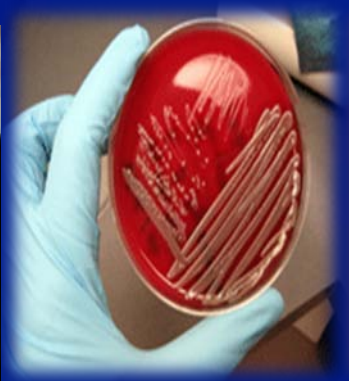
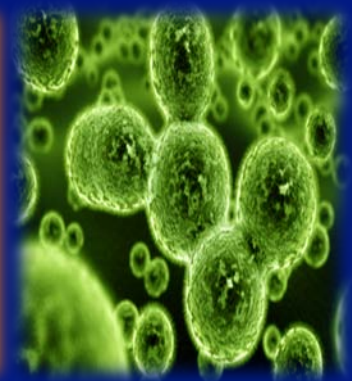
Centers for Disease Control and Prevention
Etiological Agent Import Permit Program

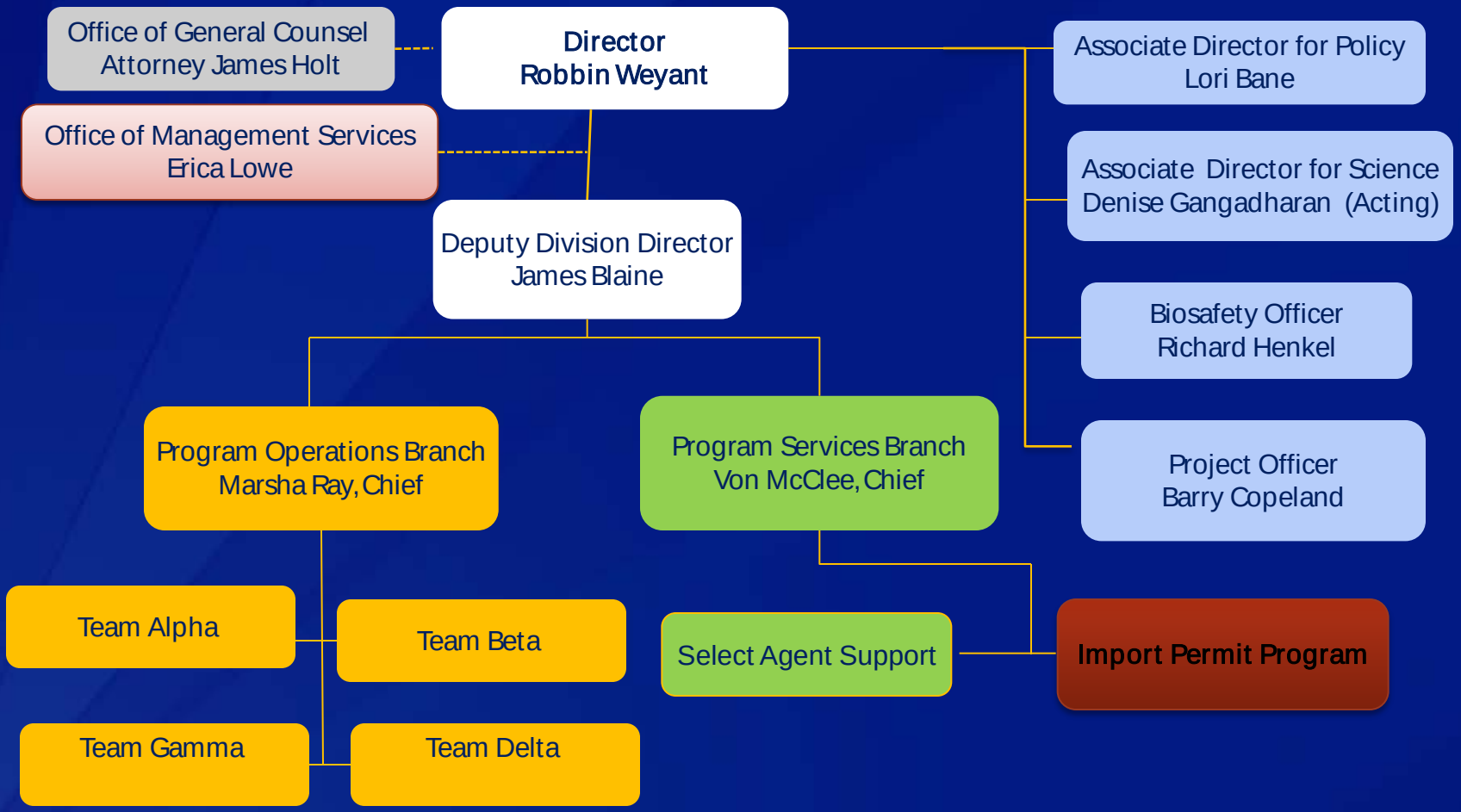

Von McClee, M.S.
Chief, Program Services Branch
Division of Select Agents and Toxins

ABSA 55th Annual Biological Safety Conference

Topics of Discussion

- Background/Purpose
- Importation Regulations
- Application Process
- Evolution of the Program (Proposed Regulations)
- Program Partners
- Frequently Asked Questions

Division of Select Agents and Toxins Organizational Chart



Background

- 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.

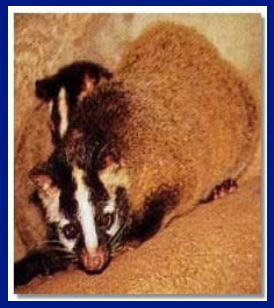
- All non-human primate materials (NHP) and trophies (unless specifically treated and rendered non-infectious)

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

Embargos

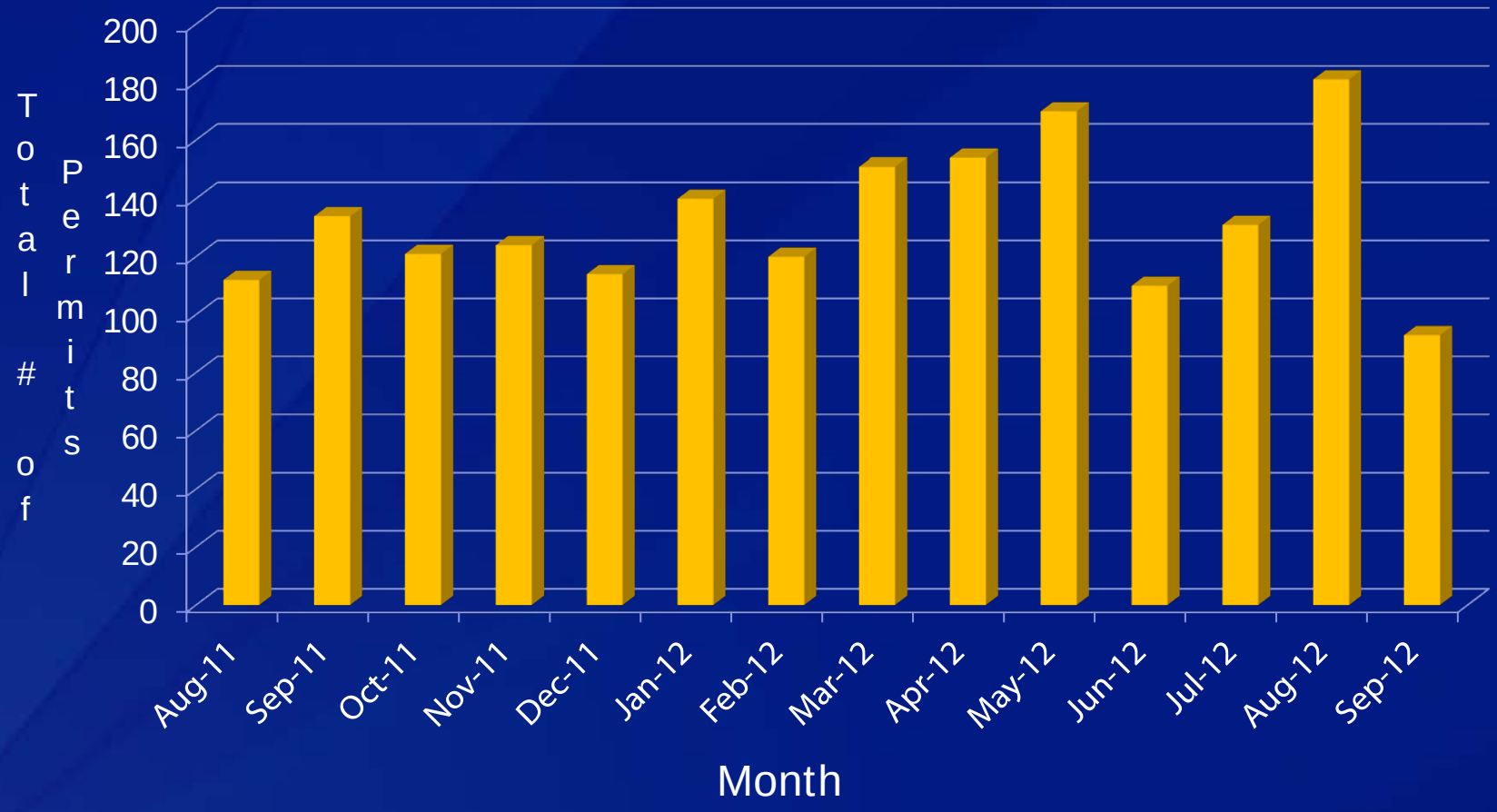
- **Embargoed Animals and Monkeypox Virus**
  Effective Date: June 11, 2003.
  Suspect Agent: Monkeypox Virus
  Area: Africa



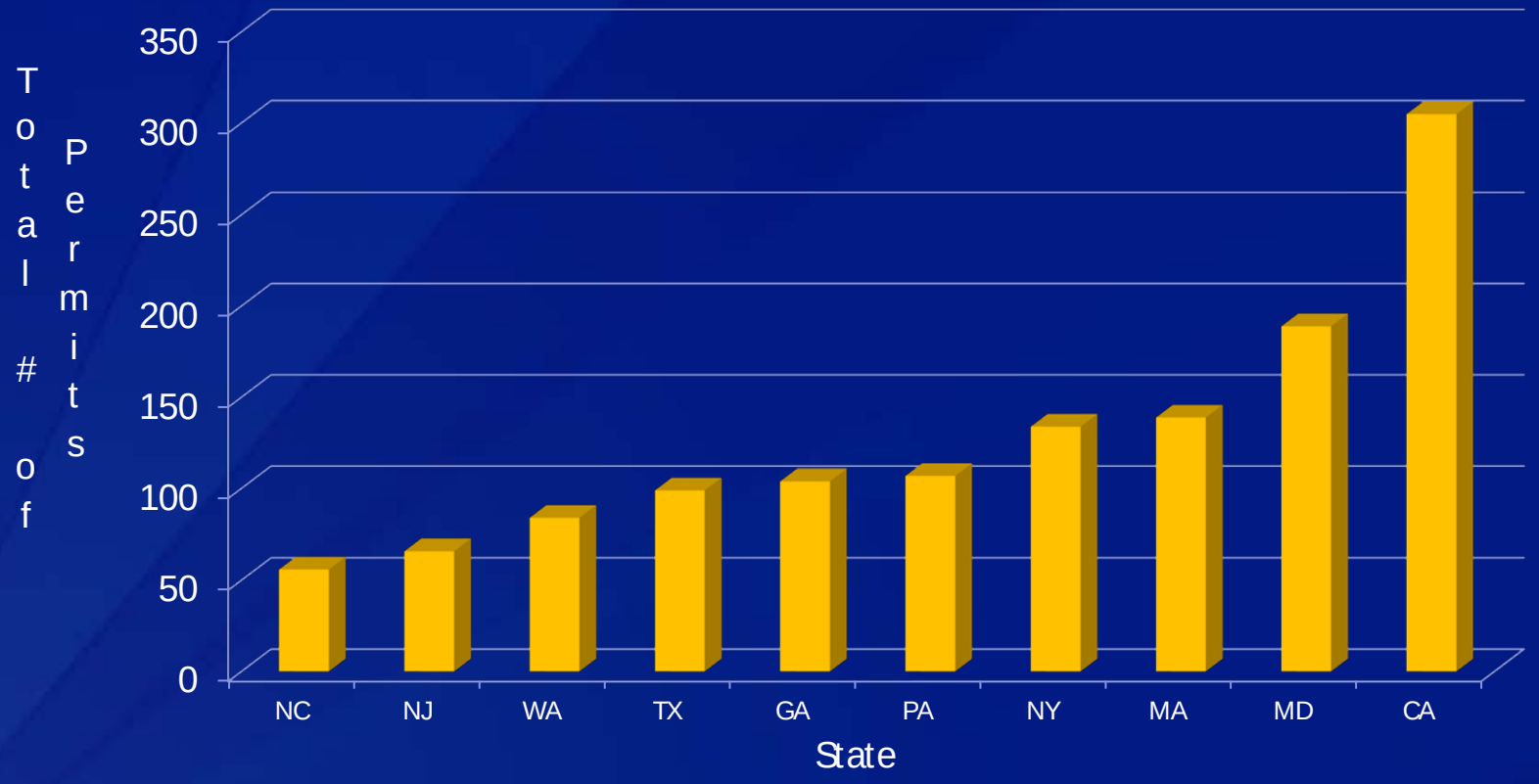
- **Embargo of Civets (civet cats)**
  Effective Date: January 13, 2004.
  Suspect Agent: SARS-associated coronavirus (SARS-CoV)
  Area: Worldwide
- **Embargo of Birds from Specified Southeast Asian Countries**
  Effective Date: February 4, 2004 (Rescinded 9/14/2009)
  Suspect Agent: Avian Influenza
  Area: Cambodia, Indonesia, Japan, Laos, Kazakhstan, Malaysia, Peoples' 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)

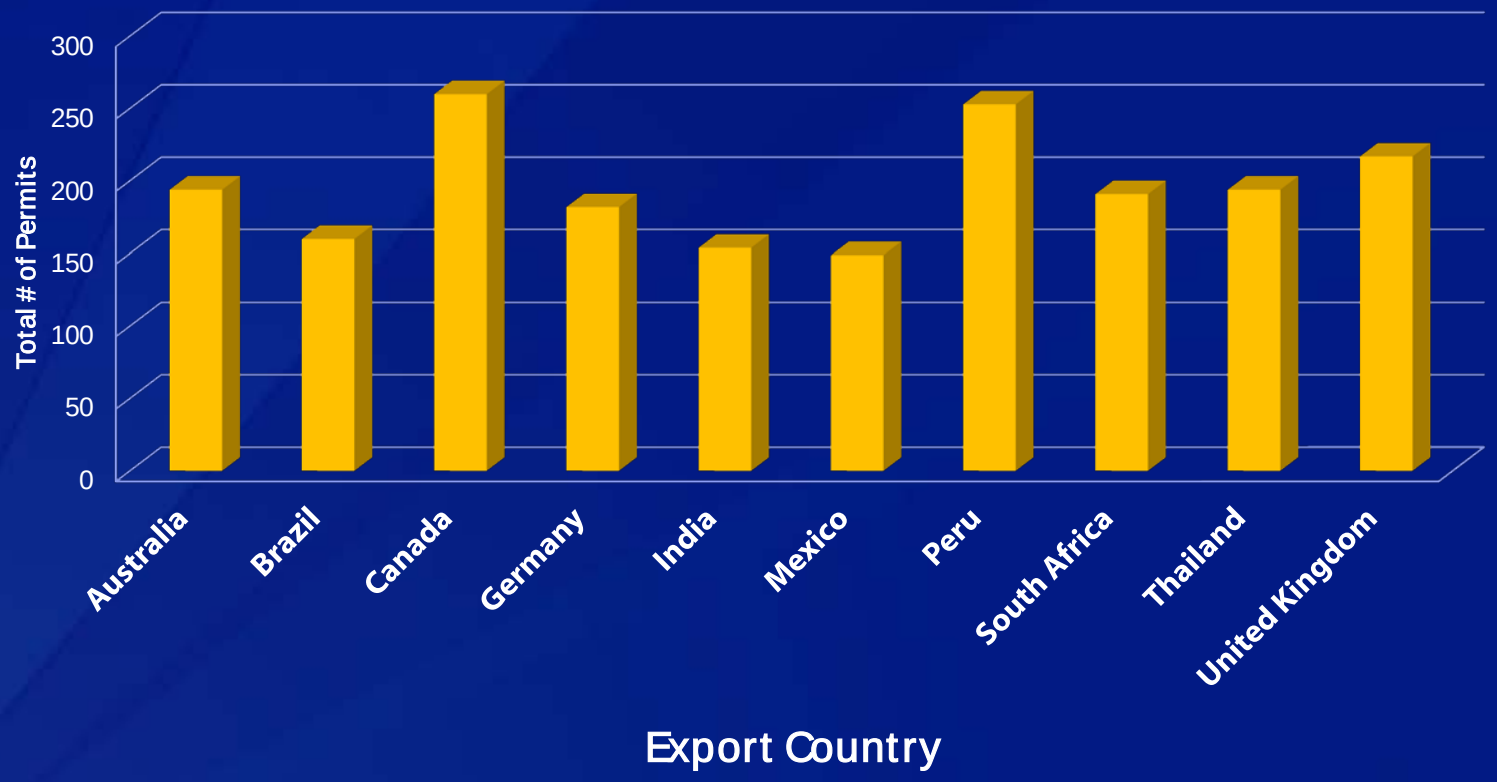
Number of Approved Import Permits Aug. 2011-Sept. 2012 (Total=1855)



Top 10 U.S Importing States for Etiologic Agents (Aug. 2011-Sept. 2012)



Top 10 Export Countries for Etiologic Agents (January 2010-August 2011)

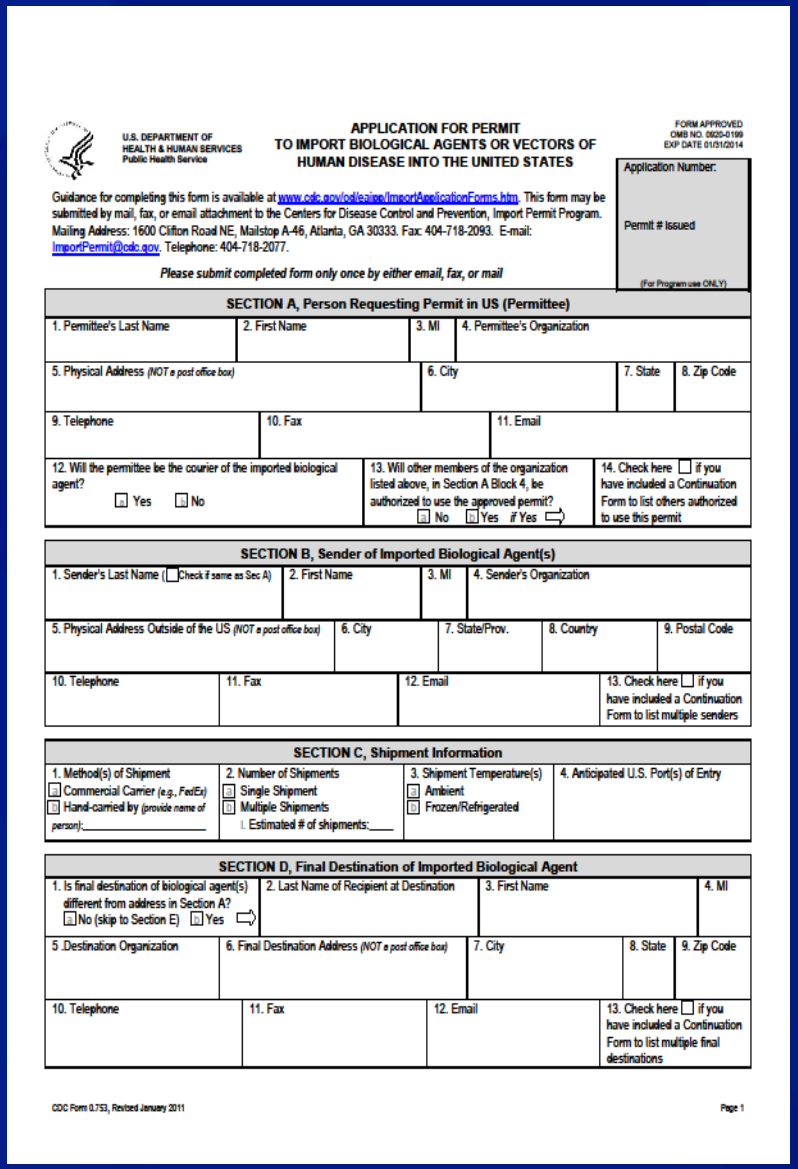


Types of Applications

- 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



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

APPLICATION FOR PERMIT TO IMPORT BIOLOGICAL AGENTS OR VECTORS OF HUMAN DISEASE INTO THE UNITED STATES

FORM APPROVED
OMB NO. 0920-0199
EXP DATE 01/31/2014

Application Number:
Permit # Issued
(For Program use ONLY)

Guidance for completing this form is available at www.cdc.gov/od/eaipp/ImportApplicationForms.htm. This form may be submitted by mail, fax, or email attachment to the Centers for Disease Control and Prevention, Import Permit Program. Mailing Address: 1600 Clifton Road NE, Mailstop A-46, Atlanta, GA 30333. Fax: 404-718-2093. E-mail: ImportPermit@cdc.gov. Telephone: 404-718-2077.

Please submit completed form only once by either email, fax, or mail

SECTION A, Person Requesting Permit in US (Permittee)

1. Permittee's Last Name	2. First Name	3. MI	4. Permittee's Organization		
5. Physical Address *(NOT a post office box)*		6. City		7. State	8. Zip Code
9. Telephone	10. Fax		11. Email		
12. Will the permittee be the courier of the imported biological agent? ☐ Yes ☐ No	13. Will other members of the organization listed above, in Section A Block 4, be authorized to use the approved permit? ☐ No ☐ Yes *if Yes* ⇨		14. Check here ☐ if you have included a Continuation Form to list others authorized to use this permit		

SECTION B, Sender of Imported Biological Agent(s)

1. Sender's Last Name (☐ Check if same as Sec A)	2. First Name	3. MI	4. Sender's Organization		
5. Physical Address Outside of the US *(NOT a post office box)*	6. City	7. State/Prov.	8. Country	9. Postal Code	
10. Telephone	11. Fax	12. Email	13. Check here ☐ if you have included a Continuation Form to list multiple senders		

SECTION C, Shipment Information

1. Method(s) of Shipment	2. Number of Shipments	3. Shipment Temperature(s)	4. Anticipated U.S. Port(s) of Entry
☐ Commercial Carrier *(e.g., FedEx)* ☐ Hand-carried by *(provide name of person)*:_____	☐ Single Shipment ☐ Multiple Shipments i. Estimated # of shipments:____	☐ Ambient ☐ Frozen/Refrigerated	

SECTION D, Final Destination of Imported Biological Agent

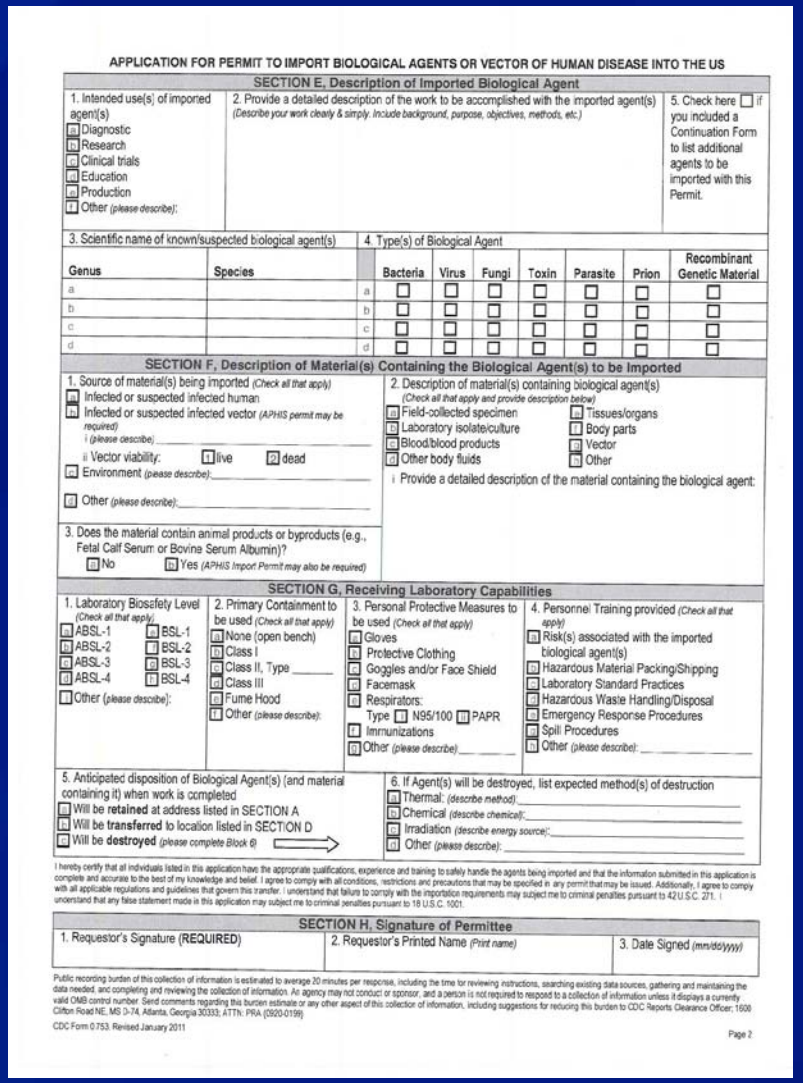
1. Is final destination of biological agent(s) different from address in Section A? ☐ No (skip to Section E) ☐ Yes ⇨	2. Last Name of Recipient at Destination	3. First Name	4. MI	
5 .Destination Organization	6. Final Destination Address *(NOT a post office box)*	7. City	8. State	9. Zip Code
10. Telephone	11. Fax	12. Email	13. Check here ☐ if you have included a Continuation Form to list multiple final destinations	

CDC Form 0.753, Revised January 2011

Page 1

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



APPLICATION FOR PERMIT TO IMPORT BIOLOGICAL AGENTS OR VECTOR OF HUMAN DISEASE INTO THE US

SECTION E, Description of Imported Biological Agent

1. Intended use(s) of imported agent(s)
   - a. Diagnostic
   - b. Research
   - c. Clinical trials
   - d. Education
   - e. Production
   - f. Other *(please describe)*:

2. Provide a detailed description of the work to be accomplished with the imported agent(s) *(Describe your work clearly & simply. Include background, purpose, objectives, methods, etc.)*

5. Check here ☐ if you included a Continuation Form to list additional agents to be imported with this Permit.

3. Scientific name of known/suspected biological agent(s)

4. Type(s) of Biological Agent

	Genus	Species		Bacteria	Virus	Fungi	Toxin	Parasite	Prion	Recombinant Genetic Material
a			a	☐	☐	☐	☐	☐	☐	☐
b			b	☐	☐	☐	☐	☐	☐	☐
c			c	☐	☐	☐	☐	☐	☐	☐
d			d	☐	☐	☐	☐	☐	☐	☐

SECTION F, Description of Material(s) Containing the Biological Agent(s) to be Imported

1. Source of material(s) being imported *(Check all that apply)*
   - a. Infected or suspected infected human
   - b. Infected or suspected infected vector *(APHIS permit may be required)*
     - i *(please describe)*: _____
     - ii Vector viability: 1 live 2 dead
   - c. Environment *(please describe)*: _____
   - d. Other *(please describe)*: _____

2. Description of material(s) containing biological agent(s) *(Check all that apply and provide description below)*
   - a. Field-collected specimen
   - b. Laboratory isolate/culture
   - c. Blood/blood products
   - d. Other body fluids
   - e. Tissues/organs
   - f. Body parts
   - g. Vector
   - h. Other

   i Provide a detailed description of the material containing the biological agent:

3. Does the material contain animal products or byproducts (e.g., Fetal Calf Serum or Bovine Serum Albumin)?
   - ☐ No
   - ☐ Yes *(APHIS Import Permit may also be required)*

SECTION G, Receiving Laboratory Capabilities

1. Laboratory Biosafety Level *(Check all that apply)*
   - a. ABSL-1 b. BSL-1
   - c. ABSL-2 d. BSL-2
   - e. ABSL-3 f. BSL-3
   - g. ABSL-4 h. BSL-4
   - ☐ Other *(please describe)*:

2. Primary Containment to be used *(Check all that apply)*
   - a. None (open bench)
   - b. Class I
   - c. Class II, Type _____
   - d. Class III
   - e. Fume Hood
   - f. Other *(please describe)*:

3. Personal Protective Measures to be used *(Check all that apply)*
   - a. Gloves
   - b. Protective Clothing
   - c. Goggles and/or Face Shield
   - d. Facemask
   - e. Respirators: Type 1 N95/100 2 PAPR
   - f. Immunizations
   - g. Other *(please describe)*: _____

4. Personnel Training provided *(Check all that apply)*
   - a. Risk(s) associated with the imported biological agent(s)
   - b. Hazardous Material Packing/Shipping
   - c. Laboratory Standard Practices
   - d. Hazardous Waste Handling/Disposal
   - e. Emergency Response Procedures
   - f. Spill Procedures
   - g. Other *(please describe)*: _____

5. Anticipated disposition of Biological Agent(s) (and material containing it) when work is completed
   - a. Will be **retained** at address listed in SECTION A
   - b. Will be **transferred** to location listed in SECTION D
   - c. Will be **destroyed** *(please complete Block 6)*

6. If Agent(s) will be destroyed, list expected method(s) of destruction
   - a. Thermal: *(describe method)*: _____
   - b. Chemical *(describe chemical)*: _____
   - c. Irradiation *(describe energy source)*: _____
   - d. Other *(please describe)*: _____

I hereby certify that all individuals listed in this application have the appropriate qualifications, experience and training to safely handle the agents being imported and that the information submitted in this application is complete and accurate to the best of my knowledge and belief. I agree to comply with all conditions, restrictions and precautions that may be specified in any permit that may be issued. Additionally, I agree to comply with all applicable regulations and guidelines that govern this transfer. I understand that failure to comply with the importation requirements may subject me to criminal penalties pursuant to 42 U.S.C. 271. I understand that any false statement made in this application may subject me to criminal penalties pursuant to 18 U.S.C. 1001.

SECTION H, Signature of Permittee

1. Requestor's Signature (REQUIRED)	2. Requestor's Printed Name *(Print name)*	3. Date Signed *(mm/dd/yyyy)*

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0199)

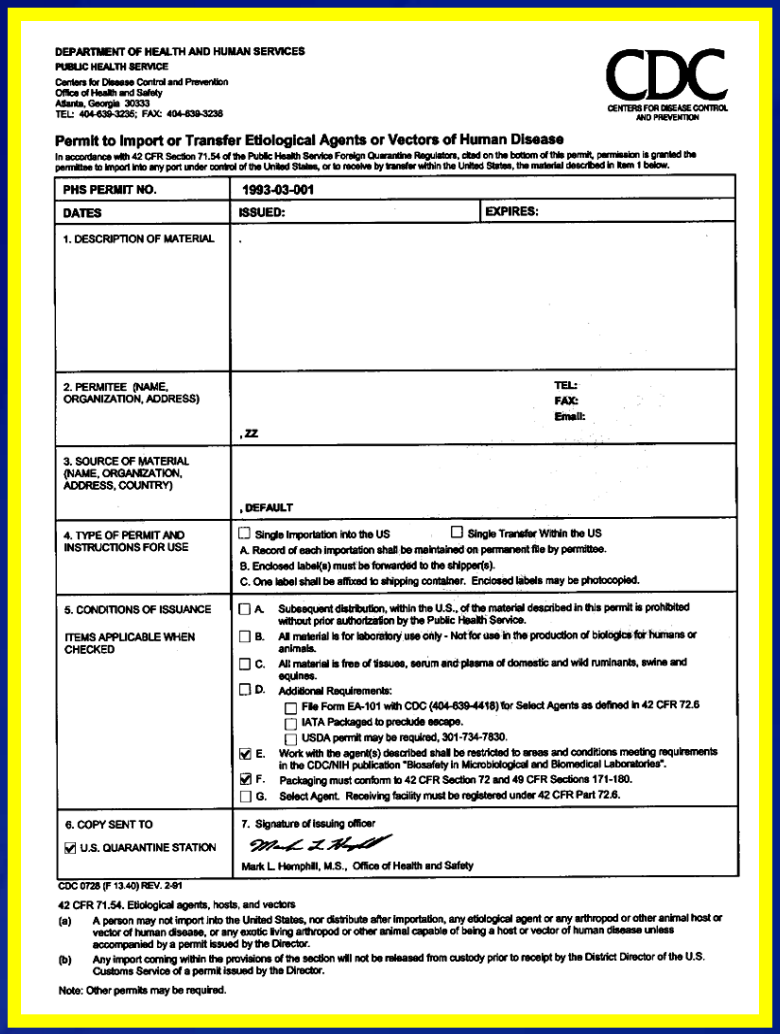
CDC Form 0.753, Revised January 2011

Page 2

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
Centers for Disease Control and Prevention
Office of Health and Safety
Atlanta, Georgia 30333
TEL: 404-639-3235; FAX: 404-639-3236

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Permit to Import or Transfer Etiological Agents or Vectors of Human Disease

In accordance with 42 CFR Section 71.54 of the Public Health Service Foreign Quarantine Regulations, cited on the bottom of this permit, permission is granted the permittee to import into any port under control of the United States, or to receive by transfer within the United States, the material described in item 1 below.

PHS PERMIT NO.	1993-03-001	
DATES	ISSUED:	EXPIRES:
1. DESCRIPTION OF MATERIAL	.	
2. PERMITEE (NAME, ORGANIZATION, ADDRESS)	, ZZ	TEL: FAX: Email:
3. SOURCE OF MATERIAL (NAME, ORGANIZATION, ADDRESS, COUNTRY)	, DEFAULT	
4. TYPE OF PERMIT AND INSTRUCTIONS FOR USE	☐ Single Importation into the US ☐ Single Transfer Within the US A. Record of each importation shall be maintained on permanent file by permittee. B. Enclosed label(s) must be forwarded to the shipper(s). C. One label shall be affixed to shipping container. Enclosed labels may be photocopied.	
5. CONDITIONS OF ISSUANCE ITEMS APPLICABLE WHEN CHECKED	☐ A. Subsequent distribution, within the U.S., of the material described in this permit is prohibited without prior authorization by the Public Health Service. ☐ B. All material is for laboratory use only - Not for use in the production of biologics for humans or animals. ☐ C. All material is free of tissues, serum and plasma of domestic and wild ruminants, swine and equines. ☐ D. Additional Requirements: ☐ File Form EA-101 with CDC (404-639-4418) for Select Agents as defined in 42 CFR 72.6 ☐ IATA Packaged to preclude escape. ☐ USDA permit may be required, 301-734-7830. ☑ E. Work with the agent(s) described shall be restricted to areas and conditions meeting requirements in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories". ☑ F. Packaging must conform to 42 CFR Section 72 and 49 CFR Sections 171-180. ☐ G. Select Agent. Receiving facility must be registered under 42 CFR Part 72.6.	
6. COPY SENT TO ☑ U.S. QUARANTINE STATION	7. Signature of Issuing officer Mark L. Hemphill, M.S., Office of Health and Safety	

CDC 0728 (F 13.40) REV. 2-91

42 CFR 71.54. Etiological agents, hosts, and vectors

(a) A person may not import into the United States, nor distribute after importation, any etiological 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 the section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

Note: Other permits may be required.

- 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).

Reason for Rulemaking

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.

Frequently Asked Questions

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

1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov