Protein Allergenicity
Technical Committee
PATC Member Companies

- BASF Plant Science
- Bayer Crop Science
- The Dow Chemical Company
- DuPont Company
- Monsanto Company
- Syngenta Biotechnology Inc.
Current Leadership

- Chair: Greg Ladics, Ph.D., DuPont
- Vice-Chair: Scott McClain, Ph.D., Syngenta
- Scientific Advisors: Lars Poulsen, Ph.D., Allergy Clinic, National University Hospital - Copenhagen, Denmark, John Kough, Ph.D., US EPA, Jeremiah Fasano, Ph.D., US FDA,
- HESI Manager: Nancy Doerrrer
PATC Mission

- To advance the scientific understanding of the relevant parameters defining allergenic proteins as well as encourage the development of reliable and accurate methodologies for characterizing the allergenic potential of novel proteins.
PATC Objectives

- Identify limitations in understanding of what makes a protein allergenic.
- Establish processes/endpoints useful in a weight-of-evidence approach for the evaluation of novel proteins expressed in biotech products.
- Develop scientific uniformity for these processes.
- Communicate findings to the academic, industry, and regulatory communities.
Strategy to Fulfill Mission

- Support and direct basic research.
- Harmonize development of common approaches (e.g., \textit{in vitro} assessments).
- Outreach activities: focused workshops/symposia.
PATC Global Outreach, 2001-2010

- Presentations to US FDA 5-07, Washington, DC
- Omics Workshop, 11-09, Paris, France
- Workshop with ILSI Japan and NIHS 9-03, Tokyo, Japan
- New Methods Workshop 10-07, Nice, FR
- Sera Bank Workshop 4-06, Seoul, Korea
- Meeting with Korean FDA 04-05, Seoul, Korea
- Joint Food Processing Workshop 6-06, Estoril, Portugal
- Bioinformatics Workshop 2-05, Mallorca, Spain
- Congress of Toxicology in Developing Countries, 9-09, Sun City, SA
- CODEX Ad Hoc Task Force on Food Derived from Biotechnology 3-02, Yokohama, Japan
- Joint Workshop with ILSI Brazil 11-06, Sao Paulo, Brazil
- ICTX Symposium 7-04, Tampere, Finland
- Joint Workshop with ILSI Argentina Course 11-06, Buenos Aires, Argentina
- Seminar in conjunction with ILSI Argentina Course 11-06, Buenos Aires, Argentina
- CODEX Ad Hoc Open-Ended Working Group 9-01, Vancouver Canada
Allergy Health Concerns in Biotech

- Transfer of an existing allergen or cross-reactive protein into another crop
- Alteration or otherwise significant increase of endogenous (existing) allergens in host GM crop
- Creation of food allergens *de novo* (*i.e.*, new allergens)
PATC Areas of Interest

- Biochemical Parameters associated with allergenic proteins
- Sequence Homology/Bioinformatics Evaluations
- Animal Models for Predicting Human Food Allergy
- Sera Bank Development
- Detection Methods to support endogenous allergen assessments
Completed Scientific Objectives

- **Proteomics Workshop**
- **New Methods**
  - workshop to catalog state of allergy science and discuss new methods...ongoing; publication of 11 papers in Reg. Toxicol. Pharmacol. (2009), 54:S1-S61.
- **Food Processing**
- **Sera Bank**
  - workshop and follow up with global scientists. Goal is to evaluate a coordinated effort in serum collection and application of in vitro studies...ongoing; publication of 7 papers in Food Chem. Toxicol. (2008), 46:S1-S40.
- **Animal model development**
Publications

Ongoing and Future Work

Basic Research, Outreach, and Workshops - 2010 and beyond
Global Biotech Issues that are Currently Driving PATC Initiatives

- Increases in regulatory requests for highly technical evaluations of endogenous soybean allergens.
  - Addressed through open collaboration amongst industry members.
  - Supported two workshops bringing together technical experts that perform 2-D gels, serology, and other proteomic approaches.
  - Newest initiative; basic research into the technical capabilities of quantitatively determining soybean allergen content.
Soybean Endogenous Allergens

- Method development project: Univ. of Missouri, Dr. Jay Thelen, Principal Investigator. Started Spring, 2009

- Objective; to develop a quantitative method using LC-mass spectrometry (AQUA peptides) to measure content of 10 allergens in 19 non-transgenic soy varieties.

- Hypothesis: if most abundant allergens can be measured precisely, question of unintended changes to endogenous allergens from GM manipulation could be better answered than from less accurate/precise methods.

- Publication(s); 1st methods paper published, September 2010. Main soybean variety analysis publication submitted September, 2010.
New Proposed Research for 2010-2011

- Comparison of 2D assay with MS approach
- Revisiting AQUA peptide work: evaluation of non-transgenic varieties grown at multiple locations (Dr. Jay Thelen)
- Evaluation of mouse epidermal stem cells as an in vitro model to predict protein allergenicity (Dr. Raymond Pieters, Utrech University)
- 2D-DIGE phase 2 validation with rice (Dr. Reiko Teshima, Japan National Institute of Health Sciences)
Interaction with other HESI Groups

- **Joint Workshop, Oct 2010.** The PATC is coordinating and sponsoring a globally focused workshop “Frontiers in Food Allergen Risk Assessment” with:
  - ILSI Europe
  - EuroPrevall
  - UK Food Standards Agency
  - Food Allergy Research and Resource Program, U of Nebraska

- Workshop focused on review of the recently completed EuroPrevall allergen prevalence study.

- PATC hosting a portion of the workshop; supporting the coordination of speaker and participant selection; providing funding.

- The goal is to summarize findings from the multi-year EuroPrevall study that is likely to have broad implications for food biotechnology, labeling practices, and public perceptions regarding food allergens.
Upcoming Issues and Future Plans

- Bioinformatics continues to be an area requiring further study into its application to novel food protein safety.

- “-omics” technologies are an ongoing focus for the next several years. Proteomics are not a fully developed technology and its impact on and use in the regulatory arena is not fully understood.