

Food Ingredients of Public Health Concern



Introduction

Big 9 Food Allergens



Food Allergy or Food Intolerance?



Food Ingredients of Public Health Concern

Terminology

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Food Allergy

A specific type of adverse immune system reaction to a particular food or food ingredient; trace amounts of an allergen could trigger a severe reaction.

Terminology

Food Intolerance

A non-allergic sensitivity to some food or color additives; usually not life-threatening; has public health significance.

Terminology

Big "9" Food Allergens

Milk, Eggs, Fish, Shellfish, Tree Nuts, Peanuts, Wheat, Soybeans, Sesame

Label Declarations

FSIS requires all ingredients should be declared on the labeling of meat and poultry products. Also, any ingredient must be declared only by its common or usual name in the ingredients statement.

Terminology

Voluntary Statements

Statements that are placed on labels to alert people who have sensitivities or intolerances to the presence of specific ingredients. For example - “Contains: milk, wheat gluten, soy” would alert consumers to these ingredients of public health concern.

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Food Allergies

What is a Food Allergy?

Food Allergy

A specific type of adverse immune system reaction to a particular food or food ingredient.

Symptoms of Exposure to a Food Allergen

- Tingling in mouth
- Tongue/throat swelling
- Breathing difficulty
- Hives
- Vomiting
- Abdominal cramps
- Diarrhea
- Drop in blood pressure
- Loss of consciousness
- Death

The "Big 9" Food Allergens

Milk



Eggs



Fish



Shellfish



Tree Nuts



Peanuts



Wheat



Soybeans



Sesame



Why the "Big 9" are MAJOR Food Allergens



Food Allergy Estimates

- Millions suffer from food allergies
- Many reactions are mild, but some are severe and life threatening



Food Allergy Estimates



- Annually:
 - 30,000 emergency room visits
 - 2,000 hospitalizations
 - 150 deaths

Avoiding Food Allergies

- An allergic reaction is potentially life threatening.
- Even trace amounts of an allergen could trigger a severe reaction.
- Consumers must rely on accurate product labeling.

Summary of Key Points

- Definition of food allergy
- Common symptoms of food allergies
- Name the "Big 9" allergens
- Explain how and why the "Big 9" allergens were selected



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Food Intolerances

What is a food intolerance?

Food Intolerance

A non-allergic sensitivity to some food or color additives.

Food Intolerance

- Significant public health concern due to potential adverse effects
- Often confused with allergic reaction
- Adverse immunological mechanisms not usually triggered
- Rarely life-threatening

Lactose Intolerance

- Lactose is milk sugar, typically broken down by lactase in the gut.
- Some people have insufficient levels of lactase.
 - Bacteria in the gut break down lactose instead. Results in production of gas, bloating, cramping, etc.
- A variety of products may contain lactose.

Lactose Intolerance

Some of the products that contain lactose:

- Milk and dairy products
- Yogurt
- Pancakes
- Mashed potatoes

Other Food Additives

- Lactose
- Monosodium glutamate (MSG)
- Sulfites
- Gluten
- FD&C (Yellow) No. 5
- Nitrates/nitrites

Food Allergies vs Food Intolerances

Food Allergies

- An allergic reaction is potentially life threatening.
- Trace amounts of an allergen could trigger a severe reaction.
- Consumers must rely on accurate product labeling.

Food Intolerances

- A non-allergic sensitivity to some food or color additive.
- Usually not life-threatening.
- Can still have public health significance.

Summary of Key Points

- Definition of food intolerance
- Public health significance of food intolerance
- Review of specific additives which may cause food intolerances, associated symptoms
 1. Lactose
 2. Sulfites
 3. FD&C #5
 4. Monosodium glutamate (MSG)
 5. Glutens
 6. Nitrates/nitrites
- Differences between food allergies and food intolerances



Food Ingredients of Public Health Concern



Establishment Responsibilities

What are establishment responsibilities?

The Hazard Analysis

- Determine if any ingredients used in product formulation are of public health concern
- Consider the controls necessary to prevent cross contact and assure accurate labeling

The Food Safety System

Must include appropriate food safety procedures necessary to ensure ingredient addition matches product formula and label.

- HACCP Plans
 - Sanitation SOPs
- Other Prerequisite Programs



Fundamental Controls

- An establishment must consider the controls necessary to ensure:
 1. Appropriate use of ingredients in its processes
 2. All ingredients are appropriately declared on finished product labels
- Procedures must be effectively implemented to ensure adequate control.

Avoiding Cross Contact

- Must avoid cross contact between products with allergens and those without allergens.
- Cross contact may result from:
 - Inadequate control of ingredients
 - Inappropriate use of ingredients

Inaccurate Labeling

Inaccurate labeling of properly formulated product is also a threat to consumers sensitive to any ingredients.

Label Declarations

- What is required?
 - Accurate, informative product labeling
 - Ingredients of public health concern must be declared in the ingredients statement

*****A product is adulterated and misbranded if it contains an allergenic ingredient not accurately declared on the label.**

Voluntary Statements

- Voluntary statements on labels alert consumers to the presence of specific ingredients
- Examples:
 - "Contains: milk"
 - "Contains: wheat"
 - "Contains: sodium caseinate (from milk)"

Statements About Processing Environment

- Examples:
 - "Produced in a plant that uses peanuts."
 - "May contain peanuts."

- May only be used when GMPs and Sanitation SOPs cannot reasonably be expected to eliminate possibility of cross-contamination.

Summary of Key Points

This Lesson covers establishment responsibilities regarding use of Food Ingredients of Public Health Concern...

- Identify ingredients of concern and consider controls
- Include controls in HACCP plans, SSOPs, or Prerequisite Programs
- Procedures for appropriate use and declaration of ingredients on labels



Summary of Key Points

Prevention of cross-contact between allergens and non-allergen ingredients/products

Understand accurate labeling

1. Voluntary statements
2. Statements about processing environments



Food Ingredients of Public Health Concern



Inspection Program Personnel Responsibilities

What are IPP responsibilities?

Food Safety System Failure

- If product containing an undeclared allergen enters commerce, the establishment's food safety system has failed.
 - May be due to failure to:
 - Address an allergen as a potential food safety hazard Adequately support the decisions made in its hazard analysis
 - Effectively implement controls

Common Reasons for Product Allergen Recalls

- Changes in ingredient suppliers
- Supplier change in formulation of ingredients
- Finished products in the wrong package
- Misprinted labels on finished products
- Product formulation change without appropriate label change
- Cross-contact contamination

General Responsibilities

Inspection program personnel should verify that the establishment has:

- Addressed any potential chemical food safety hazard(s) in its hazard analysis.
- Implemented control procedures for ingredients of public health concern.
- Properly labeled the product.

Document Noncompliance

A noncompliance occurs when the establishment fails to:

- Address a chemical food safety hazard.
- Adequately implement its HACCP plan, Sanitation SOPs, or other prerequisite program controls.
- Maintain adequate supporting documentation for decisions in its hazard analysis.
- Appropriately declare an ingredient on the finished product label.

"Big 9" Formulation Verification Task

[FSIS Directive 7230.1](#)

- A method used to verify that establishments accurately control and label the “Big 9” allergens.
- Applies to all HACCP processing categories **EXCEPT slaughter**
- The routine Priority 3 task scheduled on the PHIS establishment task list:
 - Once a month
 - Inspectors in establishments with multiple shifts should perform the task on each shift.

Performing the "Big 9" Verification Task

1. Schedule the task.
2. Determine which products will be produced on that date.
3. Select a product.
 - Generally avoid always selecting same product for consecutive tasks.
 - Use priority chart to select a product in establishments that produce more than one product.
4. Obtain the selected product specific formulation from the establishment.

Performing the "Big 9" Verification Task

1. Review formulation records and observe formulation process steps to ensure consistency with the intended formulations.
2. Review product label to verify that all ingredients are declared by common or usual name and in descending order of predominance.
3. Verify appropriate label being applied to the product.
4. Verify applied label is consistent with the establishment's label approval on file.

Documenting "Big 9" Noncompliance

- If a product contains one or more undeclared "Big 9" Allergens
- Cite the relevant food safety regulation(s)
 - AND**
 - 9 CFR 317.2(f) for meat products
 - OR**
 - 9 CFR 381.118 for poultry products



Other Undeclared Ingredients

- If NOT one of the Big 9 allergens:
 - Document noncompliance under the General Labeling task

 - Cite:
 - 9 CFR 317.2(f) for meat products
 - 9 CFR 381.118 for poultry products

 - Applies to other ingredients of public health concern

Other Actions

- Retain any affected product still on premises if necessary to prevent product from entering commerce.

- **ALWAYS** notify your immediate supervisor so that a recall request determination* can be made!

**** Recall determinations are made by OFO's Recall Management Division**