



H E S I

*ILSI Health and Environmental Sciences Institute*

---

# Protein Allergenicity Technical Committee (PATC)

Dr. Michael Holsapple  
HESI Executive Director  
(on behalf of the PATC)

HESI Assembly of Members Meeting  
January 19, 2009  
Tucson, Arizona



H E S I.

# Committee Leadership

---

**Dr. Greg Ladics**

Chair

(E.I. Dupont de Nemours and Company)

**Dr. Scott McClain**

Vice Chair

(Monsanto Company)



H E S I

# Committee Membership

---

BASF Plant Science

Bayer CropScience

The Dow Chemical Company

The DuPont Company

Monsanto Company

Syngenta Ltd.



H E S I

# Government and Academic Participation

---

- Food and Nutrition Research Institute, Philippines
  - Department of Science and Technology
- Japanese Ministry of Health, Labor and Welfare
- National Institutes of Health, Japan
- Paul Ehrlich Institute (Germany)
- Thailand Food and Drug Administration
- University of Missouri
- U.S. Environmental Protection Agency
- U.S. Food and Drug Administration



H E S I

# 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 the understanding of what makes a protein allergenic.**
- **Establish processes useful in a weight-of-evidence approach for the evaluation of novel proteins expressed in biotech products.**
- **Develop scientific uniformity for these evaluations.**



# Potential Health Risks Relative to Allergenicity Associated with the Crops Enhanced via Biotechnology

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



# Approaches Taken to Fulfill Mission

---

H E S I

- Conduct workshops with experts from government, academia, and industry.
- Basic research to evaluate utility of *in vivo* and *in vitro* methods.
- Development of common processes for *in vitro* assessment.
- Outreach activities to update state-of-the-art techniques for allergenicity evaluations.





# 2008 Activities

---

H E S I

- EPA and Health Canada Grantees workshop
- Outreach activities in Europe and Southeast Asia
- Proteomics Project (University of Missouri)
- Manuscripts:
  - Food Processing Workshop manuscripts: acceptance for publication in Regulatory Toxicology and Pharmacology.
  - Sera Bank Workshop manuscripts: acceptance for publication in Food and Chemical Toxicology.
  - Food Processing Workshop manuscripts: acceptance for publication in Molecular Nutrition and Food Research.
  - Manuscript entitled "Scientific Advancement of Novel Protein Allergenicity Evaluation: An Overview of Work from the HESI Protein Allergenicity Technical Committee (2000-2007)" submitted to Regulatory Toxicology and Pharmacology.
- Organize 2009 outreach activities



H E S I

# Research to Improve Safety Assessment of Biotechnology Products for Potential Risk of Food Allergy

Workshop held October 15-16, 2008, in Washington, D.C.  
Jointly sponsored by the  
U.S. Environmental Protection Agency (EPA)

## Objectives:

- Bring together industry, academic and government scientists to consider the issue of food allergy as it pertains to assessing the potential risks of biotechnology products.
- Review the latest research results in this area funded by the EPA, Health Canada, and National Institutes of Health (NIH).
- Determine future research and validation needs.



H E S I

# Food Allergy Workshop Outcome

---

- Workshop manuscript will be submitted for publication in *Toxicological Sciences*
- In March 2009, the PATC will host a meeting with the EPA and scientists involved with animal modeling to continue discussions surrounding the standardization and validation of animal models for safety assessment.



H E S I

# International Outreach

---

- Novel Protein Safety Evaluation Workshop - Tokyo, Japan
- Novel Protein Safety Evaluation Seminar - Manila, Philippines
- Workshop on Efforts to Improve Techniques for Identifying and Evaluating Food Allergens - Rhodes, Greece (Eurotox)
- Symposium on Biotechnology and Nutritionally Enhanced Food and Crops - Cebu, Philippines
- Protein Allergenicity: Weight-of-Evidence Allergenicity Evaluation Seminar - Bangkok, Thailand



# Endogenous Protein Allergen Variation PATC Proteomics Project

---

H E S I

**Goal:** To address the question of natural variability of the levels of endogenous allergens in commercially available non-biotech soybean.

**Approach:**

- Phase I - Quantify major soy allergens using direct analysis by LC-MS/MS (Dr. Jay Thelen, University of Missouri).
- Phase II - Validation of this approach by classical two-dimensional gel methods.



H E S I

# Proteomics Project Timeline

---

## Fall/Winter 2008 - Initiation of Phase I

- Establish utility of LC-MS/MS approach, identification of various lines to define the ranges of variability of endogenous allergen levels in soy.
- Identification of soy allergens whose levels vary (establish range of variability).
- Estimated duration of phase I is six months.

## Spring 2009 - Initiation of Phase II

- Validation of Dr. Jay Thelen's results with select soy lines and allergens by classical proteomics approach.
- Evaluate 4 most variable soy lines, prepare duplicate gels, and focus on 4 allergens or allergen families.
- Estimated duration of phase II is six months.

Late 2009 - Publication of results (submission of manuscripts)



H E S L

# Plans for 2009

---

- Continue and complete Proteomics Project
- Proposed 2009 Project Ideas:
  - Workshop on biological variation of non-transgenic crops (jointly with IFBiC)
  - State-of-the-science seminar on the utility of “omics”
  - Whole Foods Project - Focus on digestibility and allergenicity concerns in whole foods.
- Host/chair session at European Academy of Allergy and Clinical Immunology (EAACI) 2010