



ILSI Health and Environmental
Sciences Institute



ILSI

International Food
Biotechnology
Committee

FOOD ALLERGY AND SAFETY ASSESSMENT WORKSHOP

**15-16 April 2013
Guangxi Hotel
Beijing, China**

CO-SPONSORS:

ILSI FOCAL POINT IN CHINA

HESI PROTEIN ALLERGENICITY TECHNICAL COMMITTEE
ILSI Health and Environmental Sciences Institute (HESI)

ILSI INTERNATIONAL FOOD BIOTECHNOLOGY COMMITTEE (IFBiC)

CHINA NATIONAL CENTRE FOR FOOD SAFETY RISK ASSESSMENT

KEY LABORATORY OF FOOD SAFETY RISK ASSESSMENT
China Ministry of Health (MOH)

Workshop Co-Chairs:

- *Professor Junshi Chen* (China National Centre for Food Safety Risk Assessment; Director, ILSI Focal Point in China)
- *Dr. Gregory Ladics* (DuPont Pioneer, USA; HESI PATC Co-Chair)
- *Dr. Scott McClain* (Syngenta, USA; HESI PATC Co-Chair)
- *Prof. Ronald van Ree* (Academic Medical Center / University of Amsterdam, Netherlands; HESI PATC Co-Chair)
- *Prof. Yongning Wu* (Chief Expert, China National Centre for Food Safety Risk Assessment; Director, Key Laboratory on Food Safety Risk Assessment, China Ministry of Health)

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OBJECTIVES

- 1) Identify and discuss accepted standards as well as innovative approaches being utilized to address clinical allergy.
- 2) Describe the state of the science in assessing protein allergenicity, toxicity, and compositional analysis of biotechnology-based food crops.
- 3) Discuss the safety framework for genetically modified (GM) crops, the regulatory approval processes, and how they are implemented globally.

To better understand clinical allergy and the biological basis of allergy, clinicians will discuss allergy prevalence and study design strategies. The workshop program encourages open discussion by including time for interaction between the audience and speakers.

Background: An important aspect of evaluating the safety of GM crops for use as food and animal feed is a risk assessment of potential effects on human health and the environment. This risk assessment is based on evaluations of allergenicity, toxicity, and unintended adverse effects. The current state of the science for addressing the safety of protein allergens utilizes a weight-of-evidence approach, as outlined by the *Codex Alimentarius* commission (Alinorm 03/34A), recognizing that no single endpoint is sufficiently predictive of the allergenic potential of a novel protein.

Toxicity assessments are necessary to complete the safety assessment of a novel protein by determining if a protein has characteristics similar to known toxic proteins and evaluating the purified protein for toxicity in a model organism. The GM whole product, typically harvested grain from corn or soybean, is also evaluated for toxicity in animal feeding studies. However, the predictive value of such toxicology data, particularly longer-term feeding studies, has not been clearly identified and will be discussed. The GM crop product (grain) is also evaluated for its similarity with the grain from the same genetic background, as well as reference comparators utilizing a comprehensive composition analysis. Novel proteins and the crops into which they are transformed are assessed for adverse environmental effects by evaluating environmental exposure and potential effects on non-target organisms utilizing hypothesis-based testing on a case-by-case basis. A thorough molecular and protein characterization of the inserted DNA and expressed novel proteins complete the evaluation and are utilized in the assessment of allergenicity, toxicity, and risk.

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PROGRAM

DAY ONE

Monday, 15 April 2013, 09:00 – 17:30

- 09:00** **Welcome, introductions, and meeting objectives**
Prof. Junshi Chen (China National Centre for Food Safety Risk Assessment; ILSI Focal Point in China)
- 09:15** **About the HESI Protein Allergenicity Technical Committee (PATC)**
Dr. Gregory Ladics (DuPont Pioneer, USA)

SESSION I: FOOD ALLERGY

- 09:30** **Session Introduction**
Prof. Ronald Van Ree (Academic Medical Center / University of Amsterdam, Netherlands)
- 09:40** **Food Allergy Introduction, Etiology, and Mechanisms**
Prof. Lars K. Poulsen (Copenhagen University Hospital at Gentofte, Denmark)
- 10:10** **Global Prevalence of Food Allergy**
Prof. Gary WK Wong (Chinese University of Hong Kong)
- 10:40** **Break**
- 11:00** **Prevalence of Food Allergy in Indonesia and Developing Countries;
Role of Infections in the Development of Food Allergy**
Prof. Maria Yazdanbakhsh (Leiden University Medical Center, Netherlands)

- 11:30** **Epidemiology and Clinical Features of Food Allergenicity**
Wang Lianglu, MD (Peking Union Medical College Hospital, China)
- 12:00** **Lunch**
- 13:00** **Food Allergy Diagnosis / Clinical Assessment**
Prof. Barbara Ballmer-Weber (University Hospital Zürich, Switzerland)
- 13:30** **Component-Resolved Diagnosis of Peach and Mugwort Allergy and Cross-Reactivity in China**
Prof. Gao Zhong-shan (Zhejiang University, China)
- 14:00** **Innovative Approaches for Immunotherapy of Food Allergy**
Prof. Ronald Van Ree (Academic Medical Center / University of Amsterdam, Netherlands)
- 14:30** **Q&A, General Discussion**
Moderators:
- *Prof. Junshi Chen (China National Centre for Food Safety Risk Assessment; ILSI Focal Point in China)*
 - *Prof. Ronald Van Ree (Academic Medical Center / University of Amsterdam, Netherlands)*
- 15:00** **Break**

SESSION II: AGRICULTURAL BIOTECHNOLOGY SAFETY ASSESSMENT

- 15:20** **Session Introduction**
Dr. Scott McClain (Syngenta, USA)
- 15:30** **Agricultural Biotechnology Background**
Dr. Wendelyn Jones (DuPont Pioneer, USA)
- 16:00** **Safety Assessment Process to Register GM Products**
Dr. Wendelyn Jones (DuPont Pioneer, USA)

16:30 **Crop Composition Assessment**
Dr. Xiaoyun He (College of Food Science & Nutritional Engineering, China Agricultural University)

17:00 **Q&A, General Discussion**
Moderators:

- *Prof. Junshi Chen (China National Centre for Food Safety Risk Assessment; ILSI Focal Point in China)*
- *Dr. Scott McClain (Syngenta, USA)*

17:30 **Adjourn Day One**

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DAY TWO
Tuesday, 16 April 2013, 09:00 – 15:30

09:00 **Day Two Welcome**
Prof. Yongning Wu (China National Centre for Food Safety Risk Assessment; Key Laboratory on Food Safety Risk Assessment, China Ministry of Health)

CONTINUATION OF SESSION II: AGRICULTURAL BIOTECHNOLOGY SAFETY ASSESSMENT

9:10 **Molecular/Protein Characterization of GM Products**
Dr. Scott McClain (Syngenta, USA)

10:00 **Allergy Assessment**
Dr. Gregory Ladics (DuPont Pioneer, USA)

10:30 **Break**

10:45 **Toxicity Assessment**
Prof. Andrew Bartholomaeus (University of Canberra; University of Queensland)

- 11:15** **Ecological Risk Assessment**
Prof. Alan Raybould (Syngenta, UK)
- 11:45** **Detection Methods**
Dr. Petra Lutter (Nestle Research Centre, Switzerland)
- 12:15** **Lunch**
- 13:15** **GM Product Case Study**
Dr. Jason Ward (Monsanto Company, USA)
- 13:45** **Regulatory Perspective: Australia, New Zealand**
Prof. Andrew Bartholomaeus (University of Canberra; University of Queensland; formerly FSANZ [Food Standards Australia New Zealand])
- 14:15** **Regulatory Perspective: China**
Prof. Haibin Xu (China National Centre for Food Safety Risk Assessment)
- 14:40** **Safety Assessment in China**
Prof. Xue Wang (China National Center for Safety Evaluation of Drugs)
- 15:00** **Q&A, General Discussion**
Moderators:
- *Prof. Yongning Wu (China National Centre for Food Safety Risk Assessment; Key Laboratory on Food Safety Risk Assessment, China Ministry of Health)*
 - *Dr. Scott McClain (Syngenta, USA)*
- 15:15** **CLOSING REMARKS**
Prof. Yongning Wu (China National Centre for Food Safety Risk Assessment; Key Laboratory on Food Safety Risk Assessment, China Ministry of Health)
- 15:30** **ADJOURN WORKSHOP**