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Regulatory Analysis and Development
Policy and Program Development
Animal and Plant Health Inspection Service
Station 3A–03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Docket No. APHIS-2006-0188; Response to Request for Information

Dear Sir or Madam:

The Biotechnology Industry Organization (BIO) is pleased to submit these comments in response to the Request for Information on Genetically Engineered (GE) Animals, published in the Federal Register by the Animal and Plant Health Inspection Service (APHIS or the Agency) on September 19, 2008 (73 Fed. Reg. 54360.) 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.

APHIS' request for information coincided with the release of a draft guidance by the U.S. Food and Drug Administration (FDA) entitled "Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs." FDA's draft guidance presents a framework for the federal regulation of GE animals under the New Animal Drug authorities of the Federal Food, Drug, and Cosmetic Act. BIO supports FDA's draft guidance for the regulation of GE animals intended for food uses or to produce pharmaceutical or other consumer products, because FDA has the necessary expertise and authority to ensure the safety and effectiveness of these New Animal Drugs.

APHIS is also a critically important player in a comprehensive system to oversee the development and marketing of GE animals. Under the Animal Health Protection Act (AHPA), APHIS is responsible for protecting U.S. livestock from livestock diseases and pests, and the Agency has long-standing expertise in the regulation of animal health and safety under AHPA, 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."

BIO provides short responses below to the Agency's specific questions in its request for information. For additional information on the compelling benefits of GE animals, please refer to BIO's recent scientific report entitled, "Genetically Engineered Animals and Public Health," a copy of which is attached to these comments.

APHIS Question 1: What research on GE animals is currently being conducted or planned in the future?

GE animals present opportunities for advancement in several different areas, including human health, animal-derived products, environmental protection and conservation, and animal health and welfare. As the broad array of potential applications and benefits is increasingly understood, GE animals have become a growing domestic and international field of research. Following are some examples of ongoing and future research efforts in each of these areas, but other applications are in development as well:

- Advancing human health: One of the more compelling benefits of GE animal technology is its human health applications. GE animals are integral to the development of new diagnostic techniques and drugs for human disease, and they can deliver clinical and economic benefits that cannot be achieved with any other approach. Animals can be developed that produce therapeutic proteins in their milk, eggs, or blood that can then be used in the development of biopharmaceuticals to treat human disease. Diseases that are being targeted include cancer, heart disease, hemophilia, rheumatoid arthritis, pandemic flu, malaria, and smallpox, among others. In addition, scientists are conducting research on how to use GE animals, such as pigs, to produce transplant organs that can become a source of organs for humans when other options have been exhausted.

- Enhancing animal products: Many of the most common foods enjoyed by consumers are derived from animals. Not only will improved animal health and well-being (discussed below) result in safer foods for consumers, but food quality may be improved by introducing desirable traits into farm livestock and poultry. For example, meat, milk, and eggs may be nutritionally enriched through the development of GE livestock and poultry. The application of genetic engineering also may improve food production capabilities and – in an era of increased food costs – potentially decrease the costs associated with food production as a result of increased efficiency. For example, a GE salmon that grows to a mature size more quickly results in greater salmon production efficiency. Improved productivity is critical in helping to supply enough food to support an ever-growing global population.

- Benefiting the environment and conservation efforts: Just as new genes can be introduced into animals to benefit consumers, genes can be introduced to benefit the environment. Environmentally friendly animals will include farm animals that produce less waste to minimize the impact on the environment. For example, the EnviroPig™ produces dramatically lower levels of

phosphorous pollution than traditional pigs. Animals may also be developed that consume fewer resources.

- Improving animal health and welfare: Biotechnology can be applied very effectively to improve livestock herds more rapidly than enhanced husbandry practices. In addition, animals can be developed to be resistant to specific diseases or pests, or in ways that otherwise enhance the animals' overall health and well-being.

APHIS Question 2: What, if any, implications would activities such as the importation and interstate movement of such animals have for the health of the U.S. livestock population?

Given the careful regulatory oversight FDA intends to provide for GE animals, these animals should not pose any unique risks to the health of the U.S. livestock population. Nothing suggests that APHIS' existing level of oversight of livestock health will not be sufficient to regulate GE animals effectively. For example, transporters or importers of GE animals must comply with existing animal health requirements of the destination state and federal animal health requirements before these animals, like others, can be moved or imported. Moreover, GE animals developed to be resistant to infectious diseases could help maintain animal health in the larger livestock population. Traits currently being studied include resistance to diseases such as bovine spongiform encephalopathy, foot and mouth disease, mastitis, and avian influenza.

APHIS Question 3: What, if any, activities should APHIS consider with respect to U.S. livestock health under the AHPA that would complement the requirements and recommendations described in FDA's draft guidance?

FDA's paradigm for regulating the development of GE animals and the different individual drug and food products that may be derived from such animals is robust and should provide ample protections for animal health. However, APHIS' experience and current oversight of livestock health will complement the FDA's regulatory efforts, and BIO encourages coordination between the agencies. Through coordination of existing regulatory oversight, any adverse health effects or safety considerations associated with GE animals would be captured under the existing statutory and regulatory framework for preventing the spread of pests and diseases in all U.S. livestock. Of course, as the science and technology of this industry evolve, BIO supports APHIS' continued evaluation of its role in the oversight of these animals.

To conclude, BIO urges APHIS to work with its sister agencies across the federal government in the regulatory oversight of these animals. A solid and coordinated regulatory framework will ensure that GE animals pose no unique risks to animal or human health, the environment, or agriculture, and allow this technology to provide meaningful benefits in all of these areas.

Again, BIO appreciates the opportunity to provide these comments, and to provide APHIS with additional information regarding the developments of this industry.

Sincerely,

Barbara P. Glenn

Barbara P. Glenn, Ph.D.
Managing Director for Animal Biotechnology
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Attachment: Gottlieb, S. and M. Wheeler. 2008. Genetically Engineered Animals and Public Health – Compelling Benefits for Health Care, Nutrition, the Environment and Animal Welfare, Biotechnology Industry Organization.