United States Department of Agriculture
Animal and Plant Health Inspection Service
Program Aid No. 2056

Biotechnology Quality Management System Program

Improving the Management of Regulated Genetically Engineered Organisms

“I cannot imagine the agricultural biotechnology regulatory compliance industry without this type of assistance/guidance program (BQMS Program); it is the last piece of the puzzle.”

- BQMS Pilot Program Participant

Biotechnology
Regulatory
Services

ABOUT THE PROGRAM

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), Biotechnology Quality Management System Program (BQMS Program) provides compliance assistance to the regulated community for the voluntary adoption of a biotechnology quality management system (BQMS). A BQMS serves as an important tool to help organizations involved in biotechnology research and development analyze the critical control points within their management system to better maintain compliance with USDA APHIS regulations for the import, interstate movement, and environmental release of regulated genetically engineered (GE) organisms.

As part of the BQMS Program initiative, APHIS launched a pilot project to test the applicability of the BQMS draft audit standard and guidelines. APHIS gathered public feedback to refine the draft audit standard and guidelines in preparation for the Program's full implementation.

The BQMS Program staff will provide one-on-one targeted assistance when needed.

A Dynamic, Science-Based Approach

A BQMS integrates a science-based approach of risk assessment and mitigation, allowing for sound decisionmaking and effective management of the research and development of regulated GE organisms. A BQMS also integrates principles from other quality management systems, such as the Codex Alimentarius Hazard Analysis Critical Control Point System and International Organization for Standardization (ISO) 9001:2008.

"…We are better organized and equipped to ensure that internal and external associates can perpetuate good practices."

- BQMS Pilot Program Participant

Providing Assistance Every Step of the Way

The BQMS Program provides participants with the tools and guidance needed to develop a BQMS that is tailored to their organization's needs. Specifically, the Program provides:

- interactive training workshops with other BQMS Program participants and USDA officials,
- documented guidelines and templates to aid in the development of a BQMS,
- a baseline assessment of current management practices in relationship to the BQMS audit standard,
- one-on-one targeted assistance as needed,
- internal audit training,
- facilitated third-party audits of the organization's BQMS, and
- acknowledgement of BQMS Program completion.

BQMS Program Mission

Within USDA, APHIS Biotechnology Regulatory Services (BRS) provides support for the voluntary adoption of a BQMS to improve the management of an organization's domestic research and development of regulated GE organisms.

The BQMS Program staff will work with you to identify critical control points during field trials of your GE plants.

The BQMS Program will help you develop a program to train your staff in standard operating procedures for handling regulated GE organisms.

Raising the Bar

Although the Program provides support, it places ownership and responsibility on the participating organization to control identified risks to the confinement, containment, and identity of regulated GE organisms. This ownership enables researchers to document the effectiveness of their management systems for regulated GE imports, interstate movements, and environmental releases. It also requires continuous self-monitoring and verification to demonstrate that the system is working and to reveal when potential regulatory noncompliance incidents have occurred.

Expect a Difference

Participants will develop, implement, and maintain a BQMS within their organization to manage the movement and field release of regulated GE organisms. Specifically, organizations will:

- work to identify critical control points in the organization's processes for working with regulated GE organisms,
- develop or revise standard operating procedures that address critical control points,
- properly train personnel on the standard operating procedures,
- undergo a third-party audit to determine effectiveness of the organization's quality management system, and
- become an organization recognized as completing the BQMS Program.

Get Started Today

The BQMS Program is available to interested parties in the regulated community who wish to validate their approach to APHIS regulatory compliance. Participation is limited based on available resources. Please visit www.aphis.usda.gov/biotechnology/news_bqms.shtml for a list of tentative training dates.

To learn more about the BQMS Program and how you can participate, go to: **www.aphis.usda.gov/biotechnology/news_bqms.shtml**

To contact a BQMS Program representative, e-mail us at BRS.BQMS@aphis.usda.gov or call us at (301) 734-7324.

The BQMS Program will help you to better understand the value of quality management systems in biotechnology by bringing good management practices to your organization.

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