FDA Issues Final Guidance on Regulating GE Animals

Jan. 15 the U.S. Food and Drug Administration (FDA) issued a final guidance for industry on the regulation of genetically engineered (GE) animals under the new animal drug provisions of the Federal Food, Drug and Cosmetic Act (FFDCA). The guidance, titled "The Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs," clarifies the FDA's statutory and regulatory authority, and provides recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law.

Genetic engineering generally refers to the use of recombinant DNA (rDNA) techniques to introduce new characteristics or traits into an organism. When scientists splice together pieces of DNA and introduce a spliced DNA segment into an organism to give the organism new properties, it is called rDNA technology. The spliced piece of DNA is called the rDNA construct. A GE animal is one that contains an rDNA construct intended to give the animal new characteristics or traits.

"Genetic engineering is a cutting-edge technology that holds substantial promise for improving the health and well-being of people as well as animals. In this document, the agency has articulated a scientifically robust interpretation of statutory requirements," said Randall Lutter, deputy commissioner for policy. "This guidance will help the FDA efficiently review applications for products from GE animals to ensure their safety and efficacy."

The FDA released the draft guidance in September 2008 with a 60-day public comment period, and received about 28,000 comments. The agency has summarized and responded to these

USDA Launches BQMS Pilot Project

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) Jan. 16 introduced a pilot of the biotechnology quality management system (BQMS). The system is part of continued efforts to enhance compliance with the regulatory requirements for field trials and movements of certain genetically engineered (GE) organisms.

"Our goal with the biotechnology quality management system is to give developers the tools they need to better comply with our regulations," said Michael Gregoire, deputy administrator for APHIS' biotechnology regulatory services program. "The pilot project provides us with an opportunity to further develop and improve the system before its full implementation."

APHIS has accepted five volunteer participants into the pilot project: Bayer CropScience, BASF Plant Science, J.R. Simplot Plant Science, Pioneer Hi-Bred International and the University of Nebraska at Lincoln. The participants will develop, implement and maintain a quality management system within their organization to proactively manage the movement and field release of regulated GE organisms. As part of the process, they will:

- work to identify vulnerabilities in their processes for working with GE organisms;

comments online at *www.fda.gov/cvm/GEanimals.htm*.

The FDA's Center for Veterinary Medicine (CVM) has been working with developers of GE animals on both early stage and more mature applications.

"At this time, it is our intent to hold public scientific advisory committee meetings prior to making decisions on GE animal-related applications" said Bernadette Dunham, director of CVM.

The FFDCA defines "articles (other than food) intended to affect the structure or any function of the body of man or other animals" as drugs. An rDNA construct that is in a GE animal and is intended to affect the animal's structure or function meets the definition of an animal drug, whether the animal is intended for food, or used to produce another substance. Developers of these animals must demonstrate that the construct and any new products expressed from the inserted construct are safe for the health of the GE animal and, if they are food animals, for food consumption.

The guidance also describes the manufacturer's responsibility in meeting the requirements for environmental review under the National Environmental Policy Act.

For more information, see *www.fda.gov/cvm/GEanimals.htm*.

Editor's Note: *This release was provided by FDA.*

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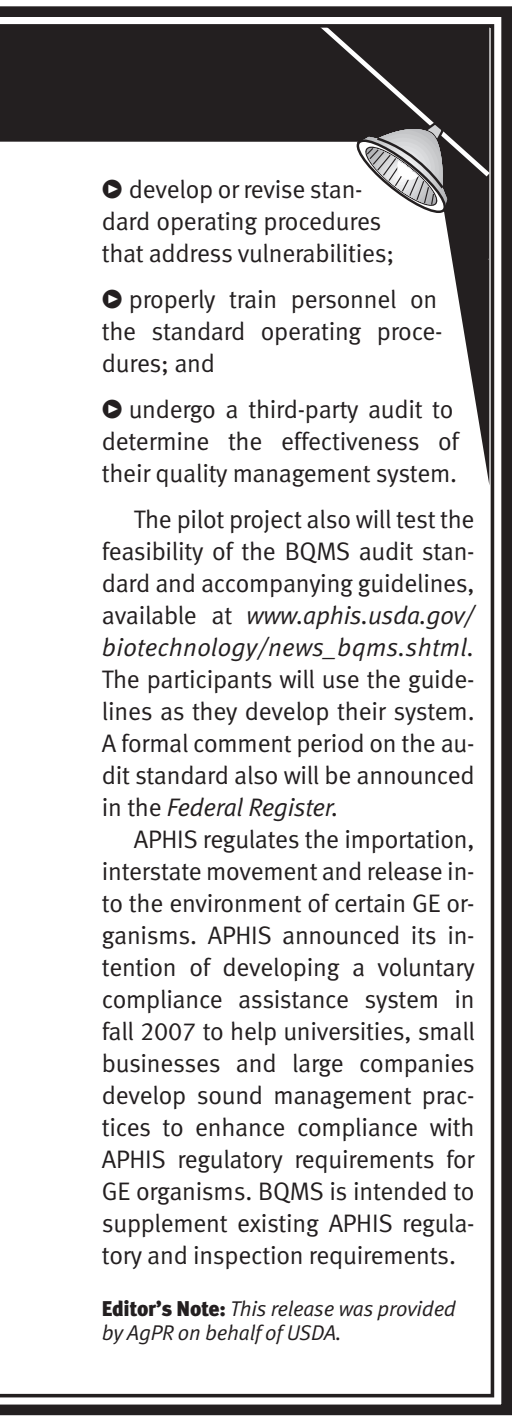

- develop or revise standard operating procedures that address vulnerabilities;
- properly train personnel on the standard operating procedures; and
- undergo a third-party audit to determine the effectiveness of their quality management system.

The pilot project also will test the feasibility of the BQMS audit standard and accompanying guidelines, available at *www.aphis.usda.gov/biotechnology/news_bqms.shtml*. The participants will use the guidelines as they develop their system. A formal comment period on the audit standard also will be announced in the *Federal Register*.

APHIS regulates the importation, interstate movement and release into the environment of certain GE organisms. APHIS announced its intention of developing a voluntary compliance assistance system in fall 2007 to help universities, small businesses and large companies develop sound management practices to enhance compliance with APHIS regulatory requirements for GE organisms. BQMS is intended to supplement existing APHIS regulatory and inspection requirements.

Editor's Note: *This release was provided by AgPR on behalf of USDA.*