



**BIOTECHNOLOGY
INDUSTRY ORGANIZATION**

News Release

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Genetic Engineering Promises to Improve Medicine, Food and the Environment *Administration Proposes Much-Anticipated Guidance on How to Regulate GE Animals*

Washington, D.C. (September 18, 2008) – The multiple benefits of animal biotechnologies are closer to being realized thanks to efforts today by the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA).

The FDA announced today the long-awaited draft guidance describing a regulatory framework for governing genetically engineered (GE) animals. In addition, USDA is seeking comment on their coordinated role in the regulatory process.

Dr. Barbara Glenn, Managing Director for Animal Biotechnology at the Biotechnology Industry Organization (BIO) released the following statement expressing the industry's support for the FDA's and USDA's actions today:

“BIO supports the release today of the first U.S. government draft guidance, which initiates a public and transparent comment process toward development of a final regulatory system.

“Through years of scientific research with goats, pigs, sheep, chicken, fish and cattle, these technologies have the proven ability to provide solutions for public health through biomedical, food and environmental applications. These benefits will not be realized without a published rigorous science-based regulatory process that assures safety for consumers, animals and the environment.

“For example, there are now many products under development derived from GE animals that hold the promise of advancing human health. Through genetic engineering, animals can produce pharmaceutical proteins and replacement tissues in their milk, eggs, and blood, which can be used in the treatment of human diseases such as cancer, heart attacks, hemophilia, rheumatoid arthritis, pandemic flu, malaria and small pox. In addition, research is being conducted to produce transplant organs in pigs that may be a source of organs for humans.

“Animals that are genetically engineered can have improved food production capabilities, enabling them to help meet the global demand for more efficient, more nutritious, higher quality and lower-cost sources of food.

“GE animals can also contribute to improving the environment by consuming fewer resources and producing less waste. In addition, genetic engineering offers tremendous benefits to the animals themselves by imparting disease resistance traits and enhancing their overall health and well-being.

“BIO supports FDA’s framework to apply a mandatory science-based regulatory process to the regulation of GE animals and their products, based on the Food, Drug and Cosmetic Act’s New Animal Drug (NAD) framework.

“Furthermore BIO supports FDA’s efforts to make this guidance consistent with international guidelines established earlier this year. On July 4, 2008, the Codex Alimentarius Commission approved guidelines for assessment of the safety of foods derived from GE animals. This move represents a policy breakthrough in the area of animal biotechnology in the international arena. Codex standards are recognized as international benchmarks and act as models for governments in the establishment of their own food safety policies.

“Regulation based upon an internationally recognized approval process will lead to more efficient commercialization of GE animals, processes and products that are proven safe for consumers, animals and the environment. The federal government has set the precedent for oversight of biotechnology through the development of its GE plant regulatory framework. The time has come for the benefits of GE animals to be realized in the areas of health care, food production and the environment.

“The potential of GE animals has been detailed in the report, *Genetically Engineered Animals and Public Health – Compelling Benefits for Health Care, Nutrition, the Environment and Animal Welfare*, released in June of this year. The report was authored by Scott Gottlieb, MD, of the American Enterprise Institute, and Matthew B. Wheeler, PhD, of the Institute for Genomic Biology, University of Illinois at Urbana-Champaign. Dr. Gottlieb and Dr. Wheeler are experts in the field of genetic engineering of animals. ”

(*Note: A copy of the full report, *Genetically Engineered Animals and Public Health – Compelling Benefits for Health Care, Nutrition, the Environment and Animal Welfare*, is posted at www.bio.org.)

About BIO

BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO also produces the BIO International Convention, the world’s largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

Upcoming BIO Events

- [Pacific Rim Summit on Industrial Biotechnology and Bioenergy](#)
Sept. 10-12, 2008
Vancouver, B.C., Canada
- [BIO Investor Forum 2008](#)
October 29-31, 2008
San Francisco, CA
- [BIO-Europe 2008](#)
November 17-19, 2008
Mannheim/Heidelberg, Germany,

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