



This document is scheduled to be published in the Federal Register on 01/18/2017 and available online at <https://federalregister.gov/d/2017-01017>, and on [FDsys.gov](https://fdsys.gov)

## **DEPARTMENT OF AGRICULTURE**

### **Animal and Plant Health Inspection Service**

**[Docket No. APHIS-2016-0079]**

#### **Updates to the Biotechnology Regulatory Services BQMS Program**

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice.

**SUMMARY:** We are advising the public that Biotechnology Regulatory Services of the Animal and Plant Health Inspection Service (APHIS) is updating its Biotechnology Quality Management System Program and renaming it the Biotechnology Quality Management Support Program to offer a more flexible, more customizable, and less costly program that is easily accessible to a wider universe of researchers and developers conducting biotechnology activities under APHIS' regulations. These updates represent the next step in the continual improvement to this voluntary quality management program.

**FOR FURTHER INFORMATION CONTACT:** Ms. Rochelle Langley, Quality Management Specialist, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1228; 301-851-3906, [Rochelle.A.Langley@aphis.usda.gov](mailto:Rochelle.A.Langley@aphis.usda.gov).

#### **SUPPLEMENTARY INFORMATION:**

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), regulates the importation, interstate movement, and environmental release of genetically engineered (GE) organisms that are, or may be, plant pests. In September 2007, APHIS' Biotechnology Regulatory Services (BRS) announced a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS) Program to assist the regulated community in achieving and maintaining compliance

with requirements for field trials and movements of GE organisms under its regulations in 7 CFR part 340.

Under the BQMS Program, APHIS-BRS has provided support for the voluntary adoption by participants of a quality management system to improve their management of domestic research and development of regulated GE organisms in order to fully comply with regulations. The BQMS Program included a mandatory audit standard that provided extensive criteria for the development, implementation, and an objective evaluation of the participant's quality management system.

We are notifying the public that BRS is updating its BQMS Program and renaming it the Biotechnology Quality Management Support Program, which will use the same BQMS acronym, in order to reach a broader audience. After engaging with current and prospective BQMS participants, APHIS-BRS determined a modularized, more flexible, Web-based approach reaches a wider universe of researchers and developers conducting biotechnology activities. Small organizations, academics, and first-time users now have access to a program that previously was only within the means of a select few with considerable resources. The new BQMS Program is no longer audit-based, and no longer requires an "all or nothing" quality management system that relies on a BRS-developed audit standard, a required 3-day BRS-led training session for all participants, and a third-party audit cycle to maintain Program recognition. The new BQMS Program remains a voluntary compliance assistance program but with fewer impediments to users – no required multi-day training, no cost-prohibitive third-party audits and associated travel expenses, and no exhaustive resource commitments.

The new BQMS Program is a flexible, Web-based, modular approach designed to enhance compliance by enabling organizations large and small to develop sound quality

management practices. Users can select any or all critical control points applicable to their organizations' compliance assistance needs such as: Site selection planning, procedures for storage, transportation (interstate movement and importation), environmental release planning and monitoring, post-harvest handling and transfer, devitalization and final disposition, potential regulatory compliance incidents, and a reporting form for regulatory compliance incidents. User costs should decrease with the ability to easily choose only the modules they need to meet their unique compliance assistance needs.

The new BQMS Program offers a comprehensive repository of user-friendly, Web-based templates, guidelines, and checklists to assist users in the implementation of processes, procedures, and the foundation for a quality management system. No matter how big or small their organization, BQMS users will continue to have the option of requesting one-on-one tailored assistance from BRS staff, as in the past.

Organizations participating in the voluntary program will be encouraged to use BQMS resources as a foundation to ensure all personnel are properly trained regarding the requirements

for working with GE organisms; identify and develop control measures to minimize the risk or occurrence of unauthorized releases; and monitor quality management practices and procedures.

These updates are the next step in the continual improvement of the voluntary BQMS Program.

Done in Washington, DC, this 11<sup>th</sup> day of January 2017.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

**BILLING CODE 3410-34-P**

[FR Doc. 2017-01017 Filed: 1/17/2017 8:45 am; Publication Date: 1/18/2017]