USDA APHIS Requirements

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USDA APHIS BRS ROP

National Alliance of Independent Crop Consultants
Annual Meeting
Tucson, AZ
January 18, 2018
APHIS BRS Requirements

Outline

– APHIS Biotechnology Regulatory Services
– What we regulate
– Regulatory Operations Program
– FY17 Accomplishments and changes
– Inspection selection, types, and numbers
– What to expect during an inspection
– Do’s and Don’ts
What Triggers our Regulations?

• APHIS regulates the following activities for regulated articles:
  
  • Importation
  • Interstate movement
  • Environmental release/field test

*Field releases = highest risk*
Goals of BRS Regulation

*Overall:* Protect Plant Health and Domestic Agriculture

Ensure that:

- Regulated material is properly contained
- Regulated GE material **does not** mix with food/feed
  - Ensure regulated materials stay out of food supply until food/feed safety assessment completed by FDA
  - *Critical for exportation of U.S. Commodity*

- GE organisms **do not** persist in the environment after the field trial is terminated
Permits and Notifications

• Permit conditions and design protocols: to prevent the unintended release of the regulated article

• Regulatory requirements to minimize the possibility that the organism will:
  – Persist in the environment
  – Produce offspring that will persist
    • Within crop species or wild relatives
  – Significantly impact non-target organisms
Regulatory Operations Program

- **Conducts** inspections to verify compliance with regulations
  - *All field trial sites are eligible for inspection*
  - *A subset of field sites are inspected, some sites inspected more than once*
- **Reviews** all inspection reports for compliance
- **Concludes** all inspections with a letter to permittee
  - *Potential compliance incidents thoroughly evaluated*
  - *Steps taken to ensure future compliance*
Analysis of Reports from Regulated Entities

BRS receives hundreds of reports every year
  - i.e. planting reports, volunteer monitoring reports, field test reports

- Planting reports used to select what will be inspected
- Other reports are also used to generate inspections
  - i.e. post-harvest inspections based on volunteer monitoring reports
Published Proposed Rule for revisions to Title 7 Code of Federal Regulations part 340 (7 CFR part 340)

- Published 19 January 2017
- Conducted three Public Meetings in June 2017
  - Kansas City, MO
  - Davis, CA
  - Riverdale, MD
FY 17 Primary BRS
Accomplishments & Progress

208 comments

• Many praised APHIS’ approach to advances in science
• Half/Half on Noxious Weed Authority
• Concern about up-front risk assessment
• Concern about new scope of regulations
  • Concern about under-regulation
  • Concern about over-regulation
Proposed Rule for revisions to 7 CFR part 340

- Withdrawn on 07 November 2017, based on:
  - Comments received
  - Interest in additional stakeholder engagement
Biotechnology Quality Management Support
BQMS

• The System
  – Modules
  – Workshops
  – Assistance
BQMS Program (2017 onward)

- **Voluntary** Compliance Assistance Program
- Available to anyone regulated by BRS
- Objectives:
  - Improve participant’s compliance with 7 CFR part 340
  - Improve participants’ awareness of their regulatory responsibilities and APHIS’ regulatory processes
Regulatory Operations Program

- 2017 Accomplishments
- Process Improvement
- 2018 Compliance Oversight
2017 Key Accomplishments

- Business Process Improvement
  - Planting Reports
  - Volunteer Monitoring Reports
  - Field Test Reports
- Inspections
  - Increased BRS-conducted Inspections
    - Over 60% done by BRS staff
    - Continued partnership with PPQ / States
Notices of Finding (NOFs)

- Received feedback
- Reviewed processes
- Increased communication
- Resolved compliance issues efficiently
2018 Focus – Compliance Oversight

• Appeals Process
• Monitoring and Evaluation Interviews
  – In-season or after trial termination (post-harvest)
  – Supplement compliance inspections
• Inspection Selection improvements
2018 Focus – Compliance Oversight

- Inspection Selection
## BRS Inspections by the Numbers

<table>
<thead>
<tr>
<th></th>
<th>FY16</th>
<th>FY17</th>
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<tbody>
<tr>
<td># of Inspections (total)</td>
<td>815</td>
<td>759</td>
</tr>
<tr>
<td># of Post-Harvest</td>
<td>147</td>
<td>185</td>
</tr>
<tr>
<td># of Unannounced</td>
<td>56</td>
<td>49</td>
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</table>
FY16 Plantings and Inspections
FY16 Inspections
FY17 Inspections
FY17
What to Expect During an Inspection

• Review of Authorization (Permit or Notification)
• Map, GPS coordinates of planting
• Design Protocols or SOPs
  – Used to meet Performance Standards - 7 CFR 340.3 (c)
  – Methods of confinement (physical isolation, etc.)
  – Methods for devitalization/disposal
• Records:
  – Constructs planted (if not submitted on planting report)
  – Equipment cleaning
  – Training of employees
  – Monitoring for deleterious effects
  – Volunteer monitoring
Do’s and Don’ts

Do:
• Reply to inspector calls, emails
• Keep records, map, GPS coordinates
• Answer questions, ask Permit/Notification holder if unsure
• Monitor separation distance
• Be prepared to monitor for and remove volunteer plants

Don’ts:
• Allow regulated material to mix with non-regulated
• Allow volunteers to persist and reach maturity
• Forget to clean equipment
• Ignore APHIS requests for information related to compliance
• Be afraid to ask questions
BRS website: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology