



ILSI Health and Environmental Sciences Institute PROTEIN ALLERGENICITY TECHNICAL COMMITTEE

MISSION

The mission of the HESI Protein Allergenicity Technical Committee (PATC) is 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.

OBJECTIVES

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

SCOPE

Since its formation in 1997, the PATC has addressed the following specific areas:

- Development of a common in vitro digestive stability (SGF) protocol
- Assessment of molecular characteristics of food allergens
- Sequence homology evaluation / bioinformatics assessment
- Sera bank development, including coordination of regional clinical managers
- Development of animal models
- Impact of food processing on allergenicity
- Workshop on the newest methods in characterizing allergens
- Basic research to develop new soybean protein characterization methods using mass spectrometry
- Workshop on multiple “-omics” that represent cutting-edge plant profiling technologies
- Symposium on sensitizing properties of proteins

PARTICIPATION

- Co-Chair:** Dr. Greg Ladics (DuPont Company, Pioneer HI-Bred)
Co-Chair: Dr. Scott McClain (Syngenta Crop Protection)
Co-Chair: Dr. Ronald van Ree (Academic Medical Center, Amsterdam University)
Staff: Nancy Doerrer, MS (HESI)

Industry:

BASF Plant Science
Bayer CropScience
DuPont Company
Monsanto Company
Dow AgroSciences
Syngenta Crop Protection

Public:

Amsterdam University, The Netherlands
Gentofte Hospital, Denmark
University of Leuven, Belgium
US Environmental Protection Agency, USA
US Food and Drug Administration, USA

CONFERENCES, SYMPOSIA AND JOINT WORKSHOPS

The PATC has directly sponsored or been involved in many international meetings to highlight the impact of its activities and productively advance the science associated with novel protein allergenicity evaluation:

- April 2012 Symposium on Sensitizing Properties of Proteins, Prague, Czech Republic.
- November 2011 joint Workshop on Safety Assessment of Novel Proteins and GM Crops with the ILSI Focal Point in China, the Chinese Centre for Disease Control and Prevention, and the ILSI International Food Biotechnology Committee (IFBiC), Beijing, China
- May 2011 joint Biotechnology Workshop 2011 with the ILSI International Food Biotechnology Committee (IFBiC) for the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology (WGHROB) and the OECD Task Force on the Safety of Novel Foods and Feeds (TFSNFF), Paris, France
- May 2011 joint Biotechnology Update Workshop with the ILSI International Food Biotechnology Committee (IFBiC) for the Canadian Food Inspection Agency (CFIA), Ottawa, Canada
- October 2010 joint symposium with ILSI Europe, EuroPrevall, UK Food Standards Agency, and FAARP on Frontiers in Food Allergen Risk Assessment, Nice, France.
- September 2010 joint Biotechnology Update Symposium with the ILSI International Food Biotechnology Committee (IFBiC), Washington, DC.
- November 2009 workshop on Evaluating Biological Variation in Non-transgenic Crops, Paris, France.
- October 2008 host of symposium on Efforts to Improve Techniques for Identifying and Evaluating Food Allergens, as part of the 45th Eurotox Annual Meeting, Rhodes, Greece.
- September 2008 joint symposium with ILSI SEA and the Thai National Science and Technology Development Agency (NSTDA), Bangkok, Thailand.
- September 2008 joint symposium with ILSI SEA on Biotechnology and Nutritionally Enhanced Food and Crops, Cebu, Philippines.
- April 2008 joint meeting with IFBiC, ILSI Research Foundation on ILSI Activities Related to Biotechnology, Washington, DC.
- February 2008 joint workshop with ILSI Japan and Japanese regulators on Sequence Homology and Bioinformatic Assessments, Tokyo, Japan.
- February 2008 joint workshop with the Biotechnology Coalition of the Philippines, ILSI Southeast Asia (SEA), Department of Agriculture (Philippines), and the International Service for the Acquisition of AgriBiotech Applications on Novel Protein Safety Evaluation, Manila, Philippines.
- October 2007 PATC workshop on New Methods for Allergenicity Assessments, Nice, France.

- November 2006 seminar with ILSI Argentina and Food and Feed Safety Authority of Argentina (SENASA), International Course on Food Risk Analysis, Buenos Aires, Argentina.
- November 2006 joint workshop with ILSI Brazil on Conducting a Comprehensive Allergenicity Evaluation of Novel Proteins, Sao Paula, Brazil.
- June 2006 International Effects of Food Processing on Allergenicity Workshop, hosted in partnership with ILSI Europe, ILSI International Food Biotechnology Committee (IFBiC), and ILSI Research Foundation, Estoril, Portugal.
- April 2006 International Sera Bank Development Workshop, Seoul, Korea.
- March 2005 poster at the American Academy of Asthma, Allergy, and Immunology (AAAI) meeting, San Antonio, TX.
- March 2005 poster at the Society of Toxicology (SOT) Annual Meeting, New Orleans, LA.
- February 2005 International Sequence Homology / Bioinformatics Workshop, Mallorca, Spain.
- July 2004 Symposium at International Congress of Toxicology Meeting (ICTX), Tampere, Finland.
- September 2003 poster at the Eurotox Annual Meeting, Florence, Italy.
- September 2003 joint workshop with ILSI Japan to present committee activities to scientists at National Institute of Health Sciences, Tokyo, Japan.
- March 2002, Committee-led ILSI delegation at CODEX Ad Hoc Task Force on Food Derived from Biotechnology Meeting, Yokohama, Japan.
- September 2001, Committee-led ILSI delegation at CODEX Ad Hoc Open-Ended Working Group on Allergenicity Meeting, Vancouver, Canada.

PUBLICATIONS

- Doerrler, N., Ladics, G., McClain, S., Herouet-Guicheney, C., Poulsen, L., Privalle, L., Stagg, N. (2010). Evaluating biological variation in non-transgenic crops: executive summary from the ILSI Health and Environmental Sciences Institute workshop, November 16-17, 2009, Paris, France. *Regul Toxicol Pharmacol* 58, S2-S7.
- Thomas, K., MacIntosh, S., Bannon, G., Herouet-Guicheney, C., Holsapple, M., Ladics, G., McClain, S., Vieths, S., Woolhiser, M., and Privalle, L. (2009). Scientific advancement of novel protein allergenicity evaluation: an overview of work from the HESI Protein Allergenicity Technical Committee (2000-2008). *Food Chem Toxicol* 47, 1041-1050.
- Thomas, K., Herouet-Guicheney, C., Ladics, G., McClain, S., MacIntosh, S., Privalle, L., and Woolhiser, M. (2008). Current and future methods for evaluating the allergenic potential of proteins: international workshop report, 23-25 October 2007. *Food Chem Toxicol* 46, 3219-3225.

- Thomas, K., Bannon, G., Herouet-Guicheney, C., Ladics, G., Lee, L., Lee, S., Privalle, L., Ballmer-Weber, B., and Vieths, S. (2007a). The utility of an international sera bank for use in evaluating the potential human allergenicity of novel proteins: workshop report. *Toxicol Sci* 97(1), 27-31.
- Thomas, K., Herouet-Guicheney, C., Ladics, G., Bannon, G., Cockburn, A., Crevel, R., Fitzpatrick, J., Mills, C., Privalle, L., and Vieths, S. (2007b). Evaluating the effects of food processing on the potential human allergenicity of novel proteins: international workshop report. *Food Chem Toxicol* 45, 1116-1122.
- Thomas, K., Bannon, G., Hefle, S., Herouet, C., Holsapple, M., Ladics, G., MacIntosh, S., and Privalle, L. (2005a). In silico methods for evaluating human allergenicity to novel proteins: International Bioinformatics Workshop meeting report, February 23–24, 2005, *Toxicol Sci* 82(2), 307-310.
- Thomas, K., Herouet, C., Bannon, G.A., Ladics, G.S., MacIntosh, S., Privalle, L., and Woolhiser, M. (2005b). Evaluation of mouse models for assessing the allergenic potential of proteins. *Toxicologist* 84 (S-1), 1307. (Abstract)
- Thomas, K., Aalbers, M., Bannon, G.A., Bartels, M., Dearman, R.J., Esdaile, D.J., Fu, T.J., Glatt, C.M., Hadfield, N., Hatzos, C., Hefle, S.L., Heylings, J.R., Goodman, R.E., Henry, B., Herouet, C., Holsapple, M., Ladics, G.S., Landry, T.D., MacIntosh, S.C., Rice, E.A., Privalle, L.S., Steiner, H.Y., Teshima, R., van Ree, R., Woolhiser, M., and Zawodny, J. (2004). A multi-laboratory evaluation of a common *in vitro* pepsin digestion assay protocol used in assessing the safety of novel proteins. *Regul Toxicol Pharmacol* 39, 87-88.

RECENTLY COMPLETED AND ONGOING PATC-SPONSORED RESEARCH

- 2D-DIGE phase 2 validation: Analysis of rice proteins with different cultivars (Dr. Reiko Teshima, Japan National Institute of Health Sciences)
- Comparison of 2D assay with AQUA MS approach (Donald Danforth Plant Science Center, St. Louis, MO)
- Proteomics method development: A quantitative approach to measuring the content of specific allergens in soybean (Dr. Jay Thelen, University of Missouri)
- Absolute quantitation of seed allergens from three varieties from soy from eight geographical locations (Dr. Jay Thelen, University of Missouri)
- Intestinal stem cells to assess safety and efficacy of various compounds (Dr. Raymond Pieters, Utrecht University of Applied Sciences, Utrecht, The Netherlands)

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