Permitting Process for the Importation, Interstate Movement and Release of Microbes Developed Using Genetic Engineering

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Outline

USDA APHIS BRS and its role
Revised Biotechnology Regulations

Regulated organisms and regulatory processes
Microbes developed using genetic engineering (modified microbes)

Permit application requirement for modified microbes:
Interstate movement and importation
Environmental release
Exemptions from permitting requirements
Biotechnology Regulatory Services Team

USDA
~ 100,000 employees

APHIS
~ 8,000 employees

BRS
92 employees

BRAP
30 employees
USDA APHIS BRS – Role

- Protects U.S. agriculture and agriculturally important natural resources by regulating organisms developed using genetic engineering (modified organisms) that may pose a plant pest risk

- Authority: Plant Protection Act of 2000
Revised Biotechnology Regulations

- Replaced the legacy 7 CFR part 340
- Governs the import, interstate movement, and environmental release of certain plants, insects, and microorganisms
- Represents a new approach for U.S. regulation of plants
- Based on three decades of experience and advances in science and technology
- Better focuses regulatory resources on areas of plausible risk
Three Regulatory Processes

1. **EXEMPTIONS AND CONFIRMATIONS**
   Determine whether your plant meets the criteria for an exemption with the option for requesting confirmation of plant’s exempt status.

2. **REGULATORY STATUS REVIEW**
   Request a regulatory status (RSR) review to determine if a plant developed using genetic engineering poses a plant pest risk.

3. **PERMITTING**
   Apply for a permit for a regulated organism that does not undergo or pass the RSR.

Processes 1 & 2 apply only to plants.
Organisms Regulated by BRS

- **Plants**
  - Unless exempt

- **Plant Pests**
  - If it produces an infectious agent or compound that causes plant disease

- **Biological Control**
  - If they could pose a plant pest risk

- **Received Pest DNA**
  - Plant-made Pharmaceutical or Industrial Compounds

- **PMPI Plants**
  - If it produces an infectious agent or compound that causes plant disease
Definitions

**Genetic engineering.** Techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.

**Plant pest.** Any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

**Plant pest risk.** The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest.
Modified Microbes

- Meets the definition of a plant pest; or
- Has received DNA from a plant pest, and the DNA is capable of producing an infectious agent, or encodes a compound, that causes plant disease; or
- Acts as a biological control agent to control plant pests and could pose a plant pest risk.
Permit Applications

Timelines for approval or denial of a permit:

- **Interstate movement and importation**: Within 45 days of receipt of a sufficiently completed permit application
- **Release**: Within 120 days of receipt of a sufficiently completed permit application
Interstate Movement and Importation Permits

**Application Requirements:**

- Name and contact information of the responsible person
- The organism's genus and species
- Information on the intended trait
- Modification method
- Construct components and donors: Genus and species of the organism(s) from which the genetic material was obtained
- Construct components: Detailed description of functions
- The origin and destination of the modified organism, including addresses and contact details of the sender and recipient
Application Requirements*:

- Location: Land area (size), GPS coordinates, address, and land use history of the site and adjacent areas
- Purpose for the introduction of the modified microbe: Including a description of the proposed experimental design
- Confinement protocols: Description of the actions that will be taken to maintain the modified microbe at the release site and to prevent the spread and persistence of the modified microbe after the termination of a field trial

*In addition to the requirements for movement permit applications
Environmental Releases

Application Requirements*:

- Information on the intended trait and the genotype of the intended trait. Including a diagnostic test to differentiate between the wild type and modified organism.
- Monitoring: Description of the monitoring duration and frequency to ensure that modified microbes will not persist in the environment.
- Final disposition for release: Description of methods to be used for final devitalization.
- APHIS will inspect to assess compliance with the permitting conditions, and require the maintenance and submission of certain records.

*In addition to the requirements for movement permit applications.
Exemptions from Permitting Requirements

**Modified disarmed *Agrobacterium* species**

- A permit for importation or interstate movement is not required for any disarmed *Agrobacterium* spp.
- Option to request a Letter of no Permit Required from BRS for importation

**Certain microbial pesticides**

- A permit is not required for the movement of any modified microorganism product that is currently registered with the EPA as a microbial pesticide; and
- Microorganism is not a plant pest
Example: A Permit from BRS Is Not Required For the Movement of

Organism's genus and species: *Bacillus subtilis*

Donor organism: Jellyfish *Aequorea victoria*

Construct component: Gene green fluorescent protein

Construct function: Fluorescent marker
Example: A Permit from BRS Is Required For the Movement of

Organism's genus and species: *Fusarium verticillioides*

Donor organism: *Aspergillus nidulans*

Construct component: Zinc finger transcription factor

Construct function: Increase asexual development
In the process of developing a microbial regulation FAQ document
Based on the inquiries received during the last 3 years
We will share the document on our website

In the process of developing a microbial guidance document with information requirements and process for submitting microbial permit applications
We will share the document and invite the public for comments
For More Information

- We encourage stakeholders to contact us for pre-consultations if they are not sure whether a modified microbe requires an APHIS permit. Contact: Martha Malapi-Wight: martha.m.wight@usda.gov

- BRS site:

- Biotech Query:
  - BiotechQuery@usda.gov

- Revised Biotechnology Regulations:

- Permitting:
  - https://efile.aphis.usda.gov/s/
Thanks!

Questions?