

Food Allergens – Basic Principles and Control Strategies

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Food Allergies

**The food of one may be
poison for another.**

Lucretius
De Rerum Natura

Percent of Households Believing They Have at Least One Food Allergic Person

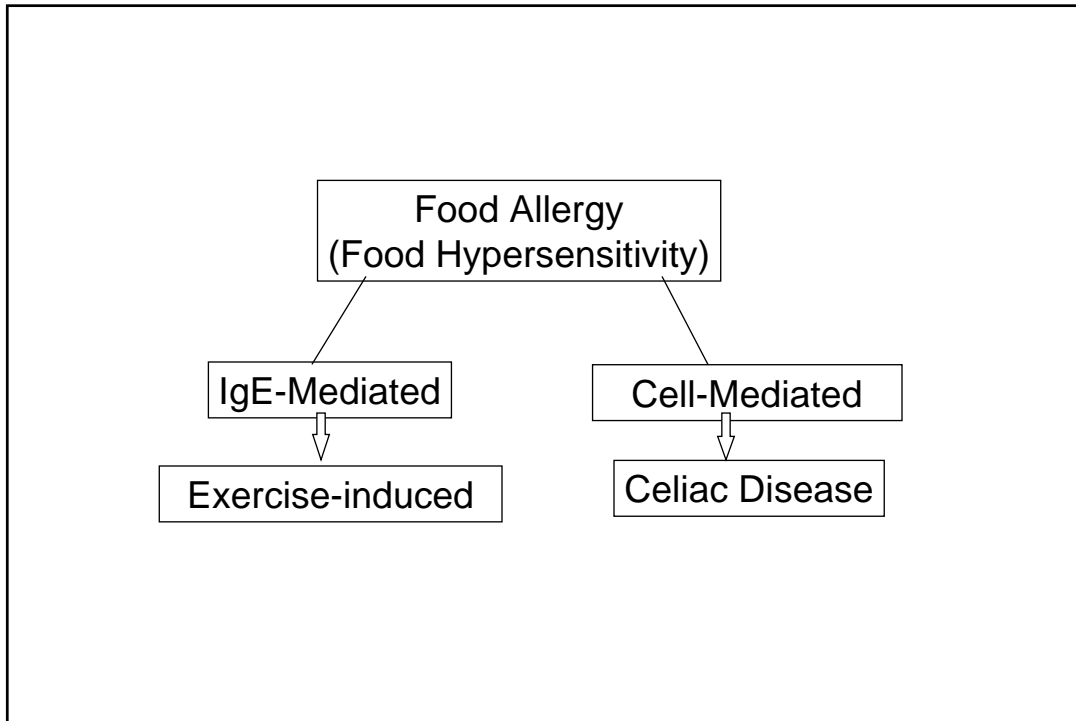
		<u>Location</u>	<u>Percent</u>
HIGH		Pacific States	20.3
		Mountain	18.4
TO		Average	16.2
		West North Central	12.5
LOW		East North Central	11.6

Data collected for the Food Allergy Center by NPD Group,
Port Washington, New York, 1989. 3943/5000 Families

Food Sensitivities
(Individualistic Adverse
Reactions to Foods)

Food Allergy

Food Intolerance



Cell-Mediated Food Allergies
(Delayed Hypersensitivity)

Celiac Disease

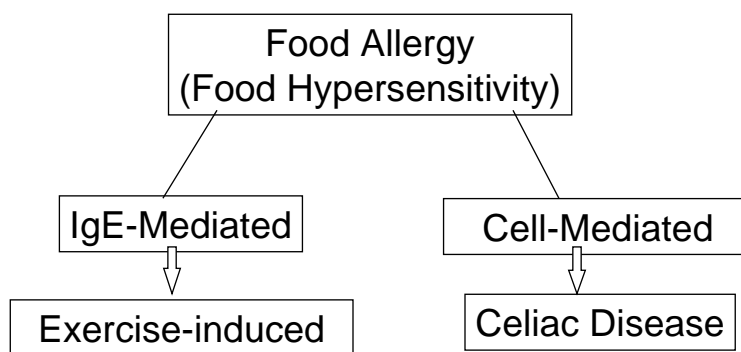
- Celiac sprue, non-tropical sprue
- Gluten-sensitive enteropathy

Celiac Disease

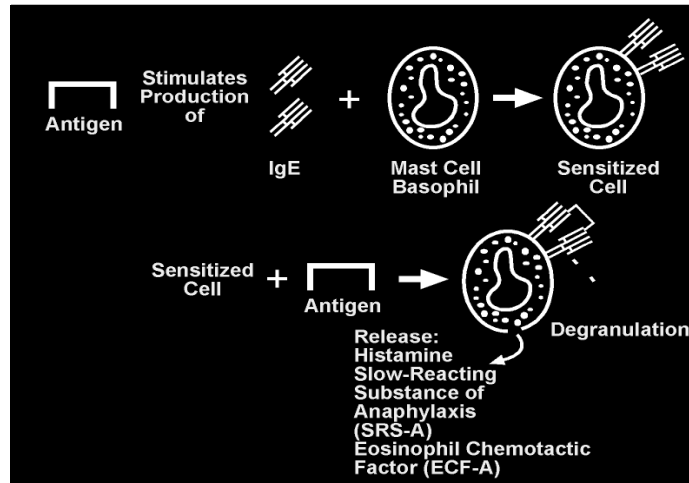
- Prevalence of at least 1 per 2000 in U.S.
- Symptoms associated with malabsorption (body wasting, anemia, diarrhea, bone pain, etc.)
 - 20%, however, do not have diarrhea symptoms
- Associated with consumption of gluten fractions of wheat, rye, barley, triticale, and sometimes oats
- Treatment with avoidance diets
- Long-term sequelae (e.g. lymphoma)

Treatment of Celiac Disease

- Avoidance of wheat, rye, barley, and oats
- Genetic manipulation of wheat



Mechanisms of Mediator Release



Factors Involved in Development of IgE-Mediated Food Allergy

- Genetics
- Exposure to allergenic food
- Age at exposure
- Dose, frequency, and duration of exposure
- Immunogenicity of the food
- Development of immunological tolerance

Prevalence of True Food Allergies

Infants/young children	-	4-8%
Adults	-	1-2%

Prevalence

- Between 3.5-4% of the U.S. population (or 10-12 million Americans) have food allergy
 - Sicherer, et al. J. Allergy Clin Immunol. 1999;103:559-62.
 - Sicherer, et al. J. Allergy Clin. Immunol. 2004;114:159-165.

Prevalence of Specific Food Allergies in the U.S.*

Crustacean shellfish	-	1.9%
Peanut	-	0.6%
Tree nut	-	0.5%
Fish	-	0.4%

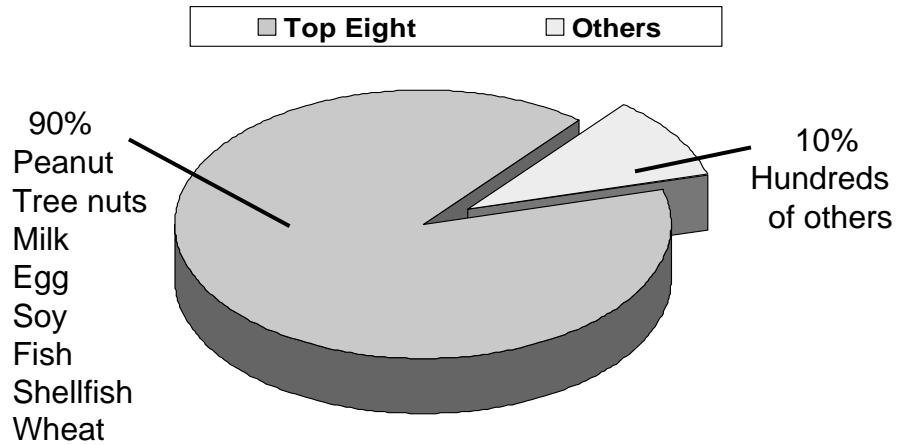
*Based on FAAN telephone surveys

Most Common Causes of IgE-Mediated Food Allergy

**From: FAO Technical Consultation, Rome,
Italy (Nov., 1995)**

- Cows' milk
- Egg
- Crustacea
- Fish
- Peanut
- Soybean
- Tree nuts
- Wheat

Food Allergies Prevalence



Other Foods That Cause Allergic Reactions

- There are 160+ other foods that can cause allergic reactions
- Hefle et al. 1996
Critical Reviews in Food Science and Nutrition 36:S69-S89

Typical Symptoms of IgE-Mediated Reactions to Foods

Gastrointestinal

- nausea
- vomiting
- abdominal pain
- diarrhea

Systemic

- anaphylactic shock

Cutaneous

- urticaria
- angioedema
- atopic dermatitis

Respiratory

- rhinitis
- laryngeal edema
- asthma

Typical Symptoms Systemic

- **Anaphylactic Shock**

Food-Induced Anaphylaxis is Not a Rare Occurrence

- Researchers estimate 29,000 emergency room visits and 150-200 deaths per year due to food-induced anaphylaxis(U.S.)
 - Bock et al. J. Allergy Clin. Immunol. 2001;107:191-193.
- 1 in 800,000 chance of dying from a food-allergic reaction (Hugh Sampson, Mt. Sinai Medical Center, FAAN Conference, 6/8/02)

Oral Allergy Syndrome

- Oropharyngeal itching, edema, urticaria
- Rarely associated with systemic reactions
- Fresh fruits and vegetables: peaches, apples, kiwi

What Are the Causative Agents of Food Allergies?

- Naturally-occurring proteins
- Heat-resistant
- Resistant to proteolysis
- Resistant to extremes in pH
- Usually major proteins of the food
- Foods can have 1 or many allergens in them

Cross-Reactions Among Foods

Within a given food group:

Crustacea: shrimp, crab, lobster, crawfish

Legumes: peanut, soybean, others

With unrelated substances:

Fruits and vegetables with pollen

Banana, kiwi, and chestnut with latex

**Treatment for
True Food Allergies**

Specific Avoidance Diets

**Exquisite Sensitivity of Some
Food-Allergic Individuals**

- Trace amounts of the offending food will trigger reactions

How Much is Too Much?

Milligram amounts!
(ppm concentrations)

Food Allergies and Sensitivities: Conclusions

- Affect a small percentage of the population
- But, reactions can occasionally, be severe, even life-threatening

Allergen Control Strategies

Where Risks Occur

- Research and Development
- Engineering and System Design
- Raw Materials/Suppliers/Co-Packers/Purchasing
- Labeling and Packaging

Where Risks Occur

- Production Scheduling/Changeovers
- Rework
- Sanitation
- Human Error

Types of Risk

- Physiological risk - allergic reaction
- Regulatory risk
- Consumer dissatisfaction
- Business risk - down time, loss of competitive edge, change in formulation, increased costs

Appropriate Actions

- Protect Consumer
- Dedicate lines
- Clean sufficiently
- Segregate product
- Don't over-label
- Clean appropriately, consistently

Product Development Strategies

- Always assure that allergenic ingredients and their sources will be readily identifiable on product labels
- Avoid using commonly allergenic foods or ingredients derived from these foods (if ingredients contain proteins) whenever possible

Product Development Strategies

- Avoid use of commonly allergenic food ingredients if other ingredients will work equally well
- Be cautious in the introduction of novel ingredients with high allergenic potential e.g. cottonseed, poppy seed, sunflower seed

Product Development Strategies

- Determine the protein content and/or allergenicity of ingredients derived from allergenic sources
- Avoid use of allergenic ingredients in such minute amounts that they have no functional effect on the finished product

Product Development Strategies

- Be very cautious about reformulation when it involves the introduction of new allergenic components
- Where possible, use ingredients that are already included in other products

Operations Strategies

- Schedule long runs of allergenic products wherever possible (minimize changeovers)
- Schedule manufacturing of allergenic products just prior to end of shifts with major clean-up
- Introduce allergenic components into the products as late in the process as possible

Operations Strategies

- Where possible, dedicate processing, personnel, and packaging lines to specific allergenic products
- Manufacture allergenic products in a specific location and on a specific line assuming the extra transportation costs
- Do not allow employees to sample products and carry from one area to another

Operations Strategies

- Institute thorough clean-up between products when the first product contains an allergenic component
- If sampling the product in-process, be certain that the sampling device is cleaned appropriately between products

Clean-up Testing Procedures

- The true test involves detecting residues of the allergenic food in the first product manufactured after changeover
- Most companies use testing to validate cleaning practices
- Recommend using specific immunoassays (ELISAs) that detect proteins from allergenic source

Clean-up Testing Procedures

- ATP/ protein tests detect non-specific contamination and are not yet known to correlate well with more specific tests
- Swabbing of equipment, conveyor belts, etc. may reveal sources of cross-contamination but tell us nothing about how much undeclared allergen will end up in the product

Clean-up Testing Procedures

- Recommend testing “push-through” for the presence of allergens
- Materials used for this can include:
 - Salt
 - Wheat flour
 - Ice
 - Whey powder
 - Finished product (“throw away”)

Operations Strategies

- Be sure that allergenic ingredients are stored in specific areas and that they are well marked
- Dedicate and clearly label in-process totes and other containers that contain allergenic products

Operations Strategies

- Avoid situations where product flow might allow allergen cross-contamination such as line cross-over
- Develop a sensible re-work policy

Operations Strategies

- Frying/roasting oil can be a source of allergen cross-contact
 - risk unproven
- Re-use allowed on dedicated lines
- Filtration systems
 - efficiency unproven
- Never buy reconditioned oils

Rework Policy

- “Exact-into-Exact” is the only sensible policy
- Assure that allergenic product for rework is stored in dedicated, clearly-labeled containers
 - Color coding
 - Plastic liners

Purchasing Strategies

- Assess allergen content of all raw materials
- Audit suppliers and co-packers
- Be vigilant about changes in ingredient specifications that might impact allergies

Purchasing Strategies

- Review possible sources of contamination coming in through raw materials
 - Ex. peanuts in jute bags used for cocoa beans

Purchasing Strategies

- Maintain records on allergens in raw materials
- Avoid re-used, reconditioned, or reworked ingredients
- Be careful about gang printing of labels

Suppliers

- Ingredients - allergen questionnaires
- Must divulge allergen information
 - refinement level of oils/protein content
 - degree of hydrolysis for protein hydrolysates
 - allergen content of flavors, spice mixes, etc.
- Audit for allergen control programs

Labeling Strategies

- Always declare the presence of any commonly allergenic foods on ingredient list
- Label the sources of ingredients when the ingredients are derived from allergenic foods e.g. soybean lecithin

Labeling of Packaged Foods

- All ingredients divulged on outside wrapper of multi-pack products
- Ingredient lists should be consistent on all apparently identical products (different manufacturing locations, different package sizes)

Labeling Strategies

- Declare the presence of allergenic source materials in flavorings when proteins from such sources are demonstrably present e.g. natural flavor (contain milk)
- Use “may contain” labeling judiciously and only in situations where contamination is documented, uncontrollable, sporadic, and potentially hazardous

Packaging Strategies

- Include ingredient labels on all products containing commonly allergenic foods including promotional products, small packages, etc.

Packaging Strategies

- For packaged, unlabeled products (e.g. individual granola bars), develop systems to assure that the correct product is packed into the containers with ingredient declarations
 - Consider development of bar-code reading systems

Packaging Strategies

- When reformulating products, discard all supplies of the old packaging material
- Design packages of similar products but different formulations with different colors or other major label declaration

Packaging Strategies

- Be careful about gang printing of labels; with combination sheets, print each version in straight rows
- Use color coding for outer-wraps on bundled, labeled, packaging
- Use color coding on labels that will be visible from sides in packaging equipment (stripes on edges)

Challenges for the Food Industry

- No information on cleaning effectiveness
 - How clean is “clean”? (thresholds)
- No information on release/ retention of allergenic proteins by processing surfaces (thousands)

Challenges for the Food Industry

- Raw materials issues
 - Ingredient and transportation issues
 - Supplier practices
 - ☞ Allergen control
- Equipment design, plant design
 - Not historically designed for allergen control
 - Not historically designed for “allergen-clean”

Challenges for the Food Industry

- No analytical tools for most allergenic foods
- Liability despite lack of information, despite GMP's

Allergen Cross-Contact Can Be Controlled

Food Allergies

An issue of growing concern

An issue that is here to stay

An issue that has increasing international aspects

An issue that can be controlled