Protein Allergy Assessment Process: 1996-2012

Laura Privalle, Ph.D.
Protein Allergenicity Technical Committee

January 22, 2013
ILSI Annual Meeting
Adverse Reactions to Food

- **Adverse Reactions to food**
  - May occur in all individuals
    - Toxic
    - Microbiological
    - Pharmacological
  - Occurs only in some susceptible individuals
    - Food hypersensitivity
      - Aversion, avoidance and psychological intolerance
    - Food allergy
      - IgE-mediated food allergy
      - Non-IgE mediated Food allergy
      - Unknown mechanism
      - Metabolic abnormality
Prevalence of Food Allergy

Prevalence of IgE antibody-mediated food allergies among the general population—
1-2% of adults
4-6% of children

Public Perception: 30%

6-7 million (U.S)
Common Allergenic Foods

Eight foods or food groups account for over 90% of food allergies (peanuts, soybeans, cow’s milk, hen’s egg, fish, crustacean, wheat, and tree nuts).

Prevalence to allergy varies geographically
- Buckwheat and rice allergy: Asia
- Fish allergy: Scandinavia
- Walnut/pecan: U.S.
- Hazelnut: Europe
- Fruit allergy: Spain

“Emerging”: avocado/kiwi; sesame seeds; spices

Disease management by avoidance (elimination diets)
Food Allergies: Conclusions

- Affect a small percentage of the population
- Of the tens of thousands of proteins in food, few (approximately 200) are actually food allergens.
- Reactions can occasionally be severe
- Treatment for true food allergies
  - Specific avoidance diets
What Are The Protein Allergenicity Concerns with Agricultural Biotechnology?
Categories of Potential Health Risks Relative to Allergenicity

- Transfer an existing allergen or cross-reactive protein into another crop.
- Creation of food allergens *de novo* (i.e., potential to become a new allergen.)
- Alteration or quantitative increase of endogenous (existing) allergens (i.e., increasing the hazard of currently allergenic foods)
What steps can be taken to minimize these risks?

- Historical perspective
  - 1996 ILSI Decision Tree
  - 2001 FAO/WHO Expert team decision tree
  - 2003 Codex Weight of evidence approach
Categories of Potential Health Risks Relative to Allergenicity

Risk:

1. Transfer an existing allergen or cross-reactive protein into another crop
2. Creation of food allergens de novo
3. Alteration or quantitative increase of endogenous (existing) allergens

Technology to reduce risk per CODEX (2003):

1. Bioinformatics/Immunological methods
2. Physical properties of protein (e.g., stability in SGF)
3. Immunological methods, proteomic approaches
Allergenicity Assessment

- Sequence homology comparison with known allergens
- Source of gene
- Digestive fate study
- Stability to heat and processing
- Examination of alteration of endogenous allergen levels (case-by-case basis)
- Glycosylation analysis
- Sera screening (case-by-case basis)
No scientific evidence that a biotech protein or a GM crop increased allergenic risk to the susceptible public