Topics of Discussion

• Background/Purpose
• Importation Regulations
• Application Process
• Evolution of the Program (Proposed Regulations)
• Program Partners
• Frequently Asked Questions
The importation of etiologic agents, hosts, and vectors is governed by the Foreign Quarantine Regulations (42 CFR 71.54). Centers for Disease Control and Prevention (CDC)’s Etiological Agent Import Permit Program (EAIPP) regulates the importation of etiologic agents (microorganisms and their associated byproducts that cause disease in humans), hosts, and vectors of human disease into the United States. Such materials imported into the United States, must be accompanied by an etiologic agent import permit issued by CDC.
Purpose of the Program

• EAIPP assists in protecting the United States public health and safety by ensuring that all imported etiologic agents are imported safely into the United States. EAIPP reviews all etiologic agent import permit applications to ensure that appropriate safety measures are in place for the imported infectious agents.

• EAIPP provides oversight to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.
Federal Regulations

USPHS 42 CFR - Part 71 Foreign Quarantine; Part 71.54 Etiological agents, hosts, and vectors.

(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.

(b) Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of U.S. Customs Service of a permit issued by the Director (Centers for Disease Control and Prevention).
Types of Material that Require an Import Permit

- **Etiologic Agents** – a microorganism including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa (causing disease in humans).
- **Animals** – Any animal capable of being a host or vector of human disease.
- **Bats** - All live bats.
- **Arthropods** – Any living insect including crustaceans, spiders, scorpions, etc. capable of being a host or vector of human disease.
Types of Material that Require an Import Permit

- **Snails** – Any freshwater snails (phylum Mollusca, class Gastropoda) capable of transmitting schistosomiasis.

- All non-human primate materials (NHP) and trophies (unless specifically treated and rendered non-infectious)
Types of Material that Do Not Require an Import Permit

- Non-infectious material (formalin-fixed slides, etc.)
- Human or animal diagnostic specimens that do not contain an etiologic agent
- Treated (rendered non-infectious) NHP material & trophies
- Genomic material (except positive strand viruses capable of producing the infectious agent)
- Material that is non-pathogenic to humans
- FDA-approved vaccines
- Laboratory mice, rats, and hamsters reared under specific pathogen-free (SPF) conditions
Embar gos

- **Embar goed Animals and Monkeypox Virus**
  - **Effective Date:** June 11, 2003.
  - **Suspect Agent:** Monkeypox Virus
  - **Area:** Africa

- **Embar go of Civets (civet cats)**
  - **Effective Date:** January 13, 2004.
  - **Suspect Agent:** SARS-associated coronavirus (SARS-CoV)
  - **Area:** Worldwide

- **Embar go of Birds from Specified Southeast Asian Countries**
  - **Effective Date:** February 4, 2004 (Rescinded 9/14/2009)
  - **Suspect Agent:** Avian Influenza
  - **Area:** Cambodia, Indonesia, Japan, Laos, Kazakhstan, Malaysia, People's Republic of China, Romania, Russia, South Korea, Thailand, Turkey, Ukraine, and Vietnam
Top Ten Etiologic Agents Imported into the U.S. (August 2011-September 2012)
Number of Approved Import Permits
(Total = 1855)
Types of Applications

• Permit to Import Biological Agents or Vectors of Human Disease

• Permit to Import or Transport Live Bats
APPLICATION FOR PERMIT TO IMPORT BIOLOGICAL AGENTS OR VECTORS OF HUMAN DISEASE

• SECTION A, Person Requesting Permit in US (Permittee)

• SECTION B, Sender of Imported Biological Agent(s)

• SECTION C, Shipment Information

• SECTION D, Final Destination of Imported Biological Agent
APPLICATION FOR PERMIT TO IMPORT BIOLOGICAL AGENTS OR VECTORS OF HUMAN DISEASE

- **SECTION E**, Description of Imported Biological Agent
- **SECTION F**, Description of Material(s) Containing the Biological Agent(s) to be Imported
- **SECTION G**, Receiving Laboratory Capabilities
Common Problems Identified with the Application

1. Applicants conducting work on open bench.
2. Description of work is vague and does not include laboratory procedures.
3. Applicants that wish to hand carry material.
4. Applicants that do not know the laboratory capabilities of the receiving laboratory.
5. Applicants that wish to conduct work involving production of aerosols at BSL-2.
6. Applicants that have several final destinations (distribution centers).
Conditions of Issuance

- USDA permit may be required
- Work with the material restricted to areas and conditions meeting Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines
- Material must be packaged and labeled in accordance with:
  - all applicable laws
- Subsequent distribution prohibited
  - SARS-CoV, select agents, bats, BSL-4 agents
Permit Not Required

Procedures for agents not requiring an import permit:

• E-mail stating permit is not required
• To facilitate clearance of materials that do not require a CDC Import Permit, it is recommended that each shipment be accompanied by a signed statement, on official letterhead, from the person responsible for the shipment of this material with the following information:
  – Description of the material;
  – Statement that material is non-infectious
  – Verification that shipment is packaged, labeled, and transported in accordance with all applicable regulations.
Evolution of the Etiological Agent Import Permit Program

Proposed Rulemaking

- On October 14, 2011, CDC published a notice of proposed rulemaking for the current regulations (42 CFR 71.54) for importation.
- To improve CDC’s ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.
- The public received a 60 day comment period (closed Dec. 13, 2011).
1. Clarification of those items that need an import permit;
2. Require that the applicant have biosafety measures that are commensurate with the hazard posed by the infectious biological agent, infectious material, and/or vector to be imported, and the level of risk given its intended use;
3. Allow CDC to review the biosafety plan and inspect the applicant’s facility prior to a permit being issued to evaluate whether the applicant’s biosafety plan is commensurate with the risk of the item to be imported, given its intended use; and
4. Create an appeals process for permit applications that are denied.
Exemptions

A permit is not required:

- Select agents or toxins
- Diagnostic specimen not known to contain an infectious biological agent and the specimen is accompanied by certification statement
- Animal being imported for educational or exhibition purposes
- Nucleic acids that cannot produce infectious forms of any infectious biological agent and the specimen is accompanied by certification statement
- A product that is 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
EAIPP Primary Partners

• CDC Division of Global Migration and Quarantine (DGMQ)
  ➢ Quarantine stations at ports of entry
  ➢ Administration of interstate and foreign quarantine regulations, which govern the international and interstate movement of persons, animals, and cargo

• Department of Homeland Security/Customs and Border Protection (CBP)
Frequently Asked Questions

Is there a fee for obtaining a CDC import permit?
No. Currently, there is no fee for processing a CDC import permit.

Is a CDC import permit required for the interstate transfer of an etiologic agent?
An additional CDC import permit will be required if the original CDC import permit had as a condition of issuance that any subsequent transfer of the material would require a permit.
What are the responsibilities of the importer once an import permit has been issued?

The importer is responsible for assuring that the foreign personnel package, label, and ship the infectious material according to Federal regulations and international standards.

Is a USDA permit also required for pandemic novel H1N1 influenza virus strains?

Yes. The novel H1N1 influenza virus has genetic components of both swine and avian influenza viruses in it which result in causing infections in those species.
Frequently Asked Questions

I have an existing import permit that is about to expire. How do I request a renewal?

All requests for renewal of an existing import permit require the submission of a new application and current signature of the permittee.

With the proposed import permit regulations, will my facility be inspected if I am currently registered with the Federal Select Agent Program (FSAP)?

No. Facilities that are currently being inspected by the FSAP will not require an additional inspection by the Import Permit Program.
Thank You

For more information please contact Centers for Disease Control and Prevention

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.