Biotechnology Regulatory Services Update

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United States Department of Agriculture

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USDA
Biotechnology Regulatory Services
Animal and Plant Health Inspection Service

Outline

- BRS FY13 Goals
- Regulatory Activities
- State Partnership and Initiatives
- APHIS Plant Biotech Appropriations
- Detection of GE Wheat

BRS FY13 Goals

1. Expedite petition determinations
2. Make revisions to 7 CFR 340
3. Carry out an increasingly effective and efficient permitting, inspection and compliance program
4. Contribute to USG strategies on LLP and other issues
5. Advance USDA comprehensive import policy for GE plants and animals
6. Create a highly effective organization and contribute to APHIS modernization efforts and cost saving initiatives

Organizational Chart

Total: 87

Improved Petition Process

Step	New Process (# Completed)	New Process (# Ongoing)	Target (Days)	Actual (Days)	Diff. (Days)	Previous[1] (Days)	Savings (Days)
Completion of initial petition review	6	0	35	28	-7	205	-177
Response from petitioner	6	0	30	26	-4	107	-81
Completion of final petition review	8	0	21	35	+14	39	-4
Preparation of draft PPRA	8	2	60	70	+10	143	-73
60-Comment on petition	13	0	60	60	0	n/a	+60
Preparation of draft EA	5	6	180	237	+57	213	+24

[1] Average of all petitions using old process since 2005

FY13 Regulatory Decisions

Recent Approvals (5)

- Bayer TwinLink Cotton (extension)
- Syngenta Rootworm Resistant (*Bt*) Corn
- Stine Seed Farm herbicide tolerant Corn
- Pioneer Glufosinate/IR Corn
- Pioneer Glyphosate Tolerant Canola

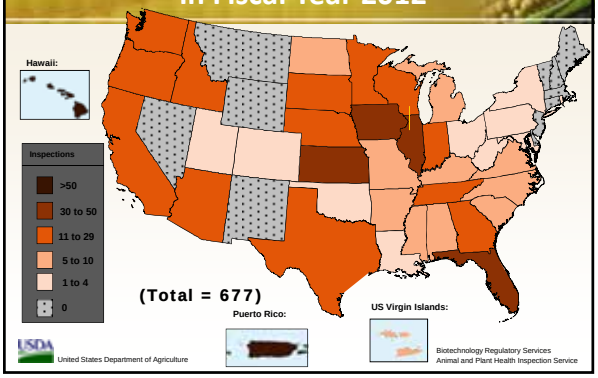
Preliminary Determinations (4)

- Monsanto Glyphosate Resistant Canola
- Genective Glyphosate Resistant Corn
- Monsanto Hybridization System Corn
- Monsanto High Yield Soybean

Environmental Impact Statements

- Freeze Tolerant Eucalyptus
- 2,4-D resistant corn and soybean
- Dicamba resistant soybean and cotton

USDA Biotech Inspections Completed in Fiscal Year 2012



Inspection Partnership

State Inspection Program

- 2013 participant States
  - Arkansas, Kansas, Florida, North Carolina, Minnesota

FY	States	Total Inspections
08	AR, KS	26
09	AR, KS, FL, NC	35
10	AR, KS, FL, NC	47
11	AR, KS, FL, NC	64
12	AR, KS, FL, NC, MN	60
13	AR, KS, FL, NC, MN	73

Inspection Partnership

State	Inspections conducted by State	Total Inspections	% conducted by State
Florida	19	45	42
Minnesota	6	12	50
Kansas	19	34	53
North Carolina	6	10	60
Arkansas	8	8	100

State Initiatives

CBI-Sharing Proposed Rule

- Proposed February 27, 2013
- Comment Period closed April 29
- 8 Comments
  - "Certain" Business Information vs Confidential Business Information
  - Paper vs Electronic Delivery
- Currently in Open Rulemaking

APHIS Plant Biotech Appropriation

- Budget
  - FY13: $16.7 Million (post sequestration and rescission)
  - FY14:
    - President's Budget: $18.2 Million
    - Senate: $18.2 Million
    - House: $18.2 Million

Detection of GE Wheat

- Reported to BRS on May 3
- Volunteers found on 123 acre field in Oregon
- Extensive testing performed on volunteers
- Confirmed as a Monsanto GT wheat event that was field tested in 1998-2005

Detection of GE Wheat

- Ongoing, active investigation
  - Interviews
  - Sample collection
  - Testing

Detection of GE Wheat

- USDA is working with trading partners to reopen markets
  - Japan – tenders open
  - Korea
- Who's testing wheat?
  - Japan
  - Korea
  - Taiwan
  - Turkey

For More Information

USDA-APHIS-BRS:
http://www.aphis.usda.gov/biotechnology/brs_main.shtml

EPA:
http://www.epa.gov/pesticides/biopesticides/pips/index.htm

FDA-CFSAN:
http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm2006889.htm