

Centers for Disease Control and Prevention Import Permit Program



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Division of Select Agents and Toxins

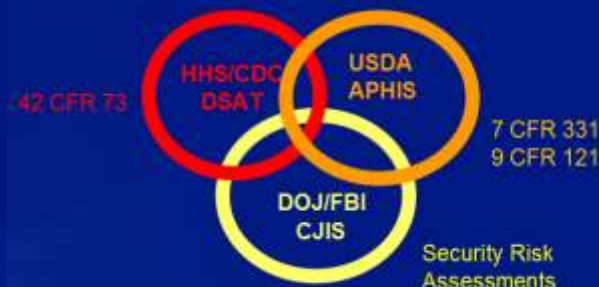
ABSA 57th Annual Biological
Safety Conference



Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

- **Federal Select Agent Program (42 C.F.R. Part 73)**
 - Regulates all entities that possess, use, or transfer biological agents or toxins that have the potential to pose a severe threat to public health and safety
- **CDC Import Permit Program (42 C.F.R. § 71.54)**
 - Regulates the importation of infectious biological agents, infectious substances, and vectors capable of causing communicable disease in humans
- **Promote laboratory safety and security**
 - Inspection Programs (Domestic and International)
 - Guidance on the regulations
 - Training
 - Developing biosafety guidelines



Section 361 of the Public Health Service Act

- ❑ **Authorizes the HHS Secretary to make and enforce regulations necessary to prevent:**
 - Introduction,
 - Transmission, or
 - Spread of communicable diseases from foreign countries into the United States.



Section 361 of the Public Health Service Act



- ❑ **Authorizes the HHS Secretary to use inspections as a public health measure to ensure that such regulations are carried out.**

Import Permit Program

- Assists in protecting the United States public health and safety by ensuring that all imported infectious biological agents, infectious substances and vectors are imported safely into the United States.
- Ensures that appropriate safety measures are in place for the imported infectious agents.
- Provides oversight to prevent the **introduction, transmission, or spread** of communicable diseases

Rulemaking

- ❑ Needed to improve CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.
- ❑ **October 14, 2011: CDC published a notice of proposed rulemaking to amend 42 CFR 71.54.**
 - ❑ 60 day comment period
- ❑ **February 4, 2013: CDC published Final Rule.**
 - ❑ Effective Date: April 5, 2013

Overview of Import Regulations for Infectious Biological Agents, Infectious Substances and Vectors (42 CFR 71.54)

- ❑ Defines items that require an import permit
 - ❑ Infectious biological agent, infectious substances and vector
- ❑ Ensure adequate biosafety measures are in place
- ❑ Increase oversight through inspections
- ❑ Exemptions are listed
- ❑ Provide an appeals process for permits that are denied, revoked, or suspended



Types of Material that Require an Import Permit

- ❑ Infectious Biological Agents – A microorganism (including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa) or prion, whether naturally occurring, bioengineered, or artificial, or a component of such microorganism or prion that is capable of causing communicable disease in a human.



Types of Material that Require an Import Permit

- ❑ Infectious substance - Any material that is known or reasonably expected to contain an infectious biological agent.
- ❑ Vector - Any animals (vertebrate or invertebrate) including arthropods or any noninfectious self-replicating system (e.g., plasmids or other molecular vector) or animal products (e.g., a mount, rug, or other display item composed of the hide, hair, skull, teeth, bones, or claws of an animal)



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).



Material That Does Not Require an Import Permit

42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ With the exception of bat or nonhuman primate specimens, it is a diagnostic specimen not known by the importer to contain, or suspected by the importer of containing, an infectious biological agent.
 - Healthy human specimens or samples
 - Rendered non-infectious
 - Material that is non-pathogenic to humans; non-infectious disease
 - Non-infectious material (e.g., formalin-fixed slides, etc.)

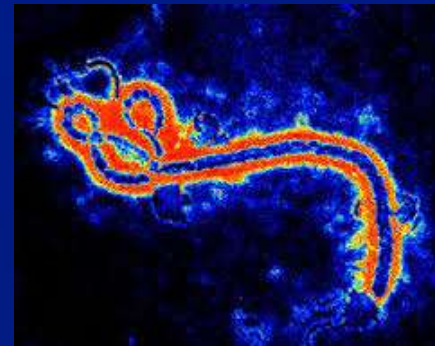
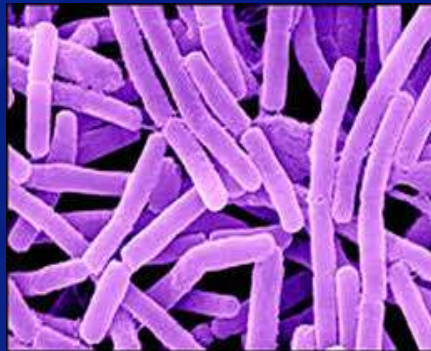


Material That Does Not Require an Import Permit

42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ It is a biological agent listed in 42 CFR Part 73 as a select agent and its importation has been authorized in accordance with 42 CFR 73.16 or 9 CFR 121.16.
 - Transfer authorization (APHIS/CDC Form 2)
 - Examples: *Bacillus anthracis*, *Francisella tularensis*, Ebola Virus



Material That Does Not Require an Import Permit 42 CFR 71.54 (f)

A permit issued under this part is not required for an item if:

- ❑ It consists only of nucleic acids that cannot produce infectious forms of any infectious biological agent
- ❑ Examples:
 - Extracted Deoxyribonucleic acid (DNA) from bacteria
 - Viral nucleic acids that cannot produce any infectious biological agent



Permit not Required Certification Statement

- ❑ A detailed description of the material and a statement on official letter head signed by the sender or the recipient clearly stating that
 - (1) the material is not known or suspected to contain an infectious biological agent and
 - (2) how the person making the certification knows that the specimen does not contain an infectious biological agent; or the basis of the belief that there is no reason to suspect that the specimen does not contain an infectious biological agent; or a detailed description of how the material was rendered noninfectious.



Denials, Revocations and Suspensions

- ❑ A permit can be denied, revoked or suspended if:
 - (1) The biosafety measures of the permit holder are not commensurate with the hazard posed by the infectious biological agent, infectious substance, or vector, and the level of risk given its intended use; or,
 - (2) The permit holder fails to comply with all conditions, restrictions, and precautions specified in the permit.



Date and Conditions of the Import Permit

□ Section 71.54(d)

The CDC permit is valid only for: (1) the time period and/or term indicated on the permit, and (2) only for so long as the permit conditions continue to be met.



42 CFR 71.54 (h)

Inspection

- ❑ Issuance of a permit may be contingent upon an inspection of the importer's facility by the CDC to evaluate whether the importer's biosafety measures are commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector, and the level of risk given its intended use.

Inspection/Biosafety

- ❑ **Verify that work is commensurate with the hazard posed by the infectious biological agent, infectious substance and/or vector to be imported, and the level of risk given its intended use.**



Criteria used to determine if an inspection may be required

- ❑ **Biological safety level where work will be conducted**
- ❑ **Risk of the agent and work conducted**
- ❑ **May not be inspected if the laboratory has been inspected by the Federal Select Agent Program**



Import Permit Inspection Program

❑ Most common agents associated with inspections:

- *Mycobacterium tuberculosis*
- Middle East Respiratory Syndrome coronavirus
- Chikungunya virus
- Avian Influenza A (H7N9) Virus

❑ Common descriptions of work:

- Human diagnostic testing
- Animal studies
- Molecular biology research



Import Permit Inspection Program

❑ Common observations noted:

- Improper donning and doffing procedures
- Laboratory not maintaining negative airflow
- Infectious material placed in non-leak-proof cardboard boxes for storage, processing, or transport
- Improper decontamination procedures
- Lack of use of centrifuge safety cups during centrifugation (production of aerosols)



Import Permit Inspection Program

❑ Common observations noted:

- Improper use of Personal Protective Equipment
- Failure testing (HVAC system)
- Facility re-verification



Compliance inspections

❑ 8 Compliance Inspections conducted in last year

Example

- Whistleblower complaint-CDC IPP notified of biosafety concerns
 - Unannounced inspection
 - Biosafety concerns noted
 - Compliance inspection report provided to entity
 - All departures were addressed adequately
-
- ❑ **OIG Hotline Contact Information:**
Voice: 1-800-HHS-TIPS (800-447-8477)
Fax: 1-800-223-8164



Change in laboratory space prior to inspection

❑ Entity 1:

- BSC not able to meet certification standards
- Additional issues in the facility exhaust flow
- Laboratory shut down
 - Work moved to a laboratory previously inspected by CDC IPP

❑ Entity 2:

- Issues with HVAC system not maintaining negative airflow
- Work moved to Select Agent registered space



Importation Investigation

- ❑ Investigation involved 7 businesses in the same city who were suspected to be fraudulent businesses
- ❑ Collaborated with Federal Bureau of Investigation/Weapons of Mass Destruction, Department of Health, Customs and Border Protection, Police Department
- ❑ Investigation resulted in revocation of all seven import permits



Import Permit Program Application changes highlights

□ Application revisions

- **SECTION A - Person Requesting Permit in U.S. (Permittee)-Secondary Contact**
- **SECTION E - Description of Infectious Biological Agent(s)**
- **SECTION G - Biosafety Measures**

SECTION E - Description of Infectious Biological Agent(s)

4. Scientific name of known/suspected biological agent(s) including Genus and species	5. Strain Designation (list "N/A" if not applicable)	6. Location		7. Laboratory or Storage (Select one or both)		8. Laboratory Safety Level (Leave blank if storage only)	9. Person Responsible for Laboratory
		Bldg	Suite/Room	Lab	Storage		
Scientific Name	Strain Designation			<input type="checkbox"/>	<input type="checkbox"/>	Safety Level	Responsible Person
a.				<input type="checkbox"/>	<input type="checkbox"/>		
b.				<input type="checkbox"/>	<input type="checkbox"/>		
c.				<input type="checkbox"/>	<input type="checkbox"/>		
d.				<input type="checkbox"/>	<input type="checkbox"/>		

Notes: #4- Scientific name of imported material (including non-human primate material)

#5- Strain Designation- for example for Influenza A virus strain designation H1N1

SECTION G - Biosafety Measures

Item #4

SECTION G - Biosafety Measures			
<p>1. Primary Containment to be used <i>(Check all that apply)</i></p> <p><input type="checkbox"/> None (open bench)</p> <p><input type="checkbox"/> Class I</p> <p><input type="checkbox"/> Class II, Type <input type="text"/></p> <p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Fume Hood</p> <p><input type="checkbox"/> Other <i>(please describe)</i>:</p> <p><input type="text"/></p> <p><input type="text"/></p>	<p>2. Personal Protective Measures to be used <i>(Check all that apply)</i></p> <p><input type="checkbox"/> Gloves</p> <p><input type="checkbox"/> Protective Clothing</p> <p><input type="checkbox"/> Goggles and/or Face Shield</p> <p><input type="checkbox"/> Facemask</p> <p><input type="checkbox"/> Respirators: Type <input type="checkbox"/> N95/100 <input type="checkbox"/> PAPR</p> <p><input type="checkbox"/> Immunizations</p> <p><input type="checkbox"/> Other <i>(please describe)</i>:</p> <p><input type="text"/></p>	<p>3. Personnel Training provided <i>(Check all that apply)</i></p> <p><input type="checkbox"/> Risk(s) associated with the imported biological agent(s)</p> <p><input type="checkbox"/> Hazardous Material Packing/Shipping</p> <p><input type="checkbox"/> Laboratory Standard Practices</p> <p><input type="checkbox"/> Hazardous Waste Handling/Disposal</p> <p><input type="checkbox"/> Emergency Response Procedures</p> <p><input type="checkbox"/> Spill Procedures</p> <p><input type="checkbox"/> Other <i>(please describe)</i>:</p> <p><input type="text"/></p>	<p>4. Has the permittee implemented biosafety measures commensurate with the hazard posed by the infectious biological agent, infectious substance, and/or vector to be imported, and the level of risk given its intended use?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes <i>(Plan may be required to be submitted)</i></p>

Highlights of Application Submission Changes

Customer Interfaced web-based Application

- Link to website: <http://eaipp.azurewebsites.net/>

The screenshot shows the top section of a web application. On the left is a vertical navigation menu with blue buttons labeled: Instructions, A - Permittee, B - Sender, C - Shipment, D - Final Destination, E - Biological Agent(s), F - Material(s), G - Biosafety, and H - Signature. The main content area has a header with the U.S. Department of Health & Human Services logo and the title 'Application for Permit to Import Infectious Biological Agents Into the United States'. Below the header, the main heading is 'Request to Import Biological Agents or Vectors of Human Disease'. A paragraph of text follows: 'For assistance in the completion of the Application for Permit to Import Biological Agents or Vectors of Human Disease, please refer to the guidance document below. This guidance document provides detailed information and direction to applicants on how to complete all sections of the import permit application form.' To the right of this text are two buttons: 'Previous' and 'Next'. At the bottom of the page, there is a footer with small text providing contact information and a disclaimer, and a box with the text: 'CDC Form 1254, Revised January 2014, HDNA APPROVED OMB NO. 0925-0159, DDP DATE 01/11/2017'.

Customer Interfaced web-based Application



Application for Permit to Import Infectious Biological Agents Into the United States

11% Completed

Instructions

A - Permittee

B - Sender

C - Shipment

D - Final Destination

E - Biological Agent(s)

F - Material(s)

G - Biosafety

H - Signature

Section A - Person Requesting Permit in U.S. (Permittee)

1. Permittee's Last Name

2. Permittee's First Name

3. Permittee's Middle Initial

4. Permittee's Organization

5. Physical Address

6. City

7. State

8. Zip Code

9. Permittee's Telephone Number

For the purposes of completing the Application for Permit to Import Infectious Biological Agents into the United States, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Customer Interfaced web-based Application



Application for Permit to Import Infectious Biological Agents Into the United States

44% Completed

- Instructions
- A - Permittee
- B - Sender
- C - Shipment
- D - Final Destination
- E - Biological Agent(s)
- F - Material(s)
- G - Biosafety**
- H - Signature

Section G - Biosafety Measures

1. Primary Containment to be used (Check all that apply)

- None (open bench)
- Class I
- Class II

Type:

- Class III
- Fume Hood
- Other

2. Personal Protective Measures to be used (Check all that apply)

- Gloves
- Protective Clothing
- Goggles and/or Face Shield
- Facemask
- Respirators
- Immunizations
- Other

3. Personal Training provided (Check all that apply)

- Risk(s) associated with the imported biological agent(s)
- Hazardous Material Packing/Shipping
- ...

Import Permit Regulations Webinar

❑ Friday, October 24, 2014

- 1:00-5:00 PM

❑ Participants:

- CDC, Import Permit Program
- CDC, Division of Global Migration and Quarantine
- Department of Transportation (DOT)
- Customs and Border Protection (CBP)
- United States Department of Agriculture/Animal and Plant Health Inspection Service (USDA/APHIS)

❑ Register at:

- <http://www.cdc.gov/od/eaipp>

Thank You



For more information contact Centers for Disease Control and Prevention's Import Permit Program

1600 Clifton Road, Atlanta, GA 30333

Telephone: 404-718-2077

Email: importpermit@cdc.gov

Web: www.cdc.gov/od/eaipp



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