Biotechnology Regulatory Services

Update

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Biotechnology Regulatory Services

National Plant Board
August 15, 2017
BRS’ Two Primary Services

1. Regulate certain GE products
   - Protect Plant Health
   - Critical to Domestic Agriculture
   - Critical to Exports of U.S. Commodities

2. Deregulate GE products
   - Same as above
Primary BRS Accomplishments & Progress Since Last NPB Meeting (1 of 3)

- Publish Proposed Rule
- Three Public Meetings
- Four deregulations
  - Apple, potato, creeping bentgrass, canola
- GE Petunia
GE Petunia
All are GE
Primary BRS Accomplishments & Progress Since Last NPB Meeting (2 of 3)

- Updated BQMS (Biotechnology Quality Management System)
- Progress on APHIS eFile
- Initiate BPI: “Am I Regulated” process
- GE Diamondback Moth EA and permit
Diamondback Moth
Primary BRS Accomplishments & Progress Since Last NPB Meeting (3 of 3)

- Published dEIS for freeze tolerant Eucalyptus
- Initiate EIS for Florida-wide release of GE CTV for control of HLB
## Authorized Activities with Regulated Articles, FY16

<table>
<thead>
<tr>
<th>Number of Release Authorizations</th>
<th>Number of Release Sites</th>
<th>Number of Phenotypic Designations (crop-trait combos)</th>
</tr>
</thead>
<tbody>
<tr>
<td>485</td>
<td>5,368</td>
<td>50,363</td>
</tr>
</tbody>
</table>
FY16 Authorizations and Field Release Sites by Crop

<table>
<thead>
<tr>
<th>Crop</th>
<th>Authorizations</th>
<th>Release Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn</td>
<td>240</td>
<td>3815</td>
</tr>
<tr>
<td>Soybean</td>
<td>77</td>
<td>1015</td>
</tr>
<tr>
<td>Cotton</td>
<td>21</td>
<td>184</td>
</tr>
</tbody>
</table>

>>> 94% of All Field Releases
FY16 Authorizations and Field Release Sites by Crop

Not shown in chart

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>>> 94% of All Field Releases
FY16 Biotechnology Authorized Sites (n = 5,363)

# of Authorized Sites

- >300
- 101 to 300
- 51 to 100
- 1 to 50
- 0

Hawaii: 1,067
Puerto Rico: 929
US Virgin Islands: 3
FY 2016 Biotechnology Inspections (n = 815)

- Puerto Rico
- US Virgin Islands
- Hawaii

# Inspections

- >50
- 26 to 50
- 16 to 25
- 1 to 15
- 0

- Hawaii: 98
- Puerto Rico: 82
- US Virgin Islands: 2
FY16 Inspections Conducted by States (n = 57)
Proposed Regulatory Revisions

• Proposed Rule published January 19, 2017

• Comment Period remained open for five months… until June 19
Documents Available To Public


• Proposed Rule
• draft Programmatic Environmental Impact Statement (dPEIS)
• Regulatory Impact Analysis (RIA)

www.aphis.usda.gov

• Questions & Answers
• Proposed Regulatory Status Evaluation Data Requirements
• Weed Risk Assessment System
• Proposed Permit Data Requirements
• Stakeholder Announcement
• List of evaluated GE organisms and their proposed regulatory status
From 340 Proposal Supporting Material, Web

<table>
<thead>
<tr>
<th>Category</th>
<th>Phenotype</th>
<th>Mechanism of Action</th>
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</thead>
<tbody>
<tr>
<td>Corn</td>
<td>Agronomic Property</td>
<td>All</td>
</tr>
<tr>
<td>Corn</td>
<td>** Bacterium Resistant</td>
<td>All</td>
</tr>
<tr>
<td>Corn</td>
<td>** Fungus Resistant</td>
<td>All</td>
</tr>
<tr>
<td>Corn</td>
<td>Herbicide Resistant</td>
<td>ACCase-Inhibitor Resistant</td>
</tr>
<tr>
<td>Corn</td>
<td>Herbicide Resistant</td>
<td>*Dicamba Resistant</td>
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<tr>
<td>Corn</td>
<td>Herbicide Resistant</td>
<td>2, 4-D Resistant</td>
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<tr>
<td>Corn</td>
<td>Herbicide Resistant</td>
<td>Glufosinate Resistant</td>
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<td>Corn</td>
<td>Herbicide Resistant</td>
<td>Glyphosate Resistant</td>
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<tr>
<td>Corn</td>
<td>Herbicide Resistant</td>
<td>Imidazolinone Resistant</td>
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<tr>
<td>Corn</td>
<td>** Insect Resistant</td>
<td>All</td>
</tr>
<tr>
<td>Corn</td>
<td>** Nematode Resistant</td>
<td>All</td>
</tr>
<tr>
<td>Corn</td>
<td>Product Quality</td>
<td>All</td>
</tr>
</tbody>
</table>

** Table shows USDA regulatory status, EPA may regulate
“Laws are like sausages, it is better not to see them being made.”

- Otto von Bismarck
Questions ?