Food Biotechnology Subcommittee[1]
of the Food Advisory Committee
Center for Food Safety and Applied Nutrition (CFSAN)
Food and Drug Administration (FDA)

SUMMARY MINUTES
August 13-14, 2002
Harvey W. Wiley Federal Building
College Park, Maryland

Members Present
Edward N. Brandt, Jr., M.D., Ph.D., Acting Chair[2]
Jonathan Arias, Ph.D.[2]
Fred McDaniel Atkins, M.D.
Bob B. Buchanan, Ph.D.
Francis Fredrick Busta, Ph.D.
Douglas Gurian-Sherman, Ph.D.[2]
Anne R. Kapuscinski, Ph.D.
Samuel Lehrer, Ph.D.[2]

Members Absent
Douglas Archer, Ph.D.
Abigail Salyers, Ph.D.

Industry Special Liaison
James Astwood, Ph.D.

Guest Speakers
Paul R. Mayers
Dean Metcalfe, M.D.
Michael Pariza, Ph.D.

FDA Participants
Robert Lake
James Maryanski, Ph.D.
Alan Rulis, Ph.D.

FDA Staff Present
Margaret E. Cole, Ph.D., Executive Secretary
Catherine A. DeRoever
Sully Jacques
Carolyn Jeletic
Linda Marmen
Sylvia M. Smith
Natasha Williford

[1] The entire meeting was open to the public. For the transcript of the meeting, contact FDA Dockets Management Branch (HFA-305), 12420 Parklawn Drive, Rockville, Maryland 20857.
[2] Temporary voting member

The Food Biotechnology Subcommittee ("FBS" or "Subcommittee") of the Food Advisory Committee convened its first meeting on August 13-14, 2002, at the Harvey W. Wiley Federal Building, College Park, Maryland. Edward N. Brandt, Jr., M.D., Ph.D., Acting Chair, called the meeting to order at 9:00 a.m., Tuesday, August 13, 2002. The chair welcomed FBS members and thanked them for participating. The executive secretary read the conflict of interest statement into the record and announced the appointment of temporary voting members.

Invited Presentations

Dr. Rulis started the invited presentations by stating the objective of the meeting—to discuss science-based approaches to assessing whether new proteins and bioengineered foods are likely to cause allergic reactions in some individuals in order to assist FDA in developing draft guidance for industry. He then presented an overview of CFSAN's Office of Food Additive Safety and food additive program and discussed CFSAN's consultation process for bioengineered foods.

Mr. Lake discussed CFSAN's plan to develop draft guidance on the evaluation of allergenicity of proteins introduced into bioengineered foods and the FBS's role during the drafting process. He asked FBS members to consider information presented in the meeting together with their own knowledge. He explained CFSAN was seeking their initial suggestions on the topic to help CFSAN prepare draft guidance for the FBS's review and discussion at a future meeting. He also introduced the FBS to the charge and questions for discussion during this meeting.

Dr. Metcalfe provided basic background information on food allergies including definitions, reactions, digestibility, sources, diagnosis, and treatment.

Dr. Pariza discussed safety assessment of enzymes and protein ingredients in foods. He presented the process for determining safety of microbial enzymes used in food processing from a historical perspective.

Dr. Maryanski provided background information on the history of and current activities related to FDA's policy on oversight of bioengineered foods and discussed FDA's current approach to assessing potential allergenicity.

Mr. Mayers discussed the work of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology and summarized the Codex Draft Annex on the Assessment of Possible Allergenicity

The chair adjourned the session at 3:50 p.m.

The chair called the meeting to order at 8:30 a.m. on Wednesday, August 14, 2002.

In place of Dr. Kathleen Jones's scheduled presentation on current issues in allergenicity assessment, Dr. Maryanski briefly reviewed FDA's recent activities in biotechnology.

Public Comment

The chair commenced the open public hearing. The following members of the public made oral presentations: Sue Macintosh, Ph.D., Bayer CropScience on behalf of the International Life Sciences Institute; Michael Hansen, Ph.D.; Consumer Policy Institute/Consumers Union; Garry A. Bannon, Ph.D., Monsanto Company; and Bill Freese, Friends of the Earth.

Summary

Following the open public hearing, Dr. Maryanski reviewed CFSAN's goals for the FBS.

Review of Charge and Questions, Discussion, and Responses to Questions

The chair began a discussion of the three questions CFSAN presented to the FBS in the charge and questions. While FBS members offered their comments and suggestions individually, the chair did not ask for a consensus or take a vote.

Question 1:
Are there particular aspects of the international approach as outlined in the Codex Annex "Assessment of Possible Allergenicity (Proteins)," that the Subcommittee believes FDA should emphasize in its draft guidelines?

Among the items FBS members mentioned in response to Question 1 were: (1) considering the sections of the Codex Annex on potential unintended consequences including hypothetical creation of unexpected allergens as a consequence of gene insertion, (2) evaluating changes in the levels of endogenous allergens in bioengineered plants, (3) developing a decision tree that lays out options for the use of different methodologies, (4) using a "tiered" approach whereby the results of one study trigger the need for subsequent studies, and (5) providing structure and detail as well as flexibility in the criteria used. Additionally, several FBS members agreed FDA should err on the side of caution given the uncertainties of some tests.

Question 2:
Are there areas of allergenicity research (e.g., basic mechanisms of food allergy, digestibility, animal models, serum testing, sequence homology, etc.,) that the Subcommittee believes would contribute to allergenicity assessment? If so, how might FDA further this research objective?

Among the items FBS members mentioned in response to Question 2 were: (1) improving coordination among federal agencies to leverage research dollars; (2) using competitive grants programs; (3) collaborating with groups that are already examining functional genomic plants in a systematic way with the ultimate goal of developing systematic efforts to study metabolic profiling; (4) considering the ultimate use of bioengineered products as food as a basis for research with studies that examine the effects of food processing and how foods are handled; (5) developing animal models that reproduce "real-life" human exposure and food allergic response; (6) developing a serum bank to standardize the type of serums in assays; (7) defining homology including epitope sequences and substitutions in sequences; and (8) studying digestibility and stability of proteins under "real-life" conditions.

Question 3:

Does the Subcommittee have suggestions regarding the development of draft guidance that may aid in enhancing public understanding of the agency's approach to assessing potential allergenicity for bioengineered foods?

Among the items FBS members mentioned in response to Question 3 were: (1) communicating to the public the lack of absolute standards for analyses and determination of allergens; (2) defining terms and describing model systems and the outputs being compared; (3) providing the public with truthful, accurate, detailed information and avoiding ambiguity; (4) using a decision tree to explain the rationale to the public; (5) finding venues to disseminate FDA's message (e.g., links to the websites of scientific societies); (6) educating the public about food allergies, the risk of allergy from the food supply, and the variety of reactions and symptoms inaccurately attributed to food allergies; and (7) using allergists to educate patients.

After FBS members completed their discussion, Dr. Maryanski responded to questions from several FBS members on the Food Advisory Committee's structure and process and FDA's plans for the draft guidance including the role of the FBS during development of the draft guidance. He also briefly addressed international activities.

The chair adjourned the meeting at 11:20 a.m.

I certify I attended the August 13-14, 2002, meeting of the Food Biotechnology Subcommittee of the Food Advisory Committee, and these summary minutes accurately reflect what transpired.

Margaret E. Cole November 27, 2002

Margaret E. Cole, Ph.D. Date
Executive Secretary

Edward N. Brandt 12/21/02

Edward N. Brandt, Jr., M.D., Ph.D. Date
Acting Chair