

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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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FORM 2-E (Modified) FOOD ALLERGEN INGREDIENT ANALYSIS

FORM 2-F (Modified) FOOD ALLERGEN LABEL VERIFICATION LIST

FORM 2-G (Modified) PRODUCTION LINE FOOD ALLERGEN ASSESSMENT

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 sesame² 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-contact³ 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.)

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- 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).)

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"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.

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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 <i>de minimis</i> 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

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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.

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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 Act⁹ (i.e., milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame¹⁰);
- 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 presence¹¹ as a “chemical hazard”; and
- The classification of an undeclared¹² 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.

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- 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 or 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 unintended 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

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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 guidance¹⁴ 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 controls¹⁷; 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) Validation¹⁸; (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

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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 control¹⁹ 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.

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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.

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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);

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- 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.

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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

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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:

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- 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.

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- 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 controls²³ 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:

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- 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

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- 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 stages²⁴:

- 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.

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- 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

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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 Procedures²⁵); 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 117.150(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 circumstances²⁹, 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.

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- 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 product³⁰) or limited (such as when an allergen present due to cross-contact is more likely to be distributed non-homogeneously³¹)) 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

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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.

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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.	<ul style="list-style-type: none"> - Questionnaire about food allergen control practices - Search FDA's "Firm/Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit 	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - Annual onsite audit - Periodic testing of shipments of vegan caramel chips (e.g., quarterly or every 5th lot)

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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	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - Annual onsite audit - Annual sampling and testing (as verification of the supplier's sampling and testing of every lot)

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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	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - Of the PCQI's determination to not carry forward an allergen advisory statement; and - To-re-evaluate the supplier.

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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	<ul style="list-style-type: none"> - The supplier uses the same processing line for almond-based beverages and soy-based beverages. - Supplier's allergen cross-contact controls and verification testing: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Supplier's CGMP measures for separation in space: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit 	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Supplier's CGMP measures for separation in space: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - Questionnaire about food allergen control practices - Search FDA's "Supplier Evaluation Resources" web page (see Table 11-8) - Onsite audit 	<ul style="list-style-type: none"> - 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.

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Dry-roasted almonds	Dry-roasted peanuts	<ul style="list-style-type: none"> - Supplier's CGMP measures for separation in space and time: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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. 	<p>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.</p>	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - Annual onsite audit - Periodic (e.g., semi-annually) checking shipments of almonds by sampling and sorting to look for peanuts

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Dry-roasted almonds	Dry-roasted cashews	<ul style="list-style-type: none"> - The supplier uses the same production line for almonds and cashews. - Supplier's CGMP measures for separation in space: <ul style="list-style-type: none"> - Separate storage areas, in different rooms, for shelled almonds and shelled cashews. - Supplier's allergen cross-contact controls and verification testing: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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)

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Dry-roasted almonds	Dry-roasted cashews	<ul style="list-style-type: none"> - The supplier uses the same production line for almonds and cashews. - Supplier's CGMP measures for separation in space: <ul style="list-style-type: none"> - Separate storage areas, in the same room, for almonds and cashews. - Supplier's allergen cross-contact controls and verification testing: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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 are³³:

- 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 amount³⁵ 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.

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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-contact³⁶. 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.

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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.

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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 allergen³⁷; 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.

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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;

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- 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

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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);

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- 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:

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- 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

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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:

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- 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

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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:

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- 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 ingredient³⁸ 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 name³⁹ 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.

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- 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

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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:

⁴⁰In 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.

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- 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:

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- 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

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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

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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

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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.

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- 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:

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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.

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- 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

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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.

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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.

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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/

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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

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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.

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- 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.

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- Use of traffic patterns 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)

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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:

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- 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).

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- 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.

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- 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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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.”

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Item	Applicable Information
Corrections	<ul style="list-style-type: none"> - 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	<p>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:</p> <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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								

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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).

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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): <ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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. 	<p>The following records, initialed and dated by the PCQI:</p> <ul style="list-style-type: none"> - 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.

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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	<p>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.</p> <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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	<p>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</p> <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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. 	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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. 	<ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - Label Management Procedures - The following records, initialed and dated by the PCQI: <ul style="list-style-type: none"> - The production sheet containing the label from the production printer, signed and dated by the Production Supervisor; and - Any corrective actions

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Draft – Not for Implementation*

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	<p>Corrective action (documented):</p> <ul style="list-style-type: none"> - 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 	<ul style="list-style-type: none"> - The line operator: <ul style="list-style-type: none"> - 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. 	<ul style="list-style-type: none"> - Label Management Procedures - The following records, initialed and dated by the PCQI: <ul style="list-style-type: none"> - 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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