

Biotechnology and USDA

Welcome!
BRS Stakeholder Meeting
November 20, 2013



Biotechnology Regulatory Services
Animal and Plant Health Inspection Service



Reflections on FY13 and a Look Forward to FY14

BRS Stakeholder Meeting

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

Changing of the Guard



- Kevin Shea new APHIS Administrator
- Dr. Jere Dick APHIS Acting Associate Administrator
- Mike Gregoire APHIS Acting Associate Administrator
- Kevin Shea's Core Beliefs include:
 - Healthy and profitable agriculture is good for America.
 - Government's role is to do collectively what no one of us can do for ourselves.
 - APHIS needs to implement non-regulatory solutions when appropriate.



APHIS Top Ten

1. Complete the more than 30-year effort to eradicate **boll weevil** from the United States
2. Complete effort to eradicate the **European grapevine moth** in California
3. Establish a national feral swine control program
4. Reduce by at least half the number of detections of the cruel and inhumane practice of **horse soring** in the Tennessee walking horse industry
5. Fully implement a functioning **animal disease traceability** program that proves its traceback value after a disease detection
6. Ensure that the sterile **screwworm** rearing facility in Panama is operating well and providing complete assurance that we will maintain the barrier established at the Darien Gap
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**
9. Implement a multi-national system that reduces the threat of **tree pests** arriving from Asia and other parts of the world
10. Eliminate all remaining **BSE** barriers to export markets



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**



CY13: Year of the Shutdown

- October 1-16 shutdown caused by lapse in appropriations
- Some things in APHIS stayed open if they were covered by user's fees
- Resolution: Continuing Resolution (CR) until January; debt ceiling increase until February
- Provides challenges in long term planning
- Nevertheless, we have the resources in BRS to accomplish our mission
- What will happen in January/February? Your guess is as good as ours



Sequestration and CARPOL

- Certification, Accreditation, Registration, Permitting, and Other Licensing
- Because of sequestration, CARPOL spending put on hold
- We are now moving forward once again with CARPOL
- e-Permits will be replaced by new system
- Permits and notifications are first area addressed by CARPOL



Petition Process Improvements

- Process was taking too long
- By 2011, process had grown to 2 - 5 years, averaging 2.8 years
- Backlog reached as high as 22 petitions
- Business Process Improvement
 - Lean Six Sigma Analysis



Petition Process Improvements

- Significantly reduced time for reviewing a petition for completeness by 259 days
- Reduced time for preparing Plant Pest Risk Assessment (PPRA)
- Completed one petition so far: start to finish in 658 days, reducing the time from the old process by 364 days
- Reduced pending petitions to 15



Petition Process Improvements

- In FY13 completed 9 petitions, ~50% more than in previous two years, bringing total determinations of nonregulated status to 103
- Have completed first 4 petitions in path 1 NEPA process
- Developed new resource management and tracking tool for the petition process



AC21: Enhancing Coexistence

- Advisory Committee on Biotechnology in 21st Century
- Seeking public comments to identify ways to foster communication and collaboration among those involved in all sectors of agriculture production
- <http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0047-0001>
- Closes January 3, 2014



Webcasting Firsts

- Webcast 2012 BRS Stakeholder Meeting for first time
- Conducted first “virtual” public comment meetings on EISs for:
 - Eucalyptus
 - 2, 4-D-tolerant crops
 - dicamba-tolerant crops
- Both enable broader participation without the time and expense of travel



Permitting and Compliance

- Continued to increase the effectiveness of our permitting, inspection and compliance program
- We authorized over 10,000 releases via permits and notifications - of these, only about 25% - 30% were planted, and trending down
- These resources could be utilized elsewhere within BRS



Permitting and Compliance

- Published updated separation distances to our website for the most common field tested crops: alfalfa, corn, cotton, rice, rapeseed/canola, safflower, soybean, tomato, and wheat
- Conducted four inspection training events for APHIS and State inspectors to improve inspection consistency and collaboration
- Enhanced compliance by conducting four permitting and compliance workshops for academic researchers and biosafety officers



BQMS

- Biotechnology Quality Management System
- 21 organizations now participate
- 97.7% of the acreage of field trials are now conducted by BQMS participants, up from 92%
- Maintained ISO 9001:2008 registration for our program
- BQMS is an example of a nonregulatory solution



GE Wheat in One Oregon Field

- Discovered May 2013
- Investigation is ongoing
- The extent of the presence of this GE wheat remains the single detection of GE wheat volunteers in one field of one farm in Oregon
- Summary information will be released soon



International Engagement

- Provided capacity building assistance to developing countries
- Trilateral Working Group - US, Canada, Mexico - moving toward harmonization of biotechnology regulatory policies in North America
- Along with EPA, FDA, and FAS, we participated in bilateral discussions with Chinese biotech regulators
- Shared expertise on regulation of plants with stacked traits in workshop for Chinese regulators



International Engagement



- Provided training on US policies and regulations to over 20 countries, including Japan, China, Indonesia, Turkey, European Union, India, Kazakhstan, Brazil, Columbia, Vietnam
- Contributed to global discussions on potential trade issues resulting from low level presence of GE events approved by the country of export, but not the importing country
- Played key role in completion of the OECD document on low level presence in seed



Looking Ahead

- Continue to improve and enhance permitting, inspection, and compliance
- Work within BRS to examine our regulations, and identify areas that we think could be improved or strengthened, including possible nonregulatory solutions
- Help USDA create next version of what was formerly known as unified website



Looking Ahead

- Continue to work internationally to promote harmonization of biotechnology regulations in the global community
- Continue to strive to meet our petition process improvement targets



Questions?

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