Biotechnology Quality Management Support Program (BQMS)

Last Modified:

The voluntary BQMS Program is designed to help organizations of any size, universities, small businesses, and large organizations, develop sound quality management practices to enhance their ability to comply with the APHIS organisms developed using genetic engineering found at 7 CFR part 340.

The BQMS Program is a modular system which allows each unique user the option of selecting from a list of web-based compliance assistance tools referred to as modules. These modules are designed in a user-friendly question and answer format to help in creating a documented self-certifying quality management system to manage critical control points consistent with the requirements at 7 CFR part 340.

Background

In September 2007, BRS introduced the Biotechnology Quality Management System (BQMS) Program as a voluntary program to help the regulated community develop sound quality management practices regarding the importation, interstate movement, and environmental release of genetically engineered (GE) organisms that are, or may be, plant pests, as described in our regulations at 7 CFR part 340. The Program was an all or nothing, recognized, quality management system which over time became too costly and burdensome for small and academic organizations.

APHIS BRS reexamined the Biotechnology Quality Management System Program after engaging with current and prospective participants, and determined that a modularized web-based approach will reach a wider universe of researchers and developers conducting biotechnology activities under APHIS regulations at 7 CFR part 340.

APHIS published a *Federal Register* notice in early 2017 announcing this new Biotechnology Quality Management *Support* Program, renaming it from the Biotechnology Quality Management System Program, but retaining the “BQMS” acronym.

The new BQMS Program remains a voluntary compliance assistance program to facilitate compliance with APHIS’ biotechnology regulations, and provides compliance assistance information and education in a more flexible and adaptable way.

BQMS Resources

The BQMS Program repository contains user-friendly question and answer formatted guidelines customized to jumpstart or complete self-certifying quality management practices.

The repository was designed to assist BQMS Program users interested in developing a documented quality management system to facilitate compliance with the APHIS regulations for the import, interstate movement, and field release of organisms developed using genetic engineering in complying with regulations found at 7 CFR part 340.

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

- 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 standard operating procedures,
- Undergo self-certification to determine effectiveness of the organization's quality management system, and
- Become an organization participating in the BQMS Program.

APHIS developed the compliance assistance modules below to better meet the needs of universities, small businesses and large companies alike in following areas:

Document Control

- Document Control (47.76 KB)
- Record Control (43.19 KB)

Internal Controls

- Competence Awareness and Training Procedure (44.7 KB)
- Management Review Meeting Form (42.1 KB)

Critical Control Points

- Site Selection Planning (37.94 KB)
- Storage (42.14 KB)

- Transport, Movement, and Import (44.11 KB)
- Environmental Release Planning and Monitoring (44.33 KB)
- Post-harvest Handling and Transfer (46.65 KB)
- Devitalization and Final Disposition (41.57 KB)
- Potential Regulatory Compliance Incidents (40.71 KB)
- Reporting Form for Potential Regulatory Compliance Incidents (37.46 KB)

Process Improvements

- Internal Audit (47.31 KB)
- Corrective Action (45.14 KB)
- Preventive Action (46.5 KB)
- CAR PAR Form (53.51 KB)

Disclaimer: This material is provided as a generalized guide for your organization's quality management practices relevant to your obligations under APHIS regulations found at 7 CFR part 340. Use of these modules and its content does not guarantee that the user's activities are in compliance with 7 CFR part 340, and it does not eliminate the user's obligations under any other statute or regulation. If your organization wishes to use formal quality management systems, it is best to rely on qualified quality management professionals.

Contact Us

Do you have questions, comments, or suggestions? Contact us via email**:** BRS.BQMS@usda.gov

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