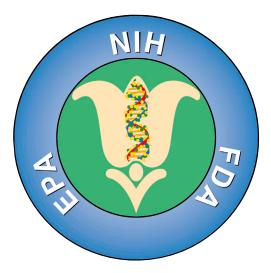
Assessment of the Allergenic Potential of Genetically Modified Foods

December 10-12, 2001

Sheraton Chapel Hill Hotel Chapel Hill, North Carolina



Sponsored by the Office of Research and Development, U.S. Environmental Protection Agency

National Toxicology Program, Department of Health and Human Services

National Institute of Environmental Health Sciences, National Institutes of Health

> Office of Rare Diseases, National Institutes of Health

Center for Food Safety and Nutrition, U.S. Food and Drug Administration

Organized by the National Institute of Environmental Health Sciences National Toxicology Program Research Triangle Park, NC





Purpose - There is growing concern among the general public and the scientific community regarding the potential toxicity of genetically modified (GM) foods. Of specific interest is the ability of GM proteins to elicit potentially harmful immunologic responses including hypersensitivity and/or autoimmunity. The lack of information on the potential toxicity of these products has created a considerable backlash against the producers and users of these crops. This meeting will gather experts in food allergy, GM crops and the regulatory aspects of these products, along with bench scientists and clinicians, to examine the current state of knowledge in the area, identify the critical issues and research needs regarding these materials and develop testing strategies to examine the allergenicity of these compounds.

AGENDA

Continental breakfast is provided each day at 7:30 AM in the Lobby. Attendees are responsible for lunch and dinner.

MONDAY, DECEMBER 10TH

7:30 AM	Registration	(Lobby)
8:30 AM	Welcome	(London)
	Christopher Portier, Environmental Toxicology Program (ETP), National Institute of Environmental Health Sciences (NIEHS)	
	Linda Birnbaum, National Health and Environmental Effects Researchaboratory (NHEERL), U.S. Environmental Protection Agency (
<i>KEYNOTE</i> Chair: Christopher 1	Portier, ETP, NIEHS	
8:45 AM	What are the Issues? Dean Metcalfe, National Institute of Allergy and Infectious Disease	2S
9:15 AM	Assessing the Allergenicity of Genetically Engineered Foods: Su Symposium at the National Center for Food Safety and Techno Steven Gendel, Food and Drug Administration (FDA)	•
	CAL ASPECTS AND CLINICAL INVESTIGATION OF FOOD an, Johns Hopkins University	ALLERGY
9:40 AM	Clinical Spectrum of Food Allergy Hugh Sampson, Mount Sinai School of Medicine	
10:10 AM	Break	
10:30 AM	Assessment of Allergenicity to Genetically Modified Foods and Proteins Samuel Lehrer, Tulane University Health Sciences Center	Novel
11:00 AM	Occupational Inhalational Allergenicity and Food Allergy Leonard Bernstein, University of Cincinnati	
11:30 AM	Clinical and Laboratory Methods in the Assessment of the Aller Foods Robert G. Hamilton, Johns Hopkins University School of Medicin	
12:00 PM	Lunch	
1:00 PM	Can Post-Marketing Surveillance Provide Useful Information A Allergenicity of Genetically Modified Foods: The StarLink Corr Carol Rubin, Centers for Disease Control and Prevention	

SESSION II: TOXICOLOGICAL EVALUATION OF NOVEL PROTEINS Chair: Dennis Hinton, FDA

1:40 PMDigestion Stability as a Criterion for Protein Allergenicity Assessment
Tong-Jen Fu, FDA

- 2:10 PM Structure and Stability of the Major Peanut Allergens Gary Bannon, Monsanto Company
- 2:40 PM Break

SESSION III: REGULATORY CONSIDERATIONS Chair: Christopher Portier, ETP, NIEHS

3:00 PM Short Presentations Followed by a Panel Discussion Kathleen Jones, FDA John Kough, EPA Katherine Sarlo, Procter & Gamble Company Val Giddings, Biotechnology Industry Organization James Astwood, Monsanto Company

SESSION IV: RISK COMMUNICATION

Chair: Dori Germolec, NIEHS

4:15 PM	What Consumers Think About Biotechnology Thomas Hoban, North Carolina State University
4:35 PM	Public-Interest Perspective on Allergenicity Rebecca Goldburg, Environmental Defense
5:00 PM	Open Discussion
5:30 PM	Meeting Adjourns

TUESDAY, DECEMBER 11TH

SESSION V: TOXICOLOGIC METHODS OF SAFETY ASSESSMENT Chairs: Ian Kimber, Syngenta & Dennis Hinton, FDA

8:30 AM	Overview
8:40 AM	Oral and Intraperitoneal Exposure of Brown Norway Rats André Penninks, TNO Nutrition and Food Research
9:15 AM	Oral and Systemic Exposure of BALB/c mice Ian Kimber, Syngenta
9:50 AM	Peanut Allergy in a Swine Model Ricki Helm, University of Arkansas for Medical Sciences
10:25 AM	Break
10:45 AM	Assessment of Allergenicity in Dogs I Bob Buchanan, University of California, Berkeley
11:20 AM	Allergenicity in Dogs II: Spontaneous Food Hypersensitivity / Allergy in Colony of Dogs Bruce Hammerberg, North Carolina State University

SESSION VI: BREAKOUT GROUP MEETINGS

12:00 PM		arge to Breakout Groups ryJane Selgrade, EPA	
	Wh	at are the Research Needs in the Areas of:	
	1.	Use of Human Clinical Data Chair: Charlotte Madsen, Danish Veterinary and Food	(Brussels) Administration
	2.	Animal Models to Assess Food Allergy Chair: Oscar Frick, University of California, San Franci	(Paris) sco
	3.	Biomarkers of Exposure and Effect Chair: Genevieve Bondy, Health Canada	(Vienna)
	4.	Sensitive Populations Chair: Mel Dong, FDA	(Amsterdam A)
	5.	Models of Dose Response Chair: Robert Frederick, EPA	(Amsterdam B)
	6.	Post-Market Surveillance Chair: Fujio Kayama, JICHI Medical School	(Amsterdam C)
12:15 PM	Lunch		
1:15 PM	Address Questions, Research Needs and Areas of Particular Focus (Within Breakout Groups)		
2:45 PM	Break		
3:00 - 3:30 PM	Observer Question and Discussion Session (Within Breakout Groups)		
5:30 PM	Bre	akout Group Meetings Adjourn	

WEDNESDAY, DECEMBER 12TH

SESSION VII: BREAKOUT GROUP PRESENTATIONS Chairs: Lynn Goldman, Johns Hopkins University & MaryJane Selgrade, EPA

8:30 AM	Presentations
10:30 AM	Break
10:50 AM	Presentations - Continued
11:15 AM	Meeting Summary and Discussion Consensus Building and Agreement on the Way Forward
12:30 PM	Meeting Adjourns

Scientific Organizing Committee

Dori Germolec, National Toxicology Program, NIEHS
Lynn Goldman, Johns Hopkins University School of Public Health
Dennis Hinton, Center for Food Safety and Nutrition, FDA

Ian Kimber, Central Toxicology Laboratory, Syngenta MaryJane Selgrade, NHEERL, EPA

Roxanne Hall

Yvette Rebollosso

