

## Additional Federal and State Regulatory Requirements That may Apply to APHIS BRS Authorizations

Organisms developed using genetic engineering (modified organisms) can be regulated by various federal and state agencies. You are required legally to obtain all necessary approvals. An authorization from the USDA Animal and Plant Health Inspection Service's (APHIS) Biotechnology Regulatory Services (BRS) does not cover or replace the need to comply with other applicable Federal regulations. Use the resource list below to identify potential requirements beyond the permitting requirements of APHIS BRS. APHIS BRS issues authorizations for the movement (i.e., importation, interstate movement, or release into the environment) of modified organisms.

### ALL ORGANISMS

#### Select Agents and Toxins

APHIS BRS cannot issue an authorization for a modified organism that is on the Federal Select Agent Program (FSAP) [Select Agents and Toxins List](#). Additionally, APHIS BRS will not issue an authorization for a modified organism that contains nucleic acids that are capable of producing infectious forms of select agent viruses or encode for the toxic form(s) of any select toxins if the nucleic acids: (i) can be expressed *in vivo* or *in vitro*, or (ii) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*. For additional information, view the [Guidance on the Regulation of Select Agent and Toxin Nucleic Acids](#).

FSAP oversees the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public, animal, or plant health, or to animal and plant products. The program is managed jointly by the Centers for Disease Control (CDC) Division of Regulatory Science and Compliance (DRSC) and the APHIS Division of Agricultural Select Agents and Toxins (DASAT).

CDC DRSC regulates select agents that pose a threat to public health. For information about the regulation of select agents and toxins, contact CDC at [LRSAT@cdc.gov](mailto:LRSAT@cdc.gov) or (404) 718-2000, or visit:

- [CDC DRSC](#)
- [FSAP Select Agents and Toxins List](#)
- [FSAP Select Agents and Toxins Exclusions](#)

APHIS DASAT regulates select agents that cause disease in animals and plants, including certain select agents that are jointly regulated with CDC DRSC (see "Overlap Select Agents and Toxins" section in the FSAP list). For more information, visit the [Federal Select Agent Program website](#) or contact DASAT at [DASAT@usda.gov](mailto:DASAT@usda.gov) or (301) 851-2070.

FSAP excludes certain materials, such as an attenuated strain of a select agent or toxin, that do not pose a severe threat to the public or agriculture from the select agent requirements. These materials are known as [excluded select agents](#). APHIS' Veterinary Services (VS) requires that certain excluded select agents—whether live, killed, or consisting of nucleic acids—must have a valid Organisms and Vectors (OV) permit for importation into the United States. APHIS VS also requires an OV permit for interstate transportation (movement from one state or territory to another) of certain live excluded select agents. As the applicant or shipper for the permit, you must confirm the regulations do not apply to your material listed as excluded on the FSAP website or granted a letter of exclusion issued by FSAP.

To determine if your modified organism requires an OV permit, refer to APHIS [excluded select agent list](#). If your modified organism is an excluded select agent or contains nucleic acids from a donor organism on this list, contact VS at [APIE@usda.gov](mailto:APIE@usda.gov) or (301) 851-3300.

### **Plant Pests, Biological Control Organisms, or Federally Listed Noxious Weeds**

APHIS' Plant Protection and Quarantine (PPQ) may require a permit for the importation, interstate movement, and environmental release of plant pests (e.g., some arthropod or microbe species), biological control organisms of plant pests and weeds, bees, parasitic plants, and federally listed noxious weeds. For more information, visit [APHIS' Regulated Organism and Soil Permits](#) website, or contact PPQ at [Pest.Permits@usda.gov](mailto:Pest.Permits@usda.gov) or (866) 524-5421. You may also search the [Agricultural Commodity Import Requirements \(ACIR\) Database](#) using the "Pest Organism Permitting" tile.

### **Soil Shipped with Modified Organisms**

APHIS PPQ regulates the importation and interstate movement of soil. If you are moving soil along with your modified organism, visit the PPQ [Soil Imports](#) website or contact PPQ at [Pest.Permits@usda.gov](mailto:Pest.Permits@usda.gov) or (866) 524-5421 for information about obtaining the appropriate permits.

### **Feeding Studies with Modified Organisms**

The U.S. Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) require that modified organisms or their products intended for food or feed meet all applicable requirements of the Federal Food, Drug, and Cosmetic Act (FD&C). For information about the regulation of biotechnology products by FDA and EPA, visit the [FDA's Regulation of Plant and Animal Biotechnology Products](#) website and the [EPA's Regulation of Biotechnology under TSCA and FIFRA](#) website.

## **PLANTS ONLY**

APHIS PPQ may require a permit for the importation or interstate movement of certain modified plants. To determine the permit requirements for specific plant materials, visit [PPQ's Plant Imports](#) website or contact PPQ at (877) 770-5990. You may also search the [ACIR Database](#) using the "Plants for Planting and Propagation" tile.

APHIS PPQ may also require a phytosanitary certificate for the importation of certain modified plants or plant parts. If you are importing a modified plant or plant part, visit [PPQ's Phytosanitary Treatments for Imported Commodities](#) website or contact PPQ at (877) 770-5990 to confirm any requirements. You may also search the [ACIR Database](#) using the "Treatments" tile.

Also, the movement of plants under a PPQ or state quarantine for plant disease may require additional permits from PPQ or individual states. To determine if your modified plant is under a disease quarantine, visit the "[Plant Diseases](#)" section of [APHIS Plant Pests and Diseases](#) website for current PPQ quarantines, requirements for each disease, and contact information for state officials. You may also contact [State Plant Regulatory Officials](#) for assistance.

## MICROBES ONLY

Use the [Unified Website interactive tool](#) from EPA, FDA, and USDA to help identify and understand the regulatory requirements for activities with genetically modified microorganisms.

CDC may require a permit for importation of infectious biological agents. For more information, contact CDC at [importpermit@cdc.gov](mailto:importpermit@cdc.gov) or (404) 718-2077. You may also visit the [Import Permit Program \(IPP\) e-Tool](#).

APHIS VS may require a permit for importation of modified microbes. If you plan to import a modified microbe that has received genetic material from a donor organism on the [VS-Regulated Livestock and Poultry Pathogens](#) (Partial List), visit the [Veterinary Services Permitting Assistant](#) or contact VS at [APIE@usda.gov](mailto:APIE@usda.gov) or (301) 851-3300.

## ARTHROPODS (INSECTS) ONLY

CDC or APHIS VS may require a permit for importation or interstate movement of arthropods that can vector animal or human pathogens. For more information on CDC requirements, visit the [CDC Import Permit Program](#) website or contact [importpermit@cdc.gov](mailto:importpermit@cdc.gov) or (404) 718-2077.

For more information on APHIS VS requirements, visit the [Veterinary Services Permitting Assistant](#) or contact [APIE@usda.gov](mailto:APIE@usda.gov) or (301) 851-3300.