

IMPORT AND TRANSFER OF ETIOLOGIC AND OTHER CDC REGULATED AGENTS

Introduction

The United States Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention (CDC) requires an import permit for a variety of materials, broadly classified as biological agents, infectious substances, vectors of human disease, genomic material, vaccines/drugs/reagents, live animals, live bats, and non-human primate material. **When issued the permit may also contain provisions related to intra- and inter- state transport following import.** These regulations are codified at 42 CFR, Subpart F. CDC provides an e-Tool to assist in determining if an import permit is needed. This tool is available at <http://www.selectagents.gov/resources/IPPetool/>. If you intend to engage in an import activity, use this tool to determine if the material requires a CDC import permit.

Scope

This SOP is specific to import permits required by the CDC. Other federal permits may be required for importing or transferring certain materials. Examples of such permits are United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) permits for plant or animal and animal-related products and materials; United States Food and Drug Administration (FDA) permits for food, biologics, cosmetics, drugs, medical devices, and electronic products that emit radiation; United States Fish and Wildlife Service permits for fish, wildlife, endangered species, etc.; United States 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; United States Department of Interior (USDI) permits for certain live animals and all live bats.

Export of a wide variety of etiologic agents of human, plant, and animal diseases may require a license from the United States Department of Commerce. The UNL Office of Research Compliance is responsible for administration of the export compliance program. EHS strongly encourages the UNL campus community to contact the UNL Office of Research Compliance before engaging in any type of export activity.

Obtaining a CDC Import Permit

CDC requires completion of an appropriate Import Application. Forms are available on the CDC web site (<http://www.cdc.gov/od/eaipp/importapplication/agents.htm>). CDC offers guidance documents to support accurate completion of the import application. Applications can be submitted by mail, email, or fax.

Transport

The importer is legally responsible for assuring that foreign personnel package, label, and ship the materials in accordance with applicable International Air Transport Association (IATA) Dangerous Goods Regulations. Persons engaged in a transport activity must have current IATA training. See EHS SOP, ***Packaging and Shipping Hazardous Materials/Dangerous Goods***. Typically, materials that are subject to import permit requirements can not be hand carried on a commercial flight.

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 official letterhead containing a description of the material and the reason why it does not require an import permit.

Materials NOT requiring a CDC Import Permit

Following are examples of materials that do NOT require a CDC import permit. EHS advises to use the CDC e-Tool to determine the correct status of a material intended for import.

- Select agents. However, authorization under the Select Agent regulations is required for any import and the receiving entity must be registered for the material. See EHS SOP, ***Select Agents and Toxins***.
- Diagnostic specimen (except bat or nonhuman primate specimens) not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent if accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent, or has been rendered noninfectious.
- Animal or animal product being imported for educational, exhibition, or scientific purposes if accompanied by documentation confirming that the animal or animal product is not known to contain (or suspected of containing) an infectious biological agent or has been rendered noninfectious.
- Nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by an importer certification statement confirming that the material is not known to contain or suspected of containing an infectious biological agent.
- Animal or animal product listed in 42 CFR Part 71 and its importation has been authorized in accordance with 42 CFR §§ 71.52, 71.53, or 71.56.
- Product that is cleared, approved, licensed, or otherwise authorized under: The

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262), or; The Virus-Serum-Toxin Act (21 U.S.C. 151-159).