

## The Biotechnology Quality Management System

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), regulates the introduction—meaning the importation, interstate movement, and environmental release—of genetically engineered (GE) organisms that are, or may be, plant pests. It is essential that applicants approved to introduce regulated GE organisms comply with all APHIS regulations and permit conditions. To improve quality compliance, APHIS is developing a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS).

BQMS will complement, not replace, APHIS' existing regulatory compliance and inspection process. The current permit and notification process will still be used to place specific requirements on applicants that wish to field test or move regulated GE organisms. Permit and notification holders will still be required to identify and self-report any potential noncompliance incidents. APHIS will also continue to conduct inspections for permits and notifications to ensure compliance with regulations.

BQMS will help the universities, producers, and companies, who introduce regulated GE organisms, to analyze their operations, identify control points where problems could occur, and apply mitigation measures to address those vulnerabilities. BQMS will take a proactive approach to compliance and will provide the opportunity to head off potential compliance problems before they happen.

APHIS will implement the voluntary BQMS through an agency directive, and participation in the program will not be a regulatory requirement. Voluntary participation in the BQMS program will enable a participant to demonstrate to APHIS and the public that it has carefully considered how planning, training, managing, and monitoring all activities associated with developing regulated GE organisms will be achieved. Participants will be able to demonstrate their commitment to meeting the requirements for introducing these organisms.

### Principles of the BQMS Standard

Recognizing that they must meet the needs of differing infrastructures among participants, APHIS

officials have designed the BQMS to be guided by eight principles of quality management. The principles of the BQMS standard will ensure that there is a system of accountability as well as a tool for open communication between APHIS and its stakeholders at all levels. APHIS is committed to a quality management system that will work as an evolving system of management and accountability, as well as a communication tool for all stakeholders to achieve their planned results.

The eight principles of the BQMS standard are:

*Meeting regulatory requirements:* Organizations must understand APHIS'— as well as other agencies'— regulatory expectations for transporting and field testing regulated GE organisms.

*Leadership:* Senior management in organizations must establish direction, unity of purpose, and a supportive work environment to achieve regulatory compliance.

*Involvement of people:* Organizations should empower employees at all levels and use their employees' abilities for the organization's benefit.

*Process approach:* Organizations must recognize that all work is accomplished through processes and manage them accordingly.

*System approach to management:* Expanding on the process principle—organizations should understand that achieving objectives requires a system of interrelated processes.

*Continual improvement:* Organizations should recognize and act on the understanding that all processes can be continually improved.

*Factual approach to decisionmaking:* Organizations should acknowledge that sound decisions must be based on the analysis of factual data and information.

*Cooperative supplier relationships:* Organizations and their suppliers (i.e., cooperators and subcontractors) should each enhance their ability to meet regulatory requirements by developing and maintaining actively cooperative relationships with one another.

## Development and Implementation

BQMS is designed to be compatible with quality management guidelines used by the agricultural, biotechnology, and seed industries. The program's best management practices will be prepared in accordance with existing examples and guidance developed by industry and other Federal agencies, such as the U.S. Food and Drug Administration, National Oceanic and Atmospheric Administration, and the Environmental Protection Agency.

As part of the program development process, APHIS has created a pilot program to introduce BQMS to a range of stakeholders at varying levels. The BQMS pilot development project is designed to:

- Evaluate the BQMS standard and guidelines by testing specific elements of the program
- Provide feedback on program strengths and areas in need of improvement
- Provide training on the standard and guidelines to pilot participants
- Track a small number of project participants who will participate in the development and implementation of a BQMS within their organizations
- Provide guidelines for audits to be conducted after organizations have implemented a BQMS

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