

GENERAL INFORMATION ON IMPORTATION PERMITS FOR ETIOLOGIC AGENTS

INTRODUCTION

Etiologic agents are those microorganisms that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsia, protozoans, and parasites. These disease-causing microorganisms may also be referred to as infectious agents. Infectious substances and biological materials, such as body fluids and tissues that contain them, are referred to as infectious materials. Organisms such as mosquitoes, ticks, or snails, that may transmit infectious diseases to animals, including humans, are called vectors.

Etiologic agents and the vectors and other materials that may contain them, are recognized by the federal government and state governments as hazardous materials. Infectious materials are regularly transported from one location to another by common land and air carriers. Containers of infectious materials must be carefully packaged to prevent breakage or leakage to avoid exposure of the package handlers, transporters, and the general public to the package contents. The package must be labeled with the universal biohazard sign to warn package handlers of the hazardous contents. When a package of infectious material is being imported into the United States, it must be accompanied by an importation permit.

IMPORTATION PERMITS

Many etiologic agents, infectious materials or vectors containing infectious agents are imported from foreign locations into the United States for domestic use (educational, scientific, commercial, etc.). Packages containing etiologic agents or vectors originating in these foreign locations must have an importation permit issued by the United States Public Health Service. 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.

The importer is legally responsible for assuring that the foreign personnel package, label, and ship the infectious materials according to USPHS and IATA regulations.

Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date, are also issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U.S. Customs Service and U.S. Division of Quarantine Personnel of the package contents.

FEDERAL REGULATION

The importation of etiologic agents is governed by the following federal regulation:

USPHS 42 CFR - Part 71 Foreign Quarantine. Part 71.54 Etiologic agents, hosts, and vectors.
(a) A person may not import into the United States, nor distribute after importation, any etiologic agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of U.S. Customs Service of a permit issued by the Director (Centers for Disease Control and Prevention).

ITEMS REQUIRING PERMITS

Etiologic agents

It is impractical to list all of the several hundred species of etiologic agents. In general, an import permit is needed for any infectious agent known or suspected to cause disease in man.

Biological materials

Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious or etiologic agent require a permit in order to be imported.

Vectors

- Animals. Any animal known or suspected of being infected with an organism capable of causing disease transmissible to man may require a CDC permit. Importation of live turtles of less than 4 inches in shell length and all nonhuman primates requires an importation permit issued by the Division of Quarantine. Telephone (404) 639-8108 for further information.
- Bats. All live bats require an import permit from the CDC and the U.S. Department of Interior, Fish and Wildlife Services.
- Insects or Arthropods. All live fleas, flies, lice, mites, mosquitoes, or ticks require a CDC import permit, regardless of infection status. Permits are required for adult forms, as well as eggs, larvae, pupae, and nymph stages. Any other living insect or arthropod, known or suspected of being infected with any disease transmissible to man requires a CDC import permit.
- Snails. Any snail species capable of transmitting a human pathogen require a permit from the Centers for Disease Control.

PACKAGING REQUIREMENTS

Infectious materials imported into this country must be packaged to withstand breakage and leakage of contents, and labeled, as specified in the following federal regulations:

- USPHS 42 CFR Part 72 - Interstate Shipment of Etiologic Agents
- DOT 49 CFR PART 173 - Transportation of Etiologic Agents
- For international shipments, the International Air Transport Association (IATA) Dangerous Goods Regulations should be consulted.

OTHER PERMITS

- United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) permits are required for infectious agents of livestock and biological materials containing animal material. Tissue culture materials and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origins are controlled by the USDA due to the potential risk of introduction of exotic animal diseases into the U.S. Further information may be obtained by calling the USDA/APHIS at (301) 734-7834.
- United States Department of Interior (USDI) permits are required for certain live animals and all live bats. Call (202) 358-2095 for further information.

EXPORTS OF INFECTIOUS MATERIALS

The export of infectious material may require a license from the Department of Commerce. Call (202) 501-7900 for further information.

COMPLETING THE "APPLICATION TO IMPORT OR TRANSPORT AGENTS OR VECTORS OF HUMAN DISEASE"

INTRODUCTION

Importation permits are issued by the Office of Health and Safety at the Centers for Disease Control and Prevention after review of a completed application form. The regulation, application, and instructions can be found at the CDC Office of Health and Safety website (www.cdc.gov/od/ohs/biosfty/imprtper.htm) or by calling the CDC fax information service at 1-888-232-3299 and requesting document number 101000. Completed application forms may be returned to the Office of Health and Safety by mail or FAXED: 404-498-2275.

- Currently there is no fee for processing a U.S. Public Health Service import permit.
- *At least 15 working days* are required to process import permit applications, renewals and modifications.
- Import permit applications, renewals and modifications are processed in the order they are received.
- Incomplete or illegible applications will result in significant delays and/or denial of a permit. Applications may be typed or handwritten. However, if handwritten, applications must be legible.
- Requests for renewal of an existing permit and modifications will require the completion of a new application and current signature of the permittee.
- Letters of Authorization are no longer issued. If you are unsure if you need a permit, complete the application and our office will determine if a permit is required.
- Our phone and fax numbers have changed. Please confirm that you are faxing your application to 404-498-2275
- Use additional sheet(s), noting the block number if more space is needed.

BLOCK 1. (PERMITTEE) The person requesting the permit (applicant) should be (1) knowledgeable and skilled in the handling of the infectious agent or biological material, (2) be directly responsible for work with the infectious material, and (3) should be located at the address within the U.S. where work with the infectious material will be performed. Regulatory affairs officers or other general administrative personnel are generally not acceptable as permittees.

Enter your complete name, address, telephone, and FAX number. Failure to include the telephone and FAX numbers where you can be reached during the day will result in prolonged delays.

The name appearing in this block, and in Block 10 should be the same. Only one name may be used here.

BLOCK 2. Enter complete name, address, telephone and FAX number of the sender. Multiple sources may be listed on an attached sheet as needed. List the corresponding infectious material that will be shipped for each source.

BLOCK 3. Describe the type of sample (isolate, whole organism, tissue, blood, DNA, etc.), name of host source from which the sample is obtained (human, mouse, snail, etc.), and the etiologic agent, if appropriate. Answer yes or no to the questions given. Incomplete information may result in significant delays or denial of your permit request.

BLOCK 4. Importation into the U.S. refers to the package as passing through the port of entry to the applicant's address. Moving imported material from one air carrier to another at the Port of Entry on the way to its domestic destination is not considered a transfer for the purposes of this permit. A transfer within the U.S. refers to shipping from one address within the U.S. to another address within the U.S.

Permits for multiple importations are valid for one year. Permits for single importations are valid for six months. For multiple shipments, enter the number of shipments you expect to receive in the next 12 months and number of transfers you expect to make in the next 12 months. One importation label is issued per shipment.

BLOCK 5. Complete as indicated.

BLOCK 6. Complete as indicated.

BLOCK 7. In describing objectives, please state the intended use(s): infectious disease research or diagnosis, genetic studies or analysis, chemical or biochemical analysis, enzyme assays, population profiles, kit development, etc.

BLOCK 8. Give the biosafety level of the laboratory where the work will occur and any other information pertinent to available facilities.

BLOCK 9. Complete as indicated. Include a list of publications, if pertinent and appropriate.

BLOCK 10. Type or print your name legibly in the appropriate space. *The application must be signed by the same person listed in Block 1, or the permit application will not be processed.*