

Update on BRS Regulatory Operations

**BRS Stakeholder Meeting
November 20, 2013
Edward Jhee, Ph.D.**



**Biotechnology Regulatory Services
Animal and Plant Health Inspection Service**

Compliance Inspections

- 735 inspections issued in FY 2013
- Compliance rate of 98.06%



Compliance Inspections

- Plans for 2014?
 - Inspections based on planting activities
 - Number of authorizations
 - *Number of inspections will be based on the activities of the regulated community*



Compliance Enforcement

- Business Process Improvement
 - Reduce paperwork
 - Increase quality and consistency of compliance reviews
 - Increase timeliness of review and response



Compliance Assistance

- BQMS Program continues to grow
 - Total of 21 recognized participants
 - Collaborative relationship with Biotechnology Industry Organization (BIO) Excellence Through Stewardship (ETS) initiative



Compliance Assistance

- 2013 Permitting and Compliance Workshops
 - Virginia Tech, LSU, UT-Knoxville, Alabama-Huntsville,
 - With NIH at the Institutional Biosafety Committee meeting
- 2014: UC-Davis (December 10)
 - Send questions to brs.bqms@aphis.usda.gov



Permit and Program Services

- Business Process Improvement
 - Courtesy Permit Plant Inspection Station Bypass
 - Courtesy permits *still issued*
 - Documentation provided by BRS will expedite importation and routing to final destination
 - Roughly 600 courtesy permits issued annually
 - Eliminate blue/white labels
 - Federal savings over \$200K



BRS-ROP Plans for 2014

- ROP Strategic Plan
 - **Vision:** Increase public value through compliance-related activities
 - **Mission:** Protect American agriculture and the environment by ensuring compliance to the regulations for the introduction of GE organisms through compliance assurance, enforcement and assistance.



BRS-ROP Plans for 2014

- ROP Strategic Plan Goals
 1. Ensure compliance with regulations, respond promptly to noncompliance incidents and provide consistent and objective enforcement
 2. Provide compliance assistance to facilitate compliance to the regulations for the introduction of GE organisms
 3. Ensure high quality of inspections
 4. Align and advance resources to support BRS activities



BRS-ROP Management

- Director: Edward Jhee, Ph.D.
- Compliance Evaluation & Enforcement Branch (CEEB), Natalia Weinsetel, Ph.D.
- Western Compliance Assistance Branch (WCAB), Doug Grant, Ph.D.
- Eastern Compliance Assistance Branch (ECAB), Wendy Jin, Ph.D.
- Office of Compliance Assistance (OCA), Samantha Simon
- Permits and Program Services (PSS), Steve Bennett



Questions?

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