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January 8, 2009

The Honorable Edward Schafer
Secretary
United States Department of Agriculture
Room 200A, Jamie L. Whitten Federal Building
12th Street and Jefferson Drive, SW
Washington, DC 20250

Dear Secretary Schafer:

In the past six years, the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) has met 21 times and generated four consensus reports, which were presented to the Office of the Secretary. In developing each report, we received a charge from the Secretary, collected information from experts, met in both plenary and workgroup sessions, and spent considerable time and effort in reaching agreement on a document that we believed would be valuable to USDA decision-makers. Each report was a product of deliberations lasting between two and four years.

In March 2008, we began our work on the following charge: *Genetically engineered (GE) food animals are being developed in the U.S. and abroad for food and non-food uses. What regulatory issues should the U.S. government consider with regard to the potential development and commercialization of these animals and the products produced from them? Since USDA's legal authorities extend beyond regulation to research, education and marketing, what issues pertaining to GE animals will USDA need to consider when exercising these authorities? How might the views of different stakeholders be obtained and considered?*

In pursuit of that charge, we met in four plenary and numerous workgroup sessions over ten months. Towards the end of our deliberations, in September 2008, the Food and Drug Administration (FDA) issued a significant draft guidance relevant to our charge. In view of the richness of the issues and the evolving regulatory landscape, ten months proved inadequate to complete our deliberations, which focused on the following:

- Safety Considerations
 - Food and Feed
 - Animal Health and Well Being
 - Imported Animals and Animal Products
 - Environmental Impact



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- Global Marketing Considerations
 - Pre-commercialization Information Exchange
 - Facilitation of International Trade
- Nature of Ethical Considerations
- Considering Stakeholder Concerns
 - Incorporating Public Participation and Transparency
 - Mechanisms for Considering Ethical Concerns

A completed report would have required further discussion of these topics.

Other topics that members identified as relevant to animal biotechnology are:

- Adequacy of existing legal authorities to regulate the technology
- Interagency coordination
- Strategic plan for technology development
- Adequacy of research funding
- Future competitiveness of US animal agriculture
- International regulatory coordination
- Viability of the domestic animal biotechnology industry

The members of AC21 appreciate USDA asking us to examine and advise on important issues related to agricultural biotechnology.

Sincerely,



Patricia A. Layton, Chair
AC21

Attachment



Members of the AC21

Patricia Layton (Chair), Clemson University

Fuller Bazer, Texas A&M University

Nancy Bryson, Holland & Hart, LLP

Daryl Buss, University of Wisconsin at Madison

Guy Cardineau, Arizona State University

Leon Corzine, Farmer

Michael Engler, Cactus Feeders

Randal Giroux, Cargill Incorporated

Steven Hensley, USA Rice Federation

Gregory Jaffe, Center for Science in the Public Interest

Jamie Jonker, National Milk Producers Federation

Russell Kremer, Missouri Farmers Union

Steven Leath, University of North Carolina

Margaret Mellon, Union of Concerned Scientists

James Robl, Hematech

Bradley Shurdut, Dow AgroSciences

Jerome Slocum, Farmer

Carol Tucker-Foreman, Consumer Federation of America

Alison Van Eenennaam, University of California at Davis

Stephanie Whalen, Hawaii Agriculture Research Center