IMPORT AND TRANSFER OF ETIOLOGIC AGENTS

(For assistance, please contact EHS at (402) 472-4925, or visit our web site at http://ehs.unl.edu/)

Introduction
The United States Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention (CDC) regulates import into the United States of etiologic agents through administration of a permit system. The permit may contain provisions related to intra- and inter-state transport of imported etiologic agents and select agents. These regulations are codified at 42 CFR - Part 71 Foreign Quarantine, Part 71.54 Etiologic agents, hosts, and vectors; and provide:

(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.

Items requiring an Etiological Agent Import Permit

Etiological agents
- Microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or an infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.
- CDC does not provide a list of agents requiring a permit, so, in general, an import permit is needed for any infectious agent known or suspected to cause disease in humans.
- Other examples of materials that require a permit are:
  - Positive (+) strand RNA viruses capable of producing the infectious agent
  - Non-FDA-approved vaccines or drugs
  - IND vaccine or drug
**Biological materials containing etiological agents**

- Unsterilized specimens of human and animal matter including tissue, blood, body discharges, fluids, excretions or similar material, when known or suspected of containing a biological organism capable of causing disease in humans (i.e., excreta, secreta, blood, body fluids, tissues, organs, cultures, human remains, etc.).

- Clarifications for Blood, Blood Products or Tissues
  - An import permit **is** required if the following apply:
    - The specimen is known or suspected to be infected with a human etiological agent or;
    - The specimen will be tested for human etiological agents.
  - An import permit **is not** required if:
    - The specimen has been treated to kill any etiological agents present (e.g., sterilized) or;
    - The specimen will **not** be tested for human etiological agents and is not known or suspected of containing human etiological agents.
  - Regardless of the testing methods used and whether a permit is necessary, you are obligated to follow the regulations outlined in the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) when handling and shipping human blood or blood products. See the **UNL Bloodborne Pathogens Exposure Control Plan** for additional information.

**Hosts and Vectors**

- **Animals** - Any animal known or suspected of being infected with an organism capable of causing disease in humans may require a permit issued by CDC. Importation of live turtles of less than 4 inches in shell length and live nonhuman primates is regulated by the CDC, Division of Global Migration and Quarantine.
- **Bats** - All live bats require an import permit from the CDC and the U.S. Department of Interior, Fish and Wildlife Services. The application for a CDC import permit for live exotic bats is on this website.
- **Arthropods** - Any living insect or other arthropod that is known or suspected of containing an etiologic agent (human pathogen) requires a CDC import permit.
- **Snails** - Snail species capable of transmitting a human pathogen require a permit from the Centers for Disease Control.
- **Non-human primate material** – all non-human primate material (e.g., blood, plasma, tissue, urine, feces) requires an import permit, unless it has been specifically treated and rendered non-infectious.
Types of Material that do NOT require an Etiological Agent Import Permit

- Non-infectious material (formalin-fixed slides, etc.).
- Human or animal diagnostic specimens in which there is no evidence or indication that such material contain an infectious agent and the specimen is accompanied by a certification statement.
- Treated (rendered non-infectious) non-human primate material including fully taxidermied or treated trophies, skins, or skulls.
- Nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by a certification statement.
- Material that is non-pathogenic to humans.
- Products that are cleared, approved, or licensed
  - Federal Food, Drug, and Cosmetic Act
  - Section 351 of the Public Health Service Act pertaining to biological products
  - The Virus-Serum-Toxin Act
- Laboratory mice, rats, and hamsters reared under specific pathogen-free (SPF) conditions. In addition, genetically altered animals do not require a CDC import permit provided that the animals contain no pathogens known to be transmissible to humans. NOTE: If the rodents are to be imported from Africa or are species of African origin, they may only be imported for scientific, education, or exhibition purposes with permission granted from CDC’s Division of Global Migration and Quarantine.

Embargoes
There are certain animals that are prohibited from being imported into the United States due to their role as disease hosts, those include:

- Civet cats (host for SARS-CoV) – effective 1/13/2004

Select Agents
Select Agents or toxins, some of which are etiologic agents, are exempt from the requirement for an Etiological Agent Import Permit, but are subject to separate requirements involving a registration process. See EHS SOP, Select Agents for additional information, including a list of select agents. Select agents may not be imported or transferred from one location to another without first obtaining registration status.
Etiologic Agents Affecting Both Humans and Animals or Only Animals

Import and transfer of infectious substances affecting only animals or plants are not regulated by CDC. Rather, they are subject to permit requirements of the United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS). APHIS permits are often required for animal and plant products as well, regardless of potential presence of pathogens. See the EHS SOPs Importing Animals and Animal Products or Non-Genetically Engineered Plant-Related Articles Requiring APHIS Transfer Permits for more information.

Importation of etiologic agents affecting both humans and animals is subject to United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) and CDC permit requirements.

Obtaining a CDC Import Permit

CDC requires completion of an appropriate Import Application. Forms are available on the CDC web site. There is currently no fee for CDC Import Permits.

CDC does not maintain a list of agents considered to be etiologic agents. As a rule-of-thumb, any agent that is classified as a risk group 2 or higher may require a CDC import permit. CDC recommends submitting a permit application when it is not clear whether an agent is considered an etiologic agent. CDC does not provide verbal consultation. A minimum of 15 days is required to process an application, and a minimum of 30 days is required to renew an existing permit.

- Importation permits are issued only to the importer, who must be located in the U.S.
- The importer is legally responsible for assuring that the foreign personnel package, label, and ship the infectious materials according to Federal and International regulations.
- Inter- or intra- state transport of etiologic agents following import typically requires another permit.
- The importer is responsible for notifying EHS when a CDC Import Permit is requested. Send a copy of the permit application to the EHS Biosafety Officer.
- When shipping infectious materials by ground or by air, shipping requirements of CDC (42 CFR 72), Department of Transportation (DOT), and International Air Transportation Association (IATA) may apply. All UNL employees who offer dangerous goods/ hazardous materials must be on the UNL designated shipper list, which is accomplished by participating in training at the required interval (every three years).
- When the permit is approved, shipping labels with the universal biohazard symbol, the address of the importer, the permit number, and the expiration date
will be issued to the importer. The importer must send the labels and one or more copies of the permit to the shipper. The labels and the permit inform the U.S. Customs Service and U.S. Division of Quarantine personnel of the package contents.

**Procedure for agent importation if a permit is not required**
To facilitate clearance of materials, CDC advises that importers of materials that do not require a CDC import permit include with the shipment a signed statement, on their official letterhead, from the person responsible for the shipment of this material with the following information:
- A description of the material;
- A statement that this material meets one of the above criteria (e.g., human urine diagnostic specimens in which there is no evidence that such material contain an etiologic agent); and,
- Verification that shipment is packaged, labeled, and transported in accordance with all applicable regulations.

**Other Agencies and Exports**
Other federal permits may be required for importing or transferring certain materials. Examples of such permits are APHIS permits for plant or animal and animal-related products and materials; FDA permits for food, biologics, cosmetics, drugs, medical devices, and electronic products that emit radiation; Fish and Wildlife Service permits for fish, wildlife, endangered species, etc.; Commerce Department, Bureau of Industry and Security permits for certain technologies and infectious agents including genetic materials and products which might be used to culture large amounts of agents; Department of Interior (USDI) permits for certain live animals and all live bats.

The export of a wide variety of etiologic agents of human, plant, and animal diseases may require a license from the Department of Commerce. The UNL Office of Research Compliance is responsible for administration of export compliance programs.