see 40 CFR 180). For a registered pesticide that could potentially result in residues in or on food, the EPA establishes a tolerance, which is the maximum amount of residue that is permitted in or on a food. FDA is responsible for enforcing pesticide tolerances for foods other than meat, poultry, and certain egg products, which are the responsibility of the U.S. Department of Agriculture Food Safety and Inspection Service (USDA FSIS) (FDA, 2012d). A detailed description of how FDA enforces pesticide residues in animal food is available in CPG Sec. 575.100 Pesticide Residues in Food and Feed – Enforcement Criteria (FDA, 2015e). If pesticide residues are present in food in the absence of, or in excess of, a tolerance, the food is deemed adulterated under section 402(a)(2)(B) of the FD&C Act (21 U.S.C. 342(a)(2)(B)). The most common reasons for adulteration of food products with pesticide residues are the improper treatment of raw materials with registered pesticides, and raw materials being exposed to prohibited pesticides.

Fruits and vegetables that have been grown in the United States usually are in compliance with EPA's pesticide tolerance regulations. If you obtain produce from a foreign country you should take steps to ensure that the imported produce will be in compliance with U.S. pesticide tolerance regulations, such as by considering pesticide residues to be chemical hazards that warrant preventive controls, such as supply-chain controls with a supplier verification program.

3.4.1.2 Animal drug residues

Animal drug residues may be of concern for foods of animal origin, including muscle meat, organ meat, fat/skin, eggs, honey, and milk. In the United States, animal drugs require approval by FDA before they can be administered to food-producing animals. Depending on the chemical property of the drug, residues of certain drugs can become concentrated during food manufacturing and processing. For example, if a fat-soluble, heat-stable drug residue is present in raw milk, the drug can get concentrated when the milk is converted to full fat cheese (Cerkvenik et al., 2004; Imperiale et al., 2004). Potential effects of drug residues range from short-term effects as a result of acute allergic reactions (e.g., penicillin) to long-term effects from drug resistant bacteria (Dayan, 1993). An example of an unapproved drug residue that has adulterated food is fluoroquinolone, which is an antibiotic that has not been approved for use on honey bees in the United States and has been detected in honey products from certain regions outside the United States (FDA, 2015a).

Drug residues in a food derived from an animal (such as milk) are considered a hazard if a tolerance has not been established for the particular drug-food combination, or if the tolerance level has been exceeded. Animal drugs used according to labeled directions should not result in residues in meat, poultry, milk, or egg products. When your hazard analysis identifies drug residues that require a preventive control, supply-chain controls with a supplier verification program could be an appropriate preventive control to manage the potential risk.

3.4.1.3 Heavy metals

Heavy metals, including lead, cadmium, arsenic, and mercury, may be of concern in certain foods as a result of agricultural practices (e.g., use of pesticides containing heavy metals or because crops are grown in soil containing elevated levels of heavy metals due to industrial waste), or the leaching of heavy metals from equipment, containers or utensils that come in contact with foods. Consumption of heavy metals in foods can lead to adverse health

consequences. For example, lead exposure can impair cognitive development in children (FDA, 2006a). Consumption of inorganic arsenic has been associated with cancer, skin lesions, developmental effects, cardiovascular disease, neurotoxicity, and diabetes in humans (JEFCA, 2010).

When your hazard analysis identifies a heavy metal that requires a preventive control, the type of control would depend on how the heavy metal could get into your food product. In some cases, high levels of heavy metals may result from the environment (e.g., high lead levels in carrots that were grown in lead-contaminated soil). If your food product contains a food crop that is known to have been contaminated with a heavy metal through contaminated soil, a preventive control such as a supply-chain control with a verification program to ensure that the grower conducts an assessment of the growing region prior to its use for agriculture may be appropriate. In other cases, an unsafe level of a heavy metal such as lead could be introduced into a food product as a result of a food-contact surface constructed with lead solder. CGMP controls, such as the controls on equipment and utensils in 21 CFR 117.40, generally can control chemical hazards such as heavy metals that can leach from food-contact surfaces.

3.4.1.4 Environmental contaminants

Environmental contaminants may be of concern in certain foods as a result of their presence in the environment. When your hazard analysis identifies an environmental contaminant that requires a preventive control, the type of control would depend on how the environmental contaminant could get into your food product. In some cases, high levels of environmental contaminants (e.g., dioxin) may result from accidental contamination of animal feed (WHO, 2014). In 2008, pork meat and pork products were recalled in Ireland when up to 200 times the safe limit of dioxins were detected in samples of pork, although risk assessments indicated no public health concern. The contamination was traced back to contaminated feed. In 1999, high levels of dioxins were found in poultry and eggs from Belgium and in several other countries. The cause was traced to animal feed contaminated with illegally disposed PCB-based waste industrial oil. Because dioxins tend to accumulate in the fat of food-producing animals, consumption of animal-derived foods (e.g., meat, poultry, eggs, fish, and dairy products) is considered to be the major route of human exposure, and FDA has developed a strategy for monitoring, method development, and reducing human exposure (FDA, 2002).

3.4.1.5 Mycotoxins and other natural toxins

Natural toxins, such as mycotoxins, histamines and other biogenic amines, and plant-produced substances (such as the toxin hypoglycin A found in the tropical fruit ackee) are well recognized as hazards in raw or processed agricultural commodities (FDA, 2005a; FDA 2005b; FDA, 2005c; FDA, 2005d).

Mycotoxins are a common group of natural toxins that include aflatoxin, fumonisin, deoxynivalenol (vomitoxin), ochratoxin, and patulin (see Table 3-7). Mycotoxins are toxic metabolites produced by certain fungi (i.e., molds) that can infect and proliferate on agricultural commodities (e.g., grains such as wheat and corn, peanuts, fruits, and tree nuts) in the field and during storage. Mycotoxins may produce various toxicological effects. Some mycotoxins are teratogenic, mutagenic, or carcinogenic in susceptible animal species and are associated with various diseases in domestic animals, livestock, and humans in many parts of the world. The occurrence of mycotoxins in human and animal foods is not entirely avoidable; small amounts of these toxins may be found on agricultural commodities. Occurrence of these toxins on commodities susceptible to mold infestation is influenced by environmental factors such as

temperature, humidity, and the extent of rainfall during the pre-harvesting, harvesting, and post-harvesting periods. The molds that produce mycotoxins typically grow and become established in the agricultural commodity during stressful growing and holding conditions, such as insect damage to the crop, drought stress, and wet storage (e.g., from condensation). Although mycotoxins are not a hazard requiring a preventive control during times and locations with good growing and harvest conditions, a preventive control such as supply-chain controls with a supplier verification program may be appropriate if you use agricultural commodities susceptible to mycotoxin formation, because growing and harvest conditions vary from year to year.

Table 3-7 Common Mycotoxins Associated with Commodities

Mycotoxins	Commodities Associated with Mycotoxins
Aflatoxin	Peanuts, dried corn, tree nuts
Ochratoxin	Coffee, raisins, cereal grains
Fumonisins	Dried corn
Deoxynivalenol	Wheat, barley
Patulin	Apples

Histamines and other biogenic amines are produced from the breakdown of amino acids by bacteria in animal-derived foods (e.g., histamine is produced from the amino acid histidine). Effects of foodborne histamines or other biogenic amines generally are acute effects, including headache, nausea, heart palpitations, facial flushing, itching, urticaria (hives), and gastrointestinal upset. Consumption of certain cheeses, especially aged cheeses, has been associated with illness from histamines (Taylor and WHO, 1985; Stratton et. al, 1991). If you determine that cheeses you use as a raw material present a histamine hazard, you must identify and implement a preventive control (see 21 CFR 117.135(a)). If you purchase such cheeses, we recommend a supply-chain control with a supplier verification program as well as temperature controls to minimize growth of histamine-producing microorganisms.

An example of a natural toxin produced by a plant is hypoglycin A, a heat stable toxin found in the tropical fruit ackee. The level of hypoglycin A in the edible portion of the ackee fruit decreases as the fruit ripens. Only properly ripened and processed ackee products with hypoglycin A at negligible levels are safe for consumption (FDA, 2015f). Although some persons consume unripe ackee with no adverse effects, other persons who consume unripe ackee with hypoglycin A exhibit symptoms that range from mild (e.g., vomiting) to severe (e.g., vomiting with profound hypoglycemia, drowsiness, muscular exhaustion, and possibly coma and death).

3.4.1.6 Chemical hazards that may be intentionally introduced for purposes of economic gain

The PCHF requirements specify that you must consider, as part of your hazard identification, known or reasonably foreseeable hazards that may be intentionally introduced for purposes of economic gain (21 CFR 117.130(b)(2)(iii)). We recommend that you focus on circumstances where there has been a pattern of such adulteration in the past, suggesting a potential for

intentional adulteration even though the past occurrences may not be associated with the specific supplier or the specific food product. Table 3-8 is a quick reference guide listing circumstances where there has been a pattern of such adulteration in the past. Additional resources include a free on-line food fraud database made available by the U.S. Pharmacopeial Convention (USP)[3] (USP, 2014 and USP, 2016), a report from the Congressional Research Service (Congressional Research Service, 2014), and a report that identifies 137 unique incidents in 11 food categories (Everstine et al., 2013).

Table 3-8. Quick Reference Guide for Hazards That May Be Intentionally Introduced for Purposes of Economic Gain

Food Containing the Hazard	Hazard	Details	Reference
Milk	Melamine	Milk firms in one country added melamine, a nitrogen-rich industrial by-product, to diluted dairy products to increase the apparent protein content	FDA, 2008
Turmeric	Lead chromate	A chemical with a vibrant yellow color that has been used as an adulterant in turmeric to change the color of the spice to suggest that it is of a higher quality	FDA, 2013d
Paprika	Lead oxide	A red chemical that has been used as an adulterant in paprika to change the color of the spice to suggest that it is of a higher quality	Lead Action News, 1995
Chili powder	Sudan I	An orange-red powder that had been added to chili powder as a coloring agent, but is now banned in many countries because the International Agency for Research on Cancer has classified it as a category 3 carcinogen (not classifiable as to its carcinogenicity to humans)	United Kingdom Food Standards Agency, 2005

In determining whether a hazard that may be intentionally introduced for purposes of economic gain is a hazard requiring a preventive control, we recommend that your hazard analysis consider both the country of origin of an ingredient that may contain the hazard and any specific supplier associated with an ingredient containing that hazard. For example, one example listed

[3] USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.

in Table 3-8 is a widespread incident of economically motivated adulteration in which some milk firms in one country added melamine, a nitrogen-rich industrial by-product, to diluted dairy products to increase the apparent protein content (FDA, 2008). This adulteration resulted in significant public health consequences, with more than 290,000 ill infants and 6 deaths in that country. In light of this incident, we recommend that you include in your hazard analysis the potential for melamine to be an economically motivated adulterant in your food products when using milk products from a country where melamine adulteration has occurred and, based on the outcome of that hazard analysis, determine whether melamine is a hazard that must be addressed in your food safety plan. At present, we do not expect you to consider the potential for melamine to be a significant hazard when using domestic milk products, or milk products from other countries when there is no history of melamine adulteration associated with those countries.

If you determine through your hazard analysis that a hazard that may be intentionally introduced for purposes of economic gain is a hazard requiring a preventive control, we recommend that you address that hazard through your supply-chain program.

3.4.2 Chemical Hazards That Can Be Either Ingredient-Related or Process-Related

3.4.2.1 Food allergens

Researchers estimate that up to 15 million Americans and more than 17 million Europeans have food allergies (FARE, 2015). A number of foods contain allergenic proteins, which are natural constituents of the food that can pose a health risk to certain sensitive individuals. The symptoms of food allergies can include a tingling sensation in the mouth, swelling of the tongue and throat, nausea, difficulty in breathing, chest pain, hives, rash, itchy skin, vomiting, abdominal cramps, diarrhea, sudden drop in blood pressure, loss of consciousness, and, in severe cases, death. Symptoms of a food allergy usually come on suddenly, can be triggered by a small amount of food, and happen every time the food is eaten. The symptoms are the result of the body's immune system reacting to a specific food or an ingredient in the food.

Allergic consumers must avoid allergens to prevent potentially life threatening reactions. Undeclared food allergens are chemical hazards that can get into food because either: (1) The food manufacturer did not properly declare a food allergen ingredient on the product label; or (2) unintended (and, thus, undeclared) food allergens are present in a food due to incorrect labeling or due to allergen cross-contact.

This section of this chapter provides a general discussion of food allergen hazards and common mechanisms to control them. For more detailed information, see Chapter 11 – Food Allergen Controls, which provides a comprehensive guide to food allergen control. An additional resource is "Managing Allergens in Food Processing Environments," a publication of the Grocery Manufacturer's Association (GMA, 2009).

3.4.2.1.1 The "Big Eight" food allergens

The Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004 amended the FD&C Act and defined the following eight foods and any ingredients that contain protein derived from these eight foods (with certain exemptions noted in section 201(qq)(2) of the FD&C Act (21

U.S.C. 321(qq)(2)) as major food allergens: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. The eight foods or food groups cause more than 90% of the food allergies in the United States (FDA, 2015c) and are commonly referred to as "the big eight" food allergens. FDA has published guidance on labeling the food allergens identified in FALCPA – See "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004" (FDA, 2006b). Immediately below, we provide more information about each of "the big eight food allergens."

- **Crustacea:** The class of Crustacea, or shellfish, includes shrimp, crab, lobster, and crayfish. Crab and shrimp are the most commonly consumed shellfish in the United States. The major shellfish allergen is tropomyosin, a muscle protein that accounts for 20% of the dry weight of shrimp (GMA, 2009).
- **Egg:** Most egg allergic proteins are found in the egg white (albumin) rather than the yolk.
- **Fish:** Different fish species (e.g., bass, cod, and flounder) have been found to have structurally-related proteins, and this may explain why individuals with a fish allergy are allergic to multiple types of fish. Cooking may reduce the allergenicity of fish, but it does not eliminate it.
- **Milk (Dairy):** Cow's milk contains a number of different proteins that are grouped into two categories: caseins, which constitute 80% of the total protein, and whey proteins, which make up 20%.
- **Peanut:** Peanut seeds contain an average of about 29% protein, classified as albumins or globulins.
- **Soy:** Globulins are the major proteins in soybeans.
- **Tree Nuts:** Tree nuts include almonds, Brazil nuts, cashews, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts. FDA lists the nuts considered "tree nuts" in its 2006 "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4)" (FDA, 2006b) and its 2013 Guidance for Industry: A Food Labeling Guide (FDA, 2013a).
- **Wheat:** Wheat proteins include the globulins, prolamins (i.e., glutenin and gliadin), and glutelins. About 25% of wheat-allergic children react to other cereal grains (i.e., barley, oats, or rye). Gluten is a mixture of proteins that occur naturally in wheat, rye, barley and crossbreeds of these grains. It is associated with celiac disease, which affects as many as 3 million people in the United States by the body's natural defense system attacking the lining of the small intestine and preventing the proper absorption of nutrients (FDA, 2015(d)).

3.4.2.1.2 Undeclared food allergen hazards due to incorrect label design

FALCPA also amended section 403 of the FD&C Act (21 U.S.C. 343) to prescribe certain requirements for what you must declare on the product label for any food product that contains any of the "big eight allergens," including allergenic whole foods (such as milk) and any ingredients that contain protein derived from these foods (such as casein derived from milk). See section 403(w) of the FD&C Act (21 U.S.C. 343(w)) and our guidance entitled "Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004" (FDA, 2006b).

An undeclared food allergen (including a food allergen contained in flavorings, colorings, and incidental additives) due to an incorrect label design that does not address all of the labeling requirements of FALCPA is a chemical hazard. See 21 CFR 117.130(b)(1)(ii).

3.4.2.1.3 Undeclared food allergen hazards due to incorrect application or use of a product label

If you apply the wrong label to a food, or use the wrong packaging (e.g., using packaging for "chocolate ice cream" rather than for "chocolate ice cream with almonds"), consumers who have a food allergy could purchase a food that would cause an allergic reaction. An undeclared food allergen due to applying the incorrect food label to a product, or using the wrong packaging, is a chemical hazard. See 21 CFR 117.130(b)(1)(ii).

3.4.2.1.4 Undeclared food allergen hazards due to allergen cross-contact

Cross-contact results from the unintentional incorporation of undeclared allergens into foods that are not intended to include those allergens. Cross-contact can occur either between foods that contain different food allergens or between foods with and without food allergens. Introduction of an allergen through cross-contact may occur during receiving, handling, processing and storage of ingredients and foods, utensils, and packaging; through improper handling and cleaning of equipment, utensils, and facilities; and through improper facility design.

An undeclared food allergen due to allergen cross-contact is a chemical hazard. See 21 CFR 117.130(b)(1)(ii). Allergen cross-contact can result from:

- Failure to schedule the production of two different products appropriately, resulting in an allergen-containing product contaminating a product without food allergens.
- Failure to adequately clean between two different formulations of a product that do and do not contain allergens, resulting in an allergen-containing product contaminating a product without the allergen.
- Failure to store allergen-containing ingredients separately from ingredients that do not contain allergens, where leakage of allergen-containing materials results in contamination of the non-allergen containing product.
- Failure to handle powdered allergens in a way that prevents particles from blowing onto foods or food contact surfaces for foods that do not contain that allergen.

3.4.2.2 Food additives, color additives, and GRAS substances, including substances associated with food intolerance or food disorder

Under sections 201(s) and 409 of the FD&C Act (21 U.S.C 321(s) and 348, respectively), a substance that is added to food requires premarket review and approval as a food additive unless it satisfies the statutory exclusion from the definition of "food additive" for a substance that is generally recognized as safe (GRAS) under the conditions of its intended use (section 201(s) of the FD&C Act or is otherwise excepted from the statutory definition of food additive (e.g., as a color additive, as a dietary ingredient intended for use in a dietary supplement, or as a new animal drug).

Under sections 201(t) and 721 of the FD&C Act (21 U.S.C 321(t) and 379(e), respectively), a color additive requires premarket review and approval; there is no statutory GRAS exclusion applicable to a color additive.

Generally, a food additive, color additive, or GRAS substance is known to be safe for use in food only under specific conditions of use, such as a maximum level of use or use only in certain food categories. The potential risk to consumers increases when these substances are not properly controlled, such as exceeding the usage rates or accidentally introducing an additive into a food for which it was not approved.

For some consumers, certain substances (including substances that are lawfully used in food as food additives, color additives, GRAS substances, and components of whole foods such as milk) can cause hypersensitivity reactions because the substance irritates the stomach, or the body cannot properly digest it. The symptoms include nausea, abdominal pain, diarrhea, vomiting, gas, cramps or bloating, heartburn, headaches, irritability, or nervousness. Symptoms of food intolerance usually occur gradually, in comparison with the sudden onset from an allergic reaction, and may only occur when a lot of a food is consumed or the food is consumed often.

- **Lactose:** Some people are intolerant to lactose, a sugar that is a component of milk, because they lack the enzyme to digest lactose. The symptoms include abdominal pain, diarrhea, vomiting, gas, cramps or bloating. People who have a lactose intolerance avoid milk or milk products and rely on the allergen labeling for milk to identify the types of products that may cause them problems.
- **Sulfiting agents:** Sulfiting agents are used as chemical preservatives in various products. People sensitive to sulfiting agents can experience symptoms that range from mild to life-threatening reactions. As noted previously, sulfites have resulted in diarrhea, headache, difficulty breathing, vomiting, nausea, abdominal pain and cramps in sulfite-sensitive individuals (Timbo et al. 2004).
- The sulfiting agents permitted in foods that must be listed on the ingredient label, unless they are added to food as an "incidental substance," are: sulfur dioxide (21 CFR 182.3862), sodium sulfite (21 CFR 182.3798), sodium bisulfite (21 CFR 182.3739), sodium metabisulfite (21 CFR 182.3766), potassium bisulfite (21 CFR 182.3616), and potassium metabisulfite (21 CFR 182.3637). Sulfiting agents are considered to be incidental only if they have no technical effect in the finished food and are present at less than 10 parts per million (ppm) (21 CFR 101.100(a)(4)). The quantity of sulfiting agents added to food should not exceed the amount necessary to achieve the intended technical effect(s).
- **Yellow No. 5:** Yellow No. 5 (tartrazine) is a color additive subject to color certification under section 721(c) of the FD&C Act. (21 U.S.C. 379e) People sensitive to Yellow No. 5 can experience symptoms that range from mild to moderately severe. For example hives occur in some intolerant individuals, but in asthmatic individuals Yellow No.5 can trigger allergic-type reactions (including bronchial asthma). To help protect people who are sensitive to Yellow No. 5, FDA's regulation for Yellow No. 5 states that any food for human use that contains Yellow No. 5 must specifically declare the presence of the color additive by listing it as an ingredient (21 CFR 74.705(d)(2)). If Yellow No. 5 is added but is not declared, the product would be both misbranded under section 403(m) of the FD&C Act (21 U.S.C. 343(m) and adulterated under section 402(c) of the FD&C Act (21 U.S.C 342(c)).
- **Cochineal extract and carmine:** Cochineal extract and carmine are color additives permitted for use in foods in the United States under conditions of safe use listed in 21 CFR 73.100. For sensitive consumers, cochineal extract and carmine can cause severe allergic reactions, including anaphylaxis (74 FR 207, January 5, 2009). Although the color additives cochineal extract and carmine cause allergic reactions, they are not included in the eight

major food allergens identified in FALCPA. As a result, the color additives cochineal extract and carmine are not included in the definition of "food allergen" in part 117 and are not subject to the food allergen controls specified in the PCHF requirements. In addition, FDA's specific labeling requirement in the color additive listing for cochineal extract and carmine (21 CFR 73.100(d)(2)), rather than the more general labeling requirements of FALCPA, govern the food labeling requirements cochineal extract and carmine. All human foods containing cochineal extract or carmine are required to declare the presence of the color additive by listing its respective common or usual name, "cochineal extract" or "carmine," in the statement of ingredients ((21 CFR 73.100(d)(2)). Additional information on the labeling requirements for these two color additives can be found in FDA industry guidance, *Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products That Contain These Color Additives; Small Entity Compliance Guide* (FDA, 2009a). Control strategies for cochineal extract and carmine are similar to those applied to food allergen labeling controls.

In addition, some consumers have celiac disease, which is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain storage proteins (referred to as gluten) occurring in wheat, rye, barley, and crossbreeds of these grains. As discussed in section 3.4.2.1.1 of this chapter, celiac disease affects as many as 3 million people in the United States (FDA, 2015(d)).

3.4.2.2.1 Unapproved food additives and color additives

A substance (other than a food contact substance subject to a notification under section 409(h)) that is a food additive or a color additive must be used in accordance with a food additive regulation permitting that specific use or a color additive listing. Otherwise, the presence of that substance in food would make the food adulterated under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)). Under the PCHF requirements, an unapproved food or color additive is a chemical hazard (see 21 CFR 117.130(b)(1)(ii)).

Some food and color additives are specifically prohibited from use in food because we have determined that the chemical additive poses a potential risk to public health (see 21 CFR part 189 and 21 CFR 81.10). Examples of such food and color additives are coumarin, safrole, and FD&C Red No. 4 (Red No. 4) (FDA, 2015b). We consider a prohibited food additive or color additive to be an unapproved food additive or color additive for the purposes of the PCHF requirements and, thus, to be a chemical hazard. You should consult 21 CFR if you have questions about the regulatory status or safety of a particular additive when formulating your food products. An additional resource for you is the *Food Additive Status List* on our website (FDA, 2014b).

3.4.2.2.2 Chemical hazards due to misformulation

A food ingredient can be a chemical hazard if it is added in excess of a maximum use level, regardless of whether the maximum use level is established due to food intolerance (such as for sulfites) or is otherwise a condition of safe use of a food additive, color additive, or GRAS substance. Control strategies to prevent misformulation of substances generally include process controls to ensure that excessive amounts are not added.

3.4.2.2.3 Chemical hazards due to incorrect labeling of substances associated with food intolerance or food disorder

Although the mechanisms whereby persons experience food intolerance or food disorder are different from the mechanisms that cause food allergy, reactions due to food intolerance or food disorder can cause significant health problems for those affected, and the principal means that consumers have to avoid the symptoms of food intolerance are the same means that consumers use to avoid symptoms of food allergy – i.e., avoid foods containing the substance that causes the problem. For example, people who are intolerant to lactose, a sugar that is a component of milk, avoid food products containing milk to avoid the symptoms associated with lactose intolerance. In addition, people who have celiac disease avoid food products containing wheat and other sources of gluten.

Undeclared substances associated with a food intolerance or food disorder are chemical hazards that can get into food because either: (1) The food manufacturer did not properly declare the substance on the product label; (2) unintended (and, thus, undeclared) substances are present in a food due to incorrect labeling. Control strategies to prevent incorrect labeling of substances associated with a food intolerance or food disorder are analogous to those used to prevent incorrect labeling of food allergens and, thus, you may find Chapter 11—Food Allergen Controls helpful in preventing incorrect labeling of substances associated with a food intolerance or food disorder. The preventive controls in that comprehensive guide to food allergen control do not explicitly address substances associated with food intolerance or food disorder, but may nonetheless be useful in addressing chemical hazards due to incorrect labeling of such substances.

3.4.2.3 Process contaminants produced during heating

There are several process-related contaminants that are produced during heating of specific ingredients or finished foods that may be a health (e.g., cancer) concern. For example, acrylamide is formed during high-temperature cooking processes (including frying, roasting, or baking) due to interaction between sugars and amino acids that are naturally present in foods. Acrylamide is found mainly in foods made from plants, including potato products, grain products, and coffee.

As noted in footnote 8, we have not included such contaminants in Table 3-6 as potential process-related chemical hazards that may require a preventive control as part of a food safety plan under part 117 because we believe that more information is needed regarding appropriate levels and effective controls. We have published a guidance document, *Guidance for Industry: Acrylamide in Foods* (FDA, 2016a) to help growers, manufacturers, and food service operators reduce acrylamide levels in certain foods. Control strategies to reduce acrylamide in food may include controlling temperatures during cooking and ingredient substitution.

3.4.2.4 Radiological hazards

Radiological hazards rarely occur in the food supply; however, when they do occur, these hazards can present a significant risk when exposures occur over a period of time (WHO, 2011). Consuming food contaminated with radionuclides will increase the amount of radioactivity a person is exposed to, which could have adverse health effects. The health effect depends on the radionuclide and the amount of radiation to which a person is exposed. For instance, exposure to certain levels of radioactive iodine is associated with increased risk of thyroid cancer (WHO, 2011).

Radiological hazards can become incorporated into food through the use of water that contains the radionuclides during food production or manufacture. There are areas in the United States where high concentrations of some radionuclides, such as radium-226, radium-228, and uranium, can be detected in well water (Ayotte et al., 2007; Focazio et al., 2001). You should be aware of the condition of the water used for production and manufacture in your facilities. For example, if your facility uses well water and there are elevated levels of radionuclides in the well water, you should not use the water. The CGMPs require that water that contacts food, food-contact surfaces, or food-packaging materials be safe and of adequate sanitary quality (see 21 CFR 117.37(a)).

Radiological hazards also may result from accidental contamination, e.g., contamination arising from accidental release from a nuclear facility or from damage to a nuclear facility from a natural disaster. In 2011, following damage to a nuclear power plant during an earthquake and tsunami in Japan, radioactivity was subsequently detected in foods, particularly milk, vegetables, and seafood produced in areas neighboring the plant (WHO, 2011). You should be vigilant regarding accidental releases of radiological hazards and their potential to contaminate your food product, either directly due to contamination of natural resources near your facility or as a result of raw materials and other ingredients that you obtain from a region that has experienced an accidental release of radiation.

3.4.3 Facility-Related Chemical Hazards

Industrial chemicals or other contaminants from the food processing environment can contaminate food during production – e.g., if chemicals used to clean a production line are not adequately removed from the production line or if heavy metals are leaching from containers or utensils. In this guidance, we do not discuss preventive controls for facility-related chemical hazards such as cleaning chemicals and the leaching of heavy metals from containers or utensils, because such hazards are usually addressed through CGMPs.

3.5 Physical Hazards

You must conduct a hazard analysis to identify and evaluate known or reasonably foreseeable physical hazards (such as stones, glass, and metal fragments). See 21 CFR 117.130(b)(1)(iii). When your hazard analysis identifies a known or reasonably foreseeable physical hazard that requires a preventive control, you must identify and implement a preventive control for the physical hazard. See 21 CFR 117.135(a)(1).

Physical hazards are broadly classified as “hard/sharp” physical hazards and “choking” hazards. Both categories can cause injury to the consumer. These injuries may include dental damage, laceration of the mouth or throat, laceration or perforation of the intestine, and choking and may even lead to the death. Because physical hazards cover a broad range of contaminants, such as glass, metal, plastic, wood, and stones, such contamination can occur throughout the processing facility, including the receiving dock for ingredients and supplies.

In this section of this guidance we describe common physical hazards – i.e., metal, glass, and hard plastic physical hazards.

- **Metal:** Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations, and some metal equipment has parts that can break or fall off, such as wire-mesh belts. FDA’s Health Hazard Evaluation Board (FDA, 2005e; Olsen, 1998) has

supported regulatory action against products with metal fragments of 0.3 inches (7 mm) to 1.0 inches (25 mm) in length. Such fragments have been shown to be a hazard to consumers. Metal hazards can be controlled by the use of metal detection devices or by regular inspection of at-risk equipment for signs of damage.

- **Glass:** Glass fragments can be introduced into food whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Ingesting glass fragments can cause injury to the consumer. FDA's Health Hazard Evaluation Board has supported regulatory action against products with glass fragments of the same size noted for metal. Most products packed in glass containers are intended to be a ready-to-eat (RTE) commodity. In your hazard analysis, you should consider the potential for glass fragments to originate from sources other than glass containers used in packaging. For example, some facilities that do not pack in glass prohibit the presence of glass in the production environment to reduce the risk of glass getting into the product. You can address glass fragments originating from sources such as overhead light fixtures through CGMPs.
- **Hard Plastic:** Hard plastic can be introduced into food when tools and equipment such as scoops, paddles, buckets or other containers develop fatigue, crack, and break as they wear. Hard plastic also can be introduced into food when plastic sieves and screens deteriorate. You should examine items to determine whether they are worn and remove worn items before they break, especially if they cannot be effectively cleaned (e.g., because of small cracks).

In general, there is overlap between facility-related physical hazards and process-related physical hazards. For example, equipment that has food-contact surfaces that break during food processing and result in physical debris being deposited in the food product can be considered a facility-related physical hazard (because the equipment is part of the facility) or a process-related physical hazard (because the equipment broke during processing). In general, in evaluating the potential for physical hazards in your food products, it does not matter whether you consider physical hazards to be facility-related or process-related. However, a few physical hazards can readily be classified as facility-related or process-related. For example, nuts and bolts used during maintenance procedures would be a facility-related hazard, but production equipment that has nuts and bolts that could fall out during production would be a process-related hazard.

Table 3-9 is a Quick Reference Guide to help you identify common sources of these physical hazards. See Chapter 13 – Preventive Controls for Physical Hazards for more detailed recommendations on control measures for physical hazards. In this guidance, we do not discuss ingredient-related physical hazards such as wood and stone, which are usually addressed through CGMPs or as a supply-chain control through your supplier program.

Table 3-9. Quick Reference Guide for Common Sources of Physical Hazards

Source	Metal – Ferrous & Non-ferrous	Plastic, Ceramic, and Glass	Other
Ingredient-related	• Farm field debris • Precut, ground, injected, sliced, items, where metal was not properly controlled by supplier.	• Farm field debris, • Packaging materials	• Pits or pit fragments, shells
Facility-related and process-related (processing/production environment, equipment, and pests (insects, birds, rodents, reptiles))	• Equipment • Grinders, slicers, knives • Sieves, screens, wire-mesh belts • Mixing paddles • Metal cans (shavings, lids) • Pumps • Cook Kettles with swept surface paddles • Drop buckets	• Equipment (inspection belts, small wares, buckets) • Facility (glass light fixtures, glass windows in doors, plastic strip curtains) • Glass containers • Scoops • Mixing paddles • Buckets	• Incomplete removal of pits or pit fragments, shells • Poor Design -- Particle size of food inappropriate for consumer – choking hazard
People-related (actions or behaviors)	• Jewelry • Hair pins	• Buttons • Zipper pulls	N/A

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 4: Preventive Controls

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 4 that we issued for public comment in August 2016.

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4.3.6 Use of Storage Conditions as a Process Control for Mycotoxins
4.3.7 Use of Physical Sorting as a Process Control for Mycotoxins
4.3.8 Use of Exclusion Strategies as a Process Control for Physical Hazards
4.3.8.1 Exclusion Strategies as a Process Control for Metal Hazards
4.3.8.2 Exclusion Strategies as a Process Control for Glass Hazards
4.4 Sanitation Controls
4.4.1 Use of Sanitation Controls for the Cleanliness of Food-Contact Surfaces
4.4.2 Use of Sanitation Controls to Prevent Allergen Cross-contact and Cross-contamination
4.5 Food Allergen Controls
4.6 Supply-chain Controls
4.6.1 Supply-chain Controls for Pesticides
4.6.2 Supply-chain Controls for Drug Residues
4.6.3 Heavy Metals
4.6.4 Supply-chain Controls for Mycotoxins
4.7 Recall Plan
4.8 References

4.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you identify and implement preventive controls. The PCHF requirements specify that you must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). (See 21 CFR 117.135(a)(1)). This chapter provides an overview of common preventive controls that you could use to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in food products and the food production environment when the outcome of your hazard analysis is that one or more of these hazards requires a preventive control.

The guidance in this chapter also is intended to help you monitor the preventive controls that you identify and implement. As appropriate to the nature of the preventive control and its role in the facility's food safety system, the PCHF requirements specify that you must establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control, and to monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. (See 21 CFR 117.145.)

This chapter does not provide all the details needed for identifying and implementing preventive controls. You have the flexibility to identify and implement preventive controls from among all procedures, practices, and processes that are available to you and that would provide assurances that the hazard is controlled (i.e., significantly minimized or prevented).

4.2 Overview of Preventive Controls

Part 117 defines "preventive controls" as 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 by the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. (See 21 CFR 117.3.) Preventive controls include: (1) Controls at critical control points (CCPs), if there are any CCPs; and (2) controls, other than those at CCPs, that are also appropriate for food safety (See 21 CFR 117.135(a)(2)). The PCHF requirements specify that preventive controls must be written. (See 21 CFR 117.135(b)).The PCHF requirements also specify that preventive controls must include, as appropriate to the facility and the food: (1) Process controls; (2) Food allergen controls; (3) Sanitation controls; (4) Supply-chain controls; (5) Recall plan; and (6) Other controls. (See 21 CFR 117.135(c)).

Table 4-1 lists the sections in this chapter in which we address process controls, sanitation controls, food allergen controls, supply-chain controls, and recall plans. Although Table 4-1 includes supply-chain controls, we intend to provide more information in our forthcoming "Chapter 15 - Supply-Chain Program for Human Food Products." See Chapters 6 through 14 of this guidance for more detailed discussion of applicable preventive controls.

Table 4-1. Preventive Controls Addressed in this Chapter

Preventive Control	Chapter Section
Process Controls	4.3
Sanitation Controls	4.4
Food Allergen Controls	4.5
Supply-chain Controls	4.6
Recall Plans	4.7

Table 4-2 lists the chapters in this guidance in which we provide additional details regarding certain preventive controls.

Table 4-2. Other Chapters in the Guidance With Additional Information About Specific Preventive Controls

Preventive Control	Chapter

Preventive Control	Chapter
Heat Treatment Process Control	6
Time/Temperature Control Process Control	7
Formulation Process Control (e.g., water activity, pH, and chemical preservatives)	8
Dehydration/Drying Process Control	9
Sanitation Controls	10
Food Allergen Controls	11
Preventive Controls for Chemical Hazards	12
Preventive Controls for Physical Hazards	13
Recall Plan	14

The PCHF requirements specify that you must validate that the preventive controls that you identify and implement are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system. (See 21 CFR 117.160(a)). The PCHF requirements also specify that validation of the preventive controls must be performed (or overseen) by a preventive controls qualified individual. (See 21 CFR 117.160(b) and the definition of a preventive controls qualified individual in 21 CFR 117.3.) You do not need to validate: (1) Food allergen controls; (2) sanitation controls; (3) the recall plan; and (4) the supply-chain program. You also do not need to validate other preventive controls, if the preventive controls qualified individual prepares (or oversees the preparation of) a written justification that validation of the other control is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system. (See 21 CFR 117.160(c).) We intend to discuss validation in "Chapter 16: Validation of a Process Control."

4.3 Process Controls

Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (1) Parameters associated with the control of the hazard; and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control. (See 21 CFR 117.135(c)(1).) Process controls do not include those procedures, practices, and processes that are not applied to the food itself, e.g., controls of personnel or the environment that may be used to significantly minimize or prevent hazards.

Examples of processing parameters that can have a minimum or maximum value (or combination of values) include time, temperature, flow rate, line speed, product bed depth, weight, product thickness or size, viscosity, moisture level, water activity, salt concentration, pH and others, depending upon the process. If a process parameter does not meet a minimum or maximum value (or critical limit), the process is not in control (i.e., a deviation has occurred) and the potential for producing a product that presents a consumer-health risk exists.

Many process controls, such as the application of heat to a food to adequately reduce pathogens, are applied in the same manner and for the same purpose as control measures established within HACCP plans and applied at CCPs as recommended by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1998) and the Codex Alimentarius Commission (CAC, 2003). When a process control is applied to a CCP in a HACCP plan, the maximum or minimum values (or combination of values) for the parameters associated with the control of the hazard are called "critical limits." Critical limits have been defined by the 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 (NACMCF, 1998).

In addition to this guidance, a number of sources of scientific and technical information can be useful in establishing process parameters or critical limits. Our guidance documents entitled "*Fish and Fishery Products Hazards and Controls Guidance*" and "*Juice HACCP Hazards and Controls Guidance*" each have information that can be broadly applied to food products. Other government agencies may also provide information through technical staff, regulations, guidelines, directives, performance standards, tolerances, and action levels. For example, the guidance documents entitled "Meat and Poultry Hazards and Controls Guide" (FSIS, 2005) and FSIS Compliance Guideline HACCP Systems Validation (FSIS, 2015), provided by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture, has information that can broadly be applied to food products, not just meat and poultry products subject to FSIS' jurisdiction. As another example, EPA lists maximum pesticide residues limits (MRLs) and tolerances in 40 CFR Part 180. (EPA, 2015) and provides Indexes to Part 180 Tolerance Information for Pesticide Chemicals in Food and Feed Commodities on its website (EPA, 2016). Trade associations, process authorities, industry scientists, university and extension scientists, and consultants can provide expertise and guidance. For example, the Grocery Manufacturer's Association (GMA) has provided guidance on Control of *Salmonella* in Low-Moisture Foods (GMA, 2009). Information can also be obtained from peer reviewed scientific literature. For a more comprehensive list of resources, see the training materials provided by the Food Safety Preventive Controls Alliance (FSPCA, 2016) In addition to (or in place of) information from such resources, you also can conduct scientific studies for specific products in-house, at a contract laboratory, or at a university to establish appropriate process parameters and associated values.

You should use care when applying information from any of these sources to processing parameters for a specific product and process. Among other reasons, there may be important differences between the application of processing parameters as discussed in these sources how you would apply the processing parameters to your specific product and process. The processing parameters and/or minimum or maximum values may need to be adjusted to account for those differences. For example, the temperature (and time at that temperature) necessary to kill microorganisms in a food product can depend on the fat level in that food product.

Table 4-3 lists examples of the application of process controls to significantly minimize or prevent ingredient-related and process-related biological, chemical, and physical hazards and the section in this chapter that addresses each listed example.

Table 4-3 Common Process Controls

Process Control Subcategory	Hazard Category	Examples	Chapter Section
Lethal Treatments	Biological	• Heat treatments (also called thermal treatments) (e.g., cooking, roasting, baking) • High Pressure Processing (HPP) • Irradiation • Antimicrobial fumigation (e.g., with polypropylene oxide (PPO))	4.3.1
Time/Temperature of Holding	Biological	• Refrigeration • Freezing	4.3.2
Formulation	Biological	• Reducing the water activity • Reducing the pH • Adding preservatives	4.3.3
Dehydration/Drying	Biological	• Air-drying (forced air and heating) • Freeze drying • Spray drying	4.3.4
Recipe Management	Chemical	• Controlling the maximum level of food ingredients	4.3.5
Storage Conditions	Chemical	• Controlling moisture during storage of raw agricultural commodities	4.3.6
Physical Sorting	Chemical	• Reducing mycotoxin content through sorting by color and physical damage in raw agricultural commodities	4.3.7
Exclusion of Metal and Glass	Physical	• Using magnets • Using metal detectors • Using sieves, screens • Using X-ray systems	4.3.8

4.3.1 Treatments lethal to biological hazards

We use the term “lethality treatment” when referring to a treatment that is used to kill/destroy or inactivate microorganisms. In general, when discussing bacterial pathogens in this document we use the terms “kill” or “destroy” when discussing treatments lethal to vegetative cells and we use the term “inactivate” when discussing treatments lethal to spores. Common lethality treatments include: (1) Heat treatments (e.g., cooking, boiling, pasteurizing, baking, frying); (2)

HPP; (3) irradiation; and (4) antimicrobial fumigation. We discuss each of these in the following sections of this chapter.

4.3.1.1 Use of Heat Treatment (Thermal Processing) as a Lethality Process Control

Heat treatment is a common lethality process control. Heat treatments generally fall into into the following two categories:

- Heat treatment that leads to commercial sterility: heat processing at high temperatures (> 212^{o}F (100°C)) under presssure with the objective of killing all forms of microorganisms, including the spores of bacteria. The treated products are shelf-stable without refrigeration. (Lower temperatures can lead to products that are shelf-stable in some cases, e.g., when the pH is low enough to prevent growth of surviving sporeformers.)
- Heat treatment that reduces microbial pathogens but does not lead to commercial sterility: heat processing at lower temperatures (e.g., 158°F (70°C) to 212°F (100°C)), with the processes designed to kill the vegetative forms of microorganisms with little to no effect on the spores of bacteria. The treated products are not shelf-stable and require controls such as refrigeration to control spores of bacterial pathogens.

This chapter does not address heat treatments that lead to commercial sterility of "low-acid canned foods." Such treatments are subject to the requirements of 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; commonly called "Low-Acid Canned Foods (LACF)) because the microbial hazards in LACF are not subject to the requirements for hazard analysis and risk-based preventive controls. Note that although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as "cans," the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term (and its abbreviation, LACF) for the purposes of this guidance.

Pasteurization is an example of a lethal heat treatment that reduces microbial pathogens but does not lead to a shelf stable product. Pasteurization typically is applied to foods to kill non-sporeforming pathogens such as *Salmonella*, *Listeria monocytogenes*, and pathogenic strains of *E. coli.* One example is the pasteurization of grade "A" milk and milk products that is covered by the 2015 Pasteurized Milk Ordinance (PMO) (FDA, 2015a). This chapter does not address pasteurization of milk; if you pasteurize milk, you should refer to 21 CFR 1240.61 and the specific requirements in your jurisdiction.

<u>Thermal Destruction of Microorganisms</u>

To design a lethal heat treatment for use as a preventive control, you should have a basic understanding of thermobacteriology (i.e., the relationship between bacteria and heat), including two key types of data and information:

- The kinetics of thermal inactivation or destruction of microorganisms, known as thermal death time data and;
- The rate at which heating occurs within the food material, also known as heat transfer or heat penetration.

Immediately below, we describe basic concepts associated with thermal death time data and heat transfer/heat penetration. For a more extensive review of thermobacteriology, including

graphical representations of the relationship of D values and z values to Thermal Death Time, refer to Stumbo, Chapter 7 (1973).

Some terms and concepts used to describe the thermal destruction of microorganisms include:

- **TDT (Thermal Death Time)** is the time necessary to kill a given number of microorganisms at a specified temperature. The TDT is obtained by keeping temperature constant and measuring the time necessary to kill the amount of cells specified.
- **D Value** (the decimal reduction time) is the time required to kill 90% of the microorganisms. Another way of expressing this is the time required at a specific temperature and under specified conditions to reduce a microbial population by one decimal (see discussion below).
- **z Value** refers to the degrees in Farhenheit required for the thermal destruction curve to cross one log cycle (i.e., for reducing the D value by a factor of 10).

Food processing experts evaluate treatments intended to kill or inactivate pathogens in food in terms of "logs" of kill, where the term "log" is a shorthand expression of the mathematical term logarithm. A logarithm is the exponent of the power to which a base number must be raised to equal a given number. In thermobacteriology, the base number is usually 10. As an example, the number 100 = 10^2 where the base number is 10 and the exponent is 2. Because the exponent is 2, the number 100 = log 2. Likewise, the number 1000 = 10^3 = log 3. The important thing to understand is that each "log" of kill is capable of causing a tenfold reduction in the number of microorganisms that the treatment is designed to kill, i.e., the most resistant microorganism of public health significance.

The decimal reduction time (D) is used synonymously with "log" in the context of thermobacteriology. A 1-log or 1D process would be one that is capable of reducing the level of the most resistant pathogen of concern in the food by 10 fold, e.g., from 10,000 cells of the microorganism per gram of food to 1,000 cells of the microorganism per gram of food. Importantly, it is not possible to technically achieve a level of reduction to zero, or "no microorganisms"; instead, as a technical matter the probability of finding the organism becomes less likely as the magnitude of reduction increases. Thus, a 5-log reduction process would be one that is capable of reducing the level of the most resistant pathogen of concern in the food by 100,000 fold, e.g., from 10,000 cells of the microorganism per gram of food to a probability of 1 cell in 10 g of food.

Table 4-4 provides examples of how food processing experts would describe the effect of lethal heat treatments on microorganisms in foods using terms commonly associated with thermobacteriology.

Table 4-4. The concept of log reductions of microorganisms in foods

Initial number of the most resistant microorganism of public health significance per gram of food	Log reduction (also known as D)	Decrease in most resistant microorganism of public health significance per gram of food	Percent of change	Final number of bacteria per gram of food
10,000 or log 4[1]	1	10-fold	90%	1,000 or log 3
10,000 or log 4	2	10 X 10 = 100 fold	99%	100 or log 2
10,000 or log 4	3	10 X 10 X 10 = 1000-fold	99.9%	10 or log 1
10,000 or log 4	4	10 X 10 X 10 X 10 = 10,000-fold	99.99%	1 or log 0

Initial number of the most resistant microorganism of public health significance per gram of food	Log reduction (also known as D)	Decrease in most resistant microorganism of public health significance per gram of food	Percent of change	Final number of bacteria per gram of food
10,000 or log 4	5	10 X 10 X 10 X 10 X 10 = 100,000-fold	99.999%	0.1 or log -1[2]
10,000 or log 4	6	10 X 10 X 10 X 10 X 10 = 1,000,000-fold	99.9999%	0.01 or log -2

[1] Additional equivalent ways to express 10,000 include 10^4, 10^4, and 10E4
[2] Additional equivalent ways to express 0.1 include 10^{-1} or 1 in 10.

Relative Heat Resistance of Microorganisms

Some microorganisms are more resistant to heat than other microorganisms and, thus, the require more stringent heating conditions to kill or inactivate them. Table 4-5 shows the relative heat resistance of common types of microorganisms.

Table 4-5. Relative Heat Resistance of Microbial Forms

Resistance to Heat	Microbial Form
Highest	Bacterial Spores
Moderate	• Some Vegetative bacterial cells • Cysts of Parasites • Fungi, including fungal spores
Least	• Some vegetative bacterial cells • Viruses

As already noted, this chapter addresses relatively mild heat treatments that reduce microbial pathogens but do not lead to commercial sterility. These relatively mild heat treatments are used to reduce the number of vegetative cells of bacterial pathogens such as *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella,* and enteropathogenic *E. coli*, and the spores of non-proteolytic strains of *Clostridium botulinum* (*C. botulinum*) and *Bacillus cereus* (*B. cereus*). These processes are designed to ensure product safety by achieving a 6-log reduction (6D). For a more detailed review of the relative heat resistance of food pathogens in mildly heat processed foods, see Jay (1996), FDA (2000), and Farkas (2007).

Factors Affecting the Heat Resistance of Microorganisms

In addition to the inherent heat resistance of specific microorganisms (or life stages of microorganisms, such as the spore stage), other factors associated with foods (such as water activity, pH, salt content, fat, and protein) can affect the heat resistance of microorganisms. Table 4-6 lists the most common factors that you should consider when designing a heat treatment as a process preventive control.

Table 4-6. Factors That Influence the Heat Resistance of Microorganisms in Foods

Factor	Effect on Microbial Heat Resistance

Factor	Effect on Microbial Heat Resistance
Water	As the humidity or moisture goes down, in general the heat resistance increases
Fat	As the fat content increases, there is a general increase in heat resistance of some microorganisms
Salts	The effect of salt varies and depends on the kind of salt and concentration. Some salts that decease water activity appear to increase heat resistance of microorganisms while other salts that may increase water activity (e.g., Ca^{2+} and Mg^{2+}) appear to decrease heat resistance.
Carbohydrates	The presence of sugars can increase the heat resistance of microorganisms due in part to the decrease in water activity. However, the impact can be variable, particularly among sugars and sugar alcohols.
pH	Most microorganisms are more heat resistant near their optimum pH for growth. Generally, as the pH increases or decreases relative to this optimum pH, the microorganisms become more sensitive to heat.
Proteins	Proteins have a protective effect and, thus, increase the heat resistance of microorganisms.

Other factors that can influence the heat resistance of microorganisms include the numbers of organisms, the age of the microorganisms, the temperatures at which microbial growth occurs, the presence of inhibitory compounds, and the time-temperature combination utilized. For a comprehensive compilation of data and research on the effect of food factors on the heat resistance of food pathogens of public health concern, see ICMSF (1996).

Lethal Heat Treatments

Cooking:

Baking, boiling, roasting, steaming, and frying are conventional heating methods used for cooking a wide variety of foods (e.g., cereal-grain products, vegetables, soups, sauces, legumes, and assembled multi-component meals). Cooking is performed for two primary reasons: to make food palatable and to make it safe by eliminating vegetative pathogens such as *Salmonella*, *L. monocytogenes*, and enteropathogenic *E. coli*. This discussion focuses on the food safety aspects of the cooking methods.

You should design a cooking process to target heat resistant vegetative pathogens, such as *L. monocytogenes*. Typically, we recommend a thermal process that achieves a 5D to 7D reduction for most cooking treatments. However, if the expected initial microbial load is low, a less severe thermal process may be adequate. For cooking processes that target pathogenic sporeformers such as *C. botulinum* type E and non-proteolytic types B and F (i.e., 194°F (90°C)) for 10 min), generally a 6D reduction in the level of contamination is suitable.

Table 3-D in Appendix 3 of this document provides 6D process times for a range of cooking temperatures, with *L. monocytogenes* as the target pathogen. It is possible that higher levels of destruction may be necessary in some foods, e.g., if you expect especially high initial levels of the target pathogen.

Table 3-E in Appendix 3 of this document provides 6D process times for a range of heating temperatures, with non-proteolytic *C. botulinum* type B (the most heat-resistant form of non-proteolytic *C. botulinum*) as the target pathogen.

There are a variety of ways to control the application of these cooking processes depending upon the type of food and the method of delivery (e.g., boiling, steaming). For example, for liquid and semi-liquid food products that are batch-cooked in a cooking vessel such as a kettle agitated during the thermal process, the simplest way to control the process is to check the internal temperature of the product at the end of the designated cooking time (i.e., check the time-temperature parameters of the treatment). A dial thermometer with a long probe works quite well. If the temperature is taken at or near the center of the cooking vessel, it is reasonable to assume that all product in the cooking vessel is at or above that temperature, because foods processed in this manner generally heat by convection or forced convection. You can monitor a simple boiling heat process by visually observing and timing the boil. Usually, a temperature distribution study is performed to ensure that no point in the cooking vessel is at a lower temperature than the minimum value (or critical limit) for temperature required during the process.

Heating food with large particles, like vegetables in stews and some soups, occurs primarily by conduction, rather than by convection. Particle size and consistency can greatly affect the rate of heating at the center of the particle. You cannot control cooking processes for products with large particles by periodically checking the internal temperature of some of the product particles as they leave the cooker because you cannot verify that each particle reached the appropriate temperature for adequate time. Therefore, you should establish the process scientifically and validate it through a scientific study demonstrating that if the minimum/maximum values are met for all the critical factors (e.g., cooking temperature, time, particle size) all particles will receive an adequate heat treatment.

Normally, a study to validate a cooking process is performed by a person or group knowledgeable in the design of thermal processes to determine the critical parameters required for the heat process being applied to ensure that it delivers the desired reduction level (logs of kill, as described in section 4.3.1.1 of this chapter). A preventive controls qualified individual must conduct (or oversee) such a study. See 21 CFR 117.180(a). (Because it is common practice for these studies to be conducted by entities with special expertise in the area, the preventive controls qualified individual likely will oversee, rather than conduct, the study.) Once that study has been completed, the person conducting the study will provide a time and temperature for the processor to monitor during processing, as well as any other parameters that are critical to delivery of an adequate heat treatment, such as maximum particle size). You can then monitor the time and temperature of the heat process to effectively ensure that all product particles have achieved the desired internal temperature. It may also be necessary to monitor other factors of the product or the process, such as the internal temperature of the product before the start of the process--called the initial temperature (IT), particle size, or relative humidity, where they affect the rate of heating. These factors, and their limits, will be determined by the process design study.

For some products, such as soups or sauces, you may be able to monitor End-Point Internal Product Temperature (EPIPT), a measurement of the internal temperature of the product at the end of the heat process, instead of performing continuous time and temperature monitoring. This approach is suitable if you have conducted a scientific study to validate that the EPIPT that you have selected will provide an appropriate reduction (e.g., 6D) in the numbers of the target pathogen in the slowest heating unit or portion of product under the worst set of heating conditions covered by the scientific study. If you want to monitor EPIPT, you should:

- Conduct a temperature distribution study within the heating system to identify any cold spots;

- Conduct a heat penetration study that accounts for the slowest heating product under the worst case heating conditions covered by the scientific study; and
- Identify other critical factors of processing and/or packaging that affect the rate of product heating when scientifically establishing a heat process.

You should use the EPIPT as a monitoring technique only under those conditions that were evaluated by the scientific study, with those conditions identified as process parameters with minimum/maximum values (or critical limits) that are monitored as part of your process controls. See "Chapter 6 – Use of Heat Treatments as a Process Control" in this guidance for additional information about the EPIPT monitoring technique.

Other common forms of cooking that are used to produce commercially manufactured foods are baking and roasting. These are essentially the same unit operation because they both use heated air to alter the eating quality of foods. However, the term "baking" is usually used when heated air is applied to flour-based foods or fruits, and the term "roasting" is usually used when heated air is applied to meats, nuts, or vegetables. Baking and roasting operations use dry heat in gas-fired or electric ovens. For some products such as bakery products, the effectiveness of the dry heat in ovens is increased by the addition of steam for various cooking purposes. Cooking equipment may be batch-type or continuous. In a continuous system the food is moved through the cooking equipment by conveyor or auger systems. The methods of controlling and monitoring the time-temperature parameters of these types of cooking processes will vary depending upon whether it is batch-type or continuous process. See "Chapter 6 – Use of Heat Treatments as a Process Control" for an example using baking as a preventive control.

Emerging Technologies Based on Thermal Effects

Microwave, radio frequency, ohmic heating, and inductive heating are heat-based processes that can kill microorganisms by thermal effects. Microwave and radio frequency heating are based on the use of electromagnetic waves of certain frequencies to generate heat in a material through two mechanisms - dielectric and ionic. Ohmic heating is the process of passing electric currents (primarily alternating) through foods or other materials to heat them. The heating occurs in the form of internal energy generation within the material. Ohmic heating is distinguished from other electrical heating methods either by the presence of electrodes contacting the food (as opposed to microwave heating, where electrodes are absent), and depends on frequency of the current and waveform (typically sinusoidal). Inductive heating is a process of inducing electric currents within the food due to oscillating electromagnetic fields generated by electric coils.

For any of these heat-based processes, the magnitude of time/temperature history and the location of the cold points will determine the effect on microorganisms. The effectiveness of these processes also depends on water activity and pH of the product. Although the shape of the destruction or inactivation curves is expected to be similar to those in conventional heating, the intricacies of each of the technologies need special attention if you plan to use them for microbial destruction or inactivation. For instance, in microwave heating a number of factors influence the location of the cold points, such as the composition, shape, and size of the food, the microwave frequency, and the applicator design. The location of the coldest-point and time/temperature history can be predicted through simulation software, and we expect that food processors may be able to use these emerging technologies in the future.

For a detailed overview of these processing technologies, as well as alternative thermal processing techniques, see Sun (2005).

4.3.1.2 Use of High Pressure Processing (HPP) as a Lethality Process Control

The pressure processing of foods for preservation was studied as early as the end of the 19th century and the beginning of the 20th century in the United States by people like Hite (1899) and Bridgman (1912). However the potential microbiological effects of HPP were not recognized by the food industry until around 1985. HPP has recently received a great deal of attention in the food, pharmaceutical, and biotechnology industries. Japan has been a leader in this technology, producing products such as jams, jellies, fruit juices, and yogurt.

Microorganisms vary in their sensitivity to high pressure. If you plan to use HPP, you should consider the organism of concern, product characteristics and, whether the process is to result in product that is to be refrigerated or that will be shelf stable. Destruction of the microorganism is primarily caused by changes in the structure and permeability of the cell wall which causes fluids to be forced into the cell.

Bacterial spores are well established as the most pressure-resistant biological forms known. Spores resist inactivation by high pressure alone and most require the addition of heat or some other mechanism to achieve appropriate levels of destruction. *C. botulinum* is one of the most pressure-resistant and hazardous microorganisms, which is a challenge in the design of high-pressure processes. Because of this, the best candidates for HPP continue to be acid foods and foods that will be refrigerated following processing (which provide control of sporeformers).

High pressure processing of foods requires pressures of 400 to 700 MPa, or 4000 - 7000 bars (58,000 - 101,000 psig). The unit of measure frequently used for HPP in the food industry is the pascal (Pa) or megapascal (MPa, 1,000,000 Pa). Most commercial food industry applications use pressures in the range of 600 to 700 MPa.

High pressure processing requires very specialized and costly equipment. Currently foods using HPP are being processed by batch systems. For batch processing, the food is packaged in a flexible or semi-flexible package, prior to placing the product in the HPP system, where the product is placed into a chamber and immersed in water or some other pressurizing fluid, then subjected to the high pressure for a time of 1 - 20 minutes, depending on the temperature and pressure. The chamber would then be depressurized and the product removed. Applications and the feasibility for commercialization for other HPP systems such as semi-continuous, continuous, and pulsed HPP have been described elsewhere (FDA, 2000; Indrawati et al. 2003; Z. Berk, 2009).

For a detailed review of the application and use of HPP as a process control, see FDA (2000 and 2001) and Hogan et al. (2005).

4.3.1.3 Use of Irradiation as a Lethality Process Control

The application of radiation treatments to food for the purpose of improving safety (e.g. by reducing or eliminating pathogenic bacteria) or extending shelf life by (e.g. by reducing or eliminating spoilage microorganisms and insects) can use sources that have high enough energy levels to cause ionization (the creation of ions by expulsion of orbital electrons from atoms) or have lower energy levels that will not cause ionization. These are known as ionizing and non-ionizing radiation, respectively. The most commonly used form of radiation to treat foods as a lethality process control is ionizing radiation and the discussion in this section of this chapter focuses on ionizing radiation. Non-ionizing radiation in the form of lower energy

electromagnetic waves such as UV light and infrared heating can be used to treat foods similar to that described for microwaves, radio frequency, and ohmic heating in the section of this chapter entitled "Emerging Technologies Based on Thermal Effects" and will not be addressed here. For more information on the application of infrared (IR) radiation in food processing operations, see the review by Krishnamurthy et al. (2008). For more information on the application and use of UV light in food processing, see the discussion by FDA (2000, 2001).

FDA is responsible for regulating the sources of radiation that are used to irradiate food (21 CFR Part 179 Subpart B). Irradiation is considered a food additive in the United States and, as such, its use in foods requires premarket approval by FDA (21 CFR Part 179). There are three sources of ionizing radiation approved for use on foods (21 CFR 179.26):

- Gamma rays – emitted from radioactive forms of the element cobalt (Cobalt 60) or the element cesium (Cesium 137). Gamma radiation is also used routinely in medicine to sterilize medical and dental products and for the radiation treatment of cancer.
- X-rays – produced by reflecting a high-energy stream of electrons into food off a target substance (usually one of the heavy metals) using electron accelerators. X-rays are also widely used in medicine and industry to produce images of internal structures.
- Electron beam – (or e-beam) is similar to X-rays and is a stream of high-energy electrons propelled from an electron accelerator into food.

Some common terms that are used when describing the application of ionizing radiation in the treatment of foods are:

- Dose (absorbed) – The amount of energy absorbed per unit mass of irradiated material.
- D_{10} value – Amount of radiation required to reduce the population of a specific microorganism by 90% (one $\log_{10}$ cycle) under the stated conditions.
- Gray (Gy) - A unit of absorbed dose of ionizing radiation, equal to 1 joule/kg of absorbed energy.
- Electron volt (eV) – A unit of energy. One electron volt is the kinetic energy acquired by an electron in passing through a potential difference of one volt in a vacuum.

The primary reason food irradiation is used as a lethal process control is to inactivate pathogens and microorganisms that cause food spoilage (Farkas et al., 2014). The application of ionizing radiation damages DNA and very effectively inhibits DNA synthesis and further cell division in microorganisms that are exposed to these forms and levels of energy. The amount of radiation energy used to bring about the control of microorganisms varies according to the radiation resistance of the particular organism, which is often specific to the species level and the number or load of the microorganisms present.

Radiation treatment at doses of 2–7 kiloGray (kGy), depending on the source of radiation and the food, have been reported to effectively eliminate potentially pathogenic non-sporeforming bacteria, including both long-time recognized pathogens such as *Salmonella* and *S. aureus,* as well as more recently emerged pathogens such as *Campylobacter*, *L. monocytogenes* or *E. coli* O157:H7, from suspected food products (Farkas, 1998). As an example, Table 4-7 provides a summary of compiled data on the ranges of decimal reduction doses (D_{10} values) for the most important non-sporeforming pathogenic bacteria determined in various foods under various conditions.

Table 4-7. D_{10} Values (kGy) for Some Foodborne Non-sporeforming Pathogenic Bacteria

Bacteria	Non-frozen food	Frozen food
Vibrio spp.	0.02-0.14	0.04-0.44
Yersinia enterocolitica	0.04-0.21	0.20-0.39
Campylobacter jejuni	0.08-0.20	0.18-0.32
Aeromonas hydrophila	0.11-0.19	0.21-0.34
Shigella spp.	0.22-0.40	0.22-0.41
Escherichia coli O157:H7	0.24-0.43	0.30-0.98
Staphylococcus aureus	0.26-0.57	0.29-0.45
Salmonella spp.	0.18-0.92	0.37-1.28
Listeria monocytogenes	0.20-1.0	0.52-1.4

Adapted from Farkas et al., 2014

Bacterial spores are more resistant to irradiation than non-sporeforming bacteria. The spores of *C. botulinum* types A and B are particularly resistant.

For illustrative purposes, Table 4-8 lists the approved uses of ionizing radiation for application as a process control in food processing as of April, 2016. We adapted Table 4-8 from 21 CFR 179.26(b), which specifies the limitations on the approved uses of ionizing radiation for the treatment of food and includes uses for purposes other than as a process control. For example, 21 CFR 179.26(b) also specifies limitations on the use of ionizing radiation for use in disinfestation of arthropod pests in food. You should refer to 21 CFR 179.26 for the most current limitations on the approved uses for the treatment of food using ionizing radiation.

Table 4-8. Approved Uses for the Treatment of Food Using Ionizing Radiation

Use	Limitations
For control of *Trichinella spiralis* in pork carcasses or fresh, non-heat-processed cuts of pork carcasses	Minimum dose 0.3 kiloGray (kGy) (30 kilorad (krad)); maximum dose not to exceed 1 kGy (100 krad).
For microbial disinfection of dry or dehydrated enzyme preparations (including immobilized enzymes)	Not to exceed 10 kGy (1 megarad (Mrad)).
For microbial disinfection of the following dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends	Not to exceed 30 kGy (3 Mrad).

Use	Limitations
For control of food-borne pathogens in fresh (refrigerated or unrefrigerated) or frozen, uncooked poultry products that are: (1) Whole carcasses or disjointed portions (or other parts) of such carcasses that are "ready-to-cook poultry" within the meaning of 9 CFR 381.l(b) (with or without non-fluid seasoning; includes, e.g., ground poultry), or (2) mechanically separated poultry product (a finely comminuted ingredient produced by the mechanical deboning of poultry carcasses or parts of carcasses)	Not to exceed 4.5 kGy for non-frozen products; not to exceed 7.0 kGy for frozen products.
For the sterilization of frozen, packaged meats used solely in the National Aeronautics and Space Administration space flight programs	Minimum dose 44 kGy (4.4 Mrad). Packaging materials used need not comply with §179.25(c) provided that their use is otherwise permitted by applicable regulations in 21 CFR parts 174 through 186.
For control of foodborne pathogens in, and extension of the shelf-life of, refrigerated or frozen, uncooked products that are meat within the meaning of 9 CFR 301.2(rr), meat byproducts within the meaning of 9 CFR 301.2(tt), or meat food products within the meaning of 9 CFR 301.2(uu), with or without non-fluid seasoning, that are otherwise composed solely of intact or ground meat, meat byproducts, or both meat and meat byproducts	Not to exceed 4.5 kGy maximum for refrigerated products; not to exceed 7.0 kGy maximum for frozen products.
For control of *Salmonella* in fresh shell eggs.	Not to exceed 3.0 kGy.
For control of microbial pathogens on seeds for sprouting.	Not to exceed 8.0 kGy.
For the control of *Vibrio* bacteria and other foodborne microorganisms in or on fresh or frozen molluscan shellfish.	Not to exceed 5.5 kGy.
For control of food-borne pathogens and extension of shelf-life in fresh iceberg lettuce and fresh spinach.	Not to exceed 4.0 kGy.
For control of foodborne pathogens, and extension of shelf-life, in unrefrigerated (as well as refrigerated) uncooked meat, meat byproducts, and certain meat food products	Not to exceed 4.5 kGy.
For control of food-borne pathogens in, and extension of the shelf-life of, chilled or frozen raw, cooked, or partially cooked crustaceans or dried crustaceans (water activity less than 0.85), with or without spices, minerals, inorganic salts, citrates, citric acid, and/or calcium disodium EDTA	Not to exceed 6.0 kGy.

Adapted from 21 CFR Part 179.26(b)

For additional information on processes, application, and equipment used in the ionizing radiation treatment of foods see FDA (2004), Lacroix (2005), Fellows (2009a), Farkas and Mohacsi-Farkas (2011) and FDA (2015b).

4.3.1.4 Use of Antimicrobial Fumigation as a Lethality Process Control

In California, treatment processes for almonds must use technologies that have been determined to achieve a minimum 4-log reduction of *Salmonella* in almonds (see 7 CFR part 981, Almonds Grown in California). The Almond Board of California (ABC) has processes in place to review treatment processes for scientific adequacy. ABC has funded research projects demonstrating that fumigation with propylene oxide (PPO) (a registered fumigant in the United States for the reduction of bacteria, yeasts, and mold on raw nut meats) is an effective treatment for achieving a minimum 4-log reduction of *Salmonella* in almonds (ABC, 2008).

4.3.2 Use of Time-Temperature as a Process Control

Temperature is an essential factor that affects the growth of bacteria. Bacterial growth can occur over a wide range of temperatures from about 23°F (-5°C) to 194°F (90° C). Table 4-9 lists four types of bacteria based on their temperature growth ranges.

Table 4-9. Temperature Ranges for the Growth of Microorganisms

Group	Minimum Temperature °C (°F)	Optimum Temperature °C (°F)	Maximum Temperature °C (°F)
Thermophiles	40 - 45 (104 - 113)	55 - 75 (131 - 167)	60 - 90 (140 - 194)
Mesophiles	5 - 15 (41 - 59)	30 - 45 (86 - 113)	35 - 47 (95 - 117)
Psychrophiles	-5 - +5 (23 - 41)	12 - 15 (54 - 59)	15 - 20 (59 - 68)
Psychrotrophs	-5 - +5 (23 – 41)	25 - 30 (77 - 86)	30 - 35 (86 - 95)

Thermophiles grow at hot temperatures above 131°F (55°C). Mesophiles grow at or near room temperatures. Psychrophiles grow at or near refrigeration temperatures. Psychrotrophs are capable of growth at refrigeration temperatures, but their optimal growth temperature is in the mesophilic range.

Most pathogenic bacteria are mesophiles and their optimum growth temperature corresponds to human body temperature (see Table 3-A of Appendix 3 of this guidance). Typically, the higher the temperature (within the normal growth range), the more rapid the growth of the microorganism.

It is not only the temperature that is of concern; it is the total time of exposure at temperatures that allow growth that needs to be controlled. The most general recommendation is to hold cold foods below 41°F (5°C) and to keep hot foods above 135°F (57°C). However, in some situations it may not be possible to completely avoid product exposure to mesophilic temperatures.

4.3.2.1 Use of Refrigeration as a Time-Temperature Process Control

Refrigeration works well for controlling the growth of most pathogenic bacteria. However, some pathogens, like *L. monocytogenes* and *Yersinia enterocolitica*, can grow at temperatures close to freezing. Refrigeration has the added advantage of slowing down biological and chemical processes that result in spoilage, oxidative rancidity, and other quality defects.

Control of temperature during storage can be accomplished in several ways, such as ice, chemical coolant gel packs, and mechanical dry refrigeration (e.g., in a cooler).

Controlling temperature with ice or gel packs can be effective if there is an adequate amount of ice or gel packs. Therefore, you should monitor the control by checking whether an adequate amount of coolant is present on the product at all times, including when it is shipped and when it is received and checking the temperature of the food with a thermometer or temperature recording device.

For mechanical dry refrigerated storage in a cooler, if the ambient temperature can be related to the product temperature, monitoring the temperature of the storage area will ensure that the product temperature is under control. Ordinarily monitoring of the cooler requires use of continuous monitoring instruments such as recorder thermometer charts, maximum-indicating thermometers, and high temperature alarms.

Time/Temperature

When food is removed from refrigeration, the temperature of the food gradually increases and can reach the temperature associated with the growth range specific to particular pathogens. Bacterial pathogens go through a lag phase, where little or no growth occurs as the microorganisms adjust to their new environment. Depending upon the ambient temperature, it is possible that food can stay out of refrigeration for at least a couple of hours with no risk of significant pathogen growth. As the product temperature approaches the growth range, pathogens enter what is called the "log phase" (because they grow logarithmically). The object is to prevent that from happening, ideally keeping pathogens in their lag phase. We call the temperature range of concern (41°F (5°C) to 135°F (57°C)) the "danger zone."

Traditionally, the rule of thumb for foods that will support microbial growth has been no more than 4 hours in the danger zone (41°F (5°C) to 135°F (57°C)). Different pathogens have different rates of growth at different temperatures, and the rate of growth will be affected by the type of food and its inherent properties. Therefore, the actual maximum time that a product may be safely held in the danger zone depends on a number of factors, including the type of pathogens that are present and the ability of the food to support their growth. Guidance on this issue is available in the US Food Code[2] (FDA, 2013) and in Table 3-B in Appendix 3 of this document. You may set limits based on these factors or based on studies done on your own specific food products, rather than relying on the 4-hour rule of thumb. Food inspectors should also use these factors when they evaluate the significance of time - temperature abuse.

Control of time and temperature during processing may be more complicated than during storage, because it involves information about the time and temperature exposure of the product during production. You can obtain this information in a variety of ways, such as marking units of product and tracking how long they remain at unrefrigerated temperatures; monitoring the ambient temperature in a chill room operation; or monitoring product temperatures during different phases of production. See "Chapter 7 – Use of Time/Temperature Control as a Process Control" of this guidance for additional information about the application of time-temperature holding conditions.

Cooling after Cooking

Cooling after cooking can be a critical function influencing the safety of a food (FDA, 2013). Depending upon the food and ingredients, cooked foods can still have viable pathogenic bacteria present. For example, the spores of sporeforming pathogens such as *C. botulinum* can survive cooking processes. For non-sporeforming pathogens that are particularly heat tolerant (such as *L. monocytogenes*), vegetative cells can sometimes survive the cooking process; however, this should not be the case if you selected the appropriate target pathogen for control by the applied process and you validated the control. More often, it is the spores of

[2] The U.S. Food Code (FDA, 2013) is a model that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes). Local, state, tribal, and federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy. Although the target audience for the U.S. Food Code does not include most food processing facilities, the U.S. Food Code nonetheless contains scientifically-based information that you can use as a resource where appropriate in establishing some preventive controls particularly regarding use of refrigeration to control the growth of microbial pathogens.

sporeforming pathogens (such as *C. botulinum*) that survive the cooking process if they are present because temperatures that can only be achieved under pressure are usually needed to inactivate spores. These spores will begin to germinate when the product temperature drops to a temperature at which they can grow (usually below 135°F (57°C)) and will be present in the food during storage. Some spores, such as those from non-proteolytic *C. botulinum* and some strains of *B. cereus*, have the ability to germinate and grow at refrigeration temperatures, although long times are required. Other spores that may be present in the food remain dormant until the product is temperature-abused (i.e., held in the temperature range at which these pathogens can grow). In such an event, pathogenic spores are able to germinate, grow, and the resulting cells can possibly produce toxin due to the fact that most spoilage bacteria (which may otherwise compete for growth) have been eliminated by the cooking process. For further discussion on the importance of cooling food after cooking see Factors that Influence Microbial Growth (Chapter 3 in the Evaluation and Definition of Potentially Hazardous Foods) (FDA, 2001).

If the cooking process is adequate to inactivate spores and the product is protected from recontamination during cooling, the cooling step will not be critical. Situations where these conditions exist are probably limited to certain pressurized steam processes.

Simply putting food in a refrigerator is not adequate to prevent microbiological growth. When large volumes of hot food are cooled, it can take a long time, sometimes as long as 36 hours, to chill the food to a point where pathogen growth is inhibited. The U.S. Food Code specifies the application of a two part cooling protocol In order to cool foods safely and keep bacteria in the lag phase. First, drop the temperature from 135°F (57°C) to 70°F (21°C) within two hours. The temperature must be lowered through this range quickly because foodborne pathogens multiply most rapidly between these temperatures. Second, after dropping the initial temperature to 70°F (21°C), you can take up to additional 4 hours to get the product down to 41°F (5°C). FSIS also recommends a two part cooling for meat and poultry, but uses slightly different temperatures: “temperature should not remain between 130°F (54°C) and 80°F (27°C) for more than 1.5 hours nor between 80°F (27°C) and 40°F (4°C) for more than 5 hours” (FSIS, 1999). Both these protocols are adequate to minimize the potential for growth of foodborne pathogens.

A blast freezer is one of the best cooling methods. High velocity cold air can drop the temperature of large volumes of hot food in less than an hour. The containers of food that have been chilled can then be shifted to a holding cooler.

Cooling tunnels and spiral freezers are similar to blast freezers but are more compatible with moving production lines. They use high velocity cold air, or liquid carbon dioxide or nitrogen for rapid cooling. Products may be frozen before or after packaging depending upon the product and package size.

Heat exchangers are used for cooling liquids like milk and juice after pasteurization. Lines containing a coolant such as water or cold, raw product run adjacent to lines of hot, pasteurized product. No actual exchange or co-mingling of coolant or raw product with heat-treated product occurs. However, the cold raw liquid, for example, picks up heat from the hot, pasteurized juice. This helps preheat the raw product and also helps precool the heat-treated liquid. See “Chapter 6 – Use of Heat Treatments as a Process Control” in this guidance for additional information about heat exchangers.

Cook-chill operations are typically used in large institutional settings such as prisons, hospitals, and schools as well as in food processing plants. Food is cooked in nylon reinforced plastic

bags or is cooked and then pumped into these bags. The bags are chilled in a tumble chiller that tumbles the bags in ice water. This drops the temperature of large volumes of hot food quickly. Typically, an ice tank where coils of refrigerant are run through the tank of water provides the large volume of cold water needed.

Be advised that food can be recontaminated during the cooling process as a result of hand contact, condensate drip, or contact with other foods. See "Chapter 10 – Sanitation Controls" in this guidance for additional information about controlling the risk of recontamination.

4.3.2.2 Use of Freezing as a Time-Temperature Process Control

Foods are microbiologically stable when held at temperatures below 17.6^{o}F (-8^{o}C). During frozen storage, populations of viable microorganisms in most foods will decrease; however, some microorganisms remain viable for long periods of time during frozen storage. Most viruses, bacterial spores, and some bacterial vegetative cells survive freezing unchanged. Some of the other microorganisms are sensitive to the freezing and thawing process (i.e., freezing, frozen storage, or thawing). Since multi-celled organisms (such as such as parasitic protozoa, nematodes, and trematodes) are generally more sensitive to low temperatures than are bacteria; freezing and frozen storage are good methods for killing these organisms in various foods. This is especially important if consumers are likely to eat the foods raw or undercooked. See Kennedy (2003) and Fellows (2009b) for a detailed review on the use of freezing technologies in the preservation of foods.

4.3.3 Use of Product Formulation as a Process Control

Most food preservation techniques used by processors employ knowledge of factors (such as water activity, pH, temperature, nutrients, chemical inhibitors, competitive microflora, and atmosphere) that affect the growth of bacteria. For more information on how these factors affect microbial growth, see International Commission on Microbiological Specifications for Foods (ICMSF) (1996, 2002), Jay (1996), and Zeuthen and Bogh-Sorensen (2003).

In this section of this chapter, we discuss two key factors that are frequently used as a formulation process control – i.e., water activity and pH. We also discuss the use of preservatives as a formulation process control.

4.3.3.1 Use of Water activity (a_w) as a Formulation Process Control

Microorganisms need water to survive as well as to grow. Water activity (a_w) refers to the availability of water to the organism. In general, microorganisms survive and grow better when the water activity is high than when the water activity is low.

If you have a closed container of water, the air over the water becomes saturated with water. The relative humidity is 100%, which equals a water activity of 1.0. Thus, water has a water activity of 1.0. Foods are more complex systems than water, and the water can bind to components of the food so not all the water in the food is available to microorganisms; thus, the water activity of most food products is less than 1.0.

Water activity is directly related to the vapor pressure of the water in a solution. You can determine water activity by measuring the equilibrium relative humidity of the air over the solution in a closed container. Relative humidity divided by 100 equals the water activity:

$$(a_w) = RH/100$$
or
$$a_w = p/p_o$$

Foods vary in their water activity as shown in Table 4-10. Although you can measure the water activity of your specific food if you have the appropriate equipment, for many purposes you can rely on the water activity values shown in Table 4-10.

Table 4-10. Principal Groups of Foods Based on Water Activity (a_w) (ICMSF, 1980)

Water Activity	Food Groups
0.98 and above	• Fresh meats and fish • Fresh fruits and vegetables • Milk and other beverages • Canned vegetables in brine • Canned fruit in light syrup
Below 0.98 to 0.93	• Evaporated milk • Tomato paste • Lightly salted pork and beef products • Canned cured meats • Fermented sausages (not dried) • Cooked sausages • Processed cheese • Gouda cheese • Canned fruits in heavy syrup • Bread
Below 0.93 to 0.85	• Dry or fermented sausage • Dried venison • Cheddar cheese • Sweetened condensed milk
Below 0.85 to 0.60	• Intermediate moisture foods • Dried fruits • Flour • Cereals • Jam and jellies • Molasses • Heavily salted fish • Meat extract • Nuts
Below 0.60	• Confectionery • Chocolate • Honey • Dried Noodles • Crackers • Potato Chips • Dried egg, milk and vegetables

Table 4-10 organizes the foods into five categories, based on their water activity. Table 4-11 further classifies these five categories into three categories – i.e., moist foods, intermediate-moisture foods (often included in the low-moisture foods category), and low-moisture foods. Moist foods (i.e., foods with water activity above 0.85) require refrigeration or another barrier to control the growth of pathogens (see Table 4-11). Intermediate-moisture foods (i.e., foods with water activities between 0.60 and 0.85) do not require refrigeration to control pathogens, but they may have a limited shelf life because of spoilage, primarily by yeast and mold. The microbiological stability of intermediate-moisture foods may depend on factors other than water activity, such as reduced pH, chemical preservatives, heat treatments, or combinations of these, even though the reduced water activity is of major importance. Low-moisture foods (i.e., foods with a water activity below 0.60) have an extended shelf life, even without refrigeration.

Table 4-11. Classification of Foods and Control Requirements Based on Water Activity

Water Activity	Classification	Requirements for Control
Above 0.85	Moist Foods	Require refrigeration or another barrier to control the growth of pathogens
0.60 and 0.85	Intermediate-Moisture Foods	• Do not require refrigeration to control pathogens • Limited shelf life because of spoilage, primarily by yeast & mold
Below 0.60	Low-Moisture Foods	Extended shelf life, even without refrigeration

See Table 4-12 for some examples of moist foods (water activities above 0.85). Most fresh meats, fruits, and vegetables, and many dairy products, fall into this category. The big surprise here is probably the bread. Most of us tend to think it is a dry, shelf-stable product. Actually, the "crumb" (interior) has a relatively high water activity. It is safe because of the multiple barriers of pH, water activity (the crust has a low water activity), and preferential growth by mold rather than pathogens. In other words, the bread spoils before it becomes hazardous.

Table 4-12. Examples of High Moisture (High Water Activity (a_w)) Foods

Moist Foods	Water Activity (a_w)
Lettuce	0.99
Apples	0.99
Milk	0.98
Bread	0.95

See Table 4-13 for some examples of intermediate-moisture foods (water activity between 0.60 and 0.85). Some unique products like soy sauce appear to be a high moisture product, but actually are in the intermediate-moisture category because salt, sugars or other ingredients bind the moisture. Because jams and jellies have a water activity that will support the growth of yeast and mold, they are mildly heat-treated immediately before packaging to prevent spoilage.

Table 4-13. Examples of Intermediate Moisture Foods

Intermediate Moisture Foods	Water Activity (a_w)
Soy sauce	0.80
Jams	0.80
Molasses	0.76
Honey	0.75
Flour	0.70
Dried fruit	0.70
Candies	0.65

See Table 4-14 for some examples of low-moisture foods (water activity below 0.60).

Table 4-14. Examples of Low-Moisture Foods

Low-Moisture Foods	Water Activity (a_w)
Dried noodles	0.50
Cookies	0.30
RTE Cereals	0.20
Crackers	0.10

Some of the intermediate and low water activity foods have naturally low water activity (e.g., molasses and flour). We do not discuss those foods because water activity does not have to be controlled during processing.

Other intermediate and low water activity foods, like dried fruit, strawberry jam, crackers, soy sauce, and dried noodles, start with a high water activity and, through processing, end up with a reduced water activity. This section of this chapter focuses on these types of foods.

Control of Water Activity

Some products require careful control of water activity for food safety, while others do not. For example, the production of jam does not need careful control of water activity for food safety because the food would not thicken (and, thus, become jam) unless the water activity was reduced through the addition of the necessary amount of sugar. On the other hand, dried fruit products need careful control of water activity for food safety, because fruit products with a variety of moisture levels could still appear to be "dried fruit."

There are two primary ways of reducing water activity in foods: (1) product formulation (such as by adding salt or sugar); and (2) dehydration (drying). In this section of this chapter, we discuss reducing water activity by product formulation. In section 4.3.4 of this document, we discuss reducing water activity by dehydration.

Every organism has a minimum, optimum, and maximum water activity for growth (see Table 3-A in Appendix 3 of this document). Yeasts and molds can grow at low water activity; however 0.85 is considered the safe cutoff level for pathogen growth. Water activity of 0.85 is based on the minimum water activity for *S. aureus* growth. For a detailed discussion and listing of the minimal water activities for microorganisms of public health concern, see ICMSF (1996).

There are two basic ways for how you can approach product formulation that uses control of water activity for food safety. One approach is to closely follow a scientifically established process for formulation that ensures a water activity of 0.85 or below. The other approach is to develop your own process for formulation and to validate it by taking finished product samples and testing them for water activity.

4.3.3.2 Use of Acidity (pH) as a Formulation Process Control

The term "pH" refers to a numeric scale used to describe acidity and alkalinity. The pH reflects the concentration of hydrogen ions and is expressed mathematically as the negative logarithm of the hydrogen ion concentration. The pH scale ranges from 0 to 14, with 7 being neutral.

pH = (-log of the [H+])

Microorganisms can only grow at certain pH levels (Table 4-15). Table 4-15 shows that mold and yeast can grow over a broad range of pH, including very low pH. Table 4-15 also shows that the pH range where bacteria can grow is more restricted in that bacteria don't grow at very low pH.

Table 4-15. Growth Limiting pH Ranges for Microorganisms

Type of Microorganism	pH Range for Growth
Bacteria (Gram+)	4.0 to 8.5
Bacteria (Gram -)	4.5 to 9.0
Molds	1.5 to 9.0
Yeast	2.0 to 8.5

Table 4-15 classifies bacteria as "Gram positive" and "Gram negative." In general, "Gram positive" and "Gram negative" are designations associated with the cell walls of bacteria, and how the bacterial cell walls appear under a microscope when a stain is used to see them. Gram positive bacteria appear blue, and gram negative bacteria appear red.

Lowering the pH is considered primarily a method of inhibiting the growth of bacteria rather than a method for killing bacteria. Although many microorganisms held at low pH for an extended time will be killed, keep in mind that some pathogenic bacteria, and in particular *E. coli* O157:H7, can survive acidic conditions for extended periods of time, even if their growth is inhibited. For details on the minimum and maximum pH limits for bacterial pathogens, see Table 3-A of Appendix 3 of this document.

Foods with a natural pH of 4.6 and below are considered acid foods. Some foods are naturally acidic, including most fruits (e.g., many peaches, pH 4.0; apples, pH 3.5). However, some tropical fruits, including some pineapple, may fall in the pH range above 4.6, depending in part on variety and growing conditions. Foods with a pH above 4.6 are said to be low-acid foods. Examples of low-acid foods include protein foods (such as milk and eggs), most vegetables, and starch based foods (such as bread and crackers).

Acidification

Because an acid pH can inhibit the growth of many bacteria, acidification of foods is a common formulation process control. Acidification is the direct addition of acid to a low-acid food. Examples of foods that are acidified as a process control include pickled beets and peppers. There are a variety of acids (such as acetic acid, lactic acid, and citric acid) that can be used to acidify foods, depending on the desired attributes of the finished product.

We have established specific CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (commonly called "low-acid canned foods" or LACF (21 CFR part 113). We also have established requirements for acidified foods (21 CFR part 114). At the time when we established these regulations, the focus of these CGMP requirements was the control of *C. botulinum*; when the pH of a food is 4.6 or below, spores of *C. botulinum* will not germinate and grow. As a result, the pH of 4.6 is a dividing line for the purpose of determining whether a food other than an acid food is subject to part 113 as an LACF or part 114 as an acidified food. See 21 CFR 114.3.

An acid food, such as tomatoes with a pH of 4.2, is not subject to either the LACF regulations or the acidified foods regulations. Under the acidified foods regulations, "acidified foods" are low-acid foods to which acid(s) or acid food(s) are added; they have a water activity greater than 0.85 and have a finished equilibrium pH of 4.6 or below (21 CFR 114.3(b)). The definition of acidified foods provides that carbonated beverages, foods that are stored, distributed, and retailed under refrigeration, and certain other foods are excluded from the coverage of 21 CFR part 114 (21 CFR 114.3(b)).

Processors of acidified foods must register with FDA to obtain a Food Canning Establishment number (21 CFR 108.25(c)(1)). Processors of acidified foods also must file a scheduled process with FDA (21 CFR 108.25(c)(2)); the scheduled process is the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of pathogens. The scheduled process includes control of pH and other critical factors equivalent to the process established by a competent processing authority (21 CFR 114.3). Acidified foods must be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods; manufacturing must be in accordance with the scheduled process (21 CFR 114.80(a)(1)). Sufficient control, including frequent testing and recording of results, must be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6 (21 CFR 114.80(a)(2)). An equilibrium pH is achieved when a natural pH balance has been reached by all ingredients - which can take several days in foods with very large particulates (National Canners Association, 1968). You should refrigerate products that require several days to reach equilibrium pH to prevent the growth of *C. botulinum* or other pathogens.

There are several different methods of adding the acid to the product. One method is called direct acidification, where predetermined amounts of acid and the low-acid foods are added to individual finished product containers during production. With this method, it is important that the processor control the acid-to-food ratio. This is probably the most common method used for acidified vegetables. Another method of acidification is batch acidification. As the name implies, acid and food are combined in large batches and allowed to equilibrate. The acidified food is then packaged.

Acidified foods must be treated sufficiently to control spoilage microorganisms in addition to vegetative pathogens. Although one reason is to prevent spoilage triggering economic loss, the food safety reason is that the action of the spoilage organisms can raise the pH, compromising the safety of the product because any spores of *C. botulinum* that are in the food can germinate, grow, and produce botulinum toxin. The acidified foods regulation requires that you thermally process the food to an extent that is sufficient to destroy the vegetative cells of pathogenic and non-pathogenic microorganisms capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. However, you may use permitted preservatives to inhibit reproduction of non-pathogenic microorganisms in lieu of thermal processing. (21 CFR 114.80(a)(1))

For further information on the use of acidification of foods as a process control, see 21 CFR part 114. The regulation provides detailed information on appropriate procedures to measure pH for foods.

Fermentation

During bacterial fermentation, acid-producing bacteria produce lactic acid, which reduces the pH. Because the reduced pH can inhibit the growth of many bacteria, bacterial fermentation of foods is a common formulation process control. Examples of low-acid foods fermented by bacterial fermentation to a pH below 4.6 include fermented olives, fermented cucumber pickles, cheeses, and sauerkraut. Molds are used to ferment some foods such as soy sauce, tamari sauce, and other oriental foods, mainly for taste and other characteristics.

In practice, fermentation is an art. You need to encourage growth of favorable organisms and discourage the growth of organisms that can cause spoilage. This is usually accomplished by adding salt or a starter culture to the food, or in some cases slightly acidifying it. A starter culture can be either yeast or bacteria.

In many fermented products, there is no process to eliminate the acid-producing bacteria. These fermented products are kept refrigerated so that the culture bacteria and bacteria not killed during the fermentation process do not spoil the product.

4.3.3.3 Use of Preservatives as a Formulation Process Control

Preservatives can be used to prevent the growth of microorganisms – e.g., if a food product is not thermally processed (or not thermally processed to an extent that is sufficient to kill the vegetative cells of non-pathogenic microorganisms (such as spoilage microorganisms) that are capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user). Preservatives work by denaturing protein, inhibiting enzymes, or altering or destroying the cell walls or cell membranes of microorganisms. Examples of products that use preservatives as a formulation process control include acidified foods that are either not thermally processed or only minimally thermally processed, hummus (which uses sodium benzoate to inhibit yeast and mold), and many breads (which use calcium propionate to inhibit mold).

Some of the more commonly used preservatives are:

- **Acetic aci**d and its salts (e.g., sodium acetate, sodium diacetate), which is added to reduce bacterial growth.
- **Benzoates**, which include benzoic acid, sodium benzoate and potassium benzoate. Benzoates are used primarily to inhibit yeast or mold. Also can inhibit bacterial pathogens (e.g., *S. aureus*, *L. monocytogenes*).
- **Natamycin** is applied on cheese to inhibit the growth of fungi.
- **Nisin** is used as an antimicrobial agent to inhibit the outgrowth of *C. botulinum* spores and toxin formation in a variety of pasteurized process cheese spreads.
- **Propionates,** which include propionic acid, and sodium, potassium and calcium propionates, are used in breads, cakes, and cheeses to inhibit mold. Also can inhibit bacterial pathogens (e.g., *S. aureus*, *Salmonella*).
- **Sorbates**, which include sorbic acid, and sodium and potassium sorbates. Sorbates are primarily used to inhibit yeast and mold. Also can inhibit bacterial pathogens (e.g., *E. coli* O157:H7, *L. monocytogenes*).

- **Sulfites,** such as sulfur dioxide, are used in a variety of products including lemon juice, seafood, vegetables, molasses, wines, dried fruit, and fruit juices. Sulfites are used primarily as an antioxidant but also have antimicrobial properties.

Table 4-16 provides examples of how some of these commonly used preservatives are used.

Table 4-16. Preservatives Commonly Used in Conjunction with Main Groups of Foods in the United States

Foodstuff	Acetic Acid	Benzoates	Natamycin	Nisin	Propionates	Sorbates	Sulfites
Fat Emulsions	+	+	-	-	-	++	-
Cheese	-	(+)	+	+	+	++	-
Vegetable Products	++	++	-	-	-	++	+
Fruit products	+	++	-	-	-	++	++
Beverages	-	++	-	-	-	++	(+)
Baked goods	+	-	-	-	++	++	-
Confectionery	-	(+)	-	-	-	++	-

Source: Adapted from Davidson and Branen 1993; Table 11 in Lück and Jager 1997, p 61
++ used frequently
+ used occasionally
(+) used in exceptional cases only
- not used

A food category that may benefit from the use of preservatives as a formulation process control is fresh, refrigerated, RTE deli salads. This category of food, which is typically formulated with multiple components, including spices and fresh vegetables, may experience a high bio-load at the time of preparation if treated ingredients are not used. Maintaining quality (e.g., by preventing spoilage by yeasts and molds) and ensuring product safety cannot always be achieved by reducing pH (e.g., by using an acidified food as a salad dressing (such as mayonnaise) or an acid food as a salad dressing (such as vinegar)). Antimicrobial substances such as potassium sorbate and propionic acid are commonly used for a variety of RTE deli salads to inhibit bacteria, yeast, and mold, extending the product shelf-life.

For further regulatory guidance on the use of antimicrobial substances, see FDA (1999). For a comprehensive review on the application of antimicrobials, see Davidson, et al. (2005).

4.3.4 Use of Dehydration/Drying as a Process Control

Dehydration (which reduces water activity) is one of the oldest methods of food preservation. In the United States, there are three primary methods of dehydration as a process control.

- Freeze-drying - used for a variety of products
- Forced air drying - used for solid foods like vegetables and fruit
- Spray drying - used for liquids and semi-liquids like milk

Dehydrated/dried products are usually considered shelf stable due to their low water activity (a_w) and, therefore, are often stored and distributed unrefrigerated. Examples of shelf-stable dehydrated/dried food products include milk powders, powdered beverages, pasta, and dried peas and beans.

If you use dehydration/drying as a process control, you should select a packaging material that will prevent rehydration of the product under the expected conditions of storage and distribution. Additionally, finished product package closures should be free of gross defects that could expose the product to moisture during storage and distribution.

See "Chapter 9 – Use of Dehydration/Drying as a Process Control" of this guidance for additional information on the use of dehydration/drying as a process control. For a detailed overview of dehydration/drying technologies commonly used in the United States (including freeze drying, forced air drying, and spray drying), as well as other dehydration technologies such as drum drying and fluid bed drying, see Greensmith (1998) and Heldman and Lund (2007). For a discussion on the effects of drying on microorganisms, see Jay (1996).

4.3.5 Use of Recipe Management as a Process Control for Food Ingredients

A food ingredient (such as a food additive, color additive, or GRAS substance) can be a chemical hazard if it is added in excess of a maximum use level, regardless of whether the maximum use level is established due to food intolerance (such as for sulfites) or is otherwise a condition of safe use of a food additive, color additive, or GRAS substance. Control strategies to prevent misformulation of food ingredients generally include recipe management to ensure that excessive amounts are not added.

4.3.6 Use of Storage Conditions as a Process Control for Mycotoxins

Mycotoxins are toxic metabolites produced by certain fungi (i.e., molds) that can infect and proliferate on raw agricultural commodities (e.g., grains such as wheat and corn, peanuts, fruits, and tree nuts) in the field and during storage. Contamination by toxigenic fungi during storage and transportation is caused by improper drying or re-wetting of the crop from rain or condensation. Thus, effective process controls involve correct drying and storage.

By far the most critical environmental factors determining whether a raw agricultural commodity will support mold growth are temperature, moisture content, and time, and each of these parameters can be manipulated and controlled to manage the prevention of mold growth in a raw agricultural commodity. The principal process control for prevention of mold growth in storage conditions is the control of moisture. Although low-temperature storage can help control mold growth in some conditions, large-scale storage of raw agricultural commodities generally takes place in structures that do not provide for low-temperature and, thus, low-temperature storage generally is not a control measure for mold during the storage of raw agricultural commodities.

4.3.7 Use of Physical Sorting as a Process Control for Mycotoxins

In most cases, mycotoxins in raw agricultural commodities are present in a very small proportion of individual seeds or kernels. As a result, removing the contaminated seeds or kernels mechanically is a practical and effective process control to reduce the mycotoxin content of the bulk raw agricultural commodity (West and Bullerman, 1991). Various techniques have been devised, based on color and visual appearance of decay or damage, to separate out

contaminated seeds during inspection processes. This may be manual or by more advanced electronic instrumental selection.

4.3.8 Use of Exclusion Strategies as a Process Control for Physical Hazards

4.3.8.1 Exclusion Strategies as a Process Control for Metal Hazards

Metal-to-metal contact during processing can introduce metal fragments into products. For example, metal fragments can break off during mechanical cutting and blending operations, and some metal equipment has parts that can break or fall off, such as wire-mesh belts. You can control metal hazards by using physical separation techniques (such as magnets, sieves, screens, or flotation tanks), by using electronic or X-ray metal detection devices, and by regularly inspecting at-risk equipment for signs of damage.

The effectiveness of physical separation techniques depends on the nature of the product. These measures are more likely to be effective in liquids, powders, and similar products in which the metal fragment will not become imbedded.

The use of electronic metal detectors is complex, especially with regard to stainless steel, which is difficult to detect. The orientation of the metal object in the food affects the ability of the equipment to detect it. For example, if a detector is not properly calibrated and is set to detect a sphere 0.08 inch (2 mm) in diameter, it may fail to detect a stainless steel wire that is smaller in diameter but up to 0.9 inch (24 mm) long, depending on the orientation of the wire as it travels through the detector. Processing factors, such as ambient humidity or product acidity, may affect the conductivity of the product and create an interference signal that may mask metal inclusion unless the detector is properly calibrated. You should consider these factors when calibrating and using this equipment.

X-ray devices can also be used for metal detection. One advantage in using such a device is that X-rays can detect non-metal foreign objects that may also be hazardous, such as glass fragments.

Preventive maintenance of equipment and periodically examining your processing equipment for damage that can contribute metal fragments can be a useful control measure, particularly when you have a piece of equipment that is prone to break, such as saw blades, or equipment that has metal-to-metal contact. The success of this strategy depends in large part on the nature of the equipment inspected and the frequency of the inspection. However, this approach will not necessarily prevent metal fragments from being incorporated into the product in all cases, but may enable you to separate products that may have been exposed to metal fragments. Visually inspecting equipment for damaged or missing parts may only be feasible with relatively simple equipment, such as band saws, small orbital blenders, and wire mesh belts. More complex equipment that contains many parts, some of which may not be readily visible, may not be suitable for visual inspection and may require controls such as metal detection or physical separation techniques.

See “Chapter 13-- Preventive Controls for Physical Hazards” of this guidance for additional information on the control of metal hazards.

4.3.8.2 Exclusion Strategies as a Process Control for Glass Hazards

Glass fragments can be introduced into food whenever processing involves the use of glass containers. Normal handling and packaging methods, especially mechanized methods, can result in breakage. Ingesting glass fragments can cause injury to the consumer. Most products packed in glass containers are intended to be a ready-to-eat (RTE) commodity that requires minimal handling on the part of the consumer before eating, so that consumers have little opportunity to detect glass inclusion.

This chapter addresses the hazard of glass fragments that may occur from the use of glass containers. You should address the hazard of glass fragments originating from sources such as overhead light fixtures through CGMPs.

You can help prevent glass from getting into your food products by periodically checking the processing areas and equipment for glass breakage. In addition, the line operator can listen for breakage and can look for broken glass on the floor. (You can enhance the utility of these controls by painting the floor under the processing line in a color that highlights the container glass.) These types of controls will not necessarily prevent glass fragments from being incorporated into your product, but they can enable you to separate products that may have been exposed to glass fragments from those that have not.

You also can help prevent glass fragments from getting into your food products by cleaning empty containers before filling into the product package. You can do so by using water or compressed air and inverting the container during or after cleaning. You should be mindful that container cleaning may not fully control glass hazards in some processes that use automated filling systems because this equipment can result in glass breakage during the filling and capping process.

See “Chapter 13--Preventive Controls for Physical Hazards” of this guidance for additional information on the control of glass hazards.

4.4 Sanitation Controls

CGMPs require sanitary operations (21 CFR 117.35) and sanitary facilities and controls (21 CFR 117.37). There are requirements applicable to the cleanliness of equipment and utensils, including food-contact surfaces (21 CFR 117.40), and plant construction and design (21 CFR 117.20(b)). To comply with these CGMP requirements, sanitation procedures, practices, and processes should take place every day in your facility.

Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the: (1) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and (2) prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. (See 21 CFR 117.135(c)(3).)

You determine which hazards require a sanitation control, rather than CGMPs, through your hazard analysis. Thus, some – but not all - of your sanitation procedures, practices, and

processes will be “sanitation controls”; other sanitation procedures, practices, and processes will be CGMPs. For your sanitation controls to be effective, you should first assess the sanitation procedures, practices, and processes that you will have in place to comply with the CGMP requirements. For example, equipment design that ensures that all surfaces can be accessed and cleaned is essential for the effective application of sanitation controls. Effective sanitary design should consider factors such as whether equipment includes hollow bodies or poorly developed welds and seams, as well as whether ease of disassembly allows adequate access to all food-contact surfaces to ensure thorough cleaning and sanitation. Sanitary design also applies to food facility structures (e.g., floors, walls, piping, and ceilings) to ensure effective cleaning and sanitation practices. The required elements for cleaning – time, temperature, mechanical force and chemical concentration – simply cannot be reliably applied if the equipment and facility structural design does not allow adequate access (Marriott and Gravani, 2010). Due to this link between your CGMP procedures, practices, and processes and your sanitation controls, your CGMP procedures, practices, and processes are sometimes called “prerequisite programs.”

The nature of the processing conditions (i.e., wet or dry) required for the manufacture of a particular product (such as a dry processing environment for spray dried milk powder, and a wet processing environment for soft cheese) impacts the selection of the appropriate CGMP sanitation procedures, practices, and processes or the appropriate sanitation control. For example, moisture control is critically important in preventing contamination by an environmental pathogen, such as *Salmonella*, in low-moisture products. Water in a dry processing environment is one of the most significant risk factors for *Salmonella* contamination, because the presence of water allows for pathogen growth leading to product contamination from the environment or from insanitary food contact surfaces. Therefore, dry cleaning or controlled wet cleaning practices should be considered for use as sanitation control measures in a dry processing environment. Any time water is used for cleaning, the equipment should be thoroughly dried before use. Wet processing operations are subject to wet cleaning. However, water, in particular standing water, should be minimized even if facilities are wet cleaned. This is particularly true for facilities that need to control *L. monocytogenes* because they are producing RTE products exposed to the environment.

The nature of a bacterial pathogen (e.g., whether it is a transient or a resident strain of an environmental pathogen) also impacts the selection of the appropriate CGMP sanitation procedures, practices, and processes, or the appropriate sanitation control. (See section 3.2.5.2 (Transient vs. resident facility-related environmental pathogens) in “Chapter 3-- Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food” in this guidance for additional information about transient and resident strains of environmental pathogens.

Table 4-17 lists examples of the application of sanitation controls to significantly minimize or prevent biological and chemical hazards and the section in this chapter that addresses each listed example.

Table 4-17. Examples of Sanitation Controls

Sanitation Control Subcategory	Examples	Chapter Section
Cleaning food-contact surfaces	• Applying a full wet clean with detergents and sanitizers for Clean in Place and Clean out of Place (CIP/COP) • Applying controlled wet clean with minimum water usage and wipe down (COP) • Dry cleaning with vacuums, brushes, wipes	4.4.1
Control cross-contact / cross-contamination	• Using hygienic zoning for separation of process operations such as raw vs. Work-in-Process (WIP) vs. finished product; wet vs. dry; personnel and materials flow; air balance • Using dedicated cleaning / sanitation practices in designated hygiene zones *(see cleaning food-contact surfaces)* • Cleaning between different products containing different allergens	4.4.2

See "Chapter 10 – Sanitation Controls" of this guidance for additional information about sanitation controls. In addition to this guidance, a number of sources of scientific and technical information can be useful in establishing sanitation controls. See Holah, 2014 and Marriott and Gravani, 2010.

4.4.1 Use of Sanitation Controls for the Cleanliness of Food-Contact Surfaces

The CGMP requirements for sanitary operations include specific requirements for cleaning food-contact surfaces. See 21 CFR 117.35(d). All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food (21 CFR 117.35(d)). Food-contact surfaces used for manufacturing/processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use (21 CFR 117.35(d)(1)). When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use (21 CFR 117.35(d)(1)). In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated (21 CFR 117.35(d)(2)). Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary (21 CFR 117.35(d)(2).

Part 117 does not define the term "cleaning." In this guidance, we use the term "cleaning" to mean removing the "soil"– i.e., bacteriological nutrients, such as fats, carbohydrates, proteins,

and minerals"– that can build up on food-contact surfaces in the plant and processing equipment. Part 117 defines "sanitize" to mean 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. (21 CFR 117.3) Although cleaning operations and sanitizing operations often are conducted separately – and sequentially – some systems (such as steam systems) both clean and sanitize the surfaces; we consider that such systems satisfy the definition of ''sanitize.'' (See 80 FR 55908 at 55956.)

Table 4-16 describes three types of cleaning strategies that you can use to remove soil, depending upon the processing conditions (wet or dry). Table 4-16 includes our recommendations for using these cleaning strategies. See Appendix 4 of this guidance for more details about these cleaning strategies.

Table 4-18. Types of Cleaning Strategies

Cleaning Strategy	Description and Recommendations
Wet Cleaning	Uses water-based and/or wet chemical cleaning solutions. When using wet cleaning, you should avoid certain practices, e.g., excessive use of water (e.g., floor is flooded with water), high pressure hoses. Instead, you should use water on an as-needed basis. You also should minimize and isolate your use of water to specific areas where possible. Drying after wet cleaning helps to minimize growth of remaining microorganisms.
Dry Cleaning	Does not use any water. Dry cleaning is the physical removal of residues (e.g., food particles and dust) without water. You should remove food residues by actions such as sweeping, brushing, scraping, or vacuuming the residues from equipment surfaces and the facility environment. Be careful to not distribute food particles to other equipment or areas during removal.
Controlled Wet Cleaning	Uses a limited amount of water, generally for dry operations. Complete drying should follow immediately after the controlled wet cleaning. You can move specific pieces of equipment out of the area to be wet cleaned, sanitized, and dried and then return the equipment after the area is cleaned.

After the surfaces are cleaned and rinsed you should sanitize food contact surfaces and other areas as appropriate. You should use all sanitizers in accordance with the EPA-registered (or similar registration in other countries) label use instructions, including approval for use in food establishments.

As noted in section 4.4, sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment. (See 21 CFR 117.135(c)(3).) Examples of sanitation controls related to the cleanliness of food-contact surfaces include cleaning and sanitizing procedures, practices, and processes (including appropriate frequencies for these procedures, concentrations of cleaning and sanitizing compounds, method of application, and contact time) (Holah, 2014). See "Chapter 10 – Sanitation Controls" of this guidance for a practical example of the application of cleaning and sanitizing of food-contact surfaces as a preventive control for bacterial contamination.

4.4.2 Use of Sanitation Controls to Prevent Allergen Cross-contact and Cross-contamination

As noted in section 4.4, sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. (See 21 CFR 117.135(c)(3).)

Table 4-19 describes three common practices that you can use to prevent allergen cross-contact and to prevent cross-contamination of foods from insanitary objects, poor hygienic practices, different processing operations, and environmental pathogens.

Table 4-19. Common Practices to Prevent Allergen Cross-contact and Cross-contamination

Practice	Description
Hygienic Zoning	Hygienic zoning for separation and segregation of process operations such as raw vs. work-in-process vs. finished product; wet vs. dry; personnel and materials traffic flow; air balance
Hygienic Zone Specific Cleaning	Dedicated cleaning / sanitation practices within hygiene zones
Allergen Specific Cleaning	Cleaning between different products containing different allergens

The objective of hygienic zoning is to reduce the potential for transient pathogens to enter sensitive areas in the facility, such as packing areas where an RTE product is exposed to the processing environment. Typically, this type of sanitation control is applied in facilities that make RTE products.

You should determine the need for, and scope of, a hygienic zoning program based on your facility, the products you make, and the outcome of your hazard analysis. For example, the need for, and scope of, a hygienic zoning program are likely to be very different for a flour mill, a facility that makes RTE refrigerated food, and a facility that makes canned acidified foods. In determining the need for, and scope of, a hygienic zoning program, you should take into account the structure of your plant, packaging, personnel and ingredient traffic flows, and any cross over areas. You also should consider potential contaminants from raw materials, air flow, support areas, and other activities taking place in the facility.

Some facilities implement hygienic zoning for quality reasons (e.g., to control mold contamination); however, the sanitation controls that are the subject of this guidance need only address food safety. See “Chapter 10 – Sanitation Controls” of this guidance for a practical example for the application of hygienic zoning to prevent recontamination by environmental pathogens.

4.5 Food Allergen Controls

Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for: (1) Ensuring protection of food from allergen cross-contact, including during storage, handling,

and use; and (2) labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). See 21 CFR 117.135(c)(2).

Examples of procedures, practices, and processes to ensure protection of food from allergen cross-contact are:

- Identifying and marking allergen-containing ingredients at receiving;
- Segregating and storing allergen-containing materials at receiving and warehousing;
- Scheduling production of products based on allergen-containing recipes;
- Physical separation of processes for non-allergen-containing and allergen-containing products;
- Sanitation and cleaning practices;
- Using full wet cleaning to remove allergenic materials prior to producing a non-allergen-containing product on the same line;
- Using dedicated cleaning utensils and equipment for removing allergenic materials from food processing equipment.

Examples of procedures, practices, and processes to label the finished food are:

- Performing label review for each new batch of labels received at the facility;
- Implementing procedures for application of correct label to product.

See "Chapter 11 - Food Allergen Controls" of this guidance for in-depth guidance on preventive control strategies for food allergen hazards.

4.6 Supply-chain Controls

Supply-chain controls include the supply-chain program required by 21 CFR part 117, subpart G (21 CFR 117.135(c)(4)). Subpart G specifies:

- The requirement to establish and implement a supply-chain program (21 CFR 117.405);
- General requirements applicable to a supply-chain program (21 CFR 117.410);
- Responsibilities of the receiving facility (21 CFR 117.415);
- Requirements for using approved suppliers (21 CFR 117.420);
- Requirements for determining appropriate supplier verification activities (including determining the frequency of conducting the activity) (21 CFR 117.425);
- Requirements for conducting supplier verification activities for raw materials and other ingredients (21 CFR 117.430);
- Requirements for an onsite audit (21 CFR 117.435); and
- Requirements for records documenting the supply-chain program (21 CFR 117.475).

In this section of this guidance, we discuss the use of ingredient specifications as a supply-chain control for several chemical hazards – i.e., pesticides, drug residues, heavy metals, and mycotoxins. See our forthcoming "Chapter 15: Supply-Chain Program for Human Food Products" for in-depth guidance on supply-chain controls.

4.6.1 Supply-chain Controls for Pesticides

Pesticides used in the growing of vegetables fruits, and grain crops include fungicides, insecticides, and rodenticides that control pests found in growing environments. These may also be used in manufacturing environments. If you determine through your hazard analysis that a pesticide hazard requires a preventive control (e.g., due to residual pesticide level violations in a particular raw agricultural commodity), and that control is applied by your supplier, you would have a supply-chain program in which you would verify that your supplier controls pesticides. You could have specifications for your supplier that pesticide levels in raw materials and other ingredients must be within permitted levels and you could ask to review your supplier's pesticide control program. Your program could have verification activities such as periodic testing by you or your supplier for pesticide residues.

4.6.2 Supply-chain Controls for Drug Residues

Drug residues due to the use of antibiotics or related drugs in livestock are principally a potential concern for milk-based products. If you determine through your hazard analysis that a drug residue hazard requires a preventive control, and that control is applied by your supplier, you would have a supply-chain program in which you would verify that your supplier controls drug residues to ensure that drug residues in raw materials and other ingredients are within permitted levels.

4.6.3 Heavy Metals

Heavy metals are principally a concern in raw agricultural commodities grown in soils that are contaminated either naturally or through industrial activity. If you determine through your hazard analysis that a heavy metal hazard requires a preventive control, and that control is applied by your supplier, you would have a supply-chain program in which you would verify that suppliers source raw agricultural commodities from regions that do not have high levels of heavy metal contamination in soil, and specifications that heavy metals in raw materials and other ingredients will be within permitted levels.

4.6.4 Supply-chain Controls for Mycotoxins

Mycotoxins are toxic metabolites produced by certain fungi (i.e., molds) that can infect and proliferate on raw agricultural commodities (e.g., grains such as wheat and corn, peanuts, fruits, and tree nuts) in the field and during storage. Critical environmental factors determining whether a raw agricultural commodity will support mold growth are temperature, moisture content, and time, and each of these parameters can be manipulated and controlled to manage the prevention of mold growth in a raw agricultural commodity. As noted in section 4.3.7 of this chapter, effective process controls for mycotoxins involve correct drying and storage as well as physical sorting techniques to remove damaged or moldy raw agricultural commodities.

If you determine through your hazard analysis that a mycotoxin hazard requires a preventive control, and that control is applied by your supplier, you would have a supply-chain program in which you would verify that your supplier controls mycotoxins. You could have specifications that mycotoxins in raw materials and other ingredients will be within permitted levels.

4.7 Recall Plan

For food with a hazard requiring a preventive control, you must establish a written recall plan for the food. The written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: (1) Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food; (2) Notify the public about any hazard presented by the food when appropriate to protect public health; (3) Conduct effectiveness checks to verify that the recall is carried out; and (4) Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food. See 21 CFR 117.139.

We recommend that you consult our general guidance on policy, procedures, and industry responsibilities regarding recalls in 21 CFR part 7, subpart C (§§ 7.40 through 7.59) and FDA's Guidance for Industry: Product Recalls, Including Removals and Corrections (FDA, 2015c).

A recall can be disruptive to your operation and business, but there are several steps you can take in advance to minimize this disruptive effect:

- Adequately code products to make possible positive lot identification and to facilitate effective recall of all violative lots.
- Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. You should maintain such records for a period of time that exceeds the shelf life and expected use of the product.

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 5: Application of Preventive Controls and Preventive Control Management Components

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5.5 Preventive Control Management Components

5.5.1 Overview of Preventive Control Management Components

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 5 that we issued for public comment in August 2016.

5.5.2 Monitoring
5.5.3 Corrective Actions and Corrections
5.5.4 Verification
5.5.5 Records
5.6 References

5.1 Purpose of this Chapter

The guidance provided in this chapter is intended to help you identify and implement preventive controls, and associated preventive control management components, as a part of your food safety plan. See 21 CFR 117.135 and 117.140. Note that if you determine through your hazard analysis that there are no hazards requiring preventive controls, you must still document that determination in your written hazard analysis (see 21 CFR 117.130(a)(2)). However, you would not need to establish preventive controls and associated preventive control management components.

This chapter provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. This chapter also provides an overview of preventive control management components (i.e., monitoring, corrective actions, and corrections, and verification activities (and their associated records)). Chapters 6 through 13 of this guidance provide more detailed examples of the application of preventive controls and associated preventive control management components.

This chapter does not provide all the details needed for complete programs. You have the flexibility to identify and implement preventive controls, and associated preventive control management components, from among all procedures, practices, and processes that are available to you and that would provide assurances that the hazard is controlled (i.e., significantly minimized or prevented).

5.2 Overview of the Application of Preventive Controls for Biological Hazards

Table 5-1 provides examples of the application of preventive controls to significantly minimize or prevent the occurrence of ingredient-related and process-related biological hazards.

Table 5-1 provides general information about the effects of the listed preventive controls but is not intended to imply that a particular preventive control has been validated for control of specific pathogens in specific foods. You are responsible for validating specific preventive controls as appropriate to the nature of the preventive control and its role in your facility's food safety system (see 21 CFR 117.160(a)).

Table 5-1 does not address the application of preventive controls to facility-related hazards. See "Chapter 10 – Sanitation Controls" of this guidance for additional information on the application of sanitation controls to address facility-related hazards.

Table 5-1 Application of Common Preventive Controls to Ingredient-Related and Process-Related Biological Hazards

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Lethal Treatments	Heat (e.g., cooking, roasting, baking)	In general, heat processes will not eliminate spores of bacterial pathogens	Eliminates vegetative cells of pathogens	Will not eliminate preformed toxins of *S. aureus* and *B. cereus* emetic toxin	Heat processing will inactivate parasites found in foods; specific times and temperatures are dependent on the parasite, food matrix, and process used
Process Control – Lethal Treatments	Irradiation, ionizing	The doses approved in the U.S. will not eliminate spores of bacterial pathogens in most foods	Eliminates vegetative cells of pathogens	Will not eliminate preformed toxins of *S. aureus* and *B. cereus* emetic toxin	Limited uses for parasite control; depending on dose, approved uses for foodborne pathogens may inactivate parasites found in foods
Process Control – Lethal Treatments	Antimicrobial Fumigation, e.g., Propylene Oxide (PPO) or Ethylene Oxide (ETO)	Will not eliminate spores of bacterial pathogens	Defined PPO processes have been shown to reduce *Salmonella* by 5 logs in certain foods	Unknown, but unlikely to have an effect on preformed toxins of *S. aureus* and *B. cereus* emetic toxin	Ozone has been found to inactivate select parasites (e.g., *C. parvum* oocysts)

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Lethal Treatments	High Pressure Processing (HPP)	In general, HPP will not eliminate spores of bacterial pathogens (FDA, 2000)	Eliminates vegetative cells of pathogens (FDA, 2000)	Will not eliminate preformed toxins of *S. aureus* and *B. cereus*	• Will eliminate parasitic worms of *Trichinella spiralis* at ≥ 200 MPa for 10 min • No infectivity of *Cryptosporidium* oocysts when treated by HPP at $5.5X10^8$ Pa (80,000 psi) for 60 sec in apple and orange juice • Information is lacking on the pressure resistances of other parasites
Process Control – Time / Temperature of Holding	Refrigeration	Used to control growth of sporeforming bacterial pathogens	Depending on the temperature, refrigeration will inhibit growth of many pathogens. However, pathogens such as *L. monocytogenes* and some strains of *B. cereus* may grow at refrigeration temperatures	Will prevent the formation of toxins of *S. aureus*. Depending on the temperature, will prevent formation of *B. cereus* toxins. Will have no effect on preformed toxins	Limited information; generally not applicable to parasites because parasites do not grow in food

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Time / Temperature of Holding	Freezing	Used to control growth of spore forming bacterial pathogens, but the spores will survive freezing well	Freezing prevents growth of vegetative cells of pathogens. Depending on the temperature, the numbers of some pathogens may be reduced over time; however you cannot count on freezing to eliminate pathogens, and many can survive for an extended time	Freezing that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxins	There are specific schedules of time and temperature shown to inactivate parasites; *Cyclospora* is known to be at least somewhat resistant to freezing because an outbreak occurred attributed to raspberries in cake that was previously frozen at about 26°F (–3.3° C)
Process Control – Formulation	Water activity control	Reducing the water activity (e.g., by adding solutes such as sugar and salt) to 0.92 or below will inhibit outgrowth of spores	Reducing the water activity (e.g., by adding solutes such as sugar and salt) to 0.85 or below will inhibit growth of vegetative cells of pathogens	Water activity that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxins	Limited information; generally not applicable to parasites because they do not grow in food

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Formulation	Acidification	Lowering the pH by the addition of acid can inhibit spores from germinating, will not eliminate the spores	In, general, you can rely on added acid to prevent growth of vegetative bacterial pathogens, but you cannot rely on added acid to eliminate vegetative cells of bacterial pathogens	A pH that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxins	No information for use as control in foods
Process Control – Formulation	Adding preservatives	Will not eliminate spores of bacterial pathogens, but can prevent germination of spores of certain species	Various preservative chemicals have specific action against some vegetative cells of bacterial pathogens and/or fungi that prevent growth	Formulations that prevent growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information for use as control in foods
Process Control – Dehydration	Air drying	Will not eliminate spores of bacterial pathogens, but limits or inhibits outgrowth	While drying may inactivate some pathogens, others (e.g., *Salmonella*) may survive drying for fairly long times	Drying that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information on effect on parasites in foods

Preventive Control	Common Procedures, Practices, and Processes	Applicability to Spore-Forming Bacterial Pathogens	Applicability to Vegetative Bacterial Pathogens	Applicability to Bacterial Toxins	Applicability to Parasites
Process Control – Dehydration	Freeze drying	In general, serves to preserve microorganisms, but inhibits outgrowth	In general, serves to preserve microorganisms, but inhibits growth	Drying that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information on effect on parasites in foods
Process Control – Dehydration	Spray drying	In general, spores of bacterial pathogens will not be eliminated, but inhibits outgrowth	Some pathogens may survive spray drying depending upon the product formulation. Growth will be inhibited	Drying that prevents growth will prevent formation of toxins of *S. aureus* and *B. cereus* but have no effect on preformed toxin	No information on effect on parasites in foods

Chapters 6 through 9 of this guidance provide specific examples of the application of some of these preventive controls. Table 5-2 lists these chapters and the examples covered in these chapters. Table 5-2 also lists examples of sanitation controls, which are covered in Chapter 10.

Table 5-2 Chapters in this Guidance that Provide Examples of the Application of Common Preventive Controls for Ingredient-Related and Process-Related Biological Hazards

Hazard	Preventive Control	Examples of Preventive Controls	Chapter
Bacterial pathogens that survive the lethal treatment	Process Control – Lethal Treatments	• Cooking of RTE soups (frozen and refrigerated) • Baking of RTE cookies	6
Bacterial pathogens that grow, including those that produce toxin, due to time/ temperature abuse	Process Control – Time / Temperature of Holding	• Refrigeration of fresh fruit salads • Control of temperature during thawing to prevent microbial growth	7
Bacterial pathogens that grow, including those that produce toxin, due to poor formulation control	Process Control - Formulation	• Acidification of prepared vegetable salads • Water activity control in refrigerated cookie dough	8

Hazard	Preventive Control	Examples of Preventive Controls	Chapter
Bacterial pathogens that grow, including those that produce toxin, due to inadequate drying	Process Control – Drying/dehydration	• Drying of milk to produce spray-dried milk powder	9
Bacterial pathogens that contaminate product due to poor sanitation	Sanitation Control – Cleaning / sanitizing food contact surfaces	• Controlling presence of bacterial pathogens in RTE prepared sandwiches by sanitation	10
Recontamination of an RTE product with an environmental pathogen	Sanitation – Prevention of recontamination from the environment	• Use of hygienic zoning as a component of a program for prevention of recontamination of ice cream with environmental pathogens	10

5.3 Overview of the Application of Preventive Controls for Chemical Hazards

5.3.1 Examples of the Application of Preventive Controls for Chemical Hazards

Table 5-3 provides examples of the application of preventive controls to significantly minimize or prevent the occurrence of ingredient-related chemical hazards in finished foods. See "Chapter 12 – Preventive Controls for Chemical Hazards" of this guidance for further examples of the implementation of preventive controls for chemical hazards.

Table 5-3 Examples of the Control of Ingredient-Related Chemical Hazards

Preventive Control	Common Procedures, Practices, and Processes	Examples of Applicability to Chemical Hazards
Supply-Chain Program	Establish and implement a risk-based supply-chain program with supplier approval and verification activities (as a means of ensuring that raw materials and other ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place)	• Applicability to heavy metals: approved suppliers control arsenic and lead in raw agricultural commodities such as rice and carrots • Applicability to naturally occurring toxins: approved suppliers control growth of mycotoxin-forming fungi in stored raw agricultural commodities that are purchased by the facility as raw materials • Applicability to food and color additives and substances associated with a food intolerance: approved suppliers control presence of or use of identified substances and ensure safe levels are not exceeded
Supply-Chain Program	Conduct verification activities appropriate to the hazard	• Sampling and testing (by supplier or receiving facility) to verify supplier control for chemical hazards such as pesticides, drug residues, heavy metals, and mycotoxins, when a supply-chain-applied control has been applied for such hazards • On-site audit to verify control of food allergens, such as when purchasing roasted almonds from a facility that handles multiple tree nuts
Process Controls	Recipe management procedures as appropriate	Facility programs to control product formulation to ensure that safe levels are not exceeded
Process Controls	Storage conditions	Control of moisture in stored raw agricultural commodities to prevent formation of mold
Process Controls	Physical sorting	Facility processing practices to sort (e.g., based on color, physical damage, or presence of mold) raw agricultural commodities to reduce levels of mycotoxins in processed foods

5.3.2 Considerations Applicable to Radiological Hazards

Contamination of foods by radionuclides (a radiological hazard) is a rare event. The most common way these radionuclides are incorporated into foods is through use of water that contains a radionuclide during the manufacture of a food. For example, in certain locations in the United States, high concentrations of radium-226, radium-228 and uranium have been detected in private wells (Ayotte et al., 200; Focazio et al., 2001). The most relevant information that would lead you to consider and evaluate a specific radiological hazard to determine whether it is a hazard requiring a preventive control would be publicly disseminated information following a particular event, such as contamination arising from accidental release from a

nuclear facility or from damage to a nuclear facility from a natural disaster. For example, in 2011, radioactivity was detected in milk, vegetables and seafood produced in areas neighboring a nuclear power plant damaged during an earthquake and tsunami in Japan. We have issued guidance on levels of concern for radionuclides that could be a known or reasonably foreseeably hazard in certain circumstances, such as after an accident at a nuclear facility (FDA, 2001).

Your hazard analysis does not need to consider sources of radiation used in accordance with a food additive regulation. Such sources are safe for their intended use. As with any other equipment and substances used in the manufacture of food, you must comply with all applicable safety requirements established either under the terms of a food additive regulation or by an authority such as the Occupational Safety and Health Administration. Although the two most likely sources of radiological hazards that you would need to address are water used in the production of foods (as an ingredient or cleaning aid), and accidental contamination of your food product (or its ingredients) from accidental release of radionuclides from a nuclear facility, the PCHF requirements do not limit your responsibilities to these two sources, because we cannot anticipate what might be a source in the future.

5.3.3 Examples of the Control of Food Allergen Hazards

Table 5-4 provides examples of the application of preventive controls to significantly minimize or prevent the occurrence of the ingredient-related and process-related undeclared food allergen hazards within finished foods. See "Chapter 11 – Food Allergen Controls" of this guidance for additional information on the application of food allergen controls.

Table 5-4 Application of Common Preventive Controls to Ingredient-Related and Process-Related Food Allergen Hazards

Preventive Control	Common Procedures, Practices, and Processes	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Incorrect Product Label	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Cross-Contact
Allergen Control – Labelling	Perform label design and review during product development prior to commercialization and label review for each new batch of labels received.	Label design and review minimize the potential for the label to not identify all of the food allergens present in the food	N/A
Allergen Control – Labelling	Implement procedures for application of correct label to product.	Label application procedures can help minimize the potential for an incorrect label to be applied to an allergen-containing food	N/A

Preventive Control	Common Procedures, Practices, and Processes	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Incorrect Product Label	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Cross-Contact
Allergen Control – Allergen cross-contact	Identify and mark food allergen-containing ingredients (e.g., by color coding or with food allergen icons) at receiving.	N/A	Clearly identifying food allergens associated with raw materials or other ingredients simplifies handling practices to prevent allergen cross-contact
Allergen Control – Allergen cross-contact	Segregate and store food allergen-containing materials at receiving and warehousing.	N/A	Segregation of different food allergens can minimize the potential for allergen cross-contact during storage
Allergen Control – Allergen Cross-contact	Open and handle food allergen-containing ingredients at separate times / contain by using separate rooms, or by scheduling use of the same rooms at different times.	N/A	Handling food allergens separately can minimize the potential for inadvertent incorporation of a food allergen into a product for which it is not an ingredient
Allergen Control – Allergen Cross-contact	Schedule production of products based on food allergen-containing recipes. Schedule production of products that do not contain food allergens before production of products that do contain food allergens or schedule production of products with a unique food allergen last.	N/A	Production scheduling can minimize the potential for inadvertent incorporation of food allergen into a product for which it is not an ingredient
Allergen Control – Allergen cross-contact	Physically separate processes for products that do not contain food allergens from products that do contain food allergens or separate processes for products that do not contain the same food allergens	N/A	Separating processes containing different food allergens can minimize the potential for inadvertent incorporation of food allergen into a product for which it is not an ingredient
Allergen Control – Allergen cross-contact	Implement production procedures for rework and work-in-process (WIP): using “like into like,” appropriate storage and handling, tracking	N/A	Control of rework can minimize the potential for inadvertent incorporation of food allergen into a product for which it is not an ingredient

Preventive Control	Common Procedures, Practices, and Processes	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Incorrect Product Label	How the Preventive Control Can Significantly Minimize or Prevent Undeclared Food Allergens due to Cross-Contact
Sanitation Control – Cleaning food contact surfaces	Use full wet cleaning to remove food allergen residues prior to producing a product that does not contain that food allergen on the same line.	N/A	Cleaning can minimize the presence of food allergen residues, preventing inadvertent incorporation of food allergen into a product for which it is not an ingredient
Sanitation Control – Cross-contact	Use hygienic zoning for physical separation of process operations, including personnel, that involve foods with and without a specific food allergen	N/A	Hygienic zoning can help prevent inadvertent incorporation of food allergen into a product for which it is not an ingredient
Sanitation Control - Cross-contact	Use dedicated cleaning utensils and equipment for removing food allergen residues from food processing equipment	N/A	Use of dedicated cleaning utensils/equipment can prevent transfer of food allergen residues, thereby preventing inadvertent incorporation of food allergen into a product for which it is not an ingredient

5.4 Overview of the Application of Preventive Controls for Physical Hazards

Table 5-5 provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of physical hazards in finished foods. See "Chapter 13 – Preventive Controls for Physical Hazards" of this guidance for further examples for the implementation of preventive controls for physical hazards.

Table 5-5 Applicability of Preventive Controls to Physical Hazards

Preventive Control Category	Common Procedures, Practices, and Processes	Applicability to Metal Hazards	Applicability to Glass Hazards (Products Packed in Glass)	Applicability to Other Hard/Sharp Physical Hazards
Process Control – Exclusion	Use screens, flotation tanks, riffle board, sifters, magnets, inversion/air to exclude metal and glass	Physically removes metal fragments	Physically removes glass	Physically removes hard plastic, wood, stones

Preventive Control Category	Common Procedures, Practices, and Processes	Applicability to Metal Hazards	Applicability to Glass Hazards (Products Packed in Glass)	Applicability to Other Hard/Sharp Physical Hazards
Process Control – Detection	Use metal or X-ray detectors to detect and divert foods containing metal and glass	Metal and X-ray detectors detect metal pieces, which generally allows for exclusion of foods containing metal	X-ray detectors detect glass pieces, which generally allows for exclusion of foods containing glass	X-rays can often detect hazardous objects such as hard plastic, stones, bones, pits

5.5 Preventive Control Management Components

5.5.1 Overview of Preventive Control Management Components

Preventive control management components include monitoring, corrective actions and corrections, and verification activities (and their associated records). You must apply appropriate preventive control management components by considering the nature of the preventive control and its role in the facility's food safety system to ensure the effectiveness of the preventive control. For example, monitoring may be limited for certain control measures such as preventive maintenance for equipment to prevent metal hazards (although you should have a record that the activity took place). When sanitation controls are required for environmental pathogens, little or no monitoring may be needed when cleaning and sanitation are conducted in accordance with established written protocols. Occasional verification that procedures are being followed may suffice. See 21 CFR 117.140.

5.5.2 Monitoring

You must establish and implement written procedures, including the frequency they are to be performed, for monitoring preventive controls (as appropriate to the nature of the preventive control and its role in your food safety system). See 21 CFR 117.145. Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish Monitoring Procedures," that provides information about appropriate monitoring procedures for each control strategy example discussed.

To fully describe your monitoring program, the procedures should answer four questions: (1) What will be monitored? (2) How will monitoring be done? (3) How often will monitoring be done (frequency)? and (4) Who will do the monitoring?

What you monitor should be directly related to control of the hazard. For example, for process controls you would monitor parameters to ensure the minimum/maximum values are met. For other preventive controls, you could monitor that the activity has been conducted consistent with a defined procedure.

The frequency of monitoring depends upon the circumstances. Continuous monitoring is always desirable, and in some cases necessary. In other cases, it may not be necessary or practical. You should monitor often enough that the normal variability in the values you are measuring can be determined and a deviation from normal will be detected. This is especially true if these values are typically close to the control values. Even with continuous monitoring, you should periodically check the paper or electronic record of the continuous monitoring to determine whether deviations from the control value have occurred. The frequency of that check should be at least daily.

If a measurement shows that a deviation from the control value has occurred, you should assume that the control value had not been met since the last check in which the value was acceptable. As a result, the greater the time span between measurements, the more products you are putting at risk.

You should specify in the written procedures the position of the employee who will do the monitoring and describe how they are to perform the monitoring procedure. See Chapters 6 through 13 of this guidance for monitoring examples that include "who" and "how."

You must document your monitoring of preventive controls. See 21 CFR 117.145(c)(1). Although, as noted above, continuous monitoring (with associated records) is desirable, in some circumstances the monitoring records may be "exception records" that document loss of control. See 21 CFR 117.145(c)(2).

5.5.3 Corrective Actions and Corrections

You must establish and implement corrective action procedures that would apply if preventive controls are not properly implemented, as appropriate to the nature of the hazard and the nature of the preventive control. These include corrective action procedures that must be taken if you detect the presence of a pathogen or appropriate indicator organism in a ready-to-eat product as a result of product testing or if you detect the presence of an environmental pathogen or appropriate indicator organism through your environmental monitoring activities. See 21 CFR 117.150(a) and (a)(1).

A predetermined corrective action procedure has the following advantages: (1) It provides detailed instructions for an employee to follow in the event of a deviation in applying a preventive control; (2) it can be prepared at a time when an emergency situation is not calling for an immediate decision; and (3) it removes the obligation to reassess the food safety plan in response to a deviation.

Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish Corrective Action Procedures," that provides information about appropriate corrective action procedures for each control strategy example discussed. An appropriate corrective action procedure must accomplish the following goals: (1) Ensure that the appropriate action is taken to identify and correct the problem that has occurred with the implementation of a preventive control; (2) ensure that the appropriate action is taken when necessary to reduce the likelihood that the problem will recur; (3) ensure that all affected food is evaluated for safety; and (4) ensure that all affected food is prevented from entering into commerce unless an evaluation has determined that the product is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342) or misbranded under 21 section 403(w) of the FD&C Act (21 U.S.C. 343(w)). See 21 CFR 117.150(a)(2).

You must document your corrective actions. See 21 CFR 117.150(d). For example, when documenting a decision that affected product is released into commerce, your documentation should explain how your decision was based on sound evidence that the deviation did not create a food safety hazard. As another example, you should document all product dispositions, including dispositions to reject or destroy the product.

If you have not established a written corrective action procedure for a preventive control, you still must take appropriate corrective actions when an unanticipated food safety problem indicates that a preventive control may not have been properly implemented. See 21 CFR 117.150(b)(1)(i). For example, you would take appropriate corrective actions if you detected a pathogen in a product when your production process should have controlled the pathogen. Although it may not be possible to anticipate all the problems that could happen, corrective actions need to be taken and fully documented when an unanticipated situation occurs. The corrective actions for the unanticipated problems would include standard corrective action procedures (e.g. identify and correct an implementation problem, take steps to reduce the likelihood it will recur, evaluate all implicated product for safety, and prevent adulterated or misbranded product from entering commerce). See 21 CFR 117.150(b)(2)(i). In addition when appropriate you must reanalyze the food safety plan (or the applicable portion of the food safety plan) to determine whether you need to modify the plan. See 21 CFR 117.150(b)(2)(ii).

A correction is an action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure. See the definition of "correction" in 21 CFR 117.3. The term ''correction'' focuses on the first step in a ''corrective action procedure'' (i.e., identify and correct the problem). Corrections may be appropriate instead of corrective actions when minor, isolated problems occur that do not directly impact product safety.

Here is an example of corrections vs. corrective actions. If you observe food residue on ''clean'' equipment prior to production, corrections would involve re-cleaning and sanitizing the equipment before it is used. Because you observed the food residue prior to production of food, and you corrected the problem in a timely manner, no food is affected and no actions are needed with respect to food. You are not required to record the correction because this isolated incident does not directly impact product safety, and you made the corrections in a timely manner (i.e., before the production starts). On the other hand, if you make an RTE creamed vegetable soup using a continuous heat exchanger and hot-fill process, and after packaging the soup your review of temperature records of the processed soup at the discharge end of the hold tube shows that the soup did not reach the temperature you identified as a critical limit, corrective actions would involve destroying the product, reheating it or sending it to animal food as appropriate,[2] investigating the cause of the problem, and taking the actions needed to reduce the likelihood that the problem will recur based on the root cause of the problem. (Using an automatic flow diversion valve that diverts low-temperature product at the end of the hold tube back to the pre-heat kettle to be re-processed would avoid the need for taking corrective actions on product, although you would still investigate the cause and correct the problem.)

You must document all corrective actions in records that are subject to verification records review. When appropriate, you also must document corrections. See 21 CFR 117.150(d). You are not required to document corrections in records that are subject to verification records

[2] For more information on sending human food to animal food use, refer to Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007, Section III.L (FDA, 2010).

review when the corrections are taken in a timely manner and you identify and correct a minor and isolated problem that does not directly impact product safety. See 21 CFR 117.150(c)(2). However, we recommend that you document corrections such as re-running product through a functioning metal detector when the one used on the production line did not reject the test pieces used to verify that the metal detector was operating correctly, because it provides a record of both the problem and the steps you took to correct the problem. If the problem recurs on a frequent basis, such documentation also can alert you that equipment may need to be repaired or replaced. We also recommend that you record corrections taken when equipment is adjusted because, for example, temperature does not meet an operating limit (although the critical limit has not been violated); such information can be useful to identify trends that indicate equipment repairs may be needed.

The record of corrective actions should include information on the following four elements:

First, document the actions taken to identify and correct the problem with implementation of the preventive control. For example, explain how you identified what went wrong with a process control and how you restored process control.

Second, explain what you did to reduce the likelihood that the problem will recur. Evaluation of historical corrective action records can help to identify recurring problems. When critical limit deviations frequently reoccur, the process and the Food Safety Plan may need reanalysis and modification. A formal process may be needed to manage major changes that need to be implemented. This may include reissuing forms, retraining employees, phasing in changes, managing label information, informing suppliers, and other tasks, depending on the nature of the change.

Third, explain how you evaluated the safety of all affected food. Specific technical expertise may be required for this evaluation, depending on the nature of the deviation.

Fourth, explain what you did with any affected food, including identifying the amount of product involved and disposition of the affected product.

5.5.4 Verification

Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, “Establish Verification Procedures,” that provides information about appropriate verification activities for each control strategy example discussed. The information covers validation of the adequacy of control measure (e.g., process establishment); evidence that monitoring is being conducted as required; evidence that appropriate decisions about corrective actions are being made as required; evidence of verification of the implementation and effectiveness of controls (such as product testing or environmental monitoring when appropriate); calibration of instruments, when appropriate, and review of records. See 21 CFR 117.155, 117.160 and 117.165. When calibration or an accuracy check of a preventive control monitoring instrument shows that the instrument is not accurate, you should evaluate the monitoring records since the last instrument calibration to determine whether the inaccuracy would have contributed to a deviation. For this reason, food safety plans with infrequent calibration or accuracy checks can place more products at risk than those with more frequent checks if a problem with instrument accuracy occurs.

5.5.5 Records

Chapters 6 through 13 of this guidance provide examples of the application of preventive controls. Each of these chapters contains a section, "Establish a Recordkeeping System," that provides information about appropriate records for each control strategy example discussed. Types and frequency of records vary, depending on factors such as the nature of the hazard and the nature of the control measure and its role in the food safety system.

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 6: Use of Heat Treatments as a Process Control

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Chapter 6 that we issued for public comment in August 2017.

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6.1 Purpose of this Chapter

The purpose of this chapter is to explain how to establish and implement a heat treatment (e.g., baking or cooking) as a process control for bacterial pathogens. See Chapter 4 – Preventive Controls for additional detail on heat and other lethal treatments.

This chapter does not address controlling bacterial pathogens by those heat treatments, such as retort processes, that are subject to 21 CFR part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers; commonly called "Low-Acid Canned Foods" (LACF)) because the microbial hazards in LACF are not subject to the requirements for hazard analysis and risk-based preventive controls.

6.2 Considerations to Keep in Mind If You Use a Heat Treatment as a Process Control

Heating is only one of the process controls that you may choose to use to produce a safe product. Based on your hazard analysis, there may be other process controls to consider. In addition, the heat treatments discussed in this chapter are designed to kill/destroy vegetative cells of bacterial pathogens (e.g., *Salmonella*), but are not adequate to inactivate spores of sporeforming bacteria (e.g., all strains of *C. botulinum*). Therefore, if you use one of the heat treatments described in this chapter, you may need to establish and implement additional preventive controls to control spores. See Chapter 4 for further information regarding additional process controls for pathogenic sporeformers. See Table 6-1 for additional strategies for controlling bacterial pathogens.

Table 6-1 Strategies Other than Heat Treatment for Controlling Bacterial Pathogens

Preventive Control	Chapter
Time/Temperature Control	7
Formulation Control (e.g., water activity, pH, and chemical preservatives)	8
Dehydration/Drying	9
Sanitation Controls	10

6.3 Examples Used in this Chapter

Sections 6.12 through 6.16 of this chapter provide examples to illustrate how to properly apply heat treatments as a process control and to establish and implement preventive control management components (i.e., monitoring, corrective actions and corrections, and verification) for those heat treatments. These examples are:

- Cookie Processor A: Cookies baked using a batch process (in batches on trays in convection ovens), wrapped by twos in plastic (Section 6.12)

- Cookie Processor B: Cookies baked using a continuous process (in a continuous band oven), packaged in boxes of 24 cookies (Section 6.13)

- Soup Processor A: Ready-to-Eat (RTE) soups containing vegetable particles, cooked using a batch process (in a kettle), packaged in 8 ounce plastic bowls, and frozen (Section 6.14)

- Soup Processor B: RTE soups (clear broths and creamed vegetable soups, without vegetable particles) cooked using a continuous process (in a continuous flow heat exchanger), packaged in 5 gallon bags, and refrigerated (Section 6.15)

- Salsa Processor A: Chopped mixed vegetable salsa (an acidified food) that is directly acidified, cooked in a kettle, and hot-filled into glass jars (Section 6.16)[2]

Each of these examples describes certain activities that must be either performed, or overseen by, a preventive controls qualified individual (PCQI). When a PCQI oversees (rather than performs) these activities, the activity could be performed by a designee of the PCQI. For simplicity, we describe the activity as performed by a PCQI, without specifying each time that the activity could be performed by a designee of a PCQI.

6.4 Understand the Potential Hazard

Heat is known to be effective against bacterial pathogens and is a common process control for these hazards. However, if heat treatments are not properly designed and implemented, the pathogens of concern may survive the process and cause illness. See Chapter 3 for more information on bacterial pathogens.

6.5 Terms Used in This Chapter

Part 117 specifies that process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (1) Parameters associated with the control of the hazard; and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control. (See 21 CFR 117.135(c)(1).)

The examples in this chapter describe:

- Process parameters such as baking/cooking time, baking/cooking temperature, dough weight, particle size, belt speed, and pump speed;

- Maximum values for some of these process parameters (e.g., 28 g portion of dough); and

[2] In forthcoming chapters, we will provide an example of formulation control for this acidified food (Chapter 8 – Use of Formulation as a Process Control) and an example of control of glass hazards (Chapter 13 – Preventive Controls for Physical Hazards).

- Minimum values for some of these process parameters (e.g., 350°F (177°C) minimum baking temperature, 13 minutes minimum baking time).

Process controls typically are established at "critical control points" (CCPs). "CCP" is a term commonly used in HACCP systems. In HACCP systems, the maximum or minimum values for a process parameter established at a CCP are called "critical limits." Our HACCP regulation for juice (21 CFR part 120) defines "critical limit" as the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

Part 117 does not preclude the use of terms (such as "critical limits" and "critical factors") that are associated with HACCP systems. Because the maximum or minimum values for the process parameters described in the examples in this chapter are established at CCPs, we see no meaningful difference between the terms "maximum value" and "minimum value" used in part 117 for a process control and the term "critical limit" used in HACCP systems for controls established at CCPs. Therefore, in this chapter we use the term "critical limit" when referring to a maximum or minimum value established for a process control parameter. Because part 117 specifies that preventive controls include controls, other than those at CCPs, that are also appropriate for food safety (21 CFR 117.135(a)(2)(ii)), in this chapter we use the more general term "process parameter" (rather than "critical factor") when referring to parameters other than those specified in the examples with critical limits.

Part 117 does not define the term "operating limit." In this guidance, we use the term "operating limit" to mean criteria that may be more stringent than critical limits and are established for reasons other than food safety. For example, if you bake cookies and establish 13 minutes as the critical limit for the minimum baking time to control bacterial pathogens, you could establish 15 minutes as an operating limit for the baking time and assess the cookies for quality if the baking time is less than 15 minutes, but still exceeds the critical limit of 13 minutes (e.g., if the baking time was 14 minutes).

Part 117 does not define the term "adjustment." In this guidance, we use the term "adjustment" when referring to an intervention that you take if you determine that there is a deviation from an operating limit, without a deviation from a critical limit. For example, if you bake cookies, establish 28 g as the maximum value (critical limit) for the weight of cookie dough deposited by an automatic dough depositor, and establish 27 g as the operating limit for the weight of cookie dough, you could make an adjustment to the dough depositor if you observe that the amount of dough deposited exceeds the operating limit of 27 g, but does not exceed the critical limit of 28 g.

6.6 Design and Validation of the Heat Treatment

The heat treatments discussed in this chapter are designed to significantly minimize (eliminate or reduce to an acceptable level) vegetative cells of bacterial pathogens that may have been introduced into the food by raw materials or during processing steps that occur before the heat step. With few exceptions, the PCHF requirements specify that you must validate that the preventive controls are adequate to control the hazard as appropriate to the nature of the preventive control and its role in your food safety system. The validation of the preventive controls must be performed (or overseen) by a PCQI. (See 21 CFR 117.160.)

To control bacterial pathogens using a heat treatment adequate to ensure that the pathogens do not survive the process, you should:

- Scientifically establish a heat treatment that will significantly minimize the target bacterial pathogens (eliminate them or reduce their numbers to acceptable levels);
- Design and operate the heat treatment equipment so that every unit of product receives at least the established minimum heat treatment; and
- Monitor the established process parameters to verify achievement of the scientifically established heat treatment (e.g., time and temperature).

You could establish process parameters and the critical limits for the process parameters based on scientific information, usually obtained by a scientific study (often from studies in the literature). You also could obtain this information from a process authority that has knowledge about process parameters and minimum/maximum values (e.g., critical limits) for the product being produced. A process authority could also conduct the studies that would establish a valid heat treatment.

For heat treatments, examples of process parameters include:

- Amount of time for the heat treatment (e.g., the amount of time exposed to heat as determined by the speed of the belt through a continuous oven, or observed number of minutes at a boil for some cooking processes)[3];
- Temperature of the heating medium (e.g., temperature of oven or steam or water used for cooking);
- Internal Temperature (IT) of the product;
- Final temperature of the product;
- Particle size (e.g., when heat must penetrate particles such as chopped vegetables so that the interior of the particles receives a complete heat treatment);
- Depth of product on a conveyor belt;
- Container size (e.g., can dimensions when products are heated in containers); and
- Product formulation.

When a study is conducted to establish a valid heat treatment, that study could identify other process parameters that affect the rate of heating of the product.

[3] When an End-Point Internal Product Temperature (EPIPT) has been determined by a study, there is no time associated with the heat treatment.

6.7 Develop a Strategy for Preventive Control Management Components

With few exceptions, part 117 specifies that preventive controls are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system: (1) Monitoring; (2) corrective actions and corrections; and (3) verification. (See 21 CFR 117.140.) In the remainder of this chapter, we discuss each of these preventive control management components when the process control is a heat treatment. See Sections 6.12 through 6.16 for examples that provide more detail about how to apply each of these preventive control management components to specific types of heat treatments.

6.8 Establish and Implement Monitoring Procedures

Part 117 requires that, as appropriate to the nature of the preventive control and its role in your food safety system, you establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control. You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. (See 21 CFR 117.145.)

6.8.1 What to Monitor

Heat treatments designed to significantly minimize pathogens play a key role in your food safety system. When a heat treatment is your preventive control and you have established critical factors for the heat treatment (e.g., as identified by a scientific study or provided by an expert in thermal processing, such as a process authority), you would monitor those critical factors. Exceptions to such monitoring include heat treatments that are designed such that a process parameter is automatically controlled, e.g., when a bar is placed at a specified height above a conveyor belt to ensure that the bed depth of product being heat treated cannot exceed the depth determined to be the critical limit for the depth of product.

6.8.2 How to Monitor

6.8.2.1 How to monitor batch heating equipment

For most temperature determinations in batch heating equipment, you should use a continuous temperature-recording device (e.g., a recording thermometer). You should install the device where it measures the coldest temperature of the cooking equipment (the cold spot determined by a study). In some instances (e.g., to determine the IT prior to heating or to determine the EPIPT), you could use a temperature-indicating device (e.g., a thermometer). Where cooking is performed at the boiling point, you could visually observe minutes at a boil.

For the heating time of a batch process, you should record the times of the start and the end of the cooking or baking cycle and calculate the heating time from this information. To help you do so, you could set timers to give an audible or visible indication that the cooking or baking time has been completed.

For most heat treatments, you should monitor both temperature and time. However, when an EPIPT has been scientifically established, you could monitor only the finished product temperature, because there is no time associated with the heat treatment.

For other process parameters, use appropriate equipment to monitor the parameter, e.g., scales when you establish a critical limit for a weight; rulers or calipers when you establish a critical limit for size.

6.8.2.2 How to monitor continuous heating equipment

For monitoring temperature in continuous heating equipment, you should use a continuous temperature-recording device (e.g., a recording thermometer). You should install the device where it measures the coldest temperature of the cooking equipment (the cold spot determined by a study). For larger heating chambers such as continuous baking or roasting ovens, you should install temperature recording devices in multiple locations, e.g., the top, middle, and bottom baking areas of the oven. For continuous monitoring of the temperature of continuous flow heated liquids, you could use a resistance temperature detector (RTD) placed in line.

For monitoring time (e.g., cooking or baking times) in continuous heating equipment, you could use a stopwatch or tachometer to monitor the speed of the belt drive wheel, or use a stopwatch to monitor the time it takes for a test unit or a belt mark to pass through the equipment. In other systems, you could determine time by the flow rate of a fluid product pumped through a continuous heating system. (In simple terms, the heating time is determined by the speed with which a food flows through the heating system. Determining the appropriate flow rate can be complicated – we recommend you use an expert in thermal processing to establish processes for such continuous heating systems.) To achieve a process-specific flow rate, you could calibrate the pump to a set RPM, mark a set point on the pump, and visually observe the pump setting (i.e., speed measured in RPM). Some systems provide a mechanism whereby you could lock the pump to prevent a change in the pump speed that would affect the product flow rate.

For other process parameters, you should use appropriate equipment to monitor the factor, e.g., scales when you establish a critical limit for a weight; rulers or calipers when you establish a critical limit for size.

6.8.3 How Often to Monitor (Frequency of Monitoring)

6.8.3.1 How often to monitor batch heating equipment

If you use a continuous temperature-recording device (e.g., a recording thermometer) for monitoring, you should do a visual check of the recorded data at least once per batch. If you establish an EPIPT, you should monitor the EPIPT for each batch.

For the heating time of a batch process, you should monitor the recorded start and end times for each batch unless you are using an EPIPT. (When using an EPIPT, the frequency of checking temperature is often designed to minimize exposure to heat once the EPIPT is reached, and it is product quality, rather than product safety, that generally would be negatively impacted.)

You should monitor other process parameters with sufficient frequency to achieve control.

6.8.3.2 How often to monitor continuous heating equipment

If you use a continuous temperature-recording device (e.g., a recording thermometer) for monitoring, you should do a visual check of the recorded data at least once per day.

For the heating time of a continuous process, you should monitor the automated timers at least once per day or pump speed setting at least twice per shift, and whenever you make any changes in the automated timer or pump speed setting.

You should monitor other process parameters with sufficient frequency to achieve control.

6.8.4 Who performs the monitoring

When a person (rather than a machine) is assigned to perform monitoring, that person must have the education, training, or experience (or a combination of these) necessary to perform the individual's assigned duties. (See 21 CFR 117.4(b)(1).)

Examples of who performs the monitoring, or devices that perform monitoring, include:

- A continuous monitoring thermometer measures the product IT or the oven temperature;
- The person who puts ingredients together before they are taken to the line determines the weight of ingredients critical to the formulation of the product or determines that particle size is within specifications;
- The line operator (e.g., kettle cook, bakers), Quality Control (QC) personnel, or any other person who has an understanding of the nature of the preventive controls;
    - Visually checks data generated by a continuous monitoring device to ensure that the critical limits have consistently been met[4];
    - Monitors the temperature for manual (non-automated or non-continuous) devices; and
    - Performs other monitoring activities that occur on the processing line.

6.9 Establish and Implement Corrective Action Procedures

Part 117 requires that, as appropriate to the nature of the hazard and the nature of the preventive control, you must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate: (1) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing; and (2) The presence of an environmental pathogen or appropriate indicator organism detected through environmental monitoring. The corrective action procedures must describe the steps to be taken to ensure that: (1) Appropriate action is taken to identify and correct a problem that has occurred with implementation of a preventive control; (2) Appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (3) All affected food is evaluated for safety; and

[4] This is sometimes considered a verification activity.

(4) All affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated or misbranded. (See 21 CFR 117.150(a).)

When your preventive control is a heat treatment, your corrective action procedures would describe the steps you will take when the heat treatment does not achieve the process-specified temperature or time (as well as any other critical limits established for the heat treatment). Examples of steps identified in corrective action procedures applicable to a heat treatment include:

- Continue heating a product that has not reached the specified temperature after the specified number of minutes;
- Extend the length of the heat cycle to compensate for a temperature drop (e.g., by continuing to heat the product for a longer time; by slowing the belt speed or flow rate to increase time of exposure to heat), using an alternate process developed by a process authority;
- Process at a higher temperature or longer time to compensate for a low IT, using an alternate process developed by a process authority;
- Reprocess the product (deliver the full process as if no heating had already occurred);
- Chill and hold the product for an evaluation of the adequacy of the heat treatment that has been delivered, and stipulate the disposition of the product if the product has not received an adequate process (e.g., destroy the product, divert it to a non-food use, or reheat it);
- Divert the product to a use in which the critical limits for the parameter are not applicable (e.g., an RTE product may become a not-RTE product or may become an ingredient for further processing by you or another manufacturer/processor);
- Divert the product to animal food (usually for animals other than pets);[5] and
- Destroy the product.

Although part 117 establishes requirements applicable to your corrective action procedures, it neither establishes requirements for other procedures, such as for adjustments, you might establish in your plant nor precludes you from establishing such procedures. Likewise, part 117 neither establishes requirements applicable to any assessment that you do for food quality if a process parameter deviates from an operating limit but does not deviate from a critical limit (e.g., if you have a procedure to assess food quality if the baking temperature for cookies is more than 5-10 degrees above the temperature set as a critical limit).

[5] FDA is developing guidance on the use of human food by-products in animal food, including diversion of human food products to animal food use. In 2016, FDA issued for public comment a draft guidance for industry entitled “Human Food By-Products For Use As Animal Food” (FDA, 2016 and 81 FR 58521, August 25, 2016). In determining whether it is appropriate to divert a food product to animal food use, we recommend that you consult the final guidance on this subject when it becomes available.

6.10 Determine Verification Procedures

Part 117 requires that verification activities include, as appropriate to the nature of the preventive control and its role in your food safety system: (1) Validation; (2) Verification that monitoring is being conducted; (3) Verification that appropriate decisions about corrective actions are being made; (4) Verification of implementation and effectiveness; and (5) reanalysis. (See 21 CFR 117.155.) For a discussion of validating a heat treatment, see section 6.6 of this chapter.

Part 117 also requires that you verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system:

- Calibration of process monitoring instruments and verification instruments (or checking them for accuracy) (21 CFR 117.165(a)(1));

- Product testing, for a pathogen (or appropriate indicator organism) or other hazard (21 CFR 117.165(a)(2));

- Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples (21 CFR 117.165(a)(3)); and

- Review of certain records by (or under the oversight of) a PCQI, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions (21 CFR 117.165(a)(4)).

Part 117 also requires, as appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, that you establish and implement written procedures for: (1) The method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy); (2) Product testing; and (3) Environmental monitoring. (See 21 CFR 117.165(b).)
Examples of verification activities applicable to heat treatments include:

- Calibrating devices used for monitoring (and for verification), such as thermometers, RTDs, timers, and scales, before use (or verifying their accuracy);

- Reviewing monitoring records (e.g., process logs) to confirm that the heat treatment was performed at the proper temperature and for the appropriate amount of time (sometimes also called "batch records review");

- Performing measurements at the monitoring points independent of the routine monitoring activity or observing line operators performing measurements;

- Verifying that appropriate decisions about corrective actions are being made when there are process deviations from critical limits; and

- Conducting, when appropriate, product testing to confirm that the heat treatment has adequately controlled bacterial pathogens that are relevant to the product.

This chapter does not discuss verification activities that are not directly related to heat treatments. For example, this chapter does not discuss environmental monitoring for an environmental pathogen as verification of sanitation controls. Likewise, this chapter does not discuss corrective action procedures that could be associated with such verification activities, such as product testing if the results of environmental monitoring for an environmental pathogen are positive.

6.11 Establish and Maintain Records

Part 117 requires that you document the preventive control management components as follows: (1) The monitoring of preventive controls in records that are subject to verification and records review; (2) all corrective actions (and, when appropriate, corrections) in records that are subject to verification and records review; and (3) all verification activities. (See 21 CFR 117.145(b)-(c), 117.150(d), and 117.155(b).)

Examples of what to document in records applicable to a heat treatment include:

- Monitoring activities of the process parameters that were established by a scientific study or provided by a process authority;
- Corrective actions that you take when a heat treatment does not achieve the process-specified temperature or time or when other critical limits are not met;
- Verification activities for implementation of the heat treatment such as:
    - Calibration records for monitoring/measuring devices, and a review of the calibration records;
    - Review of process records (e.g., logs of IT, process temperatures, process times, temperature charts);
    - Review of any corrective actions taken as a result of a deviation from any of the critical limits for the heat treatment; and
    - Any other verification activities conducted, including any product testing used to verify the adequacy of the heat treatment.

6.11.1 Records of Monitoring Activities

6.11.1.1 Records of monitoring activities for batch heating equipment

Examples of what to document in records of monitoring activities for batch heating equipment include:

- Records of temperature and time, if you monitor both temperature and time;

- Records of the finished product temperature, if you establish an EPIPT (where there is no time associated with the heat treatment);

- Records applicable to a continuous temperature recording device (e.g., a recording thermometer), if you use one, such as:

    - Recorder charts;

    - When applicable, records documenting the visual checks of recorded data (e.g., a hand written note on the recorder charts); and

    - When applicable, records noting the start time and end time of the cooking or baking periods;

- Records of monitoring of critical limits for other process parameters for your heat treatment (e.g., weight or size).

You should keep these records in a "process log" for each production line, with information to identify the plant or facility, dates (and when appropriate, the time) of monitoring, the signature or initials of the person performing the monitoring (e.g., operator initials) and evidence of review (i.e., the initials of the PCQI or designee).

6.11.1.2 Records of monitoring activities for continuous heating equipment

Examples of what to document in records of monitoring activities for batch heating equipment include:

- Records of any continuous temperature-recording device (e.g., a recording thermometer) (When applicable, this would include records of each temperature-recording device installed for each heating area in an oven with multiple temperature recording devices);

- Records of the time interval (in minutes) determined by a stopwatch and automated timer if you use a stopwatch to monitor the time interval of an automated timer;

- Records of the pump speed (RPM) in the line process log every time you do a visual check (if you determine time by the flow rate of a fluid product through a continuous heating system and you visually monitor the pump setting); and

- Records of monitoring of critical limits for other process parameters for your heat treatment (e.g., weights, size, thickness, etc.).

You should keep these records in a "process log" for each production line (or other forms of documentation), with information to identify the plant or facility, dates (and when appropriate, the time) of monitoring, the signature or initials of the person performing the monitoring (e.g., operator initials) and evidence of review (i.e., the initials of the PCQI or designee).

6.11.2 Records of Corrective Actions

Examples of what to document in records of corrective actions that you take when a heat treatment is not properly implemented include records of corrective actions if your heat

treatment does not achieve the process-specified temperature or time established for your food product, or any other critical limit you established for a process parameter for your heat treatment.

6.11.3 Record of On-going Verification Activities

Examples of what to document in records of verification activities applicable to your heat treatment include:

- Records (e.g., a log) documenting:
    - The calibration of measuring devices (such as thermometers, RTDs, timers, and scales);
    - Who conducted the calibration;
    - The method of calibration (which could be a Standard Operating Procedure);
    - The date of calibration;
    - Whether the device was in or out of specification; and
    - Adjustments needed and performed;
- A record of the process logs review, by whom, and date of review;
- A report of reviewing corrective actions taken when there are process deviations, including initials of the reviewer and the date of review; and
- A report of product testing (when determined appropriate) to verify that the heat treatment has adequately controlled bacterial pathogens that are relevant to the product.

6.12 Example of Cookie Processor A's Heat Treatment

6.12.1 Cookie Processor A's Product, Hazard Analysis, and Batch Heat Treatment

Cookie Processor A bakes cookies in batches on trays in convection ovens and packages them by wrapping the cookies by twos in plastic. Cookie dough is made and deposited on trays in the dough preparation room and racks of trays are moved to the baking room. Trays are removed from the convection oven after baking, placed on clean racks, and moved to the packaging room.

Cookie Processor A's PCQI identified *Salmonella* as the hazard associated with the ingredients (e.g., flour, eggs, peanut butter) used in making the cookies and determined that baking the cookies was the preventive control that would address this hazard. However, to ensure the adequacy of the baking process used as the preventive control in Cookie Processor A's food safety plan, Cookie Processor A's PCQI needed to determine the appropriate processing parameters, including any critical limits, that would provide adequate lethality for *Salmonella* during a batch baking process in a convection oven. To do so, Cookie Processor A's PCQI

consulted with a local university's extension specialist in process design and validation of heat treatments. Cookie Processor A's PCQI asked the extension specialist to:

- Identify processing parameters that need critical limits for food safety; and
- Determine critical limits for those processing parameters.

6.12.2 Cookie Processor A's Process Design and Validation

The extension specialist provided Cookie Processor A's PCQI with a published study by Lathrop et al., (2014) on survival of *Salmonella* during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of *Salmonella* (28 g portions of dough, water activity (a_w) of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable *Salmonella.* Cookies baked for 13 minutes showed at least a 5.2 log reduction in *Salmonella*. In that published study, the cookie temperature at the end of 15 minutes was 229°F (109°C).

The extension specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor A's heat treatment:

- Convection oven temperature (°F) to achieve specified minimum product temperature;
- Baking time in oven (minutes); and
- Dough delivery process resulting in the specified cookie portion weight (g).

To determine critical limits for those processing parameters when baking cookies in batches in Cookie Processor A's convection oven, and demonstrate that these critical limits can be achieved in Cookie Processor A's convection oven, the extension specialist conducted in-house heat distribution tests on Cookie Processor A's ovens and heat penetration tests on the cookies using a fully loaded oven (each oven rack contained a full tray of cookies, deposited in 28 g portions using a dough depositor). These in-house heat distribution and heat penetration tests showed that all parts of each of Cookie Processor A's oven were at or above 350°F (177°C) when the ovens were set at that temperature and that the coldest cookie temperature was above 230°F (110°C) after 13 minutes. In addition, a_w determinations by an outside laboratory on the cookie dough were equal to or greater than 0.82 using Cookie Processor A's recipes.

Based on the in-house tests, and the published study by Lathrop et al. (Lathrop, 2014), the extension specialist determined that the baking process of 350°F or greater for a minimum of 13 minutes (operating limit of 15 minutes) would provide adequate lethality for *Salmonella* for the recipe tested, so long as cookie dough portions did not exceed 28 g. The extension specialist informed Cookie Processor A that any subsequent change to the cookie recipe should be evaluated to determine whether it would impact these determinations.

Based on the information obtained from the extension specialist, Cookie Processor A's PCQI established three critical limits for the production of the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);
- The critical limit (minimum value) for the baking time is 13 minutes; and

- The critical limit (maximum value) for the cookie dough portion size is 28 g.

Based on the information obtained from the extension specialist, Cookie Processor A's PCQI also established three operating limits for the production of the cookies:

- The operating limit for the baking temperature is 352°F (178°C);
- The operating limit for the baking time is 15 minutes; and
- The operating limit for cookie dough portion size is 27 g.

Cookie Processor A calibrated a dough depositor to deliver 27 g portions of dough onto cookie sheets and produces cookies according to the established operating limits by baking 27 g portions of cookie dough in 352°F (178°C) ovens for 15 minutes.

6.12.3 Cookie Processor A's Monitoring

6.12.3.1 What Cookie Processor A monitors

Cookie Processor A monitors oven temperature, baking time, the dough depositor setting, and the weight of dough deposited.

6.12.3.2 How Cookie Processor A monitors

Cookie Processor A:

- Uses a recording thermometer with recording chart to continuously monitor oven temperature;
- Manually checks the temperature recorder chart and marks it with the batch number; records time when the cookies enter the oven and the oven temperature, calculates and records the time cookies should be removed, records the time the cookies are removed from the oven on baking record sheets, and calculates and records the elapsed baking time;
- Checks the set point of the dough depositor that controls the weight of dough portions deposited; and
- Periodically checks the weight of a few individual raw cookie dough portions using a calibrated scale located near the depositor.

6.12.3.3 How often Cookie Processor A monitors

Cookie Processor A:

- Checks the oven temperature (continuously recorded) before putting each batch of cookies into the oven to ensure it is reading at the minimum specified set point (i.e., at least 350°F (177°C);
- Records the start and end baking times of each batch of cookies;
- Checks the set point of the dough depositor every 2 hours; and

- Checks the weight of a few deposited cookie portions twice per shift.

6.12.3.4 Who monitors critical factors for Cookie Processor A's heat treatment

At Cookie Processor A:

- The baker checks the oven temperature before putting each batch of cookies into the oven and notes and records the start and end times of the baking cycle for each batch of cookies.

- A QC technician checks the set point of the dough depositor and the weight of the raw cookie dough portions.

6.12.4 Cookie Processor A's Corrective Action Procedures

Cookie Processor A's corrective action procedures specify that:

- If cookies were baked in an oven that was not at least 350°F (177°C), the cookies will be diverted to animal food (non-pet food) and employees will be retrained on the importance of ensuring that the oven temperature has reached the set point;

- If the bake time calculated from the start and end times is less than the critical limit of 13 minutes, the cookies will be diverted to animal food (non-pet food) and the PCQI will determine why the bake time was not met to prevent this from happening in the future;

- If the dough depositor is depositing a dough weight that exceeds the critical limit of 28 g:

    - The cookies will be diverted to animal food (non-pet food);

    - The PCQI will take steps to determine (if possible) what caused the depositor to deliver an incorrect weight so that actions can be taken to prevent such occurrences; and

    - The dough depositor will be adjusted to deliver the correct weight.

Cookie Processor A also has adjustment procedures that provide for:

- An assessment of product quality if the bake time is less than the operating limit of 15 minutes but more than the critical limit of 13 minutes, with an investigation of why the bake time was less than the operating limit to prevent this from happening in the future; and

- An adjustment of the dough depositor if the cookie dough weight exceeds the operating limit of 27 g but does not exceed the critical limit of 28 g.

6.12.5 Cookie Processor A's Verification Procedures

At Cookie Processor A:

- The following are calibrated at least annually:

    - The recording thermometer that monitors oven temperature;

  - The dough depositor; and
  - The scales used to check the weights of cookie portions.

- Within a week of their creation, the PCQI:
  - Reviews calibration logs (records of calibrating monitoring equipment) to make sure that the devices are properly calibrated using the appropriate methods and at the appropriate frequencies as specified in the calibration procedures;
  - Checks the baking record sheets and the temperature recording chart for monitoring records for temperature and time (i.e., time when the cookies enter the oven, calculated time for removal, and time the cookies were removed from the oven) to verify that the oven temperature was at least at the critical limit of 350°F (177°C) and that the cookies were baked for 15 minutes;
  - Checks the dough weight logs for the cookie dough portion weighing records to verify that none of the dough portions exceeded 28 g in weight; and
  - Initials and dates each of the records reviewed in the place marked "Verified by."
- The PCQI reviews the corrective action records within a week of a deviation, and initials and dates each of the records reviewed in the place marked "Verified by."

6.12.6 Cookie Processor A's Monitoring Records

Cookie Processor A keeps:

- The recording charts of the recording thermometer as a record of monitoring the oven temperature;
- The baking record sheets as a record of monitoring the baking times; and
- A dough weight log as a record of the dough depositor setting and the dough portioning weight.

6.12.7 Cookie Processor A's Records of Corrective Actions

Cookie Processor A keeps records:

- Documenting that cookies placed in an oven that was not at least 350°F (177°C) or cookies baked for less than 13 minutes were diverted to animal food (non-pet food);
- Of any investigations of the cause of any deviations;
- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and
- Documenting any retraining.

Cookie Processor A also keeps records of adjustments, because such records could be useful in identifying ongoing production problems that could demonstrate a need to review and change applicable production procedures.

6.12.8 Cookie Processor A's Verification Records

Cookie Processor A maintains records, initialed and dated by the PCQI, of the PCQI's review of:

- The calibration logs;
- The monitoring records (such as the oven temperature recording chart, records containing the bake time for cookies, and dough weight log); and
- The corrective action log.

6.12.9 Summary Process Control Table for Cookie Processor A

Appendix 6-A summarizes the above information for Cookie Processor A on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.13 Example of Cookie Processor B's Heat Treatment

6.13.1 Cookie Processor B's Product, Hazard Analysis, and Continuous Heat Treatment

Cookie Processor B bakes cookies in a continuous band oven and packages them in boxes of 24 cookies. Cookie dough is made in the dough preparation room and placed in totes that are taken to the dough hopper of an extruder at the front of the continuous band oven in the baking room. The dough extruder automatically deposits the dough across the oven band (solid conveyor), where the cookie dough is conveyed through the heating tunnel (oven). After baking, the band drops the cookies onto a conveyor that cools them and moves them to the packaging room.

Cookie Processor B's PCQI identified *Salmonella* as the hazard associated with the ingredients (e.g., flour, eggs, peanut butter) used in making cookies and determined that baking the cookies was the preventive control that would address this hazard. However, to ensure the adequacy of the baking process used as the preventive control in Cookie Processor B's food safety plan, Cookie Processor B's PCQI needed to determine the appropriate processing parameters, including any critical limits, that would provide adequate lethality for *Salmonella* for a continuous baking process using a band oven. To do so, Cookie Processor B's PCQI consulted with a process design specialist at a food research consulting firm regarding the process design and validation of the heat treatment. Cookie Processor B's PCQI asked the process design specialist to:

- Identify processing parameters that need critical limits for food safety; and
- Determine critical limits for those processing parameters.

6.13.2 Cookie Processor B's Process Design and Validation

The process design specialist provided Cookie Processor B's PCQI with a published study by Lathrop, et al., (2014) on survival of *Salmonella* during baking of peanut butter cookies. The published study showed that peanut butter cookie dough made with peanut butter inoculated with high levels of *Salmonella* (28 g portions of dough, a_w of 0.82) and baked at 350°F (177°C) for 15 minutes had no detectable *Salmonella.* Cookies baked for 13 minutes showed at least a 5.2 log reduction in *Salmonella*. In that published study, the cookie temperature at the end of 15 minutes was 229°F (109°C).

The process design specialist identified the following processing parameters that need critical limits for food safety in Cookie Processor B's heat treatment:

- Band oven temperature (°F) to achieve specified minimum product temperature;
- Baking time in oven (minutes) controlled by the speed of the conveyor belt through the continuous band oven; and
- Dough extrusion process resulting in the specified cookie portion weight (g).

To determine the critical limits for these processing parameters for baking cookies in Cookie Processor B's continuous band oven, and demonstrate that these critical limits can be achieved in Cookie Processor B's continuous band oven, the process design specialist conducted in-house oven temperature mapping (heat distribution) studies on the continuous band oven and heat penetration studies on the cookies. The results of these studies, and the recommendations of the process design specialist after conducting these studies, were as follows:

- Results of the in-house oven temperature mapping (heat distribution) study confirmed that the continuous band oven achieved and maintained the desired minimum temperature of 350°F (177°C) at the coldest spot in the oven at a set point temperature of 350°F (177°C) (or higher).
- The in-house heat penetration studies for the baking process used thermocouples with the sensors placed in the geometric center of the cookie dough portions (in 16 cookie dough portions deposited in 28 g portions at different points across the width of the oven band, in each of 3 trials conducted over 3 days). The speed of the conveyor belt in the band oven was set to result in a residence time of cookies in the oven of 13.0 minutes (as a worst case, or conservative, speed setting). Results from the heat penetration study demonstrated that all 28 g cookie dough portions achieved a minimum internal temperature of 231°F at the end of a 13.0-minute baking time.[6]
- Because the operating limit for Cookie Processor B's baking process is 15 minutes, the process design specialist also established the tachometer RPM reading that would result in a residence time of cookies in the continuous band oven of 15-minutes.

[6] Note that these data demonstrate that if a deviation results in a baking time less than 15 minutes but 13 or more minutes, the cookies receive more than a 5-log reduction for *Salmonella* (they reach a temperature of 231°F) and are safe for consumption.

- To ensure that the nominal weight of each raw cookie dough portion does not exceed the established process critical parameter weight of 28 g, the process design specialist specified that the cookie dough extruder should be calibrated to deliver 27 g raw cookie dough portions as an operating limit, and that the delivery should be verified by performing weight measurements at startup of the dough extruder each day.

Based on the information derived from this in-house validation study, in combination with the study published by Lathrop et al. (Lathrop, 2014), the process design specialist determined that Cookie Processor B's band oven would provide adequate lethality for *Salmonella* for the specific recipe tested, so long as the weight of the raw cookie dough portion did not exceed 28 g and the cookies were baked for at least 13 minutes at a 350°F (177°C) oven setting.

Based on the information obtained from the process design specialist, Cookie Processor B's PCQI, established three critical limits for the production of the cookies to ensure adequate lethality:

- The critical limit (minimum value) for the baking temperature is 350°F (177°C);
- The critical limit (minimum value) for the baking time is 13 minutes; and
- The critical limit (maximum value) for the cookie dough portion size is 28 g.

Based on the information obtained from the process design specialist, Cookie Processor B's PCQI also established three operating limits for the production of the cookies:

- The operating limit for the baking temperature is 352°F (178°C);
- The operating limit for the baking time is 15 minutes; and
- The operating limit for cookie dough portion size is 27 g.

Cookie Processor B calibrated a dough depositor to deliver 27 g portions of dough onto cookie sheets and produces cookies according to the established operating limits by baking 27 g portions of cookie dough in a 352°F (178°C) band oven for 15 minutes.

6.13.3 Cookie Processor B's Monitoring

6.13.3.1 What Cookie Processor B monitors

Cookie Processor B monitors oven temperature (at the identified cold spot), belt speed as indicated by tachometer RPM (for control of baking time), the dough depositor setting, and the weight of dough deposited.

6.13.3.2 How Cookie Processor B monitors

Cookie Processor B:

- Uses a recording thermometer with recording chart to continuously monitor oven temperature at the cold spot; conducts a visual check of the chart and records the check in the operator's baking log;

- Uses an automated tachometer with recorder chart to monitor the speed of the conveyor belt through the band oven (which is tied to the baking time) and conducts a visual check of the tachometer RPM;

- Checks the set point of the dough depositor that controls the weight of the raw cookie dough portions deposited; and

- Periodically checks the weight of a few individual cookie dough portions using a calibrated scale located near the depositor.

6.13.3.3 How often Cookie Processor B monitors

Cookie Processor B:

- Checks the oven continuous temperature-recording device every hour to ensure it is reading at a minimum the specified set point (i.e., at least 350^{o}F) (177°C);

- Monitors the automated tachometer recording (RPM) at start up and twice per shift;

- Checks the set point of the dough depositor at start up and every 2 hours; and

- Checks the weight of deposited cookie portions at least twice per shift.

6.13.3.4 Who monitors critical factors for Cookie Processor B's heat treatment

At Cookie Processor B:

- The baker checks the oven temperatures and monitors the automated tachometer recording; and

- A dough preparer checks the set point of the dough depositor and the weight of the raw cookie dough portions.

6.13.4 Cookie Processor B's Corrective Action Procedures

Cookie Processor B's corrective action procedures specify that:

- If cookies were baked in an oven that was not at least 350°F (177°C):

    - The cookies will be diverted to further processing (e.g., baking for cookie crumbles ingredient production) or to animal food (non-pet food);

    - Maintenance will determine the cause of the low temperature and fix the oven so the temperature is reset to the operating limit of 352°F (178°C) before more cookies are baked; and

    - Employees will be retrained, if necessary, on the importance of ensuring that the oven temperature has reached the set point before allowing the line to run.

- If the tachometer RPM recording indicates that the baking time is less than 13 minutes:

- The cookies will be put on QC hold. The PCQI will determine whether the product will be diverted to further processing (e.g., baking) to make cookie crumbles as a baking ingredient or to animal food (non-pet food); and

- The PCQI will conduct an investigation to determine why the bake time was not met and will inform plant management of actions they need to take to prevent this from happening in the future.

If the dough depositor is depositing a dough weight that exceeds the maximum 28 g:

- The PCQI will determine whether the product will be further processed into alternative products or be diverted to animal food (non-pet food), and (if possible) determine what caused the depositor to deliver an incorrect weight so that actions can be taken to prevent such occurrences; and

- The dough depositor will be adjusted by maintenance or by the equipment manufacturer to deliver the correct weight.

Cookie Processor B also has adjustment procedures that provide for:

- An assessment of product quality if the bake time is less than the operating limit of 15 minutes but more than the critical limit of 13 minutes, with an investigation of why the bake time was less than the operating limit to prevent this from happening in the future; and

- An adjustment of the dough depositor if the cookie dough weight exceeds the operating limit of 27 g but does not exceed the critical limit of 28 g.

6.13.5 Cookie Processor B's Verification Procedures

At Cookie Processor B:

- The following are calibrated at least annually:

  - Recording thermometer and chart that monitors oven temperature;

  - The automated tachometer and recorder chart that monitors belt speed (baking time);

  - The dough depositor; and

  - The scales used to check the weights of cookie portions.

- A QC technician checks the recorder charts twice per shift to confirm that the oven is maintained at the specified baking temperature of at least 350°F (177°C) and the tachometer RPM resulted in baking times of 15 minutes; the QC technician writes the date and time on the recorder charts, and initials the recorder charts.

- A QC technician checks the raw cookie dough portion weighing records (dough weight logs) twice per shift to verify that none of the dough portions exceeded 28 g in weight; the QC technician writes the date and time on the dough weight log and initials the dough weight log.

- The PCQI collects the oven recording thermometer charts, operator's baking log, tachometer charts, and dough weight sheets daily for subsequent review within 7 days of their creation.

- Within 7 days of their creation the PCQI reviews the following records, dates and initials the records or a verification cover sheet to document that review, and then files the records:

    - The calibration logs to make sure that the devices are properly calibrated using the appropriate methods and at the appropriate frequencies as specified in the calibration procedures; and

    - The oven recording thermometer charts, operator's baking log, tachometer charts, and dough weight sheets for accuracy and to ensure the parameter values were met.

- The PCQI reviews corrective action records at the end of each week, initials and dates them to document that review, and files them chronologically (based on the date of the deviation) in a folder with other corrective actions.

6.13.6 Cookie Processor B's Monitoring Records

Cookie Processor B keeps:

- The recording charts of the recording thermometer and the operator's baking log as a record of monitoring temperature in the oven;

- The recording charts of the recording tachometer with the visual observation noted on the chart as a record of monitoring the RPMs that achieve the baking time; and

- A dough weight record sheet as a record of monitoring the check of the dough depositor setting and the check of the weight of the raw dough portions deposited.

6.13.7 Cookie Processor B's Records of Corrective Actions

Cookie Processor B keeps records:

- Of any lot of cookies diverted to further processing (e.g., baking for cookie crumbles) or to animal food (non-pet food);

- Of any investigation of the cause of any deviations;

- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and

- Documenting any retraining.

Cookie Processor B also keeps records of adjustments, because such records could be useful in identifying ongoing production problems that could demonstrate a need to review and change applicable production procedures.

6.13.8 Cookie Processor B's Verification Records

Cookie Processor B maintains records initialed and dated by the PCQI, of the review of:

- Calibration logs;
- Oven recording thermometer charts;
- Operator's baking log with the hourly checks of the temperature chart and the twice-per-shift tachometer RPM reading;
- Tachometer charts;
- Dough weight logs; and
- Corrective action logs.

6.13.9 Summary Process Control Table for Cookie Processor B

Appendix 6-B summarizes the above information for Cookie Processor B on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.14 Example of Soup Processor A's Heat Treatment

6.14.1 Soup Processor A's Product, Hazard Analysis, and Batch Heat Treatment

Soup Processor A makes cooked, frozen RTE vegetable soups containing vegetable particles as ingredients. Soup Processor A cooks the soups to a minimum of 180°F (82°C) using a batch process in a 150 gallon steam-jacketed kettle, packages the soups in 8 ounce plastic bowls, and freezes the bowls of soup.

Soup Processor A's PCQI identified *L. monocytogenes* as the hazard associated with the RTE vegetable soups and determined that cooking the soup using a batch process in a steam-jacketed kettle maintained at a minimum of 180°F (82°C) was the preventive control to address this hazard. Soup Processor A's PCQI identified cooking time and vegetable particle size as processing parameters that needed critical limits to provide adequate lethality for *L. monocytogenes* during the batch kettle-cooking process. Soup Processor A's PCQI used Table 3-D in Appendix 3 of this guidance to determine process times for a range of cooking temperatures with *L. monocytogenes* as the target pathogen and arranged for food scientists at Soup Processor A to conduct in-house studies that could be used to determine the critical limits for vegetable particle size.

6.14.2 Soup Processor A's Process Design and Validation

Using Table 3-D in Appendix 3 of this guidance, Soup Processor A's PCQI determined that 0.05 minutes (3 seconds) at 180°F achieves an acceptable 6-log (i.e., 6 logarithm) reduction, typically called a 6D (6 decimal reduction) process. (See Chapter 4 for further details.) Because of the additional lethality during the heating time needed for the soup to reach 180°F (82°C), and because more than 3 seconds would elapse before cooling from 180°F could begin, Soup Processor A's PCQI decided to use an EPIPT and cook the soups until the temperature reaches 180°F rather than to continuously monitor temperature during cooking.

Food scientists at Soup Processor A conducted in-house studies to determine the critical limit for vegetable particle size. Based on those studies, Soup Processor A's PCQI determined that as long as vegetable particles in the soup did not exceed ½ inch (13 mm) square, the particles would also be at 180°F when the liquid portion of the soup reached that temperature, provided that the particles were stored refrigerated (i.e., at least 33°F) (0.6 °C) and not frozen. (Soup Processor A's SOPs specify that vegetable particles are stored refrigerated at a temperature of 33 - 40°F (0.6 - 4 °C).)

Soup Processor A established two critical limits for the production of the soup to ensure adequate lethality:

- Minimum EPIPT of 180°F (82°C); and
- Maximum size of vegetable particles (½ inch (13 mm)).

Soup Processor A determined that a critical limit for the temperature of the particles in the soup is not necessary as long as the production line follows the SOP to store the particles refrigerated.

6.14.3 Soup Processor A's Monitoring

6.14.3.1 What Soup Processor A monitors

Soup Processor A monitors the temperature of soup in the kettle and the size of any particles.

6.14.3.2 How Soup Processor A monitors

Soup Processor A:

- Uses a thermometer to periodically determine the temperature of soup in the top inch (2.5 cm) of the kettle (where it is coldest) until the EPIPT is reached and records the measured temperature in a cook log; and
- Collects a statistically-based sample of vegetable particles (e.g., diced carrots, potatoes, onions), uses digital calipers to ensure they do not exceed ½ inch (13 mm) in any direction, and records the measured size of the vegetable particles in a log.

6.14.3.3 How often Soup Processor A monitors

Soup Processor A:

- Begins measuring the temperature of the soup after approximately 30 minutes of heating;
- Measures the temperature approximately every 10 minutes after the temperature of the soup reaches approximately 170°F (77°C), until the temperature reaches 180°F (82°C); and
- Checks the particle size of every third lot of vegetable particles used as an ingredient in production upon receipt of the ingredient.

6.14.3.4 Who monitors critical factors for Soup Processor A's heat treatment

At Soup Processor A:

- The kettle cook operator measures the temperature of the soup during processing; and
- A formulation control operator checks the vegetable particle size.

6.14.4 Soup Processor A's Corrective Action Procedures

Soup Processor A's corrective action procedures specify that:

- If it is determined that the EPIPT did not reach 180°F (82°C) while the soup is being packaged but has not been frozen, packaging will be stopped and the remaining soup, including soup returned to the kettle from packages that have been filled but not frozen, will be reprocessed until the EPIPT reaches 180°F. Any packages that have already been frozen will be destroyed;
- If it is determined that the EPIPT did not reach 180°F (82°C) after the soup is packaged and frozen, the PCQI will assess the safety of the product to determine appropriate disposition. If the PCQI determines that the process delivered was inadequate to ensure product safety, the soup will be diverted to animal food (non-pet food) or destroyed;
- When soup is packaged before the EPIPT reaches 180°F (82°C) due to operator error, the kettle cook operator will be retrained, as appropriate, in proper procedures for, and the importance of, ensuring the product is not packaged before the EPIPT reaches 180°F; and
- If it is determined that the mean plus 2.5 standard deviation of the vegetable particle sizes exceeds ½ inch (13 mm) the lot of vegetables is rejected. The unopened packages will be returned to the supplier, and the PCQI will discuss the issue with the supplier so the supplier can investigate the root cause for incorrect particle size. The formulation control operator will check the vegetable particle size of every lot for the next 15 lots to verify particle sizes meet specification. If all 15 lots meet specification, the formulation control operator will return to monitoring every third lot.

6.14.5 Soup Processor A's Verification Procedures

At Soup Processor A:

- The thermometers used to measure soup temperature are:
    - Checked for accuracy at least daily by the QC technician; and
    - Calibrated by the QC technician against a NIST-calibrated reference thermometer at least annually or whenever an accuracy check shows that recalibration is needed. The PCQI reviews, dates, and initials the calibration log within a week of the calibration.

- The accuracy of digital calipers is checked by the QC technician before use by verifying that when fully closed the caliper reads zero (if not, the caliper is sent for repair or replaced);

- When calibration and accuracy checks of the thermometers and calipers are performed, the date and time are recorded in a log;

- On a weekly basis, the PCQI:

    - Reviews monitoring records (cook logs) to confirm that all soups were cooked to a minimum temperature of 180°F (82°C) as indicated by the records of the EPIPT readings;

    - Reviews the accuracy checks of the thermometers and the digital calipers;

    - Reviews the particle measurement logs to verify that vegetable particles used in the soup did not exceed ½ inch (13 mm) in size; and

- Before a lot of soup is released, the PCQI reviews corrective action records as part of a pre-shipment review to ensure all lot records are in order. (Because Soup Processor A uses an EPIPT and employees have been with Soup Processor A for many years, Soup Processor A experiences few deviations, so the PCQI has determined and documented that this timeframe, rather than 7 working days, is reasonable.)

6.14.6 Soup Processor A's Monitoring Records

Soup Processor A keeps:

- A production line cook log as a record of monitoring the temperatures; and

- A log of the size of vegetable particles checked upon receipt for the lots of raw materials used in production.

6.14.7 Soup Processor A's Records of Corrective Actions

Soup Processor A keeps records:

- Of the reprocessing of product (e.g., recooked to 180°F) (82°C) if a soup was filled before the process-specified EPIPT was achieved and had not been frozen;

- Of any product safety assessment by the PCQI (e.g., soup that had been filled before reaching the EPIPT but that had been frozen) and the disposition of such product;

- Of any investigations of the cause of any deviations (including investigation into the supplier's procedures for control of particle size);

- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and

- Documenting any retraining.

6.14.8 Soup Processor A's Verification Records

Soup Processor A maintains records with the date and initials of the PCQI for the review of:

- The log of the accuracy checks and calibration of the thermometer;
- The cook log for monitoring the soup temperatures;
- The log of the accuracy checks of the digital calipers; and
- The log of vegetable particle size;
- Corrective action records.

6.14.9 Summary Process Control Table for Soup Processor A

Appendix 6-C summarizes the above information for Soup Processor A on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.15 Example of Soup Processor B's Heat Treatment

6.15.1 Soup Processor B's Product, Hazard Analysis, and Continuous Heat Treatment

Soup Processor B makes RTE clear broths and RTE creamed vegetable soups (with no particles) that are cooked using a continuous process (in a continuous flow heat exchanger), hot-filled into 5 gallon bags, and refrigerated. The ingredients include dehydrated vegetable powders, pasteurized liquid fresh cream, spice blends, starch, and other thickeners.

Soup Processor B's PCQI, a food scientist/food engineer who functions as the facility's food processing expert[7], identified *Salmonella, L. monocytogenes, C. botulinum* type A, *C. botulinum* proteolytic type B, and *C. botulinum* non-proteolytic type B as hazards associated with the soups. Soup Processor B's PCQI determined that cooking the soups using a continuous process (in a continuous flow heat exchanger) was a preventive control to address most of these hazards. (Refrigeration will be needed to control *C. botulinum* type A and *C. botulinum* proteolytic type B in the heat-treated soups.) In identifying the processing parameters and determining the critical limits for these processing parameters, Soup Processor B's PCQI/food processing expert needed to evaluate which of the potential hazards would be the target organism.

[7] The individual who identifies critical limits, and establishes a heat treatment in a continuous flow system, for a product such as Soup Processor B's soup, should have specialized experience adequate to evaluate processing parameters, establish appropriate minimum/maximum values (e.g., the residence time in the hold tube based on flow characteristics of the product and the length and diameter of the hold tube) and ensure the safety of an RTE product packaged in reduced oxygen packaging. When the regulatory framework does not require that the individual be a "process authority," individuals with a variety of backgrounds (in this case, a food engineering background) could have such specialized experience.

Because hot-filling into 5-gallon bags would result in reduced oxygen packaging, and because the soups will be distributed refrigerated, Soup Processor B's PCQI/food processing expert determined that *C. botulinum* non-proteolytic type B is an appropriate target organism for the soup heat treatment.[8]

6.15.2 Soup Processor B's Process Design and Validation

Using Table 3-E of Appendix 3 of this guidance, Soup Processor B's PCQI/food processing expert determined that a heat treatment that targeted *C. botulinum* non-proteolytic type B as the most heat resistant pathogen would also address *Salmonella* and *L. monocytogenes* and that hot-filling at 185°F (85°C) would minimize risk of recontamination after the heat treatment.

Based on an assessment and review of the scientific literature, Soup Processor B's PCQI/ food processing expert decided to use a process of 205°F (96°C) for 2.5 minutes (equivalent to a minimum temperature of 194°F (90°C) for a minimum of 10 minutes) based on Table 3-E of in Appendix 3 of this guidance. This time and temperature combination will deliver a 6D process for the most heat resistant spores for strains of *C. botulinum* non-proteolytic type B.

Briefly, the procedure for the continuous heat and hot-fill process for clear broths and creamed vegetable soups is as follows:

- Add the dry ingredients to the blend tank with the volume of water specified in the formulation and mix at a high speed (> 2000 rpm) for 30 minutes to ensure all dry materials are wetted and in solution (no clumps), and then blend in fresh cream that has been refrigerated to 40°F - 45°F (4°C- 7°C);

- Pump the untreated soup from the blend tank to the pre-process agitated surge tank (which is water jacketed to control the contents at the set process Initial Temperature (IT) (between 40°F and 45°F) (4°C- 7°C)) through in-line sieves to ensure no mix particles larger than 0.1 inch (2.5 mm) pass to the pre-process agitated surge tank;

- Pump the untreated soup via a metering pump (at a flow rate specified in gal/min) from the pre-process agitated surge tank to the indirect continuous heat exchanger (scraped surface) and then to the hold tube (which is sized to ensure the soup mix is held at the process temperature for a minimum of 2.5 minutes);

- The heat-treated soup flows from the hold tube into an agitated hot-holding surge tank that keeps the soup at $\geq$ 185°F (85°C); the heat-treated soup is then pumped to the filling hopper for the hot-fill process;

- Hot fill the heat-treated soup into 5-gallon pre-labeled bags and seal the bags; and

- Cool the sealed, hot-filled soup bags, pack them in a carton, and store the carton under refrigeration prior to distribution.

[8] Annex 6 of the Food Code (FDA, 2013) is a source of additional information about selection of the target organism.

Soup Processor B's PCQI/ food processing expert determined that five process parameters are critical to the safety of the food product and established critical limits for each of these process parameters:

- IT of product held in the pre-process agitated surge tank (between 40°F and 45°F) (4°C-7°C);
- Metering pump speed (RPM) to deliver process-specified flow rate (gal/min);
- Hold tube size (must deliver a minimum 2.5 minute product hold time prior to hot-filling);
- Temperature of the heat-treated soup at discharge end of hold tube (minimum value of 205°F) (96°C); and
- Temperature of the heat-treated soup in the agitated hot-holding surge tank (minimum value of 185°F) (85°C).

6.15.3 Soup Processor B's Monitoring

6.15.3.1 What Soup Processor B monitors

Soup Processor B:

- Monitors the IT in the surge tank;
- Checks the pump speed RPM setting;
- Checks that the correct hold tube is in place prior to production;
- Checks the temperature of the heat-treated soup exiting the hold tube using an RTD probe connected to a recording device; and
- Monitors the temperature of the heat-treated soup held in the agitated hot-holding surge tank prior to final packaging (i.e., hot fill).

6.15.3.2 How Soup Processor B monitors

Soup Processor B:

- Uses a Resistance Temperature Detector (RTD) probe attached to a recording chart to monitor the IT of the untreated soup in the pre-processing surge tank;
- Visually observes that the RPM dial setting on the pump (i.e., pump speed in RPM) is appropriate to achieve the process-specified flow rate of the soup;
- Visually observes that the correct hold tube is in place (hold tubes are numbered and each numbered hold tube is assigned to specific soup recipes);
- Uses an RTD probe attached to a recording chart to monitor the temperature of the heat-treated soup exiting the hold tube; and

- Uses another RTD probe attached to a recording chart to monitor the temperature of the heat-treated soup in the hot-holding surge tank.

6.15.3.3 How often Soup Processor B monitors

Soup Processor B:

- Checks the continuously recorded IT (RTD chart recorder) of the untreated soup in the pre-process surge tank twice per shift;
- Checks and records the pump speed setting (flow rate) at the beginning of production and twice per shift;
- Notes the hold tube used on the pump speed log at the beginning of production and whenever the variety of soup being produced changes;
- Checks the continuously recorded temperature (RTD chart recorder) of the heat-treated soup at the exit of the hold tube twice per shift; and
- Checks the continuously recorded temperature (RTD chart recorder) of the heat-treated soup in the filling surge tank twice per shift.

6.15.3.4 Who monitors critical factors for Soup Processor B's heat treatment

At Soup Processor B, the line operator monitors the recorded temperature data (IT of the untreated soup, temperature of the heat-treated soup exiting the hold tube, and temperature of the heat-treated soup in the agitated hot-holding surge tank), the pump speed setting, and the hold tube identification.

6.15.4 Soup Processor B's Corrective Action Procedures

Soup Processor B's corrective action procedures specify:

- A list of:
    - Those soups that can be fully reprocessed in instances where soup was under-processed; and
    - Those soups that cannot be fully reprocessed and therefore will be diverted to animal food (non-pet food) or destroyed if the PCQI determines that the process delivered was inadequate to ensure product safety.
- If the IT of the untreated soup was too low during the production of that soup:
    - The product will be held until the PCQI determines whether the process was adequate or if the soup can be reprocessed; and
    - The production manager will investigate why the IT was too low and take appropriate actions to prevent the situation from reoccurring.

- If the metering pump speed during production of the soup was too fast:
    - Any ongoing production will be stopped and affected product will be held until the PCQI evaluates the safety of the product;
    - The PCQI will assess the safety of the product and determine whether it will be released, re-processed, diverted to animal food (non-pet food), or destroyed; and
    - The production manager will investigate why the pump speed was too fast and take appropriate actions to prevent the situation from reoccurring.
- If the incorrect hold tube was used:
    - The PCQI will assess the safety of the product to determine appropriate disposition;
    - The production manager will investigate why the incorrect hold tube was used; and
    - Employees will be retrained if necessary in light of the reason the incorrect hold tube was used.
- If the RTD at the end of the hold tube recorded a low temperature and the soup was not diverted to the batch tank for automatic reprocessing:
    - The PCQI will assess the safety of the product to determine appropriate disposition; and
    - The production manager will investigate the low temperature and the diversion failure and take appropriate action to fix the problem.
- If the temperature of the heat-treated soup in the agitated hot-holding surge tank is below the process set point:
    - The product will be held until the PCQI determines whether the temperature was adequate for safety or if the soup should be reprocessed, diverted to animal food (non-pet food), or destroyed.
    - The production manager will investigate why the temperature was too low and take appropriate actions to prevent the situation from reoccurring.

6.15.5 Soup Processor B's Verification Procedures

At Soup Processor B:

- An outside calibration service annually performs on-site calibration of the RTDs and recording devices used to measure IT of the untreated soup, the temperature of the heat-treated soup at the exit of the hold tube, and the hot-fill temperature. A sticker with the calibration date is affixed to each recording device and the date and results are recorded in a calibration log. Soup Processor B's PCQI also reviews, initials, and dates the monitoring device calibration logs within a week of their creation;

- The Quality Assurance Manager or designee verifies twice a year that the pump speed provides the correct flow rate for the hold tubes used for the different soups, and the PCQI reviews this within one week;

- On a daily basis, the PCQI :

    - Reviews recorder charts and pump speed log with the hold tube identification to confirm that the soup was cooked at the specified temperature of 205°F (96°C) for a minimum of 2.5 minutes; and

    - Checks the other process logs to confirm that the soup in the pre-process agitated surge tank was maintained at an IT between 40°F and 45°F (4°C- 7°C), that the temperature of the heat-treated soup at hold tube exit was at least 205 °F (96°C), and that the temperature of the heat-treated soup held in the agitated hot-holding surge tank prior to hot-filling was maintained at the specified process temperature of $\geq$ 185°F (852°C), and also checks that process log temperatures agree with the recorder charts;

- The PCQI reviews corrective action records within one week of when the deviation occurred; and

- Soup Processor B does not conduct product testing for pathogens or environmental monitoring because the product, which is subjected to a heat treatment validated to be highly lethal to vegetative pathogens and filled hot, is not exposed to the environment after the heat treatment.

6.15.6 Soup Processor B's Monitoring Records

Soup Processor B keeps:

- The recording charts from the RTDs used to monitor the IT of the untreated soup exiting the pre-process agitated surge tank, the temperature of heat-treated soup exiting the hold tube, and the temperature at the agitated hot-holding surge tank;

- The process logs for the temperature checks (IT of the untreated soup, temperature of the heat-treated soup exiting the hold tube, and temperature at the agitated hot-holding surge tank); and

- A process log for each line to record pump speeds and hold tube number for the product being processed.

6.15.7 Soup Processor B's Records of Corrective Actions

Soup Processor B keeps records:

- Of any product safety assessment by the PCQI of the safety of product to determine appropriate disposition if:

    - The IT of the untreated soup was too low;

    - The metering pump speed was too fast;

  - An incorrect hold tube was used;
  - The RTD at the end of the hold tube recorded a low temperature and the heat-treated soup was not diverted to the batch tank for automatic reprocessing; or
  - The temperature for the heat-treated soup held in the agitated hot-holding surge tank prior to hot-filling was too low.

- Of the reprocessing of a soup that can be reprocessed if the RTD at the end of the hold tube recorded a low temperature and the soup was not diverted to the batch tank for automatic reprocessing;
- Of any soup that cannot be reprocessed and thus is sent to animal food (non-pet food) or destroyed;
- Of any investigations of the cause of any deviations;
- Of all changes made to correct a problem and to prevent reoccurrence of deviations; and
- Documenting any retraining.

6.15.8 Soup Processor B's Verification Records

Soup Processor B maintains the following records with the date and initials of the PCQI for the review of:

- The monitoring records - i.e.:
  - The temperature recording chart for all RTD probes (IT of the untreated soup exiting the pre-process agitated surge tank, the temperature of heat-treated soup exiting the hold tube, and the temperature at the agitated hot-holding surge tank);
  - The process logs for the temperature checks (IT of the untreated soup exiting the blend tank, the temperature of heat-treated soup exiting the hold tube, and temperature at the agitated hot-holding surge tank); and
  - The process logs for each line with pump speeds and hold tube number for the product being processed;
- The calibration logs, including notes of the actions taken when any adjustments were needed;
- The semi-annual verification tests that the pump speed provides the correct flow rate for the hold tubes used for the different soups, including notes of when any adjustments to the pump speed were needed; and
- The corrective action records.

6.15.9 Summary Process Control Table of Soup Processor B

Appendix 6-D summarizes the above information for Soup Processor B on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.16 Example of Salsa Processor A's Heat Treatment

6.16.1 Salsa Processor A's Product, Hazard Analysis, and Heat Treatment

Salsa Processor A manufactures a shelf-stable chopped mixed vegetable salsa product that is an acidified food subject to the requirements of 21 CFR part 114 (part 114). Our regulations for acidified foods in part 114 require that an acidified food be manufactured, processed, and packaged so that the finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished products. (See 21 CFR 114.80(a)(1).) Acidified foods are shelf-stable foods and must be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. (See 21 CFR 114.80(a)(1).) The "scheduled process" (i.e., the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance) includes control of pH and other critical factors equivalent to the process established by a competent processing authority (21 CFR 114.3). Salsa Processor A's PCQI is also a thermal process authority for the purpose of establishing a scheduled process in accordance with part 114.[9]

Salsa Processor A's product consists of chopped vegetables (i.e., tomatoes, long green chilies, onions, jalapeño peppers, and garlic), salt, spices, and vinegar. Each batch is directly acidified, cooked in a kettle, and then hot-filled into glass jars. The hermetically sealed jars are shelf stable under ambient storage temperatures.

Salsa Processor A's PCQI/process authority identified *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes* and *Clostridium botulinum* as hazards associated with the salsa because these pathogenic bacteria can be present on some of the ingredients and can be a hazard if the salsa is not properly acidified to a pH that is low enough to prevent the germination of spores of *C. botulinum* and if the heat treatment is not adequate to kill vegetative cells of the pathogenic bacteria.

Salsa Processor A's PCQI/process authority consulted the scientific literature and found that some sporeforming microorganisms that are generally associated with spoilage (such as *Bacillus subtilis* (*B. subtilis)*, and *B. licheniformis*) could potentially affect the safety of an acidified food if spores that are not destroyed during the product heat treatment germinate, grow, and cause the pH to increase above 4.6 such that spores of *C. botulinum* could

[9] Our regulations require that a commercial processor engaged in the processing of acidified foods provide us with information, submitted on Form FDA 2541e, on the scheduled processes for each acidified food in each container size. (See 21 CFR 108.25(c)(2).) For additional information about submitting a "process filing" for an acidified food using Form FDA 2541e, see our guidance for industry entitled "Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format" (FDA, 2015).

germinate, grow and produce toxin (Rodriguez et al, 1992). However, the scientific literature indicated that these sporeformers do not grow at pH 4.2 or less and require oxygen for growth at pH 4.4 (Rodriguez et al, 1992). Salsa Processor A's salsa is acidified to pH 4.1; thus Salsa Processor A's PCQI/process authority determined that the heat treatment should target vegetative pathogens such as *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes.* Salsa Processor A's PCQI/process authority also determined that there were non-pathogenic sporeformers that would survive a heat treatment designed for vegetative pathogens that could spoil the product under ambient conditions.

6.16.2 Salsa Processor A's Process Design and Validation

Based on an assessment and review of scientific literature, Salsa Processor A's PCQI/ process authority selected a process (158°F (70°C) for 1.5 minutes) that will deliver a 5D process for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes* at a product pH of no higher than 4.1 (Breidt et al., 2010). Salsa Processor A's PCQI/process authority also determined that the pH of 4.1 would control sporeforming pathogens such as *C. botulinum,* as well as sporeformers that could potentially grow and raise the pH of the salsa. (See Chapter 8 – "Use of Formulation as a Process Control" for information on the use of acidification to control *C. botulinum*.) Salsa Processor A's PCQI/process authority also determined that a process that delivers 200°F (93°C) for 2 minutes is adequate to destroy any other sporeformers that could survive the process and potentially spoil the product, and thus achieve a shelf-stable product.

In-house studies determined that as long as the chopped vegetable particles in the salsa did not exceed 1.0 cm (0.4 inch) square, the particles would also be at 158°F (70°C) when the liquid portion of the salsa reached that temperature, provided that the particles were stored refrigerated (i.e., at least 33°F (0.6°C)) and not frozen. (Salsa Processor A's SOPs specify that vegetables to be chopped are stored refrigerated (at a temperature of 33 - 40°F (0.6 - 4 °C)) until used.) Salsa Processor A determined that the size of the particles in the vegetable salsa is a parameter requiring a critical limit (i.e., a maximum value of 1.0 cm square). However, Salsa Processor A's PCQI/process authority determined that a critical limit for the temperature of the particles in the vegetable salsa is not necessary as long as the production line follows the SOP to store the particles refrigerated.

Briefly, the procedure for the production of the mixed vegetable salsa is as follows:

- All vegetables, which have been held refrigerated, are washed and or peeled, cored or seeded, and chopped;

- Vinegar (5 percent acetic acid), salt, and spices are prepped and weighed per recipe;

- Salsa is made by combining all ingredients in an agitated 150 gallon steam-jacketed cook kettle that heats the salsa to 200°F (93°C); the salsa is then held for at least 2 minutes;

- Heat-treated salsa is pumped from the cook kettle to a temperature-controlled filling surge tank and equilibrated to 200°F (93°C);

- The heat-treated salsa is then hot-filled into clean pint glass jars via a volumetric filler. Jars are capped under flowing steam, then inverted and conveyed for one minute (to kill microorganisms on the container) prior to being re-inverted, and conveyed through a cold water shower for cooling; and

- Cooled and sealed jars are then dried prior to being labelled, packed 12 to a carton, and stored on pallets.

Salsa Processor A's PCQI/ process authority determined that the following process parameters related to the heat treatment are critical to the safety of the chopped vegetable salsa[10] and established critical limits for each of these process parameters:

- Maximum particle size of chopped vegetables (1.0 cm) (0.4 inch);
- Minimum process temperature for the salsa (158°F) (70°C)[11];
- Minimum process time for the salsa (1.5 minutes);
- Minimum temperature of the heat-treated salsa in the filling surge tank (158°F) (70°C); and
- Minimum inverted jar hold time (1 minute).

Because Salsa Processor A needs to make a shelf-stable food, Salsa Processor A treats the operating limits established for shelf-stability as if they were the critical limits established for food safety.

6.16.3 Salsa Processor A's Monitoring

6.16.3.1 What Salsa Processor A monitors

Salsa Processor A:

- Monitors the particle size of the chopped vegetables;
- Monitors the temperature of the in-process salsa in the cook kettle;
- Monitors the time that the in-process salsa is at the process temperature (operating limit) of 200°F (93°C) or higher in the cook kettle (which ensures that the critical limit of 158°F (70°C) will be met);
- Monitors the temperature of the heat-treated salsa held in the filling surge tank prior to final packaging (i.e., hot fill); and
- Checks conveyor belt speed as indicated by automated tachometer RPM (for control of inversion time) for inverted jars.

6.16.3.2 How Salsa Processor A monitors

Salsa Processor A:

[10] See Chapter 8 – Use of Formulation as a Process Control – for additional information about pH as a critical factor in the production of an acidified food, including the preventive control management components.
[11] This is the process for safety. However, the acidified foods regulation requires the destruction of spoilage organisms such that the food is shelf-stable. Thus the operating limits are actually 200°F (93°C) for 2 minutes.

- Collects a statistically-based sample of vegetable particles (e.g., chopped tomatoes, green chilies, onions, jalapeño peppers), uses digital calipers to ensure they do not exceed 1 cm (0.4 inch) in any direction, and records the results in the process log;

- Uses an RTD probe attached to a recording chart to monitor the temperature of the in-process salsa at the cold point in the cook kettle (in top inch (2.5 cm) of kettle), visually checks the chart and records the observed temperature in the process log;

- Visually checks the temperature recorder chart and marks it with the batch number, records the time when the in-process salsa reaches the process temperature in the process log, calculates the processing time, records the processing time on the recorder chart and in the process log, notes when product should be transferred from cook kettle in the process log, and records the time when product is transferred from the cook kettle to the filling surge tank in the process log;

- Uses another RTD probe attached to a recording chart to monitor the temperature of the heat-treated salsa in the filling surge tank, visually checks the chart, and records the temperature in the process log; and

- Uses an automated tachometer with recorder chart to monitor the conveyor speed (which is tied to the jar inversion time), visually checks the tachometer RPM, and records the RPM in the process log.

6.16.3.3 How often Salsa Processor A monitors

Salsa Processor A:

- Checks the particle size of one in-process lot of each chopped vegetable once per production shift;

- Checks the continuously recorded temperature (RTD chart recorder) of the in-process salsa in the cook kettle once for each batch;

- Checks the processing time once for each batch;

- Checks the continuously recorded temperature (RTD chart recorder) of the in-process salsa in the filling surge tank twice per shift; and

- Monitors the automated tachometer RPM (inversion conveyor belt speed) at the beginning of production and twice per shift.

6.16.3.4 Who monitors critical factors for Salsa Processor A's heat treatment

At Salsa Processor A:

- A formulation control operator checks the particle size of the chopped vegetables; and

- The line operator monitors the recorded temperature and time data (in-process salsa in cook kettle and filling surge tank, and the automated tachometer RPM (conveyor belt speed) for jar inversion.

6.16.4 Salsa Processor A's Corrective Action Procedures

Salsa Processor A's corrective action procedures specify:

- If it is determined that the mean plus 2.5 standard deviation of the vegetable particle sizes exceeds 1 cm (0.4 inch), the in-process lot of chopped vegetables is rejected and will be reworked for a different recipe. The PQCI will check with the vegetable processing operator to investigate the root cause of the incorrect particle size and, when applicable, notify maintenance to reset the vegetable chopper operation to specification. The formulation control operator will check the vegetable particle size of every in-process lot for the next 15 in-process lots to verify particle sizes meet specification. If all 15 lots meet specification, the formulation control operator will return to monitoring one in-process lot of each chopped vegetable once per production shift;

- If the RTD at the cook kettle records a low temperature or a shortened process time:

    - The product will be held until the PCQI determines whether the process was adequate for safety or if the product should be reprocessed or destroyed;

    - The production manager will investigate why the under-processing occurred and take appropriate actions to prevent the situation from reoccurring; and

    - Employees will be retrained if necessary in light of the reason for the under-processing;

- If the temperature at the filling surge tank is below the process set point:

    - The product will be held until the PCQI determines whether the fill temperature was adequate for safety or if the product should be reprocessed or destroyed;

    - The production manager will investigate why the fill temperature was too low and take appropriate actions to prevent the situation from reoccurring; and

    - Employees will be retrained if necessary; and

- If it is determined that the jar inversion time is below the process set point:

    - The product will be held until the PCQI determines whether the process was adequate or if the product can be reprocessed;

    - The production manager will investigate why the belt speed deviated from the process set point and take appropriate actions to prevent the situation from reoccurring; and

    - Employees will be retrained if necessary in light of the reason for the belt speed deviation.

6.16.5 Salsa Processor A's Verification Procedures

At Salsa Processor A:

- An outside calibration service annually performs on-site calibration of the RTDs, tachometer, and recording charts used to measure the temperature at the cook kettle and the hot-fill surge tank, and the belt speed of the jar inversion conveyor. A sticker with the calibration date is affixed to each recording device and the date and results are recorded in a calibration log. The PCQI reviews, initials, and dates the monitoring device calibration logs within a week of their creation;

- The Quality Assurance Manager or designee verifies the jar inversion belt speed and time twice each year, and the PCQI reviews this within one week;

- On a daily basis, the PCQI :

    - Checks process logs to confirm that the particle size of the chopped vegetables was at the specified value of < 1 cm (0.4 inch);

    - Reviews process logs and recorder charts to confirm that the in-process salsa was cooked to 200°F (93°C) for a minimum of 2.0 minutes, and checks that process log temperatures agree with the recorder;

    - Reviews process logs and recorder charts to confirm that the jars were filled at the specified temperature of ≥200°F (93°C), and checks that process log temperatures agree with the recorder charts; and

    - Reviews the recorded RPM for the conveyor belt to confirm that the jars were inverted for the minimum specified time of 1 minute;

- The PCQI reviews corrective action records within one week of when the deviation occurred and

- Salsa Processor A does not conduct product testing for pathogens or environmental monitoring because the product, which is acidified and subjected to a heat treatment validated to be highly lethal to vegetative pathogens and filled hot, is not exposed to the environment after the heat treatment.

6.16.6 Salsa Processor A's Monitoring Records

Salsa Processor A keeps:

- The process logs for checks of the particle size of the chopped vegetables;

- The recording charts from the RTDs used to monitor the temperature and time of the in-process salsa in the cook kettle and in the filling surge tank;

- The recording chart from the automated tachometer used to monitor the jar inversion conveyor belt speed;

- The process logs for temperature checks (cook kettle and filling surge tank) and process times in the cook kettle; and
- The process logs for the belt speed for the jar inversion conveyor belt.

6.16.7 Salsa Processor A's Records of Corrective Actions

Salsa Processor A keeps records:

- Of any product safety assessment by the PCQI of the safety of product to determine appropriate disposition if:
    - The RTD at the cook kettle recorded a low temperature;
    - The cooking process time was less than the minimum specified time;
    - The product temperature in the filling surge tank was too low; or
    - The jar inversion time was too short;
- Of the reprocessing of a product that can be reprocessed if:
    - Particle size of the chopped vegetables exceeded process set point;
    - The process temperature of the in-process salsa in the cook kettle was too low;
    - The process time was less than the minimum specified time;
    - The temperature of the heat-treated salsa in the filling surge tank was too low; or
    - The jar inversion time was too short;
- Of any product that cannot be reprocessed and thus is destroyed;
- Of any investigations of the cause of any deviations;
- Of all changes made to correct problems and to prevent reoccurrence of deviations; and
- Documenting any retraining.

6.16.8 Salsa Processor A's Verification Records

Salsa Processor A maintains the following verification records:

- The date and initials of the PCQI on the monitoring record (e.g., on the charts or in the logs) for the review of:
    - Each temperature recording chart for all RTD probes (cook kettle and filling surge tank);
    - The process logs for the temperature checks (cook kettle and filling surge tank);

- The recording charts for the automated tachometer on the jar inversion conveyor belt;

- The process logs for checks of the particle size of the chopped vegetables and belt speed of the jar inversion conveyor belt; and

- The date and initials in the calibration log of the PCQI's review of the results of the outside calibration service's calibration of the RTDs and automated tachometer, as well as any notes by the PCQI of the actions taken when any adjustments were needed;

- The date and initials of the PCQI's review of the results of the semi-annual verification tests that the jar inversion conveyor belt speed is correct, as well as any notes by the PCQI when any adjustments to the conveyor belt were needed; and

- The date and initials of the PCQI's review of corrective action records.

6.16.9 Summary Process Control Table for Salsa Processor A

Appendix 6-E summarizes the above information for Salsa Processor A on the FSPCA's Process Control Form (Form 2-C (Modified) from Appendix 2).

6.17 References

FDA. 2013. FDA Food Code 2013: Annex 6 Food processing criteria. http://www.FDA.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf.

FDA. 2015. Guidance for Industry: Submitting Form FDA 2541 (Food Canning Establishment Registration) and Forms FDA 2541d, FDA 2541e, FDA 2541f, and FDA 2541g (Food Process Filing Forms) to FDA in Electronic or Paper Format http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm309376.htm.

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Rodriguez J, Cousin M, and Nelson P. 1992. Evaluation of anaerobic growth of *Bacillus licheniformis* and *Bacillus subtilis* in tomato juice. *Journal of Food Protection* 55: 672-677.

Appendix 6. Summary Process Control Tables for the Examples in Chapter 6

Appendix 6-A: Summary Process Control Table for Baking; Cookie Processor A

FORM 2-C (Modified)[12] PROCESS CONTROLS

PAGE _____

PRODUCTS: Cookies baked in batches on trays in ovens and packaged by wrapping the cookies by twos in plastic
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: Baking
HAZARD(S): *Salmonella*

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[13]
Minimum oven temperature of 350°F (177°C) (operating limit is 352°F (178°C))	Temperature of oven	• Recording thermometer in oven • Manual check of recording chart and mark the recording with the batch number • Record temperature on baking record sheet	Continuous recording during each batch; manual check before putting cookies in oven	Baker	If oven was not at least 350°F (177°C): • Cookies will be diverted to cattle feed; and • Employees will be retrained on the importance of ensuring that the oven temperature has reached the set point.	• Annual calibration of thermometer • Records review by PCQI within one week of record creation (baking sheets, temperature recording chart, calibration logs) • Review of corrective action records within one week of a deviation	• Baking record sheets • Temperature recording charts • Calibration records • Corrective action records

[12] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.
[13] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[13]
Minimum process time of 13 minutes (operating limit is 15 minutes)	Time in oven	On baking record sheets: • Record time that cookies are placed in the oven • Calculate and record the time when the cookies should be removed from oven • Record time that cookies are removed from the oven • Calculate the elapsed baking time	Each batch	Baker	If the bake time is less than 13 minutes: • Cookies will be diverted to cattle feed; and • PCQI determines why the bake time was not met to prevent this from happening in the future.	• Records review by PCQI within one week of record creation (Baking record sheets) • Review of corrective action records within one week of a deviation	• Baking record sheets • Corrective action records
Dough weight ≤28 g (operating limit is ≤27 g)	• Dough depositor setting • Dough weight	• Check set point of depositor • Weigh dough portions	• Check set point every 2 hours • Weigh dough portions twice per shift	QC technician	If dough weight exceeds 28 g: • Product will be diverted to cattle feed; • PCQI will determine (if possible) what caused the depositor to deliver an incorrect weight; and. • Dough depositor adjusted to deliver correct weight.	• Annual calibration of dough depositor and scales • Records review by PCQI within one week of record creation (calibration logs, dough weight logs) • Review of corrective action records within one week of a deviation	• Dough weight log • Calibration records • Corrective action records

Appendix 6-B: Summary Process Control Table for Baking; Cookie Processor B

FORM 2-C (Modified)[14] PROCESS CONTROLS

PAGE _____

PRODUCTS: Cookies baked in a continuous band oven and packaged in boxes of 24 cookies
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: __Baking_____
HAZARD(S): ___*Salmonella*_____

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[15]
Minimum oven temperature of 350°F (177°C) (operating limit is 352°F (178°C))	Temperature of oven at the identified cold spot	Recording thermometer in oven, visual check of recording chart, with a note of the check in the operator's baking log	Continuous recording during each batch with visual check every hour	Baker	If oven was not at least 350°F (177°C): • Cookies will be diverted to further processing (baking for cookie crumbles) or cattle feed; • Maintenance will determine the cause of the low temperature and fix the oven so the temperature is at least 350 °F (177°C) before more cookies are baked; and • Employees will be retrained if necessary.	• Annual calibration of oven thermometer and temperature recording chart • QC technician check of thermometer recording chart • Records review by PCQI within 7 days of record creation (operator's baking log, temperature recording chart, calibration log) • Review of corrective action records at the end of each week	• Operator's baking log • Temperature recording chart • Calibration records for thermometer and temperature recording chart • Corrective action records

[14] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.
[15] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[15]
Maximum belt speed (tachometer RPM) to achieve a minimum process time of 13 minutes (operating limit is maximum tachometer RPM to achieve a process time of 15 minutes)	Belt speed (tachometer RPM)	Automated tachometer with recorder chart and visual observation of tachometer RPM	Continuous recording during each batch with visual check at start-up and twice per shift	Baker	If the tachometer reading indicates that the baking time is less than 13 minutes: • The cookies are placed on hold; • The PCQI assesses whether the cookies will be diverted to bake as cookie crumbles or diverted to cattle feed; and • The PCQI determines why the bake time was not met and informs management of actions they need to take to prevent this from happening.	• Annual calibration of tachometer and its recorder chart • QC technician check of tachometer recording chart • Records review by PCQI within 7 days of record creation (tachometer chart, calibration logs) • Review of corrective action records at the end of each week	• Recording chart for automated tachometer • Calibration records for tachometer and its recording chart • Corrective action records
Dough weight ≤28 g (operating limit is ≤27 g)	• Dough depositor setting • Dough weight	• Check set point of depositor • Weigh dough portions	• Check set point at start-up and every 2 hours • Weigh dough portions twice per shift	Dough preparer	If dough weight exceeds 28 g: • PCQI will determine whether the product will be further processed or diverted to cattle feed; and • PCQI will determine (if possible) what caused the depositor to deliver an incorrect weight. • Dough depositor adjusted to deliver correct weight.	• Annual calibration of dough depositor and scales • QC technician check of dough weight log twice per shift • Records review by PCQI within 7 days of record creation (calibration logs, dough weight logs) • Review of corrective action at the end of each week	• Dough weight record sheets • Calibration records for dough depositor and scales • Corrective action records

Appendix 6-C: Summary Process Control Table for Cooking; Soup Processor A

FORM 2-C (Modified)[16] PROCESS CONTROLS

PAGE _____

PRODUCTS: Soup cooked in a kettle, packaged in 8 ounce plastic bowls, and frozen _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: ___Cooking_____
HAZARD(S): __*Listeria monocytogenes*_____

[16] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[17]
Minimum soup temperature of 180°F (82°C) (EPIPT)	Temperature of soup in kettle	Thermometer inserted into soup in top inch (2,5 cm) of kettle; measured temperature is recorded in the cook log	Begin after 30 min; then every 10 min after reaching 170°F (77°C) until the EPIPT is reached (180°F (82°C))	Kettle cook operator	• If EPIPT did not reach 180°F (82°C) and soup is being packaged but has not been frozen: stop packaging and reprocess soup until the EPIPT reaches 180°F. Packages that have been frozen will be destroyed. • If EPIPT did not reach 180°F (82°C) and soup has been packaged and frozen, the PCQI will assess the safety of the product to determine appropriate disposition. If process delivered was inadequate to ensure product safety, soup will be diverted to animal food or destroyed. • If soup is packaged before the EPIPT reaches 180°F (82°C) due to operator error, the kettle cook operator will be retrained.	• PCQI reviews cook log weekly. • QC technician calibrates thermometers against NIST reference thermometer at least annually; PCQI reviews the calibration log within a week of the calibration. • QC technician checks accuracy of thermometers daily; PCQI reviews these accuracy checks on a weekly basis. • PCQI reviews corrective action records before shipment of each lot of soup.	• Cook log of monitoring temperature • Thermometer calibration and accuracy checks log • Corrective action records
Maximum particle size no greater than ½ inch (13 mm) in any direction	Size of diced carrots, potatoes, onions	Collect a statistically-based sample of vegetable particles and then use digital calipers to ensure they do not exceed ½ inch (13 mm) in any direction; record the measurement in a log	Every third lot on receipt	Formulation control operator	If vegetable particle sizes exceed ½ inch (13 mm): • The lot of vegetables is rejected and unopened packages are returned to the supplier; • PCQI discusses with the supplier so the supplier can investigate the root cause for incorrect particle size; and • Formulation control operator checks vegetable particle size of every lot for the next 15 lots. If all 15 lots meet specification, the formulation control operator will return to monitoring every third lot.	• QC technician checks accuracy of digital calipers before use. • PCQI reviews particle measurement log and accuracy checks of the digital calipers weekly. • PCQI reviews corrective action records before shipment of each lot of soup	• Vegetable particle size log • Digital caliper accuracy check logs • Corrective action records

[17] Records include the date and initials of the PCQI (or designee) as verification.

Appendix 6-D: Summary Process Control Table for Cooking; Soup Processor B

FORM 2-C (Modified)[18] PROCESS CONTROLS

PAGE _____

PRODUCTS: Soup cooked in a continuous flow heat exchanger, packaged in 5 gallon bag, and refrigerated
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: Cooking
HAZARD(S): Vegetative pathogens such as *Salmonella* and *Listeria monocytogenes*; and *Clostridium botulinum* (especially non-proteolytic type B)

[18] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[19]
Minimum soup IT of 40°F (4°C)	IT in pre-process agitated surge tank	RTD probe with recording chart monitors IT	Continuous recording of IT checked twice per shift	Line operator	If the IT of a batch of soup was too low during the processing of that soup: • Product will be held until the PCQI determines whether the process was adequate or if the soup can be reprocessed; and • Production manager will investigate why the IT was too low and take appropriate actions to prevent the situation from reoccurring.	• Outside service calibrates RTDs and recorder charts annually. • PCQI reviews calibration logs within 1 week of creation. • PCQI reviews recorder charts and the process logs containing IT daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for temperature checks of IT • Recording charts of IT • Calibration records for RTDs and recorder charts • Corrective action records
Metering pump speed to deliver process-specified flow rate (gal/min)	Pump RPM setting	Visual observation of RPM dial setting	At beginning of production and twice per shift	Line operator	If the metering pump speed during production of the soup was too fast: • Any ongoing production will be stopped and affected product will be held until the PCQI evaluates the safety of the product; and • The PCQI will assess the safety of the product and determine whether it will be released, re-processed, diverted to animal food, or destroyed. • Production manager will investigate why the pump speed was too fast and take appropriate actions to prevent the situation from reoccurring	• QA manager verifies pump speed provides correct flow rate for the hold tubes twice a year and PCQI reviews this within 1 week. • PCQI reviews pump speed log daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for pump speeds • Calibration records for flow rates • Corrective action records

[19] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[19]
Correct hold tube to deliver 2.5 minute hold time at specified pump speed	Correct hold tube in place	Visual observation that hold tube number is correct for the specific soup recipe	At beginning of production and when soup variety changes	Line operator	If the incorrect hold tube was used: • PCQI will assess the safety and determine disposition of the product; • Production manager will investigate why the incorrect hold tube was used; and • Employees will be retrained if necessary	• PCQI reviews pump speed log with hold tube identification daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs containing hold tube number for the product being processed (i.e., the pump speed log) • Corrective action records
Minimum product temperature at end of hold tube of 205°F (96°C)	Temperature at end of hold tube	RTD probe with recording chart monitors temperature at hold tube exit	Continuous recording of product at hold tube exit checked twice per shift	Line operator	If soup is not automatically diverted for reprocessing when the temperature at the end of the hold tube is low: • PCQI will assess the safety of the product and determine appropriate disposition; and • Production manager will investigate the low temperature and the diversion failure and take appropriate action to fix the problem.	• Outside service calibrates RTDs and recorder charts annually. • PCQI reviews calibration logs within 1 week of creation. • PCQI reviews recorder charts and the process logs containing temperature at hold tube exit daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for temperature checks of hold tube exit temperature • Recording charts of product exiting hold tube • Calibration records for RTDs and recorder charts • Corrective action records

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[19]
Minimum product temperature in agitated hot holding surge tank of 185°F (85°C)	Temperature in agitated hot holding surge tank	RTD probe with recording chart monitors temperature of product in agitated hot-holding surge tank	Continuous recording of fill temperature checked twice per shift	Line operator	If the temperature in the agitated hot-holding surge tank was below the process set point: • Product will be held until the PCQI determines whether the temperature was adequate for safety or if the soup should be reprocessed or destroyed; and • Production manager will investigate why the temperature in the agitated hot-holding surge tank was too low and take appropriate actions to prevent the situation from reoccurring.	• Outside service calibrates RTDs and recorder charts annually. • PCQI reviews calibration logs within 1 week of creation. • PCQI reviews recorder charts and the process logs containing temperature in the agitated hot-holding surge tank daily. • PCQI reviews corrective action records within one week of when deviation occurs.	• Process logs for temperature checks of filling temperature • Recording charts of filling temperature • Calibration records for RTDs and recorder charts • Corrective action records

Appendix 6-E: Summary Process Control Table for Heat Treatment; Salsa Processor A

FORM 2-C (Modified)[20] PROCESS CONTROLS

PAGE _____

PRODUCTS: Chopped mixed vegetable salsa that is an acidified food _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

PROCESS CONTROL STEP: Heat treatment_____
HAZARD(S): *Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes* and *Clostridium botulinum* _____

[20] Modified from Form 2-C in Appendix 2 to address a single process control step. Form 2-C in Appendix 2 can be used to list multiple process control steps.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Maximum particle size of chopped vegetables (1.0 cm) (0.4 inch)	Particle size of the chopped vegetables	• Collect statistically-based sample of vegetable particles; • Use digital calipers to measure particle size; and • Record results in the process log	Check one in-process lot of each chopped vegetable once per production shift	Formulation control operator	If the mean plus 2.5 standard deviation of the vegetable particle sizes exceeds 1 cm (0.4 inch): • The in-process lot of chopped vegetables is rejected and will be reworked for a different recipe. • The PQCI will check with the vegetable processing operator to investigate the root cause of the incorrect particle size and, when applicable, notify maintenance to reset the vegetable chopper operation to specification. • The formulation control operator will check the vegetable particle size of every in-process lot for the next 15 in-process lots to verify particle sizes meet specification. If all 15 lots meet specification, the formulation control operator will return to monitoring every one lot per vegetable per production shift.	On a daily basis, the PCQI checks process logs to confirm that the particle size of the chopped vegetables was at the specified value	• The process logs for checks of the particle size of the chopped vegetables • Corrective action records

[21] Records include the date and initials of the PCQI (or designee) as verification.

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum process temperature for the salsa (200°F) (93°C)	Temperature of the in-process salsa in the cook kettle	• RTD probe with recording chart monitors temperature of the in-process salsa (in top inch (2.5 cm) of kettle); • Visual check of the chart; • Record temperature in process log	Once for each batch	Line operator	If the RTD at the cook kettle records a low temperature: • The product will be held until the PCQI determines whether the process was adequate for safety or if the product should be reprocessed or destroyed. • The production manager will investigate why the under-processing occurred and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary in light of the reason for the under-processing.	• Annual calibration of the RTDs and recording chart used to measure temperature at the cook kettle, with the date and results recorded in a calibration log. The PCQI reviews, initials, and dates the calibration logs within a week of their creation. • On a daily basis, the PCQI reviews recorder charts and process logs to confirm that the in-process salsa was cooked at the specified temperature, and checks that process log temperatures agree with the recorder charts.	• The recording charts from the RTDs used to monitor the temperature of the in-process salsa in the cook kettle • The process logs for temperature checks of the cook kettle • Corrective action records • Of calibration of the RTDs and recording charts, with any notes by the PCQI about adjustments

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum process time at 200°F (93°C) for the salsa (2 minutes)	Time that the in-process salsa is at the process temperature	• Visual checks of recorder chart; • Mark chart with batch number; • Record time when in-process salsa reaches process temperature in process log; • Calculate processing time; • Record processing time on the recorder chart and in the process log; • Note when product should be transferred to filling surge tank in the process log; • Record the time when product is transferred from to the filling surge tank in the process log	Once for each batch	Line operator	If the RTD at the cook kettle records a shortened process time: • The product will be held until the PCQI determines whether the process was adequate for safety or if the product should be reprocessed or destroyed. • The production manager will investigate why the under-processing occurred and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary in light of the reason for the under-processing.	On a daily basis, the PCQI reviews recorder charts and process logs to confirm that the in-process salsa was cooked for the specified time	• Of the temperature recording chart marked with various times, and the process log, • Corrective action records

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum temperature of the heat-treated salsa in the filling surge tank (200°F) (93°C)	Temperature of the heat-treated salsa held in the filling surge tank	• RTD probe with recording chart monitors temperature of heat-treated salsa in filling surge tank; • Visual check of chart; • Record temperature in process log	Twice per shift	Line operator	If the temperature at the filling surge tank is below the process set point: • The product will be held until the PCQI determines whether the fill temperature was adequate for safety or if the product should be reprocessed or destroyed. • The production manager will investigate why the fill temperature was too low and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary	• Annual calibration of the RTDs and recording chart used to measure the temperature at the filling surge tank, with the date and results recorded in a calibration log. The PCQI reviews, initials, and dates the calibration logs within a week of their creation • On a daily basis, the PCQI reviews process logs and recorder charts to confirm that the jars were filled at the specified temperature, and checks that process log temperatures agree with the recorder charts.	• The recording charts from the RTDs used to monitor the temperature of the filling surge tank • The process logs for temperature checks of the filling surge tank • Corrective action records • Of calibration of the RTDs and recording charts, with any notes by the PCQI about adjustments

Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records[21]
Minimum inverted jar hold time (1 minute)	Conveyor belt speed as indicated by automated tachometer RPM	• Automated tachometer with recorder chart monitors conveyor speed; • Visual check of chart • Record RPM in process log	At the beginning of production and twice per shift	Line operator	If it is determined that the jar inversion time is below the process set point: • The product will be held until the PCQI determines whether the process was adequate or if the product can be reprocessed. • The production manager will investigate why the belt speed deviated from the process set point and take appropriate actions to prevent the situation from reoccurring. • Employees will be retrained if necessary in light of the reason for the belt speed deviation	• Annual calibration of the tachometer and recording chart used to measure belt speed of the jar inversion conveyor, with the date and results recorded in a calibration log. The PCQI reviews, initials, and dates the calibration logs within a week of their creation. • The QA Manager verifies the jar inversion belt speed and time twice each year, and the PCQI reviews this within one week. • On a daily basis, the PCQI reviews the recorded RPM for the conveyor belt	• The recording chart from the automated tachometer used to monitor the jar inversion conveyor belt speed • The process logs for checks of the belt speed for the jar inversion conveyor belt • Corrective action records • Of calibration of the tachometer and recording charts, and verification tests that the jar inversion time is correct, with any notes by the PCQI about adjustments

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 7: Use of Time/Temperature as a Process Control (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

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Chapter 8: Use of Product Formulation or Drying/Dehydrating as a Process Control for Biological Hazards (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

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Chapter 9: Validation of a Process Control for a Bacterial Pathogen (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 10: Sanitation Program (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 11: Food Allergen Program

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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Appendix 11-3 Summary of Bakery B's Food Allergen Controls and Associated Preventive Control Management Components

FORM 2-E (Modified) FOOD ALLERGEN INGREDIENT ANALYSIS

FORM 2-F (Modified) FOOD ALLERGEN LABEL VERIFICATION LIST

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11.1. Purpose of this Chapter

The purpose of this chapter is to explain how to establish and implement a food allergen program. Part 117 defines "food allergen" as a major food allergen as defined in section 201(qq) of the FD&C Act (21 CFR 117.3). Section 201(qq) of the FD&C Act defines the term ''major food allergen,'' in part, to mean any of the following: 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, soybeans, and sesame[2] or a food ingredient that contains protein derived from one of these foods, with certain exceptions regarding highly refined oils.

A food allergen program could include, as appropriate to the facility and its food products:

- CGMP measures that you take to comply with the requirements of part 117, subpart B, to prevent allergen cross-contact[3] due to personnel, design and construction of the plant, sanitary operations, equipment and utensils, raw materials and other ingredients, manufacturing operations, and warehousing and distribution. Your hazard analysis should consider how your CGMP measures prevent allergen cross-contact, and the preventive controls that you establish and implement to address a food allergen hazard should complement and enhance your CGMP measures for preventing allergen cross-contact.

[2] In 2004, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) amended the FD&C Act to provide FDA with additional, specific authority regarding the labeling of a food (other than a raw agricultural commodity) that bears or contains a "major food allergen." Under section 403(w) of the FD&C Act (21 U.S.C. 343(w)), a food is misbranded if it contains a major food allergen and fails to declare that major food allergen on its label in the manner specified using the major food allergen's common or usual name, including the name of the food source from which the major food allergen is derived. Section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)) defined a "major food allergen," in part, as any of the following: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. The specified labeling requirements became effective on January 1, 2006, for packaged foods. In April 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) amended section 201(qq) of the FD&C Act to add sesame to the definition of "major food allergen." This amendment applies to "any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023" (Public Law 117-11).

[3] Part 117 defines "allergen cross-contact" as the unintentional incorporation of a food allergen into a food. (See 21 CFR 117.3.)

- Food allergen controls to provide assurances that any food allergen hazards requiring a preventive control will be significantly minimized or prevented. (See 21 CFR 117.135(a) and (c)(2).) Food allergen controls include procedures, processes, and practices that are:
    - Allergen cross-contact controls – i.e., procedures, practices, and processes employed for ensuring protection of food from allergen cross-contact, including during storage, handling, and use (21 CFR 117.135(c)(2)(i)); and
    - Label controls – i.e., procedures, practices, and processes employed for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). (21 CFR 117.135(c)(2)(ii).)
- A supply-chain program as required by part 117, subpart G for those raw materials and other ingredients for which a manufacturing/processing facility has identified a food allergen hazard that is controlled before its receipt. (See 21 CFR 117.405(a)(1).) See Chapter 15 for comprehensive guidance on how to comply with the requirements of part 117, subpart G for all hazards, not just food allergen hazards.

In this chapter, we provide multiple, detailed recommendations for each of these aspects of a food allergen program. Our purpose is to provide as many examples as possible so that you can develop your own food allergen program as appropriate to your operations, not to imply that a food allergen program should have all the CGMP measures, preventive controls (including supply-chain controls), monitoring/verification activities, corrective action procedures, and records that we describe for illustrative purposes.

For background and details about food allergen hazards, see section 3.4.2.1 of Chapter 3. For a preliminary discussion of food allergen controls, see section 4.5 of Chapter 4. For an overview of the application of preventive control management components to food allergen controls, see section 5.3.3 of Chapter 5. For the definitions of terms used in this chapter, see section III in the Introduction of this guidance and section 11.3 in this chapter.

This chapter does not address substances that are associated with food allergy but are not major food allergens defined in section 201(qq) of the FD&C Act. However, you may find the recommendations in this chapter for food allergen controls to be useful for such substances if appropriate for your food and facility. This document also does not address substances (e.g., sulfites and yellow No. 5) that are associated with food intolerance or substances (e.g., gluten) that are associated with food-related disease (e.g., celiac disease) as discussed in section 3.4.2.2 of Chapter 3 of this guidance. However, you may find the recommendations in this chapter for label controls for food allergens to be a useful tool for developing your strategy for complying with any regulatory requirements for labeling such substances, even though the labeling requirements for such substances are different from the labeling requirements for the major food allergens.[4]

In a 1996 notice to manufacturers entitled “Label Declaration of Allergenic Substances in Foods” (the 1996 food allergen notice) (see Table 11-8), we advised the food industry that we were aware that some manufacturers are voluntarily labeling their products with statements such as

[4] For example, sulfiting agents permitted in foods must be listed on the ingredient label, unless they are added to food as an “incidental substance” (i.e., because they have no technical effect in the finished food and are present at less than 10 parts per million (ppm)). (See 21 CFR 101.100(a)(4).) As a second example, our regulation for the color additive Yellow No. 5 states that any food for human use that contains Yellow No. 5 must specifically declare the presence of the color additive by listing it as an ingredient. (See 21 CFR 74.705(d)(2).)

"may contain (insert name of allergenic ingredient)." In the 1996 food allergen notice and in our allergen labeling guidance (see Table 11-7), we advised that labeling such as “may contain [allergen]” is not a substitute for, and should not be used in lieu of, adherence to CGMPs. Our allergen labeling guidance also advises that labeling such as “may contain [allergen]” is not a substitute for adherence to food allergen preventive controls and that any such statement must be truthful and not misleading. In the 1996 food allergen notice, we also urged manufacturers to “take all steps necessary to eliminate cross-contamination and to ensure the absence of the identified food.” Consistent with the 1996 food allergen notice and our allergen labeling guidance, in section 11.9 of this chapter we advise that:

- You should not use allergen advisory statements (formerly called allergen precautionary labeling) in lieu of adherence to CGMPs or in lieu of the requirements for allergen cross-contact controls;
- If you use allergen advisory statements, they must be truthful and not misleading;
- If you use allergen advisory statements, your preventive controls qualified individual (PCQI) should provide a written justification, in your food safety plan, for why allergen cross-contact controls cannot ensure protection of food from allergen cross-contact;
- Your supplier approval and verification activities should include an evaluation of whether a potential supplier provides allergen advisory statements for raw materials and other ingredients that you would receive from the potential supplier. When a potential supplier would provide an allergen advisory statement on the applicable raw materials or other ingredients, you should discuss the reasons for the allergen advisory statements with the potential supplier. You should approve such suppliers only if you determine, through your supplier approval and verification activities, that such statements are not being used in lieu of adherence to CGMPs or in lieu of adherence to the requirements for allergen cross-contact controls; and
- Reanalysis of your determination regarding using allergen advisory statements is appropriate if you experience ongoing problems with your allergen cross-contact controls or your supply-chain controls.

This chapter does not broadly discuss other issues associated with allergen advisory statements. See the discussion of labeling policy statements and other guidance regarding allergen labeling in section 11.4.3 and our web page providing guidance documents and regulatory information regarding food allergens (see Table 11-8) for the most current policy statements and other guidance relevant to allergen advisory statements. You should periodically check that web page for updates to these policy statements and other guidance.

11.2 Terms Used in This Chapter

11.2.1 Definitions Established in 21 CFR 117.3

Section III.A in the Introduction of this guidance includes a glossary of terms that are used in this guidance and are defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 11-1 for additional terms that are defined in 21 CFR 117.3. We intend to include these terms in the glossary in section III.A in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 11-1 from this chapter, because it would be duplicative.

Table 11-1 Applicable Terms Defined in Part 117 (See 21 CFR 117.3.)

Term	What the Term Means
Allergen cross-contact	The unintentional incorporation of a food allergen into a food.
Audit	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.
Food allergen	A major food allergen as defined in section 201(qq) of the FD&C Act.
Lot	The food produced during a period of time and identified by an establishment's specific code.
Manufacturing/ processing	Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.
Qualified auditor	A person who is a qualified individual as defined in part 117 and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include: (1) A government employee, including a foreign government employee; and (2) An audit agent of a certification body that is accredited in accordance with regulations in 21 CFR part 1, subpart M (Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications).
Receiving facility	A facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other 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.
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.
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).

11.2.2 Other Terms That FDA Uses in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include

all terms that are used in this chapter. See Table 11-2 for additional terms that we use in this chapter. We intend to include these terms in the glossary in the Introduction of this guidance when we update the Introduction. When we do so, we will delete Table 11-2 from this chapter.

Table 11-2 Terms Used in This Chapter

Term	What the Term Means
Allergen cleaning procedure	Procedures, practices, and processes for cleaning food-contact surfaces of equipment and utensils that are used for foods with different food allergen profiles
Allergen cross-contact control	Procedures, practices, and processes employed for ensuring protection of food from allergen cross-contact, including during storage, handling, and use
Allergenic component	A food allergen (i.e., a major food allergen as defined in section 201(qq) of the FD&C Act) that is a component of an ingredient (e.g., the food allergen "milk" in a spice blend)
Allergenic ingredient	A food allergen (i.e., a major food allergen as defined in section 201(qq) of the FD&C Act) that is an ingredient of another food product (e.g., the food allergen "peanuts" added to cookies)
Allergen labeling guidance	Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry
Approved supplier	A supplier that has met the criteria of the receiving facility's supply chain program, is controlling the identified hazard, and has been approved by the receiving facility
Certificate of analysis (COA)	A document, provided by the supplier of a food prior to or upon receipt of the food, that documents the analysis of certain characteristics and attributes of the food
Changeover	Procedures used to prepare the processing line when different products are produced on the same processing line
Draft allergen labeling guidance[5]	Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry (Draft Guidance)
Exception record	A record that you establish only when there is loss of control
Food allergen label specification	All features of the product label that you will use to ensure that the finished food will not be misbranded under section 403(w) of the FD&C Act. Examples of such features are product name; the approach to naming the food source of all allergenic ingredients (and allergenic components of ingredients) (e.g., within the ingredient statement[6] or in a separate "Contains" statement); and any color coding or other distinctive features that you use to help production personnel select the correct label.
Food allergen profile	The food allergen sources present or absent in a food
Label[7]	A display of written, printed, or graphic matter upon the immediate container of a food article. (See the definition of "label" in section 201(k) of the FD&C Act ((21 U.S.C. 321(k))

[5] The draft guidance, when finalized, will explain FDA's current thinking on a number of issues related to the labeling of food allergens, including requirements in both FALCPA and the FASTER Act.
[6] See 21 CFR 101.4 Food; designation of ingredients.
[7] Note that the definition of "label" in section 201(k) of the FD&C Act specifies that a requirement that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

Term	What the Term Means
Label control	Procedures, practices, and processes employed for labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the FD&C Act
SAHCODH (Serious adverse health consequences or death to humans) hazard	A hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.
Third-party audit	An audit conducted by a qualified auditor that is not an employee of either the receiving facility or the supplier.
Unintended allergen presence[8]	The presence of an allergen due to allergen cross-contact
Visibly clean	Without visibly detectable material such as food residue, film, or protein sheen
Work-in-process (WIP)	Partially finished products that are in between different production stages (e.g., batched or pre-processed ingredients that are transferred to totes and held until moved to another processing line to be incorporated into another product).

11.2.3 Abbreviations Used in This Chapter

Section IV in the Introduction of this guidance includes a list of abbreviations that are used in this guidance. At this time, that list of abbreviations does not include all abbreviations that are used in this chapter. See Table 11-3 for additional abbreviations that are used in this chapter. We intend to include these abbreviations in section IV in the Introduction of this guidance when we update the Introduction. When we do so, we will delete Table 11-3 from this chapter. For your convenience, Table 11-3 includes some abbreviations, already included in section IV of the Introduction of this guidance, that are commonly used in this chapter.

Table 11-3 Common Abbreviations Used in This Chapter

Abbreviation	What It Means
CIP	Clean in place
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
FALCPA	Food Allergen Labeling and Consumer Protection Act
FAO	Food and Agriculture Organization of the United Nations
FCS	Food-contact surface
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSPCA	Food Safety Preventive Controls Alliance
PCHF	"Preventive Controls for Human Food" (requirements in 21 CFR part 117 for hazard analysis and risk-based preventive controls for human food in accordance with section 418 of the FD&C Act)
PCQI	Preventive controls qualified individual

[8] In the draft Chapter 3 that we made available for comment on August 24, 2016 (81 FR 57816), we used the terminology "undeclared allergen" rather than "unintended allergen presence," when an allergen is present due to cross-contact. When we finalize that chapter, we intend to use the terminology "unintended allergen presence."

Abbreviation	What It Means
WHO	World Health Organization

11.3 Understand the Hazard Requiring a Preventive Control

Section 3.4.2.1 of Chapter 3 includes food allergen information such as:

- The prevalence and symptoms of food allergies;
- The importance of susceptible consumers avoiding foods that are or contain food allergens;
- The "major food allergens" subject to the allergen labeling requirements of the FD&C Act[9] (i.e., milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame[10]);
- The presence of gluten (i.e., a mixture of proteins associated with celiac disease) in one of the major food allergens (i.e., wheat); and
- The classification of unintended allergen presence[11] as a "chemical hazard"; and
- The classification of an undeclared[12] food allergen due to applying a label that does not declare all allergenic ingredients, applying the incorrect food label to a product, or using the wrong packaging, as a "chemical hazard."

Unintended allergen presence can occur through failure to prevent allergen cross-contact. Depending on your plant, the food products you produce, and the nature of the ingredients that you use, you should design your food allergen program to prevent allergen cross-contact between foods with different "food allergen profiles" – i.e., to prevent allergen cross-contact:

- Between foods that contain different food allergens; and

[9] For additional information about allergen labeling requirements of the FD&C Act, see section 403(w) of the FD&C Act (21 U.S.C. 343(w)), the definition of "major food allergen" in section 201(qq) of the FD&C Act (21 U.S.C. 321(qq)), our guidance regarding the allergen labeling requirements of the FD&C Act (see Table 11-7), and section 11.4.2. Additional regulatory information and guidance documents applicable to food allergens are available on our website (see Table 11-8).

[10] The allergen labeling requirements of the FD&C Act for sesame are effective for food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023.

[11] In the draft Chapter 3 that we made available for comment on August 24, 2016 (81 FR 57816), we used the terminology "undeclared allergen" rather than "unintended allergen presence," when an allergen is present due to cross-contact. When we finalize that chapter, we intend to use the terminology "unintended allergen presence" when an allergen is present due to cross-contact.

[12] In contrast to "unintended allergen presence," which we use when an allergen is present due to cross-contact, we use variations of the term "declare" when that term is used in the FD&C Act, our regulations, or an FDA guidance document to describe information that is present on a food label. For example, the label requirements in 21 CFR 101.4 for the designation of ingredients and our guidance regarding the allergen labeling requirements of the FD&C Act (the allergen labeling guidance; see Table 11-7 and the discussion in section 11.4.2) both use variations of the term "declare" when describing information presented on a food label. Likewise, we use variations of the term "undeclared" when describing a label that does not comply with label requirements in the FD&C Act or our food labeling regulations. When we finalize Chapter 3, we intend to explain how we use variations of the term "declare" to describe information that is present on a food label.

- Between foods that contain certain food allergens and foods that do not contain any food allergens.

Without such controls the food is likely to present a hazard to a consumer who has a food allergy. For example:

  - If one beverage that you produce contains milk-derived ingredients, and a different beverage that you produce in that same establishment contains soy-derived ingredients, a food allergen program could help to prevent allergen cross-contact between the beverage containing milk-derived ingredients and the beverage containing soy-derived ingredients. Otherwise, the milk beverage could have unintended soy protein, and the soy beverage could have unintended milk protein.
  - If you produce some chocolate candy that contains almonds and other chocolate candy that does not contain almonds, a food allergen program could help to prevent allergen cross-contact between the chocolate candy that contains almonds and the chocolate candy that does not contain almonds. Otherwise, the chocolate candy that is formulated to not contain almonds could have unintended almonds.
  - If a milk-derived food ingredient (such as whey protein powder) has the potential to spread to foods that do not contain milk due to the powder-based nature of the ingredient, a food allergen program to reduce the potential for transmission of the powdered ingredient (e.g., as dust) could help to prevent allergen cross-contact in foods that do not contain milk.

As discussed in section 3.4.2.1 of Chapter 3, food allergen hazards are a potential hazard regardless of whether a food allergen is present in a major ingredient (such as peanuts and tree nuts that are allergenic ingredients of products such as cookies and trail mix) or is an allergenic component of a minor ingredient (such as milk that is a component of a spice blend). Therefore, the recommendations in this chapter apply to all raw materials and other ingredients used in the production of a food product, regardless of whether an allergenic ingredient is a major or minor ingredient and regardless of whether an allergenic component is a major or minor component of a major of minor raw material or other ingredient in a food product.

FDA has not established a maximum amount of food allergen that may be present in labeled food products without need for declaration. However, FDA recognizes that published data on population threshold dose responses to various food allergens are becoming increasingly available (Remington et al., 2020; FAO/WHO, 2021 and 2022). These published data raise the possibility that some low-level exposures to food allergens, and the presence of certain allergen-derived ingredients, may not cause allergic reactions in most consumers who have that food allergy. Food manufacturers/processors could evaluate such data in light of their specific products, such as through risk assessments or other scientifically valid assessments, in making decisions on appropriate food allergen controls. As discussed in sections 11.8.4 and 11.9.2, your PCQI has the responsibility to determine the appropriate approach to the potential for untended allergen presence in your food product (i.e., the potential for the presence in your food product, due to allergen cross-contact, of a food allergen from a food source that is not already an ingredient in that food product).

11.4 Considerations If You Establish and Implement a Food Allergen Program

11.4.1 Preventive Controls for Allergen Cross-Contact Enhance the CGMP Control Measures in Your Food Allergen Program

The CGMPs in part 117, subpart B specify several requirements to prevent allergen cross-contact. CGMP requirements are sometimes called a "prerequisite program" (NACMCF, 1998) to signify that the measures that you take to comply with the CGMP requirements should be in place before you conduct your hazard analysis and identify risk-based preventive controls to address specific hazards, such as the food allergen hazards that are the subject of this chapter.

The allergen cross-contact controls that you establish and implement as preventive controls should complement and enhance the measures you have in place to comply with the CGMP requirements to prevent allergen cross-contact. In developing your allergen cross-contact controls, we recommend that you consider adapting one or more of the measures for complying with the CGMP requirements to function as a preventive control by combining a CGMP measure with one or more preventive control management components such as monitoring or verifying through, e.g., visual observation, after considering the nature of your food products and the role of a CGMP measure in your food safety system. For example:

- Section 11.6.1 of this chapter provides our recommendations for allergen cleaning procedures (i.e., cleaning of FCSs of equipment and utensils that are used for foods with different food allergen profiles), and section 11.12 of this chapter provides an example in which a manufacturer of frozen desserts establishes and implements allergen cleaning procedures as an allergen cross-contact control. Such cleaning complements and enhances the CGMP requirements in 21 CFR 117.35 for preventing allergen cross-contact through sanitary operations.
- Section 11.13 of this chapter provides an example in which a bakery that produces cookies with and without peanuts establishes and implements allergen cross-contact controls on apparel, movement of personnel, utensils, and tools. These allergen cross-contact controls complement and enhance the CGMP requirements in 21 CFR 117.10, 117.20, and 117.40 for preventing allergen cross-contact due to personnel, plant construction and design, and equipment.
- Section 11.6.2 of this chapter provides our recommendations for allergen ingredient procedures that you could use to complement the CGMP requirement that raw materials and other ingredients that are food allergens, and rework that contains food allergens, be identified and held in a manner that prevents allergen cross-contact. (See 21 CFR 117.80(b)(8).) There are several ways by which you could adapt the measures you take to comply with this CGMP requirement to function as an allergen cross-contact control, such as:
    - Clearly identify allergen-containing raw materials and other ingredients using a system that adequately distinguishes between raw materials and other ingredients with different food allergen profiles to alert personnel that these materials are subject to special precautions and handling procedures throughout the plant. An example of such a system is color-coding – e.g., through use of color-coded stickers/tags, placards, or shrink-wrap, with a specific color dedicated to each of the major food allergens and a system (such as

a chart displayed at multiple locations in the plant) for alerting personnel to the assigned colors.

- Conduct periodic verification through visual observation of the identification and storage of raw materials, ingredients, and rework, document the results of your visual observations, and document corrective actions (or, when applicable, corrections) that you take if your observations indicate that food allergens in raw materials or other ingredients have not been identified (e.g., if a color-coding system that you establish was not properly implemented) or that these materials are not stored properly (e.g., if bags containing soy protein are not completely closed or if there is spillage of powder in the storage area).
- Monitor or verify that the allergenic ingredients brought to the staging area for the recipe or formulation of the scheduled product match the product label content by inspecting the ingredient labels (or stickers/tags on ingredients if, for example, you have used color-coded stickers/tags to identify allergenic-containing ingredients) and reconciling allergen-related information on the ingredient labels (or stickers/tags) with the product label or the product specifications (i.e., in the recipe or formulation).

- The CGMPs require that WIP and rework be handled in a manner that protects against allergen cross-contact. (See 21 CFR 117.80(c)(5).) One way to adapt the measures you take to comply with this CGMP requirement to function as an allergen cross-contact control is to establish and implement written procedures to manage re-entry of WIP and rework (e.g., during release of WIP and rework from storage areas, during the staging and transfer of WIP and rework, and at the re-entry points for WIP and rework in the production process). You then could monitor activities such as re-entry of rework and WIP (e.g., by recording the amount used, the product in which the WIP or rework was used, the lot number, and reconciliation of the amount used with the total amount produced), and document any corrective actions (or, when applicable, corrections) if a problem occurs.

Importantly, a food allergen program generally is used in combination with the sanitation controls required by 21 CFR 117.135(c)(3). The allergen cleaning procedures that we recommend in section 11.6.1 are similar to the sanitation controls that are the subject of Chapter 10, with targeted recommendations specific to the removal of allergenic residues and, thus, the prevention of allergen cross-contact.

11.4.2 Foods That Contain a Major Food Allergen Are Subject to the Allergen Labeling Requirements of the FD&C Act

Section 403(w) of the FD&C Act (21 U.S.C 343(w)) contains requirements (the “allergen labeling requirements of the FD&C Act”) that apply to certain foods that are, or contain, a major food allergen. Our guidance regarding the allergen labeling requirements of the FD&C Act (the allergen labeling guidance; see Table 11-7) provides information to help you comply with the allergen labeling requirements of the FD&C Act. One such labeling requirement is to name the food source of all major food allergens used as ingredients in the packaged food. As discussed in the allergen labeling guidance, this can be done in one of two ways. The first option is for you to include the name of the food source in parentheses following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major allergen does not appear elsewhere in the ingredient statement (e.g., Sugar, whey (milk), eggs). The second option is to use a “Contains” statement followed by the names of the food sources from which all major food allergens are derived (e.g., “Contains egg and milk”, “Contains egg”) immediately after or adjacent to the list of ingredients. Importantly, a “Contains” statement includes the names of the food sources of all major food allergens used as

ingredients in the packaged food. See the allergen labeling guidance for more details about how to meet the allergen labeling requirements of the FD&C Act.[13]

11.4.3 Policy Statements and Other Guidance Regarding Allergen Labeling

Our web page providing guidance documents and regulatory information regarding food allergens (see Table 11-8) provides policy statements and other guidance issued by FDA regarding allergen labeling. For example:

- The 1996 food allergen notice (see Table 11-8) advised the food industry that, because adhering to CGMPs is essential for effective reduction of adverse reactions by consumers, labeling such as "may contain [allergen]" should not be used in lieu of adherence to CGMPs and urged manufacturers to take all steps necessary to eliminate cross-contamination and to ensure the absence of the identified food.
- Question/Answer D.14 in our allergen labeling guidance advises that:
  - Labeling such as "may contain [allergen]" is not a substitute for adherence to CGMPs and food allergen preventive controls; and
  - Any statement such as "may contain [allergen]" must be truthful and not misleading;
- Question/Answer D.13 in our draft allergen labeling guidance[14] advises that the food allergen labeling requirements of the FD&C Act do not apply to a major food allergen that is unintentionally incorporated in a food as a result of cross-contact; and
- Our Compliance Policy Guide (CPG) entitled "CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" (see Table 11-6) describes various labeling requirements and policies[15,16].

You should periodically check FDA's website for updates to our policy statements and other guidance regarding allergen labeling.

[13] Note that our regulation in 21 CFR 101.91 defines the term ''gluten-free'' for voluntary use in the labeling of foods. A food label that includes the term ''wheat'' in the ingredient list or in a separate ''Contains wheat'' statement as required by the allergen labeling requirements of the FD&C Act and also bears the claim ''gluten-free'' will be deemed to be misbranded unless its labeling also bears additional language clarifying that the wheat has been processed to allow the food to meet FDA requirements for a ''gluten-free'' claim.

[14] The draft allergen labeling guidance, when finalized, will explain FDA's current thinking on a number of issues related to the labeling of food allergens, including requirements in both FALCPA and the FASTER Act.

[15] CPG Sec. 555.250 also discusses practices used to prevent potential allergen cross-contact.

[16] In 2023, FDA issued for public comment a draft compliance policy guide entitled "CPG Sec. 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact" (88 FR 31507, May 17, 2023). When finalized, this draft CPG will replace existing guidance, in CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens, for FDA staff on FDA's enforcement policy regarding major food allergen labeling and cross-contact.

11.5 Develop a Strategy for Preventive Control Management Components

11.5.1 Overview of Preventive Control Management Components

With few exceptions, part 117 specifies that preventive controls are subject to the following preventive control management components as appropriate to ensure the effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system: (1) Monitoring; (2) corrective actions and corrections; and (3) verification. (See 21 CFR 117.140.)

This chapter describes our recommendations for three types of preventive controls that are subject to preventive control management components:

- Allergen cross-contact controls;
- Label controls[17]; and
- Supply-chain controls for raw materials and other ingredients when a food allergen hazard in the raw material or other ingredient is controlled before its receipt.

Our recommended CGMP measures in Appendix 11-1 to prevent allergen cross-contact are not subject to preventive control management components. However, as discussed in section 11.4.1, you could develop and implement appropriate preventive control management components for any CGMP measure that you adapt to function as a preventive control.

11.5.2 Monitoring and Verification

11.5.2.1 Requirements for monitoring

Part 117 requires that, as appropriate to the nature of the preventive control and its role in your food safety system, you establish and implement written procedures, including the frequency with which they are to be performed, for monitoring the preventive control. (See 21 CFR 117.145(a).) You must monitor the preventive controls with adequate frequency to provide assurance that they are consistently performed. (See 21 CFR 117.145(b).) See section 11.5.6 for a discussion of the requirements of part 117 for records of monitoring activities.

11.5.2.2 Requirements for verification

Part 117 requires that verification activities include, as appropriate to the nature of the preventive control and its role in your food safety system: (1) Validation[18]; (2) Verification that

[17] Section 11.7 provides separate recommendations for "label content controls" and "label management controls." However, we do so solely as an organizational tool for presenting our recommendations for how to use label controls to prevent food from being misbranded under section 403(w) of the FD&C Act. In your food safety plan, it makes no difference whether you classify your label control as a control on label content or a control on managing your labels. Thus, when you tailor this guidance for your operations you may find it more useful to classify a label control in a different manner than we do in this chapter.

[18] During the rulemaking to establish part 117, we acknowledged that it is premature to require validation of food allergen controls (see the discussion in the proposed rule (78 FR 3646 at 3755, January 16, 2013) and Response 515 in the final rule (80 FR 55908 at 56058)). As a result, part 117 does not require

monitoring is being conducted; (3) Verification that appropriate decisions about corrective actions are being made; (4) Verification of implementation and effectiveness; and (5) Reanalysis. (See 21 CFR 117.155.)

Part 117 requires that you verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system: (1) Calibration of process monitoring instruments and verification instruments (or checking them for accuracy); and (2) Review of certain records by (or under the oversight of) a PCQI, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions. (See 21 CFR 117.165(a)(1) and (4).)

Part 117 also requires, as appropriate to the facility, the food, the nature of the preventive control, and the role of the preventive control in the facility's food safety system, that you establish and implement written procedures for the method and frequency of calibrating process monitoring instruments and verification instruments (or checking them for accuracy). (See 21 CFR 117.165(b)(1).)

See section 11.5.5 for a discussion of reanalysis. See section 11.5.6 for a discussion of the requirements of part 117 for records of verification activities.

11.5.2.3 Flexibility in complying with the requirements for monitoring and verification for allergen cross-contact controls and label controls

The requirements for monitoring provide flexibility for you to establish and implement written procedures for monitoring preventive controls as appropriate to the nature of the preventive control and its role in your food safety system. (See 21 CFR 117.145.) Likewise, the requirements for verification provide flexibility for you to conduct verification activities that are appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system. (See 21 CFR 117.165.) In many cases, the nature of an activity (such as visual observation) conducted as a preventive control management component for an allergen cross-contact control or a label control could be classified as either monitoring or as verification. In light of the flexibility that part 117 provides for monitoring and verification, it generally makes little difference whether you consider such an activity to be monitoring or verification for the purposes of your allergen program as long as you comply with requirements applicable to monitoring or verification; part 117 does not require that you establish and implement both a monitoring activity and a verification activity if the same activity (such as visual observation) would be used as both a monitoring activity and a verification activity. Regardless of what you call them, you must have procedures that are adequate to ensure the effectiveness of the preventive controls.

validation of food allergen controls (see 21 CFR 117.160(c)(1)). Therefore, this guidance does not provide recommendations for validation of food allergen controls. However, nothing in part 117 would prevent you from validating a food allergen control, if you choose to do so (see Response 513, 80 FR 55908 at 56057), and some verification procedures that we describe in this chapter could, with minimal modification, be part of a validation study. (See the discussion in Response 515, 80 FR 55908 at 56058.)

11.5.3 Corrective Actions and Corrections

Part 117 includes requirements, as appropriate to the nature of the hazard and the nature of the preventive control, for corrective action procedures that must be taken if a preventive control is not properly implemented. (See 21 CFR 117.150(a)(1).) The corrective action procedures must describe the steps to be taken to ensure that: (1) Appropriate action is taken to identify and correct the problem; (2) appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur; (3) all affected food is evaluated for safety; and (4) all affected food is prevented from entering into commerce, if you cannot ensure that the affected food is not adulterated or misbranded. (See 21 CFR 117.150(a)(2).)

However, you do not need to take corrective actions if you take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the food allergen controls in 21 CFR 117.135(c)(2)(i) (ensuring protection of food from allergen cross-contact), or if you take action, in a timely manner, to identify and correct a minor and isolated problem that does not directly impact product safety (i.e., make corrections). (See 21 CFR 117.150(c).) For example, if you observe that a CIP system failed to maintain its target temperature, and you correct the problem by determining the root cause of the problem, adjusting the temperature and running a complete CIP at the appropriate temperature before beginning production, you could consider that your prompt action corrects conditions and practices that are not consistent with your allergen cross-contact controls. As another example, if a problem occurs with a label control before a product label is applied or used in food production and you fix the problem so that only correct labels are used, you could consider the problem to be a minor problem that does not directly impact product safety.

See section 11.5.6 for a discussion of the requirements of part 117 for records of corrective actions and corrections.

11.5.4 Applying Preventive Control Management Components to Supply-Chain Controls

The supply-chain program required by part 117, subpart G includes specific requirements applicable to supplier verification activities, and the supply-chain program as a whole is subject to a subset of preventive control management components – i.e., corrective actions and corrections, review of records, and reanalysis. (See 21 CFR 117.140(b).)

11.5.5 Reanalysis

Part 117 includes requirements for you to conduct a reanalysis of the food safety plan as a whole at least once every 3 years. (See 21 CFR 117.170(a).) Part 117 also includes requirements for you to conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan: (1) Whenever a significant change in the activities conducted at your facility creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard; (2) whenever you become aware of new information about potential hazards associated with the food; (3) whenever appropriate after an unanticipated food safety problem; and (4) whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective. (See 21 CFR 117.170(b).)

See the discussions in sections 11.6.1.3, 11.6.2, 11.7.4, and 11.8.6 regarding circumstances in which reanalysis of your food safety plan is warranted in light of ongoing problems with your

allergen cross-contact controls, label controls, or supply-chain program, respectively. See the discussion in section 11.9.5 regarding reanalysis of your determination regarding allergen advisory statements.

11.5.6 Records Documenting the Preventive Control Management Components

Part 117 requires that you document the preventive control management components as follows:

- The monitoring of preventive controls in records that are subject to verification and records review. (See 21 CFR 117.145(c)(1).) However, part 117 provides flexibility for records of monitoring to be "exception records" - i.e., records that you establish only when there is loss of control. (See 21 CFR 117.145(c)(2).) See the discussion in section 11.7.5 of an example of exception records relevant to a label control.
- All corrective actions (and, when appropriate, corrections) in records that are subject to verification and records review. (See 21 CFR 117.150(d).)
- All verification activities in records that are subject to records review. (See 21 CFR 117.155(b) and 117.165(a)(4).)

11.6 Allergen Cross-contact Controls

11.6.1 Allergen Cleaning Procedures

As discussed in section 11.4.1, your allergen cross-contact controls should complement the measures you take to comply with the CGMP requirements of part 117, subpart B for preventing allergen cross-contact. In this chapter, we discuss allergen cleaning procedures as an allergen cross-contact control[19] that can complement the measures that you take to comply with the CGMP requirement that all FCSs, including utensils and FCSs of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact. (See 21 CFR 117.35(d).) As with all preventive controls, the allergen cleaning procedures must be written. (See 21 CFR 117.135(b).)

Procedures for monitoring preventive controls also must be written. (See 21 CFR 117.145(a).) Note that a form that you would use to document a monitoring activity could function as a written procedure for the monitoring activity, because the person who conducts the monitoring could use the form as a guide for what to monitor. Likewise, if you will establish any written verification or corrective action procedures, a form that you would use to document the verification activity or corrective actions could function as a written procedure for the verification activity or the corrective actions, because the person who conducts the verification activity or is responsible

[19] Alternatively, you could consider such cleaning to be a sanitation control established to satisfy the requirements of 21 CFR 117.135(c)(3)(ii). In addition, as already discussed in section 11.4, you could consider adapting one or more of the measures for complying with the CGMP requirements to prevent allergen cross-contact (e.g., the measures discussed in Appendix 11-1) to function as a preventive control by combining a CGMP measure to prevent allergen cross-contact with one or more preventive control management components such as monitoring or verifying through, e.g., visual observation, and appropriate records.

for the corrective actions could use the form as a guide for what to verify and the steps to take to comply with the requirements for corrective actions.

We recommend that you keep the required written procedures for monitoring the allergen cleaning procedures, and any written verification or corrective action procedures that you establish for the allergen cleaning procedures, together with your allergen cleaning procedures, because doing so would help communicate the overall framework and goals of the allergen cleaning procedures. In the remainder of this document, we use the term sanitation standard operating procedure (SSOP) to refer to a document that includes all procedures and forms applicable to allergen cleaning procedures that you establish and implement as a preventive control.

We recommend that your SSOP for allergen cleaning procedures include the following as appropriate to the type of cleaning process (e.g., dry cleaning or wet cleaning) and the design of the equipment or utensil to be cleaned:

- The purpose of the cleaning procedure (e.g., its role in preventing allergen cross-contact);
- The frequency of cleaning (e.g., how often the cleaning is to be conducted and the temporal relationship to changeover of a production line);
- Who is responsible for performing the cleaning procedure;
- Instructions to perform the specific cleaning procedure, including:
    - Types of cleaning agents to be used for specific equipment and utensils;
    - Concentration of cleaning agents used in wet cleaning;
    - Equipment and tools to be used during the cleaning procedure; and
    - Specific instructions for cleaning, such as the sequence of steps and whether disassembly of equipment is required;[20]
- A list of monitoring/verification activities that will be performed and any written procedures that you establish for those activities;
- Corrections or corrective actions to take when the cleaning procedure is not properly implemented; and
- Any forms that you will use to document monitoring/verification of the cleaning procedure, corrections, or corrective actions.

11.6.1.1 Monitoring and Verification for Allergen Cleaning Procedures

As discussed in section 11.5, you have flexibility to apply preventive control management components as appropriate to ensure the effectiveness of the preventive controls, and the nature of an allergen cross-contact control is such that in some cases an activity could be classified as either a monitoring activity or a verification activity, as long as you comply with

[20] For example, in wet cleaning operations a common sequence of operations is Pre-clean (e.g., scraping to remove foods), Pre-rinse, Apply detergent and Scour, Post-Rinse, Prepare for Inspection, Pre-op Inspection, Sanitize, and Assemble. In dry cleaning operations, where the objective is to minimize the use of water in the area to prevent the growth of microorganisms such as *Salmonella*, tools such as vacuum cleaners, brooms, brushes, and wipes are commonly used.

requirements applicable to monitoring or verification. For example, observing whether an FCS is visibly clean generally could be classified as either a monitoring activity or a verification activity.

In other cases, a preventive control management activity for an allergen cross-contact control would commonly be considered a monitoring activity rather than a verification activity. For example, checking the temperature of water used during a wet cleaning operation generally is classified as monitoring. Likewise, in some cases a preventive control management activity for an allergen cross-contact control would commonly be considered a verification activity rather than a monitoring activity. For example, part 117 classifies calibration as a verification activity (see 21 CFR 117.165(a)(1)).

You have flexibility to determine what monitoring/verification activities, and how many monitoring/verification activities, are appropriate for your operation to ensure the effectiveness of the preventive control. (See 21 CFR 117.140(a).) For example, in some cases you could determine to monitor the steps of a cleaning process but not verify the cleaning process by swabbing surfaces to detect food residues that remain after cleaning. In addition, you can classify observations of steps in the cleaning process to be either monitoring or verification. However, regardless of whether you classify a specific activity as monitoring or as verification, the nature and number of activities you conduct must be adequate to ensure the effectiveness of the preventive control. (See 21 CFR 117.140(a)). In addition, you must verify the results of that activity by reviewing applicable records. (See 21 CFR 117.165(a)(4).)

In this section of this chapter, we provide a combined list of examples of monitoring and verification activities without classifying the activities as either monitoring or verification. See section 11.12 for an example of how a manufacturer that establishes and implements an allergen cross-contact control could classify specific activities as monitoring or verification activities.

The specific activity to be monitored or verified depends on the type of cleaning procedure (e.g., wet cleaning or dry cleaning). Examples of monitoring and verification activities are:

- Checking the makeup of a cleaning solution (e.g., the amount of cleaning chemical added to a specified amount of water or the presence of active ingredient of a cleaning chemical in a specified amount of water) in a wet-cleaning operation;
- Recording the date and time of cleaning of equipment during a changeover from an allergen-containing product to a product that does not contain that food allergen;
- Using a checklist to document each step of the cleaning procedure as it is performed;
- Observing each step in the cleaning process as it is being conducted (e.g., by a sanitation supervisor);
- Observing that an automatic cycle begins and ends (e.g., when using automatic equipment such as a clean-in-place (CIP) system);
- Calibrating an automated cleaning system to ensure appropriate temperatures and cleaning agent concentrations if these are critical to removal of the food allergen;
- Observing that the production equipment is visibly clean (e.g., at the end of cleaning or as part of a pre-operational inspection just prior to production), taking into account the nature of the FCSs (e.g., materials from which the FCSs are constructed);

- Using rapid ATP (adenosine triphosphate) swabs, protein swabs, or allergen-specific test kits to detect food residues that remain after cleaning;[21]
- Periodically using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the matrix of your food product) to detect the presence of food allergens remaining on food-contact surfaces after cleaning by using swabs or testing final rinse water (e.g., the final rinse of a CIP cycle for equipment that is wet cleaned). If your production procedure includes a "push-through" technique in which the subsequent product, an inert ingredient (such as sugar or salt), or an allergen-containing ingredient (such as flour) that will be an ingredient in the subsequent product is pushed through the system to remove traces of food residue, you could use test kits to evaluate "push-through" material, or the first product through the line, to demonstrate that a food allergen from a previous production run has been removed; and
- Reviewing the monitoring/verification records in accordance with 21 CFR 117.165(a)(4).

11.6.1.2 Corrective Actions and Corrections for Allergen Cleaning Procedures

When cleaning procedures used to control allergen cross-contact have not been properly implemented, you must implement corrections or take corrective actions in accordance with your corrective action procedures. (See 21 CFR 117.150.)

- An example of when a correction can suffice is an observation that a CIP system failed to maintain its target temperature, if you correct the problem by adjusting the temperature and running a complete CIP at the appropriate temperature before beginning production. (See 21 CFR 117.150(c)(1), which provides that you do not need to take corrective actions if you take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the allergen cross-contact controls.)
- An example of when a corrective action is warranted is finding the presence of a food allergen during periodic testing of FCSs using an allergen test kit. The detection of the food allergen could be an indication either that the cleaning procedure was not properly implemented or that the cleaning procedure is not effective at removing the food allergen. In such a situation, corrective actions would include:
    - Identifying the problem (e.g., determining whether the food residue was detected because the cleaning procedure was not properly implemented or because the cleaning procedure was not effective);
    - Correcting the problem and reducing the likelihood that the problem will recur (e.g., by re-training employees in how to use the cleaning procedure or by revising the cleaning procedure to improve its effectiveness); and
    - Determining whether food is affected and, if so, evaluating that food for safety, and ensuring that the food with an unintended allergen does not enter commerce (or that any

[21] Note that ATP tests are considered "non-specific" tests for cleanliness because ATP is found in all living cells and its presence could reflect diverse sources such as food, microorganisms, or even human skin. ATP tests and other "non-specific" tests (such as tests that would detect any protein rather than a specific protein) have the potential to be more sensitive than visual observation but may not be sensitive enough to detect levels of a particular allergenic protein.

such food that has entered commerce is recalled). In determining which food is affected, we recommend that you consider all food lots produced from cleanup to cleanup.

We recommend that your corrective action procedures distinguish between those corrective actions you would take if you determine that the problem was due to improper implementation of the allergen cleaning procedure and those corrective actions you would take if you determine that the allergen cleaning procedure is not effective. For example, if an occasional finding of product residue on a cleaned FCS leads you to determine that the allergen cleaning procedure was not properly implemented, you could limit your corrective action procedures to retraining the personnel who conduct the cleaning. However, if repeated findings of product residue on a cleaned FCS lead you to determine that the cleaning procedure is not effective, your corrective action procedures should include reanalysis of your food safety plan to determine whether to revise your allergen cleaning procedures. (See the discussion of reanalysis in section 11.6.1.3.)

11.6.1.3 Reanalysis of Your Allergen Cleaning Procedures

As discussed in section 11.5.5, part 117 includes requirements for you to conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective, or at least every 3 years. (See 21 CFR 117.170(b)(4).) Reanalysis of your allergen cleaning procedures is appropriate if, for example, repeated findings of product residue on a cleaned FCS lead you to determine that the cleaning procedure is not effective.

See the discussions of allergen advisory statements in section 11.9. In some circumstances, reanalysis of your allergen cleaning procedures could lead you to conclude that allergen advisory statements are appropriate because, despite using appropriate CGMPs and preventive controls, residues or allergen cross-contact cannot be avoided.

11.6.1.4 Records Documenting Allergen Cleaning Procedures and Applicable Preventive Control Management Components

Your allergen cross-contact controls for cleaning are preventive controls and, thus, you must have a record of the allergen cleaning procedures (such as in the SSOP discussed in this chapter). (See 21 CFR 117.135(b) and 117.126(b)(2).)

Records of monitoring and verification activities may be created manually or automatically (e.g., if a computer record is generated automatically when a CIP system is used). For manual records, we recommend that you use standardized forms and checklists, as appropriate to the activity being monitored or verified, because such forms can help ensure that the activities are conducted in a consistent manner.

As noted in section 11.5.6, exception records for monitoring may be adequate in some circumstances. (See 21 CFR 117.145(c)(2)(ii).)

You must document all corrective actions and, as appropriate, corrections. (See 21 CFR 117.150(d).) To document corrective actions, you would describe the problem, how it was corrected (including steps you will take to prevent it from happening again, and the evaluation and disposition of any affected food). An example of when it would be appropriate to document corrections is when you want to be able to determine patterns that could suggest improvements to your procedures. For example, if you use a checklist to monitor whether equipment is clean during a pre-operational inspection before beginning production, a review of corrections noted

on the checklists could help to identify a pattern of problems such that a change to the cleaning procedure would be warranted.

All verification activities must be documented. (See 21 CFR 117.155(b).) One way to document a record review that you conduct to satisfy the requirements of 21 CFR 117.165(a)(4) is for your PCQI (or designee) to sign or initial, and date, the primary monitoring, corrective action, and verification records.

11.6.2 Allergen Ingredient Procedures

As discussed in section 11.4.1, your allergen cross-contact controls should complement the measures you take to comply with the CGMP requirements of part 117, subpart B for preventing allergen cross-contact. In this chapter, we discuss allergen ingredient procedures as an allergen cross-contact control that can complement the measures that you take to comply with the CGMP requirement that raw materials and other ingredients that are food allergens, and rework that contains food allergens, be identified and held in a manner that prevents allergen cross-contact. (See 21 CFR 117.80(b)(8).) Allergen cross-contact can result from the unintentional addition of the wrong ingredient to a food; allergen ingredient procedures can prevent such unintentional addition.

Allergen ingredient procedures could be particularly useful when it is not readily apparent, to production personnel or to consumers, that an ingredient is or contains a food allergen. In some food products, production personnel add a flavor ingredient such as a seasoning mix to the food based on the recipe or formulation of the finished food (e.g., a flavor added to chips), whereas in other food products a consumer adds a flavor packet that is provided separately in a packaged food product during preparation of that food product. It may not be readily apparent to production personnel and consumers in such circumstances that the seasoning mix contains a flavor ingredient such as soy.

If your PCQI determines that you must identify and implement allergen ingredient procedures to provide assurances that food allergen hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act, we recommend that you tailor those procedures to your facility and your operations. For example, the preventive control, and associated monitoring or verification activities, would depend on factors such as where and when you transfer ingredients from their original packaging to containers used in production, and how you identify ingredients after you have transferred them from their original packaging.

As with allergen cleaning procedures, when allergen ingredient procedures have not been properly implemented, you must implement corrections or take corrective actions in accordance with your corrective action procedures. (See 21 CFR 117.150).)

- An example of when a correction can suffice is an observation that the wrong ingredient has been brought to the staging or production area before that ingredient is used in production. (See 21 CFR 117.150(c)(1), which provides that you do not need to take corrective actions if you take action, in a timely manner, to identify and correct conditions and practices that are not consistent with the allergen cross-contact controls.)
- An example of when a corrective action is warranted is a determination that an incorrect ingredient, containing an allergen not otherwise included as an ingredient of the food, was added to the food during production. In such a situation, corrective actions would include:

- Identifying the problem (e.g., determining whether the allergenic ingredient was added because the allergen ingredient procedures were not properly implemented or because the allergen ingredient procedures were not effective);
- Correcting the problem and reducing the likelihood that the problem will recur (e.g., by re-training employees in how to use the allergen ingredient procedures or by revising the allergen ingredient procedures to improve their effectiveness); and
- Determining whether food is affected and, if so, evaluating that food for safety, and ensuring that food with unintended allergen presence (which would not be listed on the label) does not enter commerce (or that any such food that has entered commerce is recalled).

Reanalysis of your allergen ingredient procedures is appropriate if, for example, repeated findings that an allergenic ingredient was unintentionally added to your food product lead you to determine that the allergen ingredient procedures are not effective.

As with all preventive controls, the allergen ingredient procedures and any associated monitoring procedures must be written. (See 21 CFR 117.135(b) and 117.145(a).)

11.7 Label Controls

11.7.1 Preventive Controls for the Content of the Product Label and for Managing Labels

To ensure that a finished food is not misbranded under section 403(w) of the FD&C Act, we recommend that your label controls provide assurance that:

- The product label correctly names the food source of all ingredients that are, or contain, a major food allergen in the manner described by the allergen labeling requirements of the FD&C Act and includes all ingredients that are, or contain, a major food allergen; and
- The correct label is applied to the correct product in that the label applied to the product during production matches the ingredient specifications (i.e., in the recipe or formulation) of the product being manufactured/processed.

To do so, we recommend that you establish and implement label controls and associated preventive control management components for:

- The content of the product label at the following stages:
  - Development of labels;
  - Ordering labels;
  - Production of labels; and
  - Receipt of labels.[22]
- Managing printed labels, including storage, use, and disposition of product labels at the following stages:
  - Storage of labels;

[22] At some stages, such as receipt of labels, it is likely that you would monitor or verify a label control established at an earlier stage, e.g., production of labels, rather than establish a label control.

- Food production (including staging and packaging/labeling); and
- Post-production.

In this chapter, we provide separate recommendations for "label content controls" and "label management controls." However, we do so solely as an organizational tool for presenting our recommendations for how to use label controls to prevent food from being misbranded under section 403(w). In your food safety plan, label content controls and label management controls will be very inter-related, and it makes no difference whether you classify your label control as a label content control or a label management control. In addition, in some cases you could have two label controls (i.e., one for label content and another for label management), with a single monitoring/verification activity, documented by a single record, for both label controls. Thus, when you tailor this guidance for your operations you may find it more useful to classify a label control in a different manner than we do in this chapter, and to have fewer monitoring/verification activities, and fewer records, than the activities and records that we describe in this chapter. Our purpose is to provide as many examples as possible so that you can develop your own food allergen program as appropriate to your operations, not to imply that a food allergen program should have all the controls, monitoring/verification activities, and records that we describe for illustrative purposes.

We recommend that you apply such label controls to pre-printed labels that you receive, as well as to labels that you generate yourself, regardless of whether the product label is a label that you would apply to the packaged food product or is pre-printed on the package itself.

You are required to have written procedures for your label controls[23] and for monitoring your label controls. (21 CFR 117.135(b) and 117.145(a).) We recommend that you organize any written procedures for controls on the content of the product label in a manner that will help communicate the overall framework and goals of these controls. For example, you could organize your procedures that address development of labels, ordering labels, production of labels, and receipt of labels, and associated preventive control management components (such as monitoring procedures), in a single document, or collect them in one file or folder. In this document, we refer to such procedures as the "Label Content Procedures."

Likewise, we recommend that you organize any written procedures for controls for the management of product labels/packages, and for associated preventive control management components (such as monitoring procedures), in a single document, file or folder, because doing so will help communicate the overall framework and goals of these controls. In this document, we refer to such procedures as the "Label Management Procedures."

As with allergen cross-contact controls, a form that you would use to document a monitoring activity could function as a written procedure for the monitoring activity, because the person who conducts the monitoring could use the form as a guide for what to monitor. Likewise, if you will establish any written verification or corrective action procedures, a form that you would use to document the verification activity or corrective actions could function as a written procedure for the verification activity or the corrective actions, because the person who conducts the verification activity or is responsible for the corrective actions could use the form as a guide for what to verify and the steps to take to comply with the requirements for corrective actions.

[23] The requirement for you to have written procedures for your preventive controls applies even if a third party helps you to establish and implement those written procedures.

11.7.1.1 Label controls for the content of the product label

11.7.1.1.1 Label development stage

You can develop the product label yourself or you can arrange for a third party (e.g., a label design specialist or company) to develop the product label. Complete label content requirements are beyond the scope of this chapter; the focus here is the labeling related to food allergens. Examples of what your Label Content Procedures could address at the label development stage are:

- Procedures for developing the food allergen label specification for the product label to ensure that the finished food will not be misbranded under section 403(w) of the FD&C Act, such as:
  - Identifying the allergenic ingredients (e.g., peanuts) in the product specification (i.e., the recipe or formulation);
  - Identifying any allergenic components in the raw materials and other ingredients obtained from a supplier, e.g.:
    - If a spice blend you will add as an ingredient has a milk-derived component; or
    - If your supplier provides an allergen advisory statement for an ingredient you receive from that supplier and your PCQI determines and documents that an allergen advisory statement should be carried through on any of your own products; and
  - Your approach (e.g., through the ingredient statement or through a “Contains” statement) to satisfying the allergen labeling requirements of the FD&C Act to name the food source of any major food allergen that is:
    - An ingredient of your food product; or
    - An allergenic component of an ingredient in your food product; and
  - When applicable, your PCQI’s:
    - Written justification for why allergen cross-contact controls cannot ensure protection of food from allergen cross-contact during manufacture of your food product and, thus, that allergen advisory statements are appropriate (see section 11.9.2); and
    - Written determination regarding your approach to allergen advisory statements when a supplier provides an allergen advisory statement for an ingredient that you use in a food product (see section 11.9.3).
- When useful for your operation, the use of an identity coding system for printed labels and packages (e.g., color codes that are easy to visualize, such as colored striping on labels that will be stacked flat in packaging machines). The utility of such an identity coding system largely depends on the nature of the package/label and the packaging/labeling operation.

11.7.1.1.2 Ordering stage for labels

If you will order pre-printed product labels (or packages that contain pre-printed product labels) from a vendor, examples of what your Label Content Procedures could address at the ordering stage are:

- Specifying in the written purchase document the specific text of the food allergen label specification to satisfy the allergen labeling requirements of the FD&C Act to name the food source of any ingredients that are, or contain, a major food allergen;
- Specifying in the written purchase document that "proofs" or samples of product labels need to be provided for your review before you authorize the initial production run of pre-printed product labels; and
- Specifying in the written purchase document any necessary procedures to minimize the potential for commingling product labels for different products. For example, one such procedure is to use separate pallets for labels for different products, where practical. Alternatively, a copy of the label could be pasted on the outside of each box of labels or packages.

11.7.1.1.3 Label production stage for labels that you generate

If you will use computer-generated product labels that you print yourself, examples of what your Label Content Procedures could address at the label production stage for the computer-generated labels are procedures for:

- Checking that the correct electronic file for the label is used; and
- Limiting the number of personnel who are authorized to edit electronic files for product labels.

11.7.1.2 Label controls for managing product labels/packages

11.7.1.2.1 Storage stage

Examples of what your Label Management Procedures could address at the storage stage are procedures for:

- Avoiding commingling of product labels/packages for different products (e.g., on pallets or shelves where you store labels that you receive or that you generate yourself);
- Posting a copy of the product labels on the storage bins or shelves where they are stored; and
- Timely disposal of out-of-date product labels/packages.

11.7.1.2.2 Production (staging) stage

Examples of what your Label Management Procedures could address at the production (staging) stage are procedures for:

- Checking a sample of the product label (or product package, if the label is pre-printed on the product package) to ensure that it is the correct label/package for the product before placing a roll or stack of labels or packaging with pre-printed labels in the staging area; and

- Ensuring that either the only labels in the product labeling/packaging area are for the product being placed in a package at that time, or that the labels/packaging are appropriately identified or aligned so they will only be transferred to the appropriate production line.

11.7.1.2.3 Post-production stage

Examples of what your Label Management Procedures could address at the post-production stage are procedures for removing from the packaging line and appropriately storing unused packaging and labels after a production run is complete, including ensuring that product labels/packages are switched appropriately at product changeover.

11.7.2 Monitoring and Verification for Label Controls

As with an allergen cross-contact control, you have flexibility to apply preventive control management components as appropriate to ensure the effectiveness of the preventive controls, and the nature of a label control is such that in some cases a preventive control management component for a label control could be classified as either a monitoring activity or a verification activity, as long as you comply with requirements applicable to monitoring or verification. For example, checking a product label/package that you receive from a supplier against your food allergen label specification generally could be classified as either a monitoring activity or a verification activity. Thus, if you conduct such a check you could classify this check as "monitoring" the content of the product label, or you could classify this check as "verifying" the content of the product label.

In other cases, a preventive control management activity for a label control would commonly be considered a monitoring activity rather than as a verification activity. For example, checking that the correct label/package is being applied/used during a production run generally is classified as a monitoring activity. In some cases a preventive control management activity for a label control would commonly be considered a verification activity rather than a monitoring activity. For example, part 117 classifies review of records as a verification activity (see 21 CFR 117.165(a)(4)).

You have flexibility to determine what monitoring/verification activities, and how many monitoring/verification activities, are appropriate for your operation to ensure the effectiveness of the preventive control. (See 21 CFR 117.140(a).). For example, in some cases you could determine to monitor that labels/packages brought to the staging area are the correct labels/packages for the product by visually checking the labels/packages, but not verify this label control (such as by using a barcode scanner to confirm that the correct label/package is applied to/used for the correct product). In addition, you could classify visual checks and use of a barcode scanner to be either monitoring or verification as long as you comply with requirements applicable to monitoring or verification. However, regardless of whether you classify a specific activity as monitoring or as verification, the nature and number of activities you conduct must be adequate to ensure the effectiveness of the preventive control. (See 21 CFR 117.140(a)). In addition, you must verify the results of that activity by reviewing applicable records. (See 21 CFR 117.165(a)(4).)

In this section of this chapter, we provide a combined list of examples of monitoring and verification activities without classifying the activities as either monitoring or verification. See sections 11.12.3.2 and 11.13.3.2 for examples of how manufacturers that establish and implement label controls could classify specific activities as monitoring or verification.

11.7.2.1 What to monitor or verify for a label control

11.7.2.1.1 Label content

To monitor or verify the content of the product label, we recommend that you confirm that a product label/package that you receive from a label supplier, or that you generate yourself:

- Satisfies the food allergen label specification that you developed for the product; and
- Is the correct label/package for a particular product with a particular ingredient specification (i.e., recipe or formulation).

11.7.2.1.2 Label management

To monitor or verify the management of product labels/packages, we recommend that you confirm that the correct label/package is applied to/used for the correct product.

11.7.2.2 How to monitor or verify a label control

11.7.2.2.1 Label content

To monitor or verify the content of the product label/package, we recommend that you put a hold on product labels/packages that you receive, or the product labels that you generate yourself, until you compare them to your food allergen label specification by manually inspecting product labels/packages to:

- Reconcile allergen-related label information on the product label (i.e., declaration of ingredients and name of the food source of allergenic ingredients and allergenic components of ingredients) with the food allergen label specification; and
- Determine whether other specifications (e.g., for color coding related to allergen control) are satisfied.

11.7.2.2.2 Label management

To monitor or verify the management of product labels/packages, we recommend that you:

- Visually check that labels/packages brought to the staging area are the correct labels/packages for the product; and
- Use a barcode scanner to confirm that the correct label/package is applied to/used for the correct product when doing so is practical for your operation. Alternatively, you could manually confirm that the correct label/package is applied to/used for the correct product.

11.7.2.3 How often to monitor or verify a label control

11.7.2.3.1 Label content

We recommend that you monitor or verify the content of the product label before you use it for production by comparing the product labels/packages to your food allergen label specification at one or more of the following stages[24]:

- Upon receipt of the label (or, for labels that you generate yourself, soon after you print the labels);
- Before new batches of labels are released for use during production; or
- Immediately prior to production.

11.7.2.3.2 Label management

- We recommend that you visually check that labels/packages brought to the staging area (or directly to the processing line) are the correct labels/packages for the product during staging or immediately prior to production.
- When confirming that the correct label is applied to/used for the correct product, we recommend that you:
  - Do so at the beginning of production, and each time that new labels/packages are brought to the production line, if you monitor or verify by manual inspection; or
  - Monitor or verify continuously during production if the barcode scanner scans continuously, or at regular intervals if you manually operate the barcode scanner or manually confirm that the correct label/package is applied to/used for the correct product (e.g., 1-, 2-, or 4-hour intervals).

11.7.2.4 Who monitors or verifies a label control

11.7.2.4.1 Label content

- The personnel who compare the product labels/packages to your food allergen label specification depend, in part, on when the confirmation takes place (e.g., upon receipt/printing; before new batches of labels are released for production; or immediately prior to production) (see section 11.7.2.3). Note that individuals who manufacture, process, pack, or hold food must be qualified to perform their assigned duties (21 CFR 117.4). Immediately below, we list some examples of personnel positions that could conduct monitoring/verification activities; this list is not exhaustive. Although a supervisor could be appropriate (e.g., for a large operation), non-supervisory personnel with appropriate qualifications could also be appropriate. In addition, when we identify a "team" we do so for illustrative purposes rather than to recommend that you organize your personnel into such teams.

[24] The action of confirming the content of the product label before you use it for production is more important than the timeframe of when you confirm the content of the product label. We note that confirming the content of the product label upon receipt/printing can save you down time if you discover a problem before you are ready to use the labels in a production run.

- Personnel who have responsibility for operations such as receiving, quality assurance, or regulatory affairs (e.g., for label compliance) could confirm the food allergen specification of the product label/package upon receipt from the supplier of the labels/packages.
- Personnel such as the supervisor (or other qualified representative) of the Label Production Team, and personnel with responsibility for operations such as quality assurance or regulatory affairs (e.g., for label compliance) could confirm the food allergen specification of a product label that you generate yourself after printing production labels.
- Personnel such as the supervisor (or other qualified representative) of the Label Production Team, or personnel with responsibility for operations such as quality assurance or regulatory affairs (e.g., for label compliance) could confirm the food allergen specification of the product label/package before new batches of labels are released for production.
- Personnel such as the line operator could confirm the food allergen specification of the product label/package immediately prior to production.

11.7.2.4.2 Label management

- Personnel such as the line operator or supervisor, the production supervisor, and quality control personnel could confirm the check of the product labels/packages.
- When confirming that the correct label is applied to/used for the correct product:
  - Personnel such as the line operator or supervisor, the production supervisor, and quality control personnel could conduct the monitoring or verification activity if you confirm by manual inspection or manual operation of a barcode scanner.
  - The scanner does the monitoring or verification activity if you confirm using a continuous barcode scanner.

11.7.3 Corrective Actions/Corrections for Label Controls

When a label control has not been properly implemented, you must implement corrections or take corrective actions in accordance with your corrective action procedures. (See 21 CFR 117.150.)

- Examples of when a correction can suffice are:
  - **Label content**. Determining that the content of a product label/package is incorrect with respect to the allergen labeling requirements of the FD&C Act before using the label/package in production. If you correct the label before using it such that no food is affected, you could consider the problem to be a minor and isolated problem that does not directly impact product safety as specified by 21 CFR 117.150(c)(2).
  - **Label management.** An observation that the incorrect label/package was brought to the staging area. If you correct the problem by returning the incorrect label/package to storage so that it is not used to label/package food, and bringing the correct label/package to the staging area before production begins, you could consider that the problem is a minor problem that does not directly impact product safety as specified in 21 CFR 117.150(c)(2), unless the problem is a recurring problem. The provisions of 21

CFR 117.150(c)(2) for corrections apply to isolated problems rather than recurring problems; in contrast, corrective actions are appropriate for problems that affect food safety or recur frequently and include identifying the cause of the problem and taking steps to prevent the problem from happening in the future.

- Examples of when a corrective action is warranted are:
  - **Label content.** Determining that the content of a product label/package is incorrect with respect to the allergen labeling requirements of the FD&C Act after using the label/package in production. Because an incorrect label with respect to the allergen labeling requirements of the FD&C Act would misbrand the food under section 403(w) of the FD&C Act, the incorrect label content is not a minor problem as specified by 21 CFR 117.150(c)(2). In such a situation, corrective actions would include:
    - Identifying the problem (e.g., by asking the label supplier (or, for labels generated in-house by talking to the person who generated the labels) to determine what went wrong);
    - Correcting the problem and reducing the likelihood that the problem will recur (e.g., by reviewing the supplier's corrective actions and by making appropriate changes to your Label Content Procedures[25]); and
    - Evaluating the product for safety in the same manner as for a corrective action for a problem with the label management control. (See corrective actions for a problem with label management immediately below.)
  - **Label management.** Determining that an incorrect label (with respect to the allergen labeling requirements of the FD&C Act) was applied to a food product (e.g., a label for a different product, with a different food allergen profile, was applied), or that food was placed in an incorrect package (in that the product label on the package does not satisfy the allergen labeling requirements of the FD&C Act), during a production run. Because an incorrect label would misbrand the food under section 403(w) of the FD&C Act, the problem would not be a minor problem as specified in 21 CFR 117 117.150(c)(2). In such a situation, corrective actions would include:
    - Identifying the problem (e.g., by determining whether the incorrect label was brought to the production line);
    - Correcting the problem and reducing the likelihood that the problem will recur (e.g., by revising the procedure for checking that the correct label/package has been brought to the staging area, or re-training personnel);
    - Ensuring that any food with an incorrect label does not enter commerce – e.g., by re-working the food product, re-labeling the food product, re-packaging the food product with a correct label, diverting the food product to animal food (usually for animals other than pets)[26], or destroying the food product; and
    - Recalling food with an incorrect label if the food has already entered commerce.

[25] If you fail to identify an incorrect label until after it is used in production, you should also review your Label Management Procedures.

[26] FDA is developing guidance on the use of human food by-products in animal food, including diversion of human food products to animal food use. In 2016, FDA issued for public comment a draft guidance for industry entitled "Human Food By-Products For Use As Animal Food" (see Table 11-7 and 81 FR 58521, August 25, 2016). In determining whether it is appropriate to divert a food product to animal food use, we recommend that you consult the final guidance on this subject when it becomes available.

11.7.4 Reanalysis for Label Controls

As discussed in section 11.5.5, part 117 includes requirements for you to conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective. (See 21 CFR 117.170(b)(4).) Reanalysis of your label controls is appropriate if, for example, you have recurring problems with your label content controls or label management controls.

11.7.5 Records Documenting the Label Controls and Applicable Preventive Control Management Components

Your Label Content Procedure and Label Management Procedure are preventive controls and, thus, you must have a record of those procedures. (See 21 CFR 117.135(b) and 21 CFR 117.126(b)(2).)

Records of monitoring and verification activities may be created manually or automatically (e.g., if a computer record is generated automatically when you use a barcode scanner). For manual records, we recommend you use standardized forms and checklists, as appropriate to the activity being monitored or verified, because such forms can help ensure that the activities are conducted in a consistent manner.

As noted in section 11.5.6, exception records for monitoring may be adequate in some circumstances. (See 21 CFR 117.145(c)(2)(ii).) For example, if you use an automated barcode scanner to monitor that the correct label is applied to/used for the correct product, it may be adequate to generate exception records when the scanner detects that the wrong label is applied to the product. Alternatively, a checklist that you include in a production record could document that you conducted the monitoring, with exception records for any observed nonconformance. For example, you could use a checklist to document that you monitor product labels to reconcile allergen-related label information on the product label with the ingredient specifications (i.e., the recipe or formulation) of the food product and generate exception records for those instances when you determine that the label content was incorrect with respect to the label specification.

You must document all corrective actions and, as appropriate, corrections. (See 21 CFR 117.150(d).) If an incorrect label is applied to a product, you would document the corrective actions you take. An example of when it could be appropriate to document corrections is when you notify a supplier that a “proof” of a product label does not match the food allergen label specification, because review of such records could demonstrate whether a particular supplier has consistent problems in satisfying the food allergen label specification during label development.

All verification activities must be documented. (See 21 CFR 117.155(b).) One way to document your record review is for your PCQI (or designee) to sign or initial, and date, the primary monitoring, corrective action, and verification records.

11.8 Supply-Chain Program

11.8.1 Regulatory Framework for the Supply-Chain Program

A receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. (See 21 CFR 117.405(a)(1).) A supply-chain program must include using approved suppliers and conducting appropriate supplier verification activities.[27] (See 21 CFR 117.410.) When a hazard that requires a supply-chain applied control is a SAHCODH hazard (i.e., a hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans (e.g., when a recall of a violative product is designated as "Class 1" under 21 CFR 7.3(m)(1))), an audit is required as a supplier verification activity in most circumstances, before using the raw material or other ingredient from the supplier and at least annually thereafter. (See 21 CFR 117.430(b)(1).)[28] Reactions to a food allergen can be severe (e.g., anaphylaxis that can lead to cardiovascular collapse and death) (Taylor and Hefle, 2001; Boyce et al., 2010) and, thus, there is a reasonable probability that exposure to a food allergen hazard will result in serious adverse health consequences or death to humans. Therefore, in most circumstances[29], a food allergen hazard will be a SAHCODH hazard and generally an annual audit will be required as a supplier verification activity. However, see the discussion in section 11.8.3.2 regarding circumstances when it might be appropriate for your PCQI to use the flexibility provided in 21 CFR 117.430(b)(2) to make a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled.

In some cases, a supplier of a raw material or other ingredient that is, or contains, a food allergen would also be controlling other hazards that require a supply-chain applied control. For example, if your supplier dry roasts tree nuts, including almonds that you would use to make trail mix, your supplier would be controlling the biological hazard *Salmonella* in the almonds. In such a circumstance, your supply-chain program would address *Salmonella* hazards as well as food allergen hazards. See part 117, subpart G for the complete requirements for a supply-chain program and Chapter 15 for comprehensive guidance on how to comply with the requirements of part 117, subpart G.

11.8.2 When to Establish and Implement a Supply-chain Program as a Preventive Control for a Food Allergen Hazard

We recommend that you:

- Discuss the food allergen profile of a potential supplier's products during your initial consultation with the potential supplier (e.g., during a telephone conversation, or as part of any questionnaire that you use for initial consultations with potential suppliers); and

[27] See Table 11-8 for our website "Firm/Supplier Evaluation Resources for FSMA Rules."
[28] The requirement for an annual onsite audit does not apply if there is a written determination by the PCQI that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (See 21 CFR 117.430(b)(2).)
[29] Undeclared major food allergens that have been known to cause fatal reactions are generally classified as Class I recalls. FDA considers each situation on a case-by-case basis when determining the appropriate recall classification.

- Establish and implement a supply-chain program for the control of food allergen hazards if it is reasonably foreseeable that the food allergen profile(s) of food products produced by a potential supplier could lead to allergen cross-contact in raw materials or other ingredients that you would receive from that supplier.

The nature and extent of your supply-chain program would depend on the food allergen profile of the potential supplier's products (e.g., the severity of the hazard if allergen cross-contact were to occur, and whether the allergen cross-contact is likely to be extensive (such as when an allergen present due to cross-contact could be distributed homogeneously in the product[30]) or limited (such as when an allergen present due to cross-contact is more likely to be distributed non-homogeneously[31])) and the food allergen program in place at the supplier (including CGMP measures and preventive controls for allergen cross-contact). See the discussion in section 11.8.3 of examples of supplier approval and verification activities in supply-chain programs that depend on such factors.

In general, we see no reason for you to establish and implement a supply-chain program for the control of food allergen hazards if:

- You will receive a raw material or other ingredient from a supplier that does not manufacture, process, or pack any food allergens; or
- You will receive a raw material or other ingredient that is (or contains) a food allergen from a supplier, and that food allergen is the only food allergen that the supplier manufactures/processes. For example, if the supplier is an almond handler that manufactures/processes almonds, but does not manufacture/process other tree nuts, or other foods (such as milk products, soy products, or peanut butter) that are, or contain, a food allergen, there would be no need to evaluate whether the supplier has appropriate procedures in place to prevent allergen cross-contact between foods with different food allergen profiles.

11.8.3 Supplier Approval and Supplier Verification Activities in a Supply-Chain Program for the Control of Food Allergen Hazards

11.8.3.1 Evaluating whether a potential supplier provides allergen advisory statements for raw materials or other ingredients that you would receive from the supplier before approving the supplier

As discussed in section 11.9.3, we recommend that your supplier approval and verification activities include an evaluation of whether a potential supplier provides allergen advisory statements for raw materials and other ingredients that you would receive from the potential supplier. When a potential supplier would provide an allergen advisory statement on the applicable raw materials or other ingredients, we recommend that you discuss the reasons for the allergen advisory statement with the potential supplier before approving the supplier. You should approve a supplier that provides allergen advisory statements for its products only if you

[30] Liquid milk and liquid soy (such as in a soy beverage) are examples of allergens that could be distributed homogeneously.
[31] Pieces of tree nuts and peanuts are examples of allergens likely to be distributed non-homogeneously.

determine that such statements are not being used in lieu of adherence to CGMPs or in lieu of adherence to the requirements for allergen cross-contact controls.

11.8.3.2 Determining the appropriate supplier approval and verification activities

As noted in section 11.8.1, most food allergen hazards are SAHCODH hazards and, thus, an annual audit will be the appropriate supplier approval and verification activity in most circumstances when you establish and implement a supply-chain program for a food allergen hazard. (See 21 CFR 117.430(b)). However, the PCHF requirements provide flexibility for your PCQI to provide a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (See 21 CFR 117.430(b)(2).) See Table 11-4 for some examples of appropriate supplier approval and verification activities in various circumstances.

If your supplier provides allergen advisory statements for the raw materials or other ingredients that you receive from the supplier, product testing for the food source that is the subject of the allergen advisory statements can provide you with information about the frequency with which the applicable food allergen is present in the raw materials or other ingredients that you receive and, when the food allergen is present, about the levels of the applicable food allergen. If your PCQI will use the results of product testing as part of a determination of whether to carry an allergen advisory statement forward to your own food products, we recommend that you conduct such testing on multiple lots of the applicable raw material or other ingredient as part of your supplier approval process, and then periodically as an ongoing supplier verification activity to confirm the PCQI's determination about whether to carry a supplier's allergen advisory statement forward to your own food products. In developing your sampling plan for testing an individual lot, you should consider factors such as whether the food being sampled is homogeneous or non-homogeneous and whether a food allergen that is present due to allergen cross-contact is likely to be distributed homogeneously or non-homogeneously.

If your supplier does not provide allergen advisory statements for the raw materials or other ingredients that you receive from the supplier, but the information you obtain, through your supply chain program, about your supplier's food allergen program suggests that the potential for allergen cross-contact in raw materials or other ingredients obtained from that supplier is moderate or high, then periodic testing of the applicable raw material or other ingredient is an example of an ongoing supplier verification activity to verify that food from a supplier producing foods with different food allergen profiles has been protected from allergen cross-contact. Due to limitations in product testing, testing that you conduct as a supplier approval or verification activity should be in addition to other supplier approval and verification activities rather than the sole supplier approval and verification activity. You could conduct this testing yourself or request that your supplier have such testing conducted and provide you with a Certificate of Analysis (COA). The frequency of such testing could vary with the potential that the ingredient would not be protected from allergen cross-contact. For example, if a supplier that processes food products with different food allergen profiles on the same processing line combines scheduling, allergen cleaning procedures, and frequent verification testing in its food safety plan, your PCQI could determine that annual testing is appropriate. However, if a supplier that processes food products with different food allergen profiles on the same processing line does not do verification testing, more frequent testing (such as monthly or quarterly) could be appropriate.

As discussed in section 11.3, FDA has not established a maximum amount of food allergen that may be present in labeled food products without need for declaration. However, FDA recognizes

that published data on population threshold dose responses to various food allergens are becoming increasingly available. These published data raise the possibility that some low-level exposures to certain food allergens, and the presence of certain allergen-derived ingredients, may not cause allergic reactions in most consumers who have that food allergy. Because food manufacturers/processors could evaluate such data in light of their specific products, such as through risk assessments or other scientifically valid scientific assessments, in making decisions on appropriate food allergen controls, where Table 11-4 mentions the results of testing we are referring merely to the detection of unintended allergen presence and not the level of the unintended food allergen. As discussed in sections 11.8.4 and 11.9.2, your PCQI has the responsibility to determine the appropriate approach to the potential presence in your food product of a food allergen from a food source that is not already an ingredient in that food product.

Table 11-4 Examples of Supplier Approval Activities and Ongoing Supplier Verification Activities

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Vegan caramel chips that do not have any allergenic ingredients	Milk	The supplier uses separate processing lines for vegan caramel chips and caramel (or other) chips that contain milk.	Low, because the supplier uses different processing lines for vegan caramel chips and caramel (and other) chips that contain milk. Therefore, the supplier does not use allergen advisory statements.	- Questionnaire about food allergen control practices - Search FDA's "Firm/Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit	- Annual Certificate of Conformance that the supplier continues to use separate processing lines for vegan caramel chips and caramel (and other) chips that contain milk. - Supplier audit every 3 years.
Vegan caramel chips that do not have any allergenic ingredients	Milk	- The supplier uses the same processing line for vegan caramel chips and caramel (and other) chips that contain milk. - Supplier's allergen cross-contact controls and verification testing: - The supplier schedules production of vegan caramel chips before production of caramel (and other) chips that contain milk. - Before production of vegan caramel chips, the supplier's allergen cleaning procedures include scrape-down of accessible surfaces and push-through (e.g., in piping) with vegan caramel, with the push-through material used as re-work in the production of caramel products that contain milk. - During development of the food safety plan, verification testing of vegan caramel chips consistently is negative whenever verification testing of FCSs of the chip depositor is negative. - During production, the supplier routinely verifies the allergen cleaning by testing FCSs of the chip depositor for the presence of milk allergen, with repeat cleaning if necessary.	Moderate, because the supplier uses the same processing line for vegan caramel chips and caramel (and other) chips that contain milk. However, the supplier combines scheduling, allergen cleaning procedures, verification testing, and repeat cleaning in its food safety plan. The supplier does not use advisory labeling because the verification testing during development of its food safety plan demonstrates that vegan caramel chips do not contain milk allergen whenever verification testing of the chip depositor is negative, and the supplier routinely verifies the cleaning by testing the chip depositor, with repeat cleaning as necessary.	- Questionnaire about food allergen control practices - Search FDA's "Firm/Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Test several shipments of vegan caramel chips	- Annual onsite audit - Periodic testing of shipments of vegan caramel chips (e.g., quarterly or every 5th lot)

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Vegan caramel chips that do not have any allergenic ingredients	Milk	- The supplier uses the same processing line for vegan caramel chips and caramel (and other) chips that contain milk. - Supplier's allergen cross-contact controls and verification testing: - The supplier schedules production of vegan caramel chips before production of caramel (and other) chips that contain milk. - Before production of vegan caramel chips, the supplier's allergen cleaning procedures include scrape-down of accessible surfaces and push-through (e.g., in piping) with vegan caramel, with the push-through material used as re-work in the production of caramel products that contain milk. - During development of the food safety plan, verification testing of vegan caramel chips periodically is positive. - The supplier samples and tests every lot for milk allergen and discards or reworks any lots of vegan caramel chips that contain milk into caramel products that contain milk. - The supplier provides customers with a COA documenting negative test results for every lot.	Moderate, because the supplier uses the same processing line for vegan caramel chips and caramel (and other) chips that contain milk. However, the supplier combines scheduling, allergen cleaning procedures, and verification testing of every lot in its food safety plan. The supplier does not use allergen advisory statements because only those lots of vegan caramel chips that are negative for milk allergen are distributed.	- Questionnaire about food allergen control practices - Search FDA's "Firm/Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Test several shipments of vegan caramel chips for milk	- Annual onsite audit - Annual sampling and testing (as verification of the supplier's sampling and testing of every lot)

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Vegan caramel chips that do not have any allergenic ingredients	Milk	- The supplier uses the same processing line for vegan caramel chips and caramel (and other) chips that contain milk. - Supplier's allergen cross-contact controls and verification testing: - During development of the food safety plan, the supplier assessed multiple cleaning practices for efficacy in preventing allergen cross-contact, but regardless of which cleaning practice was used verification test results were periodically positive for unintended milk presence on FCSs on the chip depositor and in vegan caramel chips. - The supplier concludes that its verification testing during development of the food safety plan demonstrates that its cleaning is not always able to protect the vegan caramel chips from allergen cross-contact. - The supplier's PCQI provides a written justification, in the supplier's food safety plan, for why allergen cross-contact controls are not always able to ensure protection of food from allergen cross-contact; - The supplier's labeling for the applicable food product(s) includes allergen advisory statements that disclose the possible unintended allergen presence in the food; and, - Because the supplier provides allergen advisory statements, the supplier does not routinely do verification testing of either the FCSs on the chip depositor or the vegan caramel chips.	High. The supplier uses allergen advisory statements because it uses the same processing line for vegan caramel chips and non-vegan caramel (and other) chips that contain milk, and its verification testing during development of the food safety plan demonstrates that its cleaning is not always able to protect the vegan caramel chips from allergen cross-contact.	- Questionnaire about food allergen control practices - Search FDA's "Firm/Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Test multiple lots for the frequency and level of detectable milk as part of the PCQI's determination of whether to carry an allergen advisory statement forward	- Annual onsite audit - If an allergen advisory statement is carried forward, annual sampling and testing of vegan caramel chips for the frequency and level of detectable milk to confirm the results obtained during supplier approval and determine whether to conduct reanalysis: - Of the PCQI's determination to carry forward an allergen advisory statement, and - To re-evaluate the supplier. - If an allergen advisory statement is not carried forward, monthly sampling and testing of vegan caramel chips for the frequency and level of detectable milk to confirm the results obtained during supplier approval and determine whether to conduct reanalysis: - Of the PCQI's determination to not carry forward an allergen advisory statement; and - To-re-evaluate the supplier.

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Almond-based beverage	Soy	- The supplier uses the same processing line for almond-based beverages and soy-based beverages. - Supplier's allergen cross-contact controls and verification testing: - The supplier develops allergen cleaning procedures for use when changing from one beverage type to the other. - During development of the food safety plan, verification testing of FCSs on the processing line and in the almond-based beverage is consistently negative for the presence of soy allergen. - During routine production, the supplier monitors the cleaning procedures and conducts sampling and analytical testing for residues of soy as verification, at least quarterly or more frequently as requested by the customer.	Moderate, because the supplier uses the same processing line for almond-based and soy-based beverages. However, the supplier does not use allergen advisory statements due to the liquid nature of the food products and consistently negative test results from verification testing of its cleaning procedures during development of the food safety plan.	- Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Test several shipments for soy	- Annual onsite audit - Receive COAs with every shipment for the first 6 months - Receive quarterly COAs after the first 6 months - Annual sampling and testing (as verification of the supplier's quarterly sampling and testing)
Dry-roasted almonds	Dry-roasted peanuts	- Supplier's CGMP measures for separation in space: - The supplier has separate storage areas in separate buildings for almonds and peanuts. - The supplier has separate processing lines in separate buildings for almonds and peanuts.	Low, because the supplier stores and processes almonds and peanuts in separate buildings. Therefore, the supplier does not use allergen advisory statements.	- Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit	- Annual Certificate of Conformance that the supplier continues to use separate buildings for storing and processing almonds and peanuts. - Supplier audit every three years.
Dry-roasted almonds	Dry-roasted peanuts	- Supplier's CGMP measures for separation in space: - The supplier stores almonds and peanuts in separate rooms of the same building. - The supplier has separate processing lines in separate rooms of the same building for almonds and peanuts. - The supplier has dedicated apparel, portable equipment, utensils, and tools for almonds and peanuts. - Supplier's allergen cross-contact controls, subject to monitoring: - Almonds and peanuts are color-coded upon receipt. - Apparel, portable equipment, utensils, and tools are color-coded or tagged. - Traffic patterns restrict movement of personnel, portable equipment, utensils, and tools.	Low, because the supplier stores and processes almonds and peanuts in separate rooms, and has allergen cross-contact controls for ingredients, apparel, portable equipment, utensils, and tools. Therefore, the supplier does not use allergen advisory statements.	- Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit	- Annual Certificate of Conformance that the supplier continues to use separate rooms for storing and processing almonds and peanuts and continues to implement its allergen cross-contact controls for ingredients, apparel, portable equipment, utensils and tools - Supplier audit every other year.

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Dry-roasted almonds	Dry-roasted peanuts	- Supplier's CGMP measures for separation in space and time: - The supplier stores shelled almonds and shelled peanuts in covered containers in separate storage areas, separated by plastic curtains, in the same storage room. - The supplier has separate processing lines, separated by plastic curtains, in the same room, for almonds and peanuts. - The supplier schedules production of roasted almonds and roasted peanuts at different times. - Supplier's allergen cross-contact controls and verification testing: - Almonds and peanuts are color-coded upon receipt to facilitate storing in the correct area and ingredient identification when bringing shelled almonds and shelled peanuts to the production line. - Apparel, portable equipment, utensils, and tools are dedicated and color-coded or tagged for use with either almonds or peanuts. - Traffic patterns restrict movement of personnel, portable equipment, utensils, and tools. - During the development of the food safety plan, conducts verification procedures by sampling and sorting almonds to look for peanuts, or by analytical testing for peanut residue, is consistently negative. - During routine production, when the supplier does its quality control (QC) checks on samples of almonds for color and size, it also sorts the sample and looks for peanuts.	Low, because the supplier has CGMP measures for separation in both space and time, has allergen cross-contact controls for ingredients, apparel, portable equipment, utensils, and tools, and during development of the food safety plan verification testing for peanuts and peanut residue is consistently negative. Therefore, the supplier does not use allergen advisory statements.	- Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Sample and sort almonds from several shipments to look for peanuts	- Annual onsite audit - Periodic (e.g., semi-annually checking shipments of almonds by sampling and sorting to look for peanuts

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Dry-roasted almonds	Dry-roasted cashews	- The supplier uses the same production line for almonds and cashews. - Supplier's CGMP measures for separation in space: - Separate storage areas, in different rooms, for shelled almonds and shelled cashews. - Supplier's allergen cross-contact controls and verification testing: - Almonds and cashews are color-coded upon receipt to facilitate storing in the correct area and ingredient identification when bringing shelled almonds and shelled cashews to the production line. - Apparel, portable equipment, utensils, and tools are dedicated and color-coded or tagged for either almonds or cashews. - The supplier consults with an expert in dry cleaning techniques to develop cleaning procedures for use when changing from one nut to the other. - During development of the food safety plan, verification testing by sampling and sorting almonds to look for cashews, or by analytical testing for cashew residue, is rarely positive. - During routine production, the supplier monitors the cleaning procedure and conducts analytical tests of FCSs for cashew residue before beginning production of almonds, with repeat cleaning if necessary. - During routine production, the supplier holds each lot until receiving the results of verification procedures (sampling and sorting almonds to look for cashews) and analytical testing for cashew residue. The supplier reworks any lots of almonds that contain cashews in a mixed nuts product. - The supplier provides a COA with the results of its verification testing for each shipment of almonds.	Moderate, because the supplier uses the same processing line for almonds and cashews. However, the supplier does not use allergen advisory statements because the verification testing of its allergen cross-contact controls during development of its food safety plan demonstrates that the frequency of allergen cross-contact is low, it routinely monitors the cleaning during production, it follows "hold and test" procedures before distributing almonds, and it provides a COA with the results of verification testing for every lot of almonds.	- Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Sample and sort almonds from several shipments to look for cashews - Test several shipments for cashew residue	- Annual onsite audit - Supplier COA for each shipment - Periodic (e.g., semi-annually or every 6th lot) checking shipments of almonds by sampling and sorting to look for cashews and testing for cashew residue (as verification of the supplier's sampling and testing of every lot)

Ingredient	Potential Unintended Allergen Presence Due to Allergen Cross-Contact at the Supplier	Food Allergen Program at the Supplier	Potential for Allergen Cross-Contact at the Supplier and Supplier's Decision Regarding Allergen Advisory Statements	Examples of Supplier Approval Activities	Examples of Ongoing Supplier Verification Activities
Dry-roasted almonds	Dry-roasted cashews	- The supplier uses the same production line for almonds and cashews. - Supplier's CGMP measures for separation in space: - Separate storage areas, in the same room, for almonds and cashews. - Supplier's allergen cross-contact controls and verification testing: - Almonds and cashews are color-coded upon receipt. - Apparel, portable equipment, utensils, and tools are dedicated and color-coded or tagged for either almonds or cashews. - The supplier develops cleaning procedures for use when changing from one nut to the other. - During development of the food safety plan, assessed multiple cleaning practices for efficacy in preventing allergen cross-contact, but regardless of which cleaning practice was used verification testing by sampling and sorting almonds to look for cashews, or by analytical testing for cashew residue, is frequently positive. - The supplier concludes that its verification testing during development of the food safety plan demonstrates that its cleaning is not always able to protect the almonds from allergen cross-contact. - The supplier's PCQI provides a written justification, in the supplier's food safety plan, for why allergen cross-contact controls are not always able to ensure protection of food from allergen cross-contact. - The supplier's labeling for the applicable food product(s) includes allergen advisory statements that disclose the possible unintended allergen presence in the food. - Because the supplier provides allergen advisory labeling, the supplier does not routinely do verification testing of either the FCSs on the processing line or the almonds.	High. The supplier uses allergen advisory labeling because it uses the same production line for almonds and cashews and verification testing during development of the food safety plan demonstrates that its cleaning is not always able to protect the almonds from allergen cross-contact.	- Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit - Sample and sort almonds from several shipments to look for cashews, and test several shipments for the presence of cashew residue, as part of the PCQI's determination of whether to carry the allergen advisory labeling forward	- Annual onsite audit - If allergen advisory labeling is carried forward, periodic checking shipments of almonds by sampling and sorting to confirm the results obtained during supplier approval - If allergen advisory labeling is not carried forward, periodic checking shipments of almonds by sampling and sorting, and by testing for cashew residue, to confirm the results obtained during supplier approval and determine whether to conduct reanalysis: - Of the PCQI's determination to not carry forward allergen advisory labeling; and - To-re-evaluate the supplier. - Frequency of sampling and sorting (and, when applicable, analytical testing) varies depending on whether allergen advisory labeling is carried forward (e.g., monthly if allergen advisory labeling is not carried forward; semi-annually or every 6th lot if allergen advisory labeling is carried forward)

11.8.3.3 Conducting an audit of a supplier when the hazard requiring a supply-chain applied control is a food allergen hazard

If you will conduct an onsite audit of a supplier, the onsite audit must be performed by a qualified auditor. (See 21 CFR 117.435 and the definition of a qualified auditor in 21 CFR 117.3.) Specifically, the auditor that conducts audits to verify food allergen controls must have technical expertise obtained through education, training, or experience (or a combination of these) necessary to verify that a supplier is implementing measures adequate to control food allergens.

When you conduct an audit for a supplier that is subject to the requirements of part 117,[32] examples of activities to evaluate during the audit are[33]:

- Storage and handling practices for ingredients, WIP, rework, and finished goods;
- Methods used for physical separation, product containment, and product identification;
- Production practices, including procedures for use of rework and WIP;
- Production scheduling;
- Movement of raw materials and other ingredients that are, or contain, a food allergen;
- Use and segregation of specific utensils, implements, and tools;
- Procedures for the approval of labels and of packaging that contains pre-printed labels;
- Procedures for assuring that the correct label is applied to the correct food product;
- Handling of obsolete labels/packaging;
- Sanitation procedures;
- Post-cleaning verification to ensure the absence of food allergens prior to processing a product with a different food allergen profile;
- Procedures for monitoring food allergen controls; and
- Review of records, such as cleaning procedures, monitoring records, corrective action records, verification records, incoming inspection records of labels/packaging, training records, label/packaging approval records, and previous allergen audit reports and follow up reports to correct deficiencies, if any, found in those reports.

[32] If your supplier is a facility that is not subject to the requirements for hazard analysis and risk-based preventive controls because it satisfies one of the criteria in 21 CFR 117.5 for an exemption, you would evaluate the supplier's CGMP measures to prevent allergen cross-contact.
[33] Adapted from "Managing Allergens in Food Processing Establishments" (GMA, 2009).

11.8.4 Receiving a Raw Material or Other Ingredient From a Supplier That Provides Allergen Advisory Statements

As discussed in section 11.9.3, if you approve a supplier that provides an allergen advisory statement for a raw material or other ingredient, your supply-chain program should include a written determination by the PCQI of whether to carry an allergen advisory statement forward to any of your own products. For example:

- If your supplier provides an allergen advisory statement for vegan caramel chips (e.g., about the potential for unintended milk presence), and you will use the vegan caramel chips in a food product that contains an ingredient that is (or contains) milk (such as milk powder), your product label would already declare the food source "milk," and there would be no need for an additional allergen advisory statement on your food product.
- If your supplier provides an allergen advisory statement for vegan caramel chips (e.g., about the potential for unintended milk presence), and you will use the vegan caramel chips in a food product that is not formulated to contain any other ingredient that is (or contains) milk, you should either:
    - Carry such an allergen advisory statement forward to the product label on your food products, and specify in your Label Content Procedures for receiving the vegan caramel chips that you treat the vegan caramel chips in the same manner as you treat other ingredients that are or contain a major food allergen;[34] or
    - Rely on a scientifically valid determination (which you include in your food safety plan) that the amount[35] of milk allergen that may be present in labeled food products produced using that supplier's ingredient is low enough such that the presence may not cause allergic reactions in most consumers who have that food allergy.

11.8.5 Corrective Actions and Corrections in the Event of Supplier Non-conformance

If you determine (e.g., through your supplier verification audit, periodic testing, or consumer complaints) that the supplier is not adequately controlling food allergen hazards, the requirements for a supply-chain program specify that you must take corrective action or corrections to ensure that raw materials or other ingredients from the supplier do not cause the food that you manufacture or process to be adulterated under section 402 of the FD&C Act. (See 21 CFR 117.410(e) and 117.150.)

Corrections could be appropriate if, for example, you find (through your ongoing supplier verification activities) that a supplier has an implementation issue with certain allergen controls, (e.g., an audit indicates that some of the procedures to control the movement of employees and mobile equipment to prevent cross contact have not been followed) but the observations indicate that cross-contact was unlikely. You could consider that non-compliance to be a minor problem that would not directly impact the safety of the food product that you purchase from that supplier. In such circumstances, corrections could include assessing the supplier's explanation

[34] See the discussions in section 11.7.1.1.4 regarding Label Content Procedures for receipt of raw materials and other ingredients.
[35] See discussion in section 11.3 regarding published data on population threshold dose responses to various food allergens.

of what went wrong and the steps that the supplier is taking to prevent the problem from recurring.

See 21 CFR 117.410(e) and 117.150 for the requirements applicable to corrective actions if you determine that the supplier is not controlling hazards that you have identified as requiring a food allergen control applied by the supplier. Corrective actions (rather than corrections) are appropriate when the problem with a supplier's control of food allergen hazards impacts (or has the potential to impact) the safety of your product. For example, if your supplier recalls a powdered milk product due to unintended soy presence, and you had purchased that powdered milk product, you would follow the supplier's instructions regarding powdered milk that you have not already used. However, the problem that led to the recall of the powdered milk product could directly impact the safety of food that you manufactured/processed before becoming aware of the recall as well as the safety of milk powder that you purchase from that supplier in the future. In such circumstances, corrective actions would include:

- Identifying the problem (e.g., by determining why your supplier's food allergen program failed);
- Correcting the problem and reducing the likelihood that the problem will recur (e.g., by working with the supplier to ensure appropriate implementation of a food allergen program in the future or by changing suppliers); and
- Evaluating all affected food for safety (e.g., by evaluating the food you manufactured or processed for unintended allergen presence) and ensuring that any food with unintended allergen presence does not enter commerce (or is removed from commerce if it has been shipped).

11.8.6 Reanalysis in the Event of Ongoing Supplier Nonconformance

As discussed in section 11.5.5, part 117 includes requirements for you to conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan, whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective. (See 21 CFR 117.170(b)(4).) Reanalysis of your supply chain program is appropriate if, for example:

- A supplier of raw materials or other ingredients that are at high risk for a food allergen hazard due to allergen cross-contact does not provide allergen advisory statements for those raw materials or other ingredients, but you repeatedly detect an unintended allergen presence during routine sampling and testing of those raw materials or other ingredients. Reanalysis to address the unintended allergen presence could include discussions with the supplier about the CGMP measures and allergen cross-contact controls used by the supplier to prevent allergen cross to help determine whether modifications are needed for your food safety plan.
- A supplier of raw materials or other ingredients that are at high risk for a food allergen hazard due to allergen cross-contact provides allergen advisory statements for those raw materials or other ingredients, and the detected levels of the unintended allergen presence in raw materials or other ingredients during routine sampling and testing are sufficiently high to warrant discussion with the supplier about the CGMP measures and allergen cross-contact controls used by the supplier to prevent allergen cross-contact.

During reanalysis, your PCQI would determine whether to discontinue use of such suppliers.

See also the discussions of reanalysis of allergen advisory labeling in section 11.9.5. In some circumstances, reanalysis of your supply-chain program could lead you to conclude that an allergen advisory statement for your product has become appropriate because you are not always able to assure, through your supply-chain controls, that the ingredient you receive will be protected from allergen cross-contact.

11.8.7 Records Documenting the Supply-Chain Program

See 21 CFR 117.475 for a list of records required to document a supply-chain program. See Chapter 15 for a comprehensive discussion of those records.

11.8.8 Review of Records for the Supply-Chain Program

As specified in 21 CFR 117.475(b), you must review the records for your supply-chain program in accordance with §117.165(a)(4), which requires that a PCQI review (or oversee the review of) your supply-chain records within a reasonable time after the records were created to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.

11.9 Allergen Advisory Statements

11.9.1 How the 1996 Food Allergen Notice Applies to CGMP Measures and PCHF Requirements

In the 1996 food allergen notice (see Table 11-8), we advised that, “because adhering to CGMPs is essential for effective reduction of adverse reactions by consumers, such precautionary labeling should not be used in lieu of adherence to CGMPs.” We also urged manufacturers to “take all steps necessary to eliminate allergen cross-contamination and to ensure the absence of the identified food.”

When we issued the 1996 food allergen notice, your responsibility to prevent allergen cross-contact was solely addressed through CGMP requirements to prevent contamination and adulteration of food. In 2015 (80 FR 55908, September 17, 2015), we revised those CGMP requirements to more explicitly require that you use CGMP measures to prevent allergen cross-contact[36]. We also added new requirements for allergen cross-contact preventive controls to:

- Provide assurance that any food allergen hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act (21 CFR 117.135(a)); and
- Ensure protection of food from allergen cross-contact (21 CFR 117.135(c)(2)(i)).

[36] As noted in section 11.1, our more recent allergen labeling guidance also advises that labeling such as “may contain [allergen]” is not a substitute for adherence to either CGMPs or food allergen preventive controls.

Consistent with the 1996 food allergen notice and our allergen labeling guidance:

- You should not use allergen advisory statements in lieu of adherence to the CGMP requirements to prevent allergen cross-contact; and
- You should not use allergen advisory statements in lieu of adherence to the requirements for allergen cross-contact controls.

As discussed in section 11.1, this chapter does not broadly discuss other issues associated with allergen advisory statements. See our web page providing guidance documents and regulatory information regarding food allergens (Table 11-8) for our policy statements and other guidance relevant to allergen advisory statements. You should periodically check that web page for updates to these policy statements and other guidance.

11.9.2 Justification by Your Preventive Controls Qualified Individual That an Allergen Advisory Statement Is Appropriate

We realize that there may be circumstances in which you are not always able to provide assurance, even after implementation of appropriate CGMP measures and allergen cross-contact controls, that food can be protected from allergen cross-contact. If so:

- Your PCQI should provide a written justification, in your food safety plan, for why allergen cross-contact controls cannot ensure protection of food from allergen cross-contact; and
- Your labeling for the applicable food product(s) could include information that discloses the possible unintended allergen **presence** in the food.

The allergen labeling guidance (see Table 11-7) reiterates the statement in the 1996 food allergen notice that that allergen advisory statements such as "may contain [allergen]" should not be used as a substitute for adherence to CGMPs and adds that any allergen advisory statement such as "may contain [allergen]" must be truthful and not misleading. In developing information that is truthful and not misleading and discloses the possible unintended allergen presence in the food, you should carefully consider how to design and place the information so that it will be easily seen by consumers looking for this additional information on the label.

11.9.3 Suppliers That Use Allergen Advisory Statements

We realize that there may be circumstances in which a supplier that produces some ingredients that contain a food allergen, and other ingredients that do not contain a food allergen, may not be able to provide assurance that its food products have been protected from allergen cross-contact, even after implementation of appropriate CGMP measures and allergen cross-contact controls, and therefore provides allergen advisory statements for the raw materials and other ingredients that you would receive from that supplier. We recommend that your supplier approval and verification activities include an evaluation of whether a potential supplier provides allergen advisory statements for raw materials and other ingredients that you would receive from the potential supplier before approving the supplier. When a potential supplier would provide allergen advisory statements on the applicable raw materials or other ingredients, we recommend that you discuss the reasons for the allergen advisory statements with the potential supplier. You should approve a supplier that provides allergen advisory statements for its products only if you determine that such statements are not being used in lieu of adherence to CGMPs or in lieu of adherence to the requirements for allergen cross-contact controls.

If you approve a supplier that provides allergen advisory statements for food products that you would receive from that supplier, your PCQI should provide, in your food safety plan, a written determination of whether:

- The allergen advisory statement has no impact on the food allergen profile of your products, because all products that would contain the affected ingredient also include an ingredient that is (or contains) the food allergen that could be present in the ingredient due to allergen cross-contact at the supplier and, thus, your product labels already declare the food source of that food allergen;
- You will carry an allergen advisory statement forward to one or more of your food products produced using those raw materials and other ingredients. If so, your Label Content Procedures for receiving these ingredients should specify that you treat these ingredients in the same manner as you treat ingredients that are or contain a major food allergen[37]; or
- You will rely on a scientifically valid determination (which you include in your food safety plan) that the amount of food allergen that may be present in labeled food products produced using that supplier's ingredient is low enough such that its presence may not cause allergic reactions in most consumers who have that food allergy.

11.9.4 Reanalysis of Your Determination That Allergen Advisory Statements Are Appropriate If You Experience Ongoing Problems with Your Allergen Cross-Contact Controls or Your Supply-Chain Program

The requirements of part 117 for reanalysis specify that you must conduct a reanalysis of the food safety plan as a whole, or the applicable portion of the food safety plan whenever you find that a preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective. (See 21 CFR 117.170(b)(4).) Reanalysis of your allergen cross-contact controls, including your determination of whether allergen advisory statements are appropriate, is appropriate if you experience ongoing problems with implementation of those controls. Likewise, reanalysis of your supply-chain program is appropriate if you experience ongoing supplier nonconformance with respect to allergen cross-contact. If your food safety plan does not provide for the use of allergen advisory statements, reanalysis of your allergen cross-contact controls or your supply-chain program could lead you determine that you are not always able to provide assurance, through your allergen cross-contact controls or your supply-chain program, that food can be protected from allergen cross-contact, despite using appropriate CGMPs and preventive controls. If so:

- You should revise your food safety plan to include a written justification for why allergen cross-contact controls or your supply-chain program cannot ensure protection of food from allergen cross-contact;
- Your labeling for the applicable food product(s) should include information that discloses the possible unintended allergen presence in the food and must be truthful and not misleading; and
- In developing allergen advisory statements following reanalysis, you should carefully consider how to design and place an allergen advisory statement to call it to the attention of a consumer who is allergic to a major food allergen and checks the ingredient statements and "Contains" statements on a product label for the food source of all ingredients that are,

[37] See the discussion in section 11.7.1.1.4 regarding Label Content Procedures for receipt of raw materials and other ingredients.

or contain, that major food allergen when first making a purchase selection but may not continue to check the ingredient statements and "Contains" statements on that product label when purchasing the same product on multiple occasions.

11.10 Training

As required by 21 CFR 117.4(b), each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:

- Be a qualified individual as that term is defined in 21 CFR 117.3—i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
- Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties. (See 21 CFR 117.4(b).)

In addition, supervisory personnel who are responsible for ensuring compliance by individuals with the requirements of part 117 must have the education, training, or experience (or a combination of these) necessary to supervise the production of clean and safe food. (See 21 CFR 117.4(c).) Records that document required training must be established and maintained. (See 21 CFR 117.4(d).)

The successful control of food allergens depends on the involvement of all personnel in all phases of product development, ingredient procurement/sourcing, receiving, production and distribution of foods, and proper action by employees to control food allergens depends on their understanding of their responsibilities (GMA, 2009). Therefore, we recommend that all individuals (including individuals with responsibility for management, research and development, marketing, procurement, legal/regulatory issues, auditing, product development, design engineering, production, quality assurance, consumer complaints, and warehousing and distribution) receive general allergen awareness training. Such training should include information on the significance of food allergens, proper control of product labeling, and the prevention of allergen cross-contact, including the specific practices and procedures employed by your establishment.

Examples of training topics for all personnel are:

- Awareness of those raw materials and other ingredients that contain food allergens and that should be the subject of a food allergen program;
- How the design of your plant and equipment helps to prevent allergen cross-contact;
- Procedures that you use to prevent allergen cross-contact – e.g., procedures for storage (of raw materials and other ingredients, WIP, rework, and finished products), production scheduling, cleaning, rework, packaging products, labeling products, and waste management;

- CGMP measures to prevent allergen cross-contact due to personnel practices, including hand washing, use of protective clothing, proper disposal and cleaning of soiled clothing and protective gear, and traffic patterns for personnel to move through the plant;
- CGMP measures to prevent allergen cross-contact when moving equipment, maintenance tools, and utensils throughout the plant; and
- Actions to take when unintended allergen presence is suspected.

See Table 11-5 for examples of training topics appropriate to an individual's assigned duties.

Table 11-5 Examples of Training Topics Appropriate to an Individual's Assigned Duties

Personnel Function	Training Topics
Purchasing	Awareness that food allergen hazards may require supply-chain controls with associated supplier approval and verification activities
Receiving	Procedures for receipt, handling, and storage of allergen-containing raw materials and other ingredients to ensure that they are appropriately identified and stored
Production operations	The food allergen control measures employed during production, including the preventive measures, corrective actions, and records applicable to each employee's position
Management of WIP and rework	Awareness of the importance of controlling WIP and rework to prevent allergen cross-contact
Maintenance	Measures to prevent allergen cross-contact (e.g., through maintenance tools) between production lines
Cleaning operations	Awareness of the key role of cleaning procedures in preventing allergen cross-contact
Supervision	The plant's food allergen program applicable to the supervisory responsibilities

11.11 Examples Used in this Chapter

Sections 11.12 and 11.13 of this chapter provide examples to illustrate how to establish and implement a food allergen program. These examples are:

- Food Allergen Program Established and Implemented by Dessert Manufacturer A for the Production of Ice Cream and Other Frozen Dessert Products; and
- Food Allergen Program Established and Implemented by Bakery B for the Production of a Variety of Cookie Products.

In reviewing these examples, keep in mind that:

- Our purpose in providing multiple, detailed recommendations in each example is to provide as many examples as possible so that you can develop your own food allergen program as

appropriate to your operations, not to imply that a food allergen program should have all the CGMP measures, preventive controls (including supply-chain controls), monitoring/verification activities, corrective action procedures, and records that we describe in each example for illustrative purposes.

- Label controls have a role in ensuring that the finished food will not be misbranded under section 403(w) of the FD&C Act. Putting a label control in place to prevent such misbranding is more important than classifying that control in a particular way (e.g., as a label content control or a label management control).
- You have flexibility to determine what monitoring/verification activities, and how many monitoring/verification activities, are appropriate for your operation to ensure the effectiveness of the preventive control. (See 21 CFR 117.140(a).) For the purpose of these examples, we specified how Dessert Manufacturer A or Bakery B classified an activity as either monitoring or verification and retained that classification throughout the examples.
- Regardless of whether you identify a label control as a label content control or a label management control, you have flexibility to conduct a single activity as monitoring/verification for either type of label control, and you also have flexibility to use a single record to document either type of label controls.

As noted in sections 11.1 and 11.4.3, this chapter does not broadly discuss issues associated with allergen advisory statements. Accordingly, the examples in sections 11.12 and 11.13 do not discuss whether and how a manufacturer/processor would determine that allergen advisory statements are, or are not, appropriate.

11.12 Example of a Food Allergen Program Established and Implemented by Dessert Manufacturer A for the Production of Ice Cream and Other Frozen Dessert Products

11.12.1 Dessert Manufacturer A's Products and Hazard Analysis

Dessert Manufacturer A produces four frozen dessert products on the same processing line:

- Raspberry sorbet, which contains no ingredients that are, or contain, a food allergen;
- Vanilla ice cream, which contains two ingredients that are, or contain, a food allergen (i.e., cream and milk powder);
- Vanilla frozen custard, which contains three ingredients that are, or contain, a food allergen (i.e., cream, milk powder, and pasteurized liquid eggs); and
- Vanilla frozen custard with almonds, which contains four ingredients that are, or contain, a food allergen (i.e., cream; milk powder; pasteurized liquid eggs; and dry-roasted, chopped almonds).

The manufacturing process is as follows:

- Mix ingredients (except for almonds added to vanilla frozen custard with almonds) to form a dessert mix;
- Homogenize the dessert mix (for the ice cream and custard mixes);

- Heat process (i.e., pasteurize) the dessert mix in a high-temperature-short-time (HTST) pasteurizer;
- Partially freeze the heat-treated dessert mix in a scraped-surface freezer; and
- Pump the partially frozen heat-treated dessert mix into 56-ounce plastic-coated paperboard tubs that are the product packaging; for the vanilla frozen custard containing almonds, the almonds are added during this step.
    - The tubs have a pre-printed product label, including the product name and ingredient statement. The tubs also have a barcode that is used for multiple purposes, such as inventory management.
    - The lids are pre-printed with the product name.

Through the hazard analysis, Dessert Manufacturer A's PCQI determines that a food allergen program, with one or more preventive controls, is necessary to ensure protection of the frozen desserts from allergen cross-contact and to ensure that the finished frozen desserts are not misbranded under section 403(w) of the FD&C Act.

11.12.2 Dessert Manufacturer A's Food Allergen Program

11.12.2.1 Dessert Manufacturer A's CGMP measures in its food allergen program

In determining the appropriate preventive controls, Dessert Manufacturer A first considers the measures that it has established to satisfy the CGMP requirements to prevent allergen cross-contact. Dessert Manufacturer A has CGMP measures in place at the following operational stages:

- Receipt of ingredients: Dessert Manufacturer A uses color-coded stickers/tags to designate totes/containers of allergenic ingredients – cream and milk powder have white stickers/tags, pasteurized liquid eggs have yellow stickers/tags, and almonds have brown stickers/tags.
- Storage of ingredients: Dessert Manufacturer A:
    - Segregates (i.e. stores in a different area) allergenic ingredients (cream, milk powder, pasteurized liquid eggs, and almonds) from non-allergenic ingredients (e.g., sugar, flavorings, and coloring).
    - Dedicates one cold storage unit to allergens, with closed, clearly marked, plastic totes of cream and plastic bags (in boxes) of pasteurized liquid eggs segregated on separate sides of the unit.
    - Stores almond pieces (in boxes with liners) and milk powder (in plastic bags) in dedicated bays in the warehouse.
    - Specifies in production procedures that partially-used containers be closed before they are returned to the cooler or warehouse.
- Scheduling: Dessert Manufacturer A produces the frozen products in a sequence whereby the product with no allergens (i.e., raspberry sorbet) is produced first and the product with the most allergens (i.e., vanilla frozen custard with almonds) is produced last. The complete sequence of products manufactured on the line is as follows: raspberry sorbet, vanilla ice cream, vanilla frozen custard, and vanilla frozen custard with almonds.
- Staging: Dessert Manufacturer A:

- Uses separate areas to weigh or measure out non-allergenic ingredients (e.g., sugar, flavoring, and colors) and allergenic ingredients (cream, milk powder, pasteurized liquid eggs, and almonds) before staging the ingredients next to the line. Only one allergenic ingredient is weighed/measured at a time, the area is cleaned, and any partially-used containers are closed and returned to the cooler or warehouse before another ingredient is weighed/measured to prevent cross-contact of any partially-used ingredients.
- Dedicates (i.e., to a specific food allergen or to non-allergenic ingredients) tools, containers, and equipment used to measure ingredients, using the same color-coding used on the containers of allergen-containing ingredients.
- Prepares the weighed/measured ingredients as needed, identifies them on a sticker (name and amount), and takes them directly to the production line.

- Processing: Dessert Manufacturer A adds the almonds at the end of the production process to minimize the number of pieces of processing equipment that contact the almonds.
- Cleaning: Dessert Manufacturer A uses freshly prepared cleaning solutions to clean all equipment and utensils in the production line immediately after production of each product is complete.

11.12.2.2 Dessert Manufacturer A's food allergen controls

Because Dessert Manufacturer A processes foods with different allergen profiles on the same processing line, Dessert Manufacturer A's PCQI determined that an allergen cross-contact control during its production of frozen desserts is necessary to ensure protection of the frozen desserts from allergen cross-contact.

Because three of Dessert Manufacturer A's dessert products contain ingredients that are or contain a food allergen, Dessert Manufacturer A's PCQI determined that label controls are necessary to ensure that its frozen dessert products are not misbranded under section 403(w) of the FD&C Act.

11.12.2.3 Dessert Manufacturer A's assessment of supply-chain controls related to food allergens

Dessert Manufacturer A's PCQI assessed whether Dessert Manufacturer A needs to establish and implement a supply-chain control to ensure that the plants that supply cream, milk powder, liquid pasteurized eggs, and dry-roasted, chopped almonds significantly minimize or prevent allergen cross-contact.

- Through its supply-chain programs for the control of biological hazards in cream, milk powder, and pasteurized liquid eggs, Dessert Manufacturer A has determined that the suppliers of cream, milk powder, and pasteurized liquid eggs do not process other food allergens. Therefore, Dessert Manufacturer A's PCQI determined that Manufacturer A does not need to assess the potential for allergen cross-contact at the suppliers for the cream, milk powder, and pasteurized liquid eggs.
- Through its supply-chain program for the supplier's dry-roasting process for the control of *Salmonella* hazards in the dry-roasted, chopped almonds, Dessert Manufacturer A has determined that the almond handlers that dry roast and chop the almonds do not handle other tree nuts or other food allergens. Therefore, Dessert Manufacturer A's

PCQI determined that Dessert Manufacturer A's supply-chain program for the receipt of dry-roasted, chopped almonds does not need to assess the potential for allergen cross-contact at the almond handlers' plants.

11.12.3 Dessert Manufacturer A's Allergen Cross-Contact Control

11.12.3.1 Dessert Manufacturer A's allergen cleaning procedures

Under the production sequence established by Dessert Manufacturer A, the first product in the production sequence contains no allergenic ingredients. After that first product, each successive dessert on the production line contains allergenic ingredients, including allergenic ingredients that were in the previous dessert processed on the production line as well as one additional allergenic ingredient, until all four products have been processed and the production sequence starts again. After processing the final product in the production sequence (i.e., the vanilla custard with almonds, which contains four allergenic ingredients) the next product to be processed contains no food allergens (i.e., raspberry sorbet). Therefore, Dessert Manufacturer A's PCQI determined that:

- The production sequence, coupled with general cleaning measures established in accordance with the CGMP requirements of 21 CFR 117.35, is adequate to prevent allergen cross-contact after the processing of each of the first three products in the production sequence (i.e., after the processing of raspberry sorbet, vanilla ice cream, and vanilla custard without almonds);
- General cleaning measures established in accordance with the CGMP requirements of 21 CFR 117.35 alone are not adequate to prevent allergen cross-contact after the processing of the final product in the production sequence (i.e., after processing of vanilla almond custard with almonds), because the production sequence begins again with raspberry sorbet, which contains no allergenic ingredients. Thus, allergen cleaning procedures that are targeted to the removal of all allergenic food residues from FCSs are needed as a preventive control to prevent allergen cross-contact after the production of vanilla custard with almonds; and
- If circumstances arise in which the customary production sequence is altered, the allergen cleaning procedures (rather the general cleaning measures) are needed between production runs when a previous dessert product on the production line contains at least one allergenic ingredient not present in the subsequent production run.

Dessert Manufacturer A develops its allergen cleaning procedures in consultation with its provider of food hygiene services and cleaning compounds and with the Quality Assurance supervisor who will oversee periodic analytical tests to verify the results of visual inspection after a cleaning cycle.

11.12.3.2 Dessert Manufacturer A's monitoring/verification of allergen cleaning procedures

Dessert Manufacturer A conducts the following activities to monitor/verify that its allergen cleaning procedures are preventing allergen cross-contact:

- During each cleaning procedure to remove allergenic food residues, the Sanitation Supervisor uses a checklist (the "allergen cleaning checklist") to monitor each step in the allergen cleaning procedure and note any corrections taken during the cleaning procedure. After the equipment has been cleaned and visually inspected, the Sanitation Supervisor uses an ATP bioluminescence swab test or a protein swab test to verify that the line is clean. The Sanitation Supervisor notes the monitoring and results of the ATP swab test or protein swab test on the allergen cleaning checklist.
- Before each production run of raspberry sorbet (or before running any product that does not contain an allergenic ingredient present in the previous run), the Sanitation Supervisor conducts and documents a pre-operational visual inspection of applicable processing equipment and utensils as monitoring that they are visibly clean and notes if the visual inspection demonstrates that the allergen cleaning procedure needs to be repeated (the "pre-operational visual inspection record").
- On a quarterly basis, and whenever there is a change in the cleaning procedure, a Quality Assurance technician verifies the visual inspection by conducting allergen-specific analytical tests before a production run of raspberry sorbet that follows a run of vanilla custard with almonds and keeps the analytical test results as a record.
- On a weekly basis, Dessert Manufacturer A's PCQI reviews the allergen cleaning checklists as verification that all equipment and utensils have been cleaned prior to production, and documents that record review by initialing and dating the allergen cleaning checklists.
- On a weekly basis, Dessert Manufacturer A's PCQI reviews the pre-operational visual inspection records and documents that record review by initialing and dating the pre-operational visual inspection records.
- Within a week of any allergen-specific analytical tests to verify the visual inspection, Dessert Manufacturer A's PCQI reviews the results of the analytical tests as verification, and documents that record review by initialing and dating the results.
- Within a week of a problem that requires corrective action, Dessert Manufacturer A's PCQI reviews the corrective action records, and initials and dates each of the records reviewed in the place marked "Verified by."

11.12.3.3 Dessert Manufacturer A's corrective actions/corrections for allergen cleaning procedures

- Corrections. If the Sanitation Supervisor observes, during monitoring, that a step in the allergen cleaning procedure has not been properly implemented, the Sanitation Supervisor directs personnel to repeat the full cleaning procedure before beginning the next production run and notes this action on the allergen cleaning checklist. Similarly, if the ATP or protein swab tests indicate that the equipment has not been adequately cleaned, the Sanitation Supervisor directs personnel to repeat the full cleaning procedure, verifies the cleaning with an ATP or protein swab test, and notes this action on the allergen cleaning checklist.
- Corrective actions. If a routine analytical test detects unintended allergen presence in raspberry sorbet, or if a consumer who has an allergy to egg, milk, or almonds reports an allergic reaction to raspberry sorbet:
    - If the problem was identified through a consumer report of an allergic reaction, Manufacturer A investigates whether there were production issues that could have contributed to unintended allergen presence, conducts product testing on samples that it retained of the applicable lot to confirm the unintended allergen presence and, if there is

unintended allergen presence, determine the extent of the problem (e.g., number of affected lots).

- The Production Manager conducts a root cause investigation to try to determine whether:
  - Allergen cleaning procedures were not properly implemented (e.g., a complete clean was not conducted during an out-of-sequence changeover to raspberry sorbet to fulfill an order); or
  - The allergen cleaning procedures are not effective (e.g., if it is determined that there is a place where a particle can get hung up on the equipment, thus requiring disassembly of that part of the equipment for cleaning before a production run for raspberry sorbet);
- When appropriate based on the root cause of the problem, the Production Supervisor:
  - Re-trains sanitation managers/personnel (e.g., if it is determined that the allergen cleaning procedures were not properly implemented);
  - Revises the allergen cleaning procedures (e.g., if it is determined that the allergen cleaning procedures are not effective);
  - Appropriately disposes of impacted lots of raspberry sorbet that have not yet been distributed; and
  - Arranges for recalls of affected lots of raspberry sorbet that are in commerce and are adulterated under section 402(a)(4) of the FD&C Act due to allergen cross-contact.

11.12.3.4 Dessert Manufacturer A's records for allergen cleaning procedures and associated preventive control management components

Dessert Manufacturer A maintains the following records:

- Its SSOP, which includes:
  - Procedures for cleaning FCSs to remove all allergenic food residues; and
  - Forms it will use for documentation of carrying out the written procedures, for monitoring and verification activities and for corrections and corrective actions (the forms may serve the dual purpose of written procedures and documentation) and;
- The following records that are dated and initialed by the PCQI to document review of the records:
  - The allergen cleaning checklists for each cleaning cycle;
  - Pre-operation visual inspection records of the production line;
  - Results of any analytical test conducted to verify the results of visual inspection; and
  - Any corrective action records.

11.12.4 Dessert Manufacturer A's Label Controls

11.12.4.1 Dessert Manufacturer A's label content controls and label management controls

11.12.4.1.1 Label content

Dessert Manufacturer A applies the following Label Content Procedures during the development and production of product packaging:

- Label development stage: The product development specialist develops a food allergen label specification by reviewing the ingredients listed in the recipe or formulation, and the components listed by suppliers for all ingredients, to identify all food allergens in each product and the food source of each allergenic ingredient or component.
    - The product development specialist notes that the food allergens in the ingredients are as follows:
        - Raspberry sorbet: There are no allergenic ingredients.
        - Vanilla ice cream: The allergenic ingredients are cream and milk powder. The name of the food source for both ingredients is milk.
        - Vanilla frozen custard: The allergenic ingredients are cream, milk powder, and pasteurized liquid eggs. The names of the food sources are milk and eggs.
        - Vanilla frozen custard with almonds. The allergenic ingredients are cream, milk powder, pasteurized liquid eggs, and dry-roasted, chopped almonds. The names of the food sources are milk, eggs, and almonds.
    - The product development specialist notes that the name of the food source of all allergenic ingredients is included as a part of the common or usual name of at least one ingredient[38] that contains the allergen, i.e., “milk powder,” “eggs,” and “almonds” and that there are no additional allergenic components in other ingredients.
    - The product development specialist decides that the label specification for naming the food sources of the major food allergens that are ingredients in the dessert products is the ingredient statement declaring the allergenic ingredients as follows:
        - Vanilla ice cream: The ingredient statement declares milk powder.
        - Vanilla custard: The ingredient statement declares milk powder and eggs.
        - Vanilla custard with almonds: The ingredient statement declares milk powder, eggs, and almonds.
    - The food allergen label specification includes a requirement for each tub to be color-coded through a different colored band on the top edge of the tub (red for the raspberry sorbet, blue for the vanilla ice cream, yellow for the custard without almonds, and brown for the custard with almonds).
    - The product development specialist decides that the product name[39] will be pre-printed on the lid for the tub and, thus, that the food allergen label specification will include a requirement for each lid to be color-coded, on a band surrounding the edge of the lid, using the same color-coding as for the tubs (red for the raspberry sorbet, blue for the vanilla ice cream, yellow for the custard without almonds, and brown for the custard with almonds).
    - The Label Coordinator reviews the food allergen label specification and documents approval by signing and dating it.
- Ordering stage:

[38] The food source of the allergenic ingredient “cream” is declared as part of the common or usual name of another ingredient (i.e., milk powder).

[39] Note that a label management control applies to labeling associated with food allergens. If the lid does not provide any label information (such as the product name, the ingredient statement, or a “Contains” statement) applicable to the food allergen profile of the product, a color code for a lid (e.g., to complement the color code on the tub) would not be a label management control, because the wrong color of lid would not be relevant to the question of whether the product is misbranded under section 403(w) of the FD&C Act.

- The Label Coordinator reviews a mock-up of the product label, provided by the manufacturer of the tubs and lids, and confirms that the mock-up matches the food allergen label specification before authorizing a production run of the tubs and lids.
- The purchase order for the product tubs and lids specifies that the product tubs/lids for the different products be shipped on different pallets.

11.12.4.1.2 Label management

Dessert Manufacturer A applies Label Management Procedures during storage, staging, production, and post-production. Dessert Manufacturer A stores tubs and lids in boxes on pallets with a sticker containing the product name and carton size on the outside of the box. When tubs and lids are brought to the staging area for packaging, production personnel check product name and the ingredient statement printed on the tub, and the color on the top edge of the tub, as well as the product name on the lid and the color of the band of the lid, to confirm that the correct tub and lid have been brought to the staging area for packaging. At the end of production, Dessert Manufacturer A places unused tubs and lids in the appropriate boxes containing the product name and carton size and returns them to the warehouse.

11.12.4.2 Dessert Manufacturer A's monitoring/verification of label controls

Dessert Manufacturer A conducts the activities described in sections 11.12.4.2.1 and 11.12.4.2.2 to monitor/verify that its label controls are ensuring that its finished frozen dessert products are not misbranded under section 403(w) of the FD&C Act.

11.12.4.2.1 Monitoring/verification of label content controls

- Receipt of product packaging (tubs and lids): After the tubs and lids are manufactured and delivered to Dessert Manufacturer A, quality assurance personnel verify that the tubs and lids match the approved food allergen specification for the product label (including the product name and ingredient statement on the tubs and the color of the tubs, as well as the product name on the lid and the color of the band of the lid). Quality assurance personnel document this review on a Label Review Form included in the Label Content Procedures and sign and date the form.
- On a weekly basis, Dessert Manufacturer A's PCQI reviews, initials, and dates the records documenting the verification by quality assurance personnel that the tubs and lids match the approved food allergen label specification.
- Within a week of a problem that requires corrective action, Dessert Manufacturer A's PCQI reviews the corrective action records, and initials and dates each of the records reviewed in the place marked "Verified by."

11.12.4.2.2 Monitoring/verification of label management controls

- Storage of product packaging (tubs and lids): On a weekly basis, quality assurance personnel use a checklist to monitor that the tubs and lids are stored appropriately at receipt and following production by observation in the storage area for the tubs and lids and

document any incorrect storage on a "Storage Record for Label Controls" form included in the Label Management Procedures, and sign and date the form.

- Production (packaging): The line operator monitors and documents the staging check of the tubs and lids by observing the stacks of tubs and lids placed on the line at the beginning of packaging (and each time new tubs and lids are brought to the packaging line) to confirm that the top edge of the tub, and the band on the lid, have the proper color for the product being produced (red for the raspberry sorbet, blue for the vanilla ice cream, yellow for the custard without almonds, and brown for the custard with almonds). If the monitoring demonstrates that the tub or lid is incorrect, the line operator obtains the correct tub or lid and notes the problem on the production sheet and initialing and dating that note.
- Production (from packaging and code dating through case packing): The line operator manually uses a UPC barcode scanner to monitor that the correct tub is being used for the various products. This monitoring occurs when the line is initially set up and at hourly intervals throughout the production run. The line operator records and initials the results of the barcode scanner on the production sheet, along with the date and time of each check.[40]
- Post-production: At the end of each production run, the line operator verifies that any unused tubs and lids have been placed in the appropriately stickered boxes for return to the storage area and notes this post-production verification check on the production sheet.
- On a weekly basis, Dessert Manufacturer A's PCQI reviews, initials, and dates:
  - Storage Record for Label Controls for monitoring the correct storage of tubs and lids by quality assurance personnel.
  - The production sheet with:
    - Staging checks of the tubs and lids brought to the packaging line;
    - The records documenting the results of the barcode scanning of the production tubs when the packaging line is initially set up and at hourly intervals during production; and
    - The post-production verification check that unused tubs and lids have been placed in appropriately stickered boxes for return to storage.
- Within a week of a problem that requires corrective action, Dessert Manufacturer A's PCQI reviews the corrective action records, and initials and dates each of the records reviewed in the place marked "Verified by."

11.12.4.3 Dessert Manufacturer A's corrective actions/corrections for label controls

11.12.4.3.1 Corrective actions/corrections for label content controls

- Corrections: Receiving personnel reject lots of inaccurate/wrong tubs or lids that are sent from the packaging manufacturer. Procurement personnel follow up with the packaging manufacturer as to the cause of the problem and the steps the packaging manufacturer will take to correct the problem and prevent it in the future.
- Corrective actions: If the inaccurate label content is not discovered until after the product is packaged, Dessert Manufacturer A takes and documents the following corrective actions:

[40]In this example, the tub has a bar code but the lid does not. Therefore, the monitoring that the line operator conducts using a barcode scanner only applies to the tubs.

- Segregation of any incorrectly labeled/packaged products.
  - Mislabeled vanilla ice cream is used as rework in the vanilla ice cream and the vanilla custards.
  - Any mislabeled raspberry sorbet or vanilla frozen custard with or without almonds is either reworked into the same product during the next production run or discarded.
- Investigation by the Production Manager of the root cause of incorrectly labeled products. The Production Supervisor arranges for modification of the label content procedures, re-training of personnel, or both as appropriate.
- Initiation of a recall of any product in commerce that is misbranded under section 403(w) of the FD&C Act.

11.12.4.3.2 Corrective actions/corrections for label management controls

- Corrections: Dessert Manufacturer A:
  - Returns any incorrectly stored tubs or lids to the correct storage location and documents the correction on the Storage Record for Label Controls; and
  - Removes any tubs from the line if they have the wrong color of band at the top and removes any lids from the line if they have the incorrect color of band on the edge and returns them to storage without documenting the correction.
- Corrective actions: If product is packaged using an incorrect tub or lid, Dessert Manufacturer A takes and documents the same corrective actions as for a problem with a label content control, except that modifications to the preventive control procedures would affect Label Management Procedures rather than Label Content Procedures. (See section 11.12.4.3.1.)

11.12.4.4 Dessert Manufacturer A's records for label controls and associated preventive control management components

11.12.4.4.1 Records for label content controls

Dessert Manufacturer A maintains the following records:

- The Label Content Procedures;
- The approved food allergen label specification, dated and signed by the Label Coordinator.
- The following records, initialed and dated by the PCQI to document review of the records:
  - The Label Review Forms, signed and dated by quality assurance personnel, documenting that the final packaging (tubs and lids) has been reviewed after receipt from the packaging manufacturer and that the product name and ingredient statement on the product label, and the color on the top edge of the tubs, as well as the product name on the lid and the color of the band of the lid, match the food allergen label specification for the product; and
  - Any corrective action records.

11.12.4.4.2 Records for label management controls

Dessert Manufacturer A maintains the following records:

- The Label Management Procedures, including monitoring procedures for checking the color of the product tub and lid at staging and the Storage Record for Label Controls form.
- The following records, initialed and dated by the PCQI to document review of the records:
  - The Storage Record for Label Controls;
  - The production sheet on which the line operator notes:
    - Results of staging checks including any instance in which monitoring demonstrates that the wrong tubs or lids were brought to the staging area; and
    - The results of the UPC barcode scanner at the beginning of the production run and every hour during the production run; and
    - The post-production verification check that any unused tubs and lids have been placed in the appropriately stickered box for return to storage; and
  - Any corrective action records.

11.12.5 Summary of Dessert Manufacturer A's Food Allergen Program

Appendix 11-2 summarizes Dessert Manufacturer A's:

- Allergen cross-contact control on the FSPCA's Sanitation Control Form (Form 2-D from Appendix 2 of this guidance); and
- Label controls on the FSPCA's Food Allergen Control Form (Form 2-H (modified) from Appendix 2 of this guidance).

Appendix 11-2 also provides Dessert Manufacturer A's:

- Ingredient analysis to support both allergen cross-contact controls and label controls (Form 2E (Modified) from Appendix 2 of this guidance);
- Food allergen verification list to support label controls (Form 2F (Modified) from Appendix 2 of this guidance); and
- Production line food allergen assessment to support allergen cross-contact controls (Form 2G (Modified) from Appendix 2 of this guidance).

11.13 Example of Food Allergen Program Established and Implemented by Bakery B for the Production of a Variety of Cookie Products

11.13.1 Bakery B's Products and Hazard Analysis

Bakery B produces three types of cookies, for milk allergic-consumers, that have no ingredients containing milk:

- Oatmeal cookies, which contain two ingredients that are, or contain, a food allergen: flour (wheat) and pasteurized liquid eggs;
- Caramel chip cookies, which contain:
    - Two ingredients that are, or contain a food allergen: flour (wheat) and pasteurized liquid eggs; and
    - One ingredient (i.e., vegan caramel chips) that does not contain a food allergen but has the potential to contain a food allergen (i.e., milk) as a result of allergen cross-contact by suppliers that produce non-vegan caramel, milk chocolate, and butterscotch chips that contain milk; and
- Peanut butter cookies, which contain three ingredients that are, or contain, food allergens: flour (wheat), pasteurized liquid eggs, and peanut butter (peanuts).

All three cookies contain vegetable shortening, which contains soy. However, Bakery B sources its vegetable shortening from suppliers that produce vegetable shortening from highly refined soybean oil, which is exempt from the allergen labeling requirements of the FD&C Act. (See section 201(qq)(2)(A) of the FD&C Act.)

The manufacturing process is as follows:

- Dough preparation:
    - For oatmeal cookies: Mix the base ingredients (wheat flour, eggs, vegetable shortening, vanilla extract, salt, baking soda, brown sugar, and granulated sugar) in a spiral mixer, then add oatmeal and raisins.
    - For caramel chip cookies: Mix the same base ingredients as used for the oatmeal cookies in a spiral mixer, then add caramel chips.
    - For peanut butter cookies: Mix the same base ingredients as used for the oatmeal cookies in a spiral mixer, then add peanut butter.
- Dough depositing and baking: Form cookies using a dough depositor and bake them on parchment-lined aluminum cookie sheets in a rotating rack oven.
- Packaging: After baking, hand-pack cookies into plastic trays that are placed in in plastic-lined paper pouches.
- Labeling: Label the plastic-lined paper pouches, already filled with cookies, with labels that are computer-generated in-house. The labels are printed and applied during production (rather than printed in advance of production and stored until needed).

Through its hazard analysis, Bakery B's PCQI determines that a food allergen program, with one or more preventive controls, is necessary to ensure protection of the cookies from allergen cross-contact and ensure that the finished cookies are not misbranded under section 403(w) of the FD&C Act.

11.13.2 Bakery B's Food Allergen Program

11.13.2.1 Bakery B's CGMP measures in its food allergen program

In determining the appropriate preventive controls, Bakery B first considers the measures that it has established to satisfy the CGMP requirements to prevent allergen cross-contact. Bakery B has CGMP measures in place at the following operational stages:

- Storage of ingredients**:** The peanut-containing ingredient (peanut butter) is segregated from other ingredients in a separate warehouse bay that has signs "Only for Peanut Butter."
- Separation in space. Although all cookie products are produced in the same plant:
  - The peanut butter cookies are produced and packaged on a different processing line (with different equipment, utensils and tools) than the oatmeal cookies and caramel chip cookies.
  - The production areas for weighing the peanut butter and for staging the peanut butter cookie ingredients are physically separated by a wall and door from the rest of the production areas – next to the peanut butter cookie line but away from the production area for the oatmeal cookies and caramel chip cookies.

11.13.2.2 Bakery B's food allergen controls

Bakery B's CGMP measures segregate the processing line for cookies containing peanuts from the processing line for cookies that do not contain peanuts. Although Bakery B processes two different cookies (i.e., oatmeal cookies and caramel chip cookies) on the same production line, these cookies have the same food allergen profile. Therefore, Bakery B's PCQI determined that general cleaning measures established in accordance with the CGMP requirements of 21 CFR 117.35 for cleaning FCSs, coupled with its segregation of processing lines, are adequate to clean its production lines and sanitation controls to prevent allergen cross-contact are not needed for the production line equipment. However, due to the severity of allergic reactions in consumers who are allergic to peanuts, Bakery B's PCQI determined that allergen cross-contact controls on utensils, tools, apparel, and movement of personnel are necessary to ensure protection of the oatmeal cookies and caramel chip cookies from allergen cross-contact with peanut protein.

Because all of Bakery B's cookies contain ingredients that are or contain a food allergen, Bakery B's PCQI determined that label controls are necessary to ensure that its cookies are not misbranded under section 403(w) of the FD&C Act.

11.13.2.3 Bakery B's assessment of supply-chain controls related to food allergens

Bakery B's PCQI assessed whether Bakery B needs to establish and implement a supply-chain control to ensure that the plants that supply caramel chips, flour, eggs, vegetable shortening, and peanut butter significantly minimize or prevent allergen cross-contact.

- Bakery B's PCQI determined that the vegan caramel chips have the potential for unintended milk presence as a result of allergen cross-contact by both potential suppliers, because

each potential supplier produces non-vegan chips (caramel, milk chocolate, and butterscotch chips that contain milk) in addition to vegan caramel chips. Therefore, Bakery B's PCQI determined that supply-chain controls are necessary to ensure that the caramel chips are protected from allergen cross-contact.

- Through its initial discussions with potential suppliers of flour, Bakery B has determined that the suppliers of flour do not handle food allergens other than wheat. Therefore, Bakery B's PCQI determined that Bakery B's supply-chain program for the receipt of flour does not need to assess the potential for allergen cross-contact at the suppliers' plants.
- Through its initial discussions with potential suppliers of pasteurized liquid eggs, Bakery B has determined that the suppliers of pasteurized liquid eggs do not handle other food allergens. Therefore, Bakery B's PCQI determined that Bakery B does not need to assess the potential for allergen cross-contact at the suppliers for pasteurized liquid eggs.
- Through its initial discussions with potential suppliers of vegetable shortening, Bakery B has determined that the suppliers of vegetable shortening do not handle food allergens other than soy and all suppliers produce vegetable shortening from highly refined soybean oil, which is exempt from the allergen labeling requirements of the FD&C Act. (See section 201(qq)(2)(A) of the FD&C Act.) Therefore, Bakery B's PCQI determined that Bakery B does not need to assess the potential for allergen cross-contact at the suppliers for vegetable shortening.
- Through its initial discussions with potential suppliers of peanut butter, Bakery B has determined that the suppliers of peanut butter do not handle food allergens other than peanuts. Therefore, Bakery B's PCQI determined that Bakery B does not need to assess the potential for allergen cross-contact at the suppliers for peanut butter.

11.13.3 Bakery B's Allergen Cross-contact Controls

11.13.3.1 Bakery B's allergen cross-contact controls on utensils, tools, apparel, and movement of personnel

Bakery B establishes and implements allergen cross-contact controls on utensils, tools, and apparel and on the movement of personnel as follows**:**

- Dedicated utensils, tools, and apparel:
  - Bakery B dedicates all utensils (e.g., scoops, spatulas) and tools (e.g., scrapers, brushes) used in the production of the peanut butter cookies so that they are not used for the production of oatmeal cookies or caramel chip cookies. Bakery B color-codes all utensils and tools (peanut - blue; non-peanut - white) to make it visibly obvious if the incorrect utensil or tool is brought into the production area.
  - Bakery B dedicates all apparel (e.g., smocks, hairnets) used in the production of the peanut butter cookies so that they are not used for the production of oatmeal cookies or caramel chip cookies. Bakery B color-codes all apparel (peanut - blue; non-peanut - white) to make it visibly obvious if the incorrect apparel is brought into the production area.
- Restricted personnel movement in the plant**:** Bakery B restricts the movement of personnel in the plant by assigning personnel to work exclusively on the peanut butter cookie line or

the production line used for oatmeal cookies and caramel chip cookies during any given production shift.

11.13.3.2 Bakery B's monitoring/verification of allergen cross-contact controls

Bakery B conducts the following activities to monitor/verify that its allergen cross-contact controls are preventing allergen cross-contact:

- During each shift, the Production Supervisor for each cookie processing area monitors the utensils and tools in the area for the correct color (peanut - blue; non-peanut - white) by visual observation. The Production Supervisor documents the monitoring and any non-conformance on a "Checklist for Allergen Cross-Contact Controls."
- During each shift, the Production Supervisor for each cookie processing area monitors personnel for the appropriate color smocks and hairnets by visual observation and documents the monitoring on a "Checklist for Allergen Cross-Contact Controls."
- On a weekly basis, Bakery B's PCQI reviews the Checklist for Allergen Cross-Contact Controls (including corrective actions when applicable) and documents that verification review by initialing and dating the record in the place marked "Verified by."

11.13.3.3 Bakery B's corrective actions/corrections for allergen cross-contact controls

- If a Production Supervisor finds utensils or tools in the wrong production area, the Production Supervisor removes the item and takes it to the cleaning room for washing before it is returned to the correct production area. The Production Supervisor determines, if possible, how the utensil or tool was brought into the wrong processing area and ensures that personnel are re-trained as appropriate based on the determination of the root cause of the problem.
    - Corrections: If production has not begun, these activities are corrections and the Production Supervisor does not document the correction on the Checklist for Allergen Cross-Contact Controls.
    - Corrective actions: If production has begun, these activities are corrective actions and are documented on the Checklist for Allergen Cross-Contact Controls. The Production Supervisor determines whether product may have been affected (i.e. whether product may have come in contact with peanut protein), and, if so, evaluates any affected cookies for safety and prevents affected food from entering commerce by re-processing affected oatmeal or caramel chip cookie dough base (prior to addition of oatmeal and raisins or caramel chips) as peanut butter cookies or diverting the affected oatmeal cookies or affected caramel chip cookies or dough to animal food.
- If a Production Supervisor finds personnel wearing the incorrect color of smock or hairnet, the Production Supervisor determines whether the incorrect color was due to putting on the wrong item(s) (and, if so, why) or due to a violation of the plant traffic pattern procedures such that personnel from the peanut butter cookie area entered the oatmeal/caramel chip

cookie production area. The Production Supervisor ensures that personnel are re-trained as appropriate based on the determination of the root cause of the problem.

- Corrections: If the employee put on the wrong-colored item, the employee is required to leave the area and apply the correct apparel. The Production Supervisor makes this correction but does not document it.
- Corrective actions: If the problem was due to personnel from the peanut butter cookie production area entering the oatmeal/caramel chip cookie production area, these activities are corrective actions and are documented on the Checklist for Allergen Cross-Contact Controls. The Production Supervisor determines whether product may have been affected (i.e., whether product may have come in contact with peanut protein), and, if so, evaluates any affected dough and/or cookies for safety and prevents affected cookies from entering commerce by re-processing affected oatmeal or caramel chip cookie dough base as peanut butter cookies or diverting the affected oatmeal cookies or affected caramel chip cookies and/or dough to animal food.

11.13.3.4 Bakery B's records for allergen cross-contact controls and associated preventive control management components

Bakery B maintains the following records:

- The written procedures for the allergen cross-contact controls, with the color-code designation for utensils, tools, and apparel; and
- The Checklist for Allergen Cross-Contact Controls used for documenting monitoring of utensils, tools, and apparel for the correct colors for the specific processing area. This "Checklist for Allergen Cross-Contact Controls" record also lists the specific non-conformances, if any, describes the corrective actions, and is initialed and dated by Bakery B's PCQI to document the PCQI's review of the record.

11.13.4 Bakery B's Label Controls

11.13.4.1 Bakery B's label content controls and label management controls

In this example, Bakery B generates the labels for its cookies during production from an electronic file. As a result, Bakery B's label content controls and label management controls are so inter-related that some records document monitoring/verification activities for both label content controls and label management controls.

11.13.4.1.1 Label content

Bakery B applies the following Label Content Procedures during development and production of product labels and receipt of ingredients:

- Label development stage: The Label Team develops a food allergen label specification by reviewing the ingredients listed in the recipe or formulation, and the components listed by suppliers for all ingredients, to identify all food allergens in each product and the food source of each allergenic ingredient or component.

- The Label Team notes that the allergens contained in the ingredients are as follows:
  - Oatmeal cookies: The allergenic ingredients are flour (wheat) and pasteurized liquid eggs. The names of the food sources are wheat and egg.
  - Caramel chip cookies: The allergenic ingredients are flour (wheat) and pasteurized liquid eggs. The names of the food sources are wheat and egg.
  - Peanut butter cookies. The allergenic ingredients are flour (wheat), pasteurized liquid eggs, and peanut butter (peanuts). The names of the food sources are wheat, egg, and peanuts.
- The Label Team notes that there are no additional allergenic components in other ingredients.
- An individual in the Label Team has responsibility for the food allergen label specification for the cookies. Because the labels are printed and applied during production (rather than printed in advance of production and stored until needed), that individual determines that the food allergen label specification does not need to include a feature such as color coding to help ensure that the correct labels are retrieved from storage. Therefore, the key label content features included in the food allergen label specification are the product name and the approach to naming the food sources of the ingredients that are (or contain) a food allergen. In choosing how to comply with the allergen labeling requirements of the FD&C Act, the individual considers that the name of the ingredient "flour" does not identify the food source of the allergen (i.e., wheat) and decides that the food allergen label specification for naming the food sources of the major food allergens that are ingredients in the cookies is to place a "Contains" statement for the food sources of all the food allergens in the cookies after the ingredient statement on the product label as follows:
  - Oatmeal cookies: "Contains wheat and egg."
  - Caramel chip cookies: "Contains wheat and egg."
  - Peanut butter cookies: "Contains wheat, egg, and peanuts."
- The Label Team Supervisor prints a sample of the product label to review the food allergen label specification for the product and documents approval by signing and dating the printed label.

11.13.4.1.2 Label management

Production (staging)**:** When a production run is scheduled, one individual in the Label Team selects the electronic file to be printed and sends the file to the Label Team Supervisor. The Label Team Supervisor confirms that the electronic file is the correct file for the product and then sends the file to the production printer where the labels will be generated when they are applied to the packages.

11.13.4.2 Bakery B's monitoring/verification of label controls

Bakery B conducts the following activities to monitor/verify that its label controls are ensuring that its cookies are not misbranded under section 403(w) of the FD&C Act:

11.13.4.2.1 Label content

- Before sending the electronic file for the production label to the production printer, the Label Team Supervisor verifies the content of the production label by reviewing the electronic file for the product label, to confirm that the product name and "Contains" statement in the electronic file match the approved food allergen label specification. The Label Team Supervisor sends the electronic file to the production printer, where the Production Supervisor will print a production label from the printer on the production line, paste that printed label onto the production sheet, and sign and date the production sheet next to the printed label.[41]
- On a weekly basis, Bakery B's PCQI reviews, initials, and dates the production sheets documenting the verification review of the content of the production label.
- Within a week of a problem that requires corrective action, Bakery B's PCQI reviews the corrective action records, and initials and dates each of the records reviewed in the place marked "Verified by."

11.13.4.2.2 Label management

- Electronic label generation during production: After the electronic file for production labels is sent to the printer on the production line, the Production Supervisor prints a label from the production printer, verifies that the product name and "Contains" statement on the labels match the approved food allergen label specification for the product, and documents this review by pasting the printed label onto the production sheet for cookies, signing and dating the production sheet next to the label.
- Production of cookies (from packaging and code dating through case packing): The line operator verifies that the correct label is applied to each product through a visual check. This visual check occurs when the line is initially set up and each time newly printed labels are added to the line throughout the production run. The line operator records and initials the results of this visual check on the production sheet, along with the date and time of the check.
- On a weekly basis, Bakery B's PCQI reviews, initials, and dates the records documenting:
  - The verification that the correct electronic file has been sent to production; and
  - The results of the visual check that the correct label is applied to each product.
- Within a week of a problem that requires a corrective action, Bakery B's PCQI reviews the corrective action records, and initials and dates each of the records reviewed in the place marked "Verified by."

[41] In this example, a single record (i.e., the label printed from the production printer) documents verification activities for both the content of the product label and the selection of the correct electronic file for production.

11.13.4.3 Bakery B's corrective actions/corrections for label controls

11.13.4.3.1 Corrective actions/corrections for label content controls

- Corrections: If the Label Team Supervisor determines that the label content (product name and/or "Contains" statement) does not match the approved food allergen label specification before the electronic file is sent to the production printer, the Label Team Supervisor corrects the label content in the electronic file without creating a record of the correction.
- Corrective Actions: If the label content of production labels does not match the approved food allergen label specification and the problem is discovered only after packaged cookies have been labeled, Bakery B takes and documents the following corrective actions:
  - Segregation of any affected products;
  - Rework of affected products by manually transferring the trays of incorrectly labeled cookies to plastic-lined paper pouches and applying the correct label;
  - Investigation by the Production Manager and Label Team Supervisor to determine the root cause of the problem. As necessary to correct the problem and prevent it in the future, the Label Team modifies its procedures and arranges for re-training as appropriate; and
  - Initiation of a recall of any product in commerce that is misbranded under section 403(w) of the FD&C Act.

11.13.4.3.2 Corrective actions/corrections for label management controls

- Corrections: If the Production Supervisor determines that an electronic file for the wrong label was sent to the production printer but the label has not been applied to product, the Production Supervisor follows up with the Label Team Supervisor to obtain the correct electronic file without creating a record of the correction.
- Corrective actions: If the wrong label is applied to any products, Bakery B takes and documents the following corrective actions:
  - Segregation of any products that have the wrong label;
  - Rework of affected products by manually transferring the trays of incorrectly labeled cookies to plastic-lined paper pouches and applying the correct label;
  - Investigation by the Production Manager of the root cause of the problem. The Production Supervisor arranges for modification of the label management procedures, re-training of personnel, or both as appropriate; and
  - Initiation of a recall of any product in commerce that is misbranded under section 403(w) of the FD&C Act.

11.13.4.4 Bakery B's records for label controls and associated preventive control management components

11.13.4.4.1 Records for label content controls

Bakery B maintains the following records:

- Label Content Procedures.

- The approved food allergen label specification, signed and dated by the Label Development Team Supervisor.
- The following records that are initialed and dated by the PCQI to document review of the records:
  - The production label that is pasted onto the production sheet and signed and dated by the Production Supervisor; and
  - Any corrective action records.

11.13.4.4.2 Records for label management controls

Bakery B maintains the following records:

- Label Management Procedures.
- The following records that are initialed and dated by the PCQI to document review of the records:
  - The production label that is pasted onto the production sheet and signed and dated by the Production Supervisor;
  - The production sheet on which the line operator documents the results of the verification check that the correct label is being applied to the correct product at the beginning of each production run and each time newly printed labels are brought to the line during production; and
  - The corrective action records.

11.13.5 Bakery B's Supply-chain Controls

11.13.5.1 The ingredient with a food allergen hazard that requires a supply-chain-applied control

As discussed in section 11.13.2.3, based on initial discussions with potential suppliers of vegan caramel chips, Bakery B's PCQI determined that the caramel chips have the potential for unintended milk presence as a result of allergen cross-contact by potential suppliers, because the potential suppliers produce non-vegan caramel, milk chocolate, and butterscotch chips that contain milk.

11.13.5.2 The two vegan caramel chip processors that Bakery B evaluates as potential suppliers

Bakery B evaluates two vegan caramel chip processors as potential suppliers. The characteristics of these caramel chip processors are as follows:

- Caramel Chip Processor A uses dedicated processing lines (i.e., one processing line for production of caramel (and other) chips that contains milk and a different processing line for production of caramel (and other) chips that do not contain milk). Caramel Chip Processor A

does not provide an allergen advisory statement for caramel chips that it supplies as an ingredient to receiving facilities.

- Caramel Chip Processor B uses product scheduling, scraping, and push-through cleaning of a processing line used to produce caramel chips containing milk before using that processing line to produce caramel chips that do not contain milk. Caramel Chip Processor B uses the push-through material as re-work in the production of caramel chip products that contain milk. During production, Caramel Chip Processor B routinely verifies the allergen cleaning by testing FCSs of the chip depositor for the presence of milk allergen, with repeat cleaning if necessary. Caramel Chip Processor B does not provide an allergen advisory statement for caramel chips that it supplies as an ingredient to receiving facilities.

In this example, Bakery B will approve Caramel Chip Processor A and Caramel Chip Processor B as suppliers. In the remainder of this example, we refer to these processors as Supplier A and Supplier B, respectively.

11.13.5.3 Bakery B's supplier approval and verification activities

To approve its suppliers, Bakery B:

- Asked each potential supplier to fill out a questionnaire related to:
  - The supplier's food allergen program (including the supplier's CGMP measures, allergen cross-contact controls, and label controls); and
  - Whether the supplier provides an allergen advisory statement for the potential unintended milk presence in vegan caramel chips.[42]
- Searched FDA's "Supplier Evaluation Resources" web page (see Table 11-8) for information relevant to each supplier's compliance with applicable food safety regulations;
- Reviewed a third-party audit provided by each supplier; and
- Tested several lots of vegan caramel chips from each potential supplier to confirm that the caramel chips do not contain milk.

For ongoing verification of each approved supplier, Bakery B:

- Requires Supplier A to provide a Certificate of Conformance that the caramel chips are produced on a dedicated processing line each year and a third-party audit every three years;
- Requires Supplier B to provide a third-party audit each year; and
- Samples and tests caramel chips from Supplier B quarterly.

Bakery B's PCQI reviews the Certificate of Conformance and the results of the audit and the analytical tests for the presence of milk in the caramel chips within a week of receipt and documents this review by signing and dating the Certificate of Conformance, results of the audit, and the analytical tests.

[42] In this example, neither supplier provides allergen advisory statements for its products. Bakery B's supply-chain program specifies that Bakery B would ask any supplier that provides allergen advisory statements to provide the rationale for doing so.

11.13.5.4 Bakery B's corrective actions/corrections in the event of supplier non-conformance

- Corrections: If the results of an onsite audit raise questions about whether a supplier is controlling for unintended milk presence in the caramel chips, but it seems unlikely that allergen cross-contact has occurred, Bakery B temporarily stops using the caramel chips from that supplier until the supplier addresses the questions raised by the audit. If it appears that the supplier is not able to address the questions in a timely fashion, Bakery B takes steps to approve a new supplier, relying in the meantime on the remaining supplier.
- Corrective actions: If the results of an onsite audit indicate that cross-contact is likely to have occurred or if the results of Bakery B's sampling and testing demonstrate unintended milk presence in one or more lots of caramel chips:
    - Bakery B temporarily stops using the caramel chips from that supplier until the supplier can provide evidence that the problem has been corrected. If it appears that the supplier is not able to solve the problem in a timely fashion, Bakery B takes steps to approve a new supplier, relying in the meantime on the remaining supplier; and
    - Bakery B's PCQI evaluates caramel chip cookies that have been manufactured using caramel chips from the supplier for unintended milk presence, and evaluates whether cookies that have been released into commerce need to be recalled.

11.13.5.5 Bakery B's records documenting its supply-chain controls

Bakery B maintains the following records:

- The written supply-chain program required by 21 CFR 117.475(c)(1);
- Written procedures for the receipt of caramel chips (see 21 CFR 117.475(c)(4)), and a checklist documenting implementation of those procedures (see 21 CFR 117.475(c)(5));
- The following records that are initialed and dated by the PCQI to document review of the records:
    - Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients (see 21 CFR 117.475(c)(6));
    - Documentation of the results of its search of FDA's "Supplier Evaluation Resources" web page (see Table 11-8) for each supplier as a supplier approval activity (see 21 CFR 117.475(c)(3) and (6));
    - The results of third-party audits for each supplier of caramel chips (see 21 CFR 117.475(c)(7));
    - The results of quarterly sampling and testing by Bakery B of caramel chips provided by Supplier B; and
    - Records of any corrective actions (see 21 CFR 117.475(c)(16)).

11.13.6 Summary of Bakery B's Food Allergen Program

Appendix 11-3 summarizes Bakery B's allergen cross-contact controls and label controls on the FSPCA's Food Allergen Control Form (Form 2-H (Modified) from Appendix 2 of this guidance).

Appendix 11-3 also provides Bakery B's:

- Ingredient analysis to support both allergen cross-contact controls and label controls (Form 2E (Modified) from Appendix 2 of this guidance);
- Food allergen verification list to support label controls (Form 2F (Modified) from Appendix 2 of this guidance); and
- Production line food allergen assessment to support allergen cross-contact controls (Form 2G (Modified) from Appendix 2 of this guidance).

11.14 References

Some of these references include a website address. FDA has verified these website addresses, as of the date the notice of availability for this document publishes in the *Federal Register*, but websites are subject to change over time.

Boyce JA, Assa'ad A, Burks AW, Jones SM, Sampson HA, Wood RA, Plaut M, Cooper SF, Fenton MJ, Arshad SH, Bahna SL, Beck LA, Byrd-Bredbenner C, Camargo CA Jr, Eichenfield L, Furuta GT, Hanifin JM, Jones C, Kraft M, Levy BD, Lieberman P, Luccioli S, McCall KM, Schneider LC, Simon RA, Simons FE, Teach SJ, Yawn BP, Schwaninger JM. 2010. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. J Allergy Clin Immunol.126(6 Suppl):S1-58.

Food and Agriculture Organization of the United Nations and World Health Organization. 2021. Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens. Virtual meeting, 15 March – 2 April 2021. Summary and Conclusions. Available at https://www.who.int/news-room/events/detail/2021/03/15/default-calendar/ad-hoc-joint-fao-who-expert-consultation-on-risk-assessment-of-food-allergens-part2-review-and-establish-threshold-levels-in-foods-of-the-priority-allergens

Food and Agriculture Organization of the United Nations and World Health Organization. 2022. Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 2: Review and establish threshold levels in foods of the priority allergens. Virtual follow-up meeting on milk and sesame. Summary and Conclusions. Available at https://www.who.int/news-room/events/detail/2021/03/15/default-calendar/ad-hoc-joint-fao-who-expert-consultation-on-risk-assessment-of-food-allergens-part2-review-and-establish-threshold-levels-in-foods-of-the-priority-allergens

Grocery Manufacturers Association (GMA). 2009. Managing Allergens in Food Processing Establishments. Fourth Edition. Edited by WE Stone and KE Stevenson.

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

Remington, BC, J Westerhout, MY Meima, WM Bloma, AG Kruizinga, MW Wheeler, SL Taylor, GF Houben, JL Baumert. 2020. Updated population minimal eliciting dose distributions for use in risk assessment of 14 priority food allergens. Food and Chemical Toxicology 139: 111259. (https://doi.org/10.1016/j.fct.2020.111259)

Taylor, SL and SL Hefle. 2001. Food Allergies and Other Food Sensitivities. *Food Technology* 55(9): 68-83.

11.15 Resources

The tables in this section are a compilation of resources that are available as of the date that we make this guidance available. We have verified the website addresses listed for these resources, as of the date that we make this guidance available, but websites are subject to change over time. In addition, the policies and recommendations in these resources can change over time. We recommend that you periodically review websites listing FDA's CPGs, FDA's Guidance for Industry, and the resources listed in Table 11-8 for new or modified policies and recommendations.

Table 11-6. Applicable FDA Compliance Policy Guides*

CPG	Link
CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens. 2001	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-statement-policy-labeling-and-preventing-cross-contact-common-food-allergens-new
CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact. 2023[43]	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-draft-major-food-allergen-labeling-and-cross-contact

*In addition to the specific link we provided, you can access FDA's Manual of Compliance Policy Guides at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/manual-compliance-policy-guides. Chapter 5 addresses Food, Colors, and Cosmetics and is available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/manual-compliance-policy-guides/chapter-5-food-colors-and-cosmetics.

[43] In 2023, FDA issued for public comment a draft compliance policy guide entitled "CPG Sec. 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact" (88 FR 31507, May 17, 2023). When finalized, this draft CPG will replace existing guidance, in CPG Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens, for FDA staff on FDA's enforcement policy regarding major food allergen labeling and cross-contact.

Table 11-7. Applicable FDA Guidance for Industry*

Guidance	Link
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5). 2022. Guidance for Industry**	https://www.fda.gov/media/117410/download
Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5). 2022. Draft Guidance for Industry***	https://www.fda.gov/media/163454/download
Human Food By-Products For Use As Animal Food: Draft Guidance for Industry #239***	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-239-human-food-products-use-animal-food

*In addition to the specific link we provided, or if that link is no longer operative, you can access most of FDA's Guidance for Industry applicable to human food at https://www.fda.gov/FoodGuidances.
** In 2022, we announced the availability of both draft and final guidance for industry entitled "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5) (87 FR 73561, November 30, 2022). These guidances are revisions of a currently issued guidance, entitled "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4)." The final guidance includes the questions and answers from the currently issued guidance that remain substantively unchanged. The draft guidance, when finalized, will explain FDA's current thinking on a number of issues related to the labeling of food allergens, including requirements in both FALCPA and the FASTER Act.
*** A draft guidance, when finalized, will represent FDA's current thinking on the specified topic.

Table 11-8. Additional Resources

Source	Resource Title	Resource Link
3-A Sanitary Standards, Inc.	3-A Sanitary Standards and Accepted Practices*	https://www.3-a.org/

Source	Resource Title	Resource Link
American Meat Institute	AMI Fact Sheet. Sanitary Equipment Design. 2014.	https://www.meatinstitute.org/index.php?ht=a/GetDocumentAction/i/11006
European Hygienic Engineering and Design Group (EHEDG)	EHEDG Guidelines Doc 8. Hygienic Design Principles. Third Edition. 2018.	https://www.ehedg.org/guidelines/
FDA	Firm/Supplier Evaluation Resources for FSMA Rules	https://www.fda.gov/food/food-safety-modernization-act-fsma/firmsupplier-evaluation-resources-fsma-rules
FDA	Food Allergens/Gluten-Free Guidance Documents & Regulatory Information	https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/food-allergens-and-gluten-free-guidance-documents-and-regulatory-information
FDA	Industry Guidance For Recalls	https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls
FDA	Label Declaration of Allergenic Substances in Foods; Notice to Manufacturers. 1996	http://wayback.archive-it.org/7993/20171114013857/https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106546.htm
FDA	FSMA Final Rule on Sanitary Transportation of Human and Animal Food	https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-sanitary-transportation-human-and-animal-food

Source	Resource Title	Resource Link
Schmidt, RH and DJ Erickson, Food Science and Human Nutrition Department, Florida Cooperative Extension Service, Institute of Food and Agricultural Sciences, University of Florida	Sanitary Design and Construction of Food Equipment. 2005.	https://ucfoodsafety.ucdavis.edu/sites/g/files/dgvnsk7366/files/inline-files/26502.pdf

*Available for purchase.

Appendix 11-1 CGMP Measures to Prevent Allergen Cross-Contact

11-1.A CGMP Measures Are Part of Your Food Allergen Program

As noted in section 11.1, your hazard analysis should consider how your CGMP measures prevent allergen cross-contact, and the preventive controls that you establish and implement to address a food allergen hazard should complement and enhance your CGMP measures for preventing allergen cross-contact. To help you do so, in this Appendix we provide recommendations for measures you can take to comply with the CGMP requirements in 21 CFR part 117, subpart B, to prevent allergen cross-contact. As noted in section 11.3, you should design your food allergen program to prevent allergen cross-contact between foods with different food allergen profiles.

Although the CGMPs do not specify that you take corrective actions if you identify a failure of your CGMP measures to prevent allergen cross-contact, we recommend that you implement corrections or corrective actions as necessary and appropriate to ensure that the CGMP measures that are part of your food allergen program are operating as intended to prevent allergen cross-contact. An example of a correction is re-cleaning equipment that is not visibly clean before beginning production. Examples of corrective actions are re-training personnel who implement the CGMP measures and revising applicable procedures if the procedures do not prevent allergen cross-contact as intended.

11-1.B CGMP Measures to Prevent Allergen Cross-Contact by Personnel

Examples of CGMP measures that you can implement to prevent allergen cross-contact by personnel are:

- Provide personnel who work in direct contact with raw materials or other ingredients that are (or contain) a food allergen, or who work on a production line for a food product that contains a food allergen, with aprons, smocks, uniforms, or other appropriate types of clean, washable outer garments. When practical for your operation, an additional CGMP measure is for these outer garments and other apparel (such as hairnets) to be dedicated (e.g., to the production of products with distinct food allergen profiles) and distinguishable (e.g., through a color-coding system).
- Assign employees to work exclusively with foods containing the same food allergen profile. Alternatively, establish procedures for employees to change apparel when they move between areas that are processing foods with different food allergen profiles. When practical for your operation, an additional CGMP measure is to avoid production assignments that would require personnel to move back and forth, during the same shift, between a processing line that contains a food allergen and a different processing line for food that has a different food allergen profile.
- Provide disposable gloves for use by personnel who directly handle foods containing food allergens and direct those personnel to discard the gloves in a covered waste bin immediately after use. Alternatively, emphasize the importance of washing hands after working with foods that are, or contain, a food allergen and of maintaining reusable gloves in an intact, clean, and sanitary condition.

- Develop traffic patterns that restrict the movement of personnel (including personnel with responsibilities for production, maintenance, and clerical activities) between areas that are processing foods with different food allergen profiles.
- Provide separate break areas for use by personnel who work in processing areas with different food allergen profiles when doing so is practical for your operation. Alternatively, provide an apparel area, at the entrance to the processing area for foods that are, or contain, food allergens, where personnel obtain outer garments to be worn in the processing area and return the outer garments when they leave the area (e.g., for breaks or at the end of the shift), or instruct personnel on where to leave outer garments when they leave the production area.

In addition to these CGMP measures to prevent allergen cross-contact by personnel, we recommend that you make visitors aware of food allergen practices in the plant to prevent allergen cross-contact due to the actions of the visitors.

The sections of part 117 that are relevant to the recommendations in this chapter regarding personnel are 21 CFR 117.10(b)(1), 117.10(b)(3), 117.10(b)(5), and 117.10(b)(9).

11-1.C CGMP Measures for the Design and Construction of the Plant to Prevent Allergen Cross-Contact

When building a new plant or remodeling an existing plant, we recommend that you incorporate features in overall plant layout and design that will minimize the potential for allergen cross-contact and facilitate cleaning of equipment. When doing so is not practical (e.g., due to limitations in the design of an existing plant), we recommend that you place increased emphasis on CGMP measures for sanitary operations, equipment and utensils, storage and handling of raw materials and other ingredients, and processing operations.

Examples of features that you can incorporate in the design and construction of the plant to prevent allergen cross-contact are:

- Separation in space between areas processing foods with different food allergen profiles, such as by a dedicated plant, section of a plant, or processing line (e.g., separated by permanent or temporary doors and full or partial walls);
- Use of enclosed equipment or processing lines (e.g., closed pipes, tanks, pumps, heat exchangers, and fillers) when practical and appropriate. Alternatively, configuration of open production lines so they do not cross over to minimize the potential for an allergen-containing food to fall onto a line containing food with a different food allergen profile. Another alternative is to install barriers such as pans and shields at the crossover points.
- Use of valves to physically separate ingredients with different food allergen profiles in processing equipment or lines. When using valves, we recommend that you:
  - Ensure that all valves are clearly marked; and
  - Clean and inspect valves routinely for potential leaks.
- Use of air flow controls to prevent airborne particulate matter that is, or contains, a food allergen from being brought into areas that do not use that food allergen. Examples of such air flow controls are a microbiological air filtration system and a positive air pressure environment in the packaging area.

- Use of traffic patterns that that do not cross over open production lines and that restrict the movement of equipment, raw materials and other ingredients, WIP, rework, and finished product between areas in which foods with different food allergen profiles are exposed to the environment in the plant.
- Creation of a buffer room or clean area between areas handling foods with different food allergen profiles.

The sections of part 117 that are relevant to the recommendations in this chapter regarding the design and construction of the plant are 21 CFR 117.20(b)(2), 117.20(b)(4), and 117.20(b)(6).

11-1.D CGMP Measures for Sanitary Operations to Prevent Allergen Cross-Contact

Examples of CGMP measures that you can implement to prevent allergen cross-contact during cleaning operations are:

- Establish and implement cleaning procedures that are tailored to the removal of allergenic food residues from your equipment and utensils based on the:
  - Nature of the food or ingredient;
  - Type of food residue that is being removed (e.g., liquid, paste, or powders);
  - Type of FCS (e.g., stainless steel, rubber, or plastic);
  - Nature of the cleaning equipment (e.g., CIP or manual); and
  - Cleaning options (detergents for wet operations, vacuums and brushes for dry operations).
- Clean equipment and utensils in a manner that protects against allergen cross-contact. Examples of how to do so are:
  - Using freshly prepared cleaning solutions (rather than reusing cleaning solutions that could cause recontamination of surfaces with allergenic food residue);
  - Using vacuums, rather than compressed air or grit blasting, for removing dry food residue from difficult-to-clean areas, because compressed air and grit blasting can disperse food allergen residues from one area to another. Alternatively, if vacuums cannot remove such residues, you could disassemble the equipment to enable you to remove such residues. If you need to use compressed air or grit blasting (e.g., if vacuums cannot remove such residues and it is not practical to disassemble equipment for cleaning food residue), you should take precautions to contain food residues that are forcefully removed by the compressed air or grit blasting; and
  - Using low pressure water hoses, rather than high pressure water hoses, for removing food residues from wet processing areas, because high pressure water hoses could spread and aerosolize food allergen residues during cleaning.
- Clean bins, totes, and containers used for ingredients that are, or contain, a food allergen as soon as possible after being emptied.
- Dismantle equipment, as appropriate, to allow for manual cleaning.
- Inspect equipment after each cleaning to determine whether it is visibly clean, and periodically confirm the results of the visible inspection through periodic (e.g., quarterly)

analytical tests (whether general tests for any food residue, or specific tests for residues of food allergens).

The sections of part 117 that are relevant to the recommendations in this chapter regarding sanitary operations are 21 CFR 117.35(a), 117.35(c), and 117.35(d).

11-1.E CGMP Measures on Equipment and Utensils to Prevent Allergen Cross-Contact

Examples of CGMP measures that you can implement to prevent allergen cross-contact from equipment and utensils are:

- Purchase or design equipment with hygienic design features to prevent the accumulation of food residues, to allow easy access for dismantling, cleaning, and inspecting equipment, and (for liquid transfer systems) to minimize the potential for allergen cross-contact through cross connections or pressure differentials (e.g., through use of "make or break" connections to facilitate disconnecting CIP lines during production). Resources that you could adapt to help you do so are available online or are available for purchase (see Table 11-8). Although these publications are directed to sanitary design of equipment to prevent contamination of food from pathogenic microorganisms, the same principles generally apply to the prevention of allergen cross-contact.
- When repairing or maintaining equipment, ensure that welds are smooth; replacement materials are easily cleanable; seals and hoses do not contain cracks; and "dead ends" or other areas where pockets of materials can accumulate are eliminated.
- Provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpacked product from allergen cross-contact.
- Provide physical containment of dry ingredients by partially or completely covering specific equipment, such as conveying equipment, hoppers, storage silos, shakers, and size graders.
- Dedicate distinguishable (e.g., through color-coding) utensils and tools for processing lines with different food allergen profiles, when practical for your operation. Alternatively, place increased emphasis on sanitary operations, such as by visually inspecting equipment and tools that are shared between processing lines for products with different food allergen profiles for food residues that could contain food allergens.

The sections of part 117 that are relevant to the recommendations in this chapter regarding equipment and utensils are 21 CFR 117.40(a)(1) and (6) and 117.40(b).

11-1.F CGMP Measures for Raw Materials and Other Ingredients, and for Manufacturing Operations, to Prevent Allergen Cross-Contact

11-1.F.1 CGMP measures for raw materials and other ingredients to prevent allergen cross-contact

Examples of CGMP measures that you can implement to prevent allergen cross-contact during receipt and storage of raw materials and other ingredients are:

- Review all labels on, and documents accompanying, shipments of raw materials or other ingredients (including minor ingredients such as spice blends) to confirm that the raw material or other ingredient contains only the expected food allergen(s).
- Inspect allergen-containing raw materials and other ingredients upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, inspect nearby containers for evidence of allergen cross-contact. Either reject (or properly dispose of) raw materials and other ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that prevents allergen cross-contact. For example, you could store damaged containers in a separate location, place a damaged container inside another container, or move the contents of the damaged container to a different container, with appropriate identification of any new containers that you use. You should not move damaged containers into a production area unless leakage of allergen-containing raw materials and other ingredients has been contained.
- Clearly identify allergen-containing raw materials and other ingredients using a system that adequately distinguishes between raw materials and other ingredients with different food allergen profiles to alert personnel that these materials are subject to special precautions and handling procedures throughout the plant. An example of such a system is color-coding – e.g., through use of color-coded stickers/tags, placards, or shrink-wrap, with a specific color dedicated to each of the major food allergens and a system (such as a chart displayed at multiple locations in the plant) for alerting personnel to the assigned colors.[44] Another example of such a system is the use of distinctive pallets, totes, or bins dedicated to specific food allergens.
- Establish and implement measures to ensure that raw materials and other ingredients that are received in bulk or food not completely enclosed by a container, including those delivered by railcar or tanker, have been transported and are being transferred in a manner that does not result in allergen cross-contact.[45] Examples of such measures are verification of tanker and/or railcar cleaning (e.g., hopper, boxcar, tanker, wash-tags), prior load information, and cleaning and sanitizing vehicles and transportation equipment. You should reject the shipment if there is evidence that food has not been protected from allergen cross-contact.
- Segregate allergen-containing raw materials and other ingredients from raw materials and other ingredients that do not contain allergens – e.g., in a dedicated storage room or area of the plant, or in separate bays or areas of a storage room. If a dedicated storage room or area is not available, we recommend that you store raw materials and other ingredients that contain allergens below those that do not contain allergens to prevent allergen cross-contact in the event of a spill or leak.

[44] If your plant uses a color-coding system for purposes other than identification of food allergens, you should take steps to prevent confusion between the color-coding systems.

[45] Our regulations (in 21 CFR Part 1, Subpart O) for Sanitary Transportation of Human and Animal Food establish requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of the food. The goal of the regulations is to prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food requiring temperature control for safety, inadequate cleaning of vehicles between loads, and failure to properly protect food. For more information see our webpage “FSMA Final Rule on Sanitary Transportation of Human and Animal Food” (see Table 11-8).

- Use secure, closable containers to store allergen-containing raw materials and other ingredients.
- When receiving or using bulk storage tanks or silos:
    - Use techniques such as visual identifiers (e.g., stickers or tags), computerized verification checks, lockouts over valve openings, and employee inspection and sign-off on a valve and tank set-up to prevent mix-ups that could result in allergen cross-contact; and
    - Clean bulk storage tanks or silos used to store an allergen-containing raw material or other ingredient before using the bulk storage tanks or silos for a raw material or other ingredient that has a different food allergen profile.
- Use containers that are movable on their own, rather than containers that need to be moved with handling equipment such as dollies, forklifts, or pallet jacks, for allergen-containing raw materials and other ingredients, whenever practical. Alternatively, clean the handling equipment after moving allergen-containing raw materials and other ingredients. You should take care to avoid damage to containers or the spread of allergens within your plant from transporting or lifting devices.

The sections of part 117 that are relevant to the recommendations in this chapter regarding raw materials and other ingredients are 21 CFR 117.80(b)(1), 117.80(b)(5), 117.80(b)(7), and 117.80(b)(8).

11-1.F.2 CGMP measures for manufacturing operations to prevent allergen cross-contact

Examples of CGMP measures that you can implement to prevent allergen cross-contact during manufacturing operations are:

- Implement production scheduling to separate by time the manufacture of products with different food allergen profiles. For example, you could produce the foods in a sequence whereby the food with no allergen or the fewest allergens is produced first and the food with the most allergens is produced last. As another example, you could cluster runs of products containing the same food allergen profile to reduce the number of changeovers.
- Add allergenic ingredients as late in the production process as possible, and as far downstream as possible in the processing line (e.g., closest to the filling and packaging equipment), to minimize the amount of equipment in the production area that comes in contact with the allergen.
- Stage allergen-containing raw materials and other ingredients in designated areas as close as possible to the production area before opening, weighing, or transferring them in covered or closed containers to the processing line.
- Add raw materials and other ingredients that are, or contain, a food allergen in a manner that minimizes the potential for unintentional dispersion by dust. For example, you could minimize the formation and dispersion of dust by adding liquid ingredients to mixers at the same time as powders, using dust collection systems (e.g., local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and/or covering equipment.
- Immediately clean up spills that contain food allergens.

- Place special emphasis on the control of WIP and re-work that contain food allergens. Examples of how to control WIP and rework to prevent allergen cross-contact are:
    - Clearly identify WIP and rework (including the name of the WIP/rework, all food allergens present in the WIP/rework, the date of manufacture, which production line the materials will be added to and, where known, the date the rework is to be used) and store them in sturdy containers with secure covers in designated, clearly marked areas. Use interior disposable plastic liners where appropriate.
    - Assemble all WIP and rework for a specific batch of product in a dedicated staging area before transferring the WIP/rework to the processing line.
    - Implement a rework policy for rework to be added back to same finished product (i.e., "exact into exact") whenever practical. Alternatively, add rework to another product with the same food allergen profile.
    - Use allergen-containing WIP and rework as soon as possible to minimize the potential for the rework to be incorporated into the wrong product.
- Use allergen-specific testing procedures where necessary and when possible to identify sanitation failures or possible allergen cross-contact.
- Place waste materials that contain food allergens (e.g., spills, defective and unusable products, used ingredient packaging) in covered collection bins, totes, or containers that are identified as holding allergen-containing waste.

The sections of part 117 that are relevant to the recommendations in this chapter regarding manufacturing operations are 21 CFR 117.80(a)(5), 117.80(c)(1), 117.80(c)(5), 117.80(c)(6), 117.80(c)(7), 117.80(c)(10), 117.80(c)(12), and 117.80(c)(13).

11-1.G CGMP Measures for Warehousing and Distribution to Prevent Allergen Cross-contact

Examples of CGMP measures that you can implement to prevent allergen cross-contact during warehousing and distribution are:

- Hold food in sealed packages or closed containers.
- When moving containers of allergen-containing products using handling equipment such as dollies, forklifts, or pallet jacks, take care to avoid damage to packaging that could result in food allergen residues on packages of foods that do not contain that food allergen. (Opening the package could result in transfer of food allergens on the package exterior to the food inside.)
- Clean up spills or leaks from damaged containers of allergen-containing products as soon as they occur.

The section of part 117 that is relevant to the recommendations in this chapter regarding warehousing and distribution is 21 CFR 117.93.

Appendix 11-2 Summary of Dessert Manufacturer A's Food Allergen Controls and Associated Preventive Control Management Components

FORM 2-D (Modified) Allergen Cleaning Procedures

PAGE _____

PRODUCTS: Raspberry sorbet, vanilla ice cream, vanilla frozen custard, and vanilla frozen custard with almonds
PLANT NAME: _Dessert Manufacturer A_ **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____

Allergen Cleaning

Item	Applicable Information
Location	Production Line
Purpose	Remove all residues of allergen-containing food and ingredients
Frequency	- After production of vanilla frozen custard with almonds, when production sequence is normal as follows: (1) raspberry sorbet; (2) vanilla ice cream; (3) vanilla frozen custard; (4) vanilla frozen custard with almonds; and - Any time the production sequence does not follow the normal sequence
Who	Provider of food hygiene services and Sanitation Supervisor
Procedure	Allergen cleaning procedure
Monitoring	- During each cleaning procedure, the Sanitation Supervisor uses the allergen cleaning checklist to document monitoring of each step in the cleaning procedure and note any corrections. - Before each production run of raspberry sorbet, the Sanitation Supervisor conducts and documents a pre-operational visual inspection of applicable equipment and utensils as monitoring that they are visibly clean.
Verification	- After the equipment has been cleaned and visually inspected, the Sanitation Supervisor uses an ATP bioluminescence swab test or a protein swab test to verify that the line is clean and notes the results on the allergen cleaning checklist. - On a quarterly basis, and whenever there is a change in the cleaning procedure, a QA technician verifies the visual inspection by conducting allergen-specific analytical tests before a production run of raspberry sorbet that follows a run of vanilla frozen custard with almonds and keeps the analytical test results as a record. - On a weekly basis, the PCQI reviews the allergen cleaning checklists, including results of ATP bioluminescence swab tests or protein swab tests, as verification that all equipment and utensils have been cleaned prior to production, and documents that record review by initialing and dating the allergen cleaning checklists. - On a weekly basis, the PCQI reviews pre-operational visual inspection records and documents that record review by initialing and dating the records. - Within a week of any allergen-specific analytical tests to verify the visual inspection, the PCQI reviews the results of the analytical tests as verification, and documents that record review by initialing and dating the results. - Within a week of a problem that requires corrective action, the PCQI reviews the corrective action records, and initials and dates each of the records reviewed in the place marked "Verified by."

Item	Applicable Information
Corrections	- If the Sanitation Supervisor observes, during monitoring, that a step in the allergen cleaning procedure has not been properly implemented, the Sanitation Supervisor directs personnel to repeat the full cleaning procedure before beginning the next production run and notes this action on the allergen cleaning checklist. - If the ATP or protein swab tests indicate that the equipment has not been adequately cleaned, the Sanitation Supervisor directs personnel to repeat the full cleaning procedure and notes this action on the allergen cleaning checklist.
Corrective actions	If a routine analytical test detects unintended allergen presence in raspberry sorbet, or if a consumer who has an allergy to egg, milk, or almonds reports an allergic reaction to raspberry sorbet: - If the problem was identified through a consumer report of an allergic reaction, Manufacturer A conducts product testing to confirm the unintended allergen and, if allergen cross-contact has occurred, determine the extent of the problem (e.g., number of affected lots). - The Production Manager conducts a root cause investigation to try to determine whether: - Allergen cleaning procedures were not properly implemented; or - The allergen cleaning procedures are not effective. - When appropriate based on the root cause of the problem, the Production Supervisor: - Re-trains sanitation managers/personnel; - Revises the allergen cleaning procedures; - Appropriately disposes of impacted lots of raspberry sorbet that have not yet been distributed; and - Recalls affected lots of raspberry sorbet that are in commerce and are adulterated under section 402(a)(4) of the FD&C Act due to allergen cross-contact.
Records	- An SSOP (with procedures for cleaning food-contact surfaces and forms to communicate the written procedures and document their use, for monitoring/verification and for corrections/corrective actions); - The following records that are dated and initialed by the PCQI: - The allergen cleaning checklist for each cleaning cycle; - Pre-operational visual inspection records - A record of the results of any analytical test conducted to confirm the results of visual inspection; and - Any corrective action records.

Verification: (signature or initials)_____ Date: _____

FORM 2-E (Modified) FOOD ALLERGEN INGREDIENT ANALYSIS

PAGE _____

PRODUCTS: Raspberry sorbet, vanilla ice cream, vanilla frozen custard, and vanilla frozen custard with almonds
PLANT NAME: Dessert Manufacturer A **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____

Food Allergens in Ingredient Formulation or in Allergen Advisory Statements: Vanilla ice cream

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (almond)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Cream	Creamery A and Creamery B		X								
Milk powder	Powdered Milk Manufacturer C and Powdered Milk Manufacturer D		X								

Food Allergens in Ingredient Formulation or in Allergen Advisory Statements: Vanilla frozen custard

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (almond)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Cream	Creamery A and Creamery B		X								
Milk powder	Powdered Milk Manufacturer C and Powdered Milk Manufacturer D		X								

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (almond)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Pasteurized liquid eggs	Egg Establishment E and Egg Establishment F	x									

Food Allergens in Ingredient Formulation or in Allergen Advisory Statements: Vanilla frozen custard with almonds

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (almond)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Cream	Creamery A and Creamery B		X								
Milk powder	Powdered Milk Manufacturer C and Powdered Milk Manufacturer D		X								
Pasteurized liquid eggs	Egg Establishment E and Egg Establishment F	x									
Roasted, chopped almonds	Almond Handler G and Almond Handler H					x					

FORM 2-F (Modified) FOOD ALLERGEN LABEL VERIFICATION LIST

PAGE _____

PRODUCTS: Raspberry Sorbet, vanilla ice cream, vanilla frozen custard, and vanilla frozen custard with almonds
PLANT NAME: _Dessert Manufacturer A__ **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____

Product	**Allergen Statement [In Ingredient List]**
Raspberry sorbet	Not applicable
Vanilla ice cream	Milk powder
Vanilla frozen custard	Milk powder, eggs
Vanilla frozen custard with almonds	Milk powder, eggs, almonds

FORM 2-G (Modified) PRODUCTION LINE FOOD ALLERGEN ASSESSMENT

PAGE _____

PRODUCTS: Raspberry Sorbet, vanilla ice cream, vanilla frozen custard, and vanilla frozen custard with almonds
PLANT NAME: _Dessert Manufacturer A__ **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____

Production Line Assessment

Product Name	Production Line	Egg	Milk	Soy	Wheat	Tree Nut (almond)	Peanut	Fish (market name)	Shellfish (market name)	Sesame
Raspberry sorbet	Line A									
Vanilla ice cream	Line A		x							
Vanilla frozen custard	Line A	X	x							
Vanilla frozen custard with almonds	Line A	X	x			x				

FORM 2-H (Modified) FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: Frozen desserts
PLANT NAME: Dessert Manufacturer A **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____
ALLERGEN CONTROL STEP: Label content: Correct food allergen label specification
HAZARD(S): Food allergens (milk, eggs, almonds)

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Corrections	Verification	Records
Correct food allergen label specification for: - The product name and Ingredient statement on tubs of frozen dessert; - The product name on lids for frozen dessert; and - The color on the edge of the product tubs and lids	N/A – Dessert Manufacturer A classifies its activity as verification	N/A	N/A	N/A	- Correction (not documented): Reject lots of incorrect tubs and lids and follow up with tub/lid manufacturer - Corrective action (documented): If the inaccurate label content is not discovered until after the product is packaged: - Segregate incorrectly packaged products; - Rework or discard product as applicable; - Investigate root cause and modify procedures or re-train personnel as applicable; and - Recall if necessary	- Upon receipt of the tubs and lids, QA personnel: - Check that the product name and ingredient statement on the label pre-printed on the tubs, the product name on the label pre-printed on the lids, and the color on the edges of the tubs and lids, match the approved food allergen label specification; - Document this verification review on a Label Review Form included in the Label Content Procedures and sign and date the form. - On a weekly basis, the PCQI reviews, initials, and dates the Label Review Forms documenting the verification review of the product tubs and lids. - Within a week of any corrective actions, the PCQI reviews, initials, and dates the corrective action records.	- Label Content Procedures - The approved food allergen label specification, signed and dated by the Label Coordinator - The following records, initialed and dated by the PCQI: - Label Review Forms documenting the verification review of the product tubs and lids; and - Any corrective action records.

FORM 2-H (Modified) FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: Frozen desserts_____
PLANT NAME: _Dessert Manufacturer A___**ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____**SUPERSEDES:** (mm/dd/yy)_____
ALLERGEN CONTROL STEP: _Label management: Correct tub/lid brought to staging and correct tub/lid used in packaging
HAZARD(S): __Food allergens (milk, eggs, almonds)_____

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Storage of tubs and lids in boxes on pallets with a sticker containing the product name and carton size on the outside of the box	Storage of tubs and lids at receipt and following production	Visual observation	Weekly	QA personnel	Corrections (documented on a Storage Record for Label Controls): Return any incorrectly stored tubs or lids to the correct storage location	On a weekly basis, the PCQI reviews, initials, and dates Storage Record for Label Controls documenting monitoring storage of tubs or lids and associated corrections	- Storage Record for Label Controls
Check that tub brought to the staging area has the correct color on the edge of the tub, and that the lid brought to the staging area has the correct product name and color	The staging check of the product tub and lid	- Visually observe that the top edge of the tub and lid have the correct color	At the beginning of packaging and when new tubs or lids are brought to the line	Line operator	Correction (documented): Remove incorrect tubs or lids from the line, return to storage, and obtain the correct tub and lid.	On a weekly basis, the PCQI reviews, initials, and dates any production sheets documenting the staging checks, including when an incorrect tub or lid is on the line at the beginning of production	- Label Management Procedures, including the procedures for monitoring the staging check of the product tub and lid - The production sheets documenting the staging checks, initialed and dated by the line operator (and the PCQI).

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Use of the correct tub during packaging	That the correct tub is being used during packaging	- Manually use a barcode scanner	When the line is set up and at hourly intervals throughout the production run	Line operator	Corrective action (documented): - Segregate incorrectly packaged products; - Rework or discard product as applicable; - Investigate root cause and modify procedures or re-train personnel as applicable; and - Recall if necessary	- On a weekly basis, the PCQI reviews, initials, and dates production sheets documenting results of the barcode scanning of the tubs - Within a week of any corrective actions, the PCQI reviews, initials, and dates the corrective action records.	The following records, initialed and dated by the PCQI: - The production sheets with the results of the barcode scanner and verification check that unused tubs and lids are put in appropriately stickered boxes; and - Any corrective actions

Appendix 11-3 Summary of Bakery B's Food Allergen Controls and Associated Preventive Control Management Components

FORM 2-E (Modified) FOOD ALLERGEN INGREDIENT ANALYSIS

PAGE _____

PRODUCTS: Oatmeal cookies, caramel chip cookies, and peanut butter cookies
PLANT NAME: Bakery B **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____

Food Allergens in Ingredient Formulation or in Allergen Advisory Statements: Oatmeal cookies

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Flour	Miller C and Miller D				X						
Pasteurized liquid eggs	Egg Establishment E and Egg Establishment F	X									

Food Allergens in Ingredient Formulation or in Allergen Advisory Statements: Caramel chip cookies

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Vegan caramel chips	Carmel chip Processor A		X*								
Vegan caramel chips	Caramel chip Processor B		X**								
Flour	Miller C and Miller D				X						
Pasteurized liquid eggs	Egg Establishment E and Egg Establishment F	X									

* Low potential for unintended milk presence at Caramel Chip Processor A, because Caramel Chip Processor A uses different processing lines for the production of vegan caramel chips and non-vegan caramel (and other) chips that contain milk.
** Moderate potential for unintended milk presence at Caramel Chip Processor B, because Caramel Chip Processor B uses the same processing line for the production of vegan caramel chips and non-vegan caramel (and other) chips that contain milk. However, Caramel Chip Processor B routinely verifies its allergen cleaning procedures by testing food-contact surfaces of the chip depositor for the presence of milk allergen, with repeat cleaning if necessary.

Food Allergens in Ingredient Formulation or in Allergen Advisory Statements: Peanut butter cookies

Raw Material Name	Supplier	Egg	Milk	Soy	Wheat	Tree Nut (market name)	Peanut	Fish (market name)	Shellfish (market name)	Sesame	Food Allergens in Allergen Advisory Statements
Peanut butter	Peanut Processor A and Peanut Processor B						X				
Flour	Miller C and Miller D				X						
Pasteurized liquid eggs	Egg Establishment E and Egg Establishment F	X									

FORM 2-F (Modified) FOOD ALLERGEN LABEL VERIFICATION LIST

PAGE _____

PRODUCTS: Oatmeal cookies, caramel chip cookies, and peanut butter cookies
PLANT NAME: _Bakery B_____ **ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____ **SUPERSEDES:** (mm/dd/yy)_____

Product	**Allergen Statement**
Oatmeal cookies	Contains: Wheat and egg
Caramel chip cookies	Contains: Wheat and egg
Peanut butter cookies	Contains: Wheat, egg, and peanuts

FORM 2-G (Modified) PRODUCTION LINE FOOD ALLERGEN ASSESSMENT

PAGE _____

PRODUCTS: Oatmeal cookies, caramel chip cookies, and peanut butter cookies
PLANT NAME: _Bakery B_____**ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____**SUPERSEDES:** (mm/dd/yy)_____

Production Line Assessment

Product Name	Production Line	Egg	Milk	Soy	Wheat	Tree Nut (almonds)	Peanut	Fish (market name)	Shellfish (market name)	Sesame
Oatmeal cookies	Line A	X			X					
Caramel chip cookies	Line A	X			X					
Peanut butter cookies	Line B	X			X		X			

FORM 2-H (Modified) FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: Cookies_____ _____
PLANT NAME: _Bakery B_____**ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____**SUPERSEDES:** (mm/dd/yy)_____
ALLERGEN CONTROL STEP: _ Allergen cross-contact: correct color of utensils and tools____
HAZARD(S): __Food allergens (wheat, egg, peanuts)_ _____

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Correct color of utensils and tools	Color of the utensils and tools	- Visual observation	During each shift	Production Supervisor for each cookie processing area	Remove incorrect utensil/tool for cleaning, and then return them to the correct area. Determine, if possible, how the problem arose and re-train personnel as appropriate. - Correction (not documented): If the problem is before production, this is correction. - Corrective action (documented): If the problem is during production, this is corrective action, with documentation of the following on the non-conformance record: - Determination of whether dough and/or cookies are affected; - Evaluation of affected dough and/or cookies for safety; - Prevention of affected cookies from entering commerce (re-processing or diverting the affected dough and/or cookies); and - Recall of cookies if necessary	On a weekly basis, the PCQI reviews the Checklist for Allergen Cross-Contact Controls records (including corrective actions when applicable) and documents that verification review by initialing and dating the record.	- Allergen cross-contact control procedures for the color of utensils and tools, including monitoring procedures - Checklist for Allergen Cross-Contact Controls, initialed and dated by the PCQI, documenting: - Results of monitoring, including non-conformance; and - When applicable, associated corrective actions.

FORM 2-H (Modified) FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: Cookies_____ _____
PLANT NAME: _Bakery B_____**ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____**SUPERSEDES:** (mm/dd/yy)_____
ALLERGEN CONTROL STEP: _Allergen cross-contact: correct color of apparel and movement of personnel_
HAZARD(S): __Food allergens (wheat, egg, peanuts)_____

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Correct color of apparel and movement of personnel	Color of the apparel	- Visual observation	During each shift	Production Supervisor for each cookie processing area	Determine whether incorrect color apparel was due to putting on the wrong item(s) (and, if so, why) or due to a violation of the plant traffic pattern procedures such that personnel from the peanut butter cookie area entered the oatmeal/caramel chip cookie production area. Re-train personnel as appropriate - Correction (not documented): If the employee put on the wrong colored item, the employee leaves the area and applies the correct apparel. - Corrective action (documented): If the problem was due to personnel from the peanut butter cookie production area entering the oatmeal/caramel chip cookie production area, with documentation of the following on the non-conformance record: - Determination of whether dough and/or cookies are affected; - Evaluation of affected dough and/or cookies for safety; - Prevention of affected cookies from entering commerce (re-processing or diverting the affected dough and/or cookies); and - Recall of cookies if necessary.	On a weekly basis, the PCQI reviews the Checklist for Allergen Cross-Contact Controls records (including corrective actions when applicable) and documents that verification review by initialing and dating the record.	- Allergen cross-contact control procedures for the color of apparel and movement of personnel, including monitoring procedures - Checklist for Allergen Cross-Contact Controls, initialed and dated by the PCQI, documenting: - Results of monitoring, including any non-conformance; and - When applicable, associated corrective actions

FORM 2-H (Modified) FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: Cookies_____ _____
PLANT NAME: _Bakery B_____**ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____**SUPERSEDES:** (mm/dd/yy)_____
ALLERGEN CONTROL STEP: _Label content: Correct food allergen label specification _____
HAZARD(S): __Food allergens (wheat, egg, peanuts)_____

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Correct food allergen label specification for the product name and the "Contains" statement on product labels	N/A – Bakery B classifies its activity as verification	N/A	N/A	N/A	- Correction (not documented): If the label content does not match the approved food allergen label specification before the file is sent to the production printer, the Label Team Supervisor corrects the label content in the file. - Corrective action (documented): If the problem is discovered only after packaged cookies have been labeled: - Segregate affected product; - Rework cookies by manually transferring the trays of incorrectly labeled cookies to pouches with the correct label; - Investigate root cause and modify procedures or re-train personnel as applicable; and - Recall any product if necessary.	- Before sending the file to the production printer, the Label Team Supervisor checks that the product name and "Contains" statement on the production label matches the approved food allergen label specification. - The Production Supervisor prints a production label from the production printer, pastes that printed label onto the production sheet, and signs and dates the production sheet next to the printed label. - On a weekly basis, the PCQI reviews, initials, and dates the records documenting the verification review of the production labels. - Within a week of a problem that requires corrective action, the PCQI reviews, initials, and dates the corrective action records	- Label Content Procedures - The approved food allergen label specification, signed and dated by the Label Team Supervisor - The following records, initialed and dated by the PCQI: - The production sheet containing the label from the production printer, signed and dated by the Production Supervisor; and. - Any corrective action records.

FORM 2-H (Modified) FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: Cookies_____ _____
PLANT NAME: _Bakery B_____**ADDRESS:** _____
ISSUE DATE: (mm/dd/yy)_____**SUPERSEDES:** (mm/dd/yy)_____
ALLERGEN CONTROL STEP: _Label management_____
HAZARD(S): __Food allergens (wheat, egg, peanuts)_____

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Selection of the correct electronic file for the label	N/A – Bakery B classifies its activity as verification	N/A	N/A	N/A	- Correction (not documented): If the Production Supervisor determines that a file for the wrong label was sent to the production printer but the label has not been applied to product, the Production Supervisor follows up with the Label Team Supervisor to obtain the correct file. - Corrective action (documented): If the problem is discovered only after packaged cookies have been labeled: - Segregate affected product; - Rework cookies by manually transferring the trays of incorrectly labeled cookies to pouches with the correct label; - Investigate root cause and modify procedures or re-train personnel as applicable; and - Recall any product if necessary.	- The Production Supervisor prints a production label from the production printer, pastes that printed label onto the production sheet, and signs and dates the production sheet next to the printed label - On a weekly basis, the PCQI reviews, initials, and dates the records documenting the verification review of the production labels. - Within a week of a problem that requires corrective action, the PCQI reviews, initials, and dates the corrective action records	- Label Management Procedures - The following records, initialed and dated by the PCQI: - The production sheet containing the label from the production printer, signed and dated by the Production Supervisor; and - Any corrective actions

Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action/ Correction	Verification	Records
Application of the correct label	N/A – Bakery B classifies its activity as verification	N/A	N/A	N/A	Corrective action (documented): - Segregate incorrectly packaged products; - Rework cookies by manually transferring the trays of incorrectly labeled cookies to pouches with the correct label; - Investigate root cause and modify procedures or re-train personnel as applicable; and - Recall any product if necessary	- The line operator: - Visually checks that the correct label is applied; and - Records, initials, and dates the results of the visual check on the production sheet - On a weekly basis, the PCQI reviews, initials, and dates the production sheets with the results of the visual check for the correct application of the product label. - Within a week of any corrective actions, the PCQI review, initials, and dates the corrective action records.	- Label Management Procedures - The following records, initialed and dated by the PCQI: - The production sheets documenting the results of the visual check for the application of the correct label; and - Any corrective actions

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 12: Preventive Controls for Chemical Hazards (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 13: Preventive Controls for Physical Hazards (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 14: Recall Plan

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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14.1 Purpose of This Chapter

The purpose of this chapter is to help you establish and implement a written recall plan as required by 21 CFR 117.139. Although the written recall plan is a type of preventive control (see 21 CFR 117.135(c)(5)), the PCHF requirements specify that the written recall plan is not subject to the preventive control management components specified in 21 CFR 117.140 (i.e., monitoring, corrective actions and corrections, and verification.) (See 21 CFR 117.140(c).) Therefore, this chapter does not discuss the application of preventive control management components to your written recall plan.

14.2 Terms Used in This Chapter

14.2.1 Definitions Established in 21 CFR 117.3

See section III.A in the Introduction of this guidance for a glossary of terms that are used in this guidance and are defined in 21 CFR 117.3.

14.2.2 Other Terms That FDA Uses in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 14-1 for additional terms that we use in this chapter. We intend to include these terms in the glossary in the Introduction of this guidance when we update the Introduction. When we do so, we will delete Table 14-1 from this chapter.

Table 14-1 Terms Used in this Chapter

Term	What the Term Means
Consignee	The term defined in 21 CFR part 7 to mean anyone who received, purchased, or used the product being recalled. (See 21 CFR 7.3(m).)
Direct account	The term used in FDA's recall policy in 21 CFR part 7, subpart C to mean the first consignee in a recalling firm's distribution chain.
Direct consignee	The term used in 21 CFR 117.139 to mean the first consignee in a recalling firm's distribution chain. Part 117 uses the term "direct consignee" to have the same meaning as "direct account" in 21 CFR part 7, subpart C.
Recall	A firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery. (See 21 CFR 7.3(g).)
Recall classification	The numerical designation (i.e., I, II, or III) assigned by FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death (21 CFR 7.3(m)(1)); (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious health consequences is remote (21 CFR 7.3(m)(2)); and (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause illness or injury (21 CFR 7.3(m)(3)). (See 21 CFR 7.3(m).)

14.3 Overview of the Requirements for a Recall Plan

The PCHF requirements specify that you must establish a written recall plan for food that requires a preventive control (21 CFR 117.139(a)). The PCHF requirements also specify that the written recall plan must include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility (21 CFR 117.139(b)):

- Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food (21 CFR 117.139(b)(1));
- Notify the public about any hazard presented by the food when appropriate to protect public health (21 CFR 117.139(b)(2));
- Conduct effectiveness checks to verify that the recall is carried out (21 CFR 117.139(b)(3)); and
- Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food (21 CFR 117.139(b)(4)).

14.4 Resources That Can Help You Prepare a Recall Plan

The following resources are available to help you prepare a recall plan:

- Our general guidance on policy, procedures, and industry responsibilities regarding recalls in subpart C of 21 CFR part 7 (21 CFR 7.40 through 7.59; FDA's recall guidance);

- Our guidances for industry, available from our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls):

    - "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff. Draft Guidance" (FDA, 2019a; the draft initiation of voluntary recalls guidance)

    - "Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff" (FDA, 2019c; FDA's public warning and notification guidance);

    - "Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff. Draft Guidance" (FDA, 2018b);

    - "Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff" (FDA, 2018c);

    - "Guidance for Industry: Product Recalls, Including Removals and Corrections" (FDA, 2014; the industry recall guidance); and

- Index of Model Press Releases (available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls); and

- Chapter 7 of FDA's Regulatory Procedures Manual (FDA, 2019d), including:

    - Exhibit 7-1 – Model Effectiveness Check Letter (Industry) (FDA, 2019e);

    - Exhibit 7-2 – Model Effectiveness Check Response Format (Industry) (FDA, 2019f);

    - Exhibit 7-3 – Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry) (FDA, 2019g);

    - Exhibit 7-4 - Model Recall Letter (Generic, All Centers) (FDA, 2019h); and

    - Exhibit 7-5 - Model Recall Response Form (FDA, 2019i).

Throughout this chapter we refer you to specific recommendations in these guidances and our Regulatory Procedures Manual.

14.5 Procedures That Describe the Steps to be Taken to Perform Recall Actions

The goal of procedures that describe the steps to be taken to perform recall actions is to help you to act promptly when you determine that a recall is warranted by following your plan.

14.5.1 Notify Direct Consignees

We recommend that your recall plan describe a written recall communication that you will use to notify your direct consignees about the recall. (See 21 CFR 7.49.) A written recall communication should provide direct consignees with the specific information that they need to conduct the recall and be a reference for direct consignees to consult on an ongoing basis throughout the recall procedure.

A written recall communication can be through any effective means (e.g., through letters, email, telefax, or text messaging). If your recall plan specifies that you will contact your direct consignees by phone, we recommend that your recall plan also specify that you will confirm that phone communication in writing (e.g., follow up the phone call with a written communication such as a letter, email, telefax, or text message) and/or document your phone communication in an appropriate manner. (See 21 CFR 7.49(b)).

As discussed in sections 14.5.1.1 through 14.5.1.6, we recommend that your recall plan:

- Proactively address the questions that direct consignees are likely to have by describing in detail the components to be included in your written recall communication (e.g., identify the food, explain the reason for the recall, specify the depth of the recall, provide instructions for what direct consignees should do with the food, and make it easy for recipients to communicate with you); and

- Include model letters that you would modify based on the specific situation that warranted the recall. See our recommendation in section 14.5.1.6 for you to include a model recall letter(s) in your recall plan.

14.5.1.1 Identify the food

We recommend that your recall plan describe how your written recall communication will clearly provide pertinent, descriptive information to enable accurate and immediate identification of the food being recalled (e.g., identify the product name, size, lot number(s), code(s), expiration dates, and any other pertinent descriptive information (such as UPC codes and shipping dates)). (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(ii)). To help direct consignees identify the recalled product, we recommend that your plan specify that the written recall communication will include a product label. (See the Model Recall Letter (FDA, 2019h).)

14.5.1.2 Explain the reason for the recall

We recommend that your recall plan describe the information that your written recall communication will use to concisely explain the reason for the recall and the health hazard(s) involved. (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(iii)).

14.5.1.3 Specify the depth of the recall

We recommend that your recall plan describe how your written recall communication will specify the depth to which the recall will extend (e.g., wholesale, retail, or consumer level). (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.42(b)(1)). If you have reason to believe that your direct consignees have further distributed the food (e.g., if your direct consignees include distributors who would in turn sell to retail food establishments), then your recall plan should specify that the written recall communication will instruct your direct consignees to in turn notify their customers about the recall. (See the Model Recall Letter (FDA, 2019h), 21 CFR 7.49(a)(3), and section 14.5.1.4 of this chapter).

14.5.1.4 Provide instructions for what consignees should do with respect to the recalled food

We recommend that your recall plan describe how your written recall communication will provide specific instructions on what consignees who receive the recall communication should do with respect to the recalled food. (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(iv)). For example, your recall plan could describe how your written recall communication will instruct consignees to:

- Remove food from sale;
- Cease distribution of food;
- Notify their customers (e.g., to the wholesale or retail level as appropriate) about the recall;
- Return food to you or to another location specified in the recall communication; and/or
- Explain what to do with any food that is not returned (e.g., whether and how to destroy the food).

If your recall plan will describe how your written recall communication will ask direct consignees to notify their customers, we recommend that it specify that recipients of the written recall communication do so by sending a copy of the written recall communication to their customers. Alternatively, your recall plan could specify that you give your direct consignees a modified recall communication to use for this purpose, provided that the modified recall communication includes all pertinent information (e.g., accurate and complete information about the food, the reason for the recall, the depth of the recall, instructions for what to do with the food, and an easy way for recipients to communicate with you).

14.5.1.5 Make it easy for recipients to communicate with you

We recommend that your recall plan describe how your written recall communication will inform recipients (i.e., any consignees that receive a recall communication) about any information that they should send you (e.g., whether the recipient has any of the applicable food), explain how recipients will do so, and make it easy for recipients to do so. For example, your recall plan could specify that your written communication will provide recipients with a toll-free phone number where they can call you, or a response form that they can send you (e.g., using a

postage-paid, self-addressed postcard or envelope, an email, or an online submission). (See the Model Recall Letter (FDA, 2019h) and 21 CFR 7.49(c)(1)(v)). If your recall plan will specify that you will use a response form, we recommend that the form include all instructions from your recall letter to make it easy for recipients to indicate that they followed each instruction. See our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls) for access to an example of a model recall response form (FDA, 2019i). Your plan should also include procedures to follow up with consignees who do not respond to your written recall communication.

14.5.1.6 Include model letters in your recall plan

We recommend that your recall plan include one or more model recall letters that you would modify based on the specific situation that warranted the recall and use as your written recall communication. Including model recall letters in your recall plan will facilitate the rapid preparation of such letters when needed and can prompt you to include all the information described in your recall plan (e.g., identify the food, explain the reason for the recall, specify the depth of the recall, provide instructions for what consignees should do with the food, and make it easy for recipients to communicate with you). See the Model Recall Letter (FDA, 2019h).

14.5.2 Notify the Public When Appropriate

Your recall plan must include procedures to notify the public about any hazard presented by the food when appropriate to protect public health (See 21 CFR 117.139(b)(2).) For example, public warnings are used to alert the public that a food being recalled presents a serious hazard to health. A public warning is reserved for urgent situations where other means of preventing use of the recalled product appear inadequate. Depending on the circumstances, a public warning is issued through the general news media or through specialized news media (such as professional or trade press, or communications to medical professionals). (See 21 CFR 7.42(b)(2).)

FDA provides public access to information on recalls by posting a listing of recalls according to their classification in the FDA Enforcement Report, whether they were requested by FDA or firm-initiated, and the specific action taken by the recalling firm. (See 21 CFR 7.50.) The FDA Enforcement Report is designed to provide a public listing of products in the marketplace that are being recalled. Unlike with public warnings, the recalls listed in the FDA Enforcement Report are not limited to urgent situations that present serious hazards to health and are not necessarily used to alert the public about the risk or hazard of a product under recall.

Currently, FDA also provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products on its Web page entitled "Recalls, Market Withdrawals, & Safety Alerts" (available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts). When FDA posts removal or correction information that has been publicized by a firm, we do so as a public service and it does not necessarily mean that the situation is urgent or that the product presents a serious hazard to health, such that it would be considered a "public warning" as the term is used in this chapter.

Your recall plan should describe your criteria for determining whether a public warning is appropriate. See the public warning and notification guidance (FDA, 2019c) for

recommendations regarding the circumstances for issuance of public warnings, including a discussion of the parties responsible for issuing a public warning.

Your recall plan also should describe the steps you will take when you determine that a public warning is appropriate. See the public warning and notification guidance for recommendations regarding the use, content, and distribution of public warnings, including a discussion of what information should be included in a public warning. (See 21 CFR 7.42(b)(2) and the public warning and notification guidance (FDA, 2019c).)

See model press releases for recalls related to food allergens and some pathogens (e.g., *Listeria monocytogenes*, *Clostridium botulinum*, *Salmonella*, and *E. coli* O157:H7), which are available from the Index of Model Press Releases on our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls). We recommend that your recall plan include one or more of these model press releases (or other model press releases that you prepare), which you would modify based on the specific situation that warranted the recall. Including model recall press releases in your recall plan will facilitate the rapid preparation of such press releases when needed.

14.5.3 Conduct an Effectiveness Check

The purpose of an effectiveness check is to verify that all consignees at the specified recall depth have received notification about the recall and have taken appropriate action. (See 21 CFR 7.42(b)(3).) See the Index of Generic Model Letter Exhibits, in the FDA Regulatory Procedures Manual available from our Web site entitled "Industry Guidance for Recalls: Information on Recalls of FDA Regulated Products" (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls), for model documents (i.e., an Effectiveness Check Letter (FDA, 2019e), an Effectiveness Check Response Format (FDA, 2019f), and an Effectiveness Check Questionnaire for Telephone or Personal Visits (FDA, 2019g)) that you can use to conduct an effectiveness check. We recommend that your recall plan include one or more of these model documents, which you would modify based on the specific situation that warranted the recall. Including such model documents in your recall plan will facilitate the rapid preparation of such documents when needed.

14.5.4 Decide What to Do with the Recalled Food

We recommend that your recall plan describe the options that you will consider to appropriately dispose of recalled food (e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food) and the factors that you will use to determine the appropriate disposition of recalled food.

14.6 Procedures in Which You Assign Responsibility to Perform Recall Actions

In the procedures in your recall plan, you must assign responsibility for taking the steps to notify the direct consignees, notify the public, conduct effectiveness checks, and appropriately dispose of recalled food. (See 21 CFR 117.139(b).) The goal of such procedures is to save time during a

recall and help you to clearly communicate responsibilities to applicable managers and staff so that they can act as soon as the decision to conduct a recall is made.

We recommend that the procedures in your recall plan:

- Identify members (and alternate members[2]) of a recall management team, headed by a recall coordinator. The members (and alternate members) assigned to the recall management team could include, as applicable to your facility, those with responsibilities for distribution, production and quality assurance, consumer affairs, accounting, legal counsel, public relations, technical, marketing, and regional sales managers and staffs as shown in Table 14-2 (New Zealand Ministry of Agriculture and Forestry, 2012).

- Provide the following information about each member (and alternate member) of your recall management team:

    - Name and job position/title;

    - Business phone number (including cell phone number when applicable) and email address;

    - After-hours phone number (e.g., home or cell phone number); and

    - Responsibilities; and

- Specify who is responsible for the decision to conduct a recall.

Table 14-2 Examples of Some Roles and Responsibilities for Members of a Recall Management Team*

Role	Responsibility
Recall coordinator	Coordinate and document all recall activities
Distribution	Stop distribution and arrange for return of recalled food; prepare inventory and distribution status of affected food
Production and quality assurance	Prepare batch identification; stop production of food if related to the problem; investigate the cause of the problem and check records to determine whether other product lots should also be recalled
Consumer affairs	Prepare response to consumers; answer consumer inquiries

[2] The alternate members would replace team members who are not available when the facility is considering or implementing a recall.

Role	Responsibility
Public relations	Handle press release; manage media contacts
Marketing	Notify sales managers and brokers; arrange for pick-up at retail levels
Regional sales manager	Help contact customers; assist in product pick-up as needed

*Adapted from Recall Guidance Material available from the New Zealand Ministry of Agriculture and Forestry (New Zealand Ministry of Agriculture and Forestry, 2012).

14.7 Procedures for Notifying FDA

14.7.1 Procedures for Notifying FDA About a Reportable Food

Section 417 of the FD&C Act (21 U.S.C. 350f) requires FDA to establish a Reportable Food Registry (RFR). A ''reportable food'' is an article of food (other than dietary supplements or infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals (Section 417(a)(2) of the FD&C Act). Under section 417(d)(1) of the FD&C Act, food firms that are ''responsible parties'' as defined in the statute are required to notify FDA electronically with certain information within 24 hours of determining that a food they manufactured, processed, packed, or held is a reportable food. We have issued guidance regarding the RFR (FDA, 2009 and FDA, 2010). That guidance includes examples of circumstances under which food might be reportable.

We recommend that your recall plan include any procedures you have to comply with the RFR, or a cross-reference to such procedures, so that the procedures will be readily available to your recall management team. Doing so may save time, which is critical during a recall.

14.7.2 Procedures for Notifying the Appropriate FDA Recall Coordinator

The industry recall guidance recommends that you notify the appropriate FDA Recall Coordinator as soon as a decision is made that a recall is appropriate and prior to the issuance of press or written notification to customers (FDA, 2014). The industry recall guidance also provides our recommendations for what to send to the appropriate FDA Recall Coordinator about your recall. In addition, the draft initiation of voluntary recalls guidance encourages firms to consult with FDA while its own investigation is ongoing if the firm has questions about its examination of a product problem (FDA, 2019a). See “ORA Recall Coordinators” for a current list of FDA Recall Coordinators (FDA, 2019b).

We recommend that your recall plan include the guidances and exhibits listed in section 14.4 so that they will be readily available to your recall management team.

14.8 References

FDA, 2009. "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry As Established by the Food and Drug Administration Amendments Act of 2007," (https://www.fda.gov/FoodGuidances)

FDA, 2010. "Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry As Established by the Food and Drug Administration Amendments Act of 2007 (Edition 2)," (https://www.fda.gov/FoodGuidances)

FDA, 2014. "Guidance for Industry: Product Recalls, Including Removals and Corrections," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2018a. Index of Model Press Releases," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2018b. “Public Availability of Lists of Retail Consignees to Effectuate Certain Human and Animal Food Recalls Guidance for Industry and FDA Staff. Draft Guidance,” (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2018c. “Questions and Answers Regarding Mandatory Food Recalls: Guidance for Industry and FDA Staff,” (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2019a. “Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff. Draft Guidance,” (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2019b. Office of Regulatory Affairs (ORA) Recall Coordinators, (https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators)

FDA, 2019c, "Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C. Guidance for Industry and FDA Staff," (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls)

FDA, 2019d, Regulatory Procedures Manual, Chapter 7, (https://www.fda.gov/media/71814/download)

FDA, 2019e, Regulatory Procedures Manual, Chapter 7, Exhibit 7-1, “Model Effectiveness Check Letter (Industry),” (https://www.fda.gov/media/71814/download)

FDA, 2019f, Regulatory Procedures Manual, Chapter 7, Exhibit 7-2, “Model Effectiveness Check Response Format (Industry),” (https://www.fda.gov/media/71814/download)

FDA, 2019g, Regulatory Procedures Manual, Chapter 7, Exhibit 7-3, “Model Effectiveness Check Questionnaire for Telephone or Personal Visits (Industry),” (https://www.fda.gov/media/71814/download)

FDA, 2019h, Regulatory Procedures Manual, Chapter 7, Exhibit 7-4, "Model Recall Letter (Generic, All Centers)," (https://www.fda.gov/media/71814/download)

FDA, 2019i Regulatory Procedures Manual, Chapter 7, Exhibit 7-5, "Model Recall Response Form," (https://www.fda.gov/media/71814/download)

Ministry of Agriculture and Forestry (New Zealand), 2012. Recall Guidance Material, (https://www.mpi.govt.nz/food-safety/food-recalls/developing-your-food-recall-plan/)

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry [1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 15: Supply-Chain Program for Human Food Products

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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15.1 Purpose of this Chapter

The purpose of this chapter is to help a receiving facility comply with the requirements of subpart G for establishing and implementing a supply-chain program for its suppliers. (See section 15.3.2 and the list of terms in section 15.5.1 for the definition of "receiving facility.") This chapter also is intended to help an entity other than the receiving facility conduct certain activities on behalf of a receiving facility, provided that the receiving facility complies with applicable requirements in subpart G to review and assess the entity's applicable documentation, and document that review and assessment.

15.2 Considerations to Keep in Mind if You Establish and Implement a Supply-Chain Program

If you are an importer, see section 15.6.2.1 for a discussion of how we have aligned the provisions for supplier verification in our regulation entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (21 CFR part 1, subpart L; the FSVP regulation) with the provisions for a supply-chain program in subpart G such that importers and receiving facilities do not have to duplicate verification activities. Importantly, this chapter of this guidance does not address the responsibilities of receiving facilities that import raw materials or other ingredients to comply with applicable requirements of the FSVP regulation. If you are a receiving facility that is also a food importer, and you choose to comply with the FSVP regulation rather than conduct supplier verification activities in accordance with subpart G (see 21 CFR 117.405(a)(2)), you should refer to our guidance on the FSVP regulation.

15.3 Overview of the Requirements for a Supply-Chain Program

15.3.1 Applicable Requirements of Part 117

Subpart C requires a facility to conduct a hazard analysis to determine whether there are any hazards that require a preventive control (21 CFR 117.130) and identifies several types of possible preventive controls, including process controls (21 CFR 117.135(c)(1)), food allergen controls (21 CFR 117.135(c)(2)), sanitation controls (21 CFR 117.135(c)(3)), and supply-chain controls (21 CFR 117.135(c)(4)). The requirements for supply-chain controls are established in subpart G (Supply-Chain Program). We list the requirements of subpart G in Table 15-1. In the

remainder of this chapter, we provide recommendations for how you can comply with each of these requirements.

Table 15-1 Requirements for a Supply-Chain Program in Subpart G

Section	Description
117.405	Requirement to establish and implement a supply-chain program
117.410	General requirements applicable to a supply-chain program
117.415	Responsibilities of the receiving facility
117.420	Using approved suppliers
117.425	Determining appropriate supplier verification activities (including determining the frequency of conducting the activity)
117.430	Conducting supplier verification activities for raw materials and other ingredients
117.435	Onsite audit
117.475	Records documenting the supply-chain program

15.3.2 "Receiving Facilities" and "Suppliers"

Subpart G applies to a "receiving facility." Part 117 defines a "receiving facility" as a facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier. (See 21 CFR 117.3.) Part 117 defines a "supplier" as 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. (See 21 CFR 117.3.)

Under subpart G, entities such as brokers, produce aggregators, food distributors, and cold storage facilities are neither receiving facilities that are required to establish a supply-chain program nor suppliers, because such entities are not manufacturers/processors. However, part 117 provides that such entities can conduct certain activities specified in subpart G on behalf of a receiving facility. (See 21 CFR 117.415.)

Examples of receiving facilities are:

- A facility that manufactures/processes produce raw agricultural commodities (RACs) into bagged salads;
- A facility that mills grains such as wheat to make flour; and
- A facility that manufactures cookies using flour, sugar and other ingredients.

Examples of suppliers are:

- A farm that grows RACs such as lettuce that are supplied to a bagged salad manufacturer;
- A farm that grows wheat that is supplied to a miller; and
- A facility that mills grains and manufactures flour that is supplied to a cookie manufacturer.

See also section 15.6.4 for a discussion of the special circumstance of when a preventive control is applied by an entity other than the receiving facility's supplier (e.g., when a harvesting or packing operation applies controls to certain produce (i.e., produce covered by part 112), because growing, harvesting, and packing activities are under different management).

15.3.3 Produce Safety Regulation

In part 112 (21 CFR part 112), we have established our regulation entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the produce safety regulation; 80 FR 74354, November 27, 2015). The produce safety regulation sets forth in a new part 112 procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The produce safety regulation applies to certain produce farms, and does not apply to activities of facilities that are subject to part 117.

Some provisions of subpart G (i.e., 21 CFR 117.405(c), 117.410(d)(2)(ii), 117.430(d), and 117.475(c)(13)) refer to the provisions of the produce safety regulation.

15.3.4 Foreign Supplier Verification Program Regulation

In part 1, subpart L (21 CFR part 1, subpart L), we have established our regulation entitled "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (the FSVP regulation; 80 FR 74226, November 27, 2015). The FSVP regulation requires importers to establish foreign supplier verification programs to verify that their foreign suppliers are using processes and procedures that provide the same level of public health protection as those required under the provisions on hazard analysis and risk-based preventive controls and standards for produce safety in the FD&C Act, that the imported food is not adulterated, and that food is not misbranded with respect to food allergen labeling.

Some provisions of subpart G (i.e., 21 CFR 117.405(a)(2) and 117.475(c)(2)) refer to the provisions of the FSVP regulation.

15.3.5 Accredited Third-Party Certification Regulation

In part 1, subpart M (21 CFR part 1, subpart M), we have established our regulation entitled "Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" (the accredited third-party certification regulation; 80 FR 74570, November 27, 2015). The accredited third-party certification regulation provides for accreditation of third-party certification bodies to conduct food safety audits and to certify that eligible foreign entities (including registered foreign food facilities) and food produced by such entities meet applicable FDA requirements for purposes of sections 801(q)[2] and 806[3] of the FD&C Act.

[2] Section 801(q) of the FD&C Act gives FDA the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act.

[3] Section 302 of FSMA (Voluntary qualified importer program) amended the FD&C Act to create a new section 806 with the same name. Section 806 of the FD&C Act describes a voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of

Some provisions of part 117 (i.e., the definition of "qualified auditor" in 21 CFR 117.3 and the requirements for onsite audits in 21 CFR 117.435(d)) refer to the provisions of the accredited third-party certification regulation.

15.3.6 How We Use the Term "You" in This Chapter

In this guidance, we use the term "you" to refer to a "receiving facility," rather than to all facilities subject to the PCHF requirements, because the requirements of subpart G apply only to receiving facilities.

15.4 Understand the Potential Hazard

Part 117 defines "supply-chain-applied control" as 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. (See 21 CFR 117.3 and the list of terms in section 15.5.1.) For background and details about hazards, including hazards that could require a supply-chain-applied control, see Chapter 3 – Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food.

15.5 Terms Used in This Chapter

15.5.1 Definitions Established in 21 CFR 117.3

Section III.A in the Introduction of this guidance includes a glossary of terms that are used in this guidance and that are defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 15-2 for additional terms that are defined in 21 CFR 117.3. We intend to include these terms in the glossary in section III.A in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 15-2 from this chapter, because it would be duplicative.

Table 15-2 Applicable Terms Defined in Part 117 (See 21 CFR 117.3.)

Term	What the Term Means
Audit	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.
Manufacturing/ processing	Making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified under FDA's third-party certification rule.

Term	What the Term Means
Qualified auditor	A person who is a qualified individual as defined in this part and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by § 117.180(c)(2). Examples of potential qualified auditors include: (1) A government employee, including a foreign government employee; and (2) An audit agent of a certification body that is accredited in accordance with regulations in 21 CFR part 1, subpart M (Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications).
Qualified facility	A facility (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) that is a very small business, or a facility to which both of the following apply: (1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and (2) The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.
Raw agricultural commodity (RAC)	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.
Receiving facility	A facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier.
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.
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).
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).

15.5.2 Other Terms That FDA Uses in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 15-3 for additional terms that we use in this chapter. We intend to include these terms in the glossary in section III.B in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 15-3 from this chapter, because it would be duplicative.

Table 15-3 Terms Used in this Chapter

Term	What the Term Means

Term	What the Term Means
Approved supplier	A supplier that has met the criteria of the receiving facility's supply chain program, is controlling the identified hazard, and has been approved by the receiving facility.
Certificate of analysis (CoA)	A document, provided by the supplier of a food prior to or upon receipt of the food, that documents certain characteristics and attributes of the food.
Customer	An entity that receives a product, raw material, or ingredient from a receiving facility.
Identified hazard	A hazard identified by the receiving facility as requiring a supply-chain-applied control.
Second-party audit	An audit conducted by an employee of a receiving facility.
SAHCODH hazard	A hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.
Third-party audit	An audit conducted by a qualified auditor that is not an employee of either the receiving facility or the supplier.

15.6 Requirement to Establish and Implement a Supply-Chain Program (21 CFR 117.405)

15.6.1 Requirement to Establish and Implement a Supply-chain Program

With some exceptions (see 21 CFR 117.405(a)(2) and (a)(3)), subpart G requires a receiving facility to establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. (See 21 CFR 117.405(a)(1).)

The supply-chain program must be written. (See 21 CFR 117.405(b).) There is no standardized or required format for the written supply-chain program or its records. You can use whatever format works best for your facility, provided that the records include all the required information.

You are not required to establish and implement a supply-chain program for a particular raw material or other ingredient if you will control the hazard at your own facility, regardless of whether your supplier has also applied one or more preventive controls for that hazard to raw materials and other ingredients that your supplier provides to you. (See 21 CFR 117.405(a)(1).) In addition, you are not required to implement a preventive control if you comply with certain requirements for ensuring a hazard will be controlled by your customer or subsequent entity in the distribution chain. (See 21 CFR 117.136.)

Subpart G does not require you to establish and implement a supply-chain program to control potential hazards associated with food contact substances. A long-standing CGMP provision requires that appropriate quality control operations be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. (See 21 CFR 117.80(a)(2).) Similar provisions address other circumstances where food contact substances may migrate to the raw materials and other ingredients obtained by a receiving facility from suppliers (e.g., 21 CFR 117.40 regarding food-contact surfaces). FDA has extensive premarket review processes for food contact substances under the food contact notification process (21 CFR part 170, subpart D) and the food additive petition process (21 CFR part 171). In light of FDA's premarket oversight of food contact substances and our experience with regulatory

oversight of food-packaging material as a matter of CGMP, we consider following CGMPs by a receiving facility to be sufficient to address the safety of food contact substances in raw materials and other ingredients it obtains. Therefore, there are no hazards associated with food contact substances that are hazards requiring a supply-chain applied control under 21 CFR 117.405(a)(1).

15.6.2 How Your Corporate Parent Can Participate in Establishing and Implementing Your Supply-chain Program

As discussed in the final rule establishing part 117, your corporate parent (as the owner, operator, or agent in charge) can be active in developing and implementing your food safety plan (see Response 371, Response 668, and Response 690 at 80 FR 56022, 56100, and 56111, respectively). For example, an individual at the corporate level may be the preventive controls qualified individual (PCQI). Further, the responsibilities of the receiving facility (such as approving suppliers) could be handled at the corporate level. For example, your corporate parent could have a team that establishes written procedures for supplier approval, determines supplier verification activities, conducts supplier verification activities, and maintains required documentation. In addition, your corporate parent could establish and implement a supply-chain program that takes into consideration its knowledge of the food safety programs in place at all of the facilities under its ownership. See also the example in section 15.11.2.2 in which a facility that is part of a larger corporation determines an alternative to an onsite audit when the supplier is a subsidiary of the same corporation. The records documenting the supply-chain program are subject to the requirements, in subpart F, applying to records that must be established and maintained. Under 21 CFR 117.315, offsite storage of records (such as storage at the place of business of your corporate parent of records documenting the supply-chain program) is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. If your corporate parent establishes and maintains the records for the supply-chain program electronically and you can access applicable records maintained at the corporate level electronically, we consider the records to be onsite.

15.6.3 Exceptions to the Requirement to Establish and Implement a Supply-chain Program

Subpart G provides for two exceptions to the requirement to establish and implement a supply-chain program.

15.6.3.1 Exception for importers

We have aligned the provisions for supplier verification in the FSVP regulation with the provisions for a supply-chain program in part 117. A receiving facility that is an importer, is in compliance with the FSVP regulation, and has documentation of verification activities conducted under 21 CFR 1.506(e) (which provides assurance that the hazards to be controlled before importation for the raw material or other ingredient have been significantly minimized or prevented) need not conduct supplier verification activities for that raw material or other ingredient. (See 21 CFR 117.405(a)(2).) We are providing separate guidance to help importers

who are subject to the FSVP regulation to comply with the requirements of the FSVP regulation.[4]

15.6.3.2 Exception for food supplied for research or evaluation use

The requirements for a supply-chain program do not apply to food that is supplied for research or evaluation use, provided that such food:

- Is not intended for retail sale and is not sold or distributed to the public (21 CFR 117.405(a)(3)(i));
- Is labeled with the statement "Food for research or evaluation use" (21 CFR 117.405(a)(3)(ii));
- Is supplied in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of (21 CFR 117.405(a)(3)(iii)); and
- Is accompanied with documents, in accordance with the practice of the trade, stating that the food will be used for research or evaluation purposes and cannot be sold or distributed to the public (21 CFR 117.405(a)(3)(iv)).

You should take steps to ensure that the label statement "Food for research or evaluation use" remains securely attached to the food until the food is used for research or evaluation.

The quantity of the food should be limited to the amount anticipated to be needed to perform the research, analysis, or quality assurance procedures, and any unused portion should be properly disposed of. The amount of food used in research or for evaluation can vary based on the type of food, the nature of the research or evaluation, and other factors such as the number of repetitions required for the research or evaluation process. For example, 10 pounds of a food could be a small quantity consistent with the amount needed to perform a laboratory analysis for pesticides, and 50 pounds of the food could be a small quantity consistent with the amount needed for a mycotoxin analysis. On the other hand, only a few ounces of a color additive might be needed for research.

The exemption for food for research or evaluation does not apply to food for consumption at trade shows, because such food would be "distributed to the public" (i.e., attendees of the trade show). (See 21 CFR 117.405(a)(3)(i).) This is the case regardless of whether it is a "Research and Development" (R&D) facility that directly provides the food for consumption to a trade show, or it is the R&D facility's customer that provides the food for consumption to a trade show. However, the exemption for research or evaluation would apply to food used in a defined study, conducted during a trade show, of a food involving a discrete set of test subjects who have agreed to participate in the study, because it does not appear that such food would be sold or distributed to the general public. When the exemption does not apply, you must comply with the requirements of subpart G when your supplier applies a supply-chain-applied control even if you consider yourself an "R&D facility."

[4] Even if you implement a supply-chain program in accordance with subpart G for a raw material or other ingredient you import, you will need to ensure that you are identified as the FSVP importer of the raw material or other ingredient in accordance with 21 CFR 1.509.

15.6.4 Requirement When a Supply-Chain-Applied Control Is Applied by an Entity Other than the Receiving Facility's Supplier

When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when such an entity applies controls to certain produce (i.e., produce covered by part 112)), because growing, harvesting, and packing activities are under different management), the receiving facility must: (1) Verify the supply-chain-applied control; or (2) obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment. (See 21 CFR 117.405(c).)

The most likely circumstance where this requirement applies is included as an example in the requirement – i.e., when the supplier is a farm and growing, harvesting, and packing activities are under different management. The definition of supplier specifies that the supplier is the establishment that grows the food. However, harvesting and packing operations that are conducted by a business entity separate from the grower do not fall within the definition of "supplier," even though harvesting and packing operations include some supply-chain-applied controls, such as maintaining wash water temperature adequate to minimize infiltration of microorganisms and establishing and following water-change schedules for recirculated water. A receiving facility has an obligation to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by the facility will not be adulterated under section 402 of the FD&C Act (21 U.S.C. 342) or misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)). That obligation includes responsibilities for raw materials and other ingredients when a supply-chain-applied control is applied by an entity (such as a harvesting or packing operation) other than the receiving facility's supplier (the grower).

We do not expect the receiving facility to follow all of the requirements of subpart G applicable to "suppliers" when verifying control by another entity in the supply chain (e.g., a harvesting or packing operation). Instead, we expect the receiving facility will take steps such as a review of that entity's applicable food safety records. For example, if a receiving facility receives produce from a supply chain that includes a separate grower, harvester, and packer, the grower is the supplier and the requirements of subpart G applicable to "suppliers" apply to the grower. To verify controls applied by the harvester, the receiving facility could review the harvester's records, such as records of training for workers who hand harvest RTE produce. To verify controls applied by the packer, the receiving facility could review the packer's records, such as water-change schedules for recirculated water used in packing operations.

See also the discussion in sections 15.8.1 and 15.8.2 of provisions of part 117 that allow entities such as distributors, brokers, and aggregators to determine, conduct, and document verification activities that apply to suppliers as a service to you, provided that you review and assess applicable documentation provided by the other entity and document your review and assessment. (See 21 CFR 117.415(a)(3).) If a harvester determines, conducts, and documents verification activities that apply to the grower (your supplier), you could review and assess the harvester's documentation. Likewise, you could obtain documentation of review of applicable records maintained by the harvester or packer from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

15.6.5 Role of the Preventive Controls Qualified Individual in the Supply-Chain Program

The preventive controls are part of your food safety plan, and your food safety plan must be prepared, or its preparation overseen by, your PCQI. (See 21 CFR 117.126(a)(2), 21 CFR 117.126(b)(2), and 117.180(a)(1).) (See 21 CFR 117.3 and the Glossary in section III of the Introduction of this guidance for the definition of "PCQI.")

15.7 General Requirements Applicable to a Supply-Chain Program (21 CFR 117.410)

15.7.1 What the Supply-Chain Program Must Include

Subpart G includes a list of the general requirements for what the supply-chain program must include, and provides a cross-reference to where you can find the specific requirements. As specified in 21 CFR 117.410(a), the general requirements are:

- Using approved suppliers as required by § 117.420 (21 CFR 117.410(a)(1));
- Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425 (21 CFR 117.410(a)(2));
- Conducting supplier verification activities as required by §§ 117.430 and 117.435 (21 CFR 117.410(a)(3));
- Documenting supplier verification activities as required by § 117.475 (21 CFR 117.410(a)(4)); and
- When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by § 117.475, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by § 117.475 (21 CFR 117.410(a)(5)).

See the discussion of the specific requirements of 21 CFR 117.405(c), 117.420, 117.425, 117.430, 117.435, and 117.475 in sections 15.6.4, 15.9, 15.10, 15.11, 15.12, and 15.13, respectively.

15.7.2 Appropriate Supplier Verification Activities

Section 21 CFR 117.410(b) of subpart G specifies four appropriate supplier verification activities for raw materials and other ingredients. We discuss these in sections 15.7.2.1 through 15.7.2.4.

15.7.2.1 Onsite audits (21 CFR 117.410(b)(1))

See 21 CFR 117.430(b), 21 CFR 117.435, 21 CFR 117.475(c)(7), and sections 15.11.2, 15.12, and 15.13 for details about the requirements for onsite audits and our recommendations for how to comply with those requirements.

15.7.2.2 Sampling and testing of the raw material or other ingredient (21 CFR 117.410(b)(2))

Subpart G provides that sampling and testing of a raw material or other ingredient is an appropriate supplier verification activity. (See 21 CFR 117.410(b)(2).) Such sampling and testing can be on a periodic basis or on a lot-by-lot basis. We recommend that you establish the frequency of such testing by first conducting the sampling and testing on a relatively frequent basis (e.g., monthly) until the supplier establishes a good history of supplying an acceptable raw material or other ingredient, after which time you could sample and test less frequently, such as quarterly.

If you choose to use sampling and testing as a supplier verification activity, you should use scientifically-based sampling plans that provide reasonable assurance that the hazard has been significantly minimized or prevented and that address known limitations of sampling and testing foods as a verification activity. For example, your sampling plan should take into consideration whether a hazard is homogeneously distributed throughout the lot, and your selection of an analytical method should consider whether food components could interfere with the method of analysis, as well as whether the method is sensitive enough to detect a hazard that is present at low concentrations. To address such limitations, we recommend that you obtain samples that are representative of the lot, use a testing method that has been shown to provide reliable results when the analyte of interest is within the food matrix you will be testing, and use a method that has a sensitivity appropriate to detect that hazard.

See 21 CFR 117.475(c)(8) and section 15.13 for a list of required documentation when you conduct sampling and testing as a supplier verification activity. See section 15.8.2.2 for a discussion of the flexibility the rule provides for your supplier to conduct and document sampling and testing of raw materials and other ingredients, for the hazard it controls, and provide such documentation (such as in a Certificate of Analysis (COA)) to you in lieu of you conducting such sampling and testing yourself.

15.7.2.3 Review of the supplier's relevant food safety records (21 CFR 117.410(b)(3))

In general, by "relevant food safety records" we mean any records that will provide sufficient documentation that your supplier is following the procedures your supplier established to control a hazard and that the hazard has been controlled. Many such records relate to a particular lot of a raw material or other ingredient provided to you, such as the record created when a preventive control measure was applied. For example, if you produce frozen mixed vegetables and rely on your supplier (the farm that grows the vegetables) to control pesticide residues in the raw vegetables that you will use to produce the frozen mixed vegetables, and you determine through supplier verification activities (e.g., periodic testing for pesticides) that your supplier provided a vegetable with a pesticide level in excess of the approved tolerance for that pesticide, you could obtain a copy of the pesticide application records from the farm that grows the vegetables for a period of time adequate to demonstrate that problems that could lead to excess pesticide levels have been resolved.

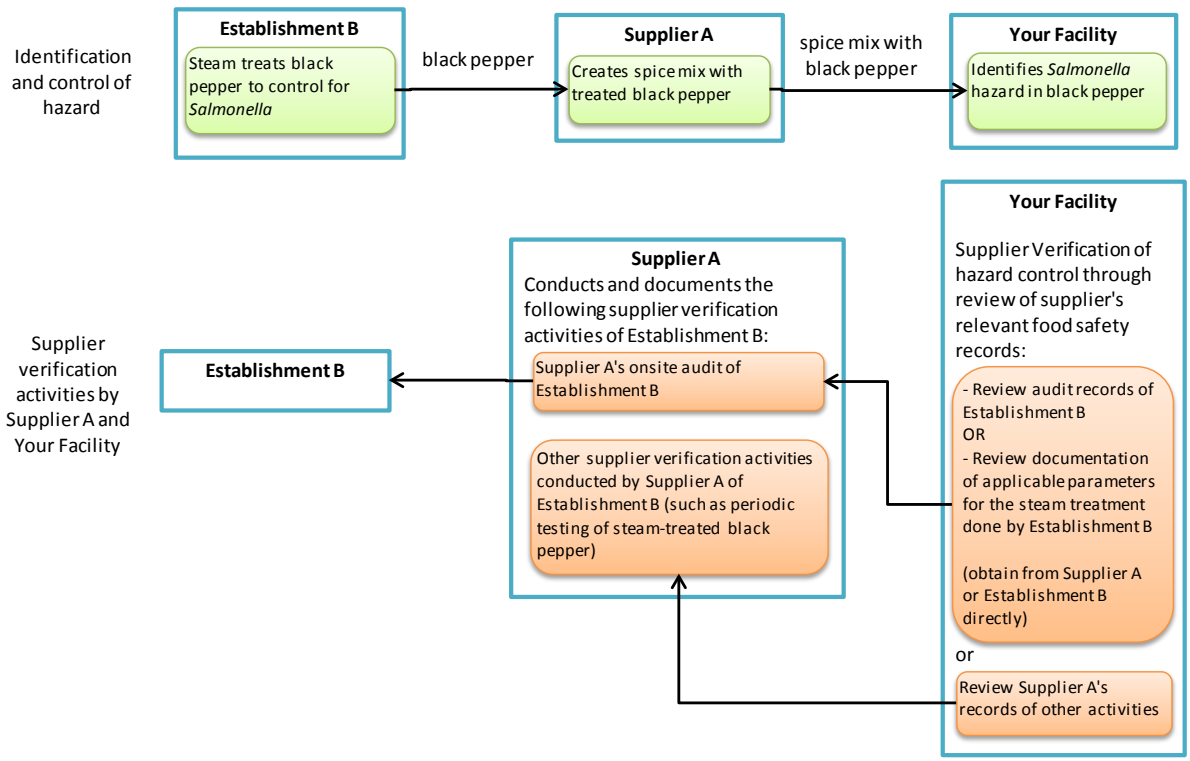
Relevant food safety records also include, when applicable, records demonstrating that your supplier has verified control of a hazard by its own supplier. Such records could relate more broadly to a supplier's food safety procedures, such as records of your supplier's audit of its supplier's food safety activities. For example, if you produce deli salads and obtain chopped

fresh vegetables from your supplier, you could obtain a copy of your supplier's records documenting his audits of the farms growing the vegetables.

Figure 1 shows an example of using relevant food safety records when the hazard requiring a supply-chain-applied control is *Salmonella* that could contaminate black pepper and your supplier (Supplier A) provides you with a spice mix containing black pepper that has been steam-treated by Establishment B (earlier in the supply chain) to control *Salmonella*. One relevant food safety record could be the applicable audit records resulting from an onsite audit of Establishment B, which you could obtain from Supplier A.[5] The applicable audit records could include copies of audit procedures, dates, conclusions of the audits, and any corrective actions taken in response to significant deficiencies identified during the audit of Establishment B. If Supplier A conducts additional verification activities such as periodic testing of the steam-treated black pepper, you could also ask Supplier A to provide records of those activities to you for your review. If you want to see documentation of the applicable parameters for the steam treatment that Establishment B delivered to a lot of black pepper, you could obtain these records either directly from Establishment B or from Supplier A.

[5] Alternatively, Supplier A may request that Establishment B obtain a third-party audit. Thus, Establishment B may also be able to provide applicable audit records for you to review.

Figure 1. Applicable Records When Supplier A Provides You With a Spice Mix Containing Black Pepper That Has Been Steam-treated by Establishment B



See 21 CFR 117.475(c)(9) and section 15.13 for a list of required documentation when you conduct a review of the supplier's relevant food safety records as a supplier verification activity.

15.7.2.4 Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient (21 CFR 117.410(b)(4))

Subpart G provides that you could conduct (and document) or obtain documentation of other supplier verification activities that are appropriate based on your supplier's performance and the risk posed by the raw material or other ingredient. This means that you could specify and design risk-based activities (other than an onsite audit, sampling and testing, and review of relevant food safety records) that can provide effective supplier verification.

As one example, you could develop and use a fact-specific questionnaire or consider information applicable to a supplier's certification to a specific audit scheme, and you could use such activities alone or in combination with other supplier verification activities. As another example, if you determine and document that you would audit a supplier on a biennial rather

than annual basis as provided by 21 CFR 117.430(b)(2), you could review the records demonstrating the results of the supplier's environmental monitoring program during the year that you do not conduct an audit.

See 21 CFR 117.475(c)(10) and section 15.13 for recommended documentation when you conduct a supplier verification activity other than an onsite audit, sampling and testing, or review of the supplier's relevant food safety records.

15.7.3 Assurance that a Hazard Has Been Significantly Minimized or Prevented

The supply-chain program in subpart G is a type of preventive control and, thus, must comply with the requirements applicable to preventive controls in 21 CFR 117.135. Under 21 CFR 117.135(a), a preventive control provides assurance that any hazards requiring a preventive control will be significantly minimized or prevented. To make this clear, 21 CFR 117.410(c) specifies that the supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. Suppliers that are subject to the PCHF requirements in part 117 are required to develop and implement a food safety plan that will significantly minimize or prevent hazards associated with the food manufactured, processed, packed or held by the facility (21 CFR 117.126) and to document they are following their plan (21 CFR 117.190). Suppliers subject to the produce safety requirements in part 112 must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act on account of such hazards. (See 21 CFR 112.11.)

15.7.4 Considerations in Approving Suppliers and Determining the Appropriate Supplier Verification Activities and the Frequency with Which They Are Conducted

As noted in section 15.7.1, subpart G specifies that you must approve suppliers and determine appropriate supplier verification activities (including determining the frequency of conducting the activity). (See 21 CFR 117.410(a)(1) and (a)(2).) Section 21 CFR 117.410(d)(1) specifies factors that you must consider in approving suppliers and determining appropriate supplier verification activities (including determining the frequency of conducting the activity). We discuss these factors in sections 15.7.4.1 through 15.7.4.4. With one exception, the requirement to consider each of these factors applies every time you approve a supplier for a raw material or other ingredient, and every time that you determine the appropriate supplier verification activity for a food received from that supplier. See a discussion of the exception, in 21 CFR 117.410(d)(2), in section 15.7.4.5.

As noted in sections 15.8.1 and 15.8.2, only you can approve suppliers, but subpart G provides some flexibility for another entity in the distribution chain to conduct certain other activities related to supplier verification, and to provide you with applicable documentation of those activities, to help you do so.

15.7.4.1 Hazard analysis

The first factor that you must consider in (1) approving suppliers, (2) determining appropriate supplier verification activities, and (3) determining the frequency of conducting those activities is the hazard analysis of the food, conducted in accordance with 21 CFR 117.130. (See 21 CFR 117.410(d)(1)(i).) To do so, you must consider the nature of the hazard controlled before receipt of the raw material or other ingredient. (See 21 CFR 117.410(d)(1)(i).) Immediately below, we explain the requirements of part 117 for a hazard analysis and provide recommendations for how to consider the hazard analysis in approving suppliers, determining appropriate supplier verification activities, and determining the frequency of those activities.

Part 117 requires that you conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control. (See 21 CFR 117.130(a).) If you determine that there are any hazards that require a preventive control, with few exceptions Part 117 further requires that you must identify and implement a preventive control. (See 21 CFR 117.135(a).) When the preventive control will be applied to a raw material or other ingredient before receipt, part 117 requires that you establish and implement a risk-based supply-chain program for that raw material or other ingredient. (See 21 CFR 117.405.)

As part of your hazard analysis, you would evaluate the hazard to assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls. (See 21 CFR 117.130(c)(1)(i).) The outcome of this aspect of the hazard evaluation impacts the type of verification activity you use (as well as the frequency of conducting the activity). For example, when the hazard is one for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death, in general you must conduct an annual onsite audit before using the raw material or other ingredient from the supplier and at least annually thereafter. (See 21 CFR 117.430(b) and the discussion in section 15.11.2.) For other hazards, the determination of supplier verification activities, and the frequency of conducting those activities, also should be risk-based – i.e., the greater the risk presented by the hazard, the more robust the verification activity, and the greater the frequency of the verification.

As part of your hazard analysis, you also would evaluate environmental pathogens whenever a ready-to-eat food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen. (See 21 CFR 117.130(c)(1)(ii).) If, for example, you are purchasing a cheese to be used in an RTE product you make, and you expect that a sanitation control will be applied to address the environmental pathogen *Listeria monocytogenes*, you could ask to review the cheese producer's written procedures for the environmental monitoring it does to verify the sanitation controls. (See 21 CFR 117.165(b)(3).) You also could periodically verify your supplier's controls by sampling and testing the cheese for *L. monocytogenes*. Because *L. monocytogenes* is a hazard for which there is a reasonable probability that exposure to the hazard will cause serious adverse health consequences or death, you also would conduct an annual onsite audit to verify that your supplier controls *L. monocytogenes* when it manufactures the cheese by using a "kill step" such as pasteurization of the milk used to make the cheese and sanitation controls to significantly minimize contamination from *L. monocytogenes* in the environment, with environmental monitoring to verify controls for *L. monocytogenes*.

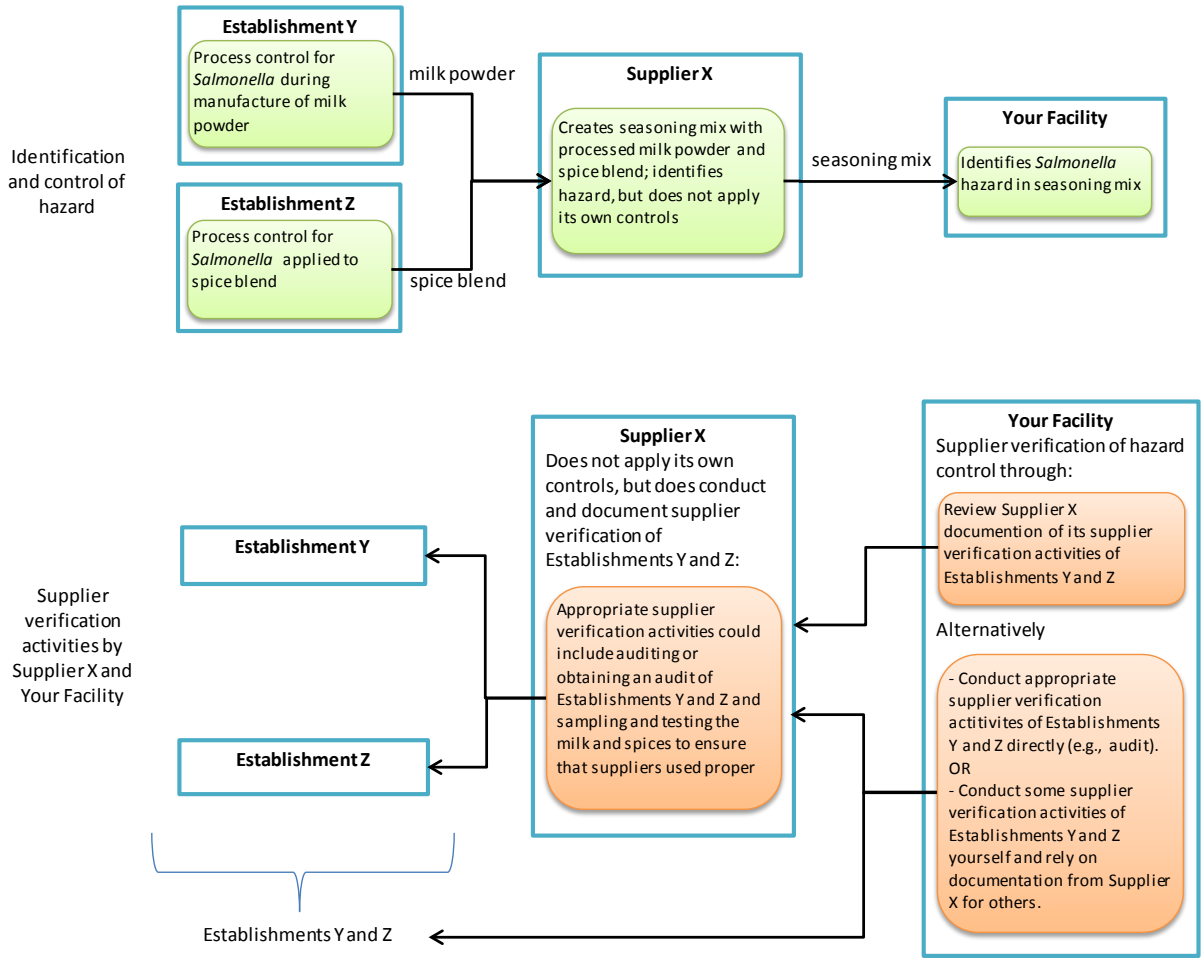
For all hazards that require a supply-chain-applied control, we recommend that you use the outcome of your hazard analysis to help you determine the extent of what you do to consider supplier performance as required by 21 CFR 117.117.410(d)(1)(iii) (see the discussion in section 15.7.4.3). The greater the risk presented by the hazard, the more stringently you should assess supplier performance as a mechanism to reduce the risk presented by the hazard.

15.7.4.2 Entity controlling the hazard

The second factor that you must consider in (1) approving suppliers, (2) determining appropriate supplier verification activities, and (3) determining the frequency of conducting those activities is the entity or entities that will be applying controls for the hazards requiring a supply-chain-applied control. (See 21 CFR 117.410(d)(1)(ii).) For example, the entity that applies the appropriate preventive control could be your direct supplier or your supplier's supplier. If the control is not applied by your direct supplier, you would direct your supplier verification activities to your supplier's supplier, but there is some flexibility in how you could do this.

Figure 2 shows an example in which you obtain a seasoning mix from Supplier X. Supplier X made the seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z). You identify *Salmonella* as a hazard in the seasoning mix, and you learn from Supplier X (your direct supplier) that it does not apply a control for *Salmonella* in its blending operation. Instead, Establishment Y applies a process control for *Salmonella* in the milk powder and Establishment Z applies a process control for *Salmonella* in the spice blend. Although Supplier X is your "supplier," Supplier X also is a receiving facility (because Supplier X is a manufacturer) and, thus, would have conducted appropriate supplier verification activities, such as auditing its suppliers (or obtaining audits) and sampling and testing the milk and the spices, to ensure that they have used proper controls. (See section 15.11.1 for a discussion of when an audit is required for certain hazards and the exception to that requirement.) With respect to supplier verification activities for Establishments Y and Z, Subpart G provides that you could rely on documentation provided by Supplier X to you regarding Supplier X's supplier verification activities. (See 21 CFR 117.415(a)(3).) Alternatively, you could conduct the appropriate supplier verification activities with respect to Establishments Y and Z yourself, or you could rely on documentation from Supplier X for some supplier verification activities with respect to Establishments Y and Z and conduct other supplier verification activities with respect to Establishments Y and Z yourself. You also would determine an appropriate supplier verification activity and associated frequency for Supplier X.

Figure 2. Supplier X makes a seasoning mix by blending milk powder (produced by Establishment Y) and a spice blend (produced by Establishment Z)



In determining whether to approve a supplier that relies on its own supplier to control the hazard requiring a supply-chain-applied control, we recommend you consider the robustness of the entity's supplier approval process and supplier verification activities.

15.7.4.3 Supplier performance

The third factor that you must consider in approving suppliers, determining appropriate supplier verification activities, and determining the frequency of conducting those activities is supplier performance. (See 21 CFR 117.410(d)(1)(iii).) Considering supplier performance includes:

- The supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients (21 CFR 117.410(d)(1)(iii)(A));
- Applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including an FDA warning letter or import alert relating to the safety of food and other FDA compliance actions related to food safety (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially

recognized as comparable or has determined to be equivalent to that of the United States, and information relevant to the supplier's compliance with those laws and regulations) (21 CFR 117.410(d)(1)(iii)(B)); and

- The supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier, including available information about results from testing raw materials or other ingredients for hazards, audit results relating to the safety of the food, and responsiveness of the supplier in correcting problems (21 CFR 117.410(d)(1)(iii)(C)).

As noted in section 15.7.4.1 regarding your hazard analysis as the first factor to consider, the greater the risk presented by the hazard, the more stringently you should assess supplier performance as a mechanism to reduce the risk presented by the hazard.

15.7.4.3.1 Supplier's procedures, processes, and practices

Understanding the supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients can help you understand the supplier's strengths and weaknesses. Mechanisms to do so include:

- Conducting a supplier "pre-assessment" questionnaire or survey to gather information about the supplier's operation, covering topics such as product information (e.g., regulatory compliance information and allergen information) and the supplier's food safety programs (e.g., a Hazard Analysis and Critical Control Point (HACCP) program, a sanitation control program, and an allergen control program);
- Asking the supplier to provide documents such as a food safety plan or HACCP plan (if applicable) and third-party food safety and good manufacturing practice audit results;
- Conducting a pre-approval site visit to assess programs and process capabilities; and
- Using a system with defined metrics to evaluate supplier performance, including compliance to specifications, third-party audit scores, number of recalls, mock recall performance, material rejections/complaints, and issue response time (e.g., the supplier's timeframe for resolving a food safety issue).

15.7.4.3.2 Applicable food safety regulations

You should determine what FDA food safety regulations a potential supplier is subject to, such as the CGMP and PCHF requirements (21 CFR part 117), the produce safety regulation (21 CFR part 112), the requirements applicable to low-acid canned foods (21 CFR parts 108 and 113), the requirements applicable to acidified foods (21 CFR parts 108 and 114), or other relevant food safety provisions. In evaluating the supplier's compliance with the relevant regulations, you should consider whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety (e.g., mandatory recall). See our Web site "Supplier Evaluation Resources" (FDA, 2016d) for resources that are available to help you evaluate the supplier's compliance with relevant FDA regulations.

Having an understanding of applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations can help you determine whether the supplier has a demonstrable history of supplying acceptable products and meeting all industry and regulatory requirements. Mechanisms to do so include:

- Asking the supplier to provide documentation of any recent regulatory inspections on file;

- Searching our online databases for warning letters, import alerts, import refusals, recalls, and inspections. All of these databases are available to the public from our Web site "Supplier Evaluation Resources" (FDA, 2016d).
- Searching for actions that we publicize, such as food outbreak investigations and suspension of a facility's registration. We generally make these available from the homepage for our human food program at http://www.fda.gov/Food/default.htm.

You should use this information to inform your decisions about whether you will approve a supplier, the type of verification activity you would use if you do approve the supplier, and the frequency of conducting the verification activity. Being subject to an FDA enforcement action such as a warning letter or an import alert should not necessarily disqualify a supplier. However, you should consider carefully the actions a supplier has taken as a result of regulatory compliance issues along with how it impacts your approval of that supplier and your verification activities.

Part 117 includes several provisions that reflect that some suppliers operate in a foreign country. (See, e.g., the definition of "qualified auditor in 21 CFR 117.3 and the provisions of 21 CFR 117.405(a)(2), 117.430(c), 117.435(c)(1)(ii), 117.435(c)(2), and 117.475(c)(15).) When the supplier is in a foreign country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, you may consider relevant laws and regulations of that country, and information relevant to the supplier's compliance with those laws and regulations. (See 21 CFR 117.410(d)(1)(iii)(B).) Thus, having an understanding of applicable laws and regulations in a foreign country can help you consider supplier performance when FDA has officially recognized that country's food safety system as comparable or determined it is equivalent to that of the United States. For example, just as you could ask a domestic supplier to provide documentation of any recent regulatory inspections on file, you could ask a foreign supplier that is in a foreign country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States to provide documentation of an inspection conducted by the applicable food safety authority. As of the date of this guidance, FDA has a Food Safety Systems Recognition Arrangement with Australia (FDA, 2017), Canada (FDA, 2016b), and New Zealand (FDA, 2015a). To determine whether we have a Food Safety Systems Recognition Arrangement or other cooperative arrangement with a foreign country, you can search the "Cooperative Arrangements" Web page (FDA, 2016a) of our "International Arrangements" Web page (FDA, 2015b) of our internet site directed to International Programs (FDA, 2016c).

15.7.4.3.3 Supplier's food safety history

Before you became subject to the requirements of subpart G, you could already have established a relationship with your suppliers and have information related to audits or have the results of sampling and testing that provide a history of how the supplier has met your specifications. If so, you already could be aware of past problems with raw materials or other ingredients provided by the supplier, and the steps the supplier took to address such problems. You may consider such prior relationships as part of your consideration of the supplier's food safety history. Likewise, as time goes on and you conduct appropriate supplier verification activities to comply with the requirements of subpart G, you would consider this same type of information for suppliers that you approve in compliance with subpart G.

You should focus your consideration of the supplier's food safety history on the hazard that the supplier is controlling because that is the most relevant information. However, you should also consider other information about the supplier, e.g., information regarding recalls or regulatory

actions. For example, if you are obtaining a product from a supplier that is controlling a microbial hazard (e.g., *Salmonella* in a spice blend) and food from this supplier has been associated with a chemical hazard (e.g., excess sulfites in another spice blend it produces), you should consider whether you should implement verification activities related to control of sulfites to prevent excess sulfites in the spice blend you receive for a period of time adequate to demonstrate that problems that could lead to excess sulfites levels have been resolved.

15.7.4.4 Other factors

Section 117.410(d)(1)(iv) specifies that you must consider any other factors as appropriate and necessary, such as storage and transportation practices, in approving suppliers, determining appropriate supplier verification activities, and determining the frequency of conducting those activities. For example, if you are receiving raw materials or other ingredients that support the growth of mold that could produce mycotoxins during storage if temperature and moisture are not controlled, you should consider the procedures that the supplier uses to control factors impacting growth of mold during the time the supplier stores the raw materials or other ingredients being supplied. As another example, if you are receiving raw materials or other ingredients that need temperature control during transportation to ensure their safety, you should consider the ability of the supplier to ensure control of temperature during transportation if the supplier will be responsible for that activity. As another example, if you are obtaining a raw material or other ingredient from a facility that is owned by your corporate parent you may consider your knowledge of corporate-wide food safety procedures, processes, and practices in determining the type of supplier verification activity and the frequency with which it is conducted. See also the discussion in section 15.6.2 of a circumstance where an individual at the corporate level is the PCQI for the purposes of the supply-chain program.

15.7.4.5 Exception to the full requirements for considerations for approving suppliers and determining appropriate supplier verification activities

Section 117.410(d)(2) provides that considering supplier performance can be limited to the supplier's compliance history (as required by 21 CFR 117.410(d)(1)(iii)(B)), if the supplier is: (i) A qualified facility as defined by 21 CFR 117.3; (ii) a farm that grows produce and is not a covered farm under 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5; or (iii) a shell egg producer that is not subject to the requirements of 21 CFR part 118 because it has less than 3,000 laying hens.

15.7.5 Supplier Nonconformance

Section 117.410(e) specifies that if you determine through auditing; verification testing; document review; relevant consumer, customer or other complaints; or otherwise that the supplier is not controlling hazards that you have identified as requiring a supply-chain-applied control, you must take and document prompt action in accordance with 21 CFR 117.150 (Corrective actions and corrections) to ensure that raw materials or other ingredients from the supplier do not cause food that you manufacture or process to be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act.

We recommend that you establish processes and procedures to handle supplier nonconformance situations. The appropriate actions you take in response to nonconformance will depend on the circumstances and the specific root cause of the nonconformance and could include:

- Discontinuing use of the supplier until the cause or causes of nonconformance, adulteration, or misbranding are adequately addressed;
- Notifying the supplier of the problem and requesting documentation of corrective actions taken by the supplier;
- Assisting the supplier's efforts to correct and prevent recurrence of the problem;
- Revising your supply-chain program; and
- Conducting, or working with your supplier to conduct, a recall of an adulterated or misbranded food.

15.8 Responsibilities of the Receiving Facility (21 CFR 117.415)

Section 117.415 describes your responsibilities as a receiving facility. As noted in section 15.3.2, subpart G includes provisions that provide for an entity other than you to conduct certain activities, provided that you review and assess the entity's applicable documentation, and document that review and assessment. Section 117.415 both specifies this flexibility provided by subpart G and places some bounds on that flexibility. We discuss this flexibility and its bounds in sections 15.8.1 through 15.8.4.

15.8.1 Your Responsibility to Approve Suppliers

Section 117.415(a)(1) specifies that the receiving facility must approve suppliers. Although 21 CFR 117.415(a)(2) through (a)(4) provide some flexibility for other entities to determine and conduct appropriate supplier verification activities (see section 15.8.2), ultimately the receiving facility is responsible for its supply-chain program (see the discussion in the final rule establishing part 117, 80 FR 55908 at 56097). See section 15.7.4 for considerations in approving suppliers and section 15.9 for the requirements to approve suppliers before receiving raw materials and other ingredients from those suppliers and have written procedures for receiving raw materials and other ingredients.

As noted in section 15.6.1, the definition of "supplier" in part 117 means that a broker or distributor is not a supplier; the supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food. Thus, if you buy raw materials or other ingredients from a broker or distributor, you should ask the broker or distributor to provide you with information that allows you to approve the establishment that manufactures/processes the food, raises the animal, or grows the food as a supplier of the food that you purchase from that broker or distributor. Likewise, if you purchase raw materials or other ingredients from a retail establishment (e.g., a warehouse-style establishment that sells to consumers), some applicable information (e.g., name and place of business of the manufacturer, packer, or distributor) would be on the product label as required by food labeling regulations. (See 21 CFR 101.5.) Also, you could ask the retail establishment to provide you with information that allows you to evaluate the establishment that manufactures/processes the food, raises the animal, or grows the food.

15.8.2 Your Responsibility to Determine and Conduct Appropriate Supplier Verification Activities

Section 117.415(a)(2) specifies that the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of subpart

G. However, sections 117.415(a)(3) and (4) provide some flexibility for other entities to determine and conduct supplier verification activities on behalf of the receiving facility. See section 15.7.4 for considerations in determining appropriate supplier verification activities and the frequency of conducting them.

15.8.2.1 Flexibility for another entity to determine, conduct, and document appropriate supplier verification activities

Under 21 CFR 117.415(a)(3), an entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

- Establish written procedures for receiving raw materials and other ingredients by the entity (21 CFR 117.415(a)(3)(i));
- Document that written procedures for receiving raw materials and other ingredients are being followed by the entity (21 CFR 117.415(a)(3)(ii)); and
- Determine, conduct, or both determine and conduct the appropriate supplier verification activities (21 CFR 117.415(a)(3)(iii)), with appropriate documentation.

Although we specify that these activities are your responsibility, subpart G accounts for one or more entities in the supply chain between you and "the supplier" by providing some flexibility for these entities to perform certain activities.

15.8.2.2 Supplier verification activities that the supplier can conduct and document

Under 21 CFR 117.415(a)(4), the supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility. However, 21 CFR 117.415(a)(4) also requires that you review and assess that documentation, and document that review and assessment. An example of documentation of the results of sampling and testing is a COA, whether of periodic testing or lot-by-lot testing of the raw material or ingredient.

We recommend that a COA document that major analytical parameters for the specific foods, or lots, contained in a specific shipment have been met (see, e.g., GMA, 2008). Testing can be performed by the supplier's in-house laboratory or contracted to an outside testing laboratory. The laboratory conducting the testing should use scientifically valid laboratory methods and procedures that can provide reliable, accurate test results.

15.8.3 What You May Not Accept from a Supplier as a Supplier Verification Activity

Section 117.415(b) specifies that a receiving facility may not accept any of the following as a supplier verification activity from its supplier:

- A determination by its supplier of the appropriate supplier verification activities for that supplier (21 CFR 117.415(b)(1));
- An audit conducted by its supplier of that supplier (21 CFR 117.415(b)(2));

- A review by its supplier of that supplier's own relevant food safety records (21 CFR 117.415(b)(3)); or
- The conduct by its supplier of other appropriate supplier verification activities for that supplier (21 CFR 117.415(b)(4)).

The only supplier verification activities in which the supplier can play a role are sampling and testing (see section 15.8.2.2) and providing an audit of the supplier conducted by a third party (see section 15.8.4).

15.8.4 Audit Provided by the Supplier

Under 21 CFR 117.415(c), your responsibilities as a receiving facility do not prohibit you from relying on an audit provided by your supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with the requirements of subpart G applicable to audits (i.e., 21 CFR 117.430(f) and 117.435). We discuss these requirements applicable to audits in sections 15.11.6 and 15.12, respectively.

15.9 Using Approved Suppliers (21 CFR 117.420)

As noted in sections 15.7.1 and 15.8.1, subpart G requires that a receiving facility approve suppliers. (See 21 CFR 117.410(a)(1) and 117.415(a)(1).)

15.9.1 Approving Suppliers

Section 117.420(a) specifies that the receiving facility must approve suppliers in accordance with the requirements of 21 CFR 117.410(d), and document that approval, before receiving raw materials and other ingredients from those suppliers. As discussed in section 15.7.4, 21 CFR 117.410(d) both specifies factors that you must consider in approving suppliers and determining appropriate supplier verification activities and provides for an exception to the full requirements for considering these factors.

15.9.2 Written Procedures for Receiving Raw materials and Other Ingredients

Section 117.420(b) specifies that:

- Written procedures for receiving raw materials and other ingredients[6] must be established and followed (21 CFR 117.420(b)(1));
- The written procedures for receiving raw materials and other ingredients must ensure that raw materials and other ingredients are received only from approved suppliers (or, when necessary and appropriate, on a temporary basis from unapproved suppliers whose raw materials or other ingredients are subjected to adequate verification activities before acceptance for use) (21 CFR 117.420(b)(2)); and

[6] As noted in the list of terms in section 15.5, part 117 defines the term "written procedures for receiving raw materials and other ingredients" to mean 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). We defined this term to simplify the provisions discussing these procedures.

- Use of the written procedures for receiving raw materials and other ingredients must be documented (21 CFR 117.420(b)(3)).

You have flexibility to design appropriate written procedures that are tailored to your facility and operations for receiving raw materials and other ingredients. The goal of these written procedures is to ensure that you can accurately identify approved suppliers and incorporate changes to your suppliers in a timely and accurate way (e.g., addition of new approved suppliers, deletion of suppliers no longer deemed approved, criteria for approving temporary suppliers). Procedures to ensure that raw materials or other ingredients are only received from approved suppliers allow consistent implementation of the supplier program by personnel who order raw materials and other ingredients, personnel who receive raw materials and other ingredients, and personnel who conduct supplier verification activities. Such procedures also can be part of training of personnel who will have responsibility for receiving raw materials and other ingredients.

The use of written procedures for receiving raw materials and other ingredients is particularly important in light of the flexibility subpart G provides for an entity other than you (such as an entity in the supply chain between you and the supplier) to conduct this activity. (See 21 CFR 117.415(a)(2).) Although such an entity can do this as a service to you, a written procedure is appropriate to ensure a robust and meaningful verification. If you purchase from a broker or distributor, you must approve the suppliers of the raw materials or other ingredients you buy from the broker/distributor (see sections 15.8.1 and 15.9.1), but the broker/distributor could document that written procedures are being followed to ensure that the raw materials and other ingredients provided to you only come from suppliers that you have approved. The broker/distributor would provide this documentation to you (e.g., in documents accompanying the shipment) for you to review and assess. Thus, if you rely on a broker/distributor to ensure that the raw materials and other ingredients provided to you only come from suppliers that you have approved, you and the broker/distributor you buy from should agree on the written procedures for how the broker/distributor will document that raw materials or other ingredients are received only from suppliers approved by you. For example, the broker/distributor could have a checklist that an employee dates and initials after reviewing the invoice from the supplier, and send a copy of that dated checklist to you together with the invoice for the raw materials or other ingredients. You could use an electronic system or specific supply chain management software to document receipt of the raw material or other ingredient and review of checklist from the broker/distributor at the time of receipt. Below, we discuss the use of checklists and computer systems in more detail.

One approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers is to maintain and use an actual “approved supplier list” to ensure that only suppliers from the lists are used for the purchase of raw materials or other ingredients (Zaura, 2005). One example of this approach is a simple paper system where the receiving personnel or quality control/assurance personnel check the origin of the purchased materials (IFS, 2012) and refer to a list of approved suppliers to verify that the raw material or ingredient is received from an approved supplier (SQFI, 2014) (e.g., put a check mark on the receiving document if the supplier is an approved supplier).

Another approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers is a computer system or specific supply chain management software that manages the procurement, receipt, and usage of raw materials and

other ingredients. An example of this approach is for authorized personnel from the receiving facility or its corporate headquarters to enter approved suppliers and approved raw materials and other ingredients into the computerized system. When raw materials and other ingredients are delivered to a facility, the receiving personnel cross reference the purchase order number, supplier name, and material received with the information previously entered into the computer system to verify the materials are from an approved supplier and the order is correct. Typically the computer system would also have a safeguard mechanism to prevent the acceptance of a raw material or other ingredient from an unapproved supplier. On an as needed basis, a facility or its corporate headquarters can use the computer system to generate a list of the approved suppliers and approved raw materials or ingredients in real time.

Another approach to a written procedure for ensuring that raw materials and other ingredients are only received from approved suppliers is use of computer programs that link inputs on items received with the list of approved suppliers for that item and flag discrepancies. You could either use your existing receiving record system or modify your existing receiving record system to record information regarding receipt from approved suppliers.

Subpart G accounts for emergency situations in which you would need to receive raw materials or other ingredients on a temporary basis from an unapproved supplier (See 21 CFR 117.420(b)(2) and SQFI, 2014.) Examples of such situations are disruptions in delivery of raw materials and other ingredients from approved suppliers due to:

- An environmental incident (e.g., an earthquake) or weather-related incident (e.g., a tornado or severe drought or flooding in the area where the supplier is located);
- A major equipment breakdown at the facility of a sole supplier of a food;
- The emergence of a contamination problem at your supplier's facility; or
- Your supplier ceases operations without giving you advance notification.

For an unapproved supplier that you plan to use on a temporary basis, we recommend that you conduct at least a minimal review of the supplier. For example, we suggest that you review FDA's Web site to determine whether the potential supplier has received a warning letter or is listed on an import alert. In addition, if you need to use an unapproved supplier under such unexpected circumstances, you must subject the applicable raw materials or other ingredients to adequate verification activities before acceptance for use. (See 21 CFR 117.420(b)(2).) For example, if you are receiving a raw material or ingredient such as black pepper and your supplier controls *Salmonella*, you could sample and test each shipment of food from the supplier for *Salmonella* using a statistically-based sampling plan. Alternatively, you could obtain and review records of the process that the temporary supplier uses to kill *Salmonella* in the black pepper.

You should use unapproved suppliers only on a temporary basis until you are able to fully evaluate and approve a new supplier, or until the problem with your previously approved supplier has been corrected and, as appropriate, you reevaluate your approval of that supplier. An appropriate time period for use of an unapproved supplier on a temporary basis might vary, depending on the circumstances, from a few weeks to a few months. For example, if your approved supplier ceases operations and you intend to continue to use a temporary supplier, you should promptly evaluate the new supplier and revise your supply-chain program accordingly. If you are considering multiple new suppliers to replace your approved supplier,

you may need some additional time to evaluate and approve the additional suppliers. As another example, it could be the case that you expect to be able to obtain the food from the approved supplier in a few weeks, but you subsequently determine that it may take several months or an indefinite period of time before you can obtain the food from the approved supplier because of an equipment breakdown or a weather-related incident. In that circumstance, you may determine that you want to use your temporary supplier or another supplier on a more permanent basis. If that occurs, you should promptly evaluate and approve the new supplier and revise your supply-chain program to reflect this. Having multiple suppliers approved for each raw material or ingredient you receive can reduce the use of temporary suppliers when one supplier becomes unavailable.

How you document use of the written procedures for receiving raw materials and other ingredients depends on what your procedures are and how you implement them. For example, if you use a checklist, or put a check mark on the receiving document if the supplier is an approved supplier, then the checklist or receiving document would be your documentation. If you use a computerized system, you can generate records, such as a list of approved suppliers and a list of approved raw materials and other ingredients received from those suppliers on an as needed basis. If you receive documentation from another entity that has documented the receipt of raw materials or other ingredients from suppliers you have approved, you would review that documentation to verify that it is correct and document your assessment (e.g., with a notation on the documentation you received or in a computerized receiving log).

If you receive raw materials or other ingredients on a temporary basis from an unapproved supplier, remember that subpart G requires you to subject raw materials or other ingredients from that unapproved supplier to adequate verification activities before you accept the raw materials or other ingredients for use. (See 21 CFR 117.420(b)(3).) To satisfy this requirement, you should document the verification activities that you conducted before accepting raw materials or other ingredients from a temporary supplier.

15.10 Determining Appropriate Supplier Verification Activities (Including Determining the Frequency of Conducting the Activity) (21 CFR 117.425)

Section 21 CFR 117.425 requires that appropriate supplier verification activities (including the frequency of conducting the activity) be determined in accordance with the requirements of 21 CFR 117.410(d). Section 21 CFR 117.410(d) specifies the considerations in approving suppliers and determining the appropriate supplier verification activities and the frequency with which they are conducted. For details about the requirements of 21 CFR 117.410(d) and our recommendations for complying with those requirements, see section 15.7.4.

15.11 Conducting Supplier Verification Activities for Raw Materials and Other Ingredients (21 CFR 117.430)

Section 21 CFR 117.430 specifies requirements to conduct one or more of the supplier verification activities specified in 21 CFR 117.410(b), provides for alternative supplier verification activities in certain circumstances, and prohibits certain financial conflicts of interest. We discuss these provisions in sections 15.11.1 through 15.11.6.

15.11.1 Requirement to Conduct Supplier Verification Activities

With some exceptions, 21 CFR 117.430(a) requires that one or more supplier verification activities (i.e., onsite audit, sampling and testing, review of food safety records, and other supplier verification activities)[7] must be conducted for each supplier before using the raw material or other ingredient from that supplier and periodically thereafter. The exceptions to this requirement are specified in 21 CFR 117.430(c), (d), and (e). See the discussion of the exceptions to this requirement in sections 15.11.3 through 15.11.5.

A successful supplier program includes supplier verification activities both before the use of the raw material or other ingredient and periodically thereafter to evaluate ongoing compliance (ASTA, 2011; Edleman, 2012; Eldridge, 2012; ERG, 2004; Neumann, 2009; Zaura, 2005). Periodic verification provides routine feedback on the supplier's performance, rather than only when a problem arises (Zaura, 2005).

Subpart G includes specific requirements for conducting onsite audits (21 CFR 117.435) and for documenting the conduct of supplier verification activities (21 CFR 117.475). See sections 15.11.2 and 15.12 for discussions of conducting an onsite audit as a supplier verification activity. See section 15.13 for a discussion of documenting of supplier verification activities.

15.11.2 Specific Requirements When the Hazard Requiring a Preventive Control is a SAHCODH Hazard

15.11.2.1 Requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODH hazard

With one exception (see section 15.11.2), 21 CFR 117.430(b)(1) requires that when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans (SAHCODH hazard):

- The appropriate supplier verification activity is an onsite audit of the supplier (21 CFR 117.430(b)(1)(i)); and
- The audit must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter (21 CFR 117.430(b)(1)(ii)).

SAHCODH hazards are those for which a recall of a violative product posing such a hazard is designated as "Class 1" under 21 CFR 7.3(m)(1) (i.e., a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans include pathogens or their toxins in RTE foods and undeclared food allergens. Foods (other than dietary supplements or infant formula) containing a SAHCODH hazard are considered "reportable foods," subject to the Reportable Food Registry requirements prescribed by the Food and Drug Administration Amendments Act of 2007. See our "Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration

[7] The list of appropriate supplier verification activities is specified in 21 CFR 117.410(b). The receiving facility determines which activity to conduct in accordance with 21 CFR 117.410(d). See the discussion of the appropriate supplier verification activities in section 15.4.2. See the discussion of determining appropriate supplier verification activities in section 15.4.4.

Amendments Act of 2007" (FDA, 2009 and FDA, 2010), and the annual reports of the Reportable Food Registry (e.g., FDA, 2016e.) for examples of foods that we have considered to be SAHCODH hazards.

Onsite audits provide the opportunity to review the food safety plan and written procedures and to observe the implementation of food safety procedures, as well as to review the records related to the past application of control measures, including laboratory test results. Audits also provide the opportunity to interview employees to assess their understanding of the food safety measures for which they are responsible.

The goal of conducting an audit "at least annually thereafter" is to receive the results of an audit with sufficient frequency to provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented. We realize there could be practical reasons which preclude meeting this timeframe, e.g., if a third-party auditor needs to delay a previously scheduled audit. We do not expect to take action if the timeframe between annual audits is reasonably close to one year (e.g., within 13-14 months).

For specific requirements that apply to an audit, see 21 CFR 117.435 and section 15.12. For a discussion of documentation associated with an audit, see section 15.13.

15.11.2.2 Exception to the requirement for an onsite audit when the hazard requiring a preventive control is a SAHCODH hazard

The exception to the requirement to conduct an annual onsite audit when the hazard requiring a preventive control is a SAHCODH hazard is when there is a written determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled. (See 21 CFR 117.430(b)(2).) The written determination is part of your food safety plan and, thus, must be prepared by (or under the oversight of) your PCQI (see the discussion in section 15.6.5).

As an example of using an alternative approach to an annual onsite audit, consider the situation in which you are part of a larger corporation, are making trail mix, and obtain roasted peanuts from a supplier that is a subsidiary of the corporation and is operating under the same food safety system as you. You could determine that the food safety requirements established by the parent company and applied at the subsidiary provide the needed assurance that *Salmonella* in raw peanuts is adequately controlled. You could support your decision by documenting this determination, including the supplier's procedures and the corporation's activities to verify that the subsidiary operates in accordance with corporate food safety policies to ensure that hazards are adequately controlled. See also the discussion in section 15.6.2 of a circumstance where an individual at the corporate level is the PCQI for the purposes of the supply-chain program.

However, if a SAHCODH hazard is identified for the food and you conclude that annual onsite auditing is not required, we recommend that your supplier verification activities generally include some frequency of onsite auditing, such as every 2 or 3 years for most suppliers not in your same corporate structure. For example, consider the situation in which you have many years of experience with the same supplier. You could document the history of the supplier's compliance with control of the hazard (including summarizing test results, audit findings and other information) to support your decision that an annual onsite audit is not needed. You would identify appropriate supplier verification activities and document these in your supply-chain program, e.g., you could determine and describe in your written program that you will require an audit every two years and sample and test for the hazard each quarter in the intervening year.

15.11.3 Alternative Supplier Verification Activity If the Supplier Is a "Qualified Facility"

Section 21 CFR 117.430(c) provides for an alternative supplier verification activity if a supplier is a qualified facility as defined by 21 CFR 117.3. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b) (i.e., audit, sampling and testing, review of the supplier's relevant food safety records, or other appropriate supplier verification activity), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, if you:

- Obtain written assurance that the supplier is a qualified facility as defined by § 117.3:
    - Before first approving the supplier for an applicable calendar year; and
    - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and
- Obtain written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States). The written assurance must include either:
    - A brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or
    - A statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

A facility is a qualified facility if it is a very small business as that term is defined in part 117. See the definitions for "qualified facility" and "very small business" in 21 CFR 117.3 and in the list of terms in section 15.5. A qualified facility is not subject to the PCHF requirements for hazard analysis and risk-based preventive controls, including the requirement to have a supply-chain program. It is the responsibility of the supplier to determine whether it is a qualified facility; it is your responsibility to obtain written assurance from the supplier that it is a qualified facility.

By specifying "by December 31" for the annual written assurance that the supplier is a qualified facility, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify you about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between "qualified facility" and "not a qualified facility" (or vice versa) in a way that works best for your specific business relationship.

The biennial written assurance aligns with the responsibilities of a qualified facility to submit an attestation to FDA every two years.[8] (See 21 CFR 117.201(a).) In its attestation, the qualified facility attests that: (1) It meets the definition of a qualified facility; and (2) either it has established and is following certain food safety practices, or it is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and

[8] For a facility that begins manufacturing, processing, packing or holding food before September 17, 2018, the facility must make its first submission by December 17, 2018. For a facility that begins manufacturing, processing, packing or holding food after September 17, 2018, the facility must make its first submission before beginning operations.

regulations of foreign countries. See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States. A qualified facility submits its attestation to FDA on Form FDA 3942a. A supplier that is a qualified facility could provide a copy of that form to its customers to help them comply with 21 CFR 117.430(c)(1). (A qualified facility that submits the attestation electronically could print a copy for this purpose.) Subpart G also requires that a receiving facility obtain a written assurance that includes a brief written description of the preventive controls that the qualified facility is implementing to control the applicable hazard in the food, or a statement that the qualified facility is in compliance with an applicable non-Federal food safety law. For example, a qualified facility that supplies honey-roasted pecans could include a brief written description of its preventive controls to control *Salmonella* on the pecans (e.g., roasting the pecans at a specified temperature for a specified time period); alternatively, a qualified facility that supplies honey-roasted pecans could provide a statement that it complies with the food safety laws of the state in which it is located.

15.11.4 Alternative Supplier Verification Activity If the Supplier is a Certain Type of Produce Farm

Section 21 CFR 117.430(d) provides for an alternative supplier verification activity if a supplier is a farm that grows produce and is not a covered farm under the produce safety regulation in 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, for produce that the receiving facility receives from the farm as a raw material or other ingredient if you:

- Obtain written assurance that the raw material or other ingredient provided by the supplier is not subject to the produce safety regulation in 21 CFR part 112 in accordance with 21 CFR 112.4(a), or in accordance with 21 CFR 112.4(b) and 112.5:
    - Before first approving the supplier for an applicable calendar year; and
    - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and
- Obtain written assurance, at least every 2 years, that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

Under 21 CFR 112.4(a), a farm or farm mixed-type facility that has less than $25,000 in annual sales of produce averaged over the previous 3-year period is not a covered farm under the produce safety regulation. Under 21 CFR 112.4(b) and 112.5, a farm is not a covered farm if the farm is eligible for a qualified exemption and associated modified requirements based on the average monetary value of all food sold and the relative value of food sold directly to qualified end users as compared to all other buyers[9], and FDA has not withdrawn the farm's exemption. It is the responsibility of the supplier to determine whether it is not subject to the produce safety regulation; it is your responsibility to obtain written assurance from the supplier that it is not subject to the produce safety regulation.

[9] See 21 CFR 112.5(a) for the requirements of the qualified exemption and 21 CFR 112.3 for the definition of "qualified end users."

By specifying "by December 31" for the annual written assurance that the supplier is a farm that grows produce and is not a covered farm under the produce safety regulation, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify you about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between "not a covered farm" and "covered farm" (or vice versa) in a way that works best for your specific business relationship.

See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

15.11.5 Alternative Supplier Verification Activity If the Supplier Is a Shell Egg Producer That Is Not Subject to the Requirements of 21 CFR Part 118

Section 21 CFR 117.430(e) provides for an alternative supplier verification activity if a supplier is a shell egg producer that is not subject to the requirements of 21 CFR part 118 for the production, storage, and transportation of shell eggs because it has less than 3,000 laying hens. If this is the case, you do not need to comply with the requirements to conduct one of the supplier verification activities specified in 21 CFR 117.410(b), or conduct an annual onsite audit if the hazard requiring a preventive control is a SAHCODH hazard, if you:

- Obtain written assurance that the shell eggs produced by the supplier are not subject to 21 CFR part 118 because the shell egg producer has less than 3,000 laying hens:
    - Before first approving the supplier for an applicable calendar year; and
    - On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and
- Obtain written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

A shell egg producer is not subject to the requirements for the production, storage, and transportation of shell eggs if it has less than 3,000 laying hens. It is the responsibility of the supplier to determine whether it is not subject to the requirements for the production, storage, and transportation of shell eggs; it is your responsibility to obtain written assurance from the supplier that it is not subject to those requirements.

By specifying "by December 31" for the annual written assurance that the supplier is a shell egg producer that is not subject to 21 CFR part 118, the provision provides some flexibility for you to work with each applicable supplier to determine the specific date within a calendar year for that supplier to annually notify the receiving facility about its status. You and your suppliers have some flexibility to approach the potential for the status of a facility to shift between "not subject to 21 CFR part 118" and "subject to 21 CFR part 118" (or vice versa) in a way that works best for your specific business relationship.

See section 15.7.4.3 for a discussion of the applicability of relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States.

15.11.6 Financial Conflict of Interest

Section 21 CFR 117.430(f) specifies that there must not be any financial conflicts of interests that influence the results of the verification activities listed in 21 CFR 117.410(b). For example, if a qualified individual has a financial conflict of interest that influences the results of supplier verification activities, the qualified individual would be precluded from being able to independently conduct supplier verification activities. You can avoid this possibility when conducting supplier verification activities by only using individuals or firms that do not have conflicts of interest.

In addition, 21 CFR 117.430(f) specifies that payment must not be related to the results of the activity. For example, you may not give a qualified auditor who conducts an onsite audit, or a qualified individual who reviews supplier food safety records, greater compensation for determining that a supplier is in compliance with applicable FDA requirements. Also, you may not reduce the compensation of a qualified auditor or qualified individual or assess financial penalties because the qualified auditor or qualified individual identified areas of supplier non-compliance. Similarly, a supplier may not make such payments.

The requirements of 21 CFR 117.430(f) do not prohibit employees of a supplier from performing the functions specified in 21 CFR 117.415 in accordance with 21 CFR 117.415. (See the discussion of functions that a supplier can perform in accordance with 21 CFR 117.415(a)(4) in section 15.8.2.2). For example, this provision would not prohibit an employee of a supplier from conducting sampling and testing so that the supplier could provide the results in documentation provided to the receiving facility; it is common for suppliers to include COAs for tests conducted on specific lots of product along with the shipment to the receiving facility. The requirements of 21 CFR 117.430(f) also do not prohibit you from relying on an audit provided by your supplier when the audit of the supplier was conducted by a third-party qualified auditor. (See the discussion of 21 CFR 117.415(c) in section 15.8.4.)

15.12 Onsite Audit (21 CFR 117.435)

Section 21 CFR 117.435 specifies requirements applicable to onsite audits, including who must conduct an onsite audit; consideration of applicable food safety regulations; and when the written results of an inspection can be substituted for an audit. We discuss these provisions in sections 15.12.1 through 15.12.3.

15.12.1 Who Conducts an Onsite Audit

Section 21 CFR 117.435(a) requires that an onsite audit of a supplier be performed by a qualified auditor. Part 117 defines “qualified auditor” as a person who is a qualified individual as defined in part 117 and has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 21 CFR 117.180(c)(2). Examples of potential qualified auditors include:

- A government employee, including a foreign government employee; and
- An audit agent of a certification body that is accredited in accordance with the accredited third-party certification regulation.

Part 117 defines “qualified individual” as 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.

See the definitions of "qualified auditor" and "qualified individual" in 21 CFR 117.3 and in the list of terms in section 15.5.) The requirements applicable to a qualified auditor are set forth in 21 CFR 117.180(c)(2), which specifies that to be a qualified auditor, a qualified individual must have technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. A qualified auditor may be, but is not required to be, an employee of the receiving facility.

We have not established specific courses, programs, or certifications, or defined the type of experiences that would be required to satisfy the requirements applicable to a qualified auditor as defined in part 117. However, consistent with the requirements for competent audit agents in 21 CFR 1.650 and the guidance entitled "Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff" (Guidance on Accredited Third-Party Certification) (FDA, 2016f), we expect a qualified auditor to have education, training, or experience that provides the person with knowledge and skills necessary to evaluate whether the equipment, processes, and procedures in a food facility or on a farm ensure that the hazards associated with the food have been controlled. For example, an individual who has previously conducted food safety inspections for a food safety authority may be a qualified auditor, provided that the individual has the knowledge and experience to assess compliance with the applicable provisions of the FD&C Act. A person should have at least some actual experience in auditing (including assisting in audits or observing audits) to meet the definition of a qualified auditor, because the necessary technical expertise likely cannot be obtained solely through education and/or training that does not involve assisting or observing others in the performance of an audit.

The example of an audit agent of a certification body that has been accredited in accordance with regulations in our accredited third-party certification regulation (21 CFR part 1, subpart M) adds context about the standard for such individuals. The requirements in 21 CFR 1.650 address how an accredited third-party certification body must ensure its audit agents are competent and objective. Although an onsite audit that is solely conducted to meet the requirements of part 117 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, is not subject to the requirements in those regulations (see section 15.12.4), the requirements for audit agents and the Guidance on Accredited Third-Party Certification with respect to competency are useful in determining appropriate education, training, or experience for a qualified auditor. For example, competency requirements for audit agents in the accredited third-party certification regulation include that they:

- Have relevant knowledge and experience that provides an adequate basis for the audit agent to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations;
- Be competent to conduct food safety audits; and
- Have completed annual food safety training (FDA 2016f).

The Guidance on Accredited Third-Party Certification (FDA 2016f) further recommends education and/or experience for entry level auditors and lead auditors, as well as auditor skills such as observational, reasoning, analytical and communication skills (FDA 2016f). Auditors should be trained to understand and properly apply FDA's food safety requirements under the

FD&C Act and FDA regulations for purposes of auditing (FDA 2016f). Technical training may vary depending on the processes and products being audited (FDA 2016f). Training methods may include classroom training, annual food safety training, and joint audits with a qualified trainer to help the audit agent apply classroom learning (FDA 2016f).

The GFSI provisions for auditor competency in ''GFSI Food Safety Auditor Competencies'' (GFSI, 2013) are also useful in determining the knowledge, experience, and skills for a qualified auditor. The GFSI's auditor competency model lists three main components for auditor competencies: (1) Auditing skills and knowledge; (2) technical skills and knowledge; and (3) behavior and systems thinking (GFSI, 2013). Within each main component, GFSI provides details of specific tasks and the required auditor knowledge and skills to perform the specific tasks (GFSI, 2013).

You or one of your employees may conduct the audit as long as you are or your employee is a qualified auditor, based on education, training, or experience, or a combination thereof.

15.12.2 Consideration of Food Safety Regulations

Section 21 CFR 117.435(b) requires that if the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, an onsite audit must consider such regulations and include a review of the supplier's written plan (e.g., HACCP plan or other food safety plan), if any, and its implementation, for the hazard being controlled (or, when applicable, an onsite audit may consider relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

The qualified auditor who audits your supplier may be your own employee ("second-party audit") or an independent third party (i.e., a qualified auditor who is neither your employee nor an employee or the supplier) (third-party audit). Both second-party audits and third-party audits allow first-hand review of the critical food safety programs in place at a supplier's establishment and can help you to obtain a sense of how effective programs are by diligently reviewing program records, observing activities, and interviewing workers.

Because FDA food safety regulations vary in scope and detail, the parameters and key components of an onsite audit conducted under section 21 CFR 117.435(a) would vary depending on what regulations apply to the supplier.

A supplier that is subject to the PCHF requirements must have a food safety plan. (See 21 CFR 117.126.) If your supplier is subject to the PCHF requirements, the onsite audit would focus on the supplier's food safety plan and assess the implementation of the preventive controls applied by the supplier to address the known or reasonably foreseeable hazards that you have determined to require a supply-chain-applied control. For example, before you obtain roasted peanuts for which you had identified *Salmonella* as a hazard from a supplier subject to the PCHF requirements, you would audit the supplier (or obtain documentation of an audit performed by a third party) to determine whether the supplier's roasting process adequately controlled the *Salmonella*. Because the supplier was subject to the PCHF requirements, the audit should include a review of the supplier's food safety plan. The auditor should review whether the roasting process had been validated to significantly minimize *Salmonella* in peanuts and should examine whether the supplier had implemented the roasting procedures in accordance with its food safety plan (e.g., through observing the establishment's procedures and reviewing records).

A supplier that is not subject to the PCHF requirements, but is subject to HACCP requirements, would have a "HACCP plan" rather than a "food safety plan." If, for example, you use juice as an ingredient in a refrigerated fruit salad, and your supplier is subject to the process control requirements in 21 CFR 120.24, the onsite audit of the juice supplier would assess the validation and implementation of the process controls in your supplier's HACCP plan.

The produce safety regulation in 21 CFR part 112 does not require farms that are subject to that regulation to have food safety plans. However, in some cases, a supplier (such as a large farming operation) might voluntarily elect to establish a food safety plan. In that case, the onsite audit of the supplier should include a review of the supplier's written plan, and its implementation of the plan, to ensure that identified hazards are being adequately controlled.

An audit of your supplier should include both records review and observation of practices to obtain a complete picture of the safety of your supplier's operations. Comprehensive systems audits that include records reviews are more likely to reflect conditions throughout the year than an audit focused only on the state of the facility at the time of the audit. An audit of a manufacturing/processing facility subject to the PCHF requirements should address process, allergen, sanitation, and supply-chain-applied controls (if any), as well as CGMPs (if applicable) and the specific hazards identified in your hazard analysis of the food.

There are several national and international auditing schemes widely used to assess food safety practices in manufacturing facilities and on farms. You could rely on the results of audits conducted in accordance with such schemes provided that the audits evaluate the farm or facility's compliance with applicable FDA regulations, review the supplier's food safety plan (if any) and its implementation, and otherwise meet the requirements for onsite audits in 21 CFR 117.435. Before relying on the results of a third-party onsite audit, you should determine whether the auditing scheme used can help you to conclude whether the supplier uses processes and procedures that comply with applicable regulations. Audit schemes that consider FDA food safety regulations and include a review of the supplier's written food safety plan (including a HACCP plan), if any, and its implementation, with respect to the hazard being controlled are likely to satisfy the requirements for an onsite audit.

15.12.3 Substitution of an Inspection for an Audit

Section 21 CFR 117.435(c) allows for the following inspections to substitute for an onsite audit, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted:

- The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture (USDA)), or by representatives of State, local, tribal, or territorial agencies (21 CFR 117.435(c)(1)(i)); or
- For a foreign supplier, the written results of an inspection by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States. (See 21 CFR 117.435(c)(1)(ii).) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country. (See 21 CFR 117.435(c)(2).)

For an inspection conducted by FDA, other Federal Agencies, or State, local, tribal, or territorial agencies, an ‘‘appropriate’’ inspection conducted for compliance ‘‘with applicable FDA regulations’’ means that the inspection must be sufficiently relevant to compliance with applicable FDA food safety regulations to credibly substitute for an onsite audit. For example, inspection by USDA to determine whether a farm satisfies the requirements of the produce safety regulation could constitute an appropriate inspection that could substitute for an audit, but an inspection by USDA to determine whether a farm satisfies the requirements of the National Organic Program could not.

In the case of a foreign supplier, a country whose food safety system FDA has officially recognized as ‘‘comparable’’ to that of the United States would be one for which there is a signed systems recognition arrangement or other agreement between FDA and the country establishing official recognition of the foreign food safety system. See section 15.7.4.3.2 for information on countries for which we have a Food Safety Systems Recognition Arrangement or other cooperative arrangement with a foreign country.

Some countries issue certifications or recognitions to facilities for compliance with certain requirements such as for HACCP systems. We would not accept a HACCP certificate issued by a foreign government as a substitute for an onsite audit because HACCP requirements are not identical to the PCHF requirements, and it would not be clear as to what basis was used to issue a HACCP certificate. However, a receiving facility could consider whether such a certificate could be part of its justification for conducting another supplier verification activity in lieu of an annual onsite audit, or for conducting an audit on a less frequent basis than annually (see section 15.11.2.2).

15.12.4 Audits Conducted to Meet the Requirements of Subpart G Do Not Have to Comply with the Requirements of the Accredited Third-Party Regulation

Section 21 CFR 117.435(d) specifies that if an onsite audit is solely conducted to meet the requirements of part 117 by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M, the audit is not subject to the requirements in those regulations.

Audits conducted under the accredited third-party certification regulation are done for specific purposes, e.g., for compliance with the requirements of the Voluntary Qualified Importer Program. Audits conducted to meet the requirements of 21 CFR 117.435 may be conducted by a person who had been accredited under these provisions; however, the requirements for audits conducted under the accredited third-party certification regulation (e.g., specific information that must be included in an audit and submission of regulatory audit reports to FDA under 21 CFR 1.652) would not apply to an audit even when the auditor is accredited to do such audits unless they are also conducted for purposes under the accredited third-party certification regulation.

15.13 Records Documenting the Supply-Chain Program

Section 21 CFR 117.475 specifies that the records documenting the supply-chain program are subject to the requirements of subpart F of part 117. (See 21 CFR 117.475(a).) Subpart F sets forth general requirements applicable to all records, such as the use of either paper or electronic records and the need for records to be accurate, indelible, and legible. Subpart F also sets forth requirements for record retention and official review. Section 117.330 in subpart F explains how you can use existing records to satisfy the recordkeeping requirements of part 117.

Section 21 CFR 117.475 requires that you must review the records of the supply-chain program in accordance with § 117.165(a)(4). (See 21 CFR 117.475(b).) Under 21 CFR 117.165(a)(4(ii)), records of the supply-chain program must be reviewed within a reasonable time after the records are made by (or under the oversight of) a PCQI to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions.

Table 15-4 lists the records required (as applicable) for the supply-chain program. (See 21 CFR 117.475(c).)

Table 15-4 List of Records Required for the Supply-Chain Program

Section	Description	Discussion
117.475(c)(1)	The written supply-chain program	There is no standardized or required format for the written supply chain program or its records. You can use whatever format works best for your facility, provided that the records include all the required information. Also, the written supply-chain program is part of the food safety plan, which must be signed and dated by the owner, operator, or agent in charge of the facility upon initial completion and upon any modification. (See 21 CFR 117.310.)
117.475(c)(2)	If you are an importer, documentation that you are in compliance with the FSVP requirements under part 1, subpart L, including documentation of verification activities conducted under §1.506(e)	If you are an importer, and you have records documenting the supplier verification activities you conducted to comply with the FSVP regulation, you can rely on those records as documentation of verification activities to comply with the supply-chain program requirements of subpart G.
117.475(c)(3)	Documentation of the approval of a supplier	• Your written determination of the basis for approving the supplier; and • The approved suppliers – e.g., a paper list of approved suppliers or an electronic system that can generate a list of approved suppliers as needed

Section	Description	Discussion
17.475(c)(4)	Written procedures for receiving raw materials and other ingredients	Examples are a paper checklist and a computer system that manages the procurement, receipt, and usage of raw materials and other ingredients.
117.475(c)(5)	Documentation demonstrating use of the written procedures for receiving raw materials and other ingredients	Examples are a paper checklist that was marked to demonstrate receipt and electronic records produced by a computer system that manages the procurement, receipt, and usage of raw materials and other ingredients.
117.475(c)(6)	Documentation of the determination of the appropriate supplier verification activities for raw materials and other ingredients	Your written determination should explain why you chose your particular supplier verification activities. See the discussion in section 15.7.4.
117.475(c)(7)	Documentation of the conduct of an onsite audit, including (i) The name of the supplier subject to the onsite audit; (ii) Documentation of audit procedures; (iii) The dates the audit was conducted; (iv) The conclusions of the audit; (v) Corrective actions taken in response to significant deficiencies identified during the audit; and (vi) Documentation that the audit was conducted by a qualified auditor	Examples of documentation of audit procedures include the process(es) and food(s) observed, types of records reviewed, and whether the audit included interviews or laboratory testing. Examples of the conclusions of an audit include whether the audit did, or did not, result in any significant deficiencies. You have some flexibility to work with the qualified auditor, or with a supplier who arranges for a third-party audit, on appropriate documentation that the auditor has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function. Examples of such documentation are a list of applicable training and examples of relevant audits conducted by the auditor.

Section	Description	Discussion
117.475(c)(8)	Documentation of sampling and testing conducted as a supplier verification activity. This documentation must include: (i) Identification of the raw material or other ingredient tested (including lot number, as appropriate) and the number of samples tested; (ii) Identification of the test(s) conducted, including the analytical method(s) used; (iii) The date(s) on which the test(s) were conducted and the date of the report; (iv) The results of the testing; (v) Corrective actions taken in response to detection of hazards; and (vi) Information identifying the laboratory conducting the testing	You have some flexibility in the format of appropriate documentation of sampling and testing, such as on a CoA. Documentation of corrective actions would apply to the steps you take when you (or a third party acting on your behalf) detect the hazard in raw materials or other ingredients that you received, including what you do with the raw material or other ingredient and the steps you take to address the problem with the supplier.
117.475(c)(9)	Documentation of the review of the supplier's relevant food safety records. This documentation must include: (i) The name of the supplier whose records were reviewed; (ii) The date(s) of review; (iii) The general nature of the records reviewed; (iv) The conclusions of the review; and (v) Corrective actions taken in response to significant deficiencies identified during the review	Records of the supply-chain program must be reviewed within a reasonable time after the records are made by (or under the oversight of) a PCQI to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the supplier's preventive controls are effective, and appropriate decisions were made about corrective actions. (See 21 CFR 117.165(a)(4).)
117.475(c)(10)	Documentation of other appropriate supplier verification activities based on the supplier performance and the risk associated with the raw material or other ingredient	Your documentation of other appropriate supplier verification activities would depend on the nature of the activity. For example, if you use a fact-specific questionnaire you would have a record of the questionnaire applied to a particular supplier. If you considered information applicable to a supplier's certification to a specific audit scheme, you would have a record of the information you considered.

Section	Description	Discussion
117.475(c)(11)	Documentation of any determination that verification activities other than an onsite audit, and/or less frequent onsite auditing of a supplier, provide adequate assurance that the hazards are controlled when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans	Because your written supply-chain program is part of your food safety plan, the written determination must be prepared by (or under the oversight of) your PCQI. See the discussion in section 15.11.2.2 for examples of what such a written determination could address.
117.475(c)(12)	The following documentation of an alternative verification activity for a supplier that is a qualified facility: (i) The written assurance that the supplier is a qualified facility as defined by §117.3, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)	You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship. For example, for documentation of its status, a qualified facility could provide you with documentation of its submission of the qualified facilities form (Form FDA 3942a). For the other assurance, you and your supplier can choose which of two options to use, based on the specific circumstances of the supplier. See the discussion in section 15.11.3 of the two different types of attestation.

Section	Description	Discussion
117.475(c)(13)	The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter: (i) The written assurance that the supplier is not a covered farm under part 112 of this chapter in accordance with §112.4(a), or in accordance with §§112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)	You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship.
117.475(c)(14)	The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens: (i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and (ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the FD&C Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States)	You and your suppliers have some flexibility to determine the appropriate documentation in a way that works best for your specific business relationship.

Section	Description	Discussion
117.475(c)(15)	The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the U.S. Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection are substituted for an onsite audit	The written results of an appropriate inspection would depend on the inspection and how the entity conducting the inspection reports its results.
117.475(c)(16)	Documentation of actions taken with respect to supplier nonconformance	Your documentation of supplier nonconformance would depend on the nature of the nonconformance. See the examples of potential supplier nonconformance in section 15.7.5.
117.475(c)(17)	Documentation of verification of a supply-chain-applied control applied by an entity other than the receiving facility's supplier	The documentation you receive from another entity should be similar to the documentation you would have if you had conducted the activity yourself.

Section	Description	Discussion
117.475(c)(18)	When applicable, documentation of the receiving facility's review and assessment of: (i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed; (ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients; (iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients; (iv) Applicable documentation, from its supplier, of: (A) The results of sampling and testing conducted by the supplier; or (B) The results of an audit conducted by a third-party qualified auditor in accordance with 21 CFR 117.430(f) and 117.435; and (v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier	You have some flexibility for how to appropriately document that you reviewed and assessed the documentation from another entity. For example, appropriate staff in your facility could date and sign the documentation received from the other entity, or you could attach a signed, dated statement, from appropriate staff in your facility, specifying that the documentation had been reviewed and assessed.

15.14 Compliance Dates

In the preamble of the final rule establishing part 117, we provided compliance dates for the requirements of the supply-chain program in subpart G. (See Table 54 in the final rule, 80 FR 55908 at 56128). The compliance dates for implementing your supply-chain program apply with respect to each of your suppliers, not to your supply-chain program as a whole, because the compliance dates depend on whether your suppliers will be subject to part 117, the produce safety regulation, or neither regulation. For those suppliers subject to part 117 or the produce safety regulation, you are not required to conduct supplier verification activities until after your supplier’s compliance date is reached.

For your convenience, Table 15-5 provides the information from Table 54 in the preamble of the final rule establishing part 117.

Table 15-5 Compliance Dates for the Requirements of the Supply-Chain Program

Situation	Compliance date:
You are a small business and your supplier will not be subject to the PCHF requirements of part 117 or the produce safety regulation	September 18, 2017
You are a small business and your supplier is subject to the PCHF requirements of part 117 or the produce safety regulation	The later of September 18, 2017, or 6 months after your supplier of that raw material or other ingredient is required to comply with the applicable requirements
You are neither a small business nor a very small business and your supplier will not be subject to the PCHF requirements of part 117 or the produce safety regulation	March 17, 2017
You are neither a small business nor a very small business and your supplier will be subject to the PCHF requirements of part 117 or the produce safety regulation	6 months after your supplier of that raw material or other ingredient is required to comply with the applicable requirements

15.15 Table of Abbreviations

Section IV in the Introduction of this guidance includes a table of abbreviations that are used in this guidance. At this time, that Table of Abbreviations does not include all abbreviations that are used in this chapter. See Table 15-6 for an additional abbreviation that we use in this chapter. For the convenience of the reader, Table 15-6 also describes what we mean by "PCHF," even though this abbreviation is already in section IV in the Introduction of this guidance. We intend to compile all abbreviations in section IV in the Introduction of this guidance when we update the Introduction. When we do so, we intend to delete Table 15-6 from this chapter, because it would be duplicative.

Table 15-6 Table of Abbreviations

Abbreviation	What It Means
PCHF	"Preventive Controls for Human Food" (requirements in 21 CFR part 117 for hazard analysis and risk-based preventive controls for human food in accordance with section 418 of the FD&C Act)
SAHCODH Hazard	Hazard for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans

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Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

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Chapter 16: Acidified Foods

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[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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16.1 Purpose of this Chapter

The guidance in this chapter is intended for persons who:

- Are subject to the PCHF requirements; and
- Manufacture, process, or pack acidified foods.

If you are subject to PCHF requirements and manufacture, process, or pack acidified foods, the guidance provided in this chapter is intended to explain:

- How you can leverage procedures, practices, and processes that you establish and implement to comply with the requirements prescribed by 21 CFR 108.25 and 21 CFR part 114, and records that you establish and keep to comply with those requirements, to address corresponding requirements of the PCHF rule; and
- How you can leverage the procedures, practices, and processes that you establish and implement to comply with the requirements of the PCHF rule, and the records that you establish and keep to comply with those requirements, to address corresponding requirements of 21 CFR 108.25 and 21 CFR part 114.

This guidance is not intended for persons that manufacture, process, or pack acidified foods, but are exempt from PCHF requirements in accordance with 21 CFR 117.5(a) as a "qualified facility." Qualified facilities that manufacture, process, or pack acidified foods remain subject to 21 CFR 108.25 and part 114 and are subject to modified requirements under 21 CFR 117.201.

16.2 Considerations to Keep in Mind If You Manufacture/Process an Acidified Food

16.2.1 Background on Specific Acidified Food Requirements

FDA has established specific CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (i.e., "low-acid canned foods," or "LACF") (21 CFR part 113; the LACF regulations[2]) and acidified foods (21 CFR part 114 ("part 114"). In the proposed and final rulemakings for LACF[3] and acidified foods,[4] FDA discussed the need for CGMP requirements to control *Clostridium botulinum* (*C. botulinum)*. *C. botulinum* is a bacterium commonly found in soil. It can produce a nerve toxin (botulinum toxin) under anaerobic conditions such as those in canned foods. Botulinum toxin can cause botulism, a rare but serious paralytic illness that can be fatal and is considered a medical emergency. For additional information about *C. botulinum* and botulinum toxin, see Chapter 3 of this guidance and the references provided in that chapter.

Part 114 defines a scheduled process as the "process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority" (21 CFR 114.3(e)). Because the pH of acidified foods is sufficiently low to prevent the germination of spores of *C. botulinum*, acidified foods may be held at ambient temperature without a heat treatment comparable to that required in the scheduled process for LACF (41 FR 30442 at 30442; see 21 CFR 113.3(r)).

[2] Note that there is a partial exemption from the PCHF requirements for food subject to part 113 in 21 CFR 117.5(d).
[3] Proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979.
[4] Proposed rule, 41 FR 30457, July 23, 1976; final rule, 44 FR 16230, March 16, 1979.

FDA also has established emergency permit control requirements, under section 404 of the FD&C Act, for acidified foods (21 CFR 108.25; the emergency permit control regulations). FDA established these requirements, in part, because of the importance of controlling the pH of acidified foods. The emergency permit control regulations are intended to ensure safe manufacturing, processing, and packing processes and to permit FDA to verify that these processes are being followed. The emergency permit control regulations require commercial processors of acidified foods to register and file with FDA information, submitted on Form FDA 2541, that includes the name of the establishment, principal place of business, location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment (21 CFR 108.25(c)(1)). The emergency permit control regulations also require commercial processors of acidified foods to provide FDA with information, submitted on Form FDA 2541e, on the scheduled processes including, as applicable, information about the product, the container type and size, pH, method of acidification, microbial preservatives critical to the scheduled process, process source, process mode, the container and container closure treatment, and details of the scheduled process (e.g., process time and temperature) for each acidified food in each container size (21 CFR 108.25(c)(2)). All plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation must be under the operating supervision of a person who has attended a school[5] approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction (21 CFR 108.25(f)).

16.2.2 Relationship Between the Requirements in the PCHF Rule and the Specific Acidified Food Requirements

Some requirements of the PCHF rule have corresponding requirements in the emergency permit control regulations, part 114, or both, but other requirements of the PCHF rule do not. For example:

- The requirement of the PCHF rule for process controls for biological hazards requiring a preventive control has corresponding requirements for a scheduled process for an acidified food under the emergency permit control regulations and part 114; but
- Neither the emergency permit control regulations nor part 114 requires a hazard analysis.

Likewise, some requirements in the emergency permit control regulations, part 114, or both have corresponding requirements in the PCHF rule, but other requirements in the emergency permit control regulations, part 114, or both do not. For example:

[5] Often referred to as “Better Process Control School.”

- The requirements in part 114 for frequent testing of pH, and recording the results of that testing, have a corresponding requirement in the PCHF rule for monitoring and for establishing and keeping records of monitoring; but
- The requirement of the emergency permit control regulations to submit the scheduled process to FDA on Form FDA 2541e has no corresponding requirement in the PCHF rule, and the requirement of part 114 for marking each container or product with an identifying code permanently visible to the naked eye has no corresponding requirement in the PCHF rule.

16.2.3 Developing a Strategy to Comply with the PCHF Rule, Emergency Permit Control Regulations, and Part 114

Sections 16.6 through 16.13 of this chapter compare the specific requirements of the emergency permit control regulations, part 114, and the PCHF rule to help you comply with all applicable requirements by explaining:

- How you can leverage procedures, practices, and processes that you establish and implement to comply with the requirements prescribed by 21 CFR 108.25 and part 114, and records that you establish and keep to comply with those requirements, to address corresponding requirements of the PCHF rule; and
- How you can leverage the procedures, practices, and processes that you establish and implement to comply with the requirements of the PCHF rule, and the records that you establish and keep to comply with those requirements, to address corresponding requirements of 21 CFR 108.25 and part 114.

Importantly, the procedures, practices, and processes that you establish and implement to comply with the requirements prescribed by 21 CFR 108.25 and part 114, and records that you establish and keep to comply with those requirements, could partially but not fully satisfy corresponding requirements of the PCHF rule. Likewise, the procedures, practices, and processes that you establish and implement to comply with the requirements of the PCHF rule, and the records that you establish and keep to comply with those requirements, could partially but not fully satisfy corresponding requirements of 21 CFR 108.25 and part 114. Sections 16.6 through 16.13 of this chapter provide details about the extent to which complying with the requirements prescribed by 21 CFR 108.25 and part 114 can address the corresponding PCHF requirements and vice versa.

In some cases, the simplest approach to complying with both sets of requirements could be to use procedures, practices, processes, or records associated with the specific acidified food requirements to address the corresponding requirements of the PCHF rule. For example, see the discussion in section 16.10.1 regarding process controls. Because process controls for acidified foods must address all parameters specified on Form FDA 2541e, a simple approach to complying with the requirement to identify and implement preventive controls that are process controls could be to complete Form FDA 2541e and include it in your food safety plan as a written process control.

In other cases, the simplest approach to complying with both sets of requirements could be to use procedures, practices, processes, or records associated with the specific requirements of the PCHF rule to address the corresponding requirements specific to acidified foods. For examples, see the discussions in:

- Section 16.10.4 regarding the recall plan required by the PCHF rule for foods with hazards that require a preventive control and the recall procedures required by 21 CFR 108.25(e);
- Section 16.11 regarding preventive control management components required by the PCHF rule and corresponding requirements in part 114; and
- Section 16.12 regarding the recordkeeping requirements of part 117 and the corresponding recordkeeping requirements of part 114.

This chapter provides you with information to help you choose an approach for complying with the PCHF rule, emergency permit control regulations, and part 114, in a way that works best for your facility and your acidified food product.

16.2.4 You Must Comply with the Specific Acidified Food Requirements Even If There Is No Corresponding Requirement in the PCHF Rule

Appendix 16-1 in this chapter summarizes key specific acidified food requirements under the emergency permit control regulations, part 114, or both that either:

- Have no explicitly corresponding requirement under the PCHF rule; or
- Exceed the corresponding requirements of the PCHF rule.

Sections 16.6 through 16.13 of this chapter provide suggestions for how you can address some of the key specific acidified food requirements (see Appendix 16-1) by complying with the PCHF rule. For example, part 114 requires that the scheduled process for an acidified food control microorganisms of non-health significance in addition to pathogens (see 21 CFR 114.80(a)(1) and Appendix 16-1), and section 16.9 explains how your hazard analysis could identify microorganisms of non-health significance as a biological hazard requiring a preventive control, even though microorganisms of non-health significance, by themselves, are not “hazards” as that term is defined in part 117. However, sections 16.6 through 16.13 of this chapter also clarify that none of the PCHF requirements address the submission of a food canning establishment registration on Form FDA 2541 as required by 21 CFR 108.25(c)(1) or suggest any way to comply with the requirement to submit Form FDA 2541e other than the mechanism specified in 21 CFR 108.25(c)(2).

If a specific acidified food requirement exceeds the corresponding requirement of the PCHF rule, you must comply with the specific acidified food requirement. As discussed in section 16.12, part 114 requires that you keep records required by part 114 for 3 years, which exceeds the 2-year record retention requirement in part 117 for records documenting the food safety plan and implementation of the food safety plan. (See 21 CFR 114.100(e) and 21 CFR 117.315.)

16.3 Understand the Hazard Requiring a Preventive Control

The PCHF rule requires a hazard analysis to determine whether there are any hazards requiring a preventive control. (See 21 CFR 117.130(a)(1).) Part 114 includes requirements to control hazards associated with *C. botulinum* and other microorganisms of public health significance. Thus, understanding the hazards that can be controlled by complying with part 114 can help to understand which known or reasonably foreseeable (potential) hazards require a preventive control under the PCHF rule. Below, we discuss the hazards that part 114 controls, as well as the importance of controlling some microorganisms of non-health significance[6] (which are not "hazards" as that term is defined in part 117).

When conditions are not conducive to growth of vegetative cells (e.g., when the availability of nutrients is limited), *C. botulinum* can form spores that are adapted for prolonged survival under adverse conditions (Larousse and Brown, 1997). Thermal processes using temperatures such as 212 °F (100°C) (i.e., the temperature of boiling water) or even lower (e.g., 150 °F (65.6°C) in some circumstances) can destroy the vegetative cells of *C. botulinum*, but do not destroy the spores of *C. botulinum* (see 41 FR 30442 at 30442, July 23, 1976).

When the pH of a food is 4.6 or below, spores of *C. botulinum* will not germinate and grow (41 FR 30442 at 30442). However, an acidified food can pose a risk of botulism if pH and other critical factors are not carefully controlled during processing to prevent the germination and growth of viable spores of *C. botulinum* (44 FR 16204 at 16204, March 16, 1979). When critical factors are not carefully controlled, the vegetative cells of some microorganisms of non-health significance (such as some spoilage bacteria, yeasts, and molds) can grow in an acid environment and, in so doing, cause the pH of the food to increase (Fields, Zamora, and Bradsher, 1977; Odlaug and Pflug, 1978; and Institute of Food Technologists, 2001). In addition, some spoilage microorganisms (such as *Bacillus licheniformis* (*B. licheniformis*)) produce heat-resistant, acid-tolerant spores that, when critical factors are not properly controlled, can germinate, grow, and cause the pH to increase; thermal processing that is sufficient to destroy vegetative cells of such microorganisms may not be sufficient to destroy their spores (Fields, Zamora, and Bradsher, 1977; Montville, 1982; Al Dujaili and Anderson, 1991; and Rodriguez, Cousin, and Nelson, 1992).

16.4 Terms Used in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 16-1 for additional terms that we use in this chapter. We intend to include these terms in the glossary in the Introduction of this guidance when we update the Introduction. When we do so, we will delete Table 16-1 from this chapter.

[6] See section 16.9 for additional discussion of microorganisms of non-health significance.

Table 16-1 Terms Used in this Chapter

Term	What the Term Means
Emergency permit control regulations	Emergency permit control requirements in 21 CFR 108.25 for acidified foods
Part 114	Requirements in 21 CFR part 114, Acidified Foods
Potential hazard	Known or reasonably foreseeable hazard (which is defined in 21 CFR 117.3)

16.5 Quick Reference Guide

Table 16-2 is a quick reference guide to help you see at a glance the relationship between the specific acidified food requirements and corresponding PCHF requirements.

Table 16-2 Quick Reference Guide Listing the Specific Acidified Food Requirements and Corresponding PCHF Requirements

Description of Requirement	Applicable Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	Applicable Requirements in Part 117 (21 CFR)	Applicable Section in This Chapter	Applicable Chapters in This Guidance
Qualifications of personnel with responsibility for supervision or other oversight	• 108.25(f) • 114.10	• 117.4(c) • 117.180(c)(1)	16.6	N/A
Oversight	• 108.25(f) • 114.10 • 114.83	• 117.126(a)(2) • 117.160(b)(1) • 117.160(c)(5) • 117.165(a)(4) • 117.170(c)(2)(ii) • 117.180(a)	16.7	Chapter 1
Written food safety plan	N/A	117.126	16.8	Chapter 1
Hazard analysis	N/A	117.130	16.9	• Chapters 2, 3, and 6 • Appendix 1 • Appendix 3

Description of Requirement	Applicable Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	Applicable Requirements in Part 117 (21 CFR)	Applicable Section in This Chapter	Applicable Chapters in This Guidance
Identifying and implementing preventive controls that are process controls for biological hazards requiring a preventive control	• 108.25(c)(2) • 108.25(c)(3) • 114.80(a)(1) • 114.80(a)(3) • 114.80(a)(4)	• 117.126(b)(2) • 117.135(a) • 117.135(b) • 117.135(c)(1)	16.10.1	Chapters 4 and 6
Identifying and implementing preventive controls for chemical or physical hazards requiring a preventive control	N/A	• 117.126(b)(2) • 117.135(a) • 117.135(b) • 117.135(c)(1) • 117.135(c)(2)	16.10.2.1	Chapters 4, 11, 12, and 13
Identifying and implementing preventive controls that are sanitation controls	N/A	• 117.126(b)(2) • 117.135(a) • 117.135(b) • 117.135(c)(3)	16.10.2.2	Chapter 10
Supply-chain controls	114.100(a)	• 117.126(b)(3) • 117.135(a) • 117.135(c)(4) • Subpart G	16.10.3	Chapters 4 and 15
Recall plan	108.25(e)	• 117.126(b)(4) • 117.135(a) • 117.135(b) • 117.135(c)(5) • 117.139	16.10.4	Chapters 4 and 14
Preventive control management components	• 108.25(c)(3)(ii) • 114.3 • 114.80(a)(2) • 114.80(a)(4) • 114.89 • 114.90	• 117.126(b)(5) • 117.126(b)(6) • 117.126(b)(7) • 117.140 • 117.145 • 117.150 • 117.155 • 117.160 • 117.165	16.11	Chapters 5 and 6

Description of Requirement	Applicable Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	Applicable Requirements in Part 117 (21 CFR)	Applicable Section in This Chapter	Applicable Chapters in This Guidance
Records	• 108.25(g) • 114.100	• 117.9 • 117.126(c) • 117.145(c) • 117.150(d) • 117.155(b) • 117.180(d) • 117.190(a) • 117.475(c) • Subpart F	16.12	Chapter 6
Coding	114.80(b)	N/A	16.13	N/A

16.6 Requirements for Qualifications of Personnel with Responsibility for Supervision or Other Oversight

Part 117 includes requirements for qualifications of personnel, including supervisory personnel (see 21 CFR 117.4). Table 16-3 shows how you can leverage compliance with corresponding training requirements in 21 CFR 108.25(f) and 114.10 to address the requirement of 21 CFR 117.4(c) to provide supervisory oversight for the production of an acidified food product. Note that, in general, satisfying the training requirements of 21 CFR 117.4 would not satisfy the specialized training requirements of 21 CFR 108.25(f) and 114.10.

Table 16-3 Qualifications of Personnel with Responsibility for Supervision or Other Oversight

Requirements in Part 117 (21 CFR)	Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Requirements in Part 117
117.4(c): Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.	108.25(f) and 114.10: All operators of processing and packaging systems shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction.	Satisfactorily completing the prescribed course of instruction in a school specified in 21 CFR 108.25(f) and 114.10 provides an individual with the qualifications necessary to provide supervisory oversight for the production of an acidified food product as required by 21 CFR 117.4(c).

16.7 Requirements for Oversight

The PCHF rule requires preparation or oversight of the food safety plan, and performance or oversight of implementation of certain activities related to the food safety plan, by one or more PCQIs. (See 21 CFR 117.126(a)(2) and 117.180(a).) Table 16-4 shows how you can leverage compliance with corresponding requirements in 21 CFR 108.25(f), 114.10, and 114.83 to address these requirements of the PCHF rule as they relate to acidification.

See Appendix 16-1 in this chapter and the discussion in section 16.6 regarding the specialized training requirements of 21 CFR 108.25(f) and 114.10 for supervisory oversight of processing and packaging of acidified foods. In general, a person who satisfies the qualification requirements of the PCHF rule for a PCQI to prepare, or oversee the preparation of, the food safety plan and to conduct or oversee activities listed in 21 CFR 117.180(a) would not be qualified to supervise the processing and packaging of acidified foods unless that person also satisfies the specialized training requirements of 21 CFR 108.25(f) and 114.10.

Table 16-4 Requirements for Oversight

Requirements in Part 117 (21 CFR)	Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Requirements in Part 117
• 117.126(a)(2): The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals. • 117.180(a): One or more preventive controls qualified individuals must do or oversee certain activities related to preparation and implementation of the food safety plan: ○ 117.160(b)(1) (validation of preventive controls) ○ 117.160(b)(1)(i)(B)(2) (justification for a validation timeframe that exceeds the first 90 days of production) ○ 117.160(c)(5) (justification that validation is not applicable) ○ 117.165(a)(4) (review of records) ○ 117.165(a)(4)(i) (justification for a timeframe that exceeds 7 days for review of certain records) ○ 117.170(c)(2)(ii) (justification for the timeframe for completion of the reanalysis, and validation of additional preventive controls, if the timeframe exceeds 90 days after production)	• 108.25(f) and 114.10: All operators of processing and packaging systems shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. • 114.83 The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods. Under 114.3(e), scheduled process means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority.	• A person who satisfactorily completes the prescribed course of instruction specified in 21 CFR 108.25(f) and 114.10 could, through job experience, be qualified to conduct or oversee the following activities listed in 21 CFR 117.180(a) as they relate to acidification: ○ Review of records (21 CFR 117.165(a)(4); and ○ Justification for a timeframe that exceeds 7 days for review of certain records (21 CFR 117.165(a)(4)(i)) • A person who is a competent processing authority and who establishes the scheduled process in accordance with 21 CFR 114.83 could, through job experience, be qualified to conduct or oversee the following activities listed in 21 CFR 117.180(a) as they relate to acidification and thermal processing of an acidified food: ○ 117.160(b)(1) (validation of preventive controls) ○ 117.160(b)(1)(i)(B)(2) (justification for a validation timeframe that exceeds the first 90 days of production) ○ 117.160(c)(5) (justification that validation is not applicable) ○ 117.165(a)(4) (review of records) ○ 117.165(a)(4)(i) (justification for a timeframe that exceeds 7 days for review of certain records) ○ 117.170(c)(2)(ii) (justification for the timeframe for completion of the reanalysis, and validation of additional preventive controls, if the timeframe exceeds 90 days after production)

16.8 Requirements for a Written Food Safety Plan

The PCHF rule requires that you prepare, or have prepared, and implement a written food safety plan (see 21 CFR 117.126). Neither 21 CFR 108.25 nor part 114 has a corresponding requirement to prepare, or have prepared, and implement a written food safety plan. However, in the remainder of this chapter we explain how you can leverage procedures, practices, and processes that you establish and implement to comply with the requirements of 21 CFR 108.25 or part 114, and records that you establish and keep to comply with those requirements, to address requirements of the PCHF rule for a food safety plan.

16.9 Requirements for Hazard Analysis

Part 117 defines hazard as any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. (See 21 CFR 117.3.) The PCHF rule includes requirements:

- To conduct a hazard analysis, which must be written regardless of its outcome (see 21 CFR 117.130(a));
- For a hazard identification that considers known or reasonably foreseeable hazards that include biological hazards, chemical hazards, and physical hazards, regardless of whether the hazard occurs naturally, is unintentionally introduced, or is intentionally introduced for purposes of economic gain (see 21 CFR 117.130(b)); and
- Applicable to the hazard evaluation (see 21 CFR 117.130(c)).

Neither 21 CFR 108.25 nor part 114 has a corresponding requirement for any requirement of the PCHF rule for hazard analysis. However, 21 CFR 108.25 and part 114 require specific controls for the biological hazard *C. botulinum*, monitoring of one of those controls (i.e., pH), and a basis for the adequacy of the process. (See 21 CFR 114.80(a)(1) and (2) and 21 CFR 108.25(c)(3)(ii), respectively.) In addition, part 114 requires thermal processing to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance. (See 21 CFR 114.80(a)(1).)

A hazard analysis that identifies and evaluates *C. botulinum* as a biological hazard requiring a preventive control can lead to appropriate preventive controls and associated preventive control management components that could address the corresponding requirements of part 114 as they relate to the biological hazard *C. botulinum*. In addition, a hazard analysis that identifies microorganisms (other than *C. botulinum)* of public health significance can lead to appropriate preventive controls and associated preventive control management components that could address the corresponding requirements of part 114 as they relate to the vegetative cells of microorganisms of public health significance other than *C. botulinum*. For example:

- As discussed in section 16.2.1, in the proposed and final rulemakings for LACF and acidified foods FDA discussed the need for CGMP requirements to control *C. botulinum*. Under part

117, a knowledgeable person would identify *C. botulinum* as a biological hazard requiring a preventive control to inactivate vegetative cells of *C. botulinum* and to prevent toxin formation due to germination and growth from spores of *C. botulinum*. A hazard analysis could reference 21 CFR 108.25 and part 114, rather than citations to published scientific literature, as the basis for a conclusion that *C. botulinum* in shelf-stable acidified foods is a hazard requiring a preventive control.

- Part 114 requires that acidified foods be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance. (See 21 CFR 114.80(a)(1).) Under part 117, a knowledgeable person could identify pathogenic bacteria such as *Salmonella, Escherichia coli* (*E. coli*) O157:H7 and *Listeria monocytogenes* (*L. monocytogenes*) as hazards associated with some acidified foods because these pathogenic bacteria can be present on some of the ingredients and can be a hazard if the heat treatment is not adequate to kill vegetative cells of the pathogenic bacteria. (See Appendix 1 of this guidance and the example of the heat processing for a salsa in Chapter 6 of this guidance.)
- Part 114 requires that the scheduled process for an acidified food control microorganisms of non-health significance in addition to pathogens. (See 21 CFR 114.80(a)(1) and Appendix 16-1.) Microorganisms of non-health significance, by themselves, are not "hazards" as that term is defined in part 117. However, as discussed in section 16.3, when critical factors are not carefully controlled, the vegetative cells of some microorganisms of non-health significance (such as some spoilage bacteria) can grow in an acid environment and, in so doing, cause the pH of the food to increase. Therefore, under part 117, a knowledgeable person could identify microorganisms of non-health significance in shelf-stable acidified foods as biological hazards requiring a preventive control.
- The parameters that you submit to us on Form FDA 2541e address critical factors such as control of pH, process time and temperature, and preservatives. (See Form 2541e and 21 CFR 114.80(a)(1).) As discussed in section 16.10.1, identifying pathogenic bacteria such as *C. botulinum, Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* as biological hazards requiring a preventive control, and identifying microorganisms of non-health significance in shelf-stable acidified foods as biological hazards requiring a preventive control, could lead to identifying the parameters that you submit to us on Form FDA 2541e as the preventive controls. As discussed in section 16.11, these parameters for process controls could lead to preventive control management components (such as monitoring pH, and verification that includes validation to establish the adequacy of the process) to address the requirement of 21 CFR 114.80(a)(2) for monitoring pH and the requirement of 21 CFR 108.25(c)(3)(ii) for adequacy of the scheduled process.[7]
- Part 114 requires that testing and examination of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination because there is a potential for recontamination with microorganisms (including pathogens and microorganisms of non-health significance that could raise the pH) if there is a loss of seam/seal integrity, especially during cooling of the sealed containers in water. (See 21 CFR 114.80(a)(4).) The hazard evaluation must consider the effect of packaging activities on the

[7] Although not specified in part 114, preventive control management components for acidified foods generally would include monitoring the thermal process and other critical factors in addition to monitoring pH, and verification activities in addition to validation. See Section 6.16 in Chapter 6 of this for a comprehensive example of preventive control management components for an acidified food.

safety of the finished food for the intended consumer. (See 21 CFR 117.130(c)(2)(vi).) A knowledgeable person would identify microorganisms (including pathogens and microorganisms of non-health significance that could raise the pH) that could recontaminate the food due to lack of container integrity as process-related biological hazards requiring a preventive control. As discussed in section 16.10.1, this outcome of the hazard analysis could lead to a preventive control during seaming/sealing after filling the container (i.e., applying a hermetic seal) to prevent recontamination. As discussed in section 16.11, this preventive control could lead to preventive control management components that include monitoring of seam/seal integrity to address the requirements of 21 CFR 114.80(a)(4).

For help in identifying other known or reasonably foreseeable biological, chemical, or physical hazards applicable to your product, see:

- Chapter 2 of this guidance regarding the hazard analysis;
- Chapter 3 of this guidance regarding hazards associated with the manufacturing, processing, packing, and holding of human food;
- Appendix 1 of this guidance regarding known or reasonably foreseeable (potential) hazards and
- Section 6.16 in Chapter 6 of this guidance regarding heat treatments as a process control, which provides an example of a hazard analysis for a salsa. In this example, a salsa manufacturer identified *Salmonella*, *E. coli* O157:H7, *L. monocytogenes*, and *C. botulinum* as hazards associated with the salsa because these pathogenic bacteria can be present on some of the ingredients and can be a hazard if the salsa is not properly acidified to a pH that is low enough to prevent the germination of spores of *C. botulinum* and if the heat treatment is not adequate to kill vegetative cells of the pathogenic bacteria. In addition, the salsa manufacturer consulted the scientific literature and found that sporeforming bacteria that are generally associated with spoilage (such as *Bacillus subtilis* and *B. licheniformis*) could affect the safety of an acidified food if spores that are not destroyed during the product heat treatment germinate, grow, and cause the pH to increase above 4.6.

16.10 Requirements for Preventive Controls

The PCHF rule includes requirements to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. (See 21 CFR 117.135(a).) Preventive controls must be written. (See 21 CFR 117.135(b).)

16.10.1 Identifying and Implementing Preventive Controls that Are Process Controls for Biological Hazards Requiring a Preventive Control

Table 16-5 shows how you can leverage the parameters that you submit on Form FDA 2541e to address the requirements of the PCHF rule for written preventive controls that are process controls for biological hazards requiring a preventive control. For example, Form FDA 2541e requires information about pH, process time and temperature, and preservatives.[8]

See Appendix 16-1 in this chapter for key additional requirements specific to acidified foods. Table 16-5 also shows how, with some limitations, you can leverage written process controls that you identify and implement for acidification to comply with the requirements of the PCHF rule to address the corresponding requirements in part 114 and Form FDA 2541e (e.g., for control of pH, process time and temperature, and preservatives). However, the requirement in 21 CFR 108.25(c)(2) to submit Form FDA 2541e to FDA has no corresponding requirement in the PCHF rule. You must submit Form FDA 2541e to FDA as required by 21 CFR 108.25(c)(2) even if you include Form FDA 2541e in your food safety plan.

As discussed in section 16.9, one outcome of the hazard analysis could be a preventive control during seaming/sealing after filling the container (i.e., applying a hermetic seal) to prevent recontamination. Although this preventive control has no directly corresponding requirement in 21 CFR 108.25(e) or part 114, there is a related requirement specific to acidified foods. As shown in Appendix 16-1 in this chapter, part 114 requires testing and examination of containers at a frequency that is often enough to ensure that the container suitably protects the food from leakage or contamination. (See 21 CFR 114.80(a)(4).) See the discussion in section 16.11 of how the requirement of part 114 for testing and examination of containers at a frequency that is often enough to ensure that the container suitably protects the food from leakage or contamination could satisfy the requirements of the PCHF rule for monitoring of seam/seal integrity as a preventive control management component for a process control of applying a hermetic seal.

For additional help regarding the requirements of the PCHF rule for process controls for biological hazards requiring a preventive control, see:

- Chapter 4 regarding preventive controls; and
- Section 6.16 in Chapter 6 (regarding heat treatments as a process control), which provides an example of process controls for a salsa.

[8] Note that you must include your process controls in the food safety plan that you keep onsite even though you submit them to FDA on Form FDA 2541e, because the food safety plan must be kept onsite (see 21 CFR 117.315(d)).

Table 16-5 Identifying and Implementing Preventive Controls that Are Process Controls for Biological Hazards Requiring a Preventive Control

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
• Requirements to identify and implement preventive controls that are process controls: ○ 117.135(a) (general requirement) ○ 117.135(c)(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (i) Parameters associated with the control of the hazard; and (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control. • Requirement for written procedures for preventive controls that are process controls: ○ 117.126(b)(2) ○ 117.135(b)	• 108.25(c)(2): Requires the submission to FDA of Form FDA 2541e. Form FDA 2541e requires, as applicable, information about the product, the container type and size, pH, method of acidification, microbial preservatives critical to the scheduled process, process source, process mode, the container and container closure treatment, and details of the scheduled process (e.g., process time and temperature), for each acidified food in each container size. • 108.25(c)(3): Requires a commercial processor engaged in processing acidified foods to process each food in conformity with at least the scheduled processes filed under 21 CFR 108.25(c)(2). • 114.80(a)(1): Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of non-health significance (in lieu of thermal processing). • 114.80(a)(3): Lists acceptable procedures for acidification to attain acceptable equilibrium pH levels in the final food	• The parameters that you establish in accordance with 21 CFR 114.80(a)(1) and submit on Form FDA 2541e could satisfy the requirement for parameters associated with control of a hazard for process controls, and applicable maximum or minimum values in 21 CFR 117.135(c)(1), as long as you include that scheduled process in the food safety plan that is signed and dated by the owner, operator, or agent in charge of the facility and kept onsite (see 21 CFR 117.310 and 117.315(c)). • Compliance with the scheduled process submitted to FDA on Form FDA 2541e could satisfy the requirements in 21 CFR 117.135(a) and (c) to implement preventive controls that are process controls for biological hazards that require a preventive control.	Complying with the PCHF requirements to identify and implement process controls, parameters associated with control of the hazard, and applicable maximum or minimum values that satisfy all requirements in 21 CFR 114.80(a)(1) and all requirements on Form FDA 2541e could satisfy all requirements of 21 CFR 108.25(c)(2) and (3) and part 114 (e.g., for control of pH, process time and temperature, and preservatives), as long as you also submit Form FDA 2541e to FDA.

16.10.2 Preventive Controls That Have No Corresponding Requirements in 21 CFR 108.25 or Part 114

As discussed in sections 16.10.2.1 and 16.10.2.2, the PCHF rule specifies some preventive control requirements that have no corresponding requirements in either 21 CFR 108.25 or part 114.

16.10.2.1 Identifying and Implementing Preventive Controls for Chemical Hazards or Physical Hazards Requiring a Preventive Control

When the hazard requiring a preventive control under part 117 is a chemical or physical hazard, neither 21 CFR 108.25 nor part 114 has a corresponding requirement to identify and implement a preventive control. Preventive controls for chemical or physical hazards could be a process control (see 21 CFR 117.135(c)(1)) or, in the case of a chemical hazard that is a food allergen hazard, a food allergen control (see 21 CFR 117.135(c)(2)).

For help in identifying and implementing preventive controls for known or reasonably foreseeable chemical and physical hazards applicable to acidified foods, see:

- Chapter 4 regarding preventive controls;
- Chapter 11 regarding food allergen controls;
- Chapter 12 regarding preventive controls for chemical hazards; and
- Chapter 13 regarding preventive controls for physical hazards.

16.10.2.2 Identifying and Implementing Preventive Controls That Are Sanitation Controls

Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the: (1) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and (2) prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. (See 21 CFR 117.135(c)(3).) Neither 21 CFR 108.25 nor part 114 has a corresponding requirement to identify and implement a sanitation control.

Complying with part 114 should make it unnecessary to identify and implement sanitation controls for the control of environmental pathogens (such as *L. monocytogenes* or *Salmonella*) for many acidified foods because part 114 requires thermal processing to an extent that is

sufficient to destroy the vegetative cells of microorganisms of public health significance (see 21 CFR 114.80(a)) and because many acidified foods are packaged (e.g., by hot filling) in a way that does not expose the thermally processed food to the environment at a temperature at which environmental pathogens would survive the filling. However, as part of the hazard analysis the PCQI would evaluate whether sanitation controls for the control of environmental pathogens are necessary if a ready-to-eat acidified food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the environmental pathogen) that would significantly minimize the environmental pathogen. (See 21 CFR 117.130(c)(1)(ii).)

Sanitation controls are one way to address food allergen hazards. You determine through your hazard analysis whether food allergen hazards require sanitation controls (which can also be considered food allergen controls, because sanitation controls are procedures to protect food from allergen cross-contact).

For help in determining whether to identify and implement sanitation controls, see:

- Chapter 4 regarding preventive controls; and
- Chapter 10 regarding sanitation controls.

16.10.3 Supply-chain Controls

The PCHF rule requires that a receiving facility establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. (See subpart G and 21 CFR 117.405(a)(1).) Supply-chain controls are not required if the receiving facility (rather than a supplier) will control a hazard requiring a preventive control. For example, supply-chain controls are not required for biological hazards that are controlled by the process controls for an acidified food.

Part 114 requires that records shall be maintained of suppliers' guarantees or certifications that verify compliance with FDA regulations and guidance documents or action levels. (See 21 CFR 114.100(a).) If your hazard analysis for a raw material or other ingredient identifies any hazards requiring a supply-chain-applied control, and your supply-chain program for that raw material or other ingredient includes sampling and testing of that raw material or other ingredient with results reported in documentation such as a Certificate of Analysis, complying with the requirements for supply-chain controls could satisfy the corresponding requirement of 21 CFR 114.100(a) for records of suppliers’ guarantees or certifications. (See 21 CFR 117.410(b)(2) (which identifies sampling and testing of raw materials or other ingredients as an appropriate supplier verification activity) and 21 CFR 117.475(c)(8) (which requires documentation of sampling and testing conducted as a supplier verification activity)).

For help in determining whether to establish and implement a supply-chain program, see:

- Chapter 4 regarding preventive controls; and
- Chapter 15 regarding a supply-chain program.

16.10.4 Recall Plan

The PCHF rule requires a recall plan for food with a hazard requiring a preventive control. (See 21 CFR 117.139.) Table 16-6 shows how you can leverage procedures, practices, and processes that you establish and implement to comply with corresponding requirements in 21 CFR 108.25(e) to address the requirements of the PCHF rule for a recall plan.

Table 16-6 also shows how, with one limitation, you can leverage a written recall plan that you establish and implement to comply with the requirements of the PCHF rule to address the corresponding requirements in 21 CFR 108.25(e) regarding recalls. However, the requirement in 21 CFR 108.25(e) for the recall procedures to include notifying FDA of any recalls has no corresponding requirement in the PCHF rule for a recall plan. Therefore, a written recall plan that you establish and implement to comply with the requirements of the PCHF rule could only satisfy all requirements of 21 CFR 108.25(e) regarding recalls if it also includes procedures for notifying FDA of any recalls.

For help regarding the recall plan, see:

- Chapter 4 regarding preventive controls; and
- Chapter 14 regarding the recall plan.

Table 16-6 Recall Plan

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
• Requirements to identify and implement preventive controls: ○ 117.135(a) (general requirement) ○ 117.135(c)(5) (recall plan) ○ 117.139 (recall plan) • Requirement for written procedures for preventive controls: ○ 117.126(b)(4) ○ 117.135(b)	108.25(e): A commercial processor engaged in the processing of acidified foods shall prepare and maintain files on a current procedure for use for products under the processor's control, which that processor will ask the distributor to follow, including plans for recalling products that may be injurious to health; for identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls; for notifying FDA of any recalls; and for implementing recall programs.	A written recall procedure that you establish and implement to comply with 21 CFR 108.25(e) could satisfy all requirements of the PCHF rule for a recall plan, as long as it includes procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility: • Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food; • Notify the public about any hazard presented by the food when appropriate to protect public health; • Conduct effectiveness checks to verify that the recall is carried out; and • Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food.	A written recall plan that you establish and implement to comply with 21 CFR 117.139 could satisfy the requirements of 21 CFR 108.25(e), as long as it includes procedures for notifying FDA about any recall.

16.11 Requirements for Preventive Control Management Components

With some exceptions, the preventive controls required by the PCHF rule are subject to the following preventive control management components as appropriate to ensure the

effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

- Monitoring in accordance with 21 CFR 117.145;
- Corrective actions and corrections in accordance with 21 CFR 117.150; and
- Verification in accordance with 21 CFR 117.155.

(See 21 CFR 117.140.) The exceptions to these requirements for preventive control management components are:

- The supply-chain program is subject to a subset of the preventive control management components (i.e., corrective actions and corrections in accordance with 21 CFR 117.150, review of records in accordance with 21 CFR 117.165(a)(4), and reanalysis in accordance with 21 CFR 117.170). (See 21 CFR 117.140(b).)
- The recall plan is not subject to the requirements for preventive control management components. (See 21 CFR 117.140(c).)

Table 16-7 lists most[9] of the specific provisions of the PCHF rule for establishing and implementing preventive control management components, including the requirements for written procedures for the preventive control management components. Table 16-7 also lists the corresponding requirements in part 114. Table 16-7 shows how you can leverage procedures, practices, and processes that you establish and implement to comply with 21 CFR 114.80(a)(2), 114.80(a)(4), or 114.89, or that are listed in 21 CFR 114.90, to address the requirements of the PCHF rule for preventive control management components. To see how you can leverage records documenting compliance with recordkeeping requirements of part 114 to address the corresponding requirements for records documenting implementation of the preventive control management components, see Table 16-8.

Table 16-7 also shows how you can leverage the preventive control management components that you implement to satisfy the requirements of the PCHF rule to address the corresponding requirements in 21 CFR 114.80(a)(2), 114.80(a)(4), and 114.89. To see how you can leverage records documenting implementation of the preventive control management components to address corresponding recordkeeping requirements of part 114, see Table 16-8.

See also Appendix 16-1 in this chapter for key additional requirements specific to acidified foods. The emergency permit control regulations require that you provide FDA with any process and procedure information that we deem necessary to determine the adequacy of the process upon request. (See 21 CFR 108.25(c)(3)(ii).) The requirements of the PCHF rule applicable to validation of preventive controls correspond to the requirements of 21 CFR 108.25 and part 114 for the adequacy of the scheduled process, and we ordinarily will review records applicable to

[9] See Table 16-8 for the records documenting implementation of the preventive control management components.

process validation during inspection. However, as required by 21 CFR 108.25(c)(3)(ii) you must send us any process and procedure information that we deem necessary to determine the adequacy of the process if we ask you to do so (e.g., as a follow-up to your submission of a scheduled process on Form FDA 2541e).

For help regarding preventive control management components, see:

- Chapter 5 regarding preventive control management components; and
- Chapter 6 regarding heat treatments as a process control.

Table 16-7 Preventive Control Management Components

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
• Requirements to establish and implement preventive control management components: ○ 117.140 ○ 117.145 (monitoring) ○ 117.150 (corrective actions and corrections) ○ 117.155 (verification) ○ 117.160 (validation) ○ 117.165 (verification of implementation and effectiveness) ○ 117.165(a)(1) (calibration) ○ 117.165(a)(2) (product testing) ○ 117.165(a)(3) (environmental monitoring) ○ 117.165(a)(4) (review of records) • Requirement for written procedures for preventive control management components: ○ 117.126(b)(5) and 117.145(a) (monitoring) ○ 117.126(b)(6) and 117.150(a)(1) (corrective action procedures) ○ 117.126(b)(7) and 117.165(b) (verification) ○ 117.165(b)(1) (calibration) ○ 117.165(b)(2) (product testing) ○ 117.165(b)(3) (environmental monitoring)	• 108.25(c)(3)(ii) Provide us with any process and procedure information that we deem necessary to determine the adequacy of the process • 114.3(e): Scheduled process means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. • 114.80(a)(2) Exercise of sufficient control, including frequent testing and recording of results, so that the finished equilibrium pH values for acidified foods are not higher than 4.6 • 114.80(a)(4) Testing and examination of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination. • 114.89 (deviations from scheduled processes) • 114.90 (methodology)	• Complying with 21 CFR 114.80(a)(2) could satisfy the requirements of the PCHF rule for monitoring pH as a preventive control management component for pH control as a process control. • Complying with 21 CFR 114.80(a)(4) could satisfy the requirements of the PCHF rule for monitoring seam/seal integrity of finished product as a preventive control management component when applying a hermetic seal is a process control. • Written procedures that you establish and implement to comply with the requirements of 21 CFR 114.80(a)(2) and (a)(4) could satisfy the requirements of 21 CFR 117.126(b)(5) and 117.145(a) for written monitoring procedures. • Written procedures that you establish and implement to comply with the requirements of 21 CFR 114.89 could satisfy the requirements of 21 CFR 117.126(b)(6) and 117.150(a)(1) for written corrective action procedures as appropriate to the nature of the hazard and the nature of the preventive control. • Written procedures that you establish and implement to comply with 21 CFR 114.90 could satisfy some requirements of the PCHF rule for written procedures for preventive control management components (e.g., written procedures for monitoring or calibration of equipment).	• Complying with the requirements of 21 CFR 117.145 for monitoring preventive controls for (1) pH and (2) applying a hermetic seal could satisfy the requirements of 21 CFR 114.80(a)(2) and (a)(4), respectively. • Complying with the requirements of 21 CFR 117.150 to establish and implement corrective action procedures could satisfy the requirements of 21 CFR 114.89 for deviations from scheduled processes. • Complying with the requirements of 21 CFR 117.155 and 117.160 for process validation would be consistent with the definition of "scheduled process" in 21 CFR 114.3, but you still must submit information about the adequacy of the process to FDA upon request as required by 21 CFR 108.25(c)(3)(ii).

16.12 Requirements for Records

Subpart A of part 117 requires that food establishments establish and maintain records that document required training. (See 21 CFR 117.9.) Subparts C and G of part 117 require that you have a written food safety plan (see 21 CFR 117.126), records documenting implementation of the food safety plan (see 21 CFR 117.190), and records documenting the supply-chain program (see 21 CFR 117.475(c)).

Subpart F of part 117 includes requirements applicable to all records required by part 117. For example:

- The owner, operator, or agent in charge of the facility must sign and date the food safety plan (21 CFR 117.310);
- Part 117 allows you to use existing records, supplemented as necessary to include all required information (§ 117.330(a)); and
- Part 117 does not require that records be kept in one set of records. If existing records contain some of the required information, any new information required by the PCHF rule may be kept either separately or combined with the existing records (§ 117.330(a)).

Table 16-8 shows how you can leverage compliance with the recordkeeping requirements of 21 CFR 108.25(g) and 114.100(a) through (c) to address the recordkeeping requirements of the PCHF rule. Table 16-8 also shows how you can leverage compliance with the recordkeeping requirements of the PCHF rule to address the corresponding requirements in 21 CFR 114.100(a), (b), and (c).[10]

See Appendix 16-1 in this chapter for key additional requirements specific to acidified foods. Importantly:

- The regulations in 21 CFR 108.25 and part 114 each have a recordkeeping requirement that exceeds the corresponding recordkeeping requirement in part 117. Specifically, the regulations in 21 CFR 108.25 and part 114 require that you keep records required by part 114 for 3 years, which exceeds the maximum 2-year record retention requirement in part 117. (See 21 CFR 108.25(g), 114.100(e), and 117.315.)
- Part 114 requires records of distribution. (See 21 CFR 114.100(d).) Part 117 does not have a corresponding recordkeeping requirement. However, compliance with 21 CFR 114.100(d) could satisfy some requirements of 21 CFR 1.345 in part 1, subpart J (Establishment, Maintenance, and Availability of Records) for the identity of the immediate, subsequent recipients of food; likewise, compliance with the requirements of 21 CFR 1.345 in part 1, subpart J for the identity of the immediate, subsequent recipients of food could satisfy the requirements in 21 CFR 114.100(d) for records of distribution of acidified foods.

[10] See also the discussions in sections 16.6 through 16.10 for limitations on whether complying with the requirements of 21 CFR 108.25 and part 114 can address the requirements of part 117 and vice versa.

For help regarding the recordkeeping requirements of the PCHF rule for acidified foods, see section 6.16 in Chapter 6 regarding heat treatments as a process control, which provides an example of records documenting implementation of the food safety plan for a salsa.

Table 16-8 Records

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114

• 117.9 (training)
• 117.126(c): Food safety plan
• 117.190(a): Implementation records, including records documenting:
  ○ Basis for not establishing a preventive control (117.136(b))
  ○ Monitoring (117.145(c))
  ○ Corrective actions and corrections (117.150(d))
  ○ Verification (117.155(b))
  ○ Supply-chain program (117.475(c))
  ○ Training of PCQI) (117.180(d))
• Subpart F:
  ○ 117.301 (Applicability)
  ○ 117.305 (General requirements)
  ○ 117.310 (Food safety plan)
  ○ 117.315 (Record retention)
  ○ 117.320 (Official review)
  ○ 117.325 (Public disclosure)
  ○ 117.330 (Use of existing records)
  ○ 117.335 (Special requirements for written assurance)
	• 114.100(a): Records of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications
	• 114.100(b): Processing and production records, including records of pH measurements and other critical factors intended to ensure a safe product
	• 114.100(c): All departures from scheduled processes having a possible bearing on public health or the safety of the food
	• 114.100(d): Records identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use
	• 108.25(g) and 114.100(e): Records shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture.
	• 108.25(f) and 114.10: All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner and who has been identified by that school as having satisfactorily completed the prescribed course of instruction.
		• Records demonstrating compliance with 21 114.100(a) could satisfy the requirements of 21 CFR 117.475(c)(8) for sampling and testing records applicable to a supply-chain program, if your supply-chain program identifies any hazards requiring a supply-chain applied control.
		• Records demonstrating compliance with 21 CFR 114.100(b) could satisfy:
		  ○ The requirements of 21 CFR 117.145(c) for records of monitoring pH as a preventive control management component for pH control as a process control.
		  ○ The requirements of 21 CFR 117.145(c) for records of monitoring when monitoring seam/seal integrity of finished product is a preventive control management component for the scheduled process.
		• Records demonstrating compliance with 21 CFR 114.100(c) could satisfy some requirements of 21 CFR 117.150(d) for records of corrective actions and corrections.
			• If your supply-chain program identifies any hazards requiring a supply-chain applied control, records that comply with 21 CFR 117.475(c)(8) could satisfy corresponding requirements in 21 CFR 114.100(a) for records of suppliers' guarantees or certifications.
			• Monitoring records that comply with 21 CFR 117.145(c) could satisfy corresponding requirements in 21 CFR 114.100(b) for records of pH measurements and other critical factors.
			• Corrective action records that comply with 21 CFR 117.150(d) could satisfy corresponding requirements in 21 CFR 114.100(c) for records of all departures from scheduled processes having a possible bearing on public health or the safety of the food.

16.13 Requirements for Coding

Part 114 requires that each container or product be marked with an identifying code permanently visible to the naked eye. (See 21 CFR 114.80(b) for the complete requirements.) There is no corresponding requirement for coding in the PCHF rule. You must comply with all requirements for coding in 21 CFR 114.80(b) even though there is no corresponding requirement for coding in the PCHF rule.

16.14 References

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Appendix 16-1 Key Specific Acidified Food Requirements

The requirements of 21 CFR 108.25 and part 114 include some requirements that either have no explicitly corresponding requirement in part 117 or exceed the corresponding requirement in part 117. Appendix Table 16-1-1 lists the key additional requirements specific to acidified foods and, when applicable, resources that are available to help you comply with those additional requirements.

Appendix Table 16-1-1 Key Specific Acidified Food Requirements

Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Submit food canning establishment registration to FDA using Form FDA 2541	21 CFR 108.25(c)(1)	Registering your establishment as a food canning establishment using Form FDA 2541 (as required by 21 CFR 108.25(c)(1)) is in addition to registering your food facility using Form FDA 3537 (as required by 21 CFR Part 1, Subpart H)	• FDA, 2016 • FDA, 2018

Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Submit scheduled process to FDA using Form FDA 2541e	21 CFR 108.25(c)(2)	See the discussion in section 16.10.1. Although you can leverage Form FDA 2541e to address the requirements of the PCHF rule for written process controls for biological hazards requiring a preventive control, including Form FDA 2541e in the food safety plan that you keep onsite does not affect your responsibility to submit Form FDA 2541e to FDA.	FDA, 2016
Provide FDA with information about the scheduled process and procedure upon FDA's request	21 CFR 108.25(c)(3)(ii)	See the discussion in section 16.11. The requirements of the PCHF rule applicable to validation of preventive controls correspond to the requirements of 21 CFR 108.25 and part 114 for the adequacy of the scheduled process, and we ordinarily will review records applicable to process validation during inspection. However, as required by 21 CFR 108.25(c)(3)(ii), you must send us any process and procedure information that we deem necessary to determine the adequacy of the process if we ask you to do so (e.g., as a follow-up to your submission of a scheduled process on Form FDA 2541e).	N/A

Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Notify FDA about problems when food is in commerce	21 CFR 108.25(d) (problems include spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance)	Notifying FDA about problems when an acidified food is in commerce is in addition to your responsibility to report problems to the Reportable Food Registry (when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals)	• FDA, 2009 • FDA, 2010
Recall procedure that incudes plans for notifying FDA of any recalls	21 CFR 108.25(e)	See the discussion in section 16.10.4. Although a plan for notifying FDA of any recalls is not required by the PCHF rule, including a plan for notifying FDA of any recalls in the written recall plan that you establish in accordance with 21 CFR 117.139 could also satisfy the requirements of 21 CFR 108.25(e) for a recall procedure.	FDA, 2003
Satisfactory completion of the prescribed course of instruction in a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification	• 21 CFR 108.25(f) • 21 CFR 114.10	See the discussions in sections 16.6 and 16.7. Satisfactorily completing the prescribed course of instruction in a school specified in 21 CFR 108.25(f) and 114.10 may not provide an individual with all qualifications applicable to supervisory personnel as required by 21 CFR 117.4 or all qualifications applicable to a PCQI as required by 21 CFR 117.180(c)(1).	N/A

Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
The scheduled process for an acidified food must control microorganisms of non-health significance in addition to pathogens.	21 CFR 114.80(a)	See the discussion in sections 16.9 and 16.10.1, and 16.11. Microorganisms of non-health significance, by themselves, are not "hazards" as that term is defined in part 117. However, when critical factors are not carefully controlled, the vegetative cells of some microorganisms of non-health significance (such as some spoilage bacteria) can grow in an acid environment and, in so doing, cause the pH of the food to increase. Therefore: • A knowledgeable person could identify microorganisms of non-health significance in shelf-stable acidified foods as biological hazards requiring a preventive control. • The preventive control could be the scheduled process that you submit to us on Form FDA 2541e. • The preventive control management components could be monitoring pH and validation that establishes the adequacy of the process.	N/A
Records of distribution	21 CFR 114.100(d)	Compliance with 21 CFR 114.100(d) could satisfy some requirements of 21 CFR 1.345 in part 1, subpart J (Establishment, Maintenance, and Availability of Records) for the identity of the immediate, subsequent recipients of food	FDA, 2012

Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Record retention for 3 years	• 21 CFR 108.25(g) • 21 CFR 114.100(e)	See the discussion in section 16.12. The regulations in 21 CFR 108.25 and part 114 each have a recordkeeping requirement that exceeds the corresponding recordkeeping requirement in part 117.	N/A
Coding	21 CFR 114.80(b)	See the discussion in section 16.13. Part 114 requires that each container or product be marked with an identifying code permanently visible to the naked eye; there is no corresponding requirement for coding in the PCHF rule.	N/A

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Chapter 17: Classification of Food as Ready to Eat or Not Ready to Eat (Coming Soon)

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Appendix 1: Potential Hazards for Foods and Processes

Appendix Organization

This appendix contains information on the potential biological, chemical, and physical hazards that are food-related and process related. The potential hazard information presented covers the following 17 food (including ingredients and raw materials) categories:

- Bakery
- Beverage
- Chocolate and Candy
- Dairy
- Dressings and Condiments
- Egg
- Food Additives
- Fruits and Vegetables
- Game Meat
- Grains
- Multi-Component Foods (such as a refrigerated entrée or a sandwich)
- Nuts
- Oil
- Snack Foods

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Appendix 1 that we issued for public comment in August 2016.

- Soups
- Spice
- Sweeteners

To help you to identify food-related and process-related hazards for the food categories listed above, this appendix contains three series of tables:

- **Tables 1A** through **1Q** contain information that you should consider for potential food-related biological hazards.
- **Tables 2A** through **2Q** contain information that you should consider for potential food-related chemical hazards.
- **Tables 3A** through **3Q** contain information that you should consider for potential process-related biological, chemical and physical hazards.

How to Use the Tables in Appendix 1

Information provided in each table is organized to describe:

- Food Categories
- Food Subcategories
- Hazards
- Example Products

Potential hazards that you should consider for each food subcategory are indicated by an "X" in the column for the hazard being assessed.

The tables in Appendix 1 encompass more than 200 pages. To reduce the printed size of this document (which includes all of the available chapters in this guidance), we have not included those tables. To access the tables in Appendix 1, see the separate Appendix 1 (complete with tables).

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Appendix 2: Food Safety Plan Forms

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FSPCA Food Allergen Control Forms

- Form 2-E: FSPCA Form for Food Allergen Ingredient Analysis
- Form 2-F: FSPCA Form for Food Allergen Label Verification List
- Form 2-G: FSPCA Form for Production Line Food Allergen Assessment
- Form 2-H: FSPCA Form for Food Allergen Controls

Form 2-I: FSPCA Form for Supply-chain-applied Preventive Controls Program

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Appendix 2 that we issued for public comment in August 2016.

Introduction

We recommend that you use worksheets to document the:

- Product description;
- Hazard analysis;
- Process controls;
- Sanitation controls; and
- Food allergen controls.

There is no standardized or mandated format for documenting the food safety plan. However, in this appendix we refer you to worksheets that were developed by Food Safety Preventive Controls Alliance (FSPCA). We recommend that you use forms such as these for documenting your food safety plan for two reasons: (1) These worksheets are used in training by the FSPCA and, thus, you will be familiar with these forms if you take this training; and (2) these worksheets are similar to forms used in documenting Hazard Analysis and Critical Control Point (HACCP) plans and prerequisite programs and, thus, these worksheets may be similar to forms you are already using.

The FSPCA makes these forms available on its website at https://www.ifsh.iit.edu/sites/ifsh/files/departments/fspca/pdfs/FSPCA_Ap2_Worksheets__V1.1_Fillable.pdf. In this Appendix, we have modified the format of FSPCA's forms for consistency with the formats we use for making documents accessible for persons using assistive technology such as a screen reader. You may obtain the current copy of FSPCA's forms from its website.

In general, regardless of whether you use these worksheets, we recommend that you arrange the information in your food safety plan in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan. For example:

- Your hazard analysis should contain information to justify:
  - Your identification of each hazard requiring a preventive control; and
  - The types of preventive controls applied;
- You should explain the details for each preventive control.

Other formats are entirely acceptable if they work for your organization. If you use another format, you should ensure that your format provides all of the information that the preventive controls rule requires for each required component of the food safety plan. See 21 CFR 117.126, 117.305, and 117.310.

Each FSPCA form has a form name, but does not have an identifying number. In this Appendix, we number each FSPCA form (Form 2-A, Form 2-B, etc.) to have a concise identifier for each form.

Form 2-A: FSPCA Form for Product Description

In Chapter 2 of this guidance, we recommend that you conduct certain preliminary steps before conducting your hazard analysis. One of these preliminary steps is to describe the product, its distribution, intended use, and consumer or end user of the product. The product description form that is commonly used in the development of HACCP plans can be used to do so. See Form 2-A.

Below, we list the information that you will see on Form 2-A. When appropriate for clarity, we explain what type of information you would include for the listed information. Regardless of whether you use Form 2-A, we recommend that you include such information in any product description that you develop.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Product Name: i.e., the full name of the finished product.
- Product Description, including Important food safety characteristics – i.e., descriptors such as ready-to-eat (RTE), frozen; factors that can influence growth of pathogens, such as whether the food has a low pH or a_w or contains preservatives.
- Ingredients.
- Packaging Used: e.g., type (bottle, box, can); material (plastic, glass, cardboard with liner); reduced oxygen packaging.
- Intended Use: e.g., intended for retail, foodservice, or further processing; whether the food is ready-to-eat or ready-to-cook by the consumers; and what the potential is for mishandling or unintended use.
- Intended Consumers: usually the general public; however, if a food product is intended specifically for susceptible populations such as hospitals, you should say so.
- Shelf Life.
- Labeling Instructions Related to Safety: e.g., "keep refrigerated" or cooking instructions.
- Storage and Distribution: e.g., whether the food is stored and/or distributed refrigerated, frozen or at ambient temperatures.

FORM 2-A PRODUCT DESCRIPTION

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Product Name(s)	
Product Description, including Important Food Safety Characteristics	
Ingredients	
Packaging Used	
Intended Use	
Intended Consumers	
Shelf Life	
Labeling Instructions related to Safety	
Storage and Distribution	

Approved: (signature or initials)_____

Date: _____

Form 2-B: FSPCA Form for Hazard Analysis

In Chapter 2 of this guidance, we explain how to set up an adaptation of the "Hazard Analysis Worksheet" used in HACCP systems to organize your hazard analysis. See Form 2-B. Note that for brevity Form 2-B uses the term "potential hazard" rather than "known or reasonably foreseeable hazard."

See section 2.2.2 in Chapter 2 for an overview of how to set up columns 1-6 of Form 2-B. See the remainder of Chapter 2 for more detail about how to provide information on Form 2-B. Regardless of whether you use Form 2-B, we recommend that you include such information in your hazard analysis.

FORM 2-B HAZARD ANALYSIS*

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

(1) **Ingredient / Processing Step**	(2) **Identify potential food safety hazards introduced, controlled or enhanced at this step** B = biological C = chemical, including radiological P = physical	(3) **Are any potential food safety hazards requiring preventive control? (Yes/No)**	(4) **Justify your decision for column 3**	(5) **What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard?** *Process including CCPs, Allergen, Sanitation, Supplier, other preventive control*	(6) **Is the preventive control applied at this step? (Yes/No)**

* The current FSPCA form includes some additional features, such as a separate column for “Yes” and “No” responses and a separate row at each step for biological, chemical, and physical hazards (labeled B, C, and P, respectively).

Form 2-C: FSPCA Form for Process Controls

Chapter 5 of this guidance provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. Chapter 5 also provides an overview of preventive control management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)). When the preventive control that you identify is a process control, Form 2-C provides a format for you to specify the process control and the associated preventive control management components.

Below, we list the information that you will see on Form 2-C. When appropriate for clarity, we explain what type of information you would include for the listed information. Regardless of whether you use Form 2-C, we recommend that you include such information in your food safety plan when you will implement a process control.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Process Control: From the Hazard Analysis form, enter the steps identified as requiring a process control
- Hazard(s): From the Hazard Analysis form, enter the hazard requiring a preventive control at each step listed in the "Process Control" column.
- Parameters, values, or critical limits: Enter the parameters, and the associated minimum or maximum value (or critical limits) associated with the parameters.
- Monitoring: In the columns provided, enter what will be monitored, how it will be monitored, the frequency that the monitoring will be done and who will do the monitoring (e.g., the position, such as "operator" or "QA technician").
- Corrective Actions: Describe the corrective actions that will be taken when deviations from the minimum/maximum values (or critical limits) for a parameter occur.
- Verification: List the ongoing verification activities, including calibration (where appropriate) and records review. Although the form was designed to focus on ongoing verification activities, rather than data and information addressing validation, you also can list information such as a validation study on FSPCA Form 2-C if you find it useful to do so.
- Records: List the names of the records that result from implementation of the process controls (e.g., cook log, cooling records, metal detector check log).

FORM 2-C PROCESS CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Process Control Step	Hazard(s)	Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Process Control Step	Hazard(s)	Critical Limits	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Form 2-D: FSPCA Form for Sanitation Controls

The forthcoming Chapter 10 of this guidance will address sanitation controls, which can vary substantially from facility to facility. When the preventive control that you identify is a sanitation control, Form 2-D provides a format for you to specify the sanitation control and the associated preventive control management components. Although Form 2-D may not always be the most effective way to describe the many sanitation controls that may be employed, you may find Form 2-D helpful to summarize cleaning and sanitizing of a particular piece of equipment or particular locations in your plant where product is exposed to the environment.

Below, we list the information that you will see on Form 2-D. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Location: Enter the location(s) in the plant where the sanitation control described on Form 2-D will be used.
- Purpose: e.g., to remove food allergens, to reduce contamination with environmental pathogens
- Frequency: How often the procedure is used (e.g., daily; after each production run; weekly;)
- Who: i.e., the position, such as "sanitation technician" or "sanitation supervisor"
- Procedure: You can write the procedure on the form or refer to a specific Standard Operating Procedure (SOP). Procedures can include cleaning procedures and monitoring procedures, such as measuring sanitizer concentration.
- Corrections (Corrective Actions Where Appropriate) - e.g., recleaning equipment that is not visibly clean prior to production. In most cases, corrections are appropriate. However, you may want to include circumstances that would trigger corrective actions.
- Records: the type of records you will maintain.
- Verification activities (such as records review) and the type of records maintained are listed.

FORM 2-D SANITATION CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Location	
Purpose	
Frequency	
Who	
Procedure	
Monitoring	
Corrections (Corrective actions where necessary)	
Records	

Verification: (signature or initials)_____

Date: _____

FSPCA Food Allergen Control Forms

Chapter 5 of this guidance provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. Chapter 5 also provides an overview of preventive control management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)). Our forthcoming Chapter 11 - Food Allergen Controls will provide a comprehensive guide to food allergen control.

When the preventive control that you identify is an allergen control, the FSPCA forms that we identify as Forms 2-E, 2-F, 2-G, and 2-H provide a format for you to specify the allergen control and the associated preventive control management components.

- Form 2-E: FSPCA form for Food Allergen Ingredient Analysis. Use for conducting an allergen-specific hazard analysis of food ingredients.
- Form 2-F: FSPCA form for Food Allergen Label Verification List. Use to list the specific allergens to be listed in the "Contains" declaration on the product label.
- Form 2-G: FSPCA form for Production Line Food Allergen Assessment. Use to identify common and unique food allergens for products produced on a production line for the purpose of making decisions on scheduling (e.g., run unique allergens last) and allergen cleaning information (e.g., conduct a full allergen cleaning before running products without the allergen)
- Form 2-H: FSPCA form for Food Allergen Controls. Use to describe any food allergen controls and associated preventive control management components.

Regardless of whether you use these FSPCA Food Allergen forms, we recommend that you conduct a food allergen ingredient analysis and include information such as you see in Form 2-E in your food safety plan. if your food allergen ingredient analysis identifies food allergens that will be (or may be) in your products, we recommend that you include information such as you see in the remaining FSPCA forms in your food safety plan.

Form 2-E: FSPCA Form for Food Allergen Ingredient Analysis

Below, we list the information that you will see on Form 2-E. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Raw Material Name: List all raw materials received in the facility
- Supplier: Identify the supplier for each raw material
- Food Allergens in Ingredient Formulation: Identify any food allergens in each listed raw material – e.g., by reviewing ingredient labels or contacting the manufacturer
- Food Allergens in Precautionary Labeling: List any allergens listed in precautionary labeling (such as a "May Contain" statement) in raw materials that you receive

FORM 2-E FOOD ALLERGEN INGREDIENT ANALYSIS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Food Allergens in Ingredient Formulation or in Precautionary Labeling

Raw Material Name	**Supplier**	**Egg**	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)	**Food Allergens in Precautionary Labeling**

Form 2-F: FSPCA Form for Food Allergen Label Verification List

Below, we list the information that you will see on Form 2-F. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Product: List each product that will contain (or may contain) a major food allergen
- Allergen Statement: Specify the "Contains" statement that you will include on the product label for that product.

FORM 2-F FOOD ALLERGEN LABEL VERIFICATION LIST

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Product	**Allergen Statement**
	Contains:
	Contains:
	Contains:
	Contains:

Form 2-G: FSPCA Form for Production Line Food Allergen Assessment

Below, we list the information that you will see on Form 2-G. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Product Name: List each product made in the plant
- Production Line: Identify the production line used for each listed product
- List the allergens that you will add to the listed product, including any allergens listed in precautionary labeling if you determine there is the potential for these to contaminate the line.

FORM 2-G PRODUCTION LINE FOOD ALLERGEN ASSESSMENT

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Product Name	**Production Line**	**Egg**	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)

Form 2-H: FSPCA Form for Food Allergen Controls

The FSPCA Food Allergen Control Form (Form 2-H) is modeled after the FSPCA Process Controls Form (Form 2-C). Below, we list the information that you will see on Form 2-H. When appropriate for clarity, we explain what type of information you would include for the listed information.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Allergen Control Step: Describe the step at which the allergen control is being applied e.g., at label receipt or label application for label controls; at post-production sanitation for equipment cleaning.
- Hazard: e.g., undeclared allergen due to incorrect label; undeclared allergen due to cross-contact.
- Criterion: Specify the criterion you are trying to meet, e.g., all finished product labels declare the allergens in the product.
- Monitoring; In the columns provided, enter what will be monitored (e.g., the label ingredient declaration), how it will be monitored (e.g., the label will be visually checked and compared to the product formulation), the frequency that the monitoring will be done (e.g., each new order of labels before they are released to production), and who will do the monitoring (e.g., label coordinator).
- Corrective Actions: In some cases, corrections will be appropriate. However, you should include circumstances that would trigger corrective actions.
- Verification: List the verification activities, such as records review.
- Records: List the names of the records that result from implementation of the food allergen controls (e.g., label review log).

FORM 2-H FOOD ALLERGEN CONTROLS

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Allergen Control Step	Hazard(s)	Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Allergen Control Step	Hazard(s)	Criterion	What to Monitor	How to Monitor	Frequency of Monitoring	Who Monitors	Corrective Action	Verification	Records

Form 2-I: FSPCA Form for Supply-chain-applied Preventive Controls Program

Chapter 5 of this guidance provides an overview of the application of preventive controls to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards in finished foods and the food production environment. Chapter 5 also provides an overview of preventive control management components (i.e., monitoring, corrective actions and corrections, and verification activities (and their associated records)). Our forthcoming Guidance for Industry, Supply-Chain Programs, Draft Guidance, will provide a comprehensive guide to supply-chain controls.

When the preventive control that you identify is a supply-chain control, Form 2-I provides a format for you to specify the preventive control and the associated preventive control management components appropriate for a supply-chain program. You would use a separate form for each ingredient that would have a supply-chain program control. Below, we list the information that you will see on Form 2-I. When appropriate for clarity, we explain what type of information you would include for the listed information. Regardless of whether you use Form 2-I, we recommend that you include such information in your food safety plan when you will implement a supplier control.

- General information such as the name and address of the plant, the issue date of the form and the old version ("supersedes"), the page number (often "Page X of Y").
- Hazards requiring a supply-chain-applied control: List each hazard requiring a preventive control
- Preventive controls applied by the supplier: When applicable, list any preventive controls applied by the supplier
- Verification activities: List the verification activities you will conduct – i.e., onsite audits; sampling and testing of the raw material or other ingredient; review of the supplier's relevant food safety records; and other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.
- Verification procedures: e.g., procedures for receiving raw materials and other ingredients; audit procedures
- Records: e.g., records documenting receipt from an approved supplier, records documenting review of supplier verification activities

Form 2-I: Supply-chain-applied Preventive Controls Program

PAGE _____

PRODUCTS: _____
PLANT NAME: _____
ADDRESS: _____
ISSUE DATE: (mm/dd/yy)_____
SUPERSEDES: (mm/dd/yy)_____

Determination of Verification Procedures

Ingredient:

Hazards requiring a supply-chain-applied control	
Preventive controls applied by the supplier	
Verification activities	
Verification procedures	
Records	

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient (requiring supply-chain-applied control)	**Approved Supplier**	**Hazard(s) requiring supply-chain-applied control**	**Date of Approval**	**Verification method**	**Verification records**

Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

[Document procedures used for receiving ingredients requiring a supply-chain-applied control.]

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting your question at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan.

Appendix 3: Bacterial Pathogen Growth and Inactivation

This appendix contains information on the growth and inactivation of bacterial pathogens. The tables in this appendix derive from our guidance entitled "Fish and Fishery Products Hazards and Controls Guidance." In these tables, and our discussion of these tables, we use the technical terms "D-value" and "z-value," which we briefly describe immediately below. For additional information about what these terms mean and how you can use the information in these tables to determine appropriate processing conditions for your product, you should consult standard food processing books and technical information.

- D-value: The relationship between the duration of a thermal treatment and the percentage of microorganisms surviving the treatment is generally logarithmic, and the results of such studies are usually presented in a plot that represents the log of the percent of surviving vegetative cells or spores versus time at a given temperature. The time required to destroy 90 percent of the vegetative cells or spores at a given temperature is called the decimal reduction time, usually referred to as the "D-value" (Larousse and Brown, 1997). The D-value usually varies inversely with temperature.
- z-value: In general, the slope of a plot of the log of the D-value versus temperature is approximately linear. A "z-value" is derived from the reciprocal of the slope of the best straight line and is equal to the increase in the number of degrees (from a given starting temperature) that results in a 90 percent reduction in the D-value (Larousse and Brown, 1997). The D-value and z-value for the vegetative cells or spores of a microbial strain at a specified temperature characterize its thermal resistance at that temperature. Therefore, D-values and z-values provide a means to compare the thermal resistance of different microorganisms, or different strains of the same microorganism, at one or more temperatures.

Table 3-A contains information on the minimum water activity (a_w), minimum and maximum pH, and minimum and maximum temperatures that limit growth for the bacterial pathogens that are of greatest concern in food processing. Table 3-A also provides data on the maximum water

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. Underlined text in yellow highlights represents a correction from the draft Appendix 3 that we issued for public comment in August 2016.

phase salt that limits growth and the oxygen requirements for the pathogens listed. The data shown in Table 3-A are the extreme limits reported among the references cited. These values may not apply to your food or processing conditions.

Table 3-B contains information on maximum cumulative exposure time at internal product temperature ranges for exposure of foods that, under ordinary circumstances, will be safe for the bacterial pathogens that are of greatest concern in food processing. These maximum, cumulative exposure times are derived from published scientific information.

Table 3-C is a Quick Reference Guide based on Table 3-B.

Because the nature of bacterial growth is logarithmic, linear interpolation using the time and temperature guidance may not be appropriate. Furthermore, the food matrix affects bacterial growth (e.g., presence of competing microorganisms, available nutrients, growth-restrictive agents). You should consider such attributes when using the information in Tables 3-A, 3-B, and 3-C.

Table 3-D contains information on the destruction of *Listeria monocytogenes* (*L. monocytogenes*). Lethal rate, as used in Table 3-D, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference internal product temperature of 158°F (70°C) (using a z = 13.5°F (7.5°C)). For example, 1 minute at 145°F (63°C) is 0.117 times as lethal as 1 minute at 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a "6D" process for *L. monocytogenes* (i.e., a process that will accomplish a 6 logarithm (factor of 1,000,000) reduction in the number of *L. monocytogenes*).

The length of time at a particular internal product temperature needed to accomplish a 6D reduction in the number of *L. monocytogenes* depends, in part, upon the food that is being heated. The values in the table are generally conservative and apply to all foods. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies. Additionally, lower degrees of destruction may be acceptable in your food if supported by a scientific study of the normal initial levels in the food. It is also possible that higher levels of destruction may be necessary in some foods, if you anticipate relatively high initial levels in the food you are processing.

Table 3-E contains information on the destruction of *Clostridium botulinum* (*C. botulinum*) type B (the most heat- resistant form of non-proteolytic *C. botulinum*). (The non-proteolytic strains of *C. botulinum* can grow at refrigeration temperatures and may be a hazard requiring a preventive control in some foods intended to be held refrigerated for extended periods of time.) Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference product internal temperature of 194°F (90°C) (for temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C)). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for *C. botulinum.* The values in the table are generally conservative. You may be able to establish a shorter process time for your food by conducting scientific thermal death time studies.

Table 3-A Limiting Conditions for Pathogen Growth

Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
Bacillus cereus	0.92	4.3	9.3	10	39.2°F 4°C	131°F[1] 55°C	facultative anaerobe[4]
Campylo-bacter jejuni	0.987	4.9	9.5	1.7	86°F 30°C	113°F 45°C	micro-aerophile[2]
Clostridium botulinum, type A, and proteolytic types B and F	0.935	4.6	9	10	50°F 10°C	118.4°F 48°C	anaerobe[3]
Clostridium botulinum, type E, and non-proteolytic types B and F	0.97	5	9	5	37.9°F 3.3°C	113°F 45°C	anaerobe[3]
Clostridium perfringens	0.93	5	9	7	50°F 10°C	125.6°F 52°C	anaerobe[3]
Pathogenic strains of *Escherichia coli*	0.95	4	10	6.5	43.7°F 6.5°C	120.9°F 49.4°C	facultative anaerobe[4]
Listeria monocyto-genes	0.92	4.4	9.4	10	31.3°F -0.4°C	113°F 45°C	facultative anaerobe[4]
Salmonella spp.	0.94	3.7	9.5	8	41.4°F 5.2°C	115.2°F 46.2°C	facultative anaerobe[4]
Shigella spp.	0.96	4.8	9.3	5.2	43°F 6.1°C	116.8°F 47.1°C	facultative anaerobe[4]
Staphylo-coccus aureus growth	0.83	4	10	20	44.6°F 7°C	122°F 50°C	facultative anaerobe[4]

Pathogen	Min. a_w (using salt)	Min. pH	Max. pH	Max. % Water Phase Salt	Min. Temp.	Max. Temp.	Oxygen Requirement
Staphylo-coccus aureus toxin formation	0.85	4	9.8	10	50°F 10°C	118°F 48°C	facultative anaerobe[4]
Vibrio cholerae	0.97	5	10	6	50°F 10°C	109.4°F 43°C	facultative anaerobe[4]
Vibrio parahaemo-lyticus	0.94	4.8	11	10	41°F 5°C	113.5°F 45.3°C	facultative anaerobe[4]
Vibrio vulnificus	0.96	5	10	5	46.4°F 8°C	109.4°F 43°C	facultative anaerobe[4]
Yersinia enterocoliti-ca	0.945	4.2	10	7	29.7°F -1.3°C	107.6°F 42°C	facultative anaerobe[4]

[1]Has significantly delayed growth (>24 hours) at 131°F (55°C).
[2]Requires limited levels of oxygen.
[3]Requires the absence of oxygen.
[4]Grows either with or without oxygen.

Table 3-B. Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products

Potentially Hazardous Condition	Product Temperature	Maximum Cumulative Exposure Time
Growth and toxin formation by ***Bacillus cereus***	39.2-43°F (4-6°C) 44-59°F (7-15°C) 60-70°F (16-21°C) Above 70°F (21°C)	5 days 1 day 6 hours 3 hours
Growth of ***Campylobacter jejuni***	86-93°F (30-34°C) Above 93°F (34°C)	48 hours 12 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type A, and proteolytic types B and F	50-70°F (10-21°C) Above 70°F (21°C)	11 hours 2 hours
Germination, growth, and toxin formation by ***Clostridium botulinum*** type E, and non-proteolytic types B and F	37.9-41°F (3.3-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	7 days 2 days 11 hours 6 hours
Growth of ***Clostridium perfringens***	50-54°F (10-12°C) 55-57°F (13-14 °C) 58-70°F (15-21°C) Above 70°F (21°C)	21 days 1 day 6 hours[1] 2 hours
Growth of pathogenic strains of ***Escherichia coli***	43.7-50°F (6.6-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth of ***Listeria monocytogenes***	31.3-41°F (-0.4-5°C) 42-50°F (6-10°C) 51-70°F (11-21°C) 71-86°F (22-30°C) Above 86°F (30°C)	7 days 1 day 7 hours 3 hours 1 hour
Growth of ***Salmonella*** species	41.4-50°F (5.2-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth of ***Shigella*** species	43-50°F (6.1-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	2 days 5 hours 2 hours
Growth and toxin formation by ***Staphylococcus aureus***	50°F (7-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	14 days 12 hours[1] 3 hours

Potentially Hazardous Condition	Product Temperature	Maximum Cumulative Exposure Time
Growth of ***Vibrio cholerae***	50°F (10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
Growth of ***Vibrio parahaemolyticus***	41-50°F (5-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
Growth of ***Vibrio vulnificus***	46.4-50°F (8-10°C) 51-70°F (11-21°C) 71-80°F (22-27°C) Above 80ºF (27ºC)	21 days 6 hours 2 hours 1 hour[2]
Growth of ***Yersinia enterocolitica***	29.7-50°F (-1.3-10°C) 51-70°F (11-21°C) Above 70°F (21°C)	1 day 6 hours 2.5 hours

[1] Additional data needed.
[2]Applies to cooked, ready-to-eat foods only.

Table 3-C is a Quick Reference Guide derived from Table 3-B:

Table 3-C Quick Reference Guide for Time and Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Food Products (for Internal Temperatures above 50°F (10°C) but below 135ºF (57.2ºC))

If the food is a …	And the food is held at an internal temperature …	Then you should limit the exposure time to …	Or, if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern, then you should limit the exposure time to …	As long as …
Raw, RTE ingredient or food product	Above 70°F (21.1°C)	2 hours	3 hours	N/A
Raw, RTE ingredient or food product	Above 70°F (21.1°C)	4 hours	N/A	No more than 2 of those hours are between 70°F (21.1°C) and 135ºF (57.2ºC)
Raw, RTE ingredient or food product	At any time above 50°F (10°C) but never above 70°F (21.1°C)	5 hours	12 hours	N/A

If the food is a …	**And the food is held at an internal temperature …**	**Then you should limit the exposure time to …**	**Or, if *Staphylococcus aureus* (*S. aureus*) is the only pathogen of concern, then you should limit the exposure time to …**	**As long as …**
Raw, RTE ingredient or food product	At internal temperatures (or at ambient air temperatures) below 50°F (10°C) throughout processing	N/A	N/A	N/A
Cooked, RTE ingredient or food product	At any time above 80°F (26.7°C)	1 hour	3 hours	N/A
Cooked, RTE ingredient or food product	At any time above 80°F (26.7°C)	4 hours	N/A	No more than 1 of those hours is above 70°F (21.1°C)
Cooked, RTE ingredient or food product	At any time above 70°F (21.1°C) but never above 80°F (26.7°C)	2 hours	3 hours	N/A
Cooked, RTE ingredient or food product	Never held above 80°F (26.7°C)	4 hours	N/A	No more than 2 of those hours are above 70°F (21.1°C)
Cooked, RTE ingredient or food product	At any time above 50°F (10°C) but never above 70°F (21.1°C)	5 hours	12 hours	N/A
Cooked, RTE ingredient or food product	At internal temperatures (or ambient air temperatures) below 50°F (10°C) throughout processing	N/A	N/A	N/A

Note that the preceding recommended critical limits do not address internal product temperatures between 40°F (4.4°C), which is the recommended maximum storage temperature for refrigerated food products, and 50°F (10°C). That is because growth of foodborne pathogenic bacteria is very slow at these temperatures and the time necessary for significant growth is longer than would be reasonably likely to occur in most food processing steps. However, if you have processing steps that occur at these temperatures that approach the maximum cumulative exposure times listed in Table 3-B for the pathogenic bacteria of concern in your product, you should consider development of a critical limit for control at these temperatures.

It is not possible to furnish recommendations for each pathogenic bacterium, process, type of food product, and temperature or combination of temperatures. Programmable models to predict growth rates for certain pathogens associated with various foods under differing conditions have been developed by the U.S. Department of Agriculture' (the Pathogen Modeling Program (PMP)) and by an international consortium of the Institute of Food Research (UK), the USDA Agricultural Research Service (USDA-ARS) and the University of Tasmania Food Safety Centre (CombBase database and Predictor). These programs can provide growth curves for selected pathogens. To use these models, you indicate the conditions, such as pH, temperature, and salt concentration that you are interested in and the models provide pathogen growth predictions (e.g., growth curve, time of doubling, time of lag phase, and generation time). FDA does not endorse or require the use of such modeling programs, but recognizes that the predictive growth information they provide may be helpful to some processors. However, you should be aware that significant deviations between actual microbiological data in specific products and the predictions may occur, including those for the lag phase of growth. Therefore, you should validate the time and temperature limits derived from such predictive models if growth of pathogens during processing requires a preventive control.

Table 3-D Inactivation of *Listeria monocytogenes*

Internal Product Temperature (°F)	Internal Product Temperature (°C)	Lethal Rate	Time for 6D Process (minutes)
145	63	0.117	17.0
147	64	0.158	12.7
149	65	0.215	9.3
151	66	0.293	6.8
153	67	0.398	5.0
154	68	0.541	3.7
156	69	0.736	2.7
158	70	1.000	2.0
160	71	1.359	1.5
162	72	1.848	1.0
163	73	2.512	0.8
165	74	3.415	0.6
167	75	4.642	0.4
169	76	6.310	0.3
171	77	8.577	0.2
172	78	11.659	0.2
174	79	15.849	0.1
176	80	21.544	0.09
178	81	29.286	0.07
180	82	39.810	0.05
182	83	54.116	0.03
183	84	73.564	0.03
185	85	100.000	0.02

Note: z = 13.5°F (7.5°C).

Table 3-E Inactivation of Non-Proteolytic *Clostridium botulinum* Type B

Internal Product Temperature (°F)	Internal Product Temperature (°C)	Lethal Rate*	Time for 6D Process (minutes)
185	85	0.193	51.8
187	86	0.270	37.0
189	87	0.370	27.0
190	88	0.520	19.2
192	89	0.720	13.9
194	90	1.000	10.0
196	91	1.260	7.9
198	92	1.600	6.3
199	93	2.000	5.0
201	94	2.510	4.0
203	95	3.160	3.2
205	96	3.980	2.5
207	97	5.010	2.0
208	98	6.310	1.6
210	99	7.940	1.3
212	100	10.000	1.0

Note: For temperatures less than 194°F (90°C), z = 12.6°F (7.0°C); for temperatures above 194°F (90°C), z = 18°F (10°C).

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