Case Study II: peanut

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Fungal-Resistant Peanut

- **Developer:** Virginia Tech & Tidewater Agricultural Research & Extension Center
- **Subject:** Peanut contains a plant-incorporated protectant (PIP); barley *oxalate oxidase* gene

- **Initial contact:** **January 2007**

Fungal-Resistant Peanut – Regulatory Authority

- Food or feed use? **Yes. (FDA)**
- New food additive? **No.**
  - FD&C Act, 201(s) defines the term food additive … and excludes pesticide chemicals.
  - FD&C Act, 201(q) defines pesticide chemicals, active and inert ingredients
- PIP? **Yes. (EPA)**
  - *oxalate oxidase* gene & resulting expression product
  - any selectable marker gene(s) & resulting expression product(s)

Peanut – Safety Assessment

- Known toxins or allergens in peanut? **Yes.**
- Major source of any nutrient? **Maybe**.
- Significant animal feed use? **Yes.**
- Substantial changes in composition?

  Case dependent.

Peanut – Compositional Analysis

Proximate nutrients	Minerals & Vitamins	Amino Acids	Fatty Acids	2° Metabolites & Anti-nutrients
• *Protein* • *Fat* • *Ash* • *Moisture* • *Fiber* • *Carbohydrates* • ……..	• *calcium* • *copper** • *iron8* • *magnesium** • *manganese** • *phosphorus** • *potassium** • *sodium* ……	• *arginine** • *cystine* • *histidine* • *lysine* • *methionine* • *threonine*…. • ……	• …… • ….. • ….. • ….	• ….. • …. • …. • …. • …

- **Possible components**: sampling from published literature
- **Comparitors**: transgenic to non-transgenic; literature; reference varieties
- **Plant tissues**: those used in food & feed

Peanut – Discussion Points

- **Food & feed uses**
  - uses can be dynamic
- **Composition & comparators**
  - identification of key nutrients, anti-nutrients, and secondary metabolites
  - variety selection: which ones & how many needed for statistical power
- **Allergenic potential of DNA recipient**

Allergenicity of DNA recipient

- **Peanut is one of the "Big 8" named in the Food Allergen Labeling Consumer Protection Act (FALCPA)**
  - multiple allergens characterized
  - food labeling (risk communication)
- **Assessment of endogenous allergenicity**
  - Soybean: FDA biotech consultation precedent
  - human sera testing via IgE immunoblot & ELISA
  - conclusions: no qualitative of quantitative difference

Peanut – Discussion Points

What if the genetic modification wasn't a PIP?

…then the gene(s) and expression products would be evaluated under FDA's authority for food and feed safety.

- **Toxic and allergenic potential of the expression products**

Potential Allergenicity of DNA donor

- **Barley OXOX**
  - germins are characterized as heat stable, resistant to protease digestion, glycoproteins
- **Assessment of potential for allergenicity**
  - history of dietary exposure
  - sequence homologies
  - heat stability & resistance to digestion
  - human sera testing

Allergen Databases

➢**There are a number of allergen databases. A whole list of such databases can be obtained through the web using the querry term "Allergen Database". Many of these databases have not been regularly updated. Refer to the following link to see a list of such databases prepared by Dr. Steve Gendel of FDA**
http://www.hesiglobal.org/files/public/GendelAllergenDatabases.pdf

➢**However, for all practical purposes, the most widely used database is the *FARRP Database* (*Food Allergy Research and Resource Program – University of Nebraska*). This database is very user-friendly and frequently used because it is designed to perform sequence search per the CODEX rcommendations to identify putative allergenic proteins**
- http://www.allergenonline.org/

➢**Another database that lists many allergenic epitopes is the *SDAP* (*Structural Database of Allergenic Proteins - University of Texas*):**
- http://fermi.utmb.edu/SDAP/

Thank you.

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