Biotechnology Regulatory Services Update

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Biotechnology Regulatory Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

National Plant Board
July 29, 2014
Outline

- BRS FY14 Goals & Organization
- Regulatory Activities
  - FY14 Decisions
  - CBI Sharing Rule
- Inspections & State Partnership
- Hot Issues
- County Level Statutes
BRS FY14 Operational Goals

1. Maintain and Enhance Compliance

2. Balance Oversight and Risk

3. Ensure the Best Science is used in Decision-making

4. Create a Highly Effective Organization
# Improved Petition Process

<table>
<thead>
<tr>
<th>Step</th>
<th>New Process (# Completed)</th>
<th>New Process (# Ongoing)</th>
<th>Target (Days)</th>
<th>Actual (Days)</th>
<th>Diff. (Days)</th>
<th>Previous¹ (Days)</th>
<th>Savings (Days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of initial petition review</td>
<td>9</td>
<td>0</td>
<td>35</td>
<td>29</td>
<td>-6</td>
<td>205</td>
<td>-176</td>
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<tr>
<td>Response from petitioner</td>
<td>9</td>
<td>0</td>
<td>30</td>
<td>26</td>
<td>-4</td>
<td>107</td>
<td>-81</td>
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<tr>
<td>Completion of final petition review</td>
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<td>0</td>
<td>21</td>
<td>29</td>
<td>+8</td>
<td>39</td>
<td>-10</td>
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<tr>
<td>Preparation of draft PPRA</td>
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<td>1</td>
<td>60</td>
<td>90</td>
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<td>143</td>
<td>-53</td>
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<tr>
<td>60-Comment on petition</td>
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<tr>
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<tr>
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<td>1</td>
<td>44</td>
<td>40</td>
<td>-4</td>
<td>91</td>
<td>-51</td>
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</tbody>
</table>

¹ Average of all petitions using old process since 2005
Recent Approvals (4)

- Monsanto Increased Yields Soybean
- BASF Herbicide (imidazolinone) Resistant Soybean
- Dow Insect Resistant and Herbicide Tolerant Soybean
- Syngenta mesotrione and glufosinate Tolerant Soybean
CBI Sharing Rule

- Withdrawal of CBI Sharing Rule published on July 18, 2014
- Potential vulnerability associated with FOIA was identified.
  - Under FOIA, States and Tribes are considered members of the public
  - Once APHIS discloses information to one member of the public, information may be subject to release to other members of the general public through FOIA.
FY 2013 USDA Biotech Inspections Completed

(Total = 677)
### State Inspection Program

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

<table>
<thead>
<tr>
<th>FY</th>
<th>States</th>
<th>Total Inspections</th>
</tr>
</thead>
<tbody>
<tr>
<td>08</td>
<td>AR, KS</td>
<td>26</td>
</tr>
<tr>
<td>09</td>
<td>AR, KS, FL, NC</td>
<td>35</td>
</tr>
<tr>
<td>10</td>
<td>AR, KS, FL, NC</td>
<td>47</td>
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<td>11</td>
<td>AR, KS, FL, NC</td>
<td>64</td>
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<tr>
<td>12</td>
<td>AR, KS, FL, NC, MN</td>
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<td>13</td>
<td>AR, KS, FL, NC, MN</td>
<td>79</td>
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<tr>
<td>14</td>
<td>AR, KS, FL, NC, MN</td>
<td>35 (as of July 21)</td>
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</table>

(States with the字母AR, KS, FL, and NC are not specified in the table, but inferred to be included based on the information provided.)
## FY13 State Inspections

<table>
<thead>
<tr>
<th>State</th>
<th>Inspections conducted by State</th>
<th>Total Inspections</th>
<th>% conducted by State</th>
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</thead>
<tbody>
<tr>
<td>Florida</td>
<td>27</td>
<td>37</td>
<td>73</td>
</tr>
<tr>
<td>Minnesota</td>
<td>8</td>
<td>12</td>
<td>67</td>
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<tr>
<td>Kansas</td>
<td>26</td>
<td>33</td>
<td>79</td>
</tr>
<tr>
<td>North Carolina</td>
<td>7</td>
<td>16</td>
<td>44</td>
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<tr>
<td>Arkansas</td>
<td>11</td>
<td>11</td>
<td>100</td>
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</tbody>
</table>
Other Topics of Interest

- 2,4-D resistant corn and soybean EIS
- Dicamba resistant soybean and cotton EIS
- Report of Investigation for OR GE Wheat
## County GE Regulation

### Enacted

- Mendicino, CA (2004)
- Marin, CA (2004)
- Trinity, CA (2004)
- San Cruz, CA (2004)
- San Juan, WA (2012)
- Kauai, HI (2013)
- Hawai‘I, HI (2013)
- Jackson, OR (2014)
- Josephine, OR (2014)

### Pending

- Maui, HI
- Benton, OR
- Lane, OR
- Humboldt, CA
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
Questions?
History of Plant Breeding

Before 1900

1900

Classical Breeding

Cell Fusion
Chemical Mutants
X-ray Mutants

1980

Add Specific DNA
(Genetic Engineering)
GE Plant Development

LABORATORY / GREENHOUSE
(not regulated by APHIS)

FIELD TESTING
(regulated by APHIS)

COMMERCIALIZATION
(not regulated by APHIS)
Introduction of a New Trait
Using Classical Breeding
Cross Back-cross
Gene for virus resistance
Transfer of gene through breeding
Chemical Mutagenesis/ X-Ray Mutants

Select for different traits for breeding or marketing
Introduction of a New Trait Using Genetic Engineering

Resistant to virus

Isolate gene for virus resistance; insert into target plant

Gene for virus resistance, from plant or plant virus

What is unique about genetic engineering?

Transfer of genes between non-sexually compatible species
## History of Plant Breeding

<table>
<thead>
<tr>
<th>Not Regulated</th>
<th>Regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classical Breeding</strong></td>
<td><strong>Add Specific DNA from Certain Hosts</strong></td>
</tr>
<tr>
<td><em>(Before 1900)</em></td>
<td><em>(After 1980)</em></td>
</tr>
<tr>
<td><strong>Cell Fusion</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Chemical Mutants</strong></td>
<td></td>
</tr>
<tr>
<td><em>(After 1900)</em></td>
<td></td>
</tr>
<tr>
<td><strong>X-Ray Mutants</strong></td>
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</table>