APHIS Factsheet

Biotechnology Regulatory Services

September 2008

APHIS Publishes Request for Information on Genetically Engineered (GE) Animals

GE Technology

Q. What is genetic engineering?
A. Genetic engineering is a process in which segments of DNA are spliced together and introduced into an organism to introduce new characteristics or traits. Genetic engineering has been widely used in agriculture to make crops resistant to certain pests or herbicides, in medicine to develop microbes that can produce pharmaceuticals for human or animal use, and in food to produce microorganisms that aid in baking, brewing, and cheese-making.

Q. What kinds of genetically engineered animals are being developed?
A. Many kinds of GE animals are in development, although none have yet been approved for commercial use by the Food and Drug Administration (FDA). At this time, the largest class of GE animals scientists are developing are those that will produce substances that can be used as human or animal pharmaceuticals. Through genetic engineering, scientists potentially have the ability to completely change the way in which certain chronic diseases, such as bleeding disorders are treated. For example, because clotting factors are so rare and difficult to obtain, people are currently treated only following acute attacks. An increased supply of these clotting factors from GE animals could allow patients to have much of their bleeding controlled by the regular administration of the medicine. Other examples include scientists attempting to develop GE cattle that are resistant to bovine spongiform encephalopathy, a chronic degenerative disease affecting the central nervous system of cattle. GE animals could also be engineered to grow more quickly, and some GE animals could be altered to reduce their environmental impact by virtue of producing a lower level of pollutants in their wastes. Other GE animals may have improved fat composition, for example, increased levels of omega-3-fatty acids, providing a more healthful nutrient profile.

The Regulatory Process

Q. Why is the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) publishing a request for information (RFI)?
A. APHIS decided to publish a RFI as part of the process of gathering information about ongoing and future research on GE animals to ensure that these animals do not pose risks to livestock health. APHIS is seeking to gain a better understanding of this issue through public input before drafting any official guidance or policy.

Q. Why is APHIS requesting this information now?
A. With the rapid development of this industry, it is important to look ahead to possible future developments. Planning ahead will allow the regulatory agencies to keep pace with the industry.

Q. What type of information is the APHIS RFI requesting from the public?
A. As part of the RFI, we are asking the public for the following information:

- Research being conducted or planned on GE animals;
- Possible implications on the health of U.S. livestock from importation and interstate movement of GE animals, and;
- Steps APHIS should consider under the Animal Health Protection Act (AHPA) to complement the requirements and recommendations described in FDA's draft guidance.

Q. Does a RFI mean that APHIS will eventually initiate rulemaking on genetically-altered animals?
A. A RFI does not commit APHIS to a decision or a course of action. It is intended to invite public comments that we can carefully consider before deciding to draft any official guidance or policy.

Q. Has FDA released any information regarding GE animals?
A. Yes. FDA simultaneously released draft guidance for public comment clarifying its oversight of GE animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Q. Why is APHIS working with FDA on regulating GE animals?
A. APHIS and FDA jointly recognize each others' important roles in the oversight of GE animals. APHIS' mission is to prevent the spread of pests and diseases in all livestock and thoroughly evaluate any and all risks to ensure the safety of America's animal agriculture, which is separate from and complementary to FDA's areas of responsibility. Additionally, APHIS is committed to continuously reexamining how advancements in technologies used in the livestock industry, such as genetic engineering, impact our ability to prevent the introduction and spread of diseases and pests.

Additional Information

Q. How does the coordinated framework (CF) apply to the regulation of GE animals?
A. The CF is a policy statement, published in the U.S. *Federal Register* in 1986, which describes the system for coordinating the activities of the Federal agencies responsible for regulating all GE organisms. The essence of the CF is that existing statutes provide a basic network of agency jurisdiction over both research and products, and that this network forms the basis for a coordinated framework and helps assure reasonable safeguards for the public. The CF policy statement said little about GE animals, but we believe that by maintaining oversight of GE animals and their products under existing law, we are being consistent with the approach put forward in the CF.

Q. Will existing requirements for interstate movement and imports of animals be affected by FDA or APHIS' Biotechnology Regulatory Services oversight of GE animals?
A. Any interstate livestock movements, which would include GE livestock, must comply with the animal health requirement of the State of destination. All imported livestock also must comply with Federal animal health requirements prior to being imported.

Q. What's the difference between animal clones and GE animals?
A. Animal cloning is a method of asexual reproduction, and results in the birth of one animal (the animal clone) that is a genetic copy of another animal. If the animal clone becomes a parent, its children are not clones, because they will have been born through sexual reproduction. So, the two things to remember about an animal clone are that (i) they are animals born as a result of asexual reproduction, and (ii) they have no new genes in them, that is, they are the same as the animal of which they are a copy. For more information, see http://www.fda.gov/cvm/cloning.htm.

Q. Where can interested parties submit comments?
A. If you wish to submit a comment, go to the Federal eRulemaking portal at http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2006-0188.

Q. Where can I find out more information on the subject?
A. Please visit www.aphis.usda.gov for additional information on this subject. For more information on FDA's draft guidance, please visit www.fda.gov/cvm/GEAnimals.htm.