

Protein Allergenicity Technical Committee



ILSI Health and
Environmental Sciences
Institute

PATC Member Companies

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



Current Leadership

- Co-Chair: Greg Ladics, Ph.D., DuPont Pioneer
- Co-Chair: Scott McClain, Ph.D., Syngenta
- Co-Chair: Ronald Van Ree, Ph.D., Univ. Amsterdam
- 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 Doerrer



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

- Focused workshops/symposia with experts from government, academia, and industry.
- Support and direct basic research to evaluate utility of *in vivo* methods.
- Harmonize development of common approaches for *in vitro* assessments.
- Peer-reviewed publications
- Outreach activities to update the state-of-the-art in allergy science and the role new information plays in the regulatory safety of food and feeds.



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

- 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.
- 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
 - workshop to determine processing effects on allergens and the methods to determine allergen content in foods; publication of 6 papers in Mol. Nutr. Food Sci. (2009), 53:945-983.
- Animal model development
 - Multi-laboratory study with standardized proteins; Reg. Toxicol. Pharmacol. (2010), 56:212-224.
- Proteomics Workshop (natural variability in non-GE crops)
 - publication of 12 papers in Reg. Toxicol. Pharmacol. (2010), 58:S1-S55



Recent Biotech Issues Engaged by PATC

- 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.
 - Basic research into the technical capabilities of quantitatively determining soybean allergen content.



Ongoing and New Research for 2012-2013

- Evaluation of mouse epidermal stem cells as an in vitro model to predict protein allergenicity (Dr. Raymond Pieters, Utrecht University)
- 2D-DIGE phase 2 validation with rice (Dr. Reiko Teshima, Japan National Institute of Health Sciences)
- Intra- and Inter-laboratory evaluation of a more physiologically based SGF assay

