Undeclared Allergen Prevention Webinar

Labeling and Program Delivery Division (LPDD)
Office Policy and Program Development
Big Eight Allergens

- Wheat
- Crustacean shellfish (e.g. shrimp, crab, lobster)
- Eggs
- Fish
- Peanuts
- Milk
- Tree Nuts (e.g. almonds, pecans, walnuts)
- Soybeans
Ingredient Labeling and Allergen Statements

• Agency regulations require all ingredients to be declared in descending order of predominance in the ingredients statement

• Food Allergen Labeling and Consumer Protection Act (FALCPA) did not amend the FMIA, PPIA, and EPIA

• FSIS supports voluntary use of allergen statements, e.g., “contains: soy”

• LPDD evaluates “may contain” type statements on a case by case basis
What or Who Initiated Allergen Recalls?

- # Discovered by FSIS Verification Activities
- # Discovered by EST
- # Discovered by a Consumer
- # Discovered by a 3rd Party
- # Discovered by FDA in dual jurisdiction EST

SOURCE: OFO/RMS
What Caused Allergen Recalls in 2011?

• New Ingredient and/or New Supplier
• Misprinted Label
• Product in wrong package
• Product reformulated
• Ingredient reformulated

ALWAYS make SURE ALL ingredients and sub-ingredients are declared on the finished product label

SOURCE: OFO/RMS
Allergen Recalls

• The occurrence of a recall indicates the establishment has failed to:
  – address the chemical (allergen) food safety hazard in its hazard analysis;
  – to support a decision in the hazard analysis;
  – reassess its hazard analysis;
  – effectively implement the controls to support a decision (see 9 CFR 417.2, 417.3, 417.4, 417.5, 417.8).
Establishment Responsibilities

• Identify
• Prevent
• Declare
Identify

• All ingredients going into a product must be identified before the assembly process.
• Inspect incoming non-meat ingredients by matching component labels, specification sheets, etc.
Prevent

- Equipment
- HACCP plan
- Sanitation Standard Operating Procedures
- Allergen Control Plan
- Packaging and storing meat products containing allergens and those that do not.
Declare

- Labeling procedures
FSIS Actions

• Issued notice, Verification Activities Related to the use of Ingredients of Public Health Concern, FSIS Notice 35-11

• Notice was issued for instructions for inspection activities for in plant personnel, FSIS Notice 54-11
Is the product manufactured from raw materials that contain allergens?

Yes

If allergens are contained in the product, you must declare on the label all allergens contained in the product.

No

Is the product manufactured on a production line or with equipment that comes in direct contact with allergenic substances?

Yes

Implement all necessary measures to eliminate the risk for allergens on the production line and equipment! HACCP and good manufacturing principles should be used. Can it be documented through cleaning controls, test results, or other means that no allergens are present on the production line or equipment or in the product?

Yes

If it can be documented that no allergen residue is in the product, no special labeling is needed.

No

If it cannot be documented that no allergen residue is in the product, and cross contact is unavoidable, special labeling should be considered. In some cases, “may contain” labeling may be applied. Be specific, such as “may contain peanuts.”

No

If no allergens are present in the product, no special labeling is needed.
“May Contain” Statement

- Notice 54-11 explained Agency’s position on carrying through “may contain” type statements from incoming product labels to final labels.

- Statement not required to be carried through provided the establishment contacts supplier and: (1) confirms, preferably 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.
Recap

• Verify labels match the product through pre-shipment review of records.

• Work with FSIS in plant personnel.
Ask FSIS

Submit additional questions to: askfsis.custhelp.com