

# Guidance for Allergen Control in Meat Establishments

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## Introduction

During the last five years, undeclared allergens have been the leading cause of product recalls in the meat industry. Recalls related to undeclared food allergens, which are classified as Class I<sup>1</sup> recalls by the Food Safety and Inspection Service (FSIS or the agency), occur when meat products leave a facility and enter commerce without an allergen declaration on the label. The most likely reason for failure to declare an allergen on a product label is a change in product formulation or a change in the supplier's ingredient formulation. The only way to prevent such a recall is to ensure allergen control programs are adequate and properly implemented.

In the United States, there are eight major allergens, as designated by the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, which cause 90 percent of food based allergic reactions. These eight, commonly referred to as the "Big 8 Allergens," are: (i) peanuts; (ii) tree nuts (almonds, pecans, walnuts, *etc.*); (iii) egg; (iv) milk; (v) soy; (vi) wheat; (vii) fish; and (viii) shellfish. In April 2014, FSIS published a guidance document, which provides recommendations for identifying allergens<sup>2</sup> and other ingredients of health concern<sup>3</sup> during a hazard analysis.

The agency's recommendations are based on principles for controlling pathogens: identify the hazard; prevent and control the hazard; and declare the hazard. Likewise, the agency expects allergens and other ingredients of public health concern to be addressed in an establishment's hazard analysis. If the hazard analysis determines the hazard is reasonably likely to occur, controls for allergens must be in the HACCP plan through one or more CCPs. Conversely, if the hazard analysis determines the hazard is not reasonably likely to occur, controls may be located alternatively in the SSOP or other prerequisite program. Adherence to a robust allergen control program will help processors meet regulatory requirements.

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<sup>1</sup> A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.

<sup>2</sup> 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).

<sup>3</sup> Ingredients of public health concern: Ingredients to which consumers have reported adverse reactions.

## Practical Steps to Identify Allergens and Methods of Control

The first step in developing an allergen control program is to identify allergens, which are most appropriately considered chemical hazards in the hazard analysis and the HACCP plan, in the establishment. When conducting a hazard analysis, allergens need to be assessed at any point that they may be introduced, any step at which the hazard may be enhanced, and any step at which control should or will be applied. Furthermore, establishments should be aware of all ingredients—including those within premixed spice blends—to be included or have the potential to be exposed to when producing the meat product. Once all allergen hazards are identified, a plan can be developed to establish control measures and procedures for allergen use. A summary of the information provided below can be found in Appendix 1.

### Identify Allergen Hazards

Review All Ingredients. Establishments should review formulation sheets and ingredient statements. Particular attention should be given to premixed spice blends. Verify with the supplier that all allergens are identified and develop a process to notify the establishment when changes occur. Additionally, there are food ingredients that individuals may have a food sensitivity to, but not an allergy (*i.e.* red wine, lactose, monosodium glutamate (MSG), sulfites, and food coloring, *etc.*). These ingredients should be monitored and labeled, as appropriate.

- *Keep a Continually Reviewed and Updated List of All Ingredients and Suppliers.* Keep a continuous spreadsheet or other form of documentation with all product ingredients listed and allergens highlighted.
  - An establishment may require a supplier to have an allergen control program and may tell the supplier the establishment reserves the right to audit the supplier's process at the establishment's discretion.
  - Suppliers should agree to notify establishments, in writing, if formulation changes occur.
- *Understand a Letter Of Guarantee (LOG) From Suppliers.*
  - An establishment should carefully read a LOG and seek additional information, as identified by the establishment's HACCP, SSOP, or other prerequisite plans.
  - An establishment should develop a checklist of information to be included in a LOG. The checklist should include where and how the ingredient is produced, what else is produced with the purchased ingredient or product, *etc.*
  - A LOG should include a statement indicating the supplier has met all Food and Drug Administration (FDA) or FSIS requirements and the ingredient or product is fit for the intended purposes.

- A LOG must be signed by the supplier.
- If a LOG is unavailable (*i.e.*, supplies are purchased from a wholesaler), the establishment should review labels for possible allergens.

Conduct a Thorough Walk Through of the Establishment to Identify Locations Where Allergen Cross-Contact Could Occur. Establishments should examine and understand how allergens and other ingredients are stored and labeled. This examination should include spice storage and blending areas. Also consider any cross-contact events that could occur during manufacturing.

Processing Aids Used During Production Must Also Be Considered a Potential Source of an Allergen Hazard. Processing aids are required to be included in ingredient statements when the processing aid contains an allergen. Releasing agents (*e.g.*, canola oil spray) are common processing aids that contain soy lecithin, a known allergen. If this processing aid is used, soy (an allergen) must be listed on the ingredient statement. Processing aids are determined by FSIS on a case by case basis.

### **Control Methods**

Good Manufacturing Practices (GMP) Should Be Followed During the Production of Meat Products.

- Establishments should ensure employees understand the importance of GMP and other process management steps during the production of meat products. Specifically, employees need to know when to change frocks and gloves; when to wash hands; how to comply with SSOPs; in addition to documenting and preparing records demonstrating compliance; and ensuring employees are aware when allergens will be used in production.
- Use disposable aprons (over frocks) and gloves when formulating spice mixtures containing allergens.
- Be careful with rework. Employees must be careful not to incorporate a product that has an allergen into rework with other product(s) not containing that allergen.
  - Rework should only be included in meat products with like ingredients.
- Color code equipment (utensils, lugs, etc.) to designate products/equipment containing allergens. For example, use red equipment for products with allergens and green equipment for non-allergen containing products.
- Record all procedures and keep track of products.

### Scheduling.

- Production scheduling is an important consideration when producing products containing allergens. This consideration could involve dedicating a separate production day for product(s) with allergens. If dedication is not feasible, establishments should consider producing allergen containing products at the end of the production day. Production at the end of the day eliminates requiring a full sanitation of exposed production areas and equipment between product line changes.
- If an establishment cannot produce allergen containing products at the end of the production day or on a dedicated day, the following practices must be done.
  - Product manufacturing areas -- Clean-up method and sanitation must be completed before any other product or allergen containing product can be produced. Surfaces must be monitored to ensure they are “visibly clean and sanitized.”
  - Packaging areas -- Clean-up protocols should ensure all food residues are removed and subsequently monitored to verify surfaces are “visibly clean and sanitized.”
  - Keep records of sanitation procedures.

Employee Training. All employees who handle allergens must receive thorough training when hired or placed into a position involving handling allergens. An effective employee allergen control training program includes, but is not limited to, education regarding: avoiding cross-contact; process flow (steps); rework handling; cleaning and sanitation; labeling; lot tracking; product formulations; dedicated supplies and equipment; ingredient storage; production scheduling; what it means to place a “hold” on products and notifying management of errors in production; uniform requirements when handling allergens; and basic GMP and SSOPs.

### **Facility Design and Storage**

Store Allergens Separately From Other Ingredients. Proper storage of allergens is necessary to reduce the potential for cross-contact of products. All ingredients in storage areas should be properly identified to prevent employees from selecting the wrong ingredient during formulation. If allergens must be stored in the same location as non-allergen ingredients, they should be stored on the bottom shelf or on a separate shelf to reduce the likelihood of cross contact

NOTE: Procedures should be in place to address potential contamination events, such as when bags may become broken during storage, movement, or cleaning the storage room.

All Products and Ingredients Containing Allergens Should Be Marked in a Conspicuous Manner For Easy Identification By Employees During Storage and Handling. Commonly used approaches include using bright colored labels or other easily identifiable visual cues for the allergen containing ingredients and products. Additional examples are provided in Appendix 2.

Establishments Should Design a Workflow to Reduce or Prevent Allergen Contamination. Establishments should avoid storing allergens in production areas and avoid transporting allergens through production areas when products not containing those allergens are being produced, among other practices.

Product Formulation, Packaging, and Labeling.

- Establishments must maintain current and accurate product formulation records.
- When creating or modifying product formulations, be aware of any allergens in the product.
  - In most establishments, R&D staff or management develop product formulations. During the formulation development or modification staff should ensure other employees understand the different product formulations and whether allergens are present.
  - If an ingredient does not contain the functional protein that causes the allergenic response, it is not considered an allergen. This rule applies to processed ingredients in which the allergenic protein is denatured, thus rendering the ingredient non-allergenic.
    - Heat treated ingredients can have their allergenicity reduced, but not necessarily eliminated (Davis and Williams, 1998). To ensure the ingredient is allergen-free establishments must have documentation from the supplier demonstrating no allergenic hazard exists.
- The establishment must ensure the formulation being produced matches the current, documented product formulation and ingredient statement on the product label.

NOTE: As a practical matter, only have the correct finished product labels in the area where labeling is applied. Also, remove outdated or other labels not currently in use from all parts of the production facility or secure them under lock and key to avoid potential use.

- Ingredient statement on packaging must be accurate and updated. If there is a change in the formulation, make sure the change is made to the ingredient statement on the label, including when allergens are added or removed from the product. Personnel must cross check labels with updated formulations to verify the label changes have been made.
  - FSIS does not require label statements indicating: “Contains: allergen 1, allergen 2, *etc.*” However, the agency supports such labeling.
    - Allergens must be listed in the ingredient statement by their common name, but they do not have to be indicated specifically. Doing so, however, is encouraged, *e.g.*, “...whey (from milk)...”
  - Though also not a labeling feature required by FSIS, “Produced in an establishment that uses peanuts” may be used by establishments in limited cases where good manufacturing practices and sanitation programs cannot reasonably eliminate cross-contact.
    - However, an establishment should not rely on such statements as a substitute for a comprehensive sanitation program. FSIS officials believe the indiscriminate use of this statement does not promote good manufacturing practices and is not beneficial to consumers as described in its compliance policy guide on statements of this type.  
(<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/ingredients-guidance/allergens-voluntary-labeling-statements>)
  - FSIS conducts monthly or more frequently if necessary “Big 8 Formulation Verification” tasks. Inspection personnel select one product from the meat establishment, verify the product formulation and production process, and verify that the label accurately identifies allergens by their common name in the ingredient list. Records will also be reviewed by inspection personnel as directed by FSIS Directive 7230.1, March 2015. This directive clarifies the inspector’s role and provides more specific methodology for allergen inspections.

#### Equipment and Sanitation.

- Employees must receive sanitation training to ensure the establishment is adequately cleaned after production. If a third party sanitation company is used, the establishment must ensure the sanitation company’s training program includes allergen sanitation and meets the establishment’s expectations.
- The product being produced, food contact surfaces used, and the allergen(s) hazards should all be considered when designing a sanitation program. Food proteins, which are the source of allergic reactions, can be difficult to properly remove from food contact surfaces. Cleaning and sanitation programs should ensure all residues are removed.

## **Corrective Action for Suspect Product**

If an establishment suspects a meat product contains an undeclared allergen or has been contaminated with an allergen, the product must be identified as suspect and put on hold until further investigation can verify if the product is contaminated. In this scenario, the product should be clearly marked as “Suspect and Hold.” This typically is done in a manner in which the product is distinguishably marked in a way to ensure it does not enter commerce.

In some situations, testing for the presence of allergens may help support a belief that cross contact did not occur or that product is not adulterated or misbranded. However, testing alone typically is not considered conclusive evidence the allergen is not present because the presence of an unintended allergenic contaminant may not be homogeneously distributed through a product. Additionally, it is important to understand the limitations and sensitivity of the allergen test being utilized. In some cases, the level of sensitivity for an allergen test exceeds the threshold associated with adverse reactions.

## **Verification Options for Sanitation Components of the Program**

Allergen diagnostic test kits exist for almond, eggs, gliadin and gluten, hazelnut, lupine, casein,  $\beta$ -Lactoglobulin, milk, mustard, peanut, sesame, crustaceans shellfish, soy and walnut residues. Test kits may be used as a tool for periodic verification; however, they are not the best tool for ongoing allergen control monitoring. Testing cannot be effectively used to replace a soundly designed allergen control program, or sufficient monitoring of the ongoing implementation of a meaningful allergen control program. Such a meaningful program would include various aspects of labeling and label verification, sanitation, and employee practices covered throughout this document.

It is common for customers to require some level of allergen testing in food safety process management programs to meet purchase specifications. It is also common for establishments to successfully utilize test kits, which measure the presence or absence of adenosine triphosphate (ATP). ATP is an indicator of organic residue present on what is being tested, *i.e.* food contact surfaces. The advantage of ATP testing is results are given almost instantaneously. However, the test is limited because ATP presence does not absolutely indicate the presence of an allergen, but rather if a particular surface is clean (*i.e.* no residual organic matter). By verifying the absence of surface organic matter, it is reasonable to conclude that any allergen residue from previous production has been removed from the surface sampled.



As with all types of testing, the establishment must determine, and be able to support that determination, what product(s) potentially would be implicated by the outcome of the test and ensure that all such products are held under company control and not released until all test results are received and are acceptable.

### **Adhering to an Allergen Program**

Establishments must create and keep a current list of all incoming raw meat and non-meat materials, which must be made available for verification of all incoming shipments. The labels and letters of guarantee (LOG) for all incoming shipments must be reviewed to verify that incoming raw materials are as expected. The establishment should refuse, tag, or put on hold incoming material if labels or LOG are not as expected. Similarly, establishments should be aware of possible changes to raw material production or formulations and have an established communication system with a supplier when notifications are necessary.

The establishment should review every formulation to ensure the ingredients used match those on the formulation or batch sheet. Every formulation sheet within an establishment must list every ingredient and production records must be kept to verify this fact. Monitoring must be conducted for every formulation and every batch on a daily basis.

Once the product is produced and packaged, labels must be checked and verified using the formulation sheet as a reference. Prior to shipment, reviews must be conducted to ensure the ingredient statement on the label accurately lists all ingredients, including any allergens, as designated by FALCPA. The listed ingredient components must accurately reflect the ingredients in the product. This verification must be done with every product, every batch, and for every production period. Additionally, lot specific records showing implementation of allergen program controls need to be reviewed to verify the product was produced as indicated on the label. These records are relatable to specific production lots, they must be reviewed as part of the HACCP pre-shipment review, regardless of whether the procedures are in the HACCP plan, SSOP, or other prerequisite program.

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## GLOSSARY OF USEFUL TERMS

**Cross-contact:** When an allergen or allergen containing product is mixed with non-allergen containing product. Cross contact poses a food safety hazard.

**Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

**Good Manufacturing Practices (GMP):** Practices that contribute to preventing food safety hazards, including but not limited to properly storing ingredients, employee hand washing, wearing gloves when handling product, changing gloves after handling allergens, *etc.*

**Letter of Guarantee (LOG):** Provides details for components used in food processing. In general, a LOG will contain supplier name and address, brand name, code that identifies the component, statement that the ingredient is safe and effective for intended use, statement that specifies applicable limits, and signature of an official of the supplier. The LOG should be attached to an invoice or may be a continuous LOG that does not come with each shipment.

**Suspect Product:** Product thought to have been contaminated by allergens.

## APPENDIX 1

### Allergen Control Program

1. Required Documents for Allergen Control Program
    - Maintain updated specification sheet with a detailed list of ingredients in spice blends and mixtures purchased for products.
    - Maintain updated formulation sheets to accompany the manufacture of products.
    - Allergens must be specifically highlighted and recognized in both documents.
  
  2. Receiving Non-Meat Ingredients
    - Review incoming non-meat ingredient labels to determine the presence or absence of allergens, and to verify no changes have been made since the last shipment of that ingredient was received. Use specification sheets for verification.
    - If allergens are present, apply appropriate warning label (examples provided in Appendix 2)
    - Fill out appropriate entries in receiving log (example provided in Appendix 3). Under “allergen label/storage,” indicate “Yes/Yes” if proper caution label is attached and placed in proper storage.
    - If the information does not match or if there is any uncertainty about whether the incoming ingredients are what was expected the product should be put on hold and appropriate establishment staff notified, *i.e.* quality assurance.
    - Records (*e.g.* receiving log) should be reviewed each day by quality assurance or other management personnel.
  
  3. Ingredient Storage
    - Store all ingredients with allergens in a separate room or a bottom shelf, away from all other ingredients. All ingredients in storage areas should be properly identified to prevent employees from selecting the wrong ingredient during formulation. Appropriate separation is necessary to prevent cross-contact.
  
  4. Production Scheduling
    - Allergen containing products must be made using one of the following schedules:
      - A. Manufactured on separate production day;
      - B. Manufactured at end of production day ensuring no other non-allergen containing products to follow; or
      - C. If manufactured within the normal production period, appropriate sanitation of equipment and production areas is required before continuing production of non-allergen containing products.
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## 5. Product Formulation and Manufacture

- Verify appropriate formulation is used to weigh non-meat ingredients.
- Use tools designated for use only with allergenic ingredients to weigh non-meat ingredients containing allergens. If not feasible, establish and implement appropriate sanitation measures between each use.
- Apply allergen warning label to batches containing allergens (examples provided in Appendix 2). Follow rework procedures to ensure allergen containing products are not mixed with non-allergen containing products.
- Complete Allergen Tracking document (example provided in Appendix 4) to accompany formulation or production logs.

## 6. Packaging and Labeling

- Do not package non-allergen containing products on the same surface as allergen-containing products without appropriately sanitizing equipment and production area to ensure no cross-contact occurs.
- Use Allergen Tracking document (Appendix 4) to identify any allergens in the meat product. If an allergen was added, it must be on product label in the correct order of predominance.
- Review all labels to verify the finished product label accurately declares all ingredients identified in the raw materials used, especially any allergens; record and sign Allergen Tracking document (Appendix 4).

## APPENDIX 2

### Allergen Warning Labels

Example of labeling that must be used on allergen ingredients and product batches. Such a warning should be printed on labels that are distinguishable from non-allergenic ingredients or product batches, *i.e.*, predetermined color coded labels.

**WARNING: ALLERGEN**

**Contains Peanuts**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Tree Nuts**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Egg**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Milk**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Soy**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Fish**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Shellfish**

**Store Separate**

**WARNING: ALLERGEN**

**Contains Wheat**

**Store Separate**



**APPENDIX 3**

**Non-Meat Ingredient Receiving Log**

Ingredient / Blend	Vendor	Lot #	Does label match specification forms? Yes or No	Allergens Yes or No	Proper Label / Storage Yes or No	Initials and Date

Reviewed by QA or Management: \_\_\_\_\_  
*Signature*
*Date*

**APPENDIX 4**

**Allergen Tracking**

**Manufacturing**

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

Product: \_\_\_\_\_

Allergens: \_\_\_\_\_

**Finished Product Labeling**

Does the label include the above-added allergens? \_\_\_\_\_

Attach Copy of label:

Verified by QA or Management: \_\_\_\_\_  
*Signature* *Date*

