2015–2016 Activities and Accomplishments

This scientific program is committed to:

- Advancing the scientific understanding of the relevant parameters defining allergenic proteins, as well as encouraging the development of reliable and accurate methodologies for characterizing the allergenic potential of novel proteins.

Areas of scientific focus:

- 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 biotechnology products.
- Develop scientific uniformity for these evaluations.
- Communicate findings to the academic, regulatory, and industry communities.

Why get involved?

- The Protein Allergenicity Technical Committee (PATC) pools expertise and resources to advance scientific tools and methods for allergenicity and safety assessment of novel proteins and genetically modified (GM) crops.
- The PATC’s work provides opportunities for engagement in cutting-edge biotechnology research.
- Participants have frequent, direct interaction with international decision makers and researchers on biotechnology safety assessment issues.
- Committee discussions and programs lead to greater awareness and application of reliable and accurate methods for characterizing allergenicity potential.

Key accomplishments:

Laboratory research:

- New Digestibility Model(s) for Investigating Allergenicity of Proteins. In collaboration with the Academic Medical Center/University of Amsterdam (The Netherlands) the Digestibility team completed the first phase of their study with the analysis of five “reference allergen” and “non-allergen” pairs, subjected to nine different novel digestion protocols. Preliminary results have been assembled in a summary report that was made available to the European Food Safety Authority Pilot Focus Group on Allergenicity.

Database developments:

- Protein Toxins Task Force. In 3Q 2015, the PATC initiated new research in a joint effort with the University of Texas Medical Branch (Galveston, Texas) and the Foundation for Applied Molecular Evolution (Gainesville, Florida) to develop informatic methods for identification and classification of protein toxins. Pooled data from four different companies were used to generate a database of 10,389 unique toxin sequences. Sequences of toxic proteins have been grouped by cluster analysis, using the functional and structural annotations. The data have also been clustered using Pfam domains to sort like proteins.
The COMPARE Allergen Database. In December 2015, the PATC initiated the development of a database for identification of protein sequences that are known or putative allergens. This is a collaborative public-private effort, in partnership with the Joint Institute for Food Safety and Nutrition at the University of Maryland (http://jifsan.umd.edu), which provides programmatic support. The COMPARE (COMprehensive Protein Allergen REsource) database will serve as a publicly accessible, transparent, and reliable tool for allergen identification and comparative analyses. COMPARE will meet needs for allergy safety assessment via an annual updating process that combines bioinformatics screening, identification of literature linked to the identified potential allergen sequences, and an external review by a public sector-only panel of allergy experts. Since the inception of the project, an expert team of 19 scientists from government, academia, and industry (across the European Union and the United States) has been assembled to oversee the process. A team of academic peer reviewers responsible for decisions about which sequences will be entered into the database will be convened by July 2016.

The Committee’s focus for May 2016–May 2017:

Research:

- **Digestibility.** Next steps include studies evaluating IgE binding and the impact of food matrices on susceptibility of digestion.
- **Allergen Rebuild.** New to the PATC in 2016 is a research project that aims to evaluate the impact of amino acid replacement, at a single dominant epitope level, on IgE binding to the epitope, as part of using an intact, full-length major protein allergen. Results will enhance understanding of the biology of allergen IgE binding.
- **GARD Assay.** The Genomic Allergen Rapid Detection (GARD) system is a novel assay platform that utilizes genomic biomarker signatures (heat map profiles) to help identify proteins that uniquely interact with a sustainable cell line. This GARD profiling has shown promise in discriminating respiratory sensitizing proteins from non-sensitizing proteins. The purpose of this pilot research is to transfer the current GARD protocols to that of investigating food allergens that are active through the oral route of exposure and to document the capacity of the GARD platform to discriminate a known food protein allergen from a non-allergen. Experiments are underway and preliminary results are expected by Summer 2016.

Databases:

- **Protein Toxins Task Force.** The task force will initiate phase 3 of their project, investigating the importance of bioinformatics and motif analysis to understand the toxic potential of an unknown protein. This research will yield a list of functional domains that are associated with toxicity and can thus be used as a hazard identification tool for novel proteins.
- **COMPARE Allergen Database.** The COMPARE database is planned to be released in early 2017.

Publications:

- A manuscript presenting results of the first two phases of the Protein Toxins Database development will be drafted. Results of work by the Digestibility and GARD Assay groups will be analyzed and interpreted for manuscript preparation as well.

International outreach:

- During 2016 and 2017, the PATC will continue its focus on international outreach with plans for a 1.5-day workshop on non-IgE–mediated immune reactions to foods, in Rome, Italy (October 2016), to discuss research needs and scientific approaches to assessing safety. This meeting is being organized as a pre-meeting workshop of the 4th Food Allergy and Anaphylaxis Meeting of the European Academy of Allergy and Clinical Immunology (EAACI).

Recent publications:

Upon conclusion of the 2D-DIGE and Adjuvanticity projects, two manuscripts were submitted in 1Q 2016.


2015–2016 Participating organizations

Academic Medical Center, University of Amsterdam
BASF Plant Science
Bayer SAS
Copenhagen University Hospital at Gentofte
Dow AgroSciences
DuPont Co.
Guangzhou Medical University
Monsanto Company
Syngenta Crop Protection
University of Maryland, Joint Institute for Food Safety and Nutrition
University of Texas Medical Branch
US Environmental Protection Agency
US Food and Drug Administration

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