FDA Releases Draft Guidance on Regulation of Genetically Engineered Animals

The Food and Drug Administration (FDA) is inviting the public to comment on draft guidance that discusses FDA's approach to regulating genetically engineered (GE) animals.

Photo courtesy of Agricultural Research Service, USDA

Buckey and Tucker have been engineered so that their female offspring will be able to express spider silk proteins in their milk. These proteins can then be used to spin silk fibers that have many applications, including artificial ligaments and bulletproof vests. Buckey, Tucker, and their mother, Virtue (top left), are part of a promising research program at the University of Wyoming.

Although the guidance, released Sept. 18, 2008, is aimed at industry, FDA believes it may also help the public gain a better understanding of this important and developing area. The guidance explains the process by which FDA is regulating GE animals.

Genetic Engineering

Genetic engineering is a process in which scientists use recombinant DNA (rDNA) technology to introduce desirable traits into an organism. DNA is the chemical inside the nucleus of a cell that carries the genetic instructions for making living organisms. Scientists use rDNA techniques to manipulate DNA molecules.

Genetic engineering involves producing and introducing a piece of DNA (the rDNA construct) into an organism so new or changed traits can be given to that organism. The rDNA construct can either come from another existing organism, or be synthesized in a laboratory. Although conventional breeding methods have been used for a long time to select for desirable traits in animals, genetic engineering is a much more targeted and powerful method of actually introducing specific desirable traits into animals.

GE animals hold great promise for human and animal health, the environment, and agriculture.

Genetic engineering is not a new technology. It has been widely used in agriculture, for example, to make crops like corn and soy resistant to pests or tolerant to herbicides. In medicine, genetic engineering is used to develop microbes that can produce pharmaceuticals. And in food, genetic engineering is used to produce enzymes that aid in baking, brewing, and cheese making.

Benefits of GE Animals

GE animals hold great promise for human and animal health, the environment, and agriculture.

Health protection of animals—Animals are under development to be more resistant to very painful and harmful diseases, such as infection of the udder (mastitis) in dairy cows and bovine spongiform encephalopathy (widely referred to as "mad cow" disease) in all cattle.

New source of medicines—Animals can be engineered to produce particular substances, such as human antibodies, to make infection-fighting drugs for people. These "biopharm" animals can change the way we treat chronic diseases, such as bleeding disorders, by providing large quantities of safe, health-restoring proteins that previously were available only from human cadavers.

Transplantation—Pigs are being engineered so that their cells, tissues, or organs could be transplanted into humans with a reduced risk of immune rejection.

Less environmental impact—Food animals are being engineered to grow more quickly, require less feed, or leave behind less environmentally damaging waste.

Healthier food—Food animals, such as pigs, are under development to contain increased levels of omega-3 fatty acids, providing a more healthful product. Livestock can also be engineered to provide leaner meat or more milk.

GE Animals Regulated Under New Animal Drug Provisions

FDA regulates GE animals under the new animal drug provisions of the law, and the agency must approve them before they are allowed on the market. Food and animal feed from GE animals will undergo FDA review before the food or feed can be marketed. The Federal Food, Drug, and Cosmetic Act defines a drug as "an article (other than food) intended to affect the structure or any function of the body of man or other animals." Therefore, the rDNA construct intended to change the structure or function of the body of the GE animal is a drug.

FDA may exercise "enforcement discretion" over some GE animals, based on their potential risk and on a case-by-case basis. This means that the agency may not require premarket approval for a low-risk animal. For example, the agency is not requiring premarket approval for GE lab animals used for research, and did not require approval of a GE aquarium fish that glows in the dark. FDA does not expect to exercise enforcement discretion for animal species traditionally consumed as food.

This guidance will help industry comply with FDA's requirements and will help the public understand FDA's oversight of GE animals and food from such animals.

This article appears on FDA's Consumer Health Information Web page (*www.fda.gov/consumer*), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*.

For More Information

FDA welcomes comments on its 25-page draft guidance document at *www.fda.gov/dockets/ecomments* or *www.regulations.gov*. Once on this Internet site, select Docket No. FDA-2008-D-0394 and follow the directions. All written comments should be identified with Docket No. FDA-2008-D-0394. The comment period runs for 60 days and closes Nov. 18, 2008.

FDA has developed a number of publications to help inform consumers about the technology of GE animals and the agency's regulation of these animals. Please visit *www.fda.gov/cvm/GEAnimals.htm*.