

United States
Animal and Veterinary Services
Department of Plant Health
National Center For Import And Export
Agriculture Inspection Import/Export Products Service
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Subject: IMPORTING BIOLOGICAL MATERIALS

More than ever, scientists in the United States are cooperating with their peers throughout the world to obtain tissues, cell lines, and other biological materials from abroad. If you obtain certain types of these materials, you may need an import permit from the U.S. Department of Agriculture (USDA). The United States is free of the most devastating diseases of livestock and poultry, including foot-and-mouth disease, rinderpest, African swine fever, hog cholera, swine vesicular disease, and exotic Newcastle disease. USDA regulations are designed to prevent the introduction of these diseases into the country.

Who Needs an Import Permit

Generally, you need an import permit for any animal-derived material or any biological material that has been in contact with materials of animal origin.

Specifically, restricted biological materials include animal tissues, blood, cells, cell lines, RNA/DNA extracts, hormones, enzymes, proteins, monoclonal and polyclonal antibodies, antisera, immunoglobins, recombinant products, immunoassay components, immunoassay kits, and microorganisms such as fungi, bacteria, viruses, and other products that are derived from or have been in contact with animal-derived materials.

For example, monoclonal antibodies are produced by hybridomas, which are hybrid cell lines formed from mammalian cells. Most hybridomas are grown in media supplemented with nutrient factors such as fetal calf serum, which is a possible source of foot-and-mouth-disease virus. This disease has not occurred in the United States since 1929, but several earlier outbreaks were attributed to contaminated cowpox vaccines that were imported.

Certain biologic specimens imported for human diagnostic purposes are not restricted by USDA. These materials include human bone marrow cells and amniocentesis samples that have not been grown or transported in tissue culture media containing animal-derived supplements. However, each shipment of patient specimens needs to be accompanied by a written description that accurately explains the contents. The declaration needs to be available for inspection at the port of entry and should be sent with the Customs declarations.

Avoiding Unnecessary Delays

To avoid unnecessary delays in your project, obtain a USDA import permit for the restricted biological materials you want to import. Materials for which there is no import permit must be held at the port of entry until a permit is applied for and issued. Import permits for restricted biological materials are issued by the USDA's Animal and Plant Health Inspection Service (APHIS).

Obtaining and Submitting an Import Permit Application

Import permit applications may be obtained from local USDA port offices. They can also be obtained from and submitted to the address at the end of this fact sheet. That office can be reached by telephone at (301) 734-7830 or 734-8499, or by facsimile at (301) 734-8226.

By properly completing the import permit application, you will facilitate the timely transport of restricted biological materials. Here are some tips for completing the application:

1. Be thorough. Incomplete, unsigned, or illegible applications cannot be processed and will result in significant delays.
2. List all the potential U.S. ports of entry. The movement of restricted biological materials could be delayed if they are transported to a port not listed on the import permit. To avoid this delay, importers should include a copy of the import permit with the U.S. Customs declaration.
3. Make it clear whether the restricted biological material is for *in vivo* use or *in vitro* use, for commercial distribution, or for research at your own facility. These distinctions will help us determine the type of import permit to issue and the restrictions and precautions required. In some cases, the materials must be safety tested at the USDA's Foreign Animal Disease Diagnostic Laboratory (FADDL), located at Plum Island, New York, using live animals.
4. Make sure to list any treatments the material has undergone, such as processing and purification steps involving pH, heat, chromatography, etc. (If you are importing antibodies or antisera, you will also need to identify the immunogens.) This treatment information will help us evaluate the material's potential as a vector of exotic livestock disease.
5. Additional information to supplement the import permit is needed when you import cell cultures and their derivatives, such as monoclonal antibodies or recombinant proteins. It is critical that we know the sources of the nutrient factors in the culturing media (fetal bovine serum or other protein/nitrogen supplements, for example). We need to know the cell line designation and history, whether enzymes were used, and what types of viruses (if any) are being studied in the laboratory of origin.
6. Plan to obtain an import permit well in advance of the proposed shipping date. This will help ensure an unimpeded and smooth importation. When collaborating with scientists in other countries, please inform your supplier of USDA's requirements. Instruct your supplier not to ship restricted materials until an import permit has been issued to you and until your supplier has received a copy of the import permit.

If you have any questions or need clarification concerning USDA's regulations, contact the Import–Export Products Staff in advance of your project. Staff members can inform you about the problems you may encounter and offer advice on alternative procedures. Our address is:

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