BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

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Dr. Michael Schechtman
Office of the Deputy Secretary, USDA
202 B Jamie L. Whitten Federal Building
12th Street and Jefferson Drive, SW
Washington, DC 20250
Michael.schechtman@ars.usda.gov

Re: Department of Agriculture, Office of the Under Secretary, Research, Education, and Economics; Notice of the Advisory Committee on Biotechnology and 21st Century Agriculture Meeting, Notice of Meeting [Federal Register: November 21, 2008 (Volume 73, Number 226) Page 70612].

Dear Dr. Schechtman:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to comment on the continued consideration by the Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) of potential U.S. Department of Agriculture (USDA) regulatory and marketing roles in the oversight of genetically engineered (GE) food animals intended for food or non-food uses. BIO is the world's largest biotechnology trade association representing more than 1,200 members in the United States and 31 nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology. BIO members are at the forefront of the development of GE animals.

Research and development of GE animals has been growing domestically and globally for over 25 years. The publication of draft guidance by the U. S. Food and Drug Administration (FDA) on the regulatory process, and the recognition of the compelling benefits of the technology to transform human health, predicts that the future, which will include approvals and commercialization, is promising. BIO thanks the AC21 for its diligence in responding to the charge from USDA in the preparation of the document for USDA on this issue. We encourage completion of the document when consensus agreement is achieved. Such a document should serve as a valuable resource for the Secretary of Agriculture.

BIO and its members engaged in animal biotechnology support a rigorous science-based federal regulatory system to oversee the safe and responsible development of all GE animals and the products derived from them. BIO supports the FDA's draft "Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs" (FDA's Draft Guidance),[1] because FDA has the necessary expertise and authority to ensure the safety and effectiveness of the New Animal Drugs (the transgenes) used to develop these animals. The USDA's Animal and Plant Health Inspection Service (APHIS) is also a critically important player in a comprehensive system to oversee the development of GE animals under the Animal Health Protection Act, the Animal Welfare Act, and other statutes. BIO supports the continued coordination of regulatory authority over GE animals among agencies and departments, consistent with the U.S. government's policy of a "Coordinated Framework for the Regulation of Biotechnology." A rigorous science-based regulatory system, harmonized internationally, is critical to maximize public acceptance, assure safety and facilitate trade.

[1] A link to FDA's Draft Guidance is available at http://www.fda.gov/cvm/Guidance/guide187.pdf (last viewed Dec. 17, 2008).

BIO appreciates the AC21's recognition of the "Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Animals," recently published by the Codex Alimentarius (the "Codex Guideline").[2] The Codex Guideline is the first international guidance for GE animals and it will serve as the foundation for guidance to countries in development of regulations. BIO supports international harmonization of the regulations for GE animals and their products, and agrees with the AC21 that consistency with the Codex Guideline is important with respect to the safety assessment of GE animals for food applications. In addition, the FDA's Draft Guidance is completely consistent with the Codex Guideline. Therefore BIO encourages the AC21 to include specific citation to the Codex Guideline in its document for USDA.

BIO appreciates that the AC21 has emphasized transparency and public participation. BIO supports transparency to the fullest extent of the law governing GE animals. In addition, BIO supports FDA's plans to use FDA advisory committee meetings for public review of science-based considerations related to the development of GE animals when appropriate. In addition, as the AC21 has suggested, BIO members may participate in multi-stakeholder dialogue sessions regarding GE technologies and convened by USDA.

BIO supports the longstanding FDA and USDA labeling policies that require labeling only of material information. To that end, BIO does not support mandatory labeling of foods derived from GE animals unless such food is materially different from food from a conventionally bred animal, such as through an enhanced level of a nutrient. BIO supports voluntary labeling of products, as long as those labels are truthful and not misleading. The responsibility to comply with labeling laws resides with the entity applying the label to the product.

BIO appreciates that genetic engineering of animals may raise public interest for reasons unrelated to human health, animal safety, or environmental safety. Public interest and ethical considerations have been noted in several fora regarding the genetic engineering of animals. However, the U. S. government regulatory process that assures public and environmental safety is science-based and should remain so. However USDA may choose to address public interest and ethical issues regarding genetic engineering of animals by participating and providing scientific expertise in public discussions as they continue to be held in various forms. Therefore, BIO recommends that the AC21 provide the Secretary with a recommendation that USDA participate in, and keep abreast of, the public discussion of public interest and ethical issues surrounding GE animals.

BIO appreciates this opportunity to comment as the AC 21 continues work on USDA's role in the regulatory oversight of genetically engineered animals. We look forward to further deliberation, and would be pleased to work with the committee and USDA to provide further input or clarification of our comments as needed.

Sincerely,

Barbara P. Glenn

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Managing Director, Animal Biotechnology
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[2] A link to the guideline is available at http://www.codexalimentarius.net/download/standards/11022/cxg_069e.pdf (last viewed Dec. 17, 2008).