Regulation of Agricultural Biotechnology in the United States: Role of USDA-APHIS Biotechnology Regulatory Services

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USDA-APHIS-BRS
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Regulation Under the Coordinated Framework

USDA
Protect Plant Health

FDA
Safe for Use in Food / Feed

EPA
Safe for Use as a Pesticide
The Plant Protection Act (PPA)

- APHIS – BRS conducts its regulatory activities under the authority of the Plant Protection Act of 2000.
- The Plant Protection Act provides two authorities that could be used in the regulation of GE organisms:
  - **Plant Pest Authority** – Basis of current 340 regulations.
  - **Noxious Weed Authority** – Proposed for new 340 in the 2008 draft rule.

*Current Regulations – Plant Pest Authority only*

- Provides APHIS-BRS with the authority to regulate the importation, interstate movement, and environmental release of articles that are likely to result in the introduction or dissemination of *plant pests*. 
APHIS-BRS Mission Delivery

Authorizations of Regulated Activities

Inspections and Compliance

Determinations of Nonregulated Status
What Organisms Does APHIS-BRS Regulate?

- **Regulated articles:**
  - If the organism has been altered or produced through genetic engineering (rDNA techniques), **AND**
  - If there is a possibility that the organism could be a plant pest or have characteristics of a plant pest.
    - Plant pests are organisms that can pose a direct or indirect risk to plants or plant products.

- APHIS – BRS Regulations are found at 7 CFR part 340.
  - CFR = Code of Federal Regulations
A developer who is unsure if their GE product meets the definition of a regulated article is welcome to send a letter of inquiry to USDA-APHIS-BRS.

Instructions for submitting “Am I Regulated?” inquiries can be found on the BRS website.

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 45 “Am I Regulated?” inquiries.
- Some of these inquiries and responses relate to the so-called new plant breeding techniques (NPBTs).
What Activities Does APHIS-BRS Regulate?

- APHIS-BRS oversees the following activities conducted with regulated articles:
  - Importation
  - Interstate Movement
  - Release into the Environment (Confined Field Trials)

- These activities are referred to as introductions and APHIS-BRS has two forms of oversight:
  - APHIS-BRS *issues* permits.
  - APHIS-BRS *acknowledges* notifications.
Containment vs. Confinement

**Containment Procedures**
- Procedures used to prevent exposure of GE organisms to the environment.
- Refers to use in greenhouses, growth chambers and during transport.
- *Probability of release should be near zero.*

**Confinement Procedures**
- Procedures used during Confined Field Trials (CFTs) to ensure that the GE organism does not persist in the environment.
- These include reproductive isolation and post-harvest monitoring.
- *Probability of persistence should be near zero.*
## Authorizations in FY2015

<table>
<thead>
<tr>
<th>Number of Release Authorizations</th>
<th>Number of Release Sites</th>
<th>Number of Phenotypic Designations (crop-trait combinations)</th>
</tr>
</thead>
<tbody>
<tr>
<td>461</td>
<td>8,750</td>
<td>54,337</td>
</tr>
</tbody>
</table>
Standard Permit Conditions

- Standard conditions are placed on both movement and release permits to minimize the possibility that the GE plant will:
  - Persist in the environment.
  - Produce offspring that will persist in the environment.
    - Within the crop or with wild relatives.
  - Significantly impact non-target organisms.

- For notifications:
  - Applicants agree to adhere to the performance standards.
Supplemental Permit Conditions

- APHIS-BRS adds permit conditions to regulated field trials in order to maximize confinement.
  - These conditions are customized to the crop, trait and release locations.

- Typical supplemental permit conditions include:
  - Minimum separation distance to fields of the cultivated crop.
  - Minimum separation distance to wild relatives.
  - Specified buffer zones around the regulated field trial.
  - Follow-crop planting restrictions.
  - Post-harvest monitoring requirements:
    - Frequency and duration; methods for devitalization.

- Regulated field trials of GE plants producing industrial or pharmaceutical substances have stricter conditions, and are subject to additional inspections.
Three Components of Compliance

- **Compliance Assurance**
  - Manage planting reports and schedule inspections.
  - Train inspectors and conduct inspections.

- **Compliance Enforcement**
  - Manage and evaluate compliance incidents.
  - Coordinate investigations.
  - Issue incident responses.

- **Compliance Assistance**
  - Provide assistance to facilitate compliance.
Common Compliance Violations

- **Movement Violations**
  - Interstate movement without the permit number on the shipping container.
  - Interstate movement or importation did not follow the APHIS-BRS container regulations or the shipping variance.

- **Environmental Release Violations**
  - Regulated field trial planted at a location not authorized in the permit.
  - Regulated field trial planted within minimum separation distance to related non-GE crop plants or wild relatives.
  - Failure to conduct post-harvest monitoring.
  - Failure to control GE volunteers.
Any person can submit to BRS a petition seeking a determination of nonregulated status.

- Nonregulated status means the GE organism would no longer be subject to this regulation.
- Petition information should support the conclusion that the regulated article is unlikely to pose a greater plant pest risk than the non-GE organism.

- Once BRS makes a determination of nonregulated status for a GE organism, that organism may be moved freely (imported and moved interstate) and planted without BRS regulatory oversight.
Evaluation of Petitions

- **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 more broadly evaluate environmental impacts of the APHIS-BRS determination.
    - Pursuant to the National Environmental Policy Act (NEPA) of 1969.
      - Includes consideration of the Endangered Species Act (ESA).
Components of a Plant Pest Risk Assessment

- Potential plant pest and disease impacts.
- Potential impacts on non-target organisms beneficial to agriculture.
- Potential for enhanced weediness.
- Potential for enhanced weediness of sexually compatible relatives.
- Potential changes to agricultural or cultivation practices.
- Potential impacts from transfer of genetic material to organisms with which the GE organism cannot interbreed.
Petition Process Steps

**PATH I**
- Review for Completeness
- Preparation of PPRA
- 60-Day Comment On Petition

**PATH II**
- Preparation of EA
- 30-Day Comment on PPRA, EA
- Revise Docs; Respond to Comments
- Final Docs, Decision

- Decision Final
- Preliminary Decision, 30-day review
- 1 month
- 2 months
- 15 months total

- 3 months
- 2 months
- 7 months
- 13 months total
GE Plants Granted Nonregulated Status

- APHIS-BRS has issued determinations of nonregulated status in response to 124 petitions, representing 17 plant species.
  - Alfalfa, Apple, Canola, Chicory, Corn, Cotton, Flax, Papaya, Plum, Potato, Rice, Rose, Soybean, Sugar Beet, Squash, Tobacco, and Tomato.
- Commercialization of nonregulated GE plants is determined by market demand, not the APHIS decision.
- All relevant documents are publicly available on the APHIS-BRS website:
### GE Plants with Nonregulated Status

<table>
<thead>
<tr>
<th>Plant</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa</td>
<td>HR, PQ</td>
</tr>
<tr>
<td>Canola</td>
<td>HR, AP, PQ</td>
</tr>
<tr>
<td>Corn</td>
<td>HR, IR, AP, PQ</td>
</tr>
<tr>
<td>Cotton</td>
<td>HR, IR</td>
</tr>
<tr>
<td>Papaya</td>
<td>VR</td>
</tr>
<tr>
<td>Soybean</td>
<td>HR, IR, AP, PQ</td>
</tr>
<tr>
<td>Sugar Beet</td>
<td>HR</td>
</tr>
<tr>
<td>Apple</td>
<td>PQ</td>
</tr>
<tr>
<td>Potato</td>
<td>IR, VR, PQ, FR</td>
</tr>
<tr>
<td>Rose</td>
<td>PQ</td>
</tr>
<tr>
<td>Squash</td>
<td>VR</td>
</tr>
<tr>
<td>Tobacco</td>
<td>PQ</td>
</tr>
<tr>
<td>Chicory</td>
<td>AP</td>
</tr>
<tr>
<td>Flax</td>
<td>HR</td>
</tr>
<tr>
<td>Plum</td>
<td>VR</td>
</tr>
<tr>
<td>Rice</td>
<td>HR</td>
</tr>
<tr>
<td>Tomato</td>
<td>PQ</td>
</tr>
</tbody>
</table>

**Abbreviations**

- **HR** – Herbicide Resistant
- **IR** – Insect Resistant
- **VR** – Virus Resistant
- **FR** – Fungus Resistant
- **AP** – Agronomic Properties
- **PQ** – Product Quality

**Production Levels**

- **Major Commercial Production**
- **Minor Commercial Production**
- **No Commercial Production**
APHIS regulations contain a list of known plant pests at 7 CFR part 340.2

The only algae listed in §340.2 are:

- **Division Chlorophyta:**
  - Genus *Cephaleuros*
  - Genus *Rhodochytrium*
  - Genus *Phyllosiphon*
An Example of an Algal Plant Pest

- *Cephaleuros virescens*  
  Algal Leaf Spot
  
  - A plant pathogen infecting tea, coffee, coconut, guava and avocado.
  - The most frequently reported algal pathogen of higher plants worldwide.
  - It is an aerophilic, filamentous green algae.
  - It lacks chlorophyll 'a' and is incapable of photosynthesis.
Most algae are not plant pests in their non-engineered state.

- GE algae would be regulated by APHIS under two scenarios:
  - The recipient algae is a plant pest (one of the three plant pest genera).
  - The recipient algae is engineered with a DNA sequence from a plant pest.
- Depending on the nature of the product, GE algae may be subject to the authority of EPA or FDA.
Regulation of GE Algae by APHIS

- APHIS has authorized the movement of a small number of GE algae.
  - APHIS has never authorized the release of a GE algae.
- APHIS has never regulated any of the plant pest algae.
  - They have not been used as DNA donors or recipients.
- APHIS has regulated some GE organisms containing DNA sequences derived from algae.
APHIS-BRS has developed a draft revision of 7 CFR part 340.

The draft rule is currently in OMB review.

Once the draft rule is published in the Federal Register, there will be a public comment period.

In February 2016, APHIS-BRS announced in the Federal Register a comment period on a Notice of Intent (NOI) to develop a draft programmatic Environmental Impact Statement (EIS).

- Docket ID: APHIS-2014-0054
- http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0054
Time for Questions