

Genetic Engineering of Animals

1. What is genetic engineering?

Genetic engineering is the deliberate modification of the animal's genome. Thanks to this technology, scientists can precisely transfer beneficial genes from one animal species to another.

2. What animals are being genetically engineered?

In research studies, animals that have been safely genetically engineered include cattle, pigs, chickens, goats, sheep, dogs, cats, fish, rats, and mice.

3. Why are animals being genetically engineered?

As scientists have sequenced the genomes of domestic animals, more is known about genes and the traits that they control. By finding genes that control beneficial traits, we are able to introduce those genes into another animal's genome, so the genetically engineered animal will possess that trait. This speeds up the breeding process.

One example is the Enviro-Pig™. Through genetic engineering, this animal emits 75 percent less phosphorus than traditional pigs fed the same conventional diet. This lessens livestock's impact in the environment.

4. Is a GE animal an animal clone?

No. A genetically engineered animal has a deliberate modification made to its genome. In genetic engineering, scientists can precisely transfer a beneficial gene (for disease resistance, for example) from one animal species to another.

Cloning technology is a type of breeding technology to produce an exact genetic copy of an animal – usually a high quality animal with desirable breeding traits.

Benefits of Genetic Engineering

1. What are the benefits of genetic engineering?

Genetic engineering of animals offer solutions for improving public health and enhancing quality of life. The benefits include advancing human health, enhancing food production, reducing environmental impact, optimizing animal health and welfare and production of cutting edge industrial applications.

2. What is the most important application of genetic engineering -- human health or food applications?

Genetic engineering provides significant opportunity to improve human health and the foods we eat. It follows that the regulatory process used by the federal government should equally

apply to all possible applications, particularly agricultural animals, which by their nature, are food animals.

3. What are the primary issues holding up realization of these benefits?

The primary issue holding up the realization of these benefits has been the lack of a U.S. federal regulatory process. Because of the lack of a regulatory process by which to have an approved product, other issues have developed including the lack of investor funding, lack of public confidence and a decline in the availability of research funding.

General Questions:

1. How many GE animals exist currently?

The numbers of GE animals in research facilities in the U. S. are unknown to BIO, but researchers/producers are required by law to keep records regarding their disposition.

2. Are GE animals in the food supply?

To date, FDA has not permitted GE animals to be placed into the human food supply.

3. Are GE animals tracked or labeled?

- As a requirement of the regulatory review process, all GE animals are identified and tracked throughout the research and development (R&D) process. Since no GE animals or products of GE animals have been approved for commercialization, this is only being done at the R&D stage at this time.
- If GE animals or the products of GE animals have been approved and deemed as safe as conventional animals by the government's arduous review and approval process, then it should not be necessary to differentiate them. Some companies, however, may choose to voluntarily implement labeling programs for specific products for marketing and branding purposes.
- BIO supports the labeling policies of FDA and USDA, which state that the labeling of foods is not required unless there has been a significant change in the nutritional components (or an anti-nutritional component) or other chemical characteristic compared to its conventional counterpart. BIO supports voluntary labeling of products.

4. Will industry propose a supply chain management program for GE animals similar to that developed to track animal clones?

Industry is exploring other aspects for such a program, such as meeting marketing claims and identity preservation to track a branded product.

5. How does genetic engineering affect animal welfare?

- Genetic engineering has the potential to greatly improve the health and welfare of agricultural animals. GE animals may be disease resistant, parasite resistant, and withstand stress. The beneficial trait can likely improve their well being because they will be more productive. Such animals may need fewer veterinary interventions, use of special feed supplements, or other growth stimulants.
- Research institutions, biotech companies and producer groups engaged in the growing field of animal biotechnology place animal well-being as a top priority. The humane care

and use of animals in genomics, cloning and genetic engineering is guided by rigorous regulatory review by the U.S. Department of Agriculture in accordance to the Animal Welfare Act. In many cases, third party and international organizations have established animal welfare guidelines for use by companies engaging in the genetic engineering of animals.

Regulatory Process

1. Why regulate GE animal and their products?

It is important that the technology is approved as safe for humans, animals and the environment.

- Industry recognizes that any new technology can create doubt and mistrust in some sectors. To forestall that doubt and to, in part, ensure consumer acceptance, strong regulation based upon an internationally recognized approval process will lead to more efficient commercialization of GE animals, processes and products.
- The federal government set the precedent for science-based oversight of biotechnology through the development of its GE plant regulatory framework.

2. How many GE animals or their products are approved?

There is only one approved product in the world from a GE animal. That product is called ATryn®, a human pharmaceutical developed to prevent blood clots. This drug is produced in the milk of GE goats. It was approved by the European Medicines Evaluation Agency (EMA) of the European Commission in August 2006. It has not yet been approved in the United States.

3. What will be the first approved product in the United States?

AquaBounty Technologies, a BIO member, has publicly announced its application with the FDA to seek approval for a rapid-growth salmon. The fish grow at three times the rate of conventional salmon to the same mature weight while producing safe and healthful salmon for human consumption, and reducing environmental impact.

In addition, the Enviropig™, whose developer, the University of Guelph is a BIO member, has publicly announced its application with the FDA. The EnviroPig™ produces dramatically lower levels of phosphorus pollution than traditional pigs, and has a decreased impact on the environment.

4. The U.S. Food and Drug Administration finalized its regulatory guidance document in January 2009. What is the purpose of the guidance and what did the FDA say?

The purpose of the guidance is to clarify the FDA regulatory framework for GE animals based on the New Animal Drug process of the Food, Drug and Cosmetic Act.

The FDA has also laid out a process for the science-based review of applications and how they would lead to an approval. The proposed framework is similar to international guidelines published by the Codex Alimentarius Commission on July 4, 2008.

5. Why is the guidance important?

The FDA guidance is the first policy statement published by the U.S. government describing how it regulates GE animals and their products. This system will ensure the products made available through this science will go through a thorough and transparent application process before being approved for the marketplace.

6. Why is the New Animal Drug (NAD) framework the regulatory process supported by the biotechnology industry, food chain, producer groups, patient groups and consumer groups?

FDA's regulatory pathway, the NAD approval process, provides the following key elements of regulation for these animals:

- The NAD pathway criteria can be applied to all transgenic animals equitably, including those agricultural animals developed for biomedical purposes and not for food.
- The NAD pathway has been used by FDA for the last decade, after scientific, regulatory, and legal experts devised this consensus-based framework to ensure coordination among all centers within FDA.
- It is a mandatory process that leads to a formal FDA 'approval.' Such formal recognition by the agency is necessary for both domestic and international government and consumer acceptance of the technology, leading to successful commercialization of the technology and products.
- This rigorous, science-based approval process has been demonstrated to be critical to consumer acceptance of the technology and the products that will result.
- The NAD process is consistent with key international standards as part of the food safety assessment for GE animals that was approved by the Codex Alimentarius Commission on July 4, 2008.

7. Will release of the guidance affect international trade?

- International trade is not expected to be affected by release of this guidance. In fact, trading partners have active research programs in genetic engineering of animals.
- On July 4, 2008, the 176 member countries of the Codex Alimentarius Commission unanimously approved international guidance for the conduct of food safety evaluation for genetically engineered animals.
- The guidance describes a framework similar to the Codex-approved guideline for evaluating food safety of GE animals. The international guideline was the end product of work of a task force led by Japan and Australia which expedited the finished document due to unprecedented support from countries around the world.

For more information:

- Visit BIO's GE Animals Web Resource Page at www.bio.org
- Visit FDA's GE Animals Web Resource Page at www.fda.gov/cvm/GEAnimals.htm
- BIO recently commissioned a scientific report entitled "*Genetically Engineered Animals and Public Health: Compelling Benefits for Health Care, Nutrition, the Environment and Animal Welfare*" by Dr. Scott Gottlieb and Dr. Matthew Wheeler. It is posted at www.bio.org or click on this link: http://www.bio.org/foodag/animals/ge_animal_benefits.pdf

