Food Allergens

Steven M. Gendel

Food Allergen Coordinator
Office of Food Additive Safety
FDA Center for Food Safety and Applied Nutrition
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 $\rightarrow$ 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?

a. Milk
b. Eggs
c. Sesame
d. Crustaceans
e. Tomatoes
f. Peanuts
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
FDA Food Allergen Recalls by Year

- FY2007
- FY2008
- FY2009
- FY2010
- FY2011
- FY2012
- FY2013

*Note: Data for FY2013 is preliminary.
## Food Allergen Recalls (1)

<table>
<thead>
<tr>
<th>Most frequent allergens</th>
<th>Most frequent foods</th>
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</thead>
<tbody>
<tr>
<td>Milk</td>
<td>Bakery (31%)</td>
</tr>
<tr>
<td>Wheat</td>
<td>Snack (12%)</td>
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<tr>
<td>Soy</td>
<td>Candy (10%)</td>
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<tr>
<td>Tree Nuts</td>
<td></td>
</tr>
<tr>
<td>Egg</td>
<td></td>
</tr>
</tbody>
</table>

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