USDA APHIS Requirements

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Eastern Compliance Assurance Branch
USDA APHIS BRS ROP

National Alliance of Independent Crop Consultants
Annual Meeting
January 19, 2017
Outline

- Regulating Biotechnology
- Notifications and Permits
- Determinations of Nonregulated Status
- Confined Field Trials
- What to Expect During an Inspection
- Things to Avoid
- Sources of Information
Biotechnology Regulatory Services

BRS Mission:
Protect and enhance U.S. agricultural and natural resources using a science- and risk-based regulatory framework to ensure the safe importation, interstate movement, and confined environmental release of regulated GE organisms.
Coordinated Framework

Most products are regulated by more than one agency
Biotechnology Regulation

- Regulated Status — An Introduction = Importation, Interstate Movement, or Field Testing (Release)
  - Permit
  - Notification

- Nonregulated Status — Removed from APHIS Oversight
  - Petition
Consist of 1 important document, the **Issued Permit:**

- Based on the application – organism, phenotypes, constructs, locations (GPS), proposed dates
- Includes **Standard Permit Conditions**  
  (7 CFR 340.4 f)
- Also includes **Supplemental Permit Conditions** – specific to the test organism and other parameters of the trial
Notifications

- Consist of 3 important documents:
  - **The application** – organism, phenotypes, constructs, locations (GPS), proposed dates
  - **Acknowledgment Letter** – approved dates for importation, interstate movement, or planting of field trials
    - Outlines Performance Standards (7 CFR 340.3 c)
  - **Design Protocols** – methods approved to be followed in order to meet the performance standards
Your notification request has been acknowledged and may be executed according to 7 CFR § 340.3(c). You are authorized to perform the importation of the regulated article between January 9, 2015 and January 9, 2016. All activities related to this introduction (except for any monitoring periods) must be completed by the expiration date (i.e. all shipments must have arrived at their destination, plants harvested, and all remaining plants and plant parts are either destroyed or moved into contained facilities).

In the event of any accidental and/or unauthorized release of the regulated article, contact BRS Compliance Evaluation and Enforcement Branch by phone (301) 851-3935 or e-mail at BRSCompliance@aphis.usda.gov

Some key details of your notification are shown here:

Importation
Notification No. 14-995-105n
Regulated Article - Barley
Origin - Pirahna, Australia
Destination - Petersburg, Iowa

***This acknowledgement letter must be provided to all cooperators.***
***Planting Report Information - All Releases & Movement / Release Notifications Only***

APHIS requires that responsible parties submit a Planting Report no later than the 15th day of the month that follows the date the environmental release occurred (e.g., a planting any time April 1-30 must be reported by May 15). This report provides APHIS with additional details about the actual releases that have taken place under an acknowledged notification. The report must include: the Notification number; name of the regulated article; trial site location data (provide state, county, northwest GPS coordinate, and site identification number (if available); acreage of regulated article planted; and planting date for each location. For additional information on planting reports see the Notification Users Guide: http://www.aphis.usda.gov/biotechnology/downloads/notification_guidance_1109.pdf

Planting Reports should be submitted via ePermits or emailed to BRS:

The planting report should be submitted via email to BRSCompliance@aphis.usda.gov, or via mail (preferabley on compact disc) or fax to:
Petition Evaluation

- Applicant provides information and data upon which to base a determination

- APHIS BRS conducts two evaluations:
  - Plant Pest Risk Assessment (PPRA)
    - To determine if the GE organism poses a risk as a plant pest (Plant Protection Act of 2000)
  - Environmental Assessment (EA) or Environmental Impact Statement (EIS)
    - To evaluate environmental impacts of the APHIS-BRS determination, as required under NEPA
**GE Plants with Nonregulated Status**

- Determinations of nonregulated status:
  - over 100 petitions, representing **17 plant species**

- Petition Table:

Applicant provides information on:

- biology of the organism
- environment, location and conditions of the release including:
  - measures to maintain physical isolation and reproductive isolation
- site security, monitoring, and inspection
- methods of devitalization and disposal, post-harvest (volunteer) monitoring
Goal of notifications and permits: 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
Eastern and Western Compliance Assurance Branches

- Management of planting report information
- Management of inspections
- Training of inspectors
- Conduct inspections
- Participate in field investigations
- Proactively promote compliance
  - Participate in education and outreach activities
  - Serve as a resource
  - Provide guidance
All sites are eligible for inspection

Notifications
randomly selected from planting report information

Permits
inspected at least once in each state with a release each year

Inspections conducted at any point during the growing season, or may be after growing season (post-harvest)

Follow-up inspections may be conducted

Locations inspected at a higher frequency:
  o winter nurseries
  o large-scale trials
  o All wheat sites inspected
## Inspection Partnership

- **BRS, PPQ and State Departments of Ag**
  - 2016 participant States: Arkansas, Kansas, North Dakota, Florida, North Carolina, Minnesota, Wisconsin

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<th>FY</th>
<th>States</th>
<th>Total Inspections</th>
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### Notification Sites Planted in FY15

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<td><strong># of Authorized Sites</strong></td>
<td>8826</td>
<td>6528</td>
<td>5988</td>
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<tr>
<td><strong># of Actual Planted Sites</strong></td>
<td>2606</td>
<td>1663</td>
<td>1019</td>
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<tr>
<td><strong>% Planted</strong></td>
<td>29.5</td>
<td>25.5</td>
<td>17.0</td>
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## Permit Sites Planted in FY15

<table>
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<th>FY 11</th>
<th>FY13</th>
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</thead>
<tbody>
<tr>
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<td>1627</td>
<td>4044</td>
<td>1947</td>
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<tr>
<td># of Actual Planted Sites</td>
<td>864</td>
<td>1333</td>
<td>443</td>
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<tr>
<td>% Planted</td>
<td>53.1</td>
<td>32.9</td>
<td>22.8</td>
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USDA Biotech Inspections Conducted in Fiscal Year 2016
(Total = 797)
Compliance

- We continue to build our staff of Regulatory Analysts who conduct inspections as part of their duties
  - BRS now has staff in 8 states plus PR
- In FY2016... ~60% of inspections conducted by BRS Regulatory Analysts (Up from 2-3% a few years ago)
  - ~30% APHIS-PPQ, ~10% State
Enhanced Compliance Oversight

- OIG recommendations
- Continuation of business process improvement
- Enhancing inspection program
Inspector Access

- 7 CFR 340.4(f)(5) - Permits
  - (5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article;

- 7 CFR 340.3(d)(6) - Notifications
  - (6) Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field test sites and any records necessary to evaluate compliance with the provisions of paragraphs (b) and (c) of this section.
Planting Report Information

- Notification or permit number
- Crop species
- Planting date
- Planting location (unique location IDs)
- Acreage
Inspection Goals

- Verify compliance with regulatory requirements (7 CFR 340)
  - Using multiple methods of verification
- Keeping regulated material separate from non-regulated material
  - Out of food and feed supply
- Prevent instances of low level presence (LLP)
- Safeguarding American Agriculture
What to Expect During an Inspection

- Inspector calls to schedule inspection but may not give much notice
- Inspector gathers names of all present
- Reviews documents and records
  - Including an up-to-date map
- Asks questions about past activities and future plans
- Makes observations, takes measurements
What to Expect
Inspection of Paperwork

- Authorization (Permit or Acknowledgement Letter)
- 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 for:
  - Equipment cleaning
  - Training of employees
  - Monitoring for deleterious effects
  - Volunteer monitoring
What to Expect During an Inspection
What to Expect
Inspection of Paperwork

- Shipping/Packing
  - Quantity received - Inventory list
  - Containers, labelling
  - Cleaning, disposal

- Map
Shipping Containers

20 lbs. Wheat seed
USDA Regulated Material

Notification/Permit:
16-995-105 R/M
January 19, 2017
Maps of Field Trial Locations

- Map obtained from cooperator
- GPS coordinates compared
- Map notes locations of other regulated trials in vicinity
- Map should include points of reference (e.g. roads, buildings)
- Map required with each inspection report
Example Plot Map of Trial

USDA Number: 16-995-103N
Species: corn

Non-regulated corn

35.77248, -78.67742
What to Expect

Inspection of Material

- **Regulated Material**
- **Storage Area**
  - Identity
  - Secure
  - Regulated separate from non-regulated
- Any other regulated trials at site
  - Permit/Notification numbers
  - Locations of sites
What to Expect
Inspection of Site

- Visit Trial Site
- Identity maintained (lines, events)
- Size of field trial
- GPS coordinates
- Isolation
- Sexually compatible plants
- Expected date of harvest/termination
- Fate of regulated material
- Plans for trial site
Avoid Compliance Issues

- Obtain authorization from BRS prior to importation, interstate movement, or environmental release
- Plan for controlling volunteers following field trial
- Remember to submit planting reports on time
  - Timeframes indicated on issued permit or acknowledgement letter
- Submit other reports and notices as required, such as volunteer monitoring reports
- Maintain separation/isolation distance
- Prevent expected animal incursions
- Cooperate with inspectors
- Self-reporting is required for loss of confinement (unusual occurrence)
Biotechnology Quality Management Support Program (BQMS)

Accurate and trustworthy information

Repository

Document Control Assistance

Internal Control Assistance

BQMS Critical Control Point Assistance

Process Improvement Assistance
Information Systems for Biotechnology

Information Systems for Biotechnology (ISB) provides information resources to support the environmentally responsible use of agricultural biotechnology products. Here you will find documents and searchable databases pertaining to the development, testing and regulatory review of genetically engineered (GE) plants, animals and microorganisms within the United States and abroad.

Spotlights

- Monthly News Report
- Guidance on Biotechnology Research

Important Announcements

Search Biotechnology Data

ISB provides a search tool that can be used to search the release and petition data on a variety of criteria including location, gene, phenotype, regulated article, and more. Charts for visualizing data based on location, phenotype and summary data.

Search Biotechnology Data (Updated daily on weekdays by 7:00 AM)

Search Biotechnology Charts

ISB provides a tool to build charts for visualizing data based on location, phenotype and summary data.

View Biotechnology Data Charts (Updated daily on weekdays by 7:00 AM)
For More Information

USDA APHIS BRS:
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology

General Inquiries:
biotechquery@aphis.usda.gov

BQMS:
BRS.BQMS@aphis.usda.gov