USDA APHIS BRS

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

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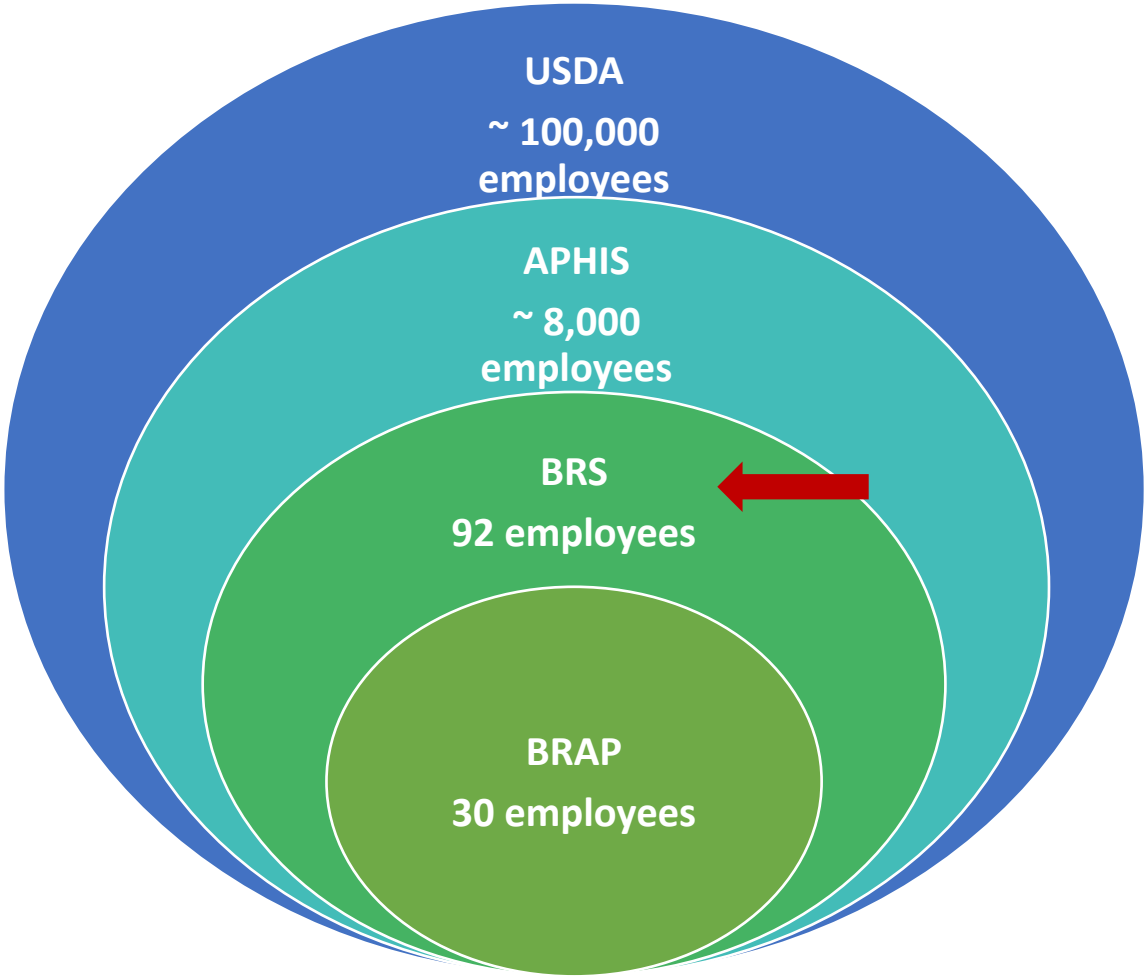
Outline

- USDA APHIS BRS and its role
- Revised Biotechnology Regulations

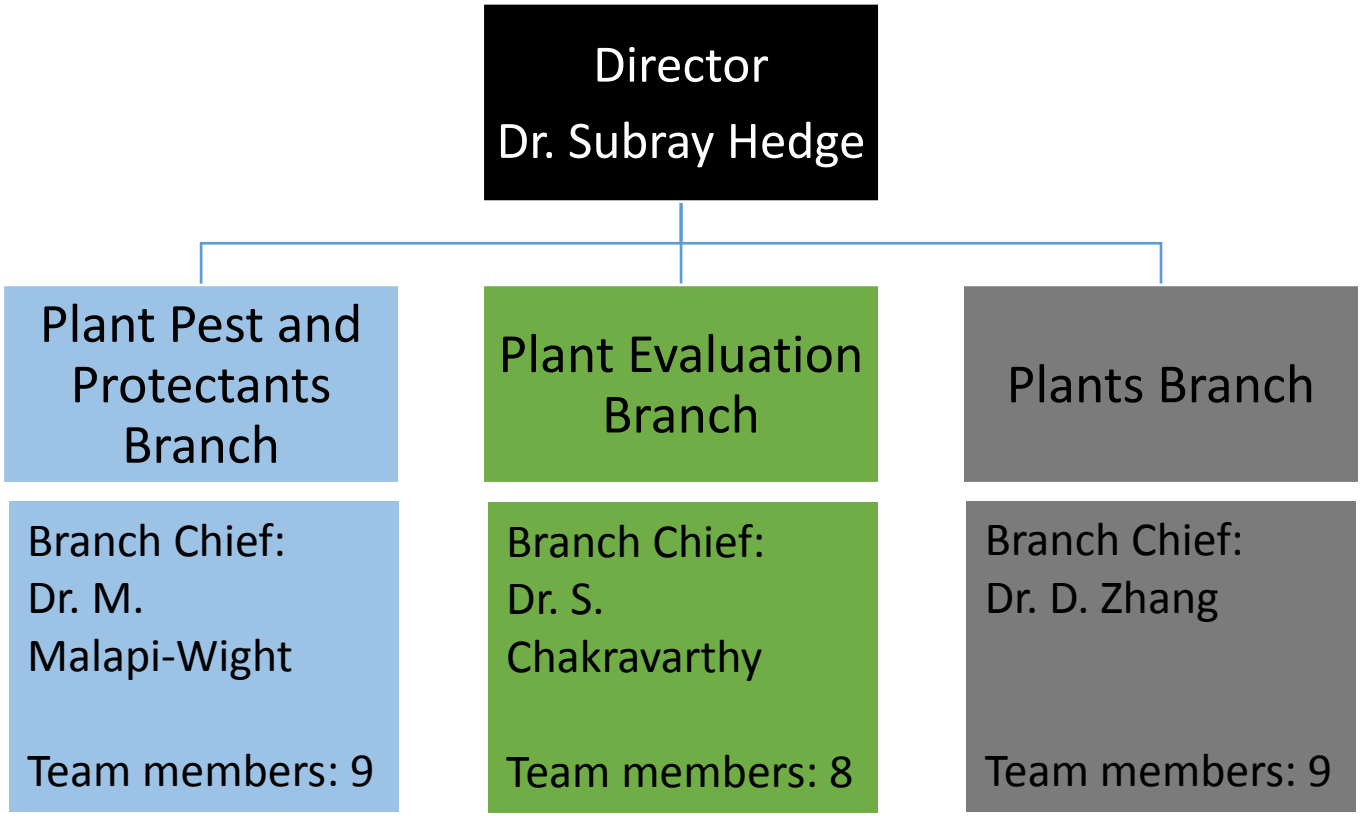
- Regulated organisms and regulatory processes
- Microbes developed using genetic engineering (modified microbes)

- Permit application requirement for modified microbes:
  - Interstate movement and importation
  - Environmental release
- Exemptions from permitting requirements

Biotechnology Regulatory Services Team



Biotechnology Risk Analysis Programs Team



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

Biological Control
If they could pose a plant pest risk

Received Pest DNA
If it produces an infectious agent or compound that causes plant disease

PMPI Plants
Plant-made Pharmaceutical or Industrial Compounds

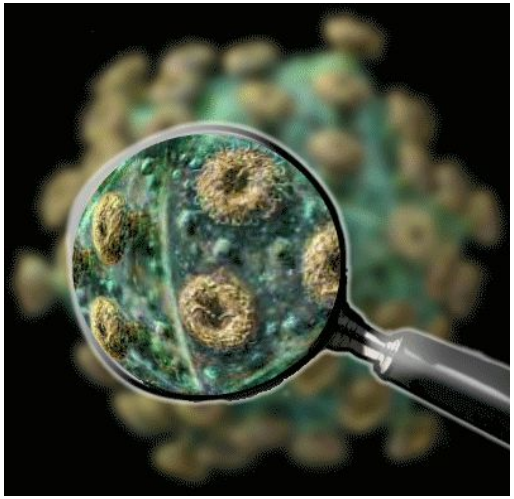
Definitions

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

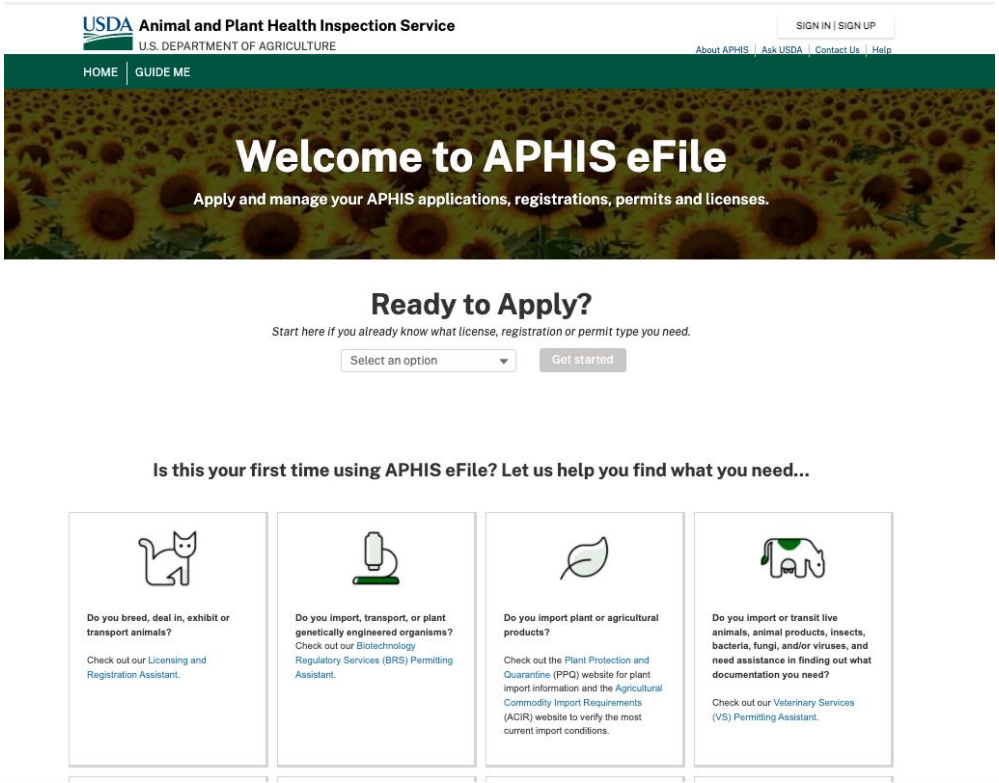


Meets the definition of a plant pest; or

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

Environmental Releases

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

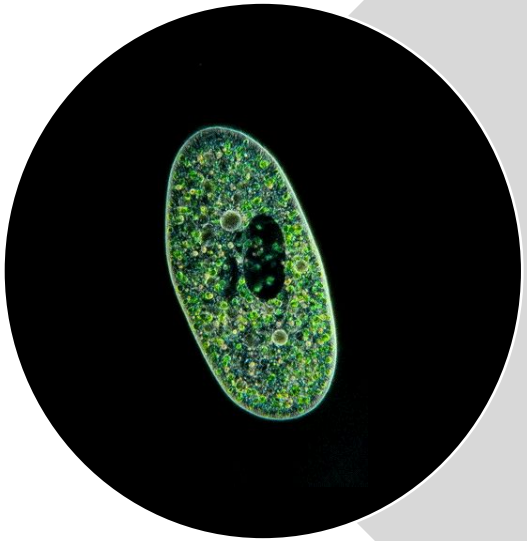
Modified disarmed *Agrobacterium* species

- 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:
  - https://www.aphis.usda.gov/aphis/ourfocus/biotechnology
- Biotech Query:
  - BiotechQuery@usda.gov
- Revised Biotechnology Regulations:
  - https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about/340_2017_perdue_biotechreg
- Permitting:
  - https://efile.aphis.usda.gov/s/

Thanks!

Questions?