Biotechnology Regulatory Services (BRS)
Stakeholder Meeting

November 15, 2017
BRS Reflections on FY17, A Look Forward to FY18

BRS Stakeholder Meeting, November 15, 2017

Michael Firko, Ph.D
APHIS Deputy Administrator
Biotechnology Regulatory Services
USDA Motto

Do right and feed everyone.

- USDA Secretary Sonny Perdue
## FY17 Authorizations & 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>188</td>
<td>2,646</td>
</tr>
<tr>
<td>Soybean</td>
<td>64</td>
<td>657</td>
</tr>
<tr>
<td>Cotton</td>
<td>14</td>
<td>162</td>
</tr>
</tbody>
</table>

**Percent of total**  
- 71%  
- 94%
FY17 Authorizations & Release Sites by Crop

<table>
<thead>
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<tr>
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<td>14</td>
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</tr>
<tr>
<td><strong>Percent of total</strong></td>
<td><strong>71 %</strong></td>
<td><strong>94 %</strong></td>
</tr>
</tbody>
</table>

Crop Authorizations Release Sites

- Tobacco
- Fruit and nut trees
- Forest trees
- Tomato
- Potato
- Wheat
- Canola
- Safflower
- Rice
- Sorghum
- Other

**Corn, Soy & Cotton Not Shown in Chart**
## Authorized Activities with Regulated Articles, FY16: Notifications

<table>
<thead>
<tr>
<th></th>
<th>Import Only</th>
<th>Interstate Only</th>
<th>Release (Field Trial)</th>
<th>TOTAL</th>
<th>Percent of Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>150</td>
<td>378</td>
<td>273</td>
<td>801</td>
<td>-</td>
</tr>
<tr>
<td>Withdrawn</td>
<td>26</td>
<td>51</td>
<td>26</td>
<td>103</td>
<td>13%</td>
</tr>
<tr>
<td>Pending</td>
<td>2</td>
<td>1</td>
<td>12</td>
<td>15</td>
<td>2%</td>
</tr>
<tr>
<td>Denied</td>
<td>2</td>
<td>18</td>
<td>5</td>
<td>25</td>
<td>3%</td>
</tr>
<tr>
<td>Authorized</td>
<td>120</td>
<td>308</td>
<td>230</td>
<td>658</td>
<td>82%</td>
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## Authorized Activities with Regulated Articles, FY16: Permits

<table>
<thead>
<tr>
<th></th>
<th>Import Only</th>
<th>Interstate Only</th>
<th>Release (Field Trial)</th>
<th>TOTAL</th>
<th>Percent of Received</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Received</strong></td>
<td>77</td>
<td>173</td>
<td>158</td>
<td>408</td>
<td>-</td>
</tr>
<tr>
<td><strong>Withdrawn</strong></td>
<td>26</td>
<td>34</td>
<td>11</td>
<td>71</td>
<td>17%</td>
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<tr>
<td><strong>Pending</strong></td>
<td>6</td>
<td>14</td>
<td>18</td>
<td>38</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Denied</strong></td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Authorized</strong></td>
<td>42</td>
<td>123</td>
<td>126</td>
<td>291</td>
<td>71%</td>
</tr>
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</table>
Authorized Activities with Regulated Articles, FY17

<table>
<thead>
<tr>
<th>Number of Release Authorizations</th>
<th>Number or Release Sites</th>
<th>Number of Phenotypic Designations (crop-trait combination, all activities)</th>
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</thead>
<tbody>
<tr>
<td>356</td>
<td>3,724</td>
<td>45,194</td>
</tr>
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</table>
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 during June 2017
  - Kansas City, MO
  - Davis, CA
  - Riverdale, MD
FY 17 Primary BRS
Accomplishments & Progress (1b of 5)

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
• Concern about too much regulatory relief
FY 17 Primary BRS
Accomplishments & Progress (1c of 5)

Proposed Rule for revisions to 7 CFR part 340

• Withdrawn on 07 November 2017, based on:
  • Comments received
  • Interest in additional stakeholder engagement
FY 17 Primary BRS
Accomplishments & Progress (2 of 5)

Three deregulation petitions completed

• Simplot late-blight resistant, low acrylamide potato
  ✓ 8 months (Extension)

• Scotts/Monsanto glyphosate resistant creeping bentgrass
  ✓ 15 months (EIS)

• Bayer male sterile/glufosinate resistant canola
  ✓ 11 months (Extension with new EA)
FY 17 Primary BRS
Accomplishments & Progress (3 of 5)

- Education & Outreach (FDA lead)
  - Authority & funding in Appropriations Bill
- APHIS/ARS Research Collaboration
- New APHIS Search Tool for Permit Data
- GE Petunia
Non-Regulatory Solution

• No APHIS “investigation”

• No regulatory actions taken by APHIS
All shown are GE
FY 17 Primary BRS Accomplishments & Progress (4 of 5)

- Updated BQMS (Biotechnology Quality Management Support program)
- Progress on APHIS eFile
- Business Process Improvement (BPI)
  - “Am I Regulated” (AIR) process
- GE Diamondback Moth EA and permit
Diamondback Moth
• Published dEIS for freeze tolerant Eucalyptus

• Initiated EIS & PRA in support of permit for Florida-wide release of GE Citrus Tristeza Virus (CTV) for control of citrus greening (HLB)
Environmental Considerations

China TWG

TTWG
APHIS Weed Risk Assessment

• Ver. 5.0 of BRS’ Tool
  • Thank you for input last year on Ver. 4.0

• Growing scientific consensus... Need for new risk assessment tools for GE plants (e.g., Weed Science Society of America (WSSA) peer-reviewed work)
Am I Regulated?

Technically: “Does my GE organism meet the definition of a regulated article under 7 CFR part 340?”

– FY 2015: 13 Answered (on web)
– FY 2016: 13 Answered (on web)
– FY 2017: 14 Answered (on web)
– Inquiries under review: 6 (all received in CY 2017)
# APHIS Issuance of Authorizations: Products of Genome Editing

<table>
<thead>
<tr>
<th>Year</th>
<th>CRISPR</th>
<th>TALEN</th>
<th>ZFN</th>
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<tr>
<td>2009</td>
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<tr>
<td>2010</td>
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<tr>
<td>2011</td>
<td>0</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>2012</td>
<td>1</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>2013</td>
<td>16</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>2014</td>
<td>37</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>2015</td>
<td>69</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>2016</td>
<td>112</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2017*</td>
<td>98*</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

* 2017 data collected through September 2017.
Cumulative Number of APHIS-Authorized Permits/Notifications

* 2017 data collected through September 2017.
## Genome Editing “Am I Regulated” Requests

<table>
<thead>
<tr>
<th>Site Directed Nuclease</th>
<th>Number of Inquires</th>
<th>Number Pending</th>
<th>Number of Responses *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meganuclease</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Zinc Finger</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>TALEN</td>
<td>9</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>CRISPR</td>
<td>6</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>19</strong></td>
<td><strong>3</strong></td>
<td><strong>16</strong></td>
</tr>
</tbody>
</table>

* All are SDN-1, All Responses = Not Regulated
Looking Forward to 2018 (1 of 4)

- Continue to focus on APHIS’ primary mission of protecting plant health
- Continual improvement of inspection processes
  - For announced and unannounced inspections
    - Selection (e.g., likelihood of persistence)
    - Consistency
    - Response
Looking Forward to 2018 (2 of 4)

Current Petitions for Non-Regulated status: 5

1. ArborGen Freeze Tolerant Eucalyptus, 2011
   • ESA Biological Assessment and dEIS in review at FWS

2. Bayer Herbicide Resistant Cotton, May 2017
   • 60-day Comment Period open until 26 December 2017

3. Verdecca Increased Yield Soybean, August 2017
   • 60-day Comment Period opened today

4-5. Two additional petitions received recently
   • 1 in August, 1 in October
   • Preparing notices for publication (request comments on petition)
Looking Forward to 2018 (3 of 4)

• Continue to improve APHIS risk assessment systems for plant pest and noxious weed risks

• Continual improvement of permit conditions
  – Clarity, consistency, enforceability
Looking Forward to 2018 (4 of 4)

• Systematize use of IT solutions to improve FOIA responses and creation of Administrative Records (eDiscovery)

• Continue intensive program of meeting with and hosting international regulatory counterparts (trading partners)
International Outreach

Ibrahim Shaqir
Associate Deputy Administrator for International and Emerging Issues
USDA APHIS Biotechnology Regulatory Services
Overview of BRS International Outreach

International Approach
Ibrahim Shaqir

International Activities and Topics
David Heron
Approach to International Collaboration

Protect Plant Health

Support International Trade

Training and Outreach
Protect Plant Health

Regulatory Capacity Building
- Regulate based on science and risk

Technical and Regulatory Information Sharing
- Whole Genome Sequencing, New Plant Breeding Techniques

Horizon Scanning
- Traits/products entering Foreign Regulatory Systems
Support International Trade

Harmonization of Biotech Regulatory Systems

Practical Solutions to Impediments to Trade

International Agreements and Obligations

Information Sharing with Foreign Counterparts
2017 Activities and Efforts

Visitors to Washington
17 Countries – 107 Visitors

Canada-Mexico-U.S.
Trilateral Technical Working Group
Overview of BRS International Outreach

International Approach
Ibrahim Shaqir

International Activities and Topics
David Heron
2017 BRS International Activities

- Foreign Government Capacity Building
- Bilateral and Trilateral Working Groups
- Support for International Trade
Visitors to Washington
(107 people / 17 countries)

Diverse visitors:
• Parliamentarians and local legislators
• Government regulatory officials
• Scientists
• Importers of seed, grain, etc.
• Journalists
Visitors: Topics Discussed
Visitors: Frequent Questions

- Do Americans eat food derived from GE crops?
- How do APHIS, EPA, and FDA coordinate roles?
- What resources are needed to implement a system?
- New Plant Breeding Techniques (e.g., gene editing)?
- Government role in co-existence in ag production?
Biotechnology Trilateral Technical Working Group

CAN – MEX – USA

• Sharing expertise and experiences
• Environmental & Food/Feed
• Harmonization
Biotechnology Trilateral Technical Working Group

Topics:

• Approvals, Consultations, etc.

• NAS 2017 Report: “Preparing for Future Products of Biotechnology”

• International Organizations
US – China Technical Working Group (TWG)

- Led by APHIS-BRS & China MOA
- Sharing expertise and experiences
- Environmental & Food/Feed safety
USA – China TWG Topics (2017)

China’s Amendments to their Guidelines for Safety Assessments

China Research: Animal biotechnology
BRS Interagency Work on International Issues

- Capacity Building
- Risk Assessment
- Synthetic Biology
Global Collaboration

• Low Level Presence
• Breeding Innovation, Regulation and Genome Editing
Global LLP Initiative


- Work collaboratively as importing and exporting countries by developing practical approaches
- Food and feed
- Asynchronous approvals
- Assure safety
- Exchange of information
- 5 international meetings
Principles, Criteria and Practical Approaches for Addressing Low-Level Presence (LLP) in International Food and Feed Trade of Plant Material (2017)
Like-Minded Group for Innovative Agricultural Biotechnologies

Issues
- LLP
- Genome editing
- Ag innovation

Objective
- Share information and work collaboratively
- Work together on trade challenges
Breeding Innovation, Regulation and Genome Editing

Issues

- Consistent approaches
- Trade disruptions
LLP, Breeding Innovation and Genome Editing in OECD

Organisation for Economic Co-operation and Development

- OECD Biotechnology Working Groups
  - Food/Feed (US FDA chairs)
  - Environment (APHIS-BRS chairs)
    - Biology consensus documents, etc.
OECD: LLP and Breeding Innovation

- New Plant Breeding Techniques (2015 onwards)
- 2018: Workshop on Health and Environmental Safety of Genome Editing Applications (in Agriculture)
BRS International Outreach

Questions?
BRS Stakeholder Meeting
Riverdale, MD
November 15, 2017

Carrie McMahon, Ph.D.
Consumer Safety Officer
Office of Food Additive Safety

Email: Carrie.McMahon@fda.hhs.gov
## Update: Biotechnology Consultations

<table>
<thead>
<tr>
<th>Crop</th>
<th>Developer</th>
<th>Traits</th>
<th>Event Designations</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canola</td>
<td>Bayer Crop Science</td>
<td>Male sterility and herbicide tolerance <em>(barstar, barnase, bar)</em></td>
<td>MS11 (BCS-BNØ12-7)</td>
<td>Oct 20, 2017</td>
</tr>
<tr>
<td>Soybean</td>
<td>Verdeca</td>
<td>Altered growth <em>(HaHB4)</em></td>
<td>HB4 (IND-ØØ41Ø-5)</td>
<td>Aug 2, 2017</td>
</tr>
<tr>
<td>Potato</td>
<td>J.R. Simplot</td>
<td>Change in composition and pest resistance <em>(VInv, Rpi-vnt1)</em></td>
<td>Y9 (SPS-ØØØY9-7), X17 (SPS-ØØX17-5)</td>
<td>Feb 21, 2017</td>
</tr>
<tr>
<td>Pineapple</td>
<td>Del Monte Fresh Produce</td>
<td>Change in color <em>(psy, blcy, elcy, flACC3’)</em></td>
<td>EF2-114</td>
<td>Dec 14, 2016</td>
</tr>
</tbody>
</table>
Update: New Protein Consultations

<table>
<thead>
<tr>
<th>Protein</th>
<th>Developer</th>
<th>Traits</th>
<th>Gene Source</th>
<th>Date Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopentenyltransferase</td>
<td>Arcadia Biosciences</td>
<td>Drought tolerance</td>
<td><em>Agrobacterium tumefaciens</em></td>
<td>Jun 23, 2017</td>
</tr>
</tbody>
</table>

[www.FDA.gov/GEPlantFoods](http://www.FDA.gov/GEPlantFoods)
FDA & Genome Editing of Food Plants

• FDA sought public input to help inform regulatory approach
• Request For Comments [82 FR 656] announced Jan 18, 2017

Go to www.regulations.gov
Search for “FDA-2016-N-4389”

• Comment period closed June 19, 2017
RFC: Genome Editing of Food Plants

1. Are the food safety risks the same as or different from those associated with other plant development methods? In what ways?

2. Are there categories for which there are scientific bases to conclude that foods from such categories are unlikely to present food safety risks different from or greater than those for traditional plant breeding? If so, please describe.
RFC: Genome Editing of Food Plants

3. Are there categories for which there are scientific bases to conclude that foods from these categories are more likely than traditionally-bred plants to present food safety risks? If so, please describe.

4. What steps can we take to help small firms to engage with FDA about any questions related to food safety or the regulatory status of foods from their new plant varieties?

Current status: FDA is reviewing the 500+ comments.
Biotechnology Education and Outreach Initiative

- Initiative Goal
- Initial Phase
  - Public meetings: Nov 7 (Charlotte, NC) Nov 14 (San Francisco, CA)
- Public Participation
  - FDA accepting comments until Nov 17
  - www.regulations.gov → search for “FDA-2017-N-5991”
- Follow the Initiative
  - https://www.fda.gov/Food/ResourcesForYou/Consumers/ucm579348.htm
USDA-APHIS-BRS
Am I Regulated (AIR) Process:
2017 Business Process Improvement (BPI) Project

Bill Doley
Government Relations Specialist
November 15, 2017
The AIR process serves as a mechanism to prevent organisms that are not regulated articles from entering the regulatory system, consequently lowering the overall cost of regulation, as well as providing appropriate regulatory relief.
The Am I Regulated (AIR) Process

- A developer who would like agency analysis and confirmation that their GE product does not meet the definition of a regulated article is encouraged to send a letter of inquiry to USDA-APHIS-BRS.

- Instructions for voluntarily submitting “Am I Regulated?” inquiries can be found on the BRS website.
The Am I Regulated (AIR) Process

- After BRS responds to the inquiry, both the inquiry and the response are posted on the BRS website.
- Since July 2011, BRS has responded to 55 “Am I Regulated?” inquiries.
- Some of these inquiries and responses relate to the so-called new plant breeding techniques (NPBTs).
## Regulated Article Letters of Inquiry

**Data Updated: October 17 2017**

### Search

### Download

<table>
<thead>
<tr>
<th>Date</th>
<th>Institution</th>
<th>Description</th>
<th>Documents</th>
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</thead>
<tbody>
<tr>
<td>10/16/2017</td>
<td>USDA ARS</td>
<td>Soybean with Drought and Salt Tolerance developed with CRISPR/Cas9</td>
<td>View Letters</td>
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<tr>
<td>9/25/2017</td>
<td>Calyxt, Inc.</td>
<td>Alfalfa with Improved Nutritional Quality Developed with TALEN Technology</td>
<td>View Letters</td>
</tr>
<tr>
<td>9/20/2017</td>
<td>Simplot Plant Sciences</td>
<td>Progeny of W8, X17 and Y9 Potatoes</td>
<td>View Letters</td>
</tr>
</tbody>
</table>
AIR Legal Analysis

- Does the GE organism meet the definition of a regulated Article?
  1. It is altered or produced through genetic engineering?
  2. Is the donor, vector or recipient a plant pest?
    AND
  2. Is the donor, vector or recipient a plant pest?
AIR Legal Analysis

- AIR Legal Analysis >>> YES + YES = Regulated

- Broad Conclusion:
  - If (2) is a NO, the GE plant is never regulated.
  - In other words, if no plant pest is used as the donor, vector, vector agent or recipient, the GE plant is not a regulated article.
The EU List of NPBTs

- Site Directed Nucleases (ZFN, TALEN, CRISPR)
- Oligonucleotide Directed Mutagenesis (ODM)
- Cisgenics and Intragenics
- RNA-Dependent Methylation (RdDM)
- Grafting
- Reverse Breeding
- Agro-Infiltration
**AIR Responses by Category**

<table>
<thead>
<tr>
<th>Number of Organisms</th>
<th>AIR Category</th>
<th>Regulated Status</th>
<th>Null Segregant</th>
<th>Genetic Modification</th>
<th>Plant Pest Components</th>
<th>Comments</th>
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<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Insertion</td>
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<td>NO</td>
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<td>NO</td>
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</tr>
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<td>NO</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* = The organism is a regulated article; however, these requests relate to the movement of *non-viable plant parts*.

** = Some NI inquiries utilized plant pest components as donor, a plant pest vector (*Agrobacterium*) and/or a plant pest vector agent (TALEN).
The AIR Business Process Improvement (BPI) Project

- Purpose of the AIR BPI Project:
  - Make response times more predictable for developers.
  - Reduce the variance in response times.
  - Ensure our responses are more consistent from a technical and policy standpoint.
Lean Six Sigma Phases of the AIR BPI

- **Define Phase** (January – February)
  - Formed the Team, developed the Team Charter and produced the “As-Is” Process Map

- **Measure Phase** (March – April)
  - Collected data for 15 data points for AIR inquiries from 2014 – 2016
  - Conducted interviews to obtain the “Voice of the Customer” (internal and external)

- **Analyze Phase** (May – June)
  - Identified and prioritized “root causes”
Lean Six Sigma Phases of the AIR BPI

- Improve Phase (July – August – September)
  - Prioritized Solutions
  - Conducted Failure Mode Effects Analysis (FMEA)
  - Developed the “To-Be” Process Map
- Control Phase (October – September 2018)
Improvements to the AIR Process

- Improved Guidance for Developers
  - Reduction in delays due to Confidential Business information (CBI) issues.
  - Reduction in delays due to requests for additional information.
- AIR Triage Review Committee
  - Small team to identify any new scientific or policy issues early in the AIR process.
Improvements to the AIR Process

- Revised Standard Operating Procedures
  - New templates and checklists for various steps in the AIR process.
- AIR Tracking System
  - In development, modeled after the petition tracking system.
Revisions to Supplemental Permit Conditions

Alan Pearson
Chief, Plant Pests and Protectants Branch

November 15, 2017
BRAP
Reviews permits, analyzes risks, assigns permit conditions

ROP
Inspects for compliance. If non-compliant determines severity, impact, and imposes remediation as needed.

Protection of Plant Health
Standard Permit Conditions
- Found at 7 CFR 340.4(f)
- Apply to ALL permits

“Standard” Supplemental Conditions
- “Standard” supplemental conditions have been developed for various permit types, e.g. field release of a microbial plant pest
- All permits have supplemental conditions

Permit-Specific Supplemental Conditions
- Unique - Tailored to address risks specific to an individual permit
Potential Breakdowns

- Permit conditions not clear to:
  - APHIS inspector
  - Permittee
- Enforcement/oversight challenges
- Inconsistency across permits
BRAP/ROP Project on Permit Conditions

All permits’ conditions are:

- Clear
- Consistent
- Enforceable
General Changes

- Consistent language
- Streamlined
- Commensurate with risk
Example: SPC that will be deleted

This Permit does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including for the use of: (1) any non-genetically engineered plant pests or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical or other approval as permitted under FIFRA; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

This is information, not a condition.

It will be provided in a separate guidance document.
Example: SPC that will be amended

Current: Harvested plant material may not be used for food or animal feed unless it is first devitalized and approved for such use by the U.S. Food and Drug Administration; and for plant-incorporated protectants or pesticide-treated products, a tolerance for the pesticide must first be established by the U.S. Environmental Protection Agency.

Amended: Viable plant material used for food or animal feed must be first devitalized or all food, feed and waste must be treated as regulated material.

The new condition accurately reflects APHIS authority. The additional information in the current condition will be provided in a separate guidance document.
Example: SPC that is clarification

This permit authorizes use of the regulated article only as described in the current permit, permit conditions, and associated design protocols/standard operating procedures (SOPs), and only at locations described in the current permit. If design protocols/SOPs are conflicting or conflict with the permit or permit conditions, the permit and permit conditions supersede the conflicting design protocols/SOPs and must be followed. This authorization for release under permit is valid for a period of one (1) year.

Adding this condition will clarify, to permit holders and inspectors, the procedures and conditions under which the release must be conducted.

Conditions specific to confinement (new) and volunteer monitoring (revision) will follow the same approach.
Next Steps

• Stakeholder outreach
  – stakeholder announcement & webinars by January 31, 2018

• Implement revisions that don’t involve changes in record keeping or reporting
  – target completion date June 30, 2018

• Implement revisions that may involve changes in record keeping or reporting
  – target completion date January 1, 2019
Permit Conditions:
Equipment Cleaning & Volunteer Monitoring

Subray Hegde
Branch Chief, Plants Branch
November 15, 2017
Topics Covered

Taking wheat permit as an example,

- Equipment Cleaning
- Volunteer Monitoring
- Case-by-Case Permit Conditions
Wheat Notification to Permit

7 CFR 340.4(f) Permit Conditions
A person who is issued a permit and his/her employees or agents shall comply with the ...standard permit] conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Administrator to be necessary to prevent the dissemination and establishment of plant pests.
Wheat: Prevention of Dissemination

Two-Phase Equipment Cleaning

- **Phase 1: Initial cleaning in field**
  - Harvest equipment must be cleaned free of wheat seed before being moved offsite or used in any non-regulated fields.

- **Phase 2: Comprehensive cleaning occurs when equipment can be dismantled.**
  - Harvest equipment cleaning must be done in an area subject to volunteer monitoring.
Prevent Establishment (~ Persistence)

- 7 CFR part 340

(i) The regulated article *will not persist* in the environment, and

(ii) *No offspring* can be produced that *could persist* in the environment

(iii) *No viable material* shall remain which is *likely to volunteer in subsequent seasons*, or

(iv) *Volunteers shall be managed to prevent persistence* in the environment.
Moist Soil: Wheat Volunteers (2-Year Monitoring)
Wheat Volunteers

- *High temperature* and *moisture stress* tend to increase seed dormancy in wheat (Biddulph 2007) up to 5 years (Pickett 1989).

- APHIS BRS internal data support the emergence of wheat volunteers beyond 2-4 years.
Evolution favors Survival
Modified Wheat Volunteer Monitoring Period

Moist Soil/Post-harvest Irrigated Field (2 Years)

Dryland wheat without Post-harvest Irrigation (4 Years)
Crop Ecology (G x E Interaction)

Population genetic variation (G)

Genetic variation created/modified by breeding methods (G)

Environmental variation (E)

Interaction (G x E)

Final phenotype (seed dormancy)
Case-by-Case Permit Conditions

Based on the known crop ecology, APHIS BRS has been modifying certain permit conditions that are commensurate with the likelihood of persistence for different regulated articles.
## Wheat Permit Processing Time

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Permits Authorized</th>
<th>Average Time</th>
<th>Range</th>
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<td>12-107</td>
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<tr>
<td>2017</td>
<td>3 + 1*</td>
<td>40</td>
<td>24-71</td>
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* One permit was issued after 141 days.
Regulatory Operations Program Overview

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

- Business Process Improvement
  - Planting Reports
  - Field Test Reports
  - Volunteer Monitoring Reports

- Inspections
  - Increased BRS-conducted Inspections
    - Over 60% done by BRS staff
    - Continued partnership with PPQ / States
Incident Response
Notices of Finding (NOFs)

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

- Appeals process
- Post-Harvest Evaluation Process
2018 Focus – Compliance Oversight

• Inspection Selection
Recap

• 2017 Accomplishments
• Process Improvement
• Incident Response
• 2018 Compliance Oversight
Biotechnology Quality Management Support (BQMS)

Chessa Huff-Woodard
Acting Director, Resource Management Program
November 15, 2017
Biotechnology Quality Management Support
BQMS

The System
– Modules
– Workshops
– Assistance
BQMS History

BQM System
(2007-2016)

BQM Support
(2017 onward)
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
Quality Management System

Plan

Act

Check

Improve

Do
BQMS Program - Modules

Your Unique BQMS

- Document Control
- Internal Control
- Critical Control Point
- Process Improvement
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<td>Post-harvest Handling and Transfer</td>
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<td>Devitalization and Final Disposition</td>
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<tr>
<td>Potential Regulatory Compliance Incidents</td>
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<td>Reporting From for Potential Regulatory Compliance Incidents</td>
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More BQMS information is available on the BRS Website.
BQMS Module

Hands-on, adaptable template
Inquiry-based approach
Personalized and tailored BQMS

Modules are available online
BQMS Training Workshops

Foundation Workshop
Sept. 25, 2017

Upcoming 2018 BQMS Workshops

BQMS and Confidential Business Information Workshop

BQMS “Building Up” Workshop
BQMS Individualized Assistance available by request:

BRS.BQMS@aphis.usda.gov.
BRS Website
New Search Tools for Permitting Data

Linda Pardoe
Lead IT Specialist
November 15, 2017
BRS Permitting Data

- Virginia Tech website provided ways to search BRS release permitting data since 1990s
- BRS has hosted ePermits and all previous permitting data on APHIS website since 2007
- As of Sept. 15, 2017, BRS permitting data is exclusively hosted on APHIS website
Previous BRS Status Page

Check Status

Last Modified: Jul 7, 2017

**The data on this page is updated every business day.**

Search Data
Search permit and notification Release data by entering specific search criteria.

View Data Chart
Create visual representation of requested permit data.

View Status of Permit, Notification, or Petition
Use the drop down menus below to check the status of permits, notifications, or petitions.

Type
Choose a report type

Institution
Choose an Institution

State
Choose a state

View Other Summary Tables

- View table of APHIS environmental release permits for plants engineered to produce pharmaceutical or industrial compounds
- View table of petitions for determination of nonregulated status
- View environmental documents associated with permits and petitions

Download all BRS Permit and Notification data

- Download all BRS Permit and Notification data in csv file
- Download data documentation in pdf file
VA Tech Search Data Page – no longer available

USDA Field Tests of GM Crops

Search the Release Data

Please select your search criteria below. In the select boxes below that allow for multiple selections, please use the "Shift" and "Control" keys on your keyboard, and click, to select multiple choices for the field. To advance to a value that begins with a particular letter, select the first value in the select box and type the letter. Your cursor will advance to the typed letter.

Complete list of column definitions for Releases, Notifications and Permits

Permit Type: (Notification, Release Permit, or Both) ▼

☐ Organism

☐ Institution

☐ Phenotype

☐ Phenotype Category

☐ Gene

☐ Location

☐ Status
### USDA Field Tests of GM Crops

**Search Again**

Search retrieved 20914 rows

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Timeframes

- VA Tech agreement ended Sept. 15, 2017
- BRS stakeholder announcement on Sept. 1
- VA Tech re-directs to APHIS website for approximately six months
Why the change?

- In-house capability to deliver the web tables
- Enhanced user experience
- Complete data has always been available on the APHIS website but only in a downloadable spreadsheet format
- Data is now available as a downloadable spreadsheet and in user-friendly search tables
- Users can search data by Institution, Article, Action, Type, Status, State, Genotype, and Phenotype, as well as by a global search field
Check Status

Last Modified: Sep 14, 2017

**The Permits and Notification data available on this page is updated every business day.**

Search APHIS BRS Permits and Notifications Data
*these tables may take a minute or two to load

- Biotechnology Release Permits and Notifications
- Biotechnology Movement Permits and Notifications
- Courtesy Permits

View Other Tables

- Petitions for Determination of Nonregulated Status
- Environmental Documents for Permits
- Environmental Documents for Pharmaceutical and Industrial Permits

Download all BRS Permit and Notification Data

- Download all BRS Permit and Notification data in csv file
- Download data documentation in pdf file

If you have questions about the biotechnology regulatory data or how to access it, please email BRS at biotechquery@aphis.usda.gov or call 1-844-820-2234 Monday-Friday - 8:30 a.m. to 5:00 p.m. ET.
## Downloadable Spreadsheet

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<th>Phenotypes</th>
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</table>
# BRS Interstate/Release and Release Permits and Notifications

**Data Updated: October 18, 2017**

## Filter

- **By Type:** Select a Type ...
- **By Action:** Select an Action ...
- **By Status:**
  - Select a Status ...
  - Acknowledged
  - Denied
  - Incomplete
  - Issued
  - Pending
  - Withdrawn
  - View all Statuses
- **By State:** Select a State ...

## Search

- **Search Article:**
- **Search Institution:**
- **Search Phenotype:**
- **Search Genotype:**

## Download

**Show 10 entries**

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**Locations**: Rel-NC

**Issue Date**

- CBI: No CBI
- Sites: 1
- Acre: 2020

**Phenotypes**: Altered Drought Tolerance / OC-Transposon Inserted

**Genotypes**

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Future Improvements

- Select data by criteria before loading the results table
- Speed up loading of data tables
- Additional proof of concept for summary charts
Number of Authorized Release Sites Effective in 2016
Thank you