



United States Department of Agriculture

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Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



**Allergen Control Management:
A Practical Look at Allergen
Prevention and Control for FSIS-
regulated Products**

Abdalla Amin

**Deputy District Manager
Office of Field Operations
Alameda District Office**

Food Safety and Inspection Service

Foodborne Illness Prevention



Perform food safety inspection at more than 6,000 establishments nationwide



Maximize domestic and international compliance with food safety policies



Public education and outreach to increase safe food-handling practices



Collaborate with internal and external stakeholders

How FSIS prevents foodborne illness

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Efforts to control allergens and minimize allergen recalls

An increase in allergen-related recalls prompted FSIS analysis, policy clarification, verification activities, and reiteration of establishment responsibilities

- FSIS Issued Notices 35-11, 54-11, and 29-13
- Draft Federal Register Notice published spring 2014
- Final Federal Register Notice published fall 2015
- FSIS Compliance Guidelines 2014 and 2015
- **FSIS Directive 7230.1**- in 2015, Ongoing Verification of Products Formulations and Labeling Targeting the 8 most common Food Allergens
- FSIS Constituent Updates
- FSIS-Conducting Food Safety Assessments (FSA) at Establishments

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Efforts to control allergens and minimize allergen recalls with FSIS Directive 7230.1

- Inspection Personnel to meet with establishment during weekly meeting to discuss **FSIS Directive 7230.1**
- Inspection Personnel to ask whether establishment has developed and implemented preventive or control measures with the HACCP plan, Sanitation SOPs, or other prerequisite program to address allergens
- Inspection Personnel to discuss whether establishment produces any products that contain any of the “Big 8” food allergens
- Inspection Personnel will inform establishment that FSIS will be verifying that establishment’s labels match its product formulations during an ongoing “Big 8 Formulation Verification” task occurring at a monthly frequency.

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Hazard Analysis

- Every establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production practice- 9 CFR 417.2
 - Hazard analysis serves as the foundation for a strong and successful HACCP plan
 - Includes food safety hazards that could occur before, during, and after entry into the establishment
 - Food safety hazard: Any biological, chemical, or physical property that may cause food to be unsafe and Injurious to Health

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Hazard Analysis and Allergens

- The introduction of ingredients into product must be taken into account during the hazard analysis
 - Allergens and ingredients of public health concern fall under the chemical hazards portion of the hazard analysis
 - Introduction of allergens and ingredients of public health concern could occur anywhere/anytime during the production process

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Hazard Analysis and Allergens

- The occurrence of an undeclared allergen recall indicates the establishment has failed to:
 - Address the chemical (allergen) food safety hazard in its hazard analysis
 - Support a decision made in the hazard analysis
 - Reassess its hazard analysis
 - Effectively implement the controls to support a decision (9 CFR 417.2, 417.3, 417.4, 417.5, 417.8)

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Practical Allergen Control

- A HACCP-based Allergen Risk Assessment Program is a key to allergen management and control
- Programs must be implemented to ensure integrity and compliance with specifications throughout the supply chain

Food Safety and Inspection Service Establishment Responsibilities

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

Prevent & Control: Equipment, Sanitation, and Processing

Declare: Packaging, Labeling, Storage

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Identify: What Steps Can I Take Right Now?

- Determine if your establishment will better control allergens through your hazard analysis as a prerequisite program or HACCP plan
- Evaluate each step in your process from receiving to packaging and shipment, noting paths of allergenic ingredients
- Identify ingredients and processing aids your establishment utilizes that may contain allergenic ingredients
- Review a list of all ingredients and products to determine which products and ingredients, including sub-ingredients, contain or do not contain allergens

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Identify: What Steps Can I Take Right Now?

At Receiving

- Inspection of all incoming ingredients
- Keep a list of ingredients and label records at receiving to compare against incoming ingredients
- Maintain an approved supplier list and become familiar with letters of guarantee (LOG) from suppliers
- Maintain open communication of expectation with suppliers and inquire about suppliers' allergen control program
- Ensure all incoming ingredients containing allergenic material are clearly labeled and identified

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Identify: What Steps Can I Take Right Now?

During Storage

- Use color coding for allergen-containing ingredients and products
- Store ingredients containing allergenic materials in separate, designated areas that are clearly identified and marked
- Avoid storing ingredients containing allergens above ingredients without
- Clearly identify and mark product storage

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Prevent and Control: What Steps Can I Take Right Now?

During Mixing/Processing

- Maintain controls to ensure the addition of correct ingredients during formulation of products
- Cleaning of equipment, utensils, and food contact surfaces when producing both product with and without allergens to prevent cross contact and misbranding
- Document cleaning procedures with checklists and spill clean-up procedures
- Employ a method for the verification and validation of cleaning
- Careful evaluation of rework and work-in-progress

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Prevent and Control: What Steps Can I Take Right Now?

During Mixing/Processing

- Dedicate equipment or separate products by time, space, etc.
- Color coding or mark ingredient packages, supplies, uniforms, equipment, and utensils used for products containing allergens throughout processing
- Avoid using same cooking medium (i.e. oil or water) when processing both ingredients with and without allergens
- Maintain documented process flow
- Maintain methods for tracking lot codes through production

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Declare: What Steps Can I Take Right Now?

At Labeling

- 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
- Ensure systems are in place for labeling of final product
- Maintain controls to prevent product reformulation without proper protocols to ensure final label accuracy
- Verify the facility has a label approval/sketch approval for all products
- Cross-reference sketch label approval, if applicable, to actual label being used in the formulation data for accuracy
- List of ingredients should include sub-ingredients
- Ensure that product is packaged in correct label
- Have procedures in place for labeling discrepancies and product disposition

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

Reducing the potential of undeclared Allergens:

- 1. Supplier and ingredient control**
- 2. Controlled on-site food storage**
- 3. Segregated handling or processing**
- 4. Equipment selection and use**
- 5. Control of labels and packaging**
- 6. Staff awareness**
- 7. Allergen audits**

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

1. Supplier and ingredient control

- Continuous review and documentation of ingredient specifications
- Identify ingredients intentionally containing allergens and investigate others
- Be aware of reformulation of ingredients without updating the specifications
- Have knowledge of suppliers' allergen management
- Have Questionnaire/Audit/Reviews to determine the overall suppliers' risk of cross contact
- Raise your concerns with your suppliers

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

2. Controlled on-site food storage

- Segregation or other validated controls
- Conduct risk assessment (e.g., high risk/low threshold) and evaluate if a complete separation is necessary
- Constant review and documentation of ingredient specifications

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

3. Segregated handling or processing

- Segregation or other validated controls in high risk products such as peanuts or tree nut production
- Conduct risk assessment (e.g., high risk/low threshold) and evaluate if complete separation is necessary
- Severe allergenic reaction (anaphylactic shock) vs. intolerance reaction (gluten)
- Constant review and documentation of ingredient specifications, formulations, and labeling
- Time and physical separation
- Monitor cross contact

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

4. Equipment selection and use

- This is an allergen management aspect that is often overlooked by establishments
- Walls, floors, hoses, equipment, utensils, containers,...etc.
- Equipment and materials selection must be influenced by cleanability and accessibility.
- Question: Can you access all surfaces easily and are they designed to facilitate a deep allergen clean to prevent them from becoming source of contamination?
- Similar to the fact that all surfaces and pieces of equipment shall be cleaned and disinfected to reduce to a safe level of bacteria, it should also be at a minimal risk of being source of allergen cross contact.

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

5. Control of labels and packaging

- Product change-over
- Multi-layer supervision over labeling and packaging (e.g., high risk/low threshold), evaluate if complete separation is necessary
- Be aware of: reformulated ingredients, new allergen being handled on site, new equipment being used, new layouts being implemented, new production/processing schedules, new employees unfamiliar with the process/allergen controls, new cleaning regimen
- *A review of the allergen risk assessment is crucial to ensure that changes to the allergen status of a product is identified and reflected on the labels and packing*

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

6. Staff awareness

- Staff Movement
- Separate, visibly identify staff (at high risk production)
- **Training, Training, and Training of all employees**
- **Training** of the staff is a key element for successful allergen control and management
- All aspects of allergen control concept and management: sources, cross-contamination, labeling, misinformation, formulation, ingredients, receiving, risk, human health, ...etc.
- Ensure that all cooks, food handlers, and employees are aware of the top 8 allergenic ingredients and other ingredients of public health concern.
- Ensure personnel are trained on the cleaning procedures the establishment employs to control food allergen cross contamination.

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Practical Allergen Control

Hazard Analysis from Interactions with Industry

7. Allergen audit

- Internal Audit Process/External Audit Program
- Audit should be true reflection and an ethical process to reflect a true condition/status of your allergen management program
- An effective audit should ideally pick a final packaged product and conduct “Trace-back” activities from all aspects of the process. (Check HACCP Pre-shipment Review 9 CFR 417.8)
- The risk of allergen contamination can be validated against the allergen declaration on labels.
- Routinely evaluate your company’s handling of allergenic ingredients to prevent adulterated or misbranded products



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