FACT SHEET

Biological Materials Import Permits

Investigators often have a requirement to transfer biological materials to their laboratory from another Institution or Facility, such as:

- 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. If you plan to apply for one of these permits, you must confirm that you are approved to work with these materials by the Institutional Biosafety Committee. Please contact the Biosafety Office at Biosafety@ehs.utah.edu or (801) 581-6590.

U.S. DHHS/CDC Permits

The CDC Import Permit Program, or IPP, regulates the importation of infectious biological materials that could cause disease in humans, in order to prevent their introduction and spread into the U.S. The program ensures that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the imported agents.

- **Infectious biological agent** A microorganism [including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa] or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.
- Infectious substance Any material that is known or reasonably expected to contain an infectious biological agent.
- **Vector** Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids, viral vector, or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal) that are known to transfer or are capable of transferring an infectious biological agent to a human.

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.

The IPP has a useful e-tool (https://www.cdc.gov/cpr/ipp/etool.htm) that will help determine if a permit is needed and provide suggestions for language for a certification statement if a permit is not required. In addition, it provides links and instructions on how to ship and pack materials.

Related websites

- General information on the IPP
- DHHS/CDC permit information and application procedures (requires a SAMS account)

USDA Animal and Plant Health Inspection Service (APHIS) Permits

The United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS) issues permits for the import, transit and release of regulated animals, animal products, veterinary biologics, plants, plant products, pests, organisms, soil, and genetically engineered organisms.

The USDA APHIS website has considerable information on the import and export of regulated materials and can be found here.

APHIS permits are granted by entities within their organization;

- 1. <u>Plant Protection and Quarantine</u> (PPQ) regulates the importation of plants and plant products under the authority of the Plant Protection Act. PPQ maintains its import program to safeguard U.S. agriculture and natural resources from the risks associated with the entry, establishment, or spread of animal and plant pests and noxious weeds.
- 2. <u>The Veterinary Services, Organisms and Vectors (OV) Permitting Unit</u> regulates the importation into the United States, and interstate transportation, of organisms and vectors of pathogenic diseases of livestock and poultry.
 - The Code of Federal Regulations, in <u>9 CFR, §122.2</u>, mandates that "no organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit".
- 3. <u>Biotechnology Regulatory Services</u> (BRS) requires a permit or notification for the importation, interstate movement, or environmental release of certain genetically engineered (GE) organisms. Permit applications, which are carefully reviewed by APHIS scientists, provide details about the nature of the GE organism to be introduced and the conditions that will used to prevent the spread and establishment of the organism in the environment. APHIS issues permits for the introduction of GE organisms that pose a plant pest risk, including plants, insects, or microbes..

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.

