Animal and Plant Health Inspection Service
Biotechnology Quality Management System Program
Draft Audit Standard
Evaluation of Public Comments

The Biotechnology Quality Management System Program is a service provided by APHIS' Biotechnology Regulatory Services, designed to improve an organization's management of domestic research and development of regulated genetically engineered organisms.

In a notice published in the *Federal Register* (74 FR 26831 – 26832) APHIS announced the availability of the draft audit standard developed for its Biotechnology Quality Management System Program Pilot Development Project, and solicited comments for a period of 60 days beginning on June 24, 2009, and subsequently extended the comment period until October 23, 2009 (74 FR 42644). APHIS received seven comments on the proposed draft audit standard. Respondents were from a State department of agriculture, an academic institution, industry organizations, and agricultural biotechnology companies.

APHIS solicited comments on the draft audit standard as a whole and specifically sought input on the following four questions:

1. Do the critical control points in Requirement 7 of the draft audit standard identify all areas and elements that organizations should focus on in order to maintain compliance with the regulatory requirements under 7 CFR part 340?

2. Is the draft audit standard consistent with current best practices used by the regulated community?

3. Can the public identify incentives USDA might employ to encourage participation in the voluntary program by commercial industry as well as academic institutions?

4. The BQMS is designed to be flexible according to the size of the participating organization. Is this flexibility apparent in the draft audit standard?

APHIS received and analyzed comments and appreciates the wide range of comments on the draft BQMS Audit Standard. Many answers to procedural and operational comments and questions may be found in the *Questions and Answers* and operational procedures found on the APHIS BRS website at http://www.aphis.usda.gov/biotechnology/news_bqms.shtml. The following is a summary and response of key issues raised by the comments, as well as technical comments and responses related to the BQMS Program and the draft audit standard. Comments are in plain text; APHIS' responses are in *italics*.

> Several comments requested APHIS consider the Office of Management and Budget (OMB) Circular A-119, "Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities". Comments suggested that OMB would favor the use of voluntary consensus standards over an agency-specific standard.

OMB Circular A-119 establishes policies for the use of standards in government agencies. The Circular directs agencies to use voluntary consensus standards in lieu of government-unique standards except where inconsistent with law or otherwise impractical.

However, the focus of the policy dictated in the Circular references "procurement" and "regulatory activities." The APHIS BQMS audit standard is a voluntary government-unique standard that does not contain regulatory requirements. It is intended to be a tool to improve an organization's management of domestic research and development of regulated articles.

Consistent with the policy described in the Circular, APHIS has determined that there is no voluntary consensus standard for management of the introduction of regulated articles regulated by 7 CFR part 340. APHIS BRS will continue to use the government-unique BQMS Audit Standard as part of an outreach and education effort within the Regulatory Operations Program, Compliance Assistance Branch.

Several comments indicated a concern of a potential duplicative nature of the BQMS audit standard with BIO's Excellence through Stewardship.

APHIS recognizes that BIO's Excellence through Stewardship (ETS) addresses global plant product integrity and stewardship of technology and biotechnology derived products from gene discovery through the discontinuation of a product.

The APHIS BQMS Program's mission is to provide compliance assistance services to the regulated community for the voluntary adoption of a Biotechnology Quality Management System to improve an organization's management of domestic research and development of regulated articles.

APHIS and BIO's ETS are currently exploring common areas to avoid any potential duplicative efforts.

Several comments indicated a concern regarding potential creation of competitive disadvantage for non-participants of BQMS.

The BQMS Audit Standard outlines the requirements for a quality management system that addresses the management of essential best practices (critical control points) for the domestic research and development of regulated articles. The BQMS Audit Standard outlines additional quality management principles such as document and record control, training, internal and external communication, oversight of external associates (i.e., cooperators), and continuous improvement.

Participation in the BQMS Program is voluntary. APHIS intends to accommodate all entities who seek participation in the BQMS Program's compliance assistance activities. Furthermore, APHIS will acknowledge entities

that have voluntarily completed the development and implementation of their BQMS.

The BQMS Program and associated compliance assistance activities are intended to provide additional information to the regulated community for those who voluntarily seek such services from APHIS BRS to improve the management of domestic regulated research and development of GE organisms. The specific purpose and intent of BQMS is to provide a standard for a quality management system that addresses the management and oversight of movements and field releases of regulated articles to support the existing notification performance standards and permit conditions found in 7 CFR part 340.

Several comments were received regarding the scope of third-party audits.

The scope of a third-party audit includes desk audit of quality management documentation, including procedures that address BQMS critical control points. The scope of the audit will include a sampling of records to determine if the implemented BQMS is continuously monitored and improved. The review of associated BQMS records will focus on the management of domestic research and development of GE organisms and does not determine compliance with APHIS regulations. APHIS provides additional information on the BQMS Program's audit activities in a set of program Questions and Answers, as well as program operational procedures, posted on the APHIS BRS website.

One comment addressed how the standard "potentially changes the confidentiality of how compliance incidents are documented including FOIA considerations".

A BQMS Program third-party audit will review evidence that a procedure exists which addresses how the organization will report potential compliance incidents to appropriate regulatory authorities. Third-party audits will not review confidential information. Auditors will only sample records as objective evidence that the process exists and functions as described within the organization's procedures. APHIS provides additional information on the BQMS Program's audit activities in a set of Questions and Answers, as well as program operational procedures, posted on the APHIS BRS website.

One comment sought clarification on the breadth of an audit: "The standards do not indicate the breadth of an audit, i.e., what facilities are visited by the auditors. If audits can include both field trials and contained facilities, like growth chambers and laboratories, then appropriate standard should be created for each type of facility".

Third-party audits focus at the system and process level related only to the requirements of the BQMS audit standard. The breadth of an audit will not extend beyond a "headquarters," or at a maximum, "regional," office where regulatory compliance personnel manage the domestic research and development of regulated GE organisms. BQMS third-party audits will not include specific

field trials or contained facilities. The purpose of a BQMS third-party audit is to validate the established system and processes in place for the management of research and development of regulated GE organisms.

One comment sought clarification on the terms "major non-conformance" and "minor non-conformance."

BQMS Program operational procedures, which are publically available, define major non-conformance and minor non-conformance and provide additional criteria for delineation.

One comment sought clarification on "how notification performance standards coexist with BQMS".

Performance standards described in 7 CFR part 340.3 are containment and confinement requirements that must be met for the introduction of regulated articles under Notification. The critical control points within the BQMS Program Audit Standard are intended to raise the awareness of critical decisions made for the management of domestic research and development of regulated articles.

One comment was received seeking clarification and a definition for "effectiveness."

Effectiveness will be added to the definitions list in the BQMS Audit Standard as: the extent to which planned activities are realized and planned results achieved. A voluntary participant defines their own effectiveness through its internal processes for monitoring, verification activities, corrective and preventive actions, continual improvement activities and management reviews.

One comment was received regarding contingency planning: "it should be part of the overall system to have contingency plans well defined so that if/when a mishap occurs the action plan is already established and just needs to be implemented. This allows for a faster and more thorough response if problems develop."

Section 8.4.1 of the BQMS Audit Standard addresses continual improvement of the BQMS through the use of a quality policy, quality objectives, audit results, corrective and preventive actions and management review. Effective analysis of problems using root-cause analysis for corrective actions is encouraged to address problems with the organization's BQMS. Section 7.2.6 requires the organization to implement a procedure for the remediation and resolution of a potential compliance incident if one were to occur.

One comment was received suggesting a section be added to the BQMS audit standard to address a procedure to clean up a containment breach during transport.

Shipping of regulated articles is considered within the critical control point address by Section 7.2.2 of the BQMS Audit Standard. The organization must

track the regulated shipment of regulated GE organisms to a destination. If a containment breach were to occur, the organization would implement the processes and procedure required by Section 7.2.6 of the Audit Standard, for the remediation and resolution of a potential compliance incident.

One comment sought clarification on records of "internal and external communications regarding regulatory compliance incident self-reporting requirements."

A BQMS third-party audit will validate that a procedure exists that meets the requirements of Section 7.2.6 of the BQMS Audit Standard for the resolution and remediation of potential compliance incidents. The scope of the audit will review objective evidence (records) that the procedure has been implemented. It is not the intent of the third-party audit to review any confidential business information. A process audit will be conducted to determine if the organization has implemented this procedure.

One comment sought clarification to the maintenance of post-harvest handling and transfer documentation: "the short distance movement of harvested material from the field to the field station presents a negligible risk. Requiring documentation of these short distance trial-site transfers would impose a considerable burden on field personnel, with no compliance benefit. The requirement to maintain transport documentation should be limited to "regulated" transport (*i.e.*, interstate movement required to be conducted under notification or permit)."

APHIS considers the maintenance of identity of regulated material during post-harvest transfers to subsequent facilities for conditioning or processing a critical control point. While some transfers may be of short geographical distance, a loss of identity leading to a potential compliance incident may occur. BQMS pilot development project participants implemented this requirement and indicated that it caused no additional burden on field personnel.

One comment suggested a change to the site selection provisions found within the BQMS Audit Standard: "The site selection provisions impose an unnecessary level of detail. While it is prudent to ensure one has control of the area surrounding a field trial, since it plays a role in confinement, historical land use and threatened and endangered species are not relevant for compliance with Part 340. These two points are thoroughly addressed in permit applications."

BQMS focuses on the essential planning and critical decisions for the management of domestic research and development of regulated GE organisms. APHIS included provisions regarding site selection, planning, and analysis of critical habitat for threatened and endangered species to address the planning of environmental field tests of regulated GE organisms.

One comment sought clarification on "devitalization and disposition" found within Section 7.2.5 of the draft BQMS Audit Standard: "Regulated material can be devitalized and disposed of in any manner consistent with the participant's permit or notification, and once devitalized, material can be transported and disposed of as solid waste."

> *The requirement was re-titled "7.2.5 Devitalization and final disposition." Key changes to this include defining final disposition as the fate or fates of materials harvested, removed, destroyed, and/or otherwise terminated from an environmental release and/or movement. Such fates include various in-field methods of termination (e.g., grinding, disking, deep burial, etc.) and off-field termination (e.g., containment, landfill disposal, etc.).*

One comment sought clarification on "management of external associates," as related to contractual and legal liabilities.

> *Section 7.3 is limited to the process of monitoring and verification activities associated with Section 7 [critical control point] activities. Any legal contracts or other agreements between the voluntary participant and its external associates are beyond the scope of the program.*

One comment suggested APHIS specify the cleaning of planting equipment both before and after planting.

> *Section 7.2.3 of the BQMS Audit Standard requires that the organization have a procedure that describes the preparation and cleaning of planting equipment. Cleaning should occur before and after planting. Objective evidence of this will be in the form of records and subject to third-party audit.*

One comment suggested APHIS specify the cleaning of harvesting equipment.

> *Section 7.2.3 of the BQMS Audit Standard requires that the organization have a procedure that describes the preparation and cleaning of harvest equipment. Cleaning of harvesting equipment should occur before and after harvest. Objective evidence of this will be in the form of records and subject to third-party audit.*

One comment suggested removing Section 6.4 from the draft BQMS Audit Standard version 1b.

> *Section 6.4 from Version 1b was stricken.*

One comment sought clarification on the BQMS requirement for internal audits (Section 8.2.1).

> *A considerable amount of resources will be input into from both APHIS and a voluntary participant for the development, implementation and monitoring of a*

BQMS. APHIS requires a participating organization to conduct an internal audit at least annually and maintain records as such for their BQMS to maximize the value of continuous improvement. The organization may choose to be as prescriptive in the scope and extent of the internal audit as they see fit. Annual internal audit of an entity's BQMS is required in order to fulfill BQMS Program requirements and receive acknowledgement from APHIS of Program completion. A template and guidance on how to develop an internal audit procedure that addresses this BQMS requirement are available on the APHIS BRS website.

One comment sought clarification on the term "appropriate data" within Section 8.3, *Analysis of data*.

Analysis of data will be defined in Version 2 of the BQMS Audit Standard as: factual approach to decision making based on data and information. The analysis of data is essential to internal measurement of quality objectives by management. In addition, the data and analysis is the foundation for continuous improvement of a 'systems' approach to quality management.