Food Allergens - Regulatory Perspective

Food Allergen Labeling and Consumer Protection Act of 2004

Greg A. Abel
Regional Retail Food Specialist
U.S. Food and Drug Administration
Office of Regulatory Affairs
Minneapolis, Minnesota
.....the plan

- Gain an understanding of FALCPA and what it requires
- Explain the FDA Food Code’s approach to food allergens
- Provide the opportunity for questions
Why FALCPA? The findings....
Prevalence

- Estimated > 11 million Americans suffer from true food allergens
  - 2% of adults and 4-8% of infants and children
  - 2.3% population allergic to fish or crustacean shellfish*
  - 1.1% population allergic to peanut or tree nuts*

- Peanuts are the leading cause of severe reactions
- Past 10 years, 18% increase in reports of food allergies in children*

* New data since FALCPA
Certain foods are predominantly accountable for food allergies

- eight major foods from five types of food or one of three food groups that accounted for 90% of the allergenic reaction in the U.S.

Milk    Egg    Fish    Crustacean shellfish
Tree nuts    Peanuts    Soybeans    Wheat
1999 Minnesota/Wisconsin Study

- Found 25% of the sampled foods failed to list peanuts or eggs as ingredients on food labels.

- FDA data showed the number of recalls due to unlabeled allergens rose to 121 in 2000 from 35 a decade earlier.
FDA called...

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— voluntary action taken by the responsible establishment

Reasons:

Omission in labeling
Employee/supplier errors
Manufacturing equipment

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Consumers unfamiliar with correctly identifying ingredients

- The Food, Drug and Cosmetic Act requires:
  - foods to be labeled
  - ingredients in foods listed by their “common or usual name”

- Some ingredients
  - can be declared as a class, e.g. spices, flavorings, colorings
  - are exempt from labeling, e.g. as incidental additives
Significant prevalence of Celiac Disease in U.S.

- Celiac Disease is an immune-mediated disease causing damage to the gastrointestinal track, central nervous system, organs
- Treatment is avoidance of gluten (wheat)
- Prevalence is estimated at 1% of the general U.S. population
FALCPA (overview)

- Public law 108-282
- Signed by President Bush: 8/2/2004
- Labeling requirements have been in effect since 1/1/2006
- Amended the Federal Food, Drug and Cosmetic Act
- Requires label to disclose all allergenic ingredients
(FALCPA)... requires labels of packaged food products to disclose certain allergenic ingredients
Major Food Allergens under FALCPA

- Milk
- Egg
- Wheat
- Fish (e.g., bass, flounder, cod)
- Crustaceans (e.g., crab, shrimp)
- Soybeans
- Peanuts
- Tree Nuts (e.g., almonds, pecans, walnuts)
The law [Sec. 203:] “…in the case of a tree nut, fish or crustacean shellfish, [use] the name of the specific type of nut or species of fish or Crustacean shellfish”

<table>
<thead>
<tr>
<th>Correct</th>
<th>Incorrect</th>
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<tbody>
<tr>
<td>“Contains Pecans”</td>
<td>“Contains Tree Nuts”</td>
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<tr>
<td>“Contains Anchovies”</td>
<td>“Contains Fish”</td>
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<tr>
<td>“Contains Shrimp”</td>
<td>“Contains Crustacean”</td>
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Ingredients Subject To Law

- Eight “major food allergens”
- A food ingredient that contains protein derived from a major food allergen
- Incidental additives, flavors
- Exceptions:
  - Highly refined oils from major food allergens
  - Ingredients exempt from labeling under petition or notification process specified in law

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Labeling Options (1 of 2)

- **Within the statement of ingredients:**
  the common or usual name of the major food allergen immediately followed parenthetically by the name of the food source

- **Examples:**
  ...whey (milk)...
  ...natural flavors (peanut, almond)...

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Labeling Options (2 of 2)

- **Separate statement:**
  the word ‘Contains’ followed by the name of the food source from which the major food allergen is derived, printed immediately after or adjacent to the list of ingredients

- **Example:**
  Contains: milk, egg, peanuts
Exceptions

- A major food allergen’s common or usual name already identifies its food source

  Example:
  - whole wheat flour, buttermilk, peanut butter

- The name of the major food allergen appears elsewhere in the ingredient list
INGREDIENTS: Enriched Degerminated Yellow Corn Meal, Enriched Bleached Wheat Flour, Vegetable Shortening (partially hydrogenated soybean oil and cottonseed oil with mono and diglycerides), Cheese Blend [cheddar cheese (pasteurized milk, cheese cultures, salt, enzymes), non-fat milk, whey, salt, partially hydrogenated soybean oil, lactic acid, disodium phosphate, citric acid and artificial color (including FD&C Yellow # 5 and FD&C Yellow # 6)], Dextrose, Salt, Sodium Bicarbonate, Sodium Aluminum Phosphate, Monocalcium Phosphate, Onion*, Parsley*, Red Bell Pepper*, Red Pepper*, Jalapeno Pepper*, Malted Barley Flour, Niacin, Iron (reduced), Thiamine Mononitrate, Riboflavin, Folate.*Dehydrated
Major Allergen Labeling

Ingredients: Yellow Corn Flour, Corn Bran Flour, Unsulphured Molasses, Oat Flour, Expeller Pressed High Oleic Oil (Canola and/or Sunflower), Salt, Baking Soda, Vitamin C.

Contains Soy.

Ingredients: D Caramel (Maltitol Syrup, Nonfat Milk, Partially Hydrogenated Soybean Oil, Cream, Glycerine, Butter, Salt, Disodium Phosphate, Soy Lecithin, Carrageenan, Natural and Artificial Flavor), Crisp Soy Nuggets (Soy Protein Isolate, Rice Flour, Malt, Salt), Chocolate Flavored Coating (Lactitol, Fractionated Palm Kernel Oil, Polydextrose, Cocoa, Natural and Artificial Flavors, Soy Lecithin, Monoglycerides, Acesulfame K), Fruit Juice and Grain Dextrins, Milled Rice, Corn Maltodextrin, Soy Protein Isolate, Glycerine, Microcrystalline Cellulose, Natural and Artificial Flavors, Peanut Butter (Ground Peanuts, Partially Hydrogenated Vegetable Oil [Cottonseed, Rapeseed], Salt) and Guar Gum.

Vitamins and Minerals: d-Alpha-Tocopheryl Acetate, Ascorbic Acid, Beta-Carotene and Chromium Chloride.

Contains Corn, Milk, Soy, Barley and Peanuts; Manufactured in a Facility That Processes Eggs, Other Nuts and Seeds.

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Advisory Statements

- e.g. “may contain [allergen]” or “processed in a faculty that also processes [allergen]"

- FDA advises
  - Not used as a substitute in adherence to good manufacturing practices
  - Must be truthful and not misleading

Not covered by law or regulation!
FALCPA also requires Gluten Labeling

- FDA to issue a propose rule to define “gluten-free”
- FDA did - Jan. 23, 2007
- FDA to issue final rule on “gluten free” labeling
FALCPA also requires

- FDA provide guidelines for preparing allergen-free foods within food establishments
FALCPA also applicable to provisions in the FDA Food Code

2005 Food Code, requires:
- Foods packaged at retail must comply with FALCPA
- Person-in-Charge must know what the major food allergens are and the associated symptoms

2009 Food Code, requires:
- Person-in-Charge to ensure all employees are properly trained in food allergy awareness
St. Paul, Food Allergy Ordinance

- **City Council Votes on Food Allergy Ordinance**

  The City Council of St. Paul, Minnesota passed a food allergy ordinance Wednesday, December 9th. It is only the second city in the U.S. to do so (New York City passed an ordinance earlier this year, and the state of Massachusetts passed a similar law).

  **Unanimous Vote for Poster**
  The first part of the ordinance, which passed 6-0, requires an awareness poster to be displayed in the employee area of restaurants. The poster, modeled on a poster developed by the national organization Food Allergy & Anaphylaxis Network (FAAN) and a flier created by the Anaphylaxis and Food Allergy Association of Minnesota (AFAA), includes........The second part of the ordinance, which passed 5-1 provides a 7% license fee discount for restaurants that view a training video provided by the City, and develop in-house procedures when an allergic customer orders food.
FALCPA also requires:

Inspections Relating to Food Allergens

- ensure compliance with practices to reduce or eliminate cross-contact
- ensure major food allergens are properly labeled
FALCPA also requires

FDA Report on Food Allergens

- Ways foods are unintentionally contaminated during manufacturing
- Ways to reduce/eliminate cross-contact
- Explore aspects of advisory statements/labeling
FALCPA also requires:

Food Allergy Response Data

- CDC in consultation with FDA to collect and publish national data on:
  - Prevalence of food allergies
  - Incidence of clinically significant/serious adverse events
  - Use of different modes of treatment for and prevention of allergic responses to food
FALCPA also requires

Additional items

- Evaluate current research efforts as well as recommend/coordinate research

- Food establishments
  - provide guidelines for allergen-free foods