

Office of Public Health Preparedness and Response

CDC Import Permit Program

Overview and Authority

The Centers for Disease Control and Prevention (CDC) Import Permit Program (IPP) regulates the importation of the following into the United States:

- Naturally occurring or bioengineered infectious biological agents capable of causing disease in a human.
- Any material that is known or reasonably expected to contain an infectious biological agent.
- Vectors, including animals/animal products (e.g., a mount, rug or other item composed of animal hide, hair, skull, teeth, bones or claws), that are known to transfer or are capable of transferring an infectious biological agent to a human.

The Secretary of Health and Human Services is authorized by Section 361 of the Public Health Service Act (42 U.S.C. 264) to make and enforce regulations to prevent introducing, transmitting, or spreading communicable diseases from foreign countries into and throughout the U.S. or possessions. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent introducing, transmitting, and spreading communicable disease from foreign countries into the U.S. Subpart F contains provisions for importing infectious biological agents, infectious substances, and vectors (42 CFR 71.54) and requires persons importing these materials to obtain a permit issued by the CDC.

Import Permit Program Permits

Before an import permit is issued to any entity, IPP reviews all applications to ensure that the requesting entity has appropriate

biosafety measures in place to work with the imported materials. Most import permits are issued to laboratory facilities at government agencies, universities, and research institutions conducting studies or diagnostic activities.

Partnerships

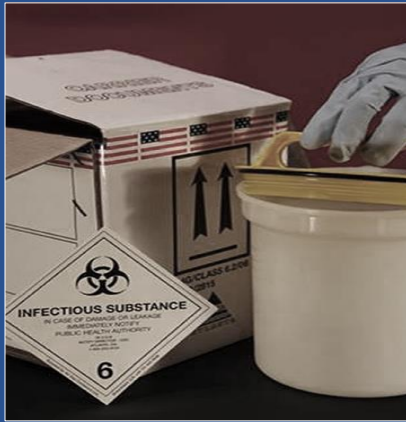
IPP partners with other federal agencies to ensure the safe handling and use of imported infectious biological agents.

- Division of Global Migration and Quarantine (CDC) promotes the health of globally mobile populations to prevent the spread of communicable diseases.
- U.S. Customs and Border Protection (DHS) secures the nation from terrorists and other threats and facilitates legitimate trade and travel.
- Animal and Plant Health Inspection Service (USDA) regulates the importation of infectious agents of livestock and biological materials containing animal material.
- Department of Transportation (DOT) regulates the shipment of infectious substances in commercial transportation to, from, or within the United States.

Benefits of the CDC Import Permit Program

- CDC monitors the importation of these agents into the United States.
- A CDC permit is only issued to facilities that have the appropriate biosafety measures in place to work with the imported agents.





Accomplishments

The Import Permit Program is continually working to increase laboratory safety by inspecting laboratories and offering guidance to the regulated community. Recent key accomplishments (calendar year 2013) to support this effort include:

- Issued 1700 Import Permits for the importation of infectious biological agents, infectious substances, and vectors.
- Conducted 47 inspections to ensure that entities had the proper biosafety measures to work safely with infectious biological agents, infectious substances, and vectors.
- Provided technical assistance and guidance to international partners in support of the CDC's Global Health Security Agenda.
- Enhanced the import permit application process by developing a more robust database capable of receiving electronic submission of applications.
- Developed a means to continue business during emergencies, natural disasters, or extenuating circumstances.
- Successfully responded to outbreaks (e.g., H7N9, MERS, Ebola virus) and response activities by ensuring the safe and expeditious importation of critical diagnostic samples and vaccine strains.
- In July, conducted the Import Permit Webinar with over 1000 participants from the U.S and abroad.



Inspections

Permit issuance may be contingent upon an inspection of the importer's facility by the IPP. An inspection includes an evaluation of the requesting importer's biosafety measures (e.g., physical structure, features, and operational and procedural safeguards of the facility) to ensure they are commensurate with the hazard posed by the imported agent and the level of risk given its intended use. These inspections provide insight to the IPP of the biosafety conditions in these laboratories and ensure that requesting laboratories adhere to appropriate biosafety practices and facility containment. IPP's inspections serve to ensure appropriate biosafety measures are in place at facilities in order to minimize the accidental release of biological agents capable of causing human disease.

Outreach

IPP provides guidance and support to assist the regulated community in meeting the requirements of import permit regulations. Up-to-date information, such as guidance documents, resource materials, and an e-mail link for questions or requests can be found on the IPP website: www.cdc.gov/od/eaipp/. Training programs are provided in workshops to inform individuals of their legal responsibilities for implementing the import permit regulations.

Additional Resources

- USDA Animal and Plant Inspection Service www.aphis.usda.gov/permits/index.shtml
- U.S. Customs and Border Protection www.cbp.gov/
- CDC's Division of Global Migration and Quarantine www.cdc.gov/ncezid/dgmgq/
- Department of Transportation <http://hazmat.dot.gov>
- U.S. Fish and Wildlife Service www.fws.gov/permits/overview/overview.html

For more information about CDC's Import Permit Program, go to www.cdc.gov/od/eaipp/ or contact:

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