

USDA Seeks Participation for its Biotechnology Quality Management System Program

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) is inviting entities to participate in the Biotechnology Quality Management System Program (BQMS Program) and the requisite training sessions.

It is essential that organizations that receive approval to introduce genetically engineered (GE) organisms comply with all APHIS regulations and permit conditions. To support their efforts to achieve compliance, APHIS' biotechnology regulatory services (BRS) developed a voluntary, audit-based compliance assistance program known as the BQMS Program. The BQMS Program is designed to assist all regulated entities—including universities, small businesses and large companies—to develop sound management practices.

APHIS anticipates scheduling two training sessions during the remainder of calendar year 2010, most likely during summer and fall, and two training sessions in 2011, most likely in spring and fall.

Regulated entities interested in participating should indicate their preference for the scheduling of a training session. Exact training session dates will be determined following discussions with interested entities. Each training session will be limited to five or six entities with approximately two or three representatives from each entity.

Participants in the BQMS Program will be expected to commit to the following:

- Attend required APHIS training sessions on the BQMS Program;
- Develop and implement a biotechnology quality management system (BQMS) within their organization;
- Establish methods and procedures for monitoring critical processes and procedures for the movement and field testing of regulated GE organisms;

- Participate in evaluations after completing training modules; and
- Submit to a third-party verification audit in order to receive full program recognition.

Participating in the BQMS Program will provide regulated entities with concrete, practical compliance assistance and will afford participants an opportunity to demonstrate their commitment to regulatory accountability, increased transparency and the identification and implementation of measures to minimize the occurrence of compliance infractions.

APHIS conducted a BQMS Program pilot development project in 2009, during which five entities participated and assisted APHIS in evaluating a BQMS draft audit standard, program training sessions and audit procedures.

Following the pilot development project and after evaluating the comments submitted on the BQMS draft audit standard, APHIS made adjustments to the BQMS Program and to the BQMS audit standard. APHIS will soon publish a notice in the *Federal Register* announcing the availability of our evaluation of the comments received and the availability of a revised BQMS audit standard.

APHIS is interested in advancing the BQMS Program in the next few months and encourages interested entities to submit letters of interest as soon as possible. APHIS will, however, accept letters of interest at any time. Interested entities may submit letters of interest by mail or e-mail to Edward Jhee, chief compliance assistant branch, USDA, APHIS, BRS, 4700 River Road, Unit 91, Riverdale, MD 20737-1236; edward.m.jhee@aphis.usda.gov.

This action is published in today's July 19 *Federal Register* and becomes effective upon publication.

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