

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 the 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.

CDC defines etiologic agents as those viable microorganisms and microbial toxins that cause disease in humans and include bacteria, bacterial toxin, viruses, fungi, rickettsiae, protozoans, and parasites. CDC's regulatory authority of etiologic agents also extends to vectors (arthropods and other organisms that can transmit pathogens to animals and humans) and other materials known or suspected of containing viable etiologic agents (i.e., excreta, secreted, blood, body fluids, tissues, cultures, etc.). Examples of other items that are subject to CDC import permits include bats, snails, non-human primates, and turtles.

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.

Regardless of the testing methods used and whether a permit is necessary or not, 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.

Select Agents

Select Agents, a sub-classification of etiologic agents, are subject to additional requirements which involve 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. 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 at <http://www.cdc.gov/od/eaipp/importApplicationForms.htm>.

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 requires a 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 two 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.

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.