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

SUMMARY MINUTES
September 24, 2003
J.W. Marriott Hotel
Washington, DC

Members Present
Francis F. Busta, Ph.D., Acting Chair[2]
Jonathan Arias, Ph.D.
Stephen Benedict, Ph.D.[3]
Bob B. Buchanan, Ph.D.
Nina Fedoroff, Ph.D.[3]
Dennis Gonsalves, Ph.D.[3]
Douglas Gurian-Sherman, Ph.D.
Anne R. Kapuscinski, Ph.D.
Calvin Qualset, Ph.D.[3]
Abigail A. Salyers, Ph.D.

Member Absent
Douglas Archer, Ph.D.

Industry Special Liaison
James Astwood, Ph.D.

FDA Participants
L. Robert Lake
Jeanette Glover Glew
James Maryanski, Ph.D.
Thomas A. Cebula, Ph.D.

FDA Staff Present
Michael Watson, Ph.D., Executive Secretary
Catherine A. DeRoever
Linda Reed
Laura Tarantino, Ph.D.
Kathleen Jones, Ph.D.

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[1] The entire meeting was open to the public. Copies of written information provided to the Committee for consideration are available from the Committee staff. The transcript of the meeting is available on the internet at http://www.fda.gov/ohrms/dockets/ac/cfsan03.html or through FDA Dockets Management Branch (HFA-305), 12420 Parklawn Drive, Rockville, Maryland 20857.
[2] Food Advisory Committee member
[3] Temporary voting member

The Food Biotechnology Subcommittee ("FBS" or "Subcommittee") of the Food Advisory Committee convened its second meeting on September 24, 2003, at the J.W. Marriott, Washington, DC. Francis F. Busta, Ph.D., Acting Chair, called the meeting to order at 8:36 a.m., Wednesday, September 24, 2003. Dr. Busta welcomed Subcommittee members, introduced himself, and asked the other subcommittee members to introduce themselves. Dr. Michael Watson, the executive secretary, announced the appointment of temporary voting members. Dr. Watson then read the conflict of interest statement and informed the Subcommittee that Drs. Buchanan and Gonsalves had been granted general applicability waivers. Dr. Watson noted that Subcommittee members Drs. Gurian-Sherman, Arias and Kapuscinski had issued a letter regarding topic selection and meeting organization as they pertain to the Subcommittee's work. Dr. Watson stated that FDA would respond to the letter in the future and suggested to Dr. Busta, that if time allows, the Subcommittee could have the opportunity to address the letter at the close of the session. Dr. Busta agreed that if time allowed, discussion of the letter could be added to the agenda.

FDA Welcome

Mr. L. Robert Lake, Director of Regulations and Policy, CFSAN, welcomed and thanked committee members for their participation. Mr. Lake then discussed policy issues related to bioengineered foods. Mr. Lake presented an update on FDA's biotechnology activities, and explained where these activities fell in the Center's list of priorities.

Charge and Questions

Dr. Busta introduced the charge and questions to the committee members.

Presentations

Ms. Jeanette Glover Glew, Office of Food Additive Safety, CFSAN, presented an overview of FDA's regulatory framework, policies, and procedures for bioengineered foods.

Dr. James Maryanski, CFSAN Biotechnology Coordinator, presented a summary of the Codex Alimentarius Commission's "Principles for the Risk Analysis of Foods Derived from Modern Biotechnology", "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants", and "Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms".

Dr. Thomas A. Cebula, Director of Applied Research and Safety Assessment and lead scientist for molecular biology, CFSAN, described FDA's safety assessment process, which focuses on the characteristics of the food product. Dr. Cebula focused in particular on the molecular characterization component of the safety assessment.

Public Comment

The chair commenced the open public hearing. Michael Hansen, Ph.D., research associate, Consumers Union, made an oral presentation.

Summary

Following the open public hearing, Dr. Maryanski reviewed the morning presentations and answered questions from the Subcommittee.

Review of Charge and Questions, Discussion, and Responses to Questions
The chair began a discussion by asking each member to express their thoughts on the issues raised by the charge and questions. Each member briefly expressed his or her views on the molecular characterization of bioengineered food plants. Dr. Busta then began a specific discussion of the questions CFSAN posed to the FBS.

Question 1:
Molecular biology data provide information that assist in identifying new substances that may be present in the food as a result of the genetic modification. Techniques such as Northern and Western blotting have been useful for identifying newly expressed substances for the purpose of a safety assessment. To what extent does sequencing information contribute to the identification of newly expressed substances? If sequence information is important for the purpose of FDA's safety assessment, what sequence information should be reviewed (for example, the entire sequence of the inserted genetic material, the sequence of the surrounding region of the plant genome)? If so, how does this information contribute to the safety assessment?

FBS members agreed that molecular biology data are useful for safety assessment, but indicated that the focus of the assessment should be on any newly expressed protein(s). Some Subcommittee members recommended that FDA update the decision tree approach used in its 1992 "Statement of Policy: Foods Derived from New Plant Varieties" to include some technologies. The Subcommittee generally agreed that sequencing of the DNA insert was helpful, but did not comment on how that information contributed to the safety assessment. FBS members discussed the need for flanking sequence data. Some Subcommittee members believed that these data might be useful for the safety assessment in certain situations. Another Subcommittee member supported the sequencing of extended regions flanking the insert site for every bioengineered food plant to detect possible translocation events, but did not comment on how this information was important for the purpose of FDA's food safety assessment.

Question 2:
Current approaches to safety assessment recommend, as part of the characterization of the introduced genetic material, certain kinds of molecular biology data, for example:

- **the number of insertion sites**
- **the number of gene copies inserted at each insertion site**
- **information on the organization of the DNA within the inserts**

- **information on potential reading frames that could express unintended proteins.**

Are there other data that would be useful to safety assessment, and if so, what data and how would the safety assessment be enhanced?

The Subcommittee agreed that the molecular biology data specified by FDA were appropriate as part of the characterization of introduced genetic material. These data were viewed as consistent with recommendations contained in the Codex Alimentarius Commission's "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants". The Subcommittee expressed support for the Codex guideline. FBS members stressed the importance of characterizing proteins expressed due to the genetic engineering process. Several subcommittee members recommended that the phenotype be the focus of the characterization.

Question 3:
There have been many technological advances in the area of molecular biology over the last decade. Are there new advances which could be used to enhance the safety assessment? If so, what and how?

Subcommittee members agreed that research and development in the field of proteomics/metabolomics should be encouraged in order to facilitate its use for food safety assessment in the future.

New Business

Dr. Busta asked the Subcommittee members for feedback on the length of FBS meetings. The members generally agreed that the topic to be discussed should dictate the length of the meeting.

Dr. Busta introduced the letter submitted by Drs. Gurian-Sherman, Arias and Kapuscinski for discussion by Subcommittee members. Dr. Gurian-Sherman discussed the major points of the letter: the need for specific protocols for risk assessment of bioengineered foods; and the need for FDA to devote more resources to this Subcommittee. Dr. Kapuscinski requested that FDA provide background materials for meetings in a more timely fashion. Dr. Kapuscinski also asked for updates from FDA regarding its biotechnology activities.

The chair adjourned the meeting at 5:05 p.m.

I certify that I attended to September 24, 2003, meeting of the Food Biotechnology Subcommittee of the Food Advisory Committee, and that these summary minutes accurately reflect what transpired.

Michael Watson 11-17-03

Michael Watson, Ph.D. Date
Executive Secretary

F F Busta 11-13-03

Francis Fredrick Busta, Ph.D. Date
Acting Chair