

FSIS Compliance Guidelines

Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling

November 2015

Purpose

This document provides guidance to assist establishments in addressing the hazard posed by allergens in their products. In doing so, establishments must comply with the Food Safety and Inspection Service (FSIS) hazard analysis and critical control point (HACCP) and labeling regulations.

This guidance document presents best practice recommendations by FSIS, based on the best scientific and practical considerations. The recommendations in this guidance do not represent requirements that must be met. The focus of this document is meat and poultry products, with an emphasis on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the “food processing plant” definition as defined in the *2013 Food Code*. This guidance represents FSIS’s current thinking, and we encourage establishments to use it.

This guidance is an update of the document that was issued and announced in the *Federal Register* of April 21, 2014 ([79 FR 22083](#)). FSIS has updated this guidance based on comments it received during the public comment period, which closed on June 20, 2014. FSIS made the following changes in response to the comments:

- Clarified and described a letter of guarantee (LOG), the difference between a LOG and a certificate of analysis (COA), and the communication and coordination between an establishment and its suppliers that FSIS recommends when establishments rely on LOGs.
- Added Appendix 6 entitled, “Allergenic Ingredients and Foods” to the guidelines as a resource to identify potential sources of “Big Eight” allergens.
- Clarified that the emphasis of the document is on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the “food processing plant” definition, as defined in the *2013 Food Code*.
- Changed to the text to emphasize the purpose of a hazard analysis, add recommendations for establishments, and clarify ingredients of public health concern.

Although comments on this guidance document will no longer be accepted through regulations.gov, FSIS will update this document as necessary should new information become available.

Table of Contents

<i>Chapter 1: Introduction and Background</i>	4
1.1 <i>Why did FSIS develop this document?</i>	4
1.2 <i>What is a food allergen?</i>	5
1.3 <i>What are the undeclared allergen trends that FSIS has observed in industry?</i>	6
1.4 <i>What is the Food Allergen Labeling and Consumer Protection Act?</i>	6
<i>Chapter 2: Prevention and Control Measures for Undeclared Allergens</i>	7
2.1 <i>Identify: Inspection of Incoming Ingredients, Cross-referencing Components, Separation</i>	7
2.2 <i>Prevent and Control: Equipment, Sanitation, and Processing</i>	10
2.3 <i>Declare: Packaging, Labeling, Storage</i>	11
<i>Chapter 3: Allergen Training Commitment</i>	13
<i>Appendix 1: How to Handle Labels of Incoming and Outgoing Products</i>	14
<i>Appendix 2: Process Flow Diagram with Mitigation Targets</i>	15
<i>Appendix 3: Allergen Risk Evaluation and Labeling Diagram</i>	16
<i>Appendix 4: Establishment Checklist</i>	17
<i>Appendix 5: Allergen Scenarios and Possible Preventive Measures</i>	20
<i>Appendix 6: Allergenic Ingredients and Foods</i>	22
<i>Appendix 7: References and Resources</i>	26

Chapter 1: Introduction and Background

This document provides recommendations for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards through hazard analysis and critical control point (HACCP) plans, Sanitation standard operating procedures (SOPs), or other prerequisite programs with respect to allergens and other ingredients of public health concern. The focus of the guidelines presented in this document is on meat and poultry products with an emphasis on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the “food processing plant” definition as defined in the Food Code. The guidelines provide information on proper procedures for processing, handling, storing, and labeling a product with an allergenic ingredient or ingredient of public health concern based on three basic principles:

1. **Identify**
2. **Prevent and control**
3. **Declare**

Key components of the identify principle include hazard analysis, inspection of incoming ingredients, cross-referencing product components, and separation of allergenic materials. The prevent and control principle focuses on recommendations for preventing cross-contact in processing areas, such as sanitation and cleaning of equipment and maintaining appropriate process flow. Finally, the declare principle emphasizes prevention of mislabeling during packing, labeling, and storage.

These guidelines represent the best practice recommendations of FSIS, based on scientific and practical considerations. The recommendations are not requirements. By following these guidelines, establishments are likely to ensure that product labels declare all ingredients, as required in the regulations, and that products do not contain undeclared allergens or other undeclared ingredients. FSIS recommends that establishments consider incorporating the practices set out in this document in their HACCP plan or Sanitation SOPs or other prerequisite programs.

1.1 Why did FSIS develop this document?

From 2008 through 2012, there has been a

Food Allergy Statistics

- The Centers for Disease Control and Prevention (CDC) reports that approximately four out of every 100 children has a food allergy
- The prevalence of reported food allergies has increased. CDC reports an increase of 18% from 1997 to 2007 among children
- The average number of hospital discharges per year related to food allergy diagnosis has increased significantly from 1998 to 2006 among children with approximately 9,500 hospital discharges yearly from 2004 to 2006 (CDC)
- An estimated 29,000 episodes of anaphylaxis related to food occur in the United States each year, resulting in approximately 150 deaths (Atkins)

Recall Trends: FSIS-regulated Product Related to Undeclared Allergens

- The number of recalls of FSIS-regulated product attributed to undeclared allergens and ingredients of public health concern has increased from 7 in 2008 to 29 in 2012
- The proportion of recalls attributed to undeclared allergens and ingredients of public health concern has also increased, from 13% in 2008 to 35% in 2012

The “Big Eight” Allergens

- 1) Wheat
- 2) Crustacean shellfish (e.g. shrimp, crab, lobster)
- 3) Eggs
- 4) Fish
- 5) Peanuts
- 6) Milk
- 7) Tree nuts (e.g. almonds, pecans, walnuts)
- 8) Soybeans

sustained increase in the number of recalls of FSIS-regulated product that contained undeclared allergens. These recalls are preventable as many have been the result of ingredient changes, product changes, products in the wrong package, or products with misprinted labels.

The consumption of meat and poultry products containing ingredients of public health concern, such as undeclared allergens, may result in adverse health outcomes for certain individuals. According to the National Institute of Allergy and Infectious Diseases (NIAID), the “Big Eight” allergens account for approximately 90 percent of all food allergy reactions. Situations involving the non-declaration of the “Big Eight” allergens may result in a Class I or Class II recall. (Refer to [FSIS Directive 8080.1](#) for additional information on product recall.)

1.2 What is a food allergen?

More than 170 foods have been reported to cause allergic reactions; however, eight of the most common allergenic foods account for 90 percent of all food allergic reactions and are the sources from which many other ingredients are derived. Food allergies are an important public health problem that affect adults and children and are increasing in reported prevalence. There is currently no cure for severe allergic reactions. Therefore, it is necessary to provide guidance on avoiding specific foods, reviewing labels, and managing the relevant signs and symptoms of those that are affected.

According to the NIAID, some food allergens cause allergic reactions primarily if eaten raw; however, most food allergens can still cause reactions even after they have been cooked or have undergone digestion in the stomach and intestines.

Establishments are required to declare all ingredients on the label. While the “Big Eight” allergens are the most common allergenic foods, people may have adverse reactions to other substances as well. Consumption of some ingredients, such as sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG), may result in an adverse reaction in certain susceptible individuals, yet they are not considered allergens.

It should also be noted, especially for establishments producing product for export, that countries outside of the U.S. may have concerns for other allergens that may need to be addressed. For example, Canada and the European Union recognize more than the “Big Eight” allergens.

Ingredients of public health concern: Ingredients to which consumers have reported adverse reactions

Food allergens: Specific components of food or ingredients within food (typically proteins) that are recognized by allergen-specific immune cells and cause specific immunologic reactions, resulting in characteristic signs and symptoms (NIAID)

Food allergy: Adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food (NIAID)

Signs and symptoms of food allergy: According to the CDC, depending on the individual and allergy, the signs and symptoms can vary from mild to sudden and severe, including one or more of the following:

- Hives
- Tingling in the mouth
- Swelling in the tongue and throat
- Difficulty breathing
- Abdominal cramps
- Vomiting or diarrhea
- Eczema or rash
- Coughing or wheezing
- Loss of consciousness
- Dizziness

Anaphylaxis: Severe, life-threatening, whole body allergic reaction that occurs seconds to minutes after exposure and can result in respiratory distress, shock, and death

1.3 What are the undeclared allergen trends that FSIS has observed in industry?

FSIS has recognized a notable increase in the number of recalls that have occurred because of undeclared allergens and ingredients of public health concern in product. FSIS has found that many of these recalls occurred because of a change in product formulation by the establishment or a change in a supplier's ingredient formulation that was not reflected on the labeling of the finished meat or poultry product.

If an establishment recalls product because of an undeclared ingredient, an establishment likely has: 1) failed to address the chemical (allergen) food safety hazard in its hazard analysis, 2) failed to support the decisions made in the hazard analysis, 3) failed to reassess the hazard analysis, or 4) failed to effectively implement the controls to support the decisions made in the hazard analysis (see 9 CFR 417.2(a)(1), 417.5(a)(1), 417.4(a)(3), 417.3(b) respectively).

In some cases, FSIS requested that establishments recall product in commerce because FSIS in-plant inspection personnel or Enforcement, Investigations, and Analysis Officers (EIAOs) found undeclared allergen problems. Establishments should take steps to identify such problems instead of relying on FSIS to find them. Establishment controls should be in place to address the presence of undeclared allergens and ingredients of public health concern.

Establishments are required to declare ingredients on the label if they are included in the product formulation (9 CFR 317.2 and 381.118). Allergen-containing products must be handled, processed, formulated, and stored properly. If allergens are not declared, then the product is adulterated and misbranded. If adulterated and misbranded product has already been shipped into commerce, FSIS would request that it be recalled.

What is causing undeclared allergen recalls?

- New Ingredient
- New Supplier
- Misprinted Label
- Product in Wrong Package
- Product Reformulation
- Ingredient Reformulation

1.4 What is the Food Allergen Labeling and Consumer Protection Act (FALCPA)?

The [2004 Food Allergen Labeling and Consumer Protection Act \(FALCPA\)](#) requires that products under the jurisdiction of the Food and Drug Administration (FDA) that contain a major food allergen clearly identify the allergen on the label (Public Law 108-282, Title II). FSIS supports the voluntary addition of allergen statements (e.g. "contains" statements) on meat and poultry product labels immediately following the ingredients statement as discussed in the [FSIS Compliance Assistance: Allergens-Voluntary Labeling Statements](#).

All ingredients used in the formulation of meat, poultry, or egg products must be declared by their common or usual name in the ingredients statement. Occasionally a substance may be used in a meat, poultry, or egg product whose use in that product, consistent with FDA's labeling definition, would be as an incidental additive or a processing aid (21 CFR 101.100(a)(3)). If an establishment believes that a substance is a processing aid or incidental additive in a meat, poultry, or egg product, it should contact FSIS for a determination. FSIS makes these determinations on a case-by-case basis, as discussed in the FSIS [Compliance Guide on the Determination of Processing Aids](#).

Chapter 2: Prevention and Control Measures for Undeclared Allergens

For comprehensiveness, FSIS recommends control measures throughout an establishment's HACCP system to prevent the potential of undeclared allergens based on three basic principles: **identify, prevent and control**, and **declare**. Below are steps establishments should take that could be incorporated within the HACCP plan or Sanitation SOPs or other prerequisite program.

As appendices to this document, there are several resources that can be used in conjunction with the **identify, prevent and control**, and **declare** concepts:

- Page 14 depicts "How to Handle Labels of Incoming and Outgoing Products" in a diagram detailing recommended procedures to maintain proper handling of labels.
- Page 15 contains a process flow diagram that illustrates the targets for mitigation in a hypothetical flow diagram for fresh pork sausage. This mitigation targets are highlighted to correspond with the **identify, prevent and control**, and **declare** principles emphasized in this guidance.
- Page 16 illustrates an allergen risk evaluation and labeling flow chart to assist with an establishment's evaluation of whether or not special labeling is needed.
- Page 17 is the beginning of the specific "Establishment Checklists" that are provided to assist establishments with questions to consider as they brainstorm the identification, prevention and control, and labeling of allergens.
- Page 20 includes "Allergen Scenarios and Possible Preventive Measures" that are hypothetical scenarios along with preventive measures that could have been taken to illustrate the concepts from the guidelines.
- Page 22 is the beginning of a resource entitled "Allergenic Ingredients and Foods" which was adapted from Food Allergy Research and Education (FARE) to help establishments identify "Big Eight" allergens.
- Page 26 highlights the references and sources of information used throughout this document along with other resources for additional information.

2.1. Identify: Inspection of Incoming Ingredients, Cross-referencing Components, Separation

A meticulous, comprehensive hazard analysis is crucial to identify and control allergens in an establishment. The hazard analysis serves as the foundation for a strong and successful HACCP plan. Therefore, it is important for the establishment to invest time and resources in the analysis, particularly in hazard identification.

Food safety hazard: Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption

The introduction of ingredients into product **must be taken into account** during the hazard analysis

According to 9 CFR 417.2(a)(1), the establishment is required to identify all food safety hazards reasonably likely to occur through a hazard analysis. Doing so would include identifying any chemical hazards, such as allergens and ingredients of public health concern, as well as any biological and physical hazards that are reasonably likely to occur in the production process. The introduction of an allergen could occur anywhere during the production process. Therefore, an establishment should be sure to evaluate each step in its process from receiving to packaging and shipment. Allergens fall under the chemical hazards portion of the hazard identification.

A hazard analysis is not only used to assess the food safety hazards reasonably likely to occur in the production process but is also used to identify the measures through Critical Control Points (CCPs) that the establishment can apply to control those hazards. The hazard analysis **must** consider food safety hazards that can occur before, during, and after entry into the establishment.

Establishments should be especially thorough during the hazard identification phase of their hazard analysis to identify food safety hazards and ultimately to mitigate the possibility of preventable recalls because of undeclared allergens and ingredients of public health concern. In these guidelines, FSIS has provided measures for controlling the presence of undeclared allergens in product that may be included in an establishment's HACCP system. Measures may also be included within an establishment's Sanitation SOPs or other prerequisite program that sufficiently and effectively prevent the presence of undeclared allergens in product.

As a result of the identification of chemical hazards in the hazard analysis, an establishment should have a list of allergens and other ingredients of public health concern that are used in production. According to the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), establishments should evaluate each of these identified hazards based on severity as well as likelihood of occurrence. This evaluation could be based upon historical data, scientific literature, or establishment records. Once the hazard evaluation is completed, establishment personnel should work to develop approaches to control those hazards.

As part of food safety and hazard control under federal regulation, every establishment is required to have a written HACCP plan based on its hazard analysis (9 CFR 417.2(b)(1)). The HACCP plan is required to include the food safety hazards reasonably likely to occur in the production process.

The establishment is required to have a flow chart describing the steps of each control process and product flow in the establishment (9 CFR 417.2(a)(2)). Every establishment must validate the HACCP plan's adequacy in controlling the food safety hazards, such as undeclared allergens, identified during the hazard analysis

FSIS has found that establishments have not been aware of the potential presence of allergens within a new ingredient or formulation when changing suppliers or the formulation of an ingredient. It is essential that establishments routinely verify that the ingredient's label reflects its formulation.

When a change in suppliers or formulation occurs, establishments should be on high alert for the presence of allergens in the new ingredient or product. It is the establishment's responsibility to routinely check the ingredient's formulation.

What are some straightforward, practical steps I can take to identify allergens in my establishment?

- Review a list of all ingredients and products that you use to determine whether they are or contain allergens
- Using an establishment schematic, do a walk-through noting paths of allergenic ingredients and products and areas of concern where cross-contact may occur
- Keep a list of ingredients used in product formulations and label records at the receiving area to compare against incoming ingredients
- Ensure that all incoming ingredients containing allergenic material are clearly labeled and identified
- Use color coding for allergen-containing ingredients and products
- Store ingredients containing allergenic materials in separate, designated areas that are clearly identified and marked
- Become familiar with letters of guarantee from suppliers
- Maintain open communication of expectations with suppliers and inquire about suppliers' allergen control programs

and verify that the plan is being effectively implemented to reduce the potential for the presence of undeclared allergens in the product.

To fully address all allergens and ingredients of public health concern in the final product, an establishment should first assess ingredients present in the incoming meat or poultry and non-meat or non-poultry components. The establishment should seek out information about the allergens and ingredients of public health concern used by its suppliers. In addition, it should seek information on its suppliers' production practices, such as whether they employ practices to prevent the cross-utilization of equipment or cross-contact of product. This information may come in the form of a Letter of Guarantee (LOG) that should not to be confused with a Certificate of Analysis (COA). A COA typically includes test results associated with a specific lot, while a LOG may be provided by the supplier to describe the ingredients used in the production of products. Based on the component and complexity of the supplier's process, the content of the LOG can vary significantly, from a general statement, which is common, to a more detailed description of the supplier's process (e.g., details including ingredient components, processing aids, rework, processing steps, environmental conditions, or product carry over). In either situation, the LOG should accomplish the same function and be detailed enough to support the decisions made in the hazard analysis. An establishment should review and update the LOGs regularly to ensure that the decisions made in the hazard analysis are supported and to ensure that any formulation changes made by its suppliers are detected prior to incorporating the associated ingredient into the production process. Generally, an annual LOG will not be sufficient to support decisions made in the hazard analysis.

An establishment that fails to routinely review and verify the components and ingredients it receives may overlook the presence of an allergen. The result may be the inclusion of a component that is not declared in a product resulting in adulteration and misbranding, which could ultimately lead to a product recall.

FSIS recommends that an establishment maintain an approved supplier list along with ingredient information from each supplier. The establishment should use the list when receiving incoming ingredients to verify proper identification of each lot of ingredients.

For accuracy, an establishment should also cross-reference the sketch label approval, if applicable, to the actual label being used and the formulation data. It is imperative that the label approval, the actual label, and formulation all match for proper ingredient identification. If there is a discrepancy between the label and the formulation,

What is a letter of guarantee (LOG)?

A LOG is a document that provides details for components that are used in the areas of food processing, handling, and storage. Generally, a LOG contains:

- Supplier name and address
- Brand name
- Statement that the material is safe and effective under intended conditions of use and will not adulterate the food product
- Signature of an official of the supplier

The LOG may be attached to an invoice or may be a continuing LOG that does not accompany each shipment.

Every establishment must reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)(i)).

These changes may include:

- **Raw materials or source of raw materials**
- **Product formulation**
- Slaughter or processing methods or systems
- Production volume
- Personnel
- **Packaging**
- Finishing product distribution systems
- The intended use by consumers of the finished product
- Outbreaks or illnesses associated with this type of product

The reassessment and the reasons for any changes to the HACCP plan must be documented. Reasons that the HACCP plan is not changed must also be documented, unless it is an annual reassessment, and no changes are needed (9 CFR 417.4(a)(3)(ii)).

establishment should separate the product and ingredients in question and hold them in a secure place, so that they are not used until the ingredients can be properly identified for use in specific products. [FSIS labeling guidance](#), including the Food Standards and Labeling Policy Book, is available on the FSIS website.

An establishment can prevent the presence of undeclared allergens by ensuring that appropriate mechanisms for labeling all ingredients are in place. A comprehensive chart, on page 15, details recommended procedures to maintain proper handling of labels on both incoming and outgoing product. As exhibited, this process should be conducted on an ongoing basis.

2.2 Prevent and Control: Equipment, Sanitation, and Processing

It is especially critical for establishments to address cleaning of equipment, utensils, and food contact surfaces (FCS) when producing both allergenic and non-allergenic product, to prevent cross-contact and misbranding.

Personnel should be trained on the cleaning procedures the establishment employs to control food allergens and should be aware of which products contain allergenic ingredients. Establishments should track work-in-progress product with at least the product name, lot code, and allergenic ingredients or ingredients of public health concern to minimize potential cross-contact during processing. Equipment and utensils used for the preparation, processing, or other handling of all product, including allergenic product, in the establishment need to be suitable for the purpose intended and be of such material and construction that will facilitate thorough cleaning and ensure cleanliness in the preparation and handling of products.

Cleaning of equipment, utensils, and FCS areas should be conducted after an allergenic product has had contact with a utensil, surface, or piece of equipment, and before the equipment, utensils, and FCS areas are used for an allergen-free product. It is important that equipment used to handle allergenic product be sufficiently sanitized before handling non-allergenic product.

The type of product an establishment is producing, the food contact surfaces being used, and the allergens present in the product all should be considered when designing a cleaning program. A review by *Jackson et al.* presents cleaning, control, and validation strategies to prevent cross-contact with allergens. They note that, generally speaking, food proteins, which would include allergenic proteins, are some of the most difficult to remove from surfaces.

Planning plays a key role when handling and processing both allergenic and non-allergenic product. The most effective and appropriate protocol for handling and processing both allergenic and non-allergenic

Cross-contact: Inadvertent transfer of allergens to a food product from other food products, food contact surfaces, equipment, utensils, etc. if ingredients or allergen-containing products are not handled properly

What are some straightforward, practical steps I can take to prevent cross-contact in processing areas within my establishment?

- Color coding of ingredient packages, supplies, uniforms, and utensils used for products containing allergens throughout processing to facilitate simple identification
- Documenting cleaning procedures with checklists including procedures for spill clean-up
- Employing a method for the verification and validation of cleaning
- Maintaining documented process flow along with mapping the route of allergenic product through the establishment
- Employing a method for tracking of lot codes through production
- Carefully evaluating rework and work-in-progress
- Dedicating equipment or, if not feasible, separate allergenic products by time, space, etc.

products is to handle and process non-allergenic products **before** handling and processing allergenic products to reduce the possibility of cross-contact and misbranding. This approach eliminates the need to hold utensils and equipment for proper cleaning before handling and processing allergenic product.

FSIS **does not recognize** a threshold for any allergenic ingredient. Thus, all allergenic ingredients need to be declared on the product label.

FSIS recommends conspicuously and distinctly marking all equipment and utensils used for handling allergenic products. Cleaning and sanitizing equipment, FCS, and utensils is effective at not only removing soil and microorganisms but also food allergen residues. Additionally, FSIS recommends that establishments avoid using the same cooking medium (e.g., oil or water) when processing both allergenic and non-allergenic products. If an establishment chooses to utilize the same cooking medium, it is important that non-allergenic product does not become adulterated with the allergenic product in the cooking medium. Adulteration can be prevented by processing the non-allergenic product before the allergenic product.

Allergen test kits as well as laboratory testing using reference laboratories targeted at allergens of interest are available. AOAC International maintains a listing of [Performance Tested Methods](#) which includes food allergen kits. This type of allergen testing program may be considered to verify and document sanitation effectiveness in an establishment. Note that an allergen testing program would be a supplement to documenting cleaning procedures and a visual cleaning assessment.

2.3 Declare: Packaging, Labeling, Storage

Properly declaring allergens in product is just as important as properly identifying incoming ingredients and handling and processing allergenic product. Once an establishment has identified the potential allergens among the ingredients used and has handled and processed products according to its HACCP system, it is the establishment's responsibility to ensure that the product is properly packaged, labeled, and stored.

An establishment should set procedures for personnel to easily distinguish allergenic product from non-allergenic product. Procedures should be in place to ensure that the label being applied to a given product within a production lot is correct and matches the label on other packaged units of product within the lot. These procedures should include the accurate identification of all potential allergens. If the product is incorrectly or insufficiently identified, it can lead to both adulteration and misbranding.

What are some straightforward, practical steps I can take to prevent mislabeling during packing, labeling, and storage of final product?

- Systems and checklists in place for the labeling of final product
- Conduct simulations with inaccurate product labels to test systems, checklists, and procedures
- Color coding of products containing allergenic ingredients
- Procedures in place for labeling discrepancies to ensure product disposition is evaluated
- Verification of the accuracy of product labels
- Methods of tracking lot codes through production, storage, and shipping
- Storage of products containing allergenic materials in areas that are clearly identified and marked

Additionally, the storage of the allergenic and non-allergenic products needs to be easily identifiable through product separation. An establishment should ensure that cross-contact of products does not occur when products are placed in freezers, refrigeration units, or dry warehouses. It should also take care when storing ingredients in dry warehouses or formulation rooms. An establishment should ensure that all ingredients in storage areas are properly identified to prevent employees from selecting the wrong ingredient during formulation.

Question: *How should an establishment label its product when an incoming seasoning packet contains a “may contain” statement on its labeling?*

Answer: *All the ingredients in a “may contain” or “produced in a facility” statement of a purchased ingredient need not be listed on the final label if the official establishment: 1) Contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; and 2) Includes a written statement in its hazard analysis documentation to support why the “may contain” or “produced in a facility” statement is not carried forward to the finished meat or poultry product label.*

It is important that an establishment verify the accuracy of the final label to ensure that it includes all allergenic and non-allergenic ingredients in the product. An establishment should check the accuracy of labels in relation to the product being packaged. It may also include this procedure within its HACCP plan or other prerequisite program. The product in the package must precisely match the product described by the label on the package.

Question: *If an establishment produces a product that incorporates a non-meat or non-poultry ingredient that includes flour (an ingredient derived from wheat) and also produces a product that does not contain wheat, is the establishment required to notate on the non-allergenic product’s final label that the product “may contain wheat” or was “manufactured in a plant with wheat” to prevent false or misbranding information to consumers?*

Answer: *No, the presence of wheat in the establishment does not require a “may contain” statement on products formulated without wheat. Only in limited situations does FSIS allow the use of factual labeling statements about a product’s manufacturing environment (e.g. “Produced in an establishment that uses wheat”). Statements of this type may only be used where good manufacturing practices **cannot reasonably eliminate** the unintended presence of ingredients of public health concern. In this case, the HACCP plan, Sanitation SOP, or other prerequisite program should be implemented by the establishment to control this issue.*

Note: See the FSIS [Compliance Assistance: Allergens-Voluntary Labeling Statements](#) for additional information on the use of voluntary allergen statements of this type.

Additionally, 9 CFR 317.2(b) and 9 CFR 381.116(a) require that the ingredients statement on the label be prominently placed with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The ingredients statement must also identify the common or usual names of the ingredients arranged in descending order of predominance. A complete and accurate ingredients statement is essential with the presence of an allergen. If a discrepancy is found between the packaged product and the label, or if a product has been mislabeled, it is critical that the product be separated from product entering commerce and held. The occurrence should be immediately reported to the establishment management on duty.

Chapter 3: Allergen Training Commitment

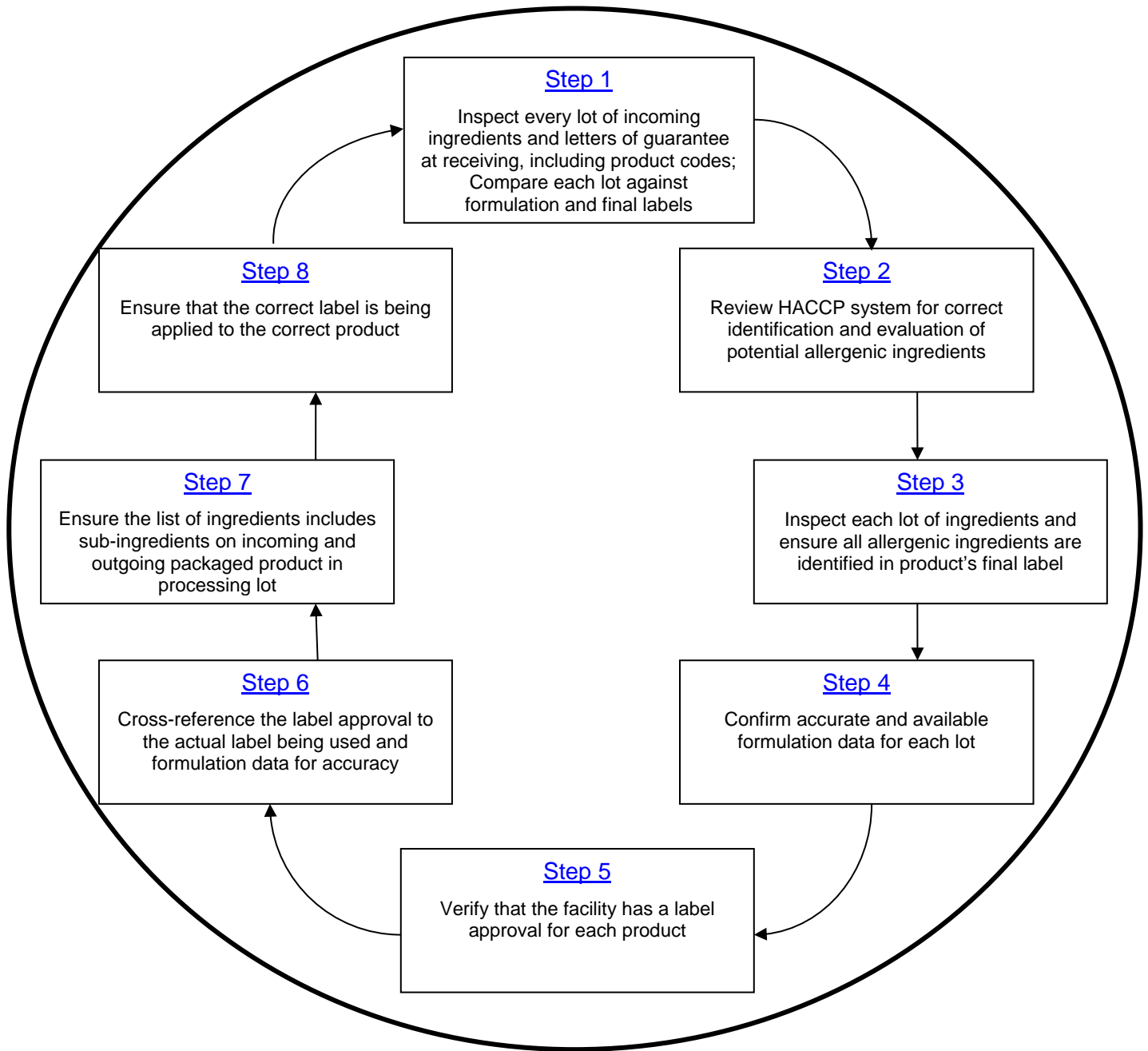
All staff that handle and order ingredients, supplies, and equipment, as well as those who are responsible for handling ingredients and products from receiving through shipping, should be aware of the dangers of allergens. **Each establishment employee needs to understand his or her food safety role in this process.** An establishment should maintain written procedures to **identify, prevent and control**, and **declare** allergens and make those procedures readily available to staff. Staff should review the procedures frequently, especially when changes occur.

Management should communicate the importance of allergen control and the establishment's allergen control program to all employees. The success of any system depends on education and training of management and employees in the importance of their role in producing safe foods.

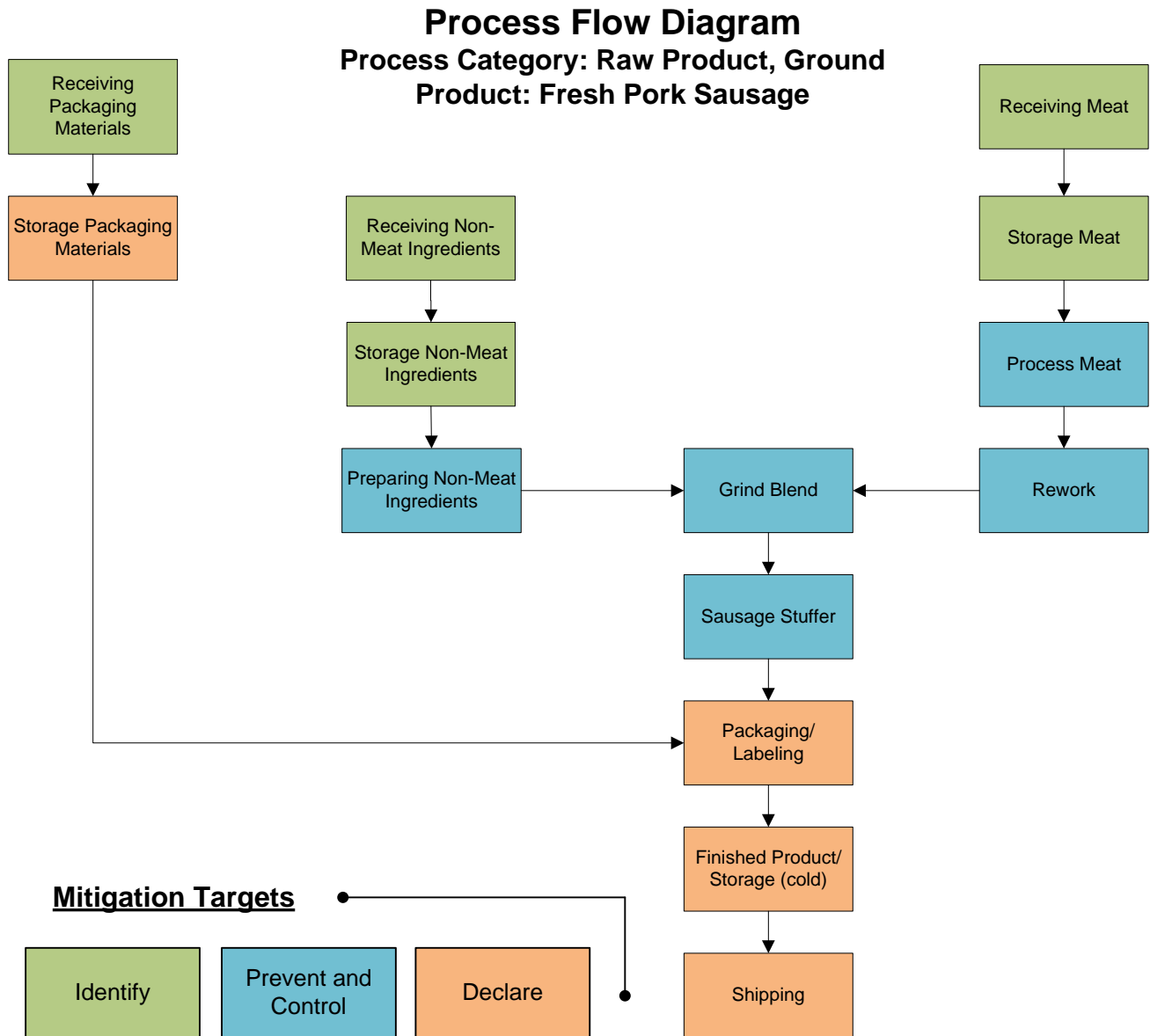
Key Training Areas

- Avoiding cross-contact
- Flow of allergenic ingredients and products
- Allergen control policies
- Hygiene procedures including handwashing and uniform requirements
- Waste control
- Rework and work-in-progress procedures
- Cleaning procedures and documentation including spill clean-up
- Dedicated supplies and equipment
- Storage of ingredients and final products
- Labeling procedures
- Scheduling of production
- Management notification for discrepancies and other allergen and labeling issues
- Product formulations
- Letters of guarantee

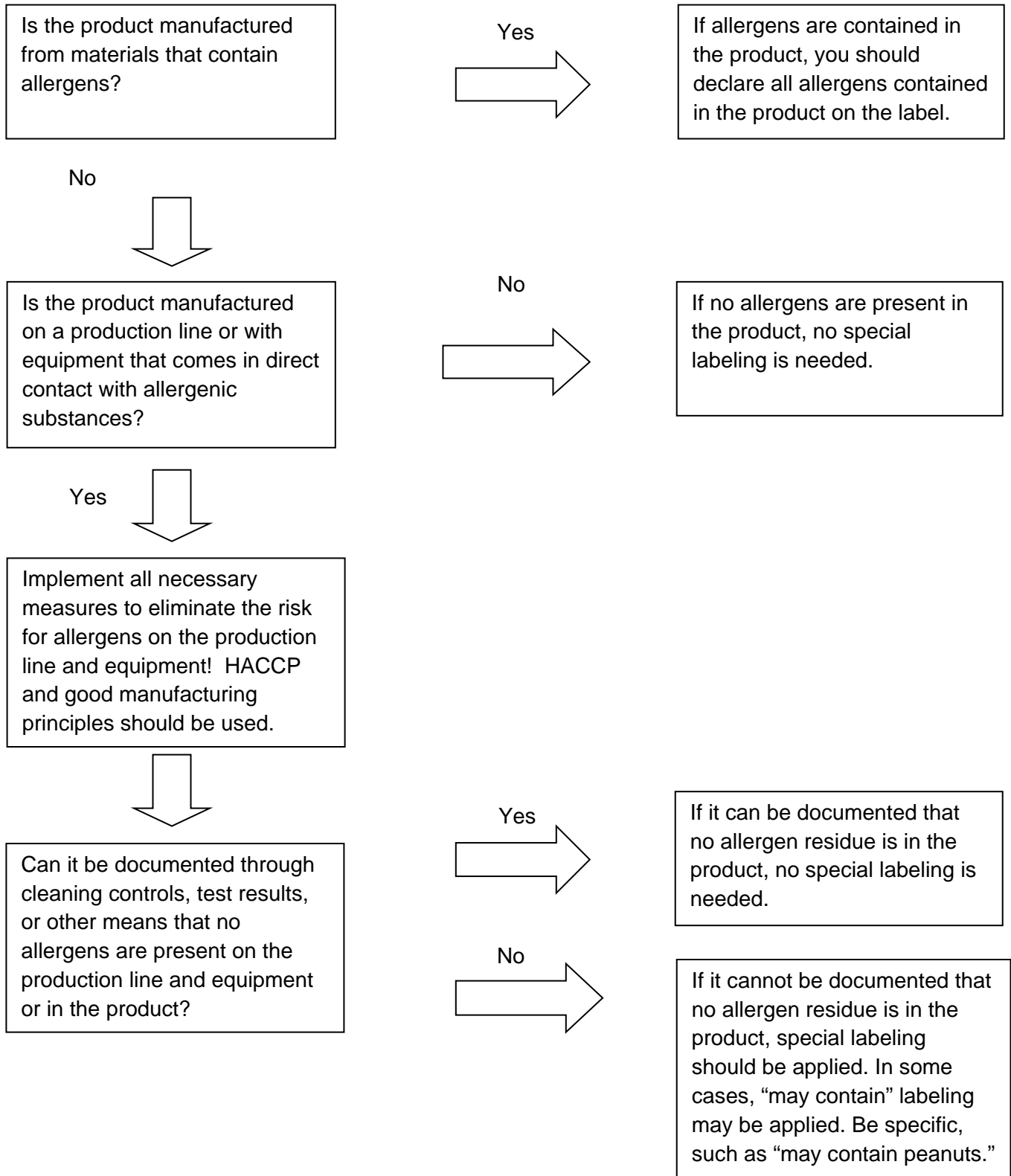
Appendix 1: How to Handle Labels of Incoming and Outgoing Products



Appendix 2: Process Flow Diagram with Mitigation Targets



Appendix 3: Allergen Risk Evaluation and Labeling



Appendix 4: Establishment Checklist

Identify: Hazard Analysis, Inspection of Incoming Ingredients, Cross-referencing Components, and Separation

Questions	Yes	No	Comment
Do we use non-meat or non-poultry ingredients from a supplier in our product?			
Have we created a listing of the non-meat or non-poultry ingredients that we use from a supplier in our product?			
Do suppliers of ingredients have a documented allergen control program?			
Do our non-meat or non-poultry ingredients contain allergens or other ingredients of public health concern?			
Are ingredient specifications reviewed for formula changes?			
Is there a system in place to verify that purchased ingredients are correct when received?			
Are we addressing the accuracy of incoming ingredient labels?			
Are ingredients labeled if they contain an allergen?			
Are the product codes of purchased ingredients monitored for changes?			

Prevent and Control: Equipment, Sanitation, and Processing

Questions	Yes	No	Comment
Do we have preventive measures in place in our HACCP plan or other prerequisite program that prevent the presence of undeclared allergens? If so, what measures are applied?			
Are ingredients stored and transported through the establishment in a manner that prevents cross-contact?			
Is the labeling and identification of allergenic ingredients maintained throughout establishment processing (from receiving to shipment)?			
Is it possible to process products with allergens with dedicated supplies and equipment? If not, are allergenic products separated to prevent cross-contact?			
Is rework that contains allergenic ingredients only used with "like" items?			
Does our establishment have standardized procedures for sanitation for food allergens?			
Does our establishment have an established procedure for verification of the sanitation effectiveness for food allergens?			

Declare: Packaging, Labeling, and Storage

Questions	Yes	No	Comment
Are we addressing the accuracy of outgoing final packaged product?			
Does the finished product label, including sub-ingredients, match both the final label and formulation data on the non-meat or non-poultry ingredient label?			
Is there a system in place for traceback of non-meat and non-poultry ingredients in the event of a concern, investigation, or recall?			
Do we ensure that employees responsible for labeling are aware if there are formulation changes?			

Overall

Questions	Yes	No	Comment
Have we trained our employees on how to properly inspect, process, store, and label allergenic product?			
Do employees have an understanding of the establishment's allergen control program?			
Are our control procedures for allergens being applied appropriately and verified of their effectiveness?			

Appendix 5: Allergen Scenarios and Possible Preventive Measures

NOTE: An establishment is required to notify the district office within 24 hours of learning or determining that it has shipped or received in commerce adulterated or misbranded product (9 CFR 418.2).

Scenario 1: Establishment A notified in-plant inspection personnel of a problem that it has discovered with a particular meat snack stick that it produced on five separate days in the last two weeks. The establishment's supplier changed its seasoning blend to include eggs; however, the snack stick label was not updated to include the presence of this allergen.

IDENTIFY: The establishment should communicate with suppliers of ingredients to ensure they advise them of any changes in product formulation and allergens in the final product.

IDENTIFY: The establishment should routinely check an ingredient's formulation, in this case, the seasoning used in the snack sticks. One possible solution is to keep product formulation and label records at receiving to compare against incoming ingredients. Additionally, establishment management should maintain active and open communication with suppliers and become familiar with letters of guarantee, packaging of ingredients, and ingredient product codes.

DECLARE: The establishment could verify the ingredients within each product during the packaging and labeling of the snack sticks. Establishments should verify the accuracy of all labels on products and ensure that they appropriately reflect the ingredients used in the formulation. Not identifying the presence of an allergen or ingredient of public health concern means that the label is false and misleading, and the product is misbranded and adulterated. Verification of the product labels should be carried out and include a comparison of the formulation and ingredients contained in non-meat products.

Scenario 2: Establishment B produced multiple products including two chicken entrees: one containing shrimp, and one containing vegetables but no shrimp. On two days, the establishment packaged and shipped the chicken and shrimp entree in the chicken and vegetables package. The problem was discovered by two consumers who purchased the entree and reported the wrong packaging to FSIS.

DECLARE: Properly declaring allergens using the appropriate package is just as important as identifying ingredients and processing product. The establishment should consider using color-coding of products containing allergenic ingredients and should have a mechanism for verification of product labels, such as checklists at the point of packaging and labeling.

Scenario 3: As a result of rising costs for a teriyaki sauce mix used in a stir fry meal produced by Establishment C, establishment management searched for a less expensive supplier. The sauce produced by the current supplier contained wheat and soy, which were properly declared on the meal label. A new supplier was found that could supply teriyaki sauce at a much lower price, and the establishment began using the product. After an investigation of four consumer complaints, in-plant inspection personnel discovered that the new teriyaki sauce contained milk and almonds, which were not declared on the meal label.

IDENTIFY: In instances when establishments are changing suppliers, it is essential to communicate about expectations regarding ingredients and allergens. Prior to the change, the establishment should thoroughly review the ingredients contained in non-meat products, such as mixes or sauces. Again, at receipt at the establishment, the establishment should cross-check the ingredients used by the supplier against formulation and label records before accepting the ingredient at the establishment.

Scenario 4: Store D conducted testing of a pizza product produced by Establishment D. The testing revealed a peanut-containing ingredient that was not declared on the label, and Store D reported the

presence of the ingredient to Establishment D. An FSIS Enforcement, Investigations, and Analysis Officer (EIAO) was dispatched to the establishment to investigate. He discovered that on the day of production, a peanut-containing product was run prior to the pizza on some of the same equipment, and that the establishment routinely uses the same utensils throughout the production day.

PREVENT AND CONTROL: Cleaning procedures need to be in place at establishments that produce both allergenic and non-allergenic products to prevent cross-contact and misbranding. Dedicated equipment and supplies should be considered, although separation by time can also be carried out effectively. In this instance, maintaining a documented process flow may have suggested a better production schedule to minimize cross-contact.

Appendix 6: Allergenic Ingredients and Foods

[Food Allergy Research and Education](#) is a source of information regarding food allergies. One of the organization's resources for consumers lists allergenic ingredients and foods that may contain allergenic ingredients. The list of ingredients and foods below can be used to help identify "Big Eight" allergens.

1. Wheat

Consumers allergic to wheat products are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain wheat.

bread crumbs	Farina	sprouted wheat	wheat gluten
bulgur	flour*	triticale	wheat grass
cereal extract	hydrolyzed wheat protein	vital wheat gluten	wheat malt
club wheat	Kamut	wheat	wheat protein isolate
couscous	matzoh/matzo, matzah/matza	wheat bran	wheat sprouts
cracker meal	Pasta	wheat bran hydrolysate	wheat starch
durum	Seitan	wheat durum	whole wheat berries
einkorn	semolina	wheat germ	
emmer	Spelt	wheat germ oil	

* *all purpose, bread, cake, durum, enriched, graham, high gluten, high protein, instant, pastry, self-rising, soft wheat, steel ground, stone ground, whole wheat flour*

Additionally, wheat is sometimes found in the following foods:

baking powders (particularly imported)	glucose syrup	starch	Worcestershire sauce
bouillon	soy sauce	surimi	

2. Crustacean Shellfish

Consumers allergic to crustacean shellfish are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products have these ingredients, they contain a "Big Eight" allergen

barnacle	crawfish	lobster	shrimp
crab	Krill	prawns	

Additionally, crustacean shellfish are sometimes found in the following foods:

bouillabaisse	fish stock	imitation fish/shellfish	surimi
cuttlefish ink	glucosamine	seafood flavoring	

3. Eggs

Consumers allergic to eggs are advised to avoid foods that may contain these ingredients. If meat or poultry products contain any of these, they likely contain eggs.

albumin/albumen	egg white	lysozyme	ovalbumin
dried egg	egg yolk	mayonnaise	powdered eggs
egg solids	eggnog	meringue	surimi

Additionally, eggs are sometimes found in the following foods:

baked goods	lecithin	marzipan	nougat
egg substitutes	macaroni	marshmallows	pasta

4. Fish

It is generally recommended that consumers allergic to fish should avoid all fish. The most common kinds of fish that individuals are allergic to are salmon, tuna, and halibut.

Additionally, fish is sometimes found in the following foods:

Asian foods	bouillabaisse	meatloaf	Worcestershire sauce
barbeque sauce	imitation fish/shellfish	salad dressing	

5. Peanuts

Consumers allergic to peanuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain peanuts.

artificial nuts	ground nuts	nut meat	peanut flour
beer nuts	mixed nuts	nut pieces	peanut protein hydrolysate
goobers	monkey nuts	peanut butter	

Additionally, peanuts are sometimes found in the following foods:

African, Asian, Latin American foods	Chili	marzipan	
baked goods	egg rolls	mole sauce	
candy	enchilada sauce	nougat	

The FDA exempts highly refined peanut oil from being labeled as an allergen.

6. Milk

Consumers allergic to milk are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain milk.

butter	caseinates	half-and-half	recaldent
butter fat	cheese	lactalbumin	rennet casein
butter oil	cottage cheese	lactoferrin	sour cream
butter acid	cream	lactose	sour milk

butter ester	curds	lactulose	tagatose
buttermilk	custard	milk*	whey
casein	diacetyl	milk protein hydrolysate	whey protein hydrolysate
casein hydrolysate	ghee	pudding	yogurt

* milk in all forms (including condensed, derivative, dry, evaporated, goat's milk and milk from other animals, low fat, malted, milkfat, nonfat, powder, protein, skimmed, solids, whole)

Additionally, milk is sometimes found in the following foods:

artificial butter flavor	chocolate	margarine	sausages
baked goods	hot dogs	nisin	
bouillon	lactic acid starter culture and other bacterial cultures	nondairy products	
caramel candies	luncheon meat	nougat	

7. Tree Nuts

Consumers allergic to tree nuts are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain a "Big Eight" allergen.

almond	coconut	Nangai nut	pili nut
artificial nuts	filbert/hazelnut	natural nut extract	pine nut
beechnut	gianduja	nut butters	pistachio
Brazil nut	ginkgo nut	nut meal	praline
butternut	hickory nut	nut paste	shea nut
cashew	litchi/lichee/lychee nut	nut pieces	walnut
chestnut	macadamia nut	pecan	
chinquapin	marzipan/almond paste	pesto	

Additionally, tree nuts are sometimes found in the following foods:

alcoholic extracts	black walnut hull extract	nut distillates	walnut hull extract
Asian foods	natural nut extract	nut oils	

8. Soybeans

Consumers allergic to soybeans are advised to avoid foods that may contain these ingredients. If meat, poultry, or egg products contain any of these, they likely contain soybeans.

edamame	soy fiber	soy sprouts	tamari
miso	soy flour	soy yogurt	tempeh
natto	soy grits	soya	textured vegetable protein
shoyu	soy ice cream	soybean	tofu
soy albumin	soy milk	soy protein	

soy cheese	soy nuts	soy sauce	
------------	----------	-----------	--

** FDA exempts highly refined soybean oil from being labeled as an allergen. However cold-pressed soybean oil, which is less commonly used, is not exempt from allergen labeling as it likely contains more residual protein.*

Additionally, soybeans are sometimes found in the following foods:

Asian foods	vegetable broth	vegetable starch	
soy lecithin*	vegetable gum	Worcestershire sauce	

** With the exception of a few specific products, FDA does not exempt soy lecithin from allergen labeling as it generally contains residual protein. The use of soy lecithin in non-stick sprays and coatings (i.e. releasing agents) has led to recalls of FSIS-regulated product when the soy was not properly declared.*

Appendix 7: References and Resources

- Atkins D, Bock SA. Fatal Anaphylaxis to Foods: Epidemiology, Recognition, and Prevention. *Current Allergy and Asthma Reports*, 2009;9:179-185.
- Beef Industry Food Safety Council Executive Committee (March 2008). *Best Practices for Raw Ground Products*. Retrieved at <http://www.bifsc.org/CMDocs/BIFSCO/Best%20Practices/groundproducts2933.pdf>
- Boyce, Joshua, et al, National Institute of Allergy and Infectious Diseases (December 2010). Guidelines for the Diagnosis and Management of Food Allergy in the United States: *Summary of the NIAID-Sponsored Expert Panel Report*. Retrieved at <http://www.niaid.nih.gov/topics/foodallergy/clinical/documents/faguidelinesexecsummary.pdf>
- Centers for Disease Control and Prevention (October 2008). *Food Allergy Among U.S. Children: Trends in Prevalence and Hospitalizations*. Retrieved at <http://www.cdc.gov/nchs/data/databriefs/db10.pdf>
- Food Allergy Research and Education (FARE). Tips for Avoiding Your Allergen. Retrieved at <http://www.foodallergy.org/document.doc?id=133>
- Food Allergy Research and Resource Program, University of Nebraska at Lincoln. Components of an Effective Allergen Control Plan: A Framework for Food Processors. Retrieved at <http://www.foodallergy.org/files/AllergenControlPlan.pdf>
- Food Safety and Inspection Service (December 2010). Fact Sheets: *Safe Food Handling*. Retrieved at <http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/safe-food-handling/be-smart-keep-foods-apart>
- Food Safety and Inspection Service (March 2007). Regulations and Policies: *Compliance Assistance: Allergens-Voluntary Labeling Statements*. Retrieved at [Compliance Assistance: Allergens-Voluntary Labeling Statements](http://www.fsis.usda.gov/Food/ComplianceAssistance/ComplianceAssistance-Allergens-Voluntary-Labeling-Statements)
- Food Safety and Inspection Service (September 2013). Recall of Meat and Poultry Products. Retrieved at [FSIS Directive 8080.1](http://www.fsis.usda.gov/Food/Recalls/Recall-8080.1)
- Government of Alberta, Agriculture and Rural Development (August 2008). Alberta HACCP Advantage Chapter 11: Developing and Allergen Control Program. Retrieved at [http://www1.agric.gov.ab.ca/\\$Department/deptdocs.nsf/all/afs12301](http://www1.agric.gov.ab.ca/$Department/deptdocs.nsf/all/afs12301)
- Jackson, Lauren S, et al. Cleaning and Other Control and Validation Strategies to Prevent Allergen Cross-Contact in Food-Processing Operations. *Journal of Food Protection*, 2008;71(2):445-58.
- National Advisory Committee on Microbiological Criteria for Foods. Hazard Analysis and Critical Control Point Principles and Application Guidelines. *Journal of Food Protection*, 1998; 61(9):1246-1259
- Taylor, Steve (2000). *Emerging Problems with Food Allergens*. Retrieved at <ftp://ftp.fao.org/docrep/fao/003/x7133m/x7133m02.pdf>
- United States Food and Drug Administration (August 2004). Guidance, Compliance, and Regulatory Information. *Food Allergen Labeling and Consumer Protection Act of 2004*. Retrieved at <http://www.fda.gov/food/labelingnutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.htm>
- United States Food and Drug Administration (October 2009). Guidance for Industry: A Food Labeling Guide. Retrieved at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064880.htm#label>
- Wisconsin Division of Food Safety. Allergen Control Program Worksheet. Retrieved at http://datcp.wi.gov/Food/Food_Code_Fact_Sheets/index.aspx