FSIS Compliance Guidelines

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

April 2014

This document provides guidance to assist establishments in meeting Food Safety and Inspection Service (FSIS) regulations. Guidance represents best practice recommendations by FSIS, based on the best scientific and practical considerations, and does not represent requirements that must be met. Although FSIS is requesting comments on this document, this guidance represents FSIS's current thinking. FSIS encourages establishments to use it.

Request for comments:

FSIS requests that all interested persons submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items: Send to Docket Room Manager, U.S. Department of Agriculture (USDA), FSIS, Patriot's Plaza 3, 1400 Independence Avenue SW, Room 8-163B, Mailstop 3782, Washington, DC, 20250-3700.

All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2013-0029. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to http://www.regulations.gov.

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Chapter 1: Introduction and Background

This document provides recommendations for identifying hazards when conducting a hazard analysis and to prevent and control hazards through hazard analysis and critical control point (HACCP) plans or Sanitation standard operating procedures (SOPs) or other prerequisite programs with respect to allergens and other ingredients of public health concern. The emphasis of the guidelines presented in this document is on meat and poultry products. 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**

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 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 sustained increase in the number of recalls of FSIS-regulated product that contained undeclared allergens. These recalls are preventable as many have been due to 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

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

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, management of signs and symptoms and food avoidance for those affected are needed.

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.

While the "big eight" allergens are the most common allergenic foods, people may be allergic to other substances as well. In addition to food allergens, some ingredients such as sulfur based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients of concern that may result in an adverse reaction in susceptible individuals. FSIS is concerned about all foods or food ingredients that may cause adverse health effects.

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

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.

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 in which the ingredient was used.

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.

What is causing undeclared allergen recalls?

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

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.

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, except for substances whose use has been determined to be, consistent with FDA’s labeling definition, an incidental additive or a processing aid (21 CFR 101.100(a)(3)). For FSIS-regulated products, the Agency makes determinations of whether ingredients are incidental additives or processing aids 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.

Within this document are several resources to 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
- 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 concepts from the guidelines
- Page 23 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 to 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.

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 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.

The hazard analysis is to assess the food safety hazards reasonably likely to occur in the production process and 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 carry the hazard identification out thoroughly to mitigate preventable recalls associated with 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 may 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, which 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 and verify that the plan is being effectively implemented to reduce the potential for the presence of undeclared allergens in the product.

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 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

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
- Code that identifies the component
- Statement that the material is safe and effective under intended conditions of use, and will not adulterate the food product
- Statement that specifies applicable limits
- 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.

When an establishment uses ingredients from a supplier, they typically receive a letter of guarantee (LOG) from the supplier of the non-meat/poultry and meat/poultry components. The LOG may contain information that identifies ingredients, ingredient components, processing aids, rework, processing steps, environmental conditions, and product carry over because of the use of common equipment for each ingredient received. Establishments should review the LOG closely before inclusion of a non-meat or non-poultry ingredient or product. **A review should be conducted on a continuous basis, for each lot, with increased attention when an establishment has changed suppliers, or the supplier has modified the ingredient formula.**

Establishments that fail to routinely review and verify the components and ingredients they receive 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 product recall.

FSIS recommends that establishments 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.

Establishments should also cross reference the sketch label approval, if applicable, to the actual label being used and the formulation data for accuracy. 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, establishments 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.

Every establishment must reassess the adequacy of the 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 of 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)).

Establishments can prevent the presence of undeclared allergens by ensuring that appropriate mechanisms for labeling of 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.

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

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.

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.

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.

FSIS **does not recognize** a threshold of any allergenic ingredient that does not require declaration.

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

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. This can be prevented by processing the non-allergenic product before the allergenic product.

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 the 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.

Establishments 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. This includes 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
- 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

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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 procedures 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, the storage of the allergenic and non-allergenic final product needs to be easily identifiable with product separation. Establishments should ensure that product is not cross-contaminated when placed in freezers, refrigeration units, or dry warehouses. FSIS recommends this process be included within an establishment's HACCP system. Establishments should also take care when storing ingredients in dry warehouses or formulation rooms. Establishments should ensure that all ingredients in storage areas are properly identified to prevent employees from selecting the wrong ingredient during formulation.

It is important that establishments verify the accuracy of the final label to ensure that it includes all allergenic and non-allergenic ingredients in the product. Establishments should check the accuracy of labels in relation to the product being packaged. Establishments may also include this procedure within its

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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.*

HACCP plan or other prerequisite program. The product in the package must precisely match the product described by the label on the package.

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

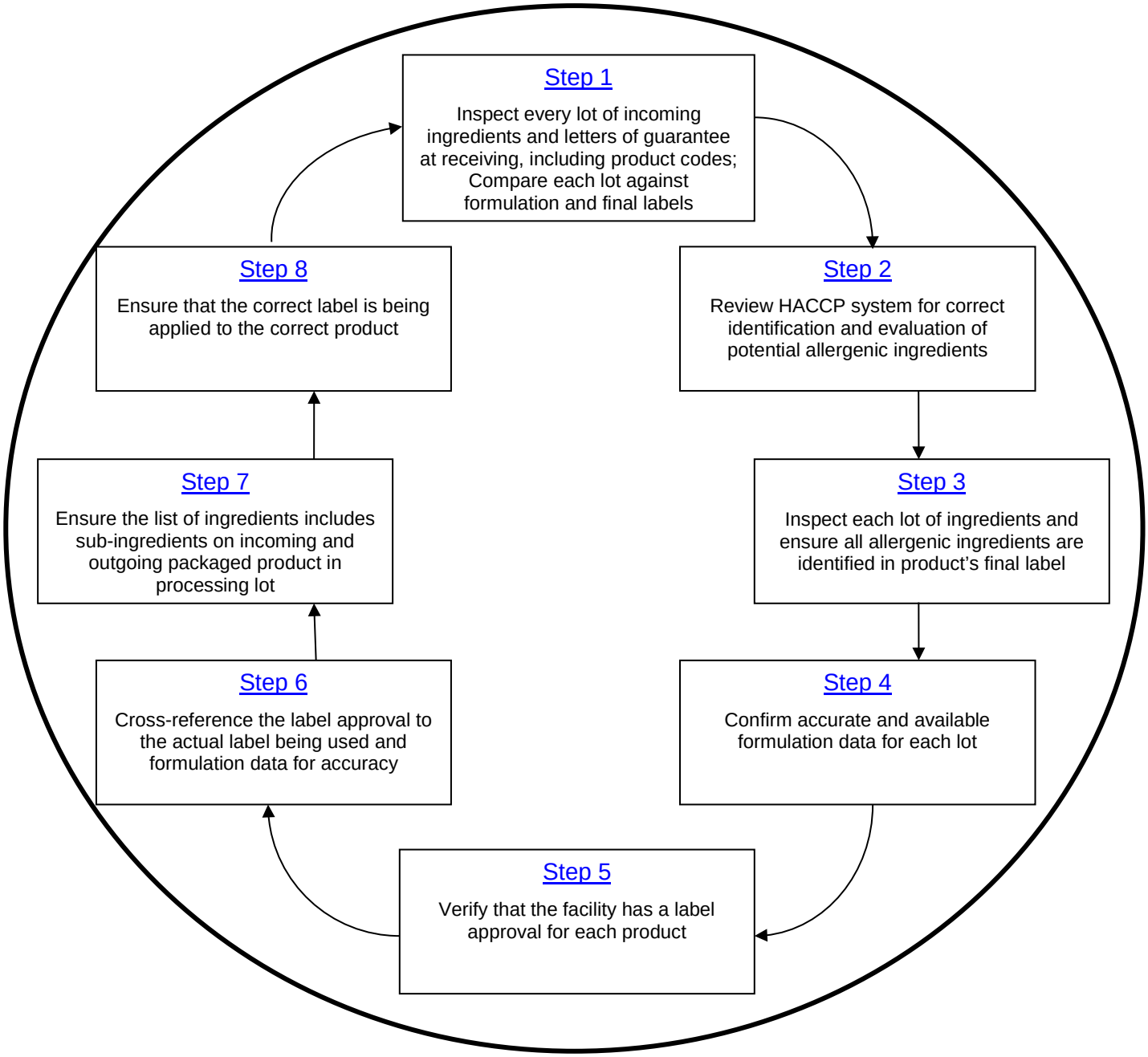
All staff that handle and order ingredients, supplies, and equipment, as well as those who are responsible for handling ingredients and products from receiving through shipping, should be aware of the dangers of allergens. **Each establishment employee needs to understand his or her food safety role in this process.** Establishments 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

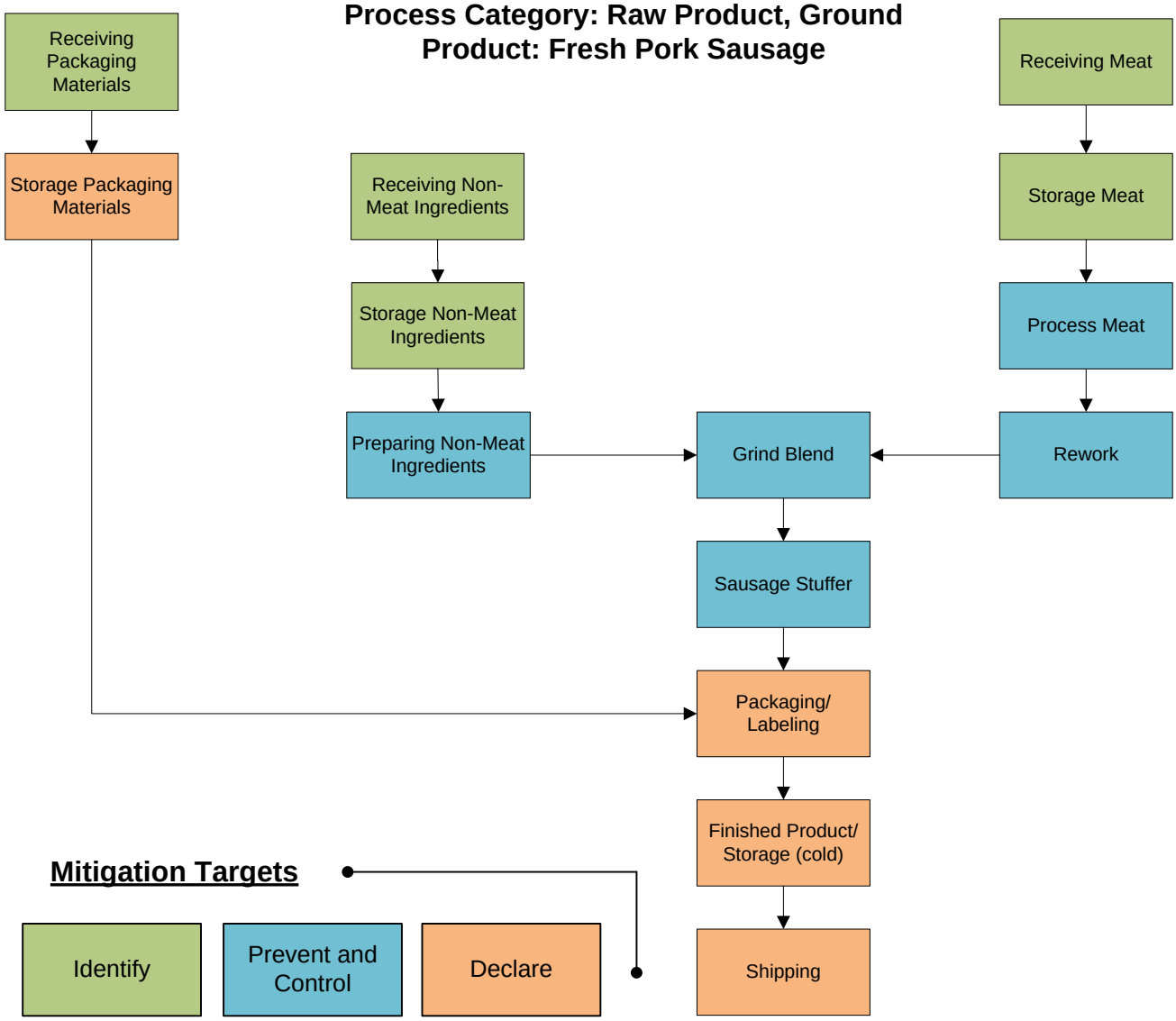
How to Handle Labels of Incoming and Outgoing Products



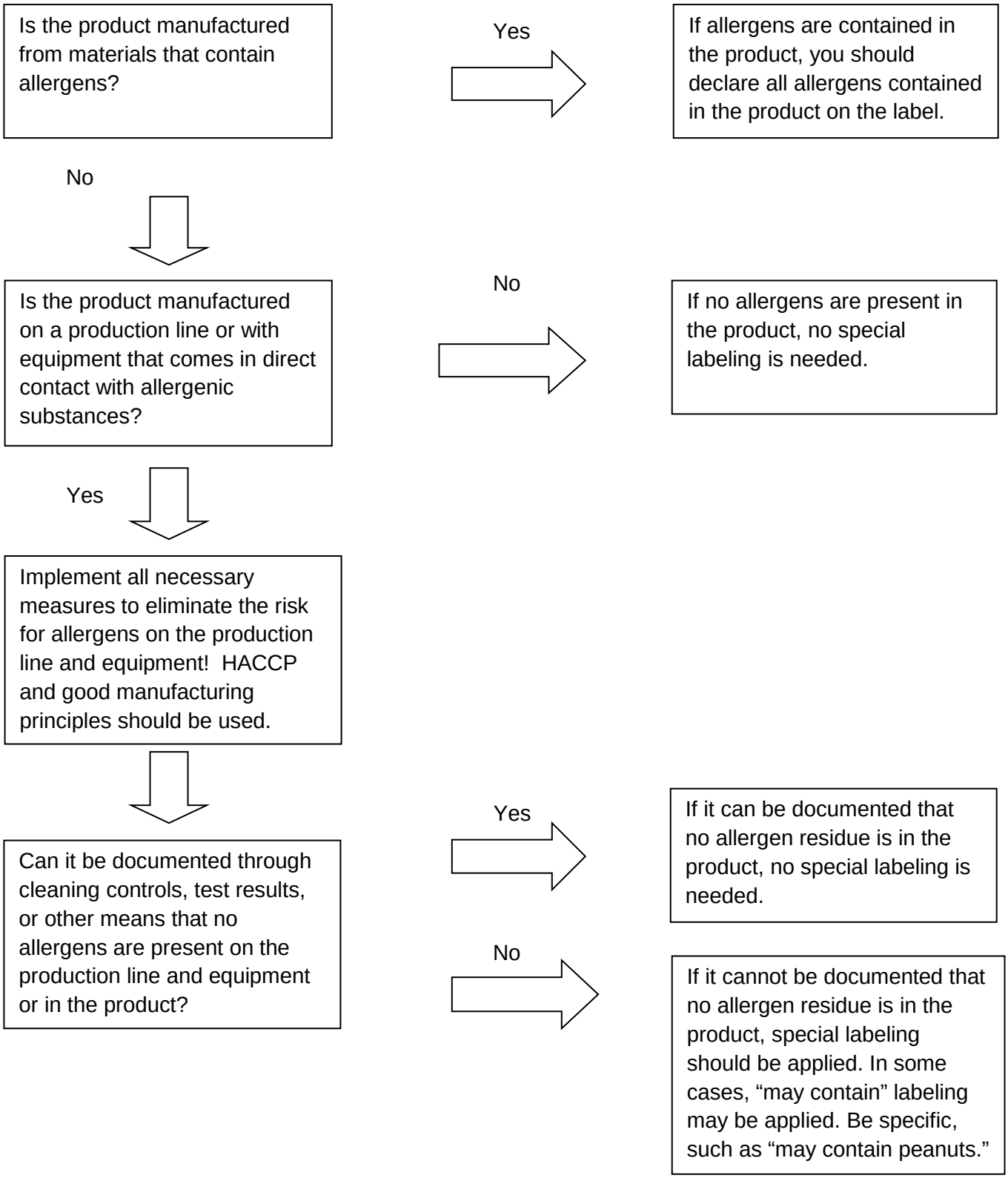
Process Flow Diagram

Process Category: Raw Product, Ground

Product: Fresh Pork Sausage



Allergen Risk Evaluation and Labeling



Establishment Checklist

Identify

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

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

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 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?			

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 did not get updated to include the presence of this allergen.

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 problem could also have been prevented 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 with 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.

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