

Are You Permitted? A Guide to Biological Materials Permits

It is common, often necessary, practice to transfer biological materials while conducting biological research. Biological materials may be introduced to or removed from research facilities for a variety of reasons including:

- Exchange of research materials with collaborators
- Movement of faculty or research personnel for technical training
- Faculty assignment/job transfer
- Field studies



Whatever the reason, it is important to remember that import, interstate movement, and export (in some cases) of biological materials are tightly regulated by various federal agencies and may require permits. Biological materials permits are intended to ensure that these materials that may bear an infectious disease or environmental impact risk are not inadvertently released. Additionally, permits minimize the potential for clandestine or inappropriate use of such materials.

Please ensure that the Biosafety Office has been provided with a copy of all currently active biological materials permits. If you will be applying for any of the permits listed below, please contact the Biosafety Office (974-1938 or 974-9836) prior to your application submission since it may be necessary to assess or implement specific biosafety/biocontainment procedures prior to agency approval.

U.S. DHHS/CDC Permits (42 CFR, Part 71.54)

The Etiologic Agent Import Permit Program (EAIPP) of the CDC requires an import permit for all etiologic agents, biological materials, and hosts and/or vectors entering the U.S. As defined by the CDC:

- **Etiologic agents** are microorganisms and microbial toxins that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsiae, protozoans, and parasites. Etiologic agents are sometimes referred to as infectious agents.
- **Biological materials** are unsterilized specimens of human and animal tissues (such as blood, cell lines, body discharges, fluids, excretions or similar material) containing or suspected to contain an etiologic agent.
- **Hosts and vectors** are organisms that contain and/or may transmit etiologic agents to humans and other animals. Examples include arthropods, bats, snails, rodents, and any animal known or suspected of being infected with an organism capable of causing disease in humans.

Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the United States Public Health Service Division of Quarantine and release by U.S. Customs.

Additionally, the importer is legally responsible to ensure that the import-permitted material is packaged and shipped in accordance with all applicable shipping regulations by the party initiating the shipment.

There is no service charge for CDC import permits.

Related websites:

[General information on the EAIPP](#)

[DHHS/CDC permit information and application forms](#)

USDA Animal and Plant Health Inspection Service (APHIS) Permits

APHIS is the branch of the USDA that provides leadership in ensuring the health and care of animals and plants, especially those that are vital agricultural commodities. Biological materials that may pose a risk to plants and/or animals or their environment are tightly regulated by APHIS. APHIS permits are granted by one of three agencies based on the biological material involved and the at-risk population (i.e. plants or animals):

- **Veterinary Services (VS; 9 CFR, Part 122 *inter alia*)**
- **Plant Protection and Quarantine (PPQ; 7 CFR, Part 330 *inter alia*)**
- **Biotechnology Regulatory Services (BRS; 7 CFR, Part 340)**

Veterinary Services is dedicated to preventing, controlling and/or eliminating animal diseases, and monitoring and promoting animal health and productivity. VS provides permits for the import, interstate movement, and export of materials derived from animals or exposed to animal-source materials. Examples include:

- Animal tissues including blood, cells or cell lines of livestock or poultry origin
- Animal semen, ova or embryos
- RNA/DNA extracts
- Hormones and enzymes
- Monoclonal antibodies for *in vivo* use in non-human species and certain polyclonal antibodies/antisera
- Microorganisms including bacteria, viruses, protozoa, and fungi

VS permits have a service charge of \$137, though this price can vary depending on number of revisions reviewed, need for facilities inspections, etc.

Related websites:

[General information on the USDA APHIS Animal Health program](#)

[Veterinary Services permit information and application forms](#)

Plant Protection and Quarantine safeguards agriculture and natural resources from the risks associated with the entry, establishment, or spread of animal and plant pests and noxious weeds to ensure an abundant, high-quality, and varied food supply. PPQ provides permits for the import, interstate movement, and export of:

- **Plant pests and pathogens** including insects, mites, bees, butterflies and moths, earthworms, entomopathogens/biocontrol agents, snails and slugs, earthworms, bacteria, fungi, nematodes, viruses, live arthropods for display or education, and noxious weeds.
[More information on plant pests and pathogens permits and PPQ Form 526](#)
- **Plants and plant products** including fruits, vegetables, rice, maize, sugarcane and associated products, foreign cotton, cut flowers, and miscellaneous products associated with Khapra beetle.
[More information on plants and plant products permits and PPQ Form 587](#)
- **Timber and timber products** including unfinished lumber.
[More information on timber and timber products permits and PPQ Form 585](#)
- **Prohibited plants/plant products for purposes of research only.**
[More information on permits for the research use of prohibited plants/plant products and PPQ Form 588](#)
- **Plants or plant products for transit through the U.S.**
[More information on transit permits and PPQ Form 586](#)
- **Protected or rare plant species.**
[More information on rare and endangered plants, CITES, and PPQ Form 621](#)
- **Soil of foreign origin.**
[More information on soil permits and PPQ Form 525A](#)
- **Post-entry quarantine materials.**
[More information on post-entry quarantine and PPQ Form 546](#) (pdf)

There is no service charge for PPQ permits.

Related websites:

[General information on the USDA APHIS Plant Health program](#)

[General information on PPQ permits](#)



Biotechnology Regulatory Services (BRS) protects America's agriculture and environment using a dynamic and science-based regulatory framework that allows for the safe development and use of genetically engineered (GE) organisms. BRS regulates genetically engineered organisms including plants, plant pests, and transgenic arthropods through either a notification or permit system.

BRS Notifications constitute an expedited permitting process for GE plants that BRS has extensive experience regulating in the past.

- GE plants must meet six eligibility requirements that are related to safety. [BRS notification requirements and guidance](#) (pdf)
- Performance standards are established and applicants must comply with these for movement, planting, growing, harvesting, and isolation.
- BRS reviews the application for meeting eligibility requirements and assesses whether performance standards can be met, taking up to 30 days to process.
- Notifications require submission of a letter to BRS or e-submission (see below).
- [More information on the BRS notification criteria and process](#)

BRS Permits are used for crops that don't meet current notification criteria including pharmaceutical and industrial products, plants with a high potential to persist outside the field site, and multi-year field trials.

- Permits require up to 120 days to process for the science review of conditions and confinement protocols.
- BRS authorizes the procedures for field production and isolation in the permit.
- All organisms and all traits are eligible.
- [More information on BRS permits and application forms](#)



There is no service charge for BRS notifications or permits.

USDA APHIS Electronic Permits

Many of the APHIS permits are available as e-permits through the APHIS website. E-permitting is highly recommended because it is more time efficient than the conventional mail-in forms, sometimes cutting days to weeks off of the permit approval process. However, to meet eligibility requirements for e-permitting, an investigator must complete an e-permit registration form and obtain a security code prior to submitting an e-permit. This process takes approximately one week. Below are some links that may be useful:

- [General information on USDA APHIS E-permits](#)
- [Register for an E-permit](#)

Like CDC permits, holders of APHIS permits assume all legal responsibility for the materials, their transport, and their security.

U.S. Fish & Wildlife Service Permits (50 CFR, Part 13)

The U.S. Fish & Wildlife Service (a branch of the U.S. Department of the Interior) issues permits under various wildlife laws and treaties at different offices at the national, regional, and/or wildlife port levels. These permits cover a wide range of import/export regulations including the trapping, buying, selling, and trading of live animals (non-agricultural), preserved animal trophies, animal hides, and animal tissues. For further information, visit:

- [General information on U.S. Fish & Wildlife Service permits](#)
- [More information on applicable laws, treaties, and regulations](#)

Tennessee Wildlife Resources Agency Import and Collection Permits (Title 70, Chapter 2)

Live wildlife animal species may require a TWRA import permit before being brought into the state of Tennessee. A scientific collector's permit may also be required for capture of certain species for study in Tennessee. For further information, visit:

- [Tennessee Wildlife Resources Agency information](#)
- [Tennessee Wildlife Resources Agency animal importation regulations](#) (pdf)
- [Scientific collections permit information](#)

U.S. Department of Commerce Export of Biological Agents (15 CFR, Parts 730-774)

The DOC has developed a list of biological agents (among other products and technologies) that are restricted by licensing requirements for export. The list includes many items on the current DHHS/USDA "select agent" list as well as specific viruses and *Escherichia coli*, serotype O157, and other verotoxin producing strains.

Below are links to the current Commerce Control List of biological agents and toxins:

- [Commerce Control List](#) (pdf; biological agents/toxins list begins on p. 61)
- [Commerce-controlled biological agents/toxins](#) (pdf).

For further information the Department of Commerce, the Commerce Control List, or export license requirements, contact:

- **UTK** – Dairin Malkemus at (865) 974-0232 or dmalkemu@utk.edu;
- **UTIA** – Jane Burns at (865) 974-7375 or janeburns@utk.edu;
- **GSM** – Francine Rogers at (901) 448-3537 of fr Rogers1@uthsc.edu.

Please contact the UTK/UTIA/GSM Biosafety Office at (865) 974-1938 or branger@utk.edu for further information about biological materials permits or permitting requirements:



<http://biosafety.utk.edu>