



NEWS RELEASE

United States Department of Agriculture • Animal and Plant Health Inspection Service • Legislative and Public Affairs
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USDA OPENS PUBLIC COMMENT ON BIOTECHNOLOGY QUALITY MANAGEMENT SYSTEM PROJECT

WASHINGTON, June 11, 2009--The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) is seeking public comment on the draft standard developed for its pilot of the biotechnology quality management system (BQMS). The BQMS is a voluntary program that aims to enhance compliance with the regulatory requirements for field trials and interstate movements of certain genetically engineered (GE) organisms.

Participants in the pilot program used the draft standard to develop and review sound management practices that help improve compliance with APHIS' biotechnology regulations for environmental releases, importations and interstate movements of regulated articles. The standard is expected to provide a management framework that users can apply to base their current regulatory practices. The standard is flexible enough to address the specific needs of the entire regulated community, including large corporations, small businesses and academia, and allow them to develop a BQMS that suits their scope and scale of work while demonstrating their commitment to regulatory compliance.

This notice was published in the June 4 *Federal Register*. APHIS is soliciting comments on the draft audit standard as a whole, and particularly a portion of the standard (element 7) that requires participants develop:

- Procedures that address critical control points for the introduction of regulated articles;
- Measures for the identification of regulated articles in storage, being moved, imported or transferred and, in field locations;
- Procedures for planning and monitoring environmental releases of regulated articles;
- Methods for post-harvest handling activities and maintaining labeling or some other form of identification of regulated material;
- Procedures for the safe disposal of regulated articles; and,
- Procedures for the submission of regulatory compliance incidents to the appropriate regulatory authorities.

Participants have applied the standard to their organization's regulated biotechnology program to plan, implement, document and examine the efficacy of quality assurance and quality control measures related to introductions of regulated articles. APHIS is soliciting comments for

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a period of 60 days on the above standard currently used in the BQMS pilot project. Upon conclusion of the BQMS pilot project, APHIS will consider all comments received during the comment period to revise the draft standard to improve the efficacy of this project. This feedback, as well as comments from the participants on the BQMS pilot project, will be used to inform the development of a BQMS audit standard and any future BQMS initiative.

Consideration will be given to comments received on or before Aug. 3. Send two copies of postal mail or commercial delivery comments to Docket No. APHIS-2008-0098, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2008-0098. If you wish to submit a comment using the Internet go to the Federal eRulemaking portal at <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0098>.

Comments are posted on the Regulations.gov Web site and also can be reviewed at USDA, Room 1141, South Building, 14th St. and Independence Ave., S.W., Washington, D.C., between 8 a.m. and 4:30 p.m., Monday through Friday, excluding holidays. To facilitate entry into the comment reading room, please call (202) 690-2817.

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