

# USDA Announces Biotechnology Quality Management System Pilot Project

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) today announced a pilot project for its biotechnology quality management system (BQMS). This system is a voluntary compliance assistance program that will help universities, small businesses and large companies develop sound management practices to enhance compliance with regulatory requirements for field trials and movement of regulated genetically engineered (GE) organisms.

The pilot project will test the applicability of a biotechnology quality management audit standard and accompanying guidelines. APHIS' goal is to obtain feedback from participants on the strengths and needed improvements to the audit standard and guidelines. The pilot project will assist APHIS in further development of the BQMS prior to its full implementation.

For the pilot project, APHIS is seeking voluntary participants who will serve as a broad representation of the regulated community. APHIS will select participants who are:

1. Currently conducting regulated environmental field release and movements under notification or permit, and who
2. Intend to apply for a renewal or new notification or permit, annually for the next three years.

APHIS will select three applicants to participate in the pilot project: One applicant from a large corporate business (greater than 50 employees), one applicant from a small business (less than 15 employees) and one applicant from an academic institution.

Participants in the pilot project will review the BQMS process and provide feedback. Specifically, participants will test the feasibility of the BQMS standards and guidelines by developing and implementing a quality management system for their organization that proactively manages regulated movements and field releases.

A draft audit standard for the BQMS program and a series of guidelines to assist participants in using this compliance assistance program are currently

undergoing a technical review with audit industry experts. This review will be completed before the pilot project begins.

Organizations that wish to participate in the BQMS pilot project should submit a letter of interest (1-2 pages) that includes the following:

1. A short description of current active notifications and permits; and
2. A statement of the organization's commitment to:
  - Develop and implement a BQMS program within their organization;
  - Attend all required training sessions held by APHIS' biotechnology regulatory services;
  - Participate in surveys after completing training;
  - Establish methods and procedures for monitoring critical processes and procedures for the movement and field testing of regulated GE agriculture;
  - Provide required data and feedback to APHIS' biotechnology regulatory services; and
  - Submit to a third-party external verification audit.

This notice was published in the Sept. 2 *Federal Register*.

Letters of interest will be accepted from Sept. 2 to Oct. 1. APHIS will evaluate letters and notify all applicants of its final selections. Participation letters of interest can be submitted by postal mail, commercial delivery or e-mail to:

Edward Jhee, Manager, USDA-APHIS-BRS-BQMS, 4700 River Road, Unit 91, Riverdale, MD 20737-1236; via e-mail [edward.m.jhee@aphis.usda.gov](mailto:edward.m.jhee@aphis.usda.gov).

Note to Stakeholders: For more information phone (301) 734-6356, or visit the BQMS Web site at [http://www.aphis.usda.gov/biotechnology/news\\_bqms.shtml](http://www.aphis.usda.gov/biotechnology/news_bqms.shtml).

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