



## IMPORT AND TRANSFER OF INFECTIOUS BIOLOGICAL MATERIALS AND OTHER CDC REGULATED AGENTS

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### Introduction

The United States Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention (CDC) Import Permit Program, or IPP, regulates the importation of infectious biological materials that could cause disease in humans in order to prevent their introduction and spread into the U.S. The program ensures that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the imported agents.

### Materials requiring import permits include:

- Infectious biological agents capable of causing illness in humans;
- Materials known or reasonably expected to contain an infectious biological agent;
- Vectors of human disease (such as insects or bats).

These regulations are codified at 42 CFR, Part 71 Subpart F. The CDC IPP website (<https://www.cdc.gov/cpr/ipp/>) provides an e-Tool to assist in determining if an import permit is needed. If you intend to engage in an import activity, use this tool to determine if the material to be imported requires a CDC import permit.

### Scope

This SOP is specific to import permits required by the CDC. Additional federal permits may be required for importing or transferring certain materials. Examples of such permits include:

- United States Department of Agriculture Animal and Plant Health Inspection Service (APHIS) permits for import, transit or release of an animal, animal-related product or an organism/vector capable of infecting livestock or poultry or infected with a livestock or poultry pathogen; United States Food and Drug Administration (FDA) permits for food, human and veterinary drugs; vaccines and other biological products;
- United States Fish and Wildlife Service permits for fish, wildlife, endangered species, etc.;

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. UNL Research Compliance Services in the Office of Research and Economic Development is responsible for administration of the Export Control Compliance Program (ECCP). EHS strongly encourages the UNL campus community to contact the Export Control staff before engaging in any type of export activity.

### Obtaining a CDC Import Permit

The CDC e-tool for determining whether a permit is required includes a link to the e-permit system if a permit is required. All permit applications require a Service Access Management Systems (SAMS) account. Please consult the training resources on the CDC website for instructions to set up your account and apply for the proper permit.

### Special Provisions for Import of SARS-CoV-2

Requesting permits to import Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) requires a CDC Import Permit application to be submitted electronically using the eIPP system (<https://eipp.cdc.gov/>).



**Subsequent transfers of previously imported material containing SARS-CoV-2 within the United States also require a CDC import permit.**

#### Permit Required

- Import of isolates or cultures of SARS-CoV-2.
- Import of infectious substances (e.g., blood, bodily fluids, tissues) that are reasonably expected to contain SARS-CoV-2.
- Import of nucleic acids capable of producing SARS-CoV-2 (i.e., full-length genomic RNA extracted from SARS-CoV-2).

A permit is required to transfer SARS-CoV-2 materials described above within the United States.

#### Permit Not Required

- Specimens or isolates/cultures of SARS-CoV-2 within the United States or its territories that were not generated from imported material.
- Nucleic acids encoding partial sections or fragments of SARS-CoV-2 incapable of producing infectious virus (i.e., partial or degraded SARS-CoV-2 genomic RNA).
- Diagnostic samples not known or suspected of containing SARS-CoV-2. See FAQ “Do I need an import permit” <https://www.cdc.gov/cpr/ipp/faq.htm>

## Transport

While compliance with DOT/IATA regulations is the responsibility of the offeror of dangerous goods/hazardous materials, CDC regulations require that the importer take measures to help ensure that the shipper complies with all applicable legal requirements concerning the packaging, labeling, and shipment of infectious substances. 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 cannot be hand carried on a commercial flight.

## Transfer of permitted material to other researchers/entities

- The permit holder is responsible for all requirements and restrictions included with the issued permit.
- If noted as a condition of the issued permit, subsequent transfers of any infectious biological agent, infectious substance or vector within the United States will require an additional permit issued by the CDC.
- In addition to CDC requirements, other federal regulations may apply and need to be satisfied (e.g., Select Agent regulations) prior to transfer of any permitted material(s) to a new location or owner.

## Import Procedures When a CDC Import Permit is NOT Required

To facilitate clearance of materials through U.S. Customs, the CDC requires that each shipment be accompanied by a certification statement, on an official letterhead, from either the sender or recipient of the material. The certification statement **must** include:

- Detailed description of the materials;
- Statement affirming the following:
  - The material is not known or suspected to contain an infectious biological agent **and one** of the following:
    - How the person knows that the material does not contain an infectious biological agent;
    - Why there is no reason to suspect that the material contains an infectious biological agent;
    - A detailed description of how the material was rendered non-infectious.

## Materials NOT requiring a CDC Import Permit

As of the date of this SOP revision, 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 (except live bats or bat or nonhuman primate products) 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).