



Food Allergens

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Overview

- Review of food allergy
- Allergen labeling and control
- Allergen recalls



Food Allergy

- Immune-mediated intolerance to food
 - IgE antibodies in a sensitive individual react with specific proteins in a food
- Major Public Health Issue
 - Food allergy affects ~ 6-8% of children and ~1-2% of adults
- Estimated 29,000 ER visits each year in US
- Estimated 125-150 people die each year in US from food-related anaphylaxis



Allergic Reactions

- SKIN - itchiness, flushing, hives, swelling, eczema
- GI - nausea, vomiting, abdominal pain, diarrhea
- RESPIRATORY - chest tightness, runny nose, wheezing, throat closing/swelling
- VASCULAR - dizziness, low blood pressure, heart irregularities, shock
- Anaphylaxis → Death



Food Allergy Regulatory Challenges

- Allergic response is to a food component that is nutritious and desirable for most of the population
- Sensitivity and severity vary widely in the population
- No cure for food allergy



Protecting Allergic Consumers

- Individual Actions
 - Strict avoidance
 - Patients and families must be assiduous readers of food labels
- Agency Actions
 - Working with industry to
 - Ensure the declaration of all intended allergens
 - Avoid the presence of unintended allergens



Food Allergen Labeling

Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

- Amended the Federal Food, Drug, and Cosmetic Act to:
 - Define the term “major food allergen”
 - Establish labeling requirements



Quiz: Which of these foods is NOT a major food allergen in the US?

- a. Milk
- b. Eggs
- c. Sesame
- d. Crustaceans
- e. Tomatoes
- f. Peanuts

Definition of a Major Food Allergen

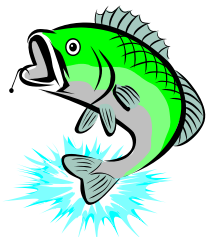
- Milk



- Egg



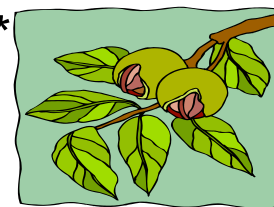
- Fish*



- Crustacean Shellfish*



- Tree Nuts *



- Wheat



- Peanuts



- Soybeans





Quiz Answer: Which of these foods is NOT a major food allergen in the US?

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Two Ways to Declare Allergens

- Within the ingredient list
 -ovalbumin (egg).....
 -wheat flour.....
- With a “contains” statement
 - Contains: Milk, egg,.....
- Note – all other labeling requirements still apply

Advisory Labeling

- FALCPA does NOT address advisory statements
- Advisory statements must be truthful and not misleading and should not be used in lieu of Good Manufacturing Practices



Food Allergen Control

- Preventive Controls
 - Proposed rule based on Food Safety Modernization Act
 - Allergens identified as hazards that need to be considered
 - Allergen preventive controls will be needed if appropriate
 - GMPs modernized to prevent cross-contact



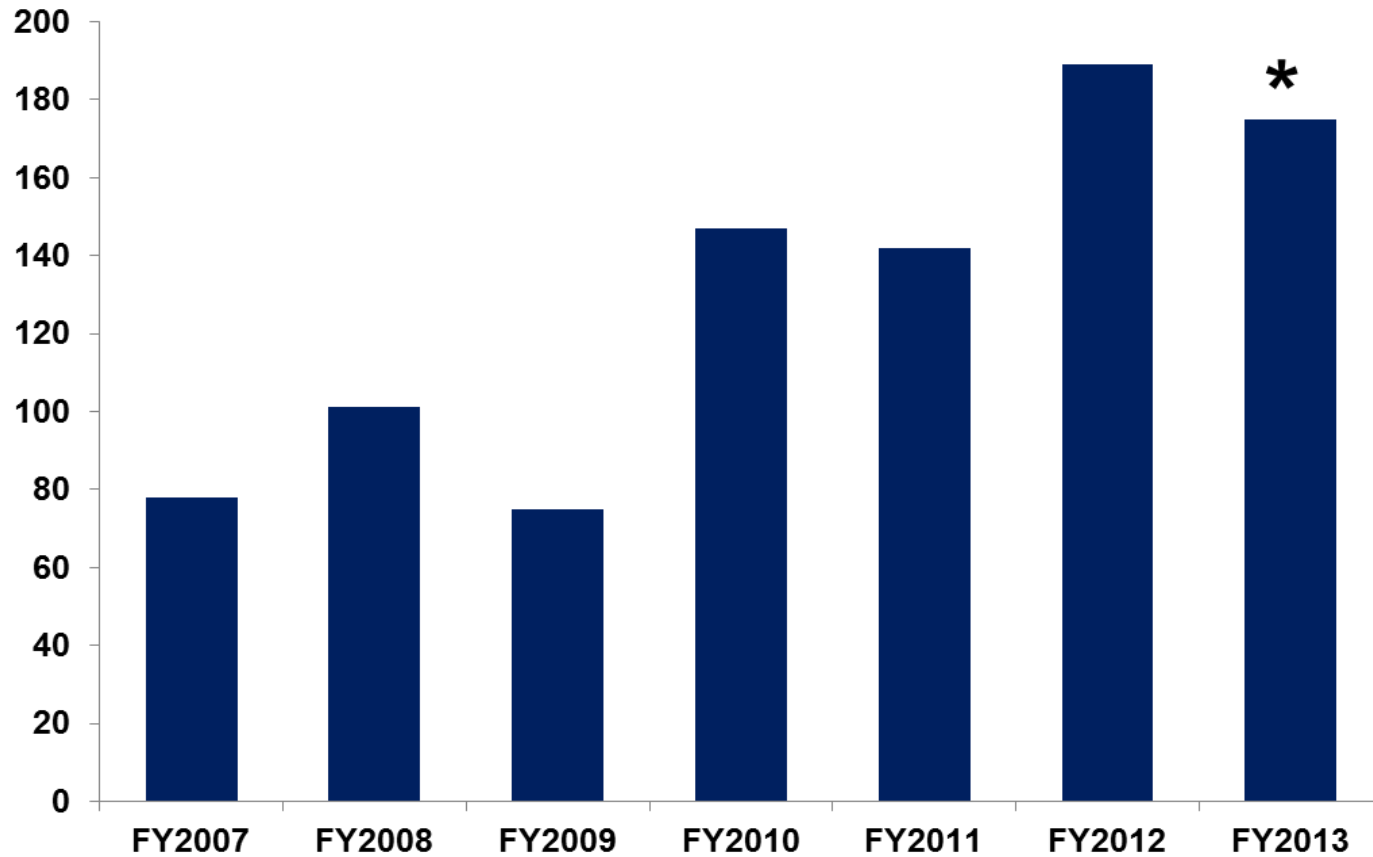
Allergen Recalls

- Food Allergen Recalls
 - Undeclared allergens are the leading cause of recalls for FDA regulated foods
 - Understanding why there are so many allergen-related recalls will help focus resources where they are most needed



Nutrition Facts
Serving Size 1 Cup (28g)
Serving Per Container about 3

FDA Food Allergen Recalls by Year





Food Allergen Recalls (1)

Most frequent allergens:

- Milk (296)
- Wheat (171)
- Soy (153)
- Tree Nuts (119)
- Egg (108)

Most frequent foods:

- **Bakery (31%)**
- **Snack (12%)**
- **Candy (10%)**



Food Allergen Recalls (2)

Most frequent causes

- Wrong package or label
- Wrong terminology
- No carry through of information from an ingredient
- Cross-Contact



Food Allergen Recalls

- Emerging Issues
 - Computer generated labels
 - Imports and differences in regulated allergens
 - Allergen thresholds



Future Directions

- Preventive Controls
 - Final rule
 - Guidance
- Education and outreach



Thanks
Questions?

