

USDA APHIS Biotechnology Quality Management System (BQMS) Program

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National Alliance of Independent Crop Consultants
Annual Meeting

Memphis, TN
January 29, 2009

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Overview of APHIS BQMS

- Voluntary, compliance assistance and outreach program
- Complementary to BRS regulations
- Designed to facilitate compliance
- Draft standards and guidelines
- Pilot Project - 2009

BQMS Pilot Project - 2009

- 5 Organizations volunteered to participate
 - University of Nebraska-Lincoln
 - Bayer CropScience
 - BASF Plant Science
 - J.R. Simplot Plant Science
 - Pioneer Hi-Bred International

- Pilot project in 2009
 - Testing of the BQMS standard
 - Full implementation likely in 2010

BQMS Pilot Project

Goals:

1. Evaluate BQMS Standard and Guidelines
2. Provide training to pilot participants
3. Obtain feedback on strengths and areas for improvement
4. Track implementation of BQMS
5. Develop guidelines for audits and accreditation

APHIS BQMS

- Assist universities, companies and researchers to:
 - Analyze own operations
 - Identify control points where problems could occur
 - Apply mitigation measures to address potential problems

Background: What is BQMS?

- BQMS Standard designed on the concepts found within traditional quality management systems
 - ISO Quality Management
 - ISO Food Safety
 - ISO Traceability
 - Codex HACCP

8 Principles of BQMS

1. Focus on Meeting Regulatory Requirements
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continuous Improvement
7. Factual Approach to Decisions
8. Cooperative Supplier Relationship

BQMS Development

- BQMS Guidelines *how to*:
 - Develop and implement
 - Conduct a critical control point analysis to refine SOPs
 - Write SOPs
 - Conduct internal audits
 - Conduct root cause analysis

PHASE 1: INITIATION

PHASE 2: DEVELOPMENT

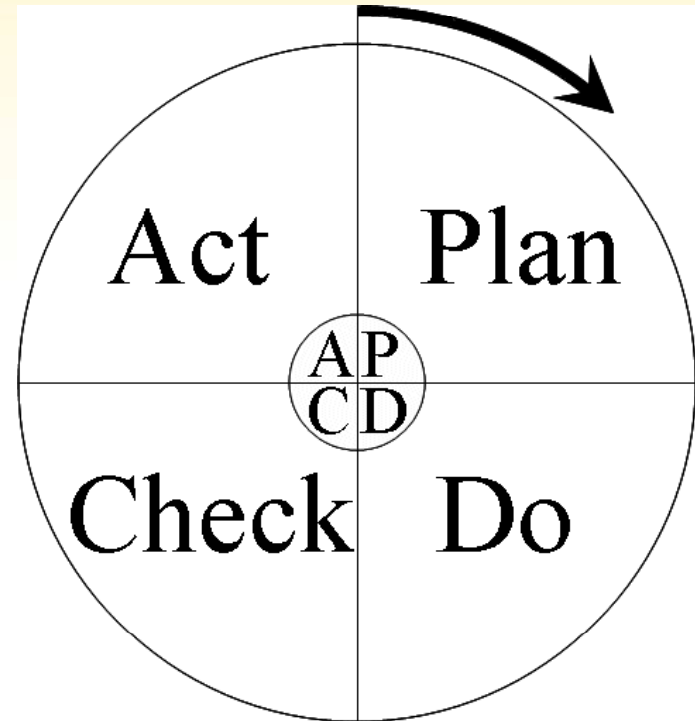
PHASE 3: IMPLEMENTATION

PHASE 4: ONGOING
MAINTENANCE AND
IMPROVEMENT

BQMS Development

Proactive and preventive:

- Management commitment
- Written procedures
- Internal audits by participant of own procedures
- Earlier detection of problems
- Minimize escalation of problems



APHIS BQMS

- The APHIS BQMS will:
 - *Augment* current BRS compliance operations
 - Be a flexible, audit-based program
 - Apply to specific activities covered by USDA-APHIS-BRS regulations (7 CFR 340)
 - Importation
 - Interstate movement
 - Environmental release



Why BQMS ?



Human Error:

- **Maintaining identity**
- **Field trial boundaries, isolation**
- **Labeling of viable material before and after trials**
- **Inadvertent mixing with food or feed crops**
- **Largely Avoidable**

Environmental Conditions:

- **Weather events (wind, rain, flooding, etc.)**
- **Human or Animal incursions**
- **Field Conditions**

BQMS Standard & Critical Control Points

- Scope – defined by the organization
- Quality Manual – identifies quality objective
 - SOPs and detailed work instructions
- Designated Quality Management Representative (QMR)
 - Manages QMS
 - Ensures training
 - Document control
 - Reports to top management



BQMS – Critical Control Points

- Storage
 - Labeling and containment
 - Segregation of regulated from non-regulated materials

- Movement, shipping
 - Tracking identity (traceability)
 - Meet 7 CFR 340 container requirements
 - Prevent accidental release



BQMS – Critical Control Points

- Environmental release
 - Planning
 - Isolation
 - Identity
 - Equipment cleaning
 - Monitoring

- Final disposition
 - Post-harvest processing
 - Preservation for future use
 - Devitalization and disposal

BQMS Standard & Critical Control Points

- Regulatory reporting requirements
 - Time sensitive
- Records of activities
- Communication/control of external associates
- Internal audits, control of nonconformance
- Continual evaluation and improvement
 - Corrective action

BQMS Operation



APHIS

- Program oversight
- Initiation of audits
- Review of audit reports



Agriculture Marketing Service (AMS)

- Audit service
- Accreditation of certifying bodies
(3rd Party Auditors)

BQMS Implementation

- After BQMS Pilot Development Project
- Establishment of:
 - Training programs for additional participants
 - Guidance on the Standard
 - Audit protocols
 - Accreditation protocols

BQMS Contacts

Questions?

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