Food Allergy

- No cure – avoidance of allergenic food
- Individuals and families become avid readers of food labels
- Labels should be informative and accurate
Food Allergy - What Is Different?

- Allergic response is to a food component that is nutritious for most of the population
- Sensitivity and severity (biological endpoints) have large range in the population
- Sensitivity and severity can vary in an individual
- No applicable animal models or in vitro tests
Allergen Thresholds

• Why are we interested now?
  - Food Allergen Labeling and Consumer Protection Act (FALCPA)
  - Requires label to disclose certain allergenic ingredients
Eight Most Common Allergenic Foods or Food Groups Identified in FALPCA

- Milk
- Egg
- Wheat
- Fish (e.g., bass, flounder, cod)
- Crustacean shellfish (e.g., crab, shrimp)
- Soybeans
- Peanuts
- Tree Nuts (e.g., almonds, pecans, walnuts)
Ingredients Subject to Law

- Major food allergens: an ingredient that is, or contains protein derived from, one of the eight foods or food groups
- Includes incidental additives, flavors
- Exceptions:
  - Any highly refined oil derived from a major food allergen
  - Food ingredient exempt from labeling under a petition or notification process specified in law
Exemption Standards

- **Petition** - “does not cause an allergic response that poses a risk to human health”
- **Notification** - “does not contain allergenic protein”
Allergen Thresholds

Scientific Questions:

• Does a level exist below which “does not cause” or “does not contain” apply (i.e., a threshold)?

• If so, how can this level be established?
Threshold Report

Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food
Purpose of the Report

- To identify approaches to establish thresholds for major food allergens and gluten
- To identify advantages, disadvantages, and data needs for each approach
Approaches To Establish Thresholds For Food Allergens

• Analytical Methods-Based
• Safety Assessment-Based
• Risk Assessment-Based
• Statutorily Derived
Analytical Methods-based Approach

- Based on sensitivity of methods
- Used when validated methods are available
- Not directly linked to public health outcomes
- Moderate data needs
Safety Assessment-Based Approach

- LOAELs or NOAELs from clinical data
- Uncertainty factors based on data gaps
- Moderate data needs
Risk Assessment-Based Approach

- Response distributions from clinical data
- Quantitative estimates of risk and uncertainty
- Greatest data needs
- Most technically rigorous approach
Statutorily Derived Approach

- Based on “highly refined oil” language in FALCPA
- Link between thresholds established using this approach and public health unclear
Risk Assessment Example

Undeclared peanuts in a baked product – model overview
Risk Assessment Example

Undeclared peanuts in a baked product - risk characterization