

Biotechnology Quality Management System

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), is responsible for regulating the introduction—meaning the importation, interstate movement, and environmental release—of genetically engineered (GE) organisms that are, or could be, plant pests. It is essential that applicants approved to introduce GE organisms comply with all APHIS regulations and permit conditions. To assist their efforts to develop sound management practices and to enhance compliance, APHIS is developing a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS). APHIS intends to oversee the BQMS program in partnership with USDA's Agricultural Marketing Service (AMS), which will manage the audit component of the program and accredit third party auditors.

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

The goal of BQMS is to assist universities, producers, and companies, who introduce 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 compliance problems before they occur.

APHIS will implement the voluntary BQMS through an agency notice. Participation in the program will not be a regulatory requirement. Voluntary participation in the BQMS program will enable a participant to demonstrate that it has carefully considered the planning, training, management, and monitoring of all activities associated with development of GE organisms, and

that it is committed to meeting the requirements of APHIS regulations.

BQMS Overview

In order to address the specific needs of participants, BQMS will consist of two program levels. Both programs will include guidelines for training and qualification, for work processes and procedures, and for recordkeeping and document control.

The Level-A program will be designed for applicants that do not have formal management systems in place and will help participants develop good management procedures. It will be geared toward small businesses and universities. Level-A BQMS certification focuses on a program participant's ability to develop documented quality management controls and procedures and to identify risk control points for the introduction of GE organisms.

Applicants that have formal management systems in place may choose to participate in the Level-B program. This program is intended for applicants that grow GE plants at multiple sites, often through the use of cooperators. The Level-B program will work to ensure accountability at all levels and by all parties involved.

Applicants that participate in the voluntary BQMS program will be required to:

- Ensure all personnel are properly trained on the standard operating procedures for working with GE organisms;
- Work to identify vulnerabilities in their processes and to identify potential risk control points for any GE introduction;
- Identify and develop quality control measures to minimize the risk or occurrence of unauthorized releases; and
- Monitor BQMS procedures for the introduction of GE organisms

Audits will confirm that these activities are taking place. AMS has a great deal of expertise and experience in this area through its work with USDA's Process Verified Programs. In these programs, participating suppliers of agricultural products or services conform to specific standards—set in accordance with International Organization for Standardization (ISO) 9001—to assure customers of their ability to provide consistent quality products or services.

Standards

Part of APHIS' role in regulating biotechnology involves helping to develop international biotechnology standards to ensure that GE products can be traded between nations. Both BQMS program levels will be based on quality management systems that are domestically and internationally recognized.

The Level-A BQMS program will be based on industry best management practices and the Codex Alimentarius Commission's principles and guidelines on the application of the Hazards Analysis and Critical Control Point (HACCP) system. The Codex Alimentarius Commission is an internationally recognized standard-setting body that was created to develop standards and guidelines to ensure fair trade practices, protect the health of consumers, and promote the coordination of food and feed safety standards. The HACCP system is a science-based system used to assess hazards and establish control systems that focus on prevention. The HACCP approach provides users with flexibility and accommodates change, such as advances in equipment design, processing procedures, or technological developments.

Level-B best management practices will be based on the principles and guidelines of the internationally recognized ISO 9001, "Quality Management System Requirements," and also will incorporate the principles of HACCP. ISO is an international standard-setting body with a network of national standards institutes in 157 countries. ISO standards provide governments with a technical base for health, safety, and environmental legislation. The generic standard for companies that produce a product or provide a service is ISO 9001.

The best management practices that are part of the HACCP principles and the ISO standards and guidelines will provide a strong foundation for BQMS. Incorporating these best management practices with APHIS' scientific and technical guidelines will enable participants to develop effective planning and oversight practices specific to the regulatory requirements for field releases and movements of GE organisms. Audits will verify that participants in both BQMS program levels have sound management procedures in place for introductions of GE organisms and that they are performed correctly. As part of the program's emphasis on preventive measures, participants will be encouraged to correct deficiencies discovered in an audit before compliance problems develop.

Implementation

BQMS will be designed to be compatible with quality management standards used by the agricultural biotechnology and seed industries. As part of the program development process, APHIS will establish audit criteria, develop procedures for obtaining verification services, describe the verification activities, and outline program advantages for successful certification. During the development process, APHIS will provide opportunities for industry, academia, and interest groups to contribute their input concerning the scope of the BQMS program as well as Level-A and Level-B audit verification criteria. APHIS will hold meetings throughout the development process, and various focus groups and working groups will have the opportunity to provide input on the development of the BQMS program.

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