

The Challenge of Food Allergen Thresholds

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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

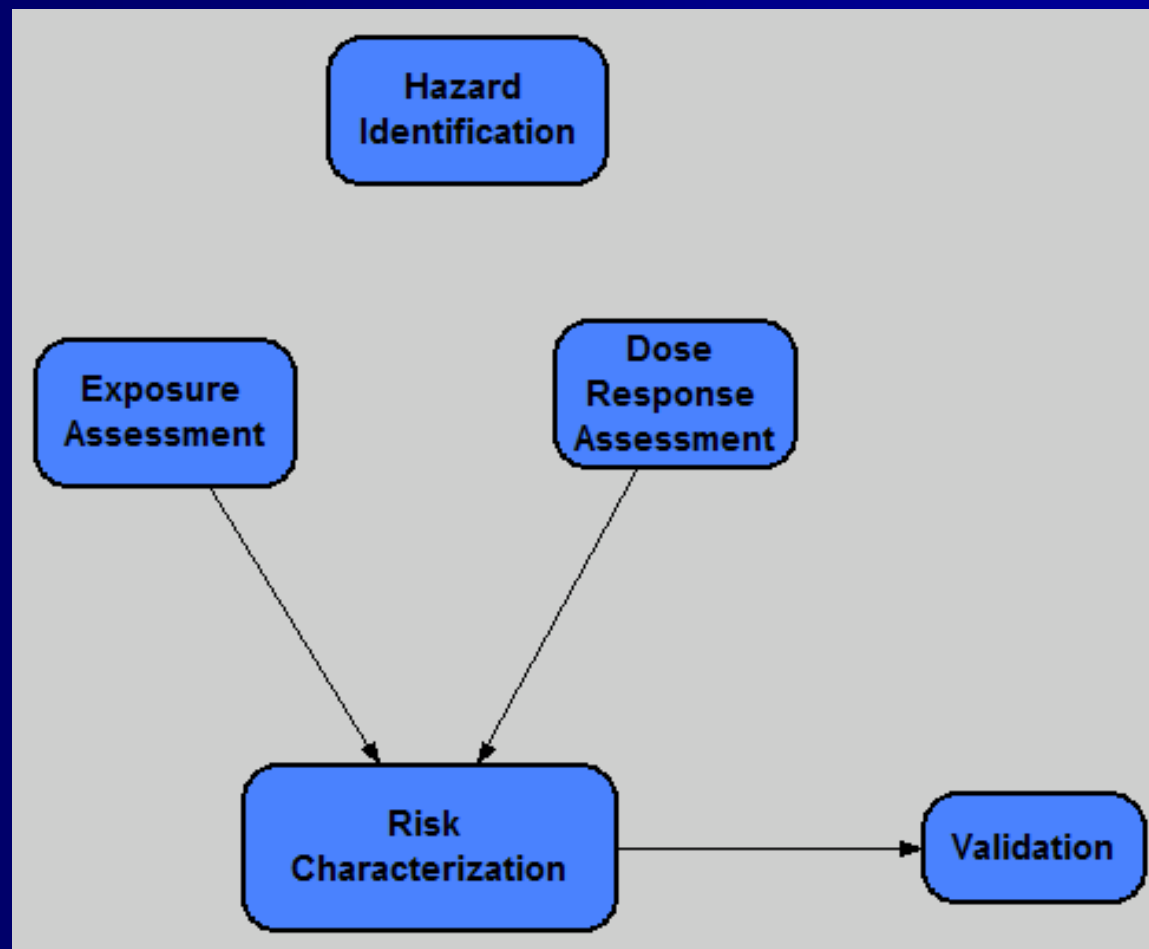
- Response distributions from clinical data
- Quantitative estimates of risk and uncertainty
- Greatest data needs
- Most technically rigorous approach

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

