



United States Department of Agriculture

One Team, One Purpose



# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness





## Directive 7230.1

# Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (“Big 8”) Food Allergens

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**Office of Policy and Program Development (OPPD)**

# Background

- Sustained increase in the number of recalls containing undeclared allergens and ingredients of public health concern
- For first 80 recalls of 2015, 40 (50%) related to undeclared allergens/ingredients
  - 45 total in 2014

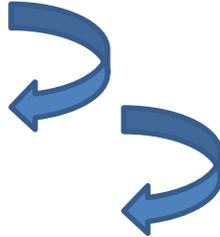
# Directive Issuance

- Instructions to Inspection Program Personnel (IPP) for verifying control and labeling of Big 8 food allergens
- Issued: 3/10/15
- Monthly verification began: 4/12/15
- Two portions of the directive
  - Part I: Meeting with establishment management
  - Part II: Big 8 formulation verification task

# Directive Issuance

- Development based on FSIS Notice 29-13
  - One time formulation verification task
  - Issued on 4/30/13
- Provided critical data for compliance guidelines, options for targeting prevention, future plans
  - 4 recalls
  - 44 establishments received NRs
  - Advanced analysis underway

# Compliance Guidance

- Available on FSIS website; Click on:
  - Programs & Services
  - Compliance Assistance 
    - Labeling
- Allergens and Ingredients of Public Health Concern
  - Principle I: Identify
  - Principle II: Prevent and Control
  - Principle III: Declare through Labeling

# Early Directive/Task Successes

- IPP have completed 2015 round of establishment meetings raising awareness of concerns
- IPP have begun Big 8 Formulation Verification task
- Data captured in PHIS for analysis
- Uncovered undeclared allergens
- Measures taken to prevent undeclared allergen recalls

# AskFSIS Questions Received

- Approximately 75 questions received since issuance
- Three major topics:
  - Eligibility of establishments
  - Functionality of PHIS
  - Specific allergen or labeling queries

# Eligibility of Establishments

- Applicable to all HACCP categories except slaughter
- Not applicable to establishments that do not formulate product
- **Applicable to establishments whether or not they produce product containing Big 8 allergens**

# Functionality of PHIS

- Scheduling of task for egg products plants resolved
- Functionality to delete task for non-eligible establishments is underway

# “May Contain” or “Produced in Facility”

- Statements on incoming food and food ingredients must be listed on final product label, **EXCEPT** when the establishment contacts the supplier of the component and addresses the statement
- Ingredient would not need to be listed on final label:
  - If establishment confirms in writing that the statement is cautionary and no such ingredient is in the product, **AND**
  - Includes a written statement in documentation to support why statement is not carried forward

# Sulfiting Agents (Policy Memo 094B)

- Sulfur Dioxide, Sodium Sulfite, Sodium Bisulfite, Potassium Bisulfite, Sodium Metabisulfite, Potassium Metabisulfite
- Must be declared on label if concentration in finished meat or poultry product is 10ppm or higher
  - Also applies to individual, separable components even if total is less than 10ppm

# Soy Lecithin and Soybean Oil (Directive 7230.1 – Attachment 1)

- With few specific exceptions, FDA **does not** exempt soy lecithin from allergen labeling as it contains residual protein
- The use of soy lecithin as a releasing agent must be properly declared
- FDA **does** exempt highly refined soybean oil from being labeled as an allergen
- Cold-pressed soybean oil is not exempt, but is much less commonly used



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Questions?

**Submit through AskFSIS**

- Subject Field: Enter **Directive 7230.1**
- Question Field: Enter question with as much detail as possible.
- Product Field: Select **General Inspection Policy** from the drop-down menu.
- Category Field: Select **Sampling** from the drop-down menu.
- Policy Arena: Select **Domestic (U.S.) Only** from the drop-down menu.

**or call 1-800-233-3935**