USDA APHIS Biotechnology Quality Management System (BQMS) Program

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USDA APHIS BRS

National Alliance of Independent Crop Consultants Annual Meeting

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# Regulatory Operations Program

## Administrative Support

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Tom Sim</td>
<td>Director</td>
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<tr>
<td>Cathy Hill</td>
<td>Program Assistant</td>
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## Document Management Branch

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<thead>
<tr>
<th>Name</th>
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<tr>
<td>Steve Bennett</td>
<td>Branch Chief</td>
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<tr>
<td>D’Ann Clayton</td>
<td>Management Analyst</td>
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<tr>
<td>Cindy Eck</td>
<td>Document Control Officer</td>
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<td>Kim Diggs</td>
<td>Regulatory Permits Specialist</td>
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<td>Anita Drummond</td>
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<td>Mary Jackson</td>
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<td>Linda Lightle</td>
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<td>Denise McRae</td>
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<td>Kacie LaCovey</td>
<td>Permit Assistant</td>
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## Compliance and Inspection Branch

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<td>Emily Pullins</td>
<td>Branch Chief</td>
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<tr>
<td>Tracy Dukes</td>
<td>Staff Assistant</td>
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<td>Natalia Weinsetel</td>
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<td>Ed Jhee</td>
<td>BQMS Program Manager</td>
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<td>Andrea Marks</td>
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<td>Sr. Regional Biotechnologist Raleigh, NC</td>
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<td>Doug Grant</td>
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<td>Carl Etsitty</td>
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<tr>
<td>Dasha Sanchez</td>
<td>Program Support Assistant Fort Collins, CO</td>
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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
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
• 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
BQMS Development

Proactive and preventive:

- Management commitment
- Written procedures
- Internal audits by participant of own procedures
- Earlier detection of problems
- Minimize escalation of problems
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)
After BQMS Pilot Development Project

Establishment of:

- Training programs for additional participants
- Guidance on the Standard
- Audit protocols
- Accreditation protocols
Questions?

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