

**CODE 4160
A1 AGENDA**



**Food and Drug Administration
Center for Food Safety and Applied Nutrition**

**Food Advisory Committee Meeting
July 13-15, 2005
Advice on CFSAN's Draft Report:
Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food**

Wednesday, July 13, 2005: Approaches to Establish Thresholds for Food Allergens

- 8:30** **Call to Order, Welcome, and Introductions**
Charge to the Food Advisory Committee
Richard Durst, Ph.D.
Acting Chairman, Food Advisory Committee
- 8:40** **Conflict of Interest Statement & Other Instructions**
Marcia Moore
Executive Secretary, Food Advisory Committee, FDA
- 8:45** **Opening Statement**
Michael M. Landa, Esq.
Deputy Director for Regulatory Affairs, CFSAN, FDA
- 8:50** **Use of Food Allergen Thresholds**
Catherine L. Copp, Esq.
Policy Advisor, CFSAN, FDA
- 9:00** **Introduction to Food Allergens**
Robert Wood, M.D.
Professor, Johns Hopkins University School of Medicine
- 9:40** **Patient Perspectives on Food Allergies**
Anne Munoz-Furlong

The times indicated on this agenda are approximations. Breaks will be also called as deemed appropriate by the Chairman.

Director, Food Allergy & Anaphylaxis Network

10:00

Allergenicity: Analytical Methods

Susan Hefle, Ph.D.

*Associate Professor and Co-Director, Food Processing Center, University of
Nebraska*

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Chairman.*

- 10:30** **Break**
- 10:40** **Clinical Studies: Interpreting Oral Challenge Studies**
Stefano Luccioli, M.D.
Senior Medical Advisor, CFSAN, FDA
- 11:30** **Threshold Modeling Approach**
Rene Crevel, Ph.D.
Senior Scientist, Unilever, Safety and Environmental Assurance Centre, United Kingdom
- 12:00** **Food Allergen Thresholds**
Steve Taylor, Ph.D.
Maxcy Distinguished Professor & Director, Food Processing Center, University of Nebraska
- 12:30** **Lunch**
- 2:00** **Overview of Approaches to Establishing Thresholds: Allergens**
Steven M. Gendel, Ph.D.
Senior Scientist, National Center for Food Safety and Technology, FDA
- 2:15** **Public Comments (Pre-registration is required)**
- 3:15** **Break**
- 3:30** **Committee Discussion**
Review of the charge and questions from FDA

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Thursday, July 14, 2005: Approaches to Establishing Thresholds for Gluten

- 8:30** **Call to Order and Welcome and Introductions**
Richard Durst, Ph.D.
Acting Chairman, Food Advisory Committee
- 8:40** **Use of Gluten Thresholds**
Catherine L. Copp, Esq.
Policy Advisor, CFSAN, FDA
- 8:45** **Introduction to Celiac Disease**
Joseph Murray, M.D.
Professor of Medicine, the Mayo Clinic of Rochester, Minnesota
- 9:30** **Patient Perspectives on Celiac Disease**
Cynthia Kupper, R.D., C.D.
Executive Director
Gluten Intolerance Group of North America
- 9:50** **Grains**
Donald Kasarda, Ph.D.
Consultant and Retired Senior Scientist, Agricultural Research Service, USDA
- 10:30** **Break**
- 10:45** **Prospective Studies on Celiac Disease**
Alessio Fasano, M.D.
Professor of Pediatrics, Medicine & Physiology and Director, the Mucosal Biology Research Center, Center for Celiac Research, University of Maryland School of Medicine
- 11:25** **Retrospective Studies**
Pekka Collin, M.D., M.P.H.
Professor, University of Tampere, Medical School, Finland
- 12:05** **International Perspectives on Gluten-Free**
Rhonda R. Kane, M.S., R.D.
Consumer Safety Officer, CFSAN, FDA
- 12:30** **Lunch**
- 2:00** **Overview of Approaches to Establishing Thresholds: Gluten**
Steven M. Gendel, Ph.D.
Senior Scientist, National Center for Food Safety and Technology, FDA

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2:15 **Public Comments (Pre-registration is required)**

3:15 **Break**

3:30 **Committee Discussion**
Review of the charge and questions from FDA

(Please note that the meeting begins at 8:00a.m. tomorrow, July 15, 2005.)

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Friday, July 15, 2005: Discussion and Response

- 8:00** **Call to Order and Welcome and Introductions**
Richard Durst, Ph.D.
Acting Chairman, Food Advisory Committee
- 8:10** **Committee's Discussion and Response to FDA's Charge and Questions**
- 11:55** **Closing Comments**
Michael M. Landa, Esq.
Deputy Director for Regulatory Affairs, CFSAN, FDA
- 12:00** **Adjourn**
Richard Durst, Ph.D.
Chairman, Food Advisory Committee

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