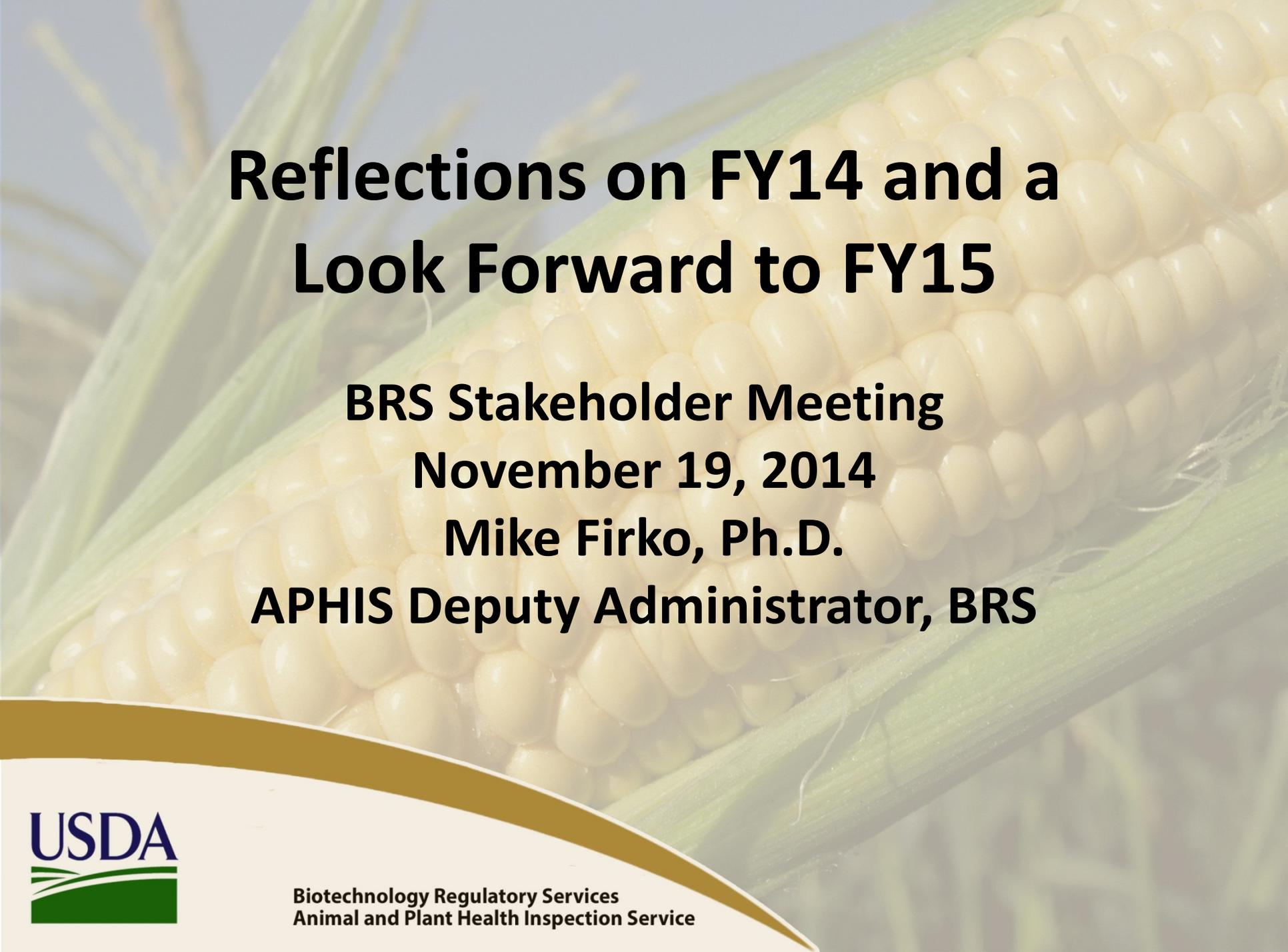


Biotechnology and USDA

Welcome!
BRS Stakeholder Meeting
November 19, 2014



Biotechnology Regulatory Services
Animal and Plant Health Inspection Service



Reflections on FY14 and a Look Forward to FY15

BRS Stakeholder Meeting

November 19, 2014

Mike Firko, Ph.D.

APHIS Deputy Administrator, BRS



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

APHIS Top Ten

- 7. Implement business process improvements for veterinary biologics and biotechnology and meet or exceed the goals to safely move important new technology to market faster**
- 8. Prevent citrus greening disease from causing damage in California**



CARPOL

- Certification, Accreditation, Registration, Permitting, and Other Licensing
- e-Permits will be replaced by “APHIS e-File”
- Permits and notifications are first functional area addressed in “APHIS e-File”
- Considerable time and resources are dedicated to an expeditious implementation
- Contract awarded to PhaseOne – Agile PM
- More from Mimi Fowler-Coristine later



Administrative Non-Regulatory Options

- This year, APHIS established a project to more fully explore alternatives to regulation/ rulemaking, and to help prepare our agency to succeed in reaching this goal. As part of this program, APHIS will:
 - Systematically consider non-regulatory options to address new, emerging or changing issues
 - Continue to pursue overarching or performance-based regulations when possible, and
 - **Consider flexibilities within existing regulations**



Regulatory Flexibilities

- Fresh look at utilization of APHIS extension process
- Am I Regulated (AIR): Determine if a GE organism is regulated under 7 CFR part 340 **BEFORE** the article is regulated
 - Does my GE organism meet the definition of a regulated article found at 7 CFR §340.1?
 - Developers encouraged – must initiate contact
 - Other APHIS authorities are considered



Petition Process Improvements

- FY14: completed seven petitions (2 more than estimated); **112** total determinations of nonregulated status to date
- Petitions backlog down to four (of 23):
 - Monsanto's Dicamba-Resistant Soybean
 - ArborGen's Freeze-Tolerant Eucalyptus
 - Scotts' Glyphosate-Resistant Creeping Bentgrass
 - Okanagan's Non-browning Apple



Small Developers Petition Guide

- Published guidance to the web for smaller developers/academia to assist in navigating the petition process
- Intended for petitioners having limited staff and resources with preparation of an effective petition application



APHIS Response to 360 Petition

- APHIS received a petition to add the Enlist 2,4-D, glyphosate and glufosinate-resistant corn and soybeans as Federal noxious weeds under 7 CFR part 360
- APHIS received a petition to add dicamba-resistant cotton and soybean as Federal noxious weeds under 7 CFR part 360
- Currently being analyzed



AC21: Enhancing Coexistence

- Advisory Committee on Biotechnology in the 21st Century
- High priority initiative of Secretary Vilsack and BRS continues to provide material support for this endeavor
- More from Neil Hoffman



Webcasting

- Webcasting or “virtual public comment meetings” enable broader participation without the time and expense of travel
- Continue to enhance the process for participants, exploring different systems to webcast and ways to encourage participation
- All public meetings will now include an option to participate remotely



Permitting and Compliance

- Continued to increase the effectiveness of our permitting, inspection and compliance program
- We authorized over 11,000 site locations via permit and notification - of these, only about 25% - 30% were planted, and trending down
- Resources could be utilized elsewhere within BRS



Permitting and Compliance

- Conducted three permitting and compliance training events for academic researchers and biosafety officers



Permitting and Compliance

- Processed 90% of permits and notifications within the designated timeframes
- Enhanced compliance program effectiveness by implementing a staff realignment to focus compliance efforts on inspections
- Increased inspections by over 5% from 2013, conducting over 700* inspections

**inspection number will not be final until the end of Q1 FY15*



BQMS

- Biotechnology Quality Management System
- 21 organizations now participate



GE Wheat

- Oregon investigation closed
 - APHIS was not able to determine how the GE wheat came to be in one field on one farm
 - Found no evidence of GE wheat in commerce
- Montana: Montana State University's Southern Agricultural Research Center (SARC)
- OR and MT volunteers are genetically different
- We will follow-up on current and future trials



Looking Forward to 2015

Our goal to enhance compliance by:

- Improving the authorization condition development process for clarity and enforceability
- Enhancing inspection and oversight processes
- Streamlining report handling
- Delivering a final BRS Compliance Incident Response Plan



Looking Forward to 2015

- We're evaluating the service/benefits provided by BQMS
- We want to focus this effort where it will have the greatest positive impact
- More info to come from Ed Jhee



New BRS ODA Personnel

- Janet Bucknall – APHIS Associate Deputy Administrator for BRS
- Donna Lalli, Ph.D. – BRS Chief of Staff



Any Questions?

