

# FEDERAL AND INTERNATIONAL PARTNERS IMPORT/EXPORT REGULATIONS WEBCAST



August 3 & 4, 2016



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

## **Federal and International Partners**

- **Department of Agriculture, Animal and Plant Health Inspection Service (APHIS)**
- **Department of Commerce**
- **Department of Health and Human Services**
  - **Assistant Secretary for Preparedness and Response**
  - **Customs and Border Protection**
  - **Centers for Disease Control and Prevention**
    - **Division of Global Migration and Quarantine**
    - **Division of Select Agents and Toxins**
  - **Food and Drug Administration**
- **Department of the Interior, Fish and Wildlife Service**
- **Department of Transportation**
- **Public Health Agency of Canada**

# Import Permit Program Centers for Disease Control and Prevention



Glen DeGruy  
Acting Branch Chief  
Program Services Branch  
Import Permit Program  
Division of Select Agents and Toxins



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

## 42 CFR 71.54 – Import Regulations

- Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances and vectors.



- The following infectious biological agents, infectious substances and vectors, would require a permit prior to entry into the United States.



## 42 CFR 71.54

- ❑ Infectious biological agent

A microorganism (*including, but not limited to, bacteria (including rickettsiae), viruses, fungi, or protozoa*) or prion, or a component of such, that is capable of causing communicable disease in a human.

- ❑ Infectious substance

Any material that is known or reasonably expected to contain an infectious biological agent.

- ❑ Vector

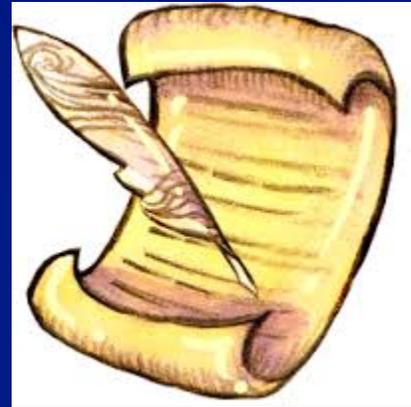
Any animals including arthropods, or any noninfectious self-replicating system, or animal products, that are known to transfer, or are capable of transferring an infectious biological agent to a human.

## IMPORTATION CRITERIA

- A person may not import into the United States any infectious biological agent, infectious substance or vector unless:
  - It is accompanied by a permit issued by the CDC
  - The importer is in compliance with all permit requirements and conditions
  - Importer help ensure the shipper complies with all legal requirements. (e.g., packaging/labeling)
  - Importer has implemented adequate biosafety measures

## Material that does not require an Import Permit

- Each shipment must be accompanied by a signed certification statement.



## Certification Statement

- ❑ The certification statement must include:
  - ✓ A detailed description of material
  - ✓ 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
    - ✓ (2) how the person making the certification knows that the specimen does not contain an infectious biological agent; or a detailed description of how the material was rendered noninfectious.

## The following items do not require an Import Permit

- ❑ Select agents
- ❑ Diagnostic specimens that do not contain an infectious biological agent.
- ❑ Animal or animal products being imported for educational, exhibition, or scientific purposes.
- ❑ Nucleic acids that cannot produce infectious forms of any infectious biological agent.

## Emerging Agents/Outbreaks

- Applications expedited – 24hour release
  - Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
  - Avian influenza A virus (*H7N9*)
  - Material suspected to contain the Ebola virus
  - Zika virus – (currently in expedite status)

## Zika virus – Applications

- ❑ 133 approved permits (January 1 - July 15, 2016)
- ❑ Common application descriptions:
  - Type of work
    - Diagnostic testing and research
    - Vaccine development
  - Specimens imported
    - Human blood, body fluids
    - Isolates, Mosquito pools
  - Common sender locations
    - United Kingdom; South American countries (Brazil, Columbia); and the Caribbean

# The Big Picture

- The CDC Import Permit Program (IPP)
  - Provides active oversight to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.
  - Accomplished in part by:
    - Reviewing and approving Import permit applications
    - Conducting Inspections

# APPLICATION FOR PERMIT TO IMPORT

- SECTION A - Person Requesting Permit
- SECTION B - Sender
- SECTION C - Shipment Information
- SECTION D - Final Destination



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

**APPLICATION FOR PERMIT TO IMPORT INFECTIOUS BIOLOGICAL AGENTS INTO THE UNITED STATES**

FORM APPROVED  
OMB NO. 0925-0199  
EXP. DATE 01/31/2017

Guidance for completing this form is available at <http://www.cdc.gov/od/cepi/import/application/>. 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: 404-471-8333. E-mail: [importpermit@cdc.gov](mailto:importpermit@cdc.gov). Telephone: 404-718-2077.

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

Application Number: \_\_\_\_\_

Permit # Issued: \_\_\_\_\_

(For Program use ONLY)

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

1. Permittee's Last Name	2. Permittee's First Name	3. MI	4. Permittee's Organization	
5. Physical Address (NOT a post office box)			6. City	7. State
8. Zip Code				
9. Permittee's Telephone Number	10. Permittee's Fax Number	11. Permittee's Email		
12. Secondary Contact's Name		13. Secondary Contact's Telephone Number	14. Secondary Contact's Email	
15. Will the permittee be the courier of the imported biological agent? <input type="checkbox"/> Yes <input type="checkbox"/> No		16. Will other members of the organization listed above, in Section A Block 4, be authorized to use the approved permit? <input type="checkbox"/> No <input type="checkbox"/> Yes # Yes <input type="checkbox"/>		17. Check here <input type="checkbox"/> if you have included a Continuation Form to list others authorized to use this permit

SECTION B - Sender of Imported Infectious Biological Agent(s) or Vector(s)

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

SECTION C - Shipment Information

1. Method(s) of Shipment <input type="checkbox"/> Commercial Carrier (e.g., FedEx) <input type="checkbox"/> Hand-carried by (provide name of person): _____	2. Number of Shipments <input type="checkbox"/> Single Shipment <input type="checkbox"/> Multiple Shipments Estimated # of shipments: _____	3. Shipment Temperature(s) <input type="checkbox"/> Ambient <input type="checkbox"/> Frozen/Refrigerated	4. Anticipated U.S. Port(s) of Entry
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SECTION D - Final Destination of Imported Infectious Biological Agent(s) or Vector(s)

1. Is final destination of biological agent(s) or vector(s) different from address in Section A? <input type="checkbox"/> No (skip to Section E) <input type="checkbox"/> Yes <input type="checkbox"/>	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 <input type="checkbox"/> if you have included a Continuation Form to list multiple final destinations

CCC Form 0.753, Revised January 2014
Page 1

# APPLICATION FOR PERMIT TO IMPORT

- SECTION E - Description of Biological Agent
- SECTION F - Description of Material(s) Containing the Agent(s)
- SECTION G - Receiving Laboratory Capabilities

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

FORM APPROVED (OMB NO. 0920-0196) EXP. DATE 01/31/2017

### SECTION E - Description of Infectious Biological Agent(s)

1. Intended use(s) of imported agent(s) <input type="checkbox"/> Diagnostic <input type="checkbox"/> Research <input type="checkbox"/> Clinical trials <input type="checkbox"/> Education <input type="checkbox"/> Production <input type="checkbox"/> 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.)	3. Check here <input type="checkbox"/> if you included a Continuation Form to list additional agents to be imported with this Permit.
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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
Scientific Name	Strain Designation	Bldg	Suite/Room	Lab	Storage	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"/>		

### SECTION F - Description of Material(s) Containing the Infectious Biological Agent(s) or Vector(s) to be Imported

1. Source of material(s) being imported (Check all that apply) <input type="checkbox"/> Infected or suspected infected human <input type="checkbox"/> Infected or suspected infected vector (APHIS permit may be required) (please describe) i. Vector viability: <input type="checkbox"/> live <input type="checkbox"/> dead <input type="checkbox"/> Environment (please describe): <input type="checkbox"/> Other (please describe):	2. Description of material(s) containing biological agent(s) (Check all that apply and provide description below) <input type="checkbox"/> Field-collected specimen <input type="checkbox"/> Laboratory isolate/culture <input type="checkbox"/> Blood/blood products <input type="checkbox"/> Other body fluids <input type="checkbox"/> Tissues/organs <input type="checkbox"/> Body parts <input type="checkbox"/> Vector <input type="checkbox"/> Other Provide 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)? <input type="checkbox"/> No <input type="checkbox"/> Yes (APHIS Import Permit may also be required)	

### SECTION G - Biosafety Measures

1. Primary Containment to be used (Check all that apply) <input type="checkbox"/> None (open bench) <input type="checkbox"/> Class I <input type="checkbox"/> Class II, Type _____ <input type="checkbox"/> Class III <input type="checkbox"/> Fume Hood <input type="checkbox"/> Other (please describe):	2. Personal Protective Measures to be used (Check all that apply) <input type="checkbox"/> Gloves <input type="checkbox"/> Protective Clothing <input type="checkbox"/> Goggles and/or Face Shield <input type="checkbox"/> Facemask <input type="checkbox"/> Respirators: Type <input type="checkbox"/> N95/100 <input type="checkbox"/> PAPR <input type="checkbox"/> Immunizations <input type="checkbox"/> Other (please describe):	3. Personnel Training provided (Check all that apply) <input type="checkbox"/> Risk(s) associated with the imported biological agent(s) <input type="checkbox"/> Hazardous Material Packing/Shipping <input type="checkbox"/> Laboratory Standard Practices <input type="checkbox"/> Hazardous Waste Handling/Disposal <input type="checkbox"/> Emergency Response Procedures <input type="checkbox"/> Spill Procedures <input type="checkbox"/> Other (please describe):	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? <input type="checkbox"/> No <input type="checkbox"/> Yes (Plan may be required to be submitted)
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5. Anticipated disposition of Infectious Biological Agent(s) (and material containing it) when work is completed <input type="checkbox"/> Will be retained at address listed in SECTION A <input type="checkbox"/> Will be transferred to location listed in SECTION D <input type="checkbox"/> Will be destroyed (please complete Block 6) <input type="checkbox"/>	6. If Agent(s) will be destroyed, list expected method(s) of destruction <input type="checkbox"/> Thermal: (describe method): _____ <input type="checkbox"/> Chemical: (describe chemical): _____ <input type="checkbox"/> Irradiation (describe energy source): _____ <input type="checkbox"/> Other (please describe): _____
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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 18 U.S.C. 857i. 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. Permittee's Signature (REQUIRED)	2. Permittee's Printed Name (Print name)	3. Date Signed (mm/dd/yyyy)
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Public recording 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 (0620-0196) CDC Form 0753, Revised January 2014 Page 2

## Application – Common problems

- Applicants requesting:
  - Work on an open bench.
  - Work in a fume hood.
  - Work at inappropriate biosafety levels.
  - Work with minimal PPE and/or minimal training for staff

# Inspections

- Conducted to verify:
  - accuracy of the IP application (e.g. , lab rooms, Safety levels, agents)
  - importer has implemented adequate biosafety measures.



## 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



## Notification of Inspection

- Contact the permittee by phone to coordinate the inspection
  - Date of Inspection
  - Duration of the inspection
- Request the following information:
  - Biosafety plan
  - Personal protective equipment (PPE) requirements
  - Laboratory floor plan
  - Entrance requirements (Vaccines/PPD results)
  - Directions to the facility



## Notice of Inspection Letter

- Send an Official Notice of Inspection letter via email:
  - Authority to conduct the inspection
  - Confirmed inspection date
  - Identification of inspectors
  - List the items that will be reviewed



## Day of Inspection

- ❑ A brief introduction period
  - Inspectors explain purpose of visit
  - Entity provide an overview of the work conducted
- ❑ Begin the laboratory inspection.



## Inspection/Biosafety

- ❑ Verify that biosafety measures are 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.



# Inspection/Biosafety

- Physical structure and features of the facility, and operational and procedural safeguards.



## Facility Design and Records (BSL-3)

- **Inspectors will verify the following:**
  - Readily available eyewash stations
  - Ducted air ventilation systems
  - Availability of an autoclave
  - HEPA filter certifications
  - Hands free or automatically operated sinks
  - Annual biosafety cabinet certifications
    - (the above list is not all inclusive)



# Biosafety Cabinet (BSC) Certification

Verify the following test were performed by the certifying organization:

- HEPA filter leak testing for any biosafety cabinet
- Class II cabinets
  - Down flow velocity
  - Face velocity
  - Airflow smoke patterns



## HVAC/Facilities inspection (BSL-3)

### □ Inspectors will:

- Verify negative airflow
- Methods to confirm directional airflow
- View the HEPA housing and exhaust fans



# HVAC/Facilities Inspection (BSL-3)

Request  
documentation:

Decontamination  
procedures

Failure testing (Exhaust  
fans & Electrical)

Facility re-verification  
procedures



# Practices and Procedures

- Inspectors will also review:
  - Practices to ensure aerosols are minimized
  - Hand washing procedures
  - Decontamination and waste handling procedures
  - Proper use of biosafety cabinet
  - Laboratory entry and exit procedures
  - Spill procedures
  - Biosafety training



\* Please note that this list is not all-inclusive

## Document Review

We ask that a location be made available for inspectors to:

- Review documentation
- Discuss findings
- Complete checklist



## Inspection Close-Out Meeting

- ❑ Inform the entity of deficiencies
- ❑ Interpret any safety standards departures
- ❑ Answer any questions



# Inspection Report

- ❑ Inspection report
  - emailed to the permittee 1-2 weeks.
- ❑ Report will include:
  - observations
  - a request for further information
- ❑ A written response to the inspection report should be provided to CDC within 2 weeks.



## Inadequate Response Report

- ❑ A report written by the CDC when additional information is required.
- ❑ Sent to the entity within one to two weeks.
- ❑ A response is required from the entity within two weeks.



## Adequate Response Letter

- ❑ Sent to the entity when all inspection deficiencies are adequately addressed.
- ❑ Letter signifies the inspection report is closed and no further information is required.
- ❑ If no major changes are made to an application, the permittee may not be inspected by the IPP for up to two years.



# Import Permit Inspection Program

- ❑ Completed over 120 Inspections since April 2013
- ❑ Inspected the following:
  - ❑ Biosafety Level -2
  - ❑ Animal Biosafety Level-2
  - ❑ Arthropod Containment Level –2
  - ❑ Biosafety Level -3
  - ❑ Animal Biosafety Level-3



# Import Permit Inspection Program

- Common descriptions of work associated with Import Permit Inspections:
  - Human diagnostic testing
  - Susceptibility testing
  - Animal studies
  - Molecular biology research



# Import Permit Inspection Program

- Most common agents associated with Import Permit Inspections:
  - *Mycobacterium tuberculosis*
  - Chikungunya virus
  - Zika virus



# Import Permit Inspection Program

- Common safety standard departures:
  - Donning and doffing procedures
  - Visitor training
  - Inappropriate signage
  - Agents stored in inappropriate containers
  - Failure testing (HVAC system)
  - Facility reverification not conducted



## Conclusion

- The import permit program
  - prevents the introduction, transmission, or spread of communicable diseases from foreign countries into the United States.
  - accomplished in part by
    - reviewing applications ( over 3,000 reviewed & under 2000 approved annually)
    - conducting inspections (30-40 annually)

## Conclusion

- ❑ Our website is <https://www.cdc.gov/od/eaipp/>
  - FAQ
  - Import Permit Regulations
  - Inspection Checklist
  - Import Permit Applications
  - Guide for Shipping Infectious Substances

**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](mailto:importpermit@cdc.gov)

Web: [www.cdc.gov/od/eaipp](http://www.cdc.gov/od/eaipp)



# Importation of Animals That Pose a Threat to Human Health

**Kendra Stauffer, DVM, Dipl ACVPM**  
Importations and Animal Contact Team Lead

CDC Import Permit Program Webinar  
August 3, 2016

## Quarantine and Border Health Services Branch Mission



The mission of the Quarantine and Border Health Services Branch (QBHSB) is to protect U.S. communities from global disease threats.

QBHSB supports this mission by:

- Preventing the introduction and spread of communicable diseases
- Enhancing federal, state and industry partnerships
- Enforcing public health regulations



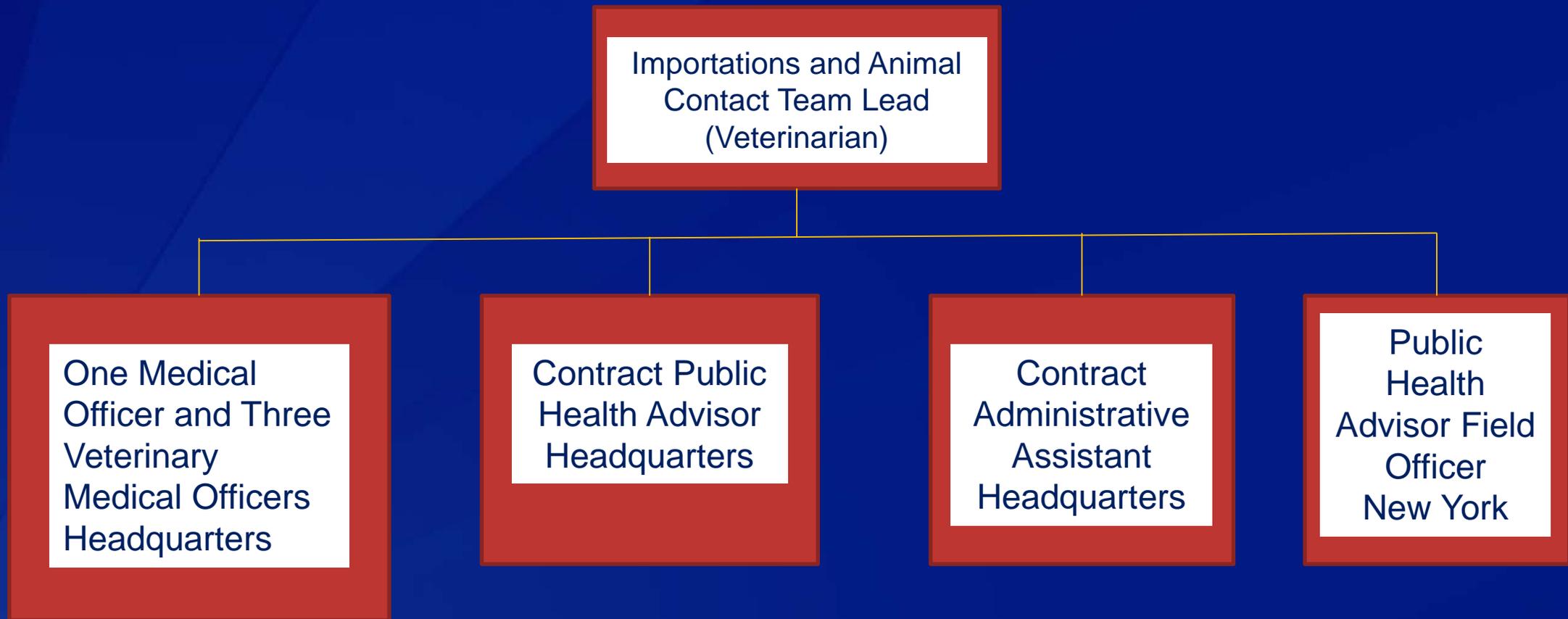
## Importations and Animal Contact Team



Prevent the introduction and spread of diseases of public health significance to humans from imported live animals or cargo containing infectious animal products



# Current Importations and Animal Contact Team Organization



# Live Animal Importation – 2008 U.S. Fish & Wildlife Service LEMIS Data

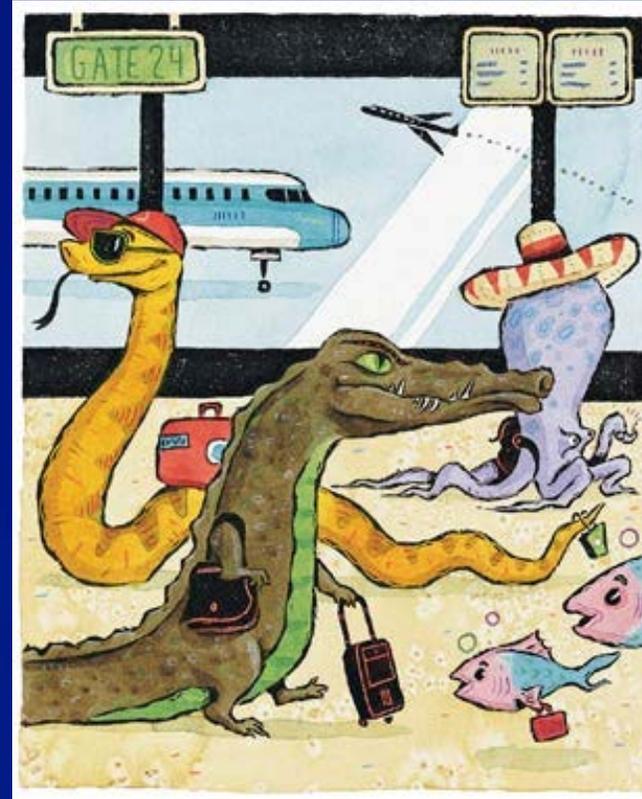
- ❑ 157 million fish
- ❑ 3.5 million amphibians
- ❑ 946,243 reptiles
- ❑ 289,843 mammals
- ❑ 159,795 birds

## CDC Animal Data

- ❑ 287,000 dogs\*
- ❑ 24,000 nonhuman primates\*\*

\*McQuiston JH et al. Importation of Dogs into the United States: Risks from Rabies and Other Zoonotic Diseases. *Zoonoses and Public Health*, 2008: 55;421–426

\*\*Bob Mullan, CDC Zoonoses Team, Personal Communication



## QBHSB Role in Import Permits

- **Issuance of selected permits and letters of permission**
  - Restricted live animals
  - Restricted animal products
- **Enforcement of import regulations at U.S. ports of entry**
  - CDC Quarantine Stations
  - Partnership with U.S. Customs and Border Protection and other federal, state, and local agencies

# **CDC Regulatory Authority**

## **Importation of Animals & Animal Products**

### **42 Code of Federal Regulations (CFR) 71 – Foreign Quarantine**

#### **Subpart F – Importations**

- ❑ **71.51 – Dogs and cats**
- ❑ **71.52 – Turtles, tortoises, and terrapins**
- ❑ **71.53 – Nonhuman Primates**
- ❑ **71.56 – African rodents**

#### **Subpart D – Health Measures at U.S. Ports: Communicable Diseases**

- ❑ **71.32(b) – Persons, carriers, things**

## Issuance of Permits and Letters of Permission

- **Restricted live animals**
  - Family Viverridae (civets and related animals)
  - Freshwater turtles, tortoises, and terrapins <4 inches in length (including viable eggs)
  - Nonhuman primates
  - African rodents
- **Restricted animal products**
  - Family Viverridae (civets and related animals)
  - Nonhuman primates\*
  - African rodents
- **Other live animals and animal products restricted by CDC IPP (e.g., bats, certain species of snails)**

\* Nonhuman primate product import permits are currently issued by the CDC IPP after approval by QBHSB



## Dogs and Cats

### 42 CFR 71.51



- ❑ Dogs and cats must be healthy upon arrival at the port of entry into the United States
- ❑ Animals that are ill upon arrival may be required to be taken for an examination by a licensed veterinarian at importer's expense



# Dogs and Cats

## Rabies Vaccination Requirements

- ❑ **Cats: No rabies vaccination required**
- ❑ **Dogs: Must have proof of current rabies vaccination**
  - Puppies must have been at least 3 months of age when vaccinated
  - Vaccine must be given at least 30 days before entry
- ❑ **Unvaccinated or improperly vaccinated dogs may be allowed entry into the country on a case by case basis**
  - Applications must be submitted in advance by sending a request to [cdcanimalimports@cdc.gov](mailto:cdcanimalimports@cdc.gov)
  - Decision is made based on the risk of rabies in the country of origin

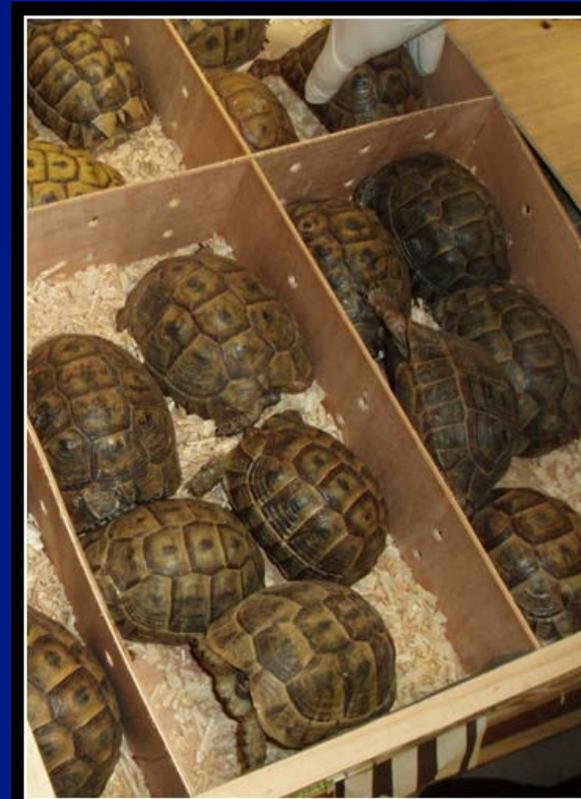
# Freshwater Turtles, Tortoises, and Terrapins

- *Salmonella* infection outbreaks in children associated with contact with small turtles
- Commercial purposes
  - Turtles with carapace <4" may NOT be imported
  - Viable turtle eggs may NOT be imported
- Noncommercial purposes
  - Up to a total of 6 viable eggs or live turtles with carapace <4" may be allowed
  - More than 6 allowed for science, educational, or exhibition purposes, with CDC permission



## Freshwater Turtles, Tortoises, and Terrapins

- CDC regulations do not apply to sea turtles
- Upon admission to the United States, turtles <4 inches in length become subject to FDA restrictions
- Submit request for letter of permission via email to [CDCAnimalImports@cdc.gov](mailto:CDCAnimalImports@cdc.gov)



## Nonhuman Primate (NHP) Import History

- NHP import regulations strengthened in 1990 following 1989 Ebola Reston outbreak in the United States
- NHP regulations revised further in 2013



## 1989 Outbreak of Ebola Reston

- Viral hemorrhagic fever in a group of imported NHPs
- First thought to be simian hemorrhagic fever
- Illness spread through monkeys at the facility
- Facility was depopulated — 500 animals euthanized
- Six people associated with this outbreak seroconverted
- No human illness



# Requirements for Importing NHPs

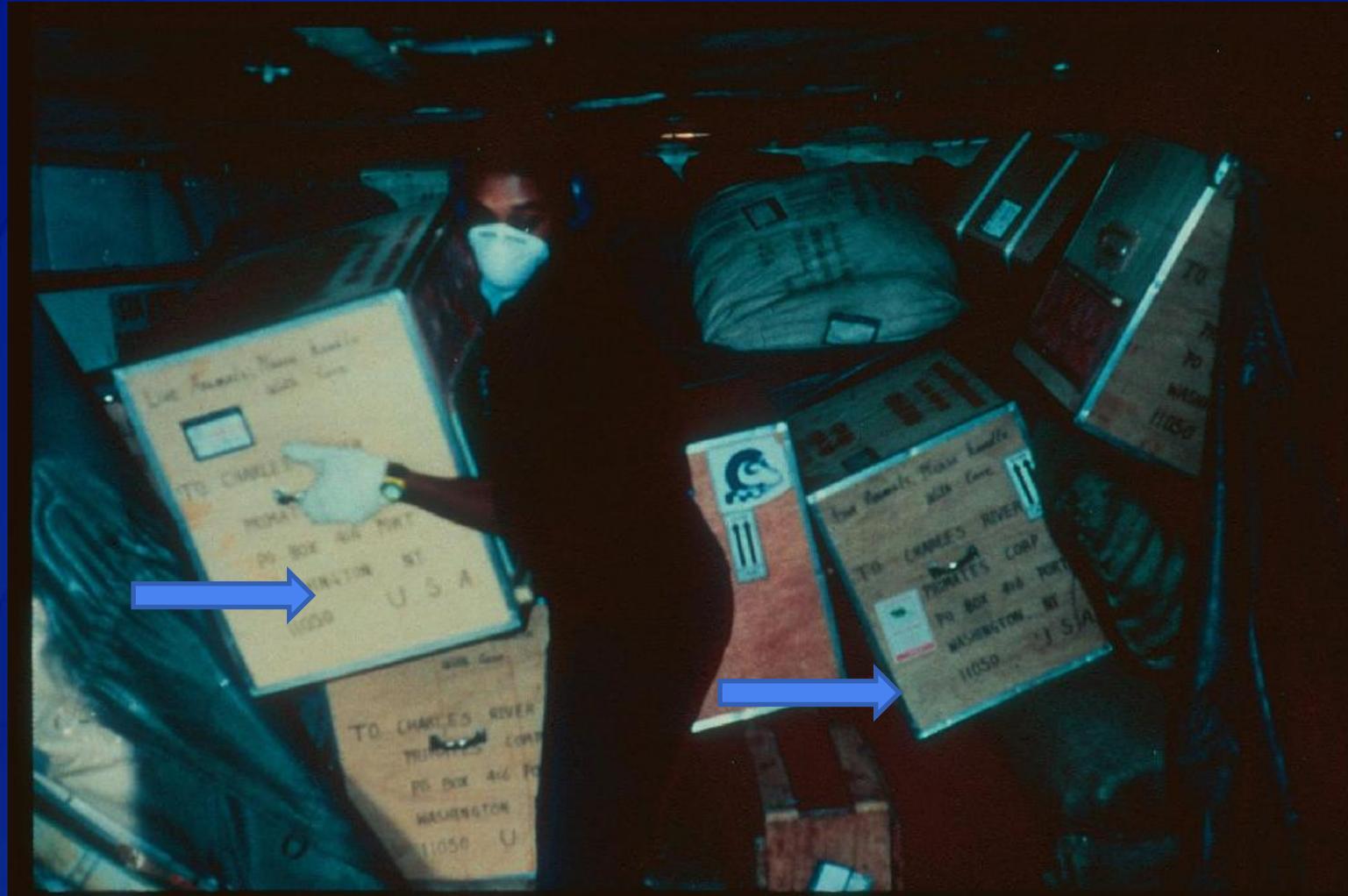
- ❑ NHPs can be imported only for science, exhibition or education
- ❑ Importers must register with CDC
- ❑ Imported NHPs must be quarantined for 31 days
- ❑ Each animal must have 3 consecutive negative TSTs tests at 2-week intervals



## Live NHPs

- **Registration/permit process**
  - Importers must be registered with CDC
  - Entry allowed only for science, education or exhibition
  - For more information on registering as an NHP importer, contact CDC at [CDCAnimalImports@cdc.gov](mailto:CDCAnimalImports@cdc.gov)
- **Strict procedures for shipping animals and transporting them to the CDC-approved quarantine facility**
- **Post-arrival quarantine period**
- **Quarantine facility inspection by CDC**

## Prior to 1990 Regulations



## After 1990 Regulations



## NHP Products

- **NHP products include any tissue or sample from an NHP**
  - Trophies or souvenirs
  - Diagnostic or scientific samples
  - Other
- **CDC import permit required**
  - Products may be imported without a permit if rendered noninfectious
  - Shipment must be accompanied by a statement of how the products were rendered noninfectious using one of the methods listed at <http://www.cdc.gov/importation/animal-products.html>
- **Permit application process**
  - Entry allowed only for science, education or exhibition
  - Apply for permit through CDC Import Permit Program
  - Application routed to QBHSB for review and approval

## **NHP Summary**

- ❑ **Since 1990, the NHP Import Program and the regulations regarding the importation of NHPs has resulted in a drop in the morbidity and mortality of imported animals from 25% prior to the 1990 regulation update to a current rate of <1%, resulting in lower potential risk to the U.S. public and in a healthier NHP for research**

## Family Viverridae (Civets and Related Animals)

- Severe Acute Respiratory Syndrome (SARS) outbreak during 2002–2003
- Civets linked to SARS transmission
- Emergency embargo effective as of January 13, 2004
- Still covered under embargo order authorized by 42 CFR 71.32(b)



## Family Viverridae (Civets and Related Animals)

- **Embargo includes all members of Family Viverridae**
  - Genets
  - Linsangs
  - Binturongs
  - Civets, except for African Palm Civet (Family Nandiniidae)
- **Applies to live animals and animal products**
  - Products may be imported without a permit if rendered noninfectious
  - Shipment must be accompanied by a statement of how the products were rendered noninfectious using one of the methods listed at <http://www.cdc.gov/importation/animal-products.html>
- **Permission letter application process**
  - Entry allowed only for science, education or exhibition
  - Submit request to [CDCAAnimalImports@cdc.gov](mailto:CDCAAnimalImports@cdc.gov)

## African Rodents

- Restrictions followed a 2003 monkeypox outbreak in the United States
- Linked to African rodents imported for the pet trade
- A total of 71 human cases were investigated
- First human monkeypox cases reported outside of Africa



## African Rodents

- Immediate embargo and domestic ban by Health and Human Services (HHS) effective June 11, 2003
- International import embargo later codified as a regulation, 42 CFR 71.56
- FDA domestic interstate movement restrictions lifted in September 2008



## African Rodents

- **Embargo includes all African rodents**
  - All rodents imported directly from Africa
  - All rodents born in Africa, even if imported from a third country
  - All rodents with a native range that includes Africa, even if born outside of Africa
- **Applies to live animals and animal products**
  - Products may be imported without a permit if rendered noninfectious
  - Shipment must be accompanied by a statement of how the products were rendered noninfectious using one of the methods listed at <http://www.cdc.gov/importation/animal-products.html>
- **Permission letter application process**
  - Entry allowed only for science, education or exhibition
  - Submit request to [CDCAAnimalImports@cdc.gov](mailto:CDCAAnimalImports@cdc.gov)

# **ENFORCEMENT OF CDC IMPORT REGULATIONS**

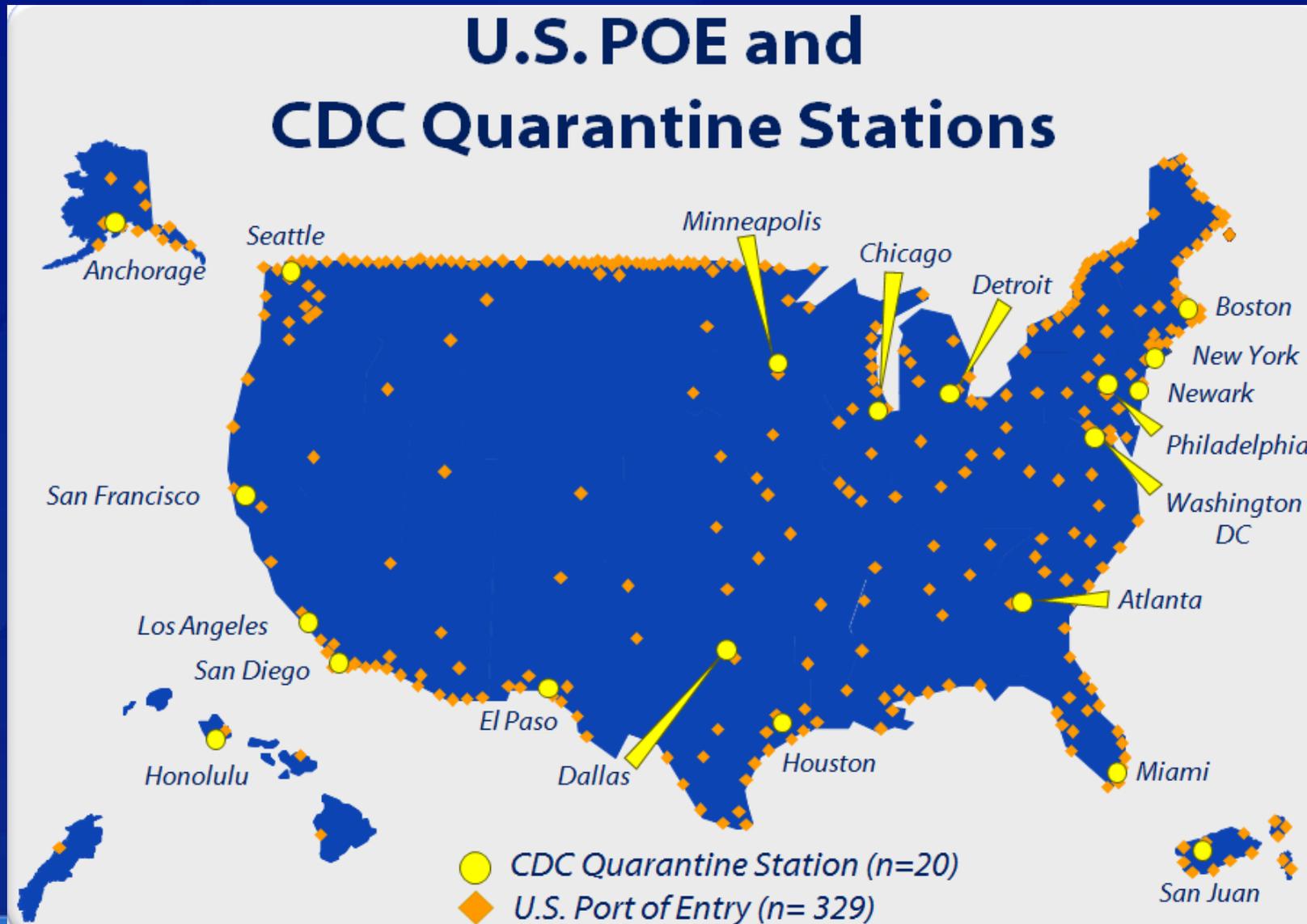
CDC Quarantine Stations and Partnerships at U.S. Ports of Entry

## QBHSB Operations

- Manage CDC Quarantine Stations and strategically lead the U.S. Quarantine System with key partners
- Execute federal authority for quarantine, isolation, and communicable disease surveillance at U.S. ports of entry



# U.S POE and CDC Quarantine Stations



# CDC Quarantine Station Jurisdictions



## QBHSB Import Operations

- Provide support to U.S. Customs and Border Protection at ports of entry for CDC-regulated imports
- Coordinate with other federal, state, and local agencies as needed
- Make entry decisions on CDC-regulated imports
- Coordinate with CDC Import Permit Program to ensure that CDC-restricted imports have proper permits or documentation
- For assistance with an import issue at a specific port of entry, contact the CDC Quarantine Station with jurisdiction
  - <http://www.cdc.gov/quarantine/quarantinestationcontactlistfull.html>
  - Direct more general questions or requests for permits to the CDC Import Permit Program or Importations and Animal Contact Team

# Upcoming Year

- Updating website
- Gov Delivery
- Permitting system replacing permission letters

The screenshot shows the CDC website's 'Importation' page. At the top, it features the CDC logo and the text 'Centers for Disease Control and Prevention' with the tagline 'CDC 24/7: Saving Lives. Protecting People.™'. Below this is an alphabetical index from A to Z. The main heading is 'Importation'. A left-hand navigation menu lists various topics: 'Importation', 'Frequently Asked Questions About Animal Importation', 'Bringing an Animal into the U.S.', 'Bringing Animal Products into the United States', 'Traveling with Pets', 'Forms', 'International Pet Adoption Scams', and 'Laws and Regulations'. The main content area includes social media icons for Facebook, Twitter, and a plus sign. The primary section is titled 'What Are You Importing?' and contains two paragraphs of text. The first paragraph states that CDC has regulatory authority over several types of imported items and advises visitors to visit the 'CDC Import Permit Program (IPP) site' if importing infectious biological agents, infectious substances, and vectors of human disease. The second paragraph advises visitors to visit the 'Federal Select Agent Program' site if importing biological agents and toxins that could pose a severe threat to public health and safety. Below this text is a small graphic titled 'Crossing the Border With Your Dog?' showing a dog and flags of Mexico and the United States. A third paragraph mentions that the 'Federal Food and Drug Administration (FDA) Import Program' regulates the importation of most other items. At the bottom, there are two columns of 'Related Links'. The first column includes links for 'Importation and Human Remains', 'Import Permit Program (IPP)', 'Travelers' Health', 'Healthy Pets Healthy People', and 'United States - Mexico'. The second column has a heading 'About Animal Importation' with a paragraph explaining that millions of animals and animal products are brought into the United States, increasing the potential for infectious diseases, and that CDC works with other federal agencies to protect US borders. The second column also has a heading 'Internet Adoption Scams Involving Imported Pets' with a small image of a dog and a paragraph stating that the CDC has learned that internet scammers are falsely representing themselves as CDC employees in e-mails to U.S. citizens.

CDC Home  
Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives. Protecting People.™

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

## Importation

**Importation**

- Frequently Asked Questions About Animal Importation
- Bringing an Animal into the U.S.
- Bringing Animal Products into the United States
- Traveling with Pets
- Forms
- International Pet Adoption Scams
- Laws and Regulations

**Related Links**

- Importation and Human Remains
- Import Permit Program (IPP)
- Travelers' Health
- Healthy Pets Healthy People
- United States - Mexico

**What Are You Importing?**

CDC has regulatory authority over several types of imported items.

If you are importing infectious biological agents, infectious substances, and vectors of human disease into the United States, please visit the [CDC Import Permit Program \(IPP\) site](#).

If you are importing biological agents and toxins that could pose a severe threat to public health and safety (select agents), please visit the [Federal Select Agent Program](#) site.

The [Federal Food and Drug Administration \(FDA\) Import Program](#) regulates the importation of most other items.

**About Animal Importation**

Each day millions of animals and animal products are brought into the United States, increasing the potential for the introduction of infectious diseases. CDC works with other federal agencies to protect US borders against diseases carried by animals and animal products.

**Internet Adoption Scams Involving Imported Pets**

The CDC has learned that Internet scammers are falsely representing themselves as CDC employees in e-mails to U.S. citizens.



# Acknowledgements

## Branch Chief

Dr. Clive Brown

## Quarantine Communications Team

Dr. Heather Bair Brake

## Importations and Animal Contac Team

Dr. Gale Galland

Dr. Robert Mullan

Dr. Nelva Bryant

Dr. Gleeson Murphy

Ms. Sheryl Shapiro

Ms. Renee Crawford

Ms. Lisa Bevel

## Quarantine Station Staff and Regional Officers in Charge

# Questions?



For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop C-01, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: [CDCAnimalImports@cdc.gov](mailto:CDCAnimalImports@cdc.gov)

Web: <http://www.cdc.gov/importation/>



National Center for Emerging and Zoonotic Infectious Diseases

Division of Global Migration and Quarantine

# Bushmeat

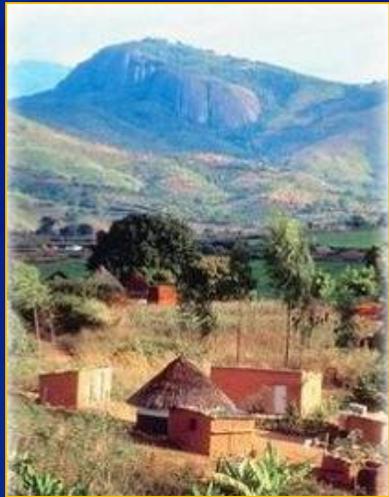


- ❑ Meat hunted from wild animals – particularly from *Africa*
- ❑ Includes NHPs, wild ruminants, rodents, bats, lizards, snails, crocodile, elephants
- ❑ Most often smoked
- ❑ CDC concerned about bushmeat from animals that are CDC-regulated



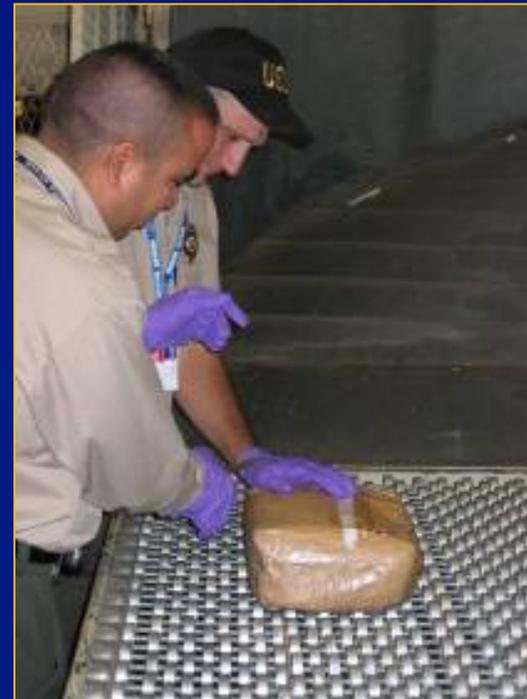
# Bushmeat Trade in Developing Countries

- ❑ Hunted by villagers as the main source of food for their families
- ❑ Hunted by others as main source of income
  - Sold at roadside stands
  - Brought into the cities
  - Exported to countries around the world



# Arrival of Bushmeat into the United States

- ❑ With air passengers
  - Average 250,000 arrivals from Africa\*
- ❑ Cargo
- ❑ Mail



\* Office of Travel and Tourism, U.S. Dept. of Commerce

# Most Commonly Reported Countries of Bushmeat Origin 2005-2006



Country of Origin	Frequency	Relative %
Ghana	19	35.85%
Nigeria	13	24.53%
Cameroon	8	15.09%
Unspecified	4	7.55%
Liberia	3	5.66%
Senegal	2	3.77%
Ivory Coast	2	3.77%
Guinea	1	1.89%
Laos	1	1.89%
<b>Total</b>	<b>53</b>	<b>100.00%</b>

# Understanding the Bushmeat Trade: Focus Group Studies

- **CDC partnered with Bushmeat Crisis Taskforce and Zoo Atlanta**
  - **Conducted focus group studies among West Central African expatriates in 3 cities**
  - **Goals of focus groups**
    - **Determine why people desire bushmeat**
    - **Acceptable alternatives**
    - **Improve targeted messaging**

## Results: Feelings about Bushmeat

- Bushmeat is fresh and wholesome
- Bushmeat is safe as long as it is properly prepared and stored.....and as long as you don't over eat it
- Most individuals polled had eaten bushmeat
- Most individuals knew where to get it in the United States



## Results: Bushmeat Substitutes

- ❑ Substitutes were difficult to identify
- ❑ Bushmeat is considered more fresh and wholesome than meat in the United States
- ❑ Possible alternatives
  - Smoked venison, turkey or chicken



## Results: Importation of Bushmeat

- ❑ Most knew that bushmeat importation was illegal
- ❑ Some confusion over commercial imports and whether purchasing the meat from stores was illegal



## **Results: Feelings About Wildlife**

- ❑ **Bushmeat and wildlife are different**
- ❑ **Individuals didn't really understand concepts of biodiversity or sustainability**
  - **They felt that wildlife reproduced at a sufficient rate to replenish itself**
- ❑ **Conservation is not a priority**
  - **Poverty, hunger, and war have to take precedence**

## **Results: What is the Best Way to Present Educational Materials**

- ❑ **Trust family and friends most**
- ❑ **Active in social networking**
- ❑ **Little trust in media**
  - **Regularly read newspapers online from their countries of origin**
- ❑ **Open to being contacted again**
- ❑ **Open to hearing messages about conservation, restrictions on importation, and disease transmission**

## Other Bushmeat Activities

- **Selected bushmeat “blitzes”**
  - **Targeted inspections**
    - **Selected flights based on country of origin**
    - **Selected postal facilities**
  - **Multiple agencies involved including CDC, USFWS, and CBP**

## **Other Bushmeat Activities**

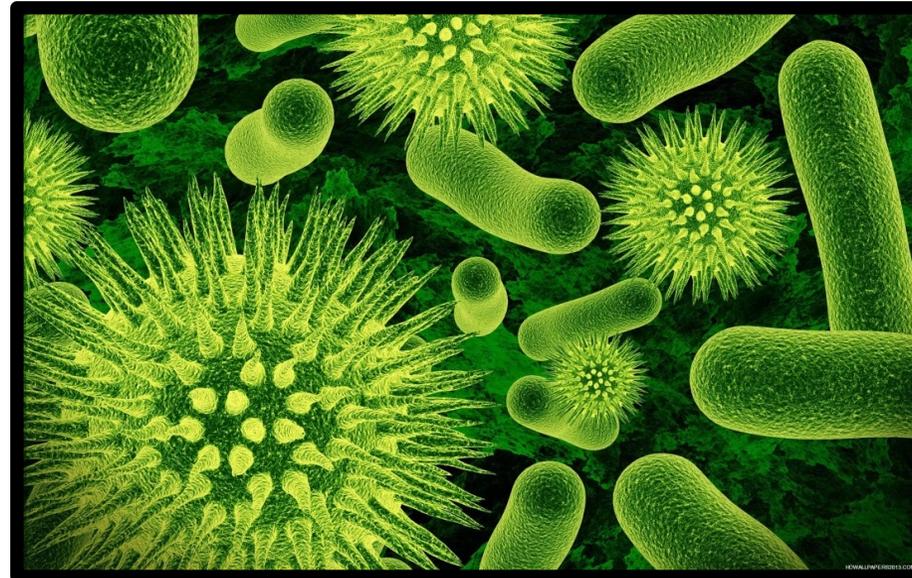
- ❑ **Collaborative study with Wildlife Conservation Society**
  - **Samples collected from bushmeat confiscated at points of entry into the U.S.**
  - **Samples stored in liquid nitrogen**
  - **Samples sent to different labs to test for organisms that may pose a threat to human health**
- ❑ **Results**
  - **Evidence of viral DNA and RNA such as Simian foamy viruses and herpes viruses from a variety of samples**



Veterinary Services

National Import and Export Services

# Organisms and Vectors permitting unit

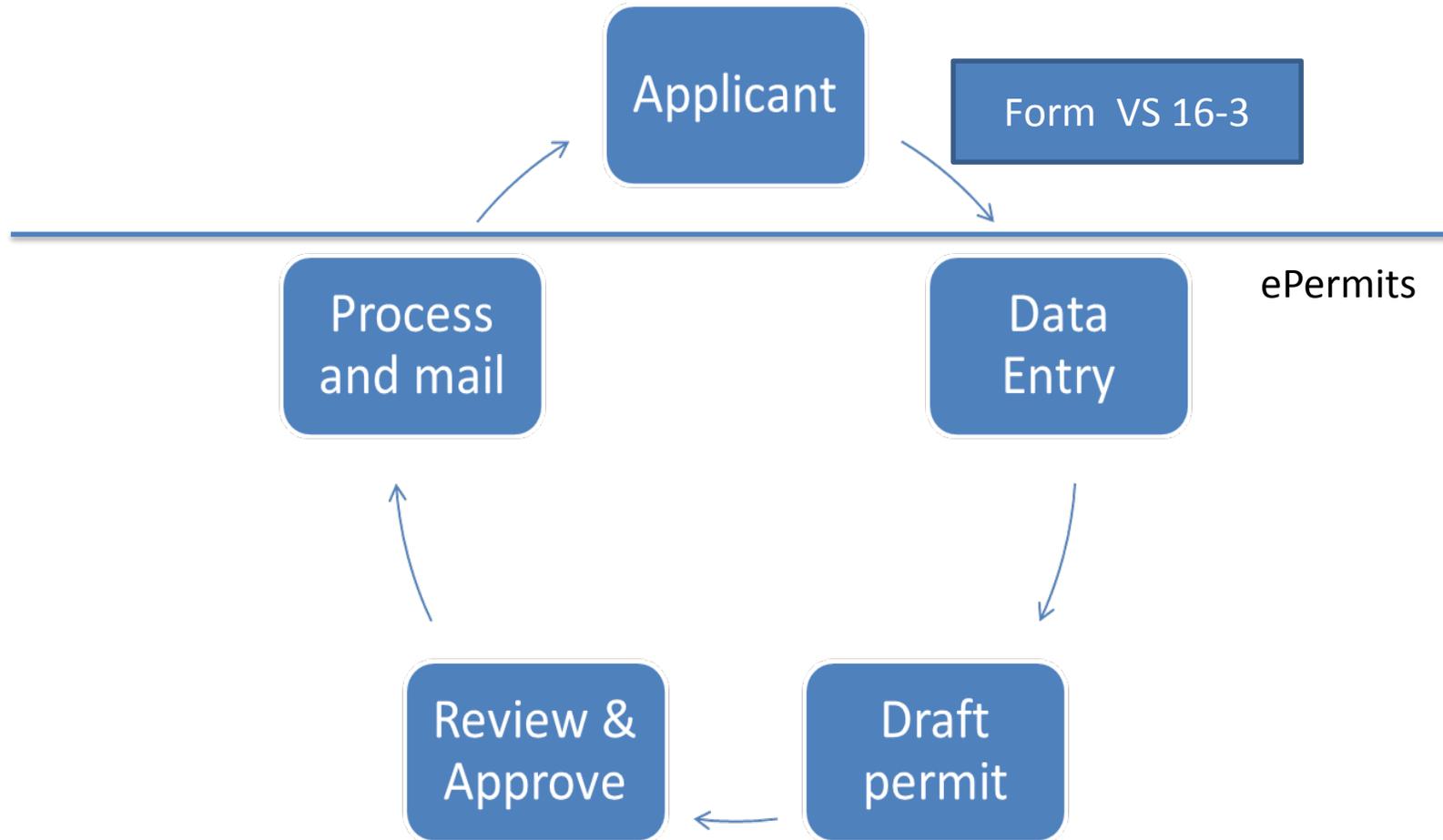


“No **organisms or vectors** shall be  
**imported**  
into the United States or **transported**  
from one State or Territory or  
the District of Columbia to another  
State or Territory or the District of  
Columbia without a **permit**”

Federal law (9 CFR, part 122)

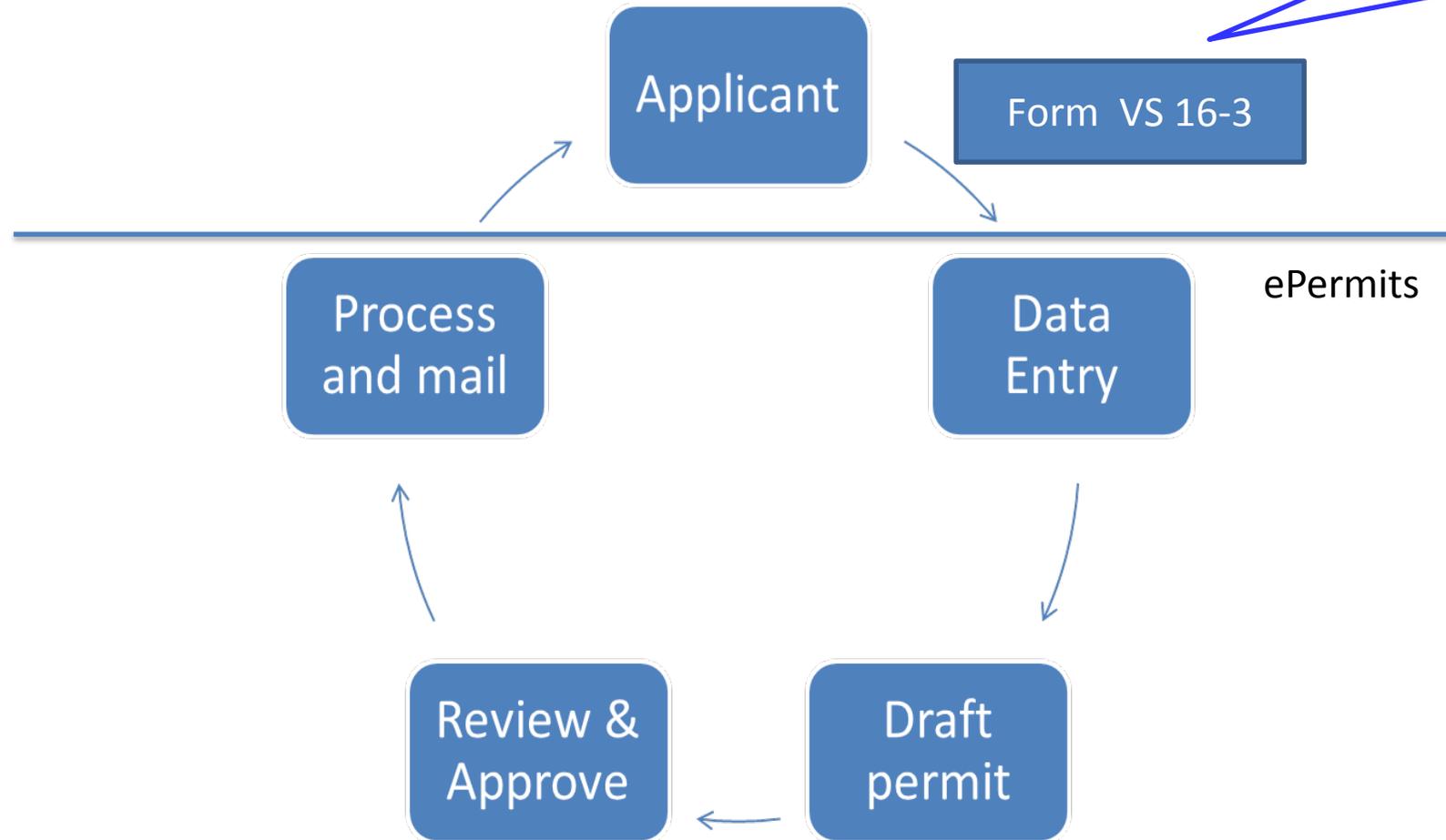


# OV Application process



# OV Application process

Researcher-  
university, medical,  
pharmaceutical R&D



# Applicant

- Do I need an OV permit?
  - Web page: <http://www.aphis.usda.gov/animal-health/organisms-vectors>
  - Email: [OV@aphis.usda.gov](mailto:OV@aphis.usda.gov)
  - Phone: 301-851-3300, option 3

VS permit is required  
to receive livestock and  
poultry pathogens  
from outside of the  
state or the country

bacteria  
virus  
fungi  
parasite



VS does not control  
transportation within  
a state

Intrastate transport

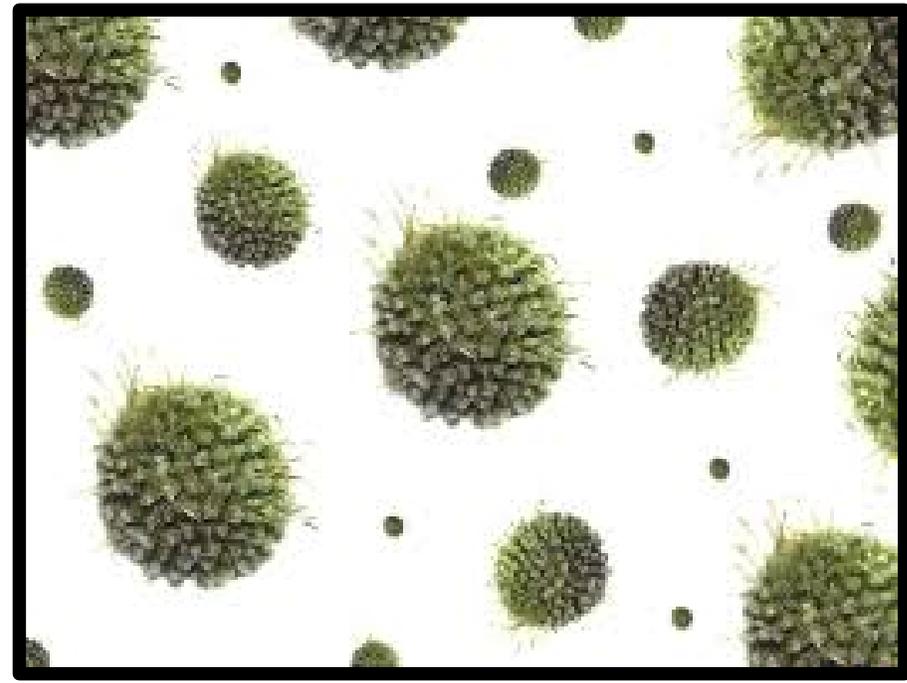
VS also controls  
movement of any  
potential vector of  
pathogen of livestock or  
poultry

*Insect vector:*  
mosquito, ticks, beetles etc.

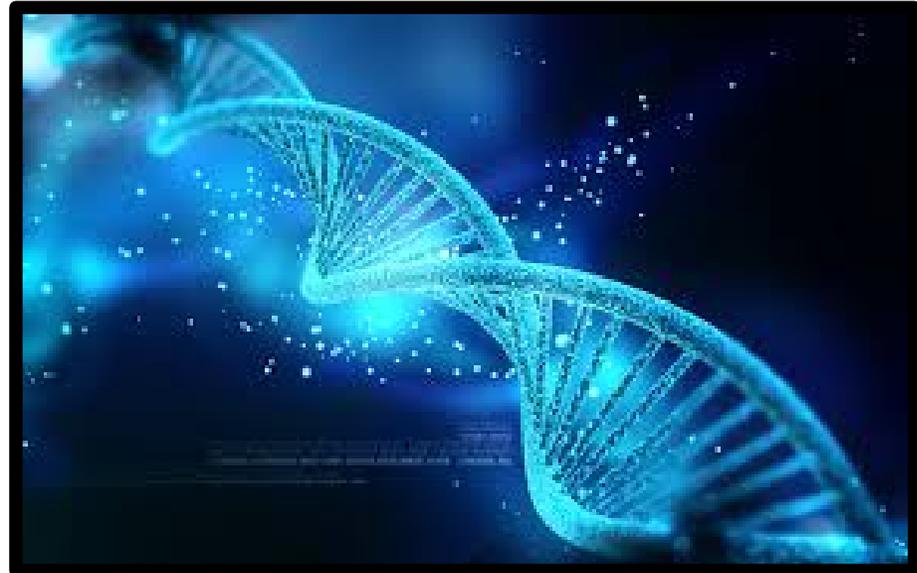
*Imported media vector:*  
FBS, trypsin, egg etc.



Permit is also required for movement of **killed** pathogens and vectors and their derivatives



Antigens  
Vaccine components  
DNA/RNA



VS permit is required for **importation** into U.S. of any organism (including **non-pathogens**) if exposed to medium of animal origin

## Vectors!

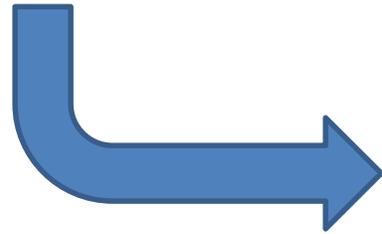


**Not every organism requires a VS permit**

VS does not  
control  
movement of  
non-  
pathogens  
e.g., yeast,  
mold,  
lactobacillus



VS does not control  
human pathogens



VS controls  
zoonotic  
pathogens that  
cause disease to  
livestock or poultry

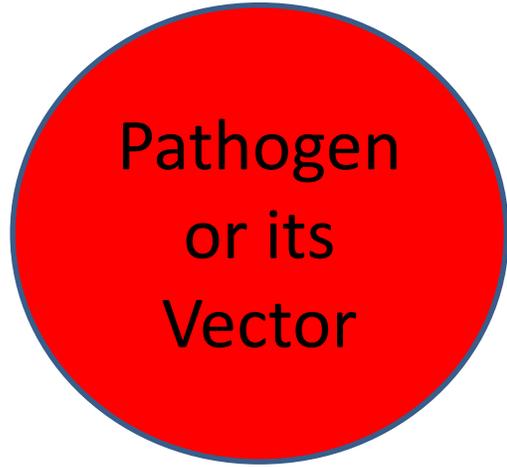


# Guidelines - no permit required

- *1100 Human Pharmaceuticals and Human Vaccines Containing Animal Components*
- *1101 Non-Human Primate Material (excluding cell cultures)*
- *1102 Feline and Canine Material*
- *1103 Live Laboratory Mammals and Their Material (for research purposes)*
- *1104 Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom)*
- *1105 Chemically Synthesized Materials*
- *1110 Microbially Produced Materials*
- *1114 Recombinant Microbes and Their Products*
- *1116 Non-Pathogenic Microorganisms (and their extracts)*
- *1119 Pet Chews/Treats Made of Antlers or Rawhide*
- *1120 Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)*
- *1121 Test Kits*
- *1122 Vitamins and Minerals*
- *1123 Histopathological fixed slides*

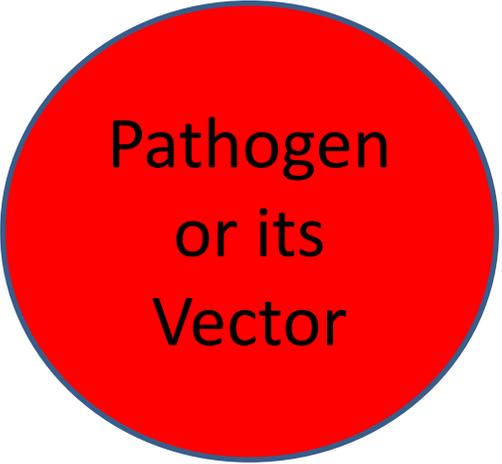
## Summary: do I need a permit?

USDA controls movement of livestock or poultry pathogens and their vectors

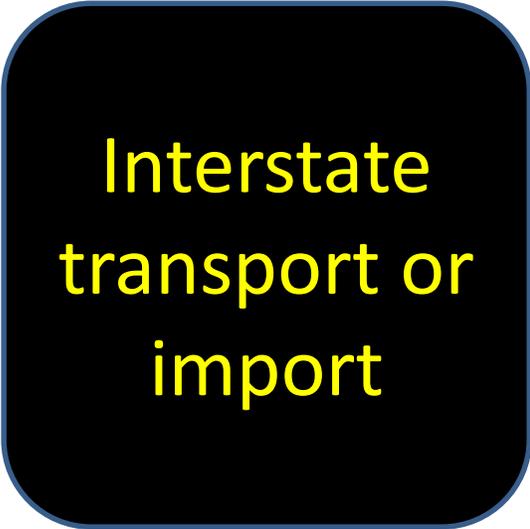


Pathogen  
or its  
Vector

USDA controls movement of livestock or  
poultry pathogens and their vectors

A red circle with a thin blue border containing the text "Pathogen or its Vector".

Pathogen  
or its  
Vector

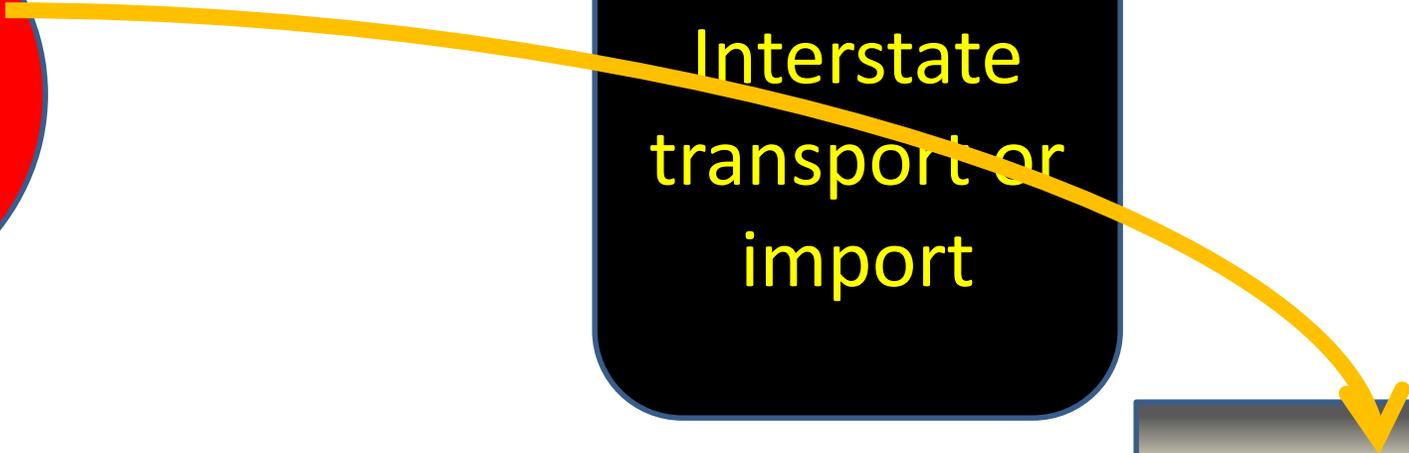
A black rounded square with a thin blue border containing the text "Interstate transport or import" in yellow.

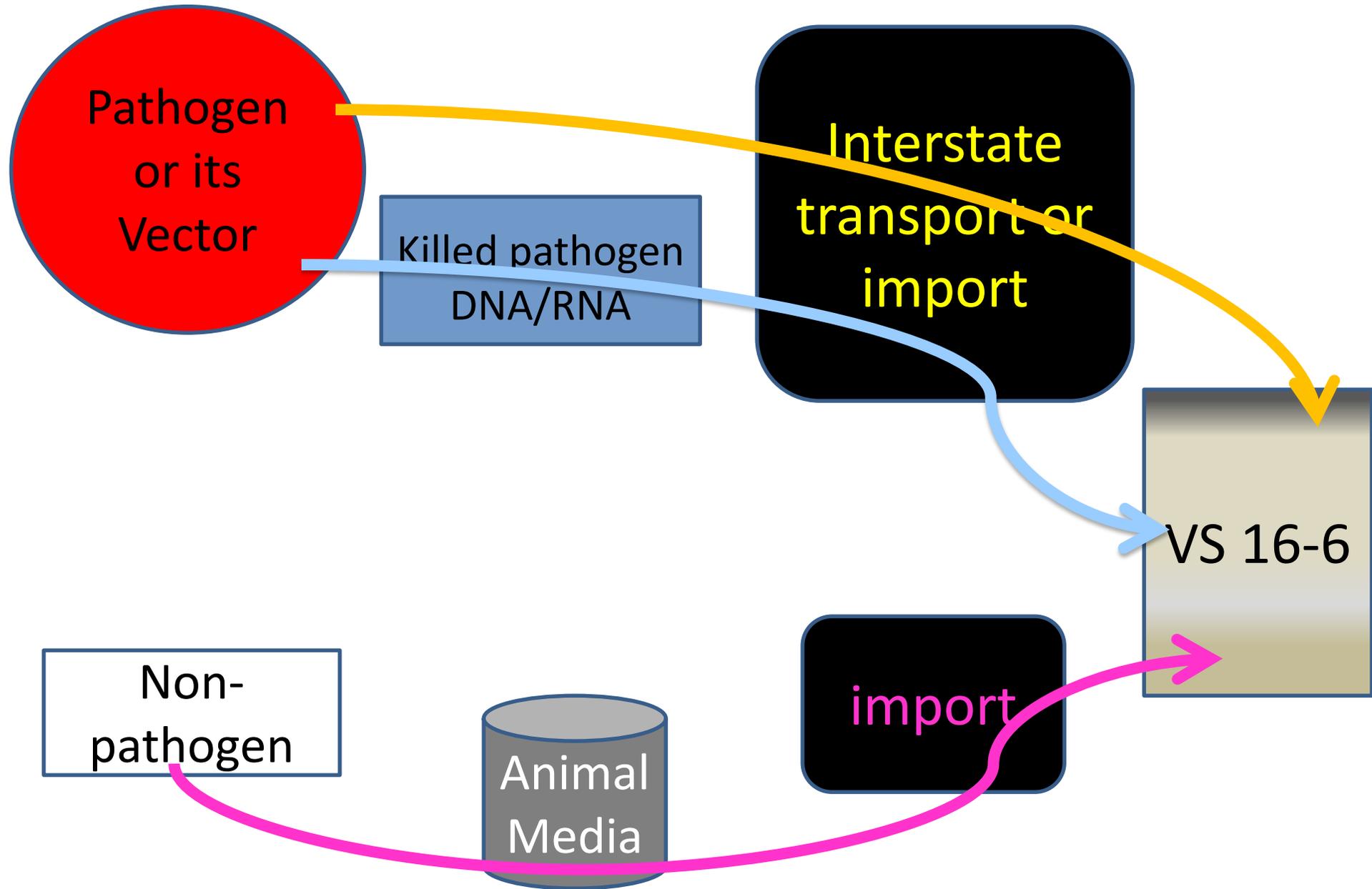
Interstate  
transport or  
import

Pathogen  
or its  
Vector

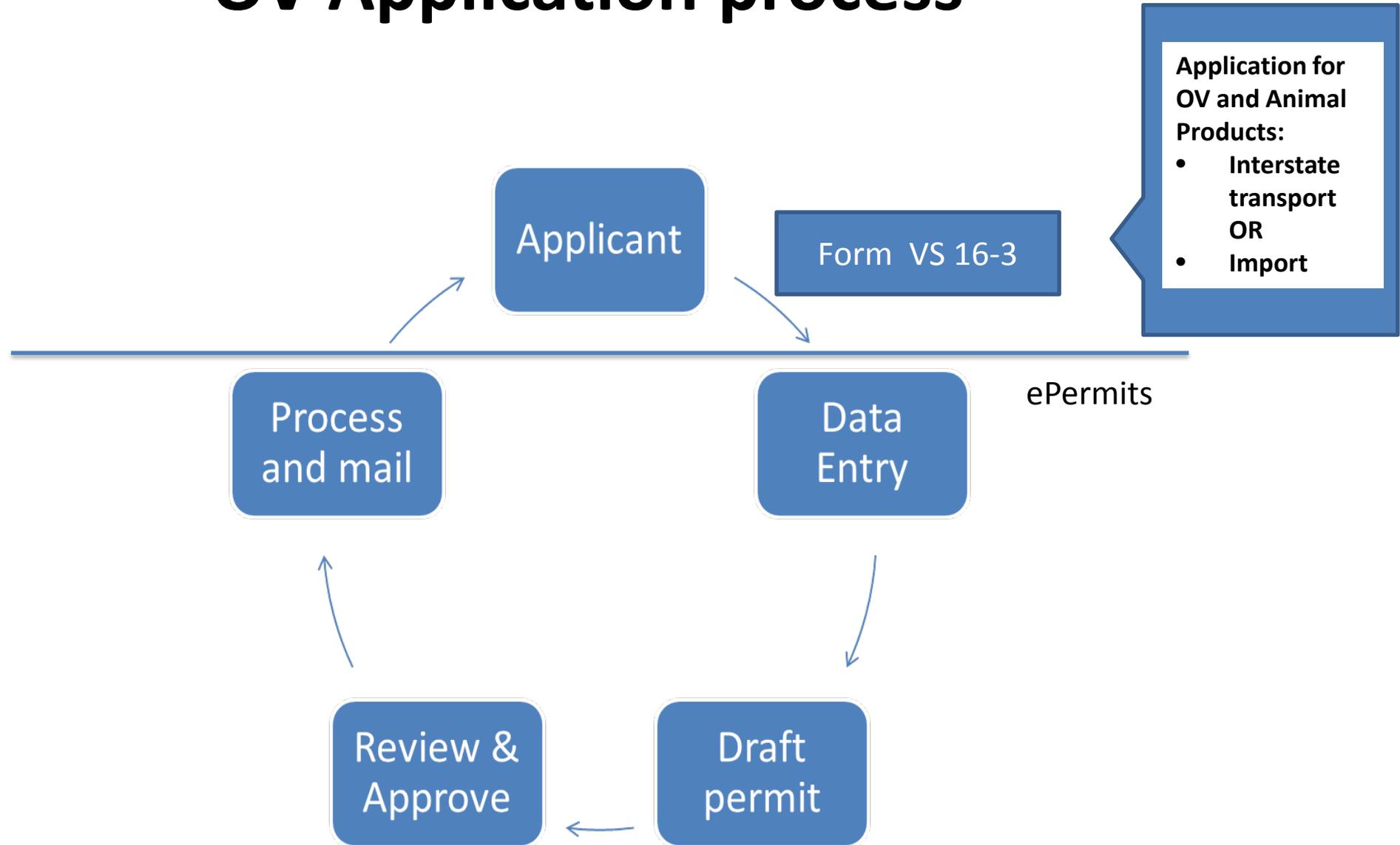
Interstate  
transport or  
import

VS 16-6





# OV Application process

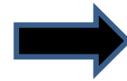


# VS 16-3

- How do I apply?
  - Web page has info:  
<http://www.aphis.usda.gov/animal-health/organisms-vectors>
  - ePermits
  - Email: [OV@aphis.usda.gov](mailto:OV@aphis.usda.gov)
  - US Mail:       USDA-APHIS-VS-NIES  
                  4700 River Road, Unit 2  
                  Riverdale, MD 20737
  - Fax: 301-851-2239

Application Form

VS 16-3

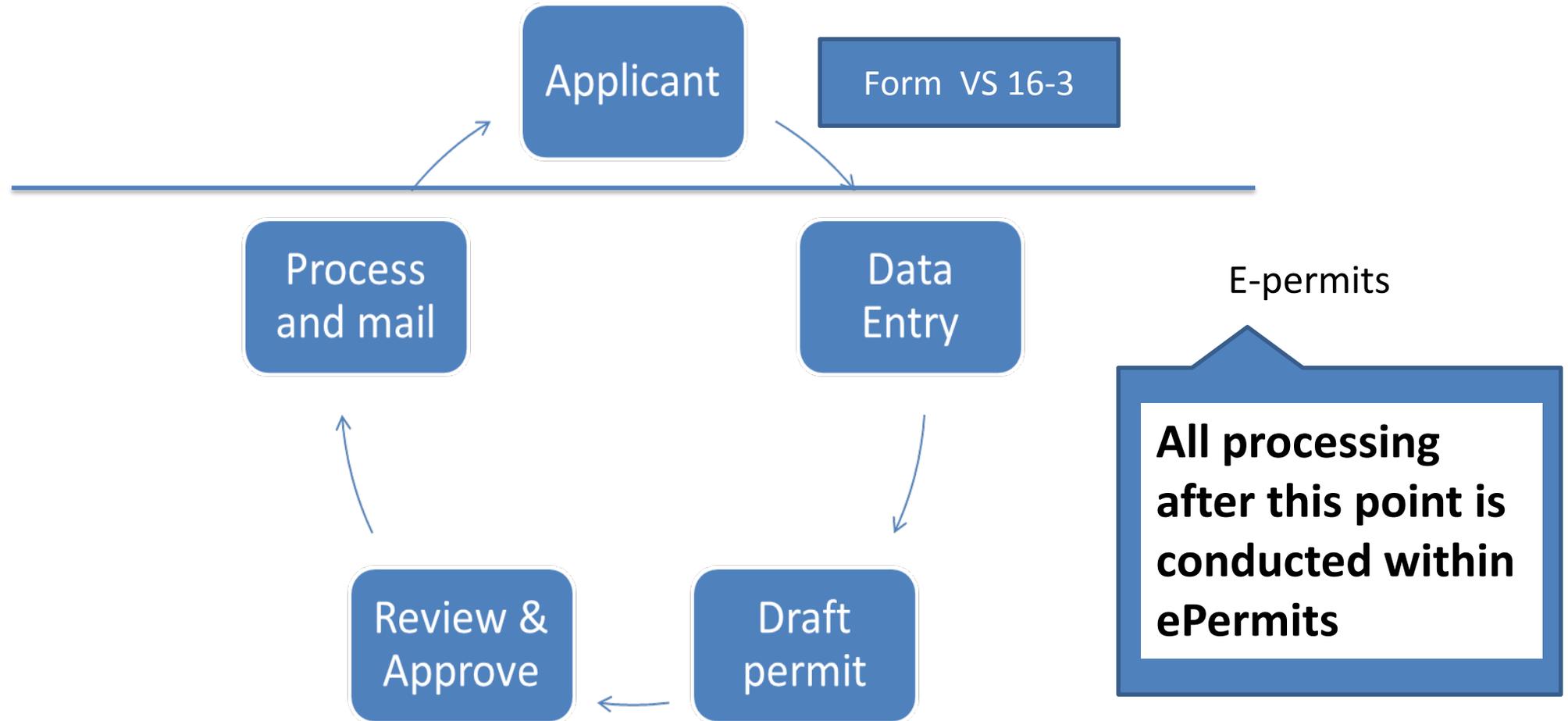


Transport  
or Import Permit for  
Controlled Organisms  
and Vectors Interstate

VS-16-6

**VS permit is not required for in-state transport**

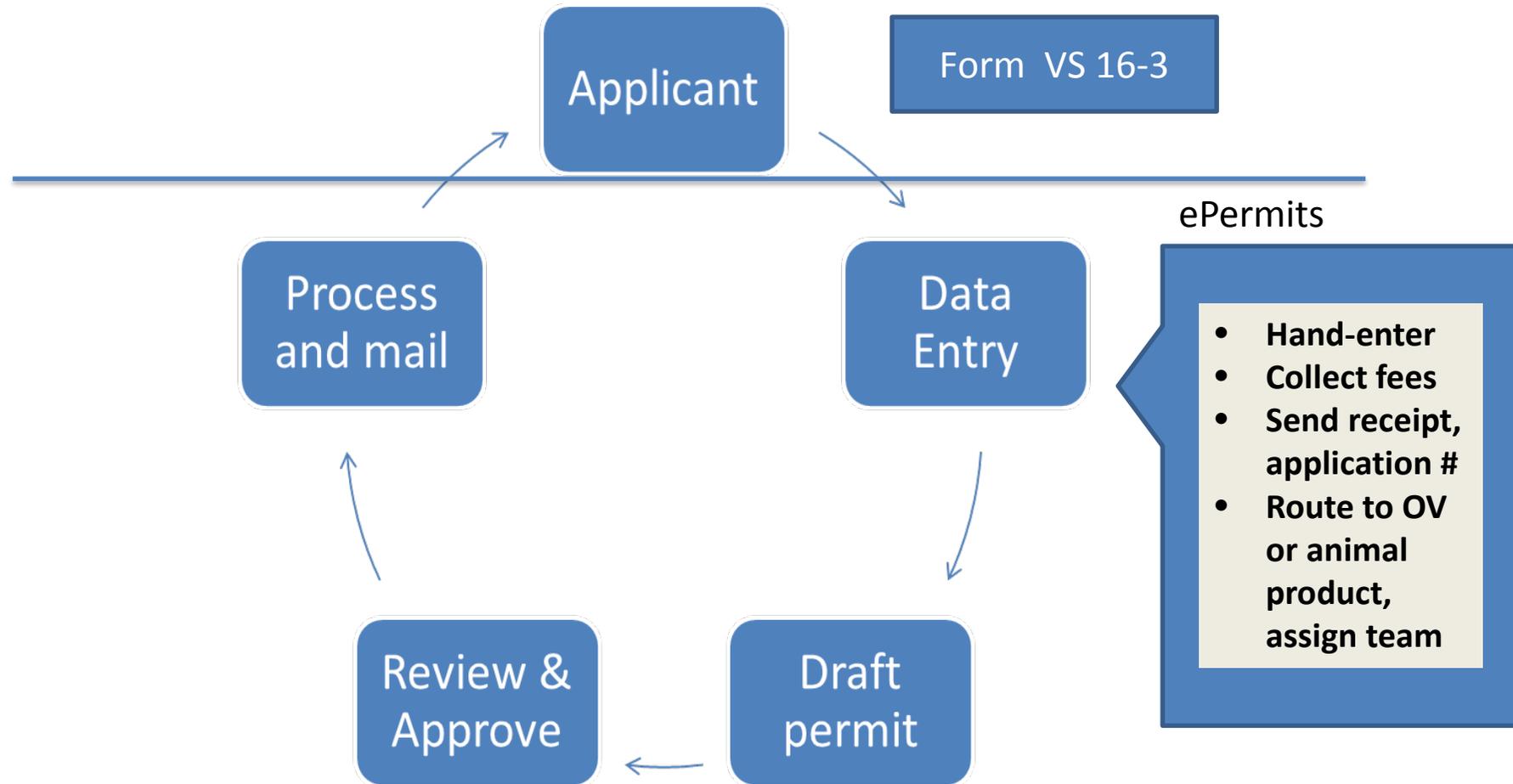
# OV Application process



# ePermits

- ePermits help:
  - [ePermitsHelp@aphis.usda.gov](mailto:ePermitsHelp@aphis.usda.gov)
  - 866-794-2827
- ePermits FAQs:  
[https://www.aphis.usda.gov/permits/downloads/ePermits\\_FAQs.pdf](https://www.aphis.usda.gov/permits/downloads/ePermits_FAQs.pdf)
- eAuthentication: easier now, doesn't require trip to Federal facility

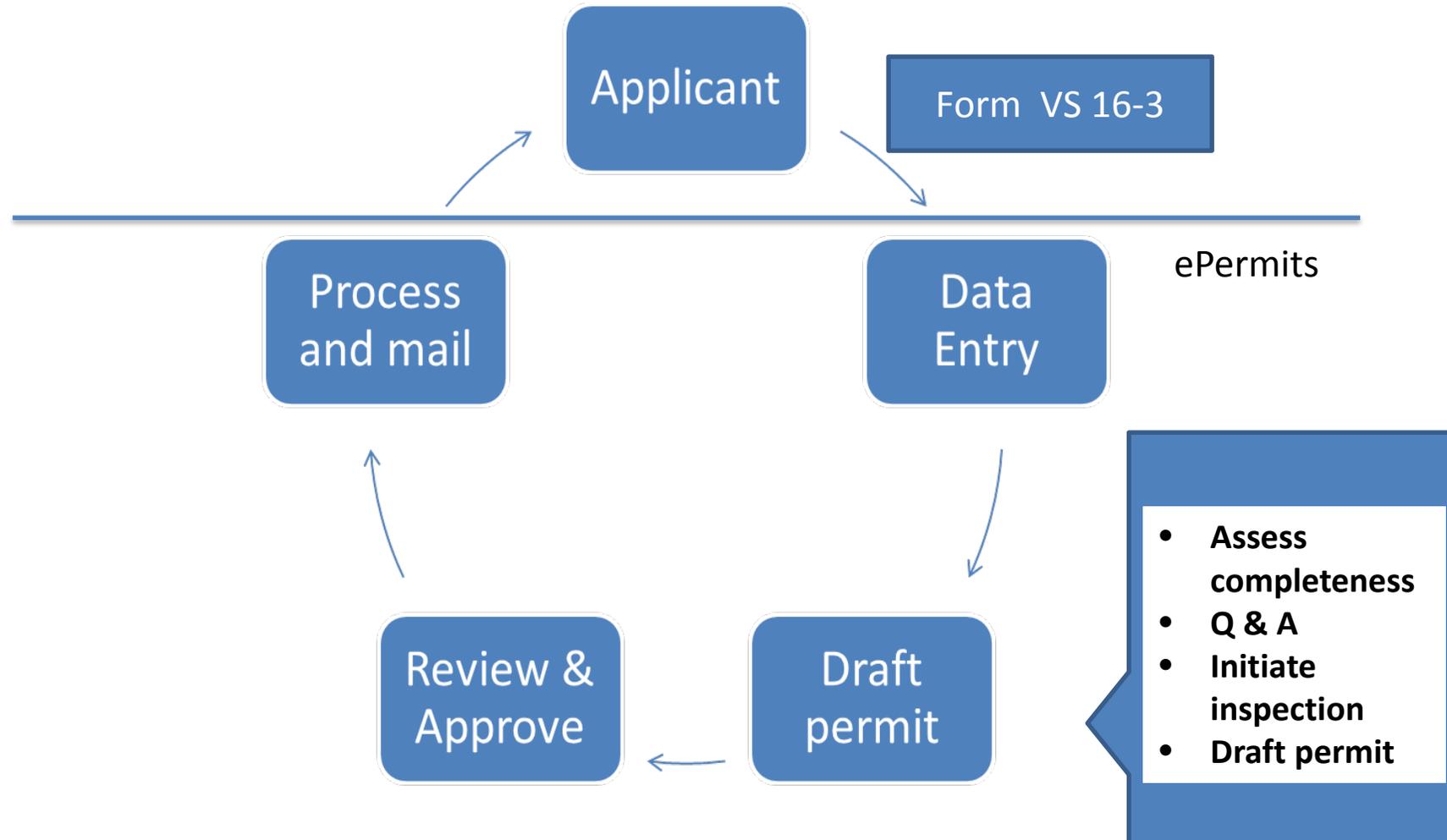
# OV Application process



# Data entry

- Applications are hand entered if not submitted via ePermits (takes time)
- Application fee is collected before processing
- Fastest processing (in this order):
  1. ePermits
  2. Email, fax submission
  3. FedEx, UPS, USPS

# OV Application process



# Draft Permit

- Determines if material/movement w/in jurisdiction
- Assess completeness of application, request additional information
- Determines need for lab inspection, informs applicant, receives consent
- Communicates with Senior Staff Officer
- Communicates lab inspection information to Service Center
- Receives lab inspection documents, enters into application file and ePermits lab inspection section
- Drafts permit

# Biocontainment

- Permit restrictions prevent importation of CSF, ASF, SVD, FMD, HPAI, NDV
- Safety testing/treatment (FADDL/DVL)
- Biosafety levels – Veterinary pathogens do not necessarily have BSLs
  - *Biosafety in Microbiological and Biomedical Laboratories*, appendix D
- Lab inspection – NIES Service Centers, SA inspectors

# Is inspection required - organism

- National/OIE Reportable Disease?
- Endemic?
- Importance to industry/economic impact
- Level of pathogenicity
- Risk of spread/infectivity/mode of transmission
- Would VS respond to outbreak?
- Emerging

# Is inspection required - permit?

- Analytical



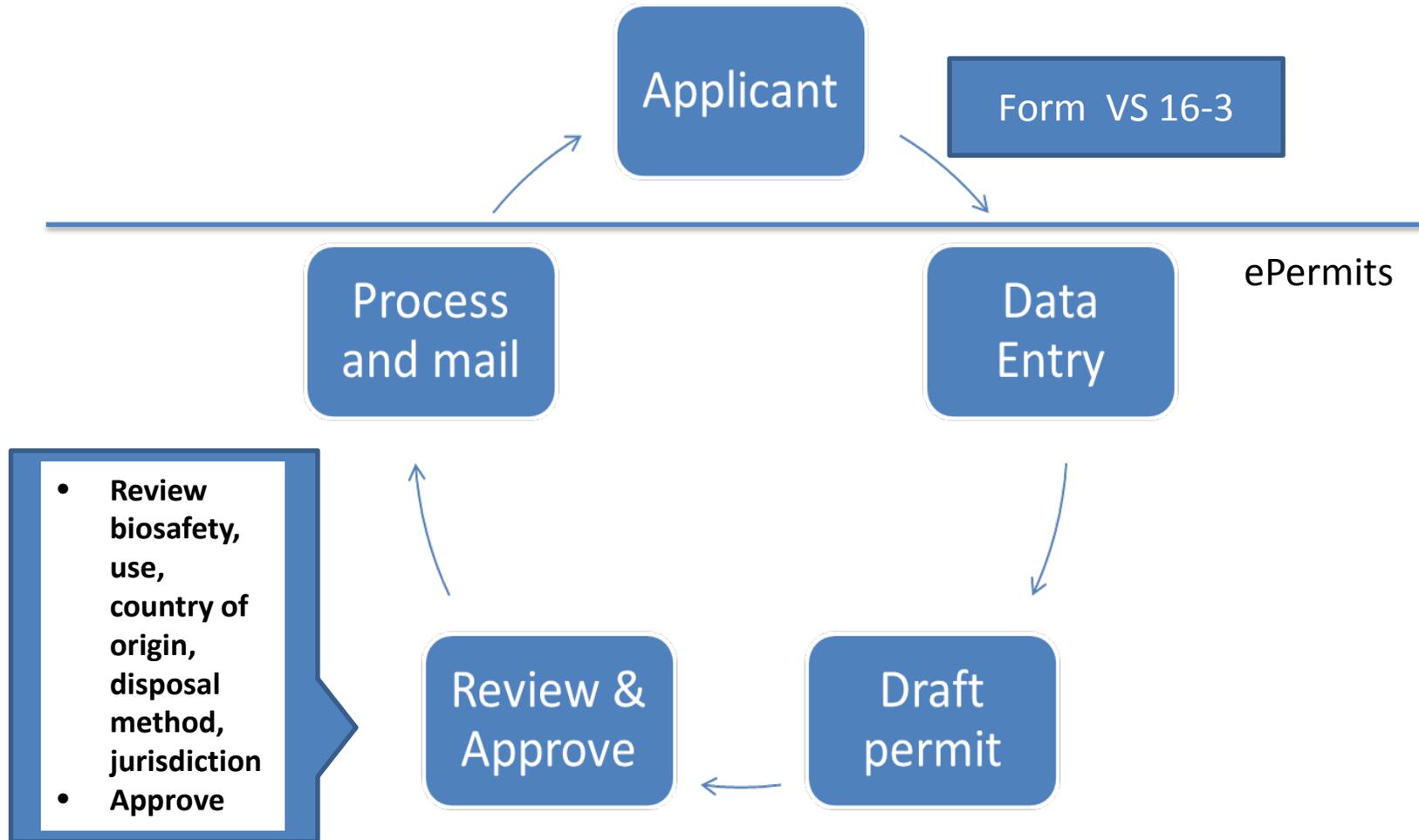
- Live culture

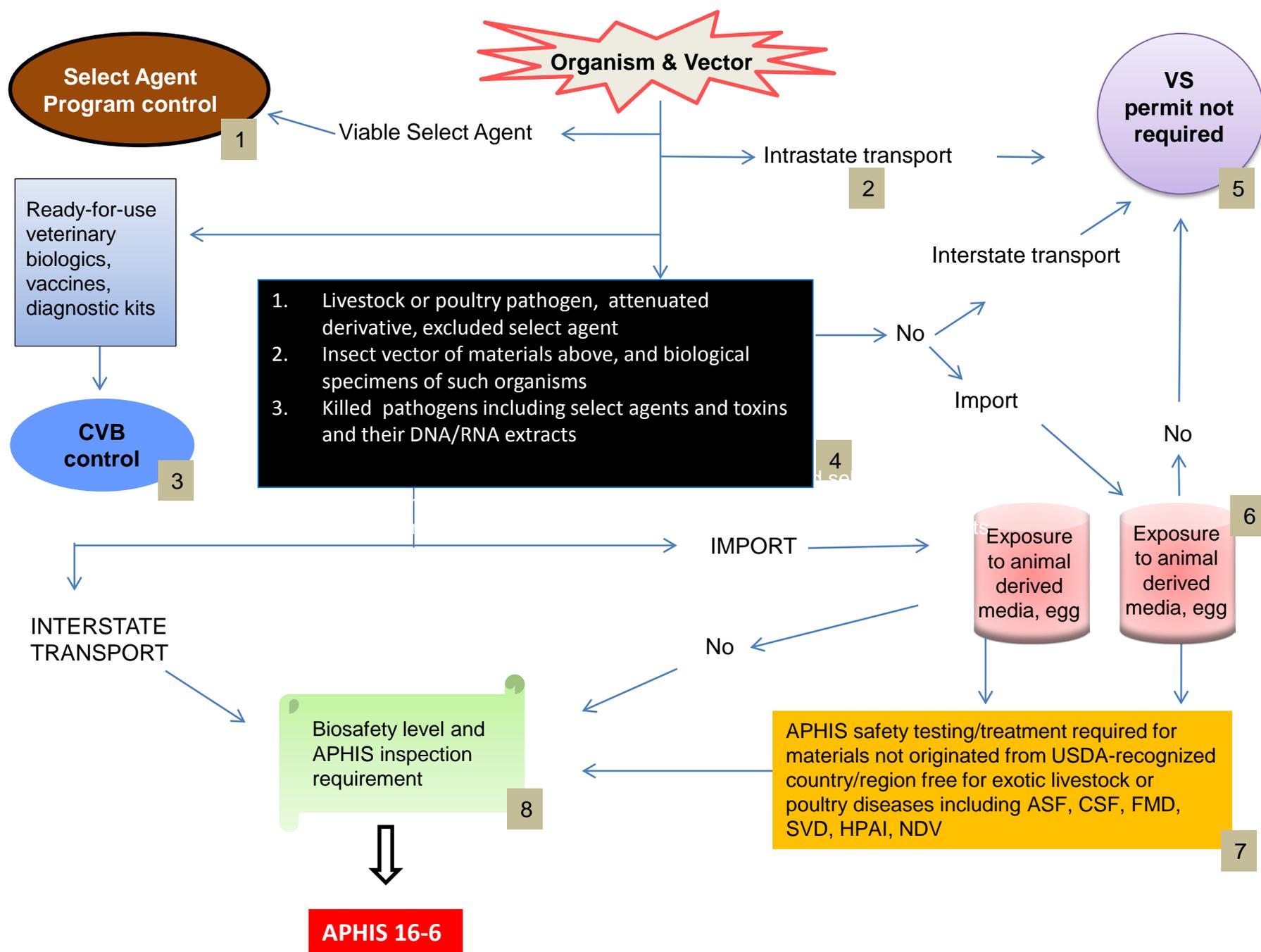


# Inspection

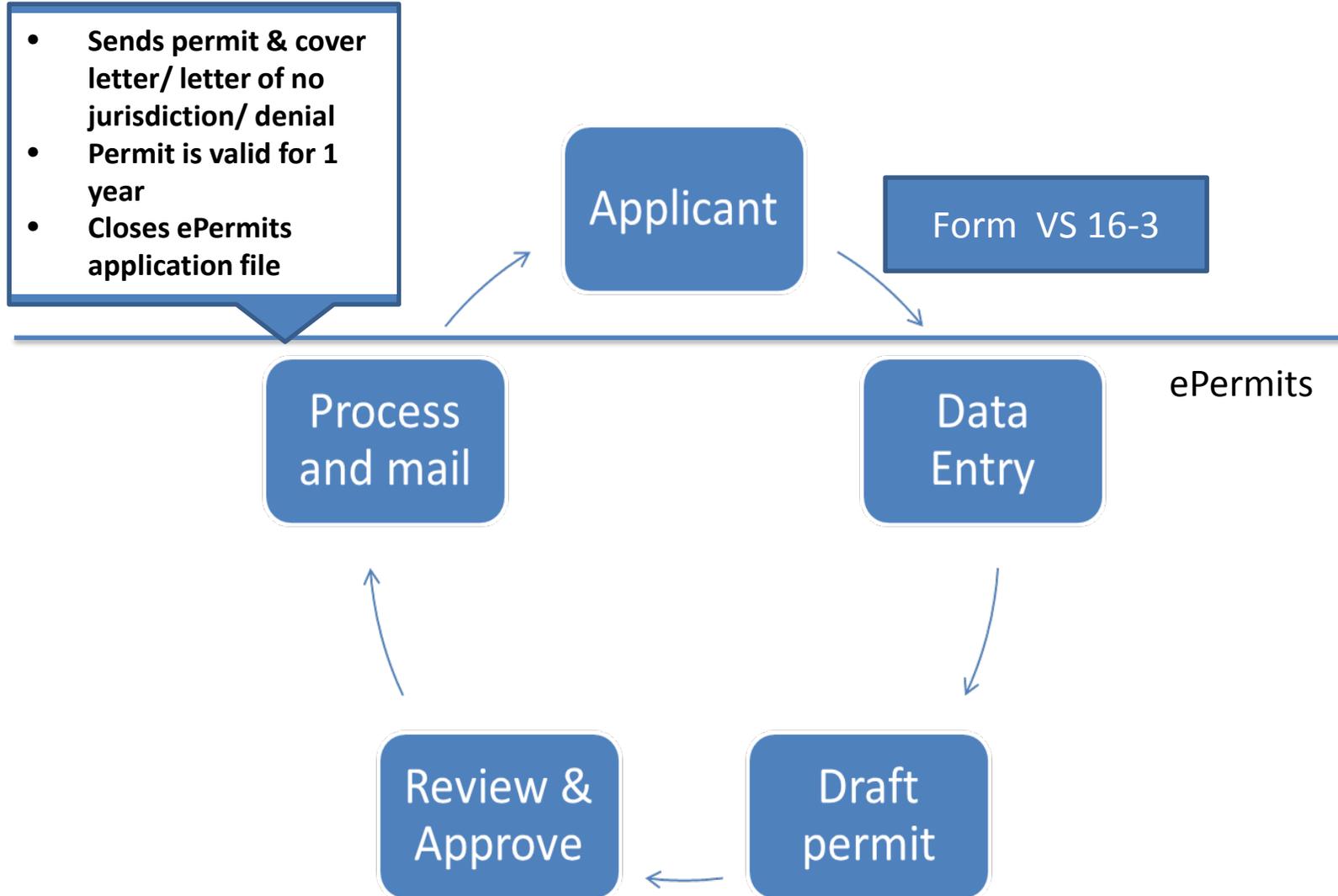
- BMBL is basis for inspection checklists
- Inspected lab database in ePermits
- Inspection valid for 3 years
- Approval of labs – based on inspector recommendation
- Deficiencies – addressed with applicant
- CFR 130 covers inspection fees

# OV Application process

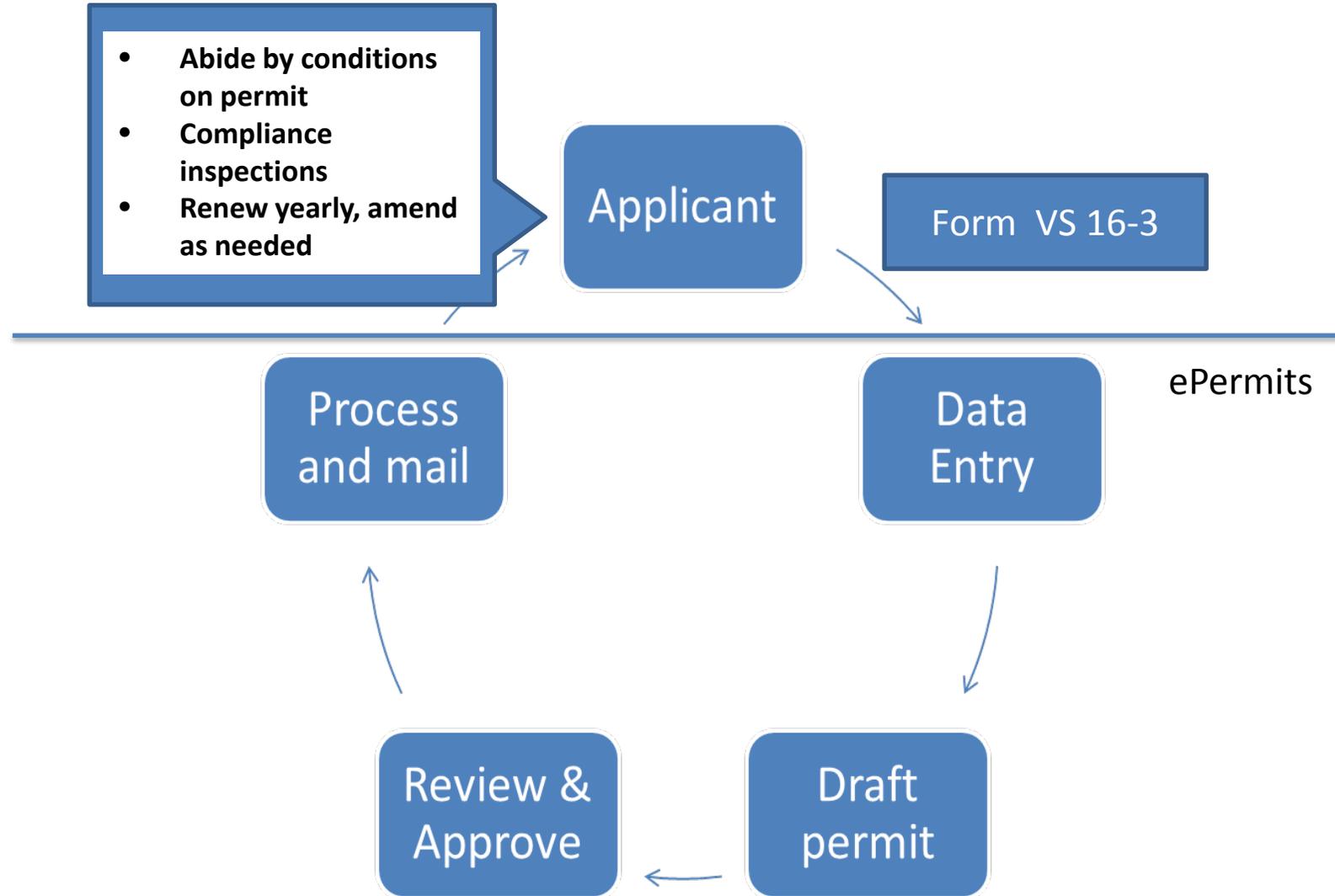




# OV Application process



# OV Application process



# Web tools

<http://www.aphis.usda.gov/animal-health/organisms-vectors>

- Do I need a permit?
- Frequently Asked Questions
  - Guidelines - No permit required
- List of foreign country disease status
- Application form

# Contact Info

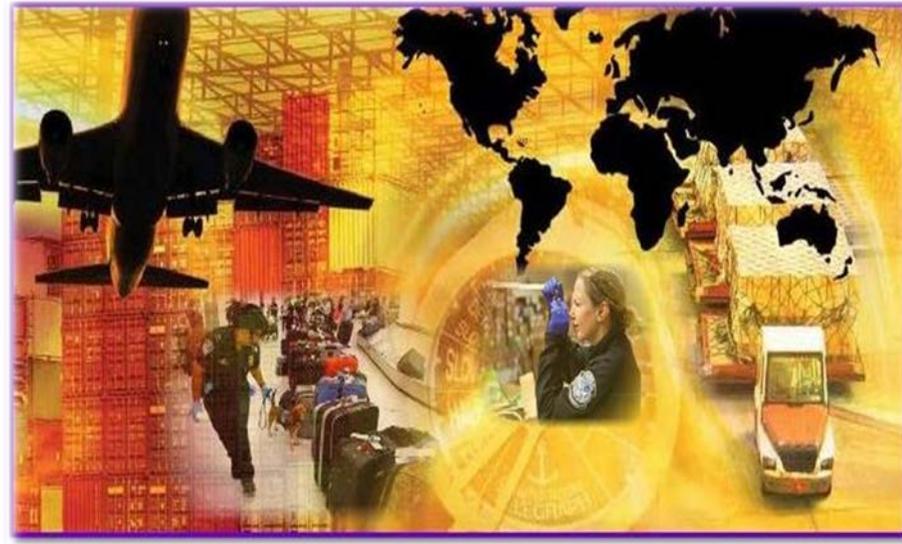
- Dr. Abu Sayed, Dr. Deb Dufficy
- <http://www.aphis.usda.gov/animal-health/organisms-vectors>
- [OV@aphis.usda.gov](mailto:OV@aphis.usda.gov)
- Phone: 301-851-3300, option **3**  
Fax: 301-851-2239

# U.S. Customs and Border Protection (CBP) Office of Field Operations (OFO) Agriculture Programs and Trade Liaison (APTL)

## Regulatory Role of CBP at U.S. Ports of Entry

CDC Import-Export Permit  
Webcast

Romelito Lapitan, *Ph.D.*  
Director  
Ag/Bio-Terror Countermeasures (ABTC)



U.S. Customs and  
Border Protection

Field Operations



# Missions of CBP and APTL

- Facilitate legitimate trade and travel
- Agricultural pest and disease exclusion
- Prevent entry of terrorists and tools of agriculture and biological terrorisms

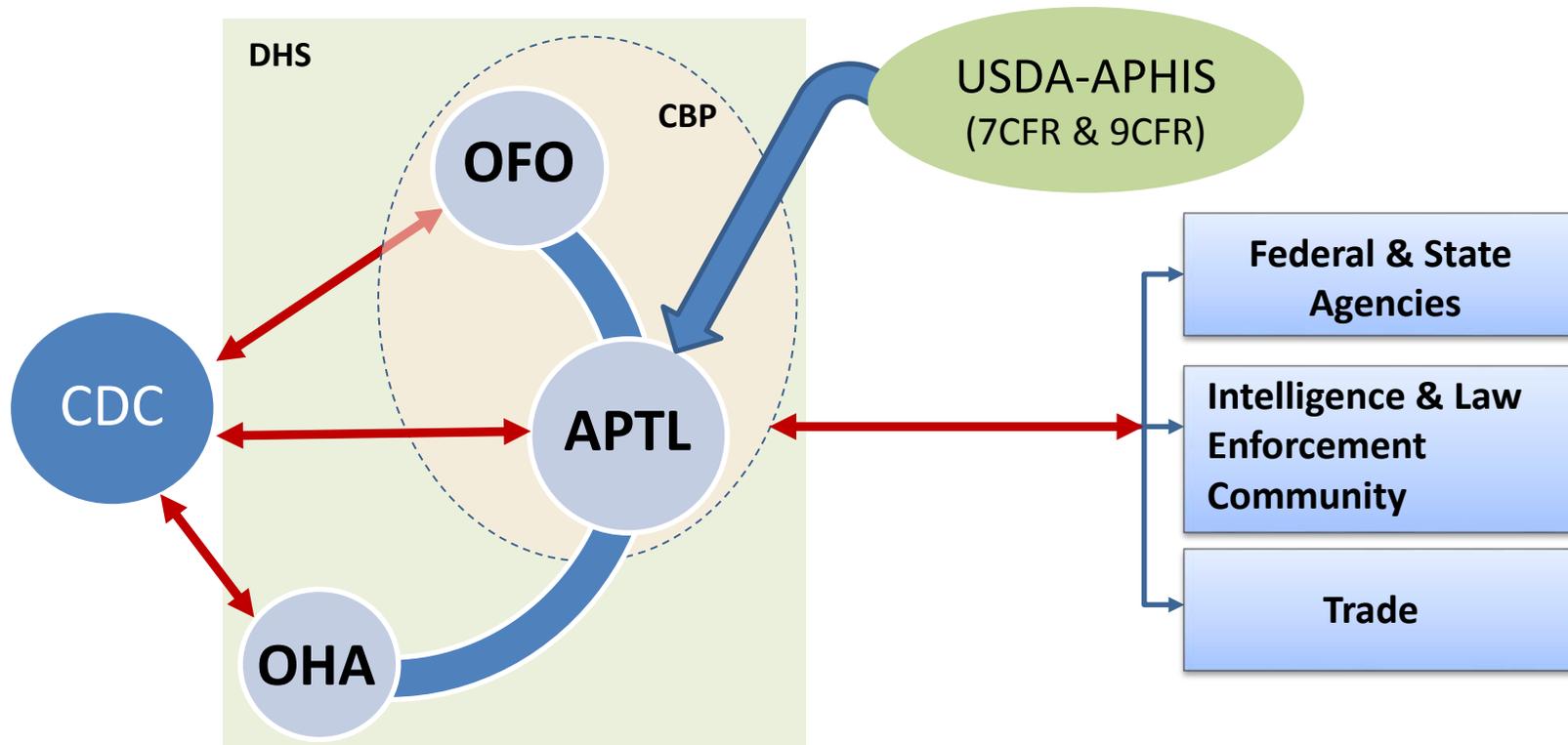


# U.S. CBP Ports of Entry (POE)

- Total POE – 328
- Pre-Clearance – 16
- Express Consignment Carrier Facility - 19
- POE Staffed by Agriculture Specialists -182
- Total CBPAS - 2,417



# CBP-APTL Collaborations



# How CBP Assist CDC Enforce its Regulations

## Screening Potentially Sick Travelers

### Operational Procedure:

- Assist “No boarding”
- Visual assessment for signs and symptoms
- Temperature checks (e.g., Ebola)
- Secure, isolate, referral of ill traveler to CDC Quarantine Station staff and public health officials



# Trade Compliance to Regulations

**Importation of bushmeat and carriers of pathogenic human diseases**

**Operational Procedure:**

- Referral/transfer custody of restricted products to CDC or Fish & Wildlife Services (FWS)



U.S. Customs and  
Border Protection

Field Operations



# Trade Compliance to Regulations

**Importation of live non-human primates, turtles, African rodents, and dogs**

**Operational Procedure:**

- Entry Verification
- Check Permit Compliance
- Notification to CDC Quarantine Station staff (or APHIS, FWS)



**U.S. Customs and  
Border Protection**

**Field Operations**



# Trade Compliance to Regulations

## Importation of etiologic agents and vectors

### Operational Procedure:

- Entry Verification
- Check Permit Compliance
- Notification to CDC  
Quarantine Station staff  
(or APHIS)



U.S. Customs and  
Border Protection

Field Operations

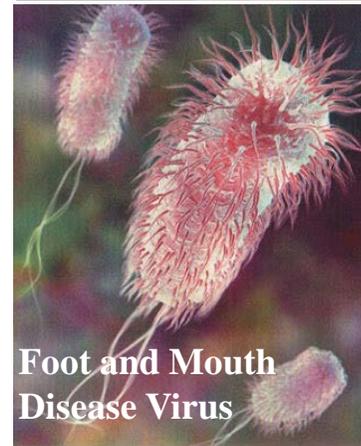


# Trade Compliance to Regulations

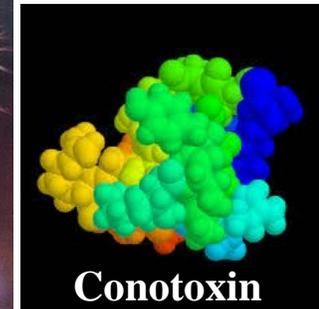
## Importation of select agents and toxins

### Operational Procedure:

- Entry Verification
- APHIS/CDC Form 2
- Letter of Authorization (APHIS)
- Referral to APHIS/AgSAS or CDC/DSAT for adjudication (with issues)



Foot and Mouth Disease Virus



Conotoxin



# International Garbage Compliance Agreement

- Joint USDA/CBP effort
- Regulated Garbage Handling
- Compliance Agreements
- Training, Handling, Destruction
- Monitoring and Inspection



U.S. Customs and  
Border Protection

Field Operations



# Commercial Cargo Environment

- Entry examination includes:
  - Advanced screening of imports
  - Document review (only) at POE
- All packages and luggage referrals to CBP agriculture secondary are subject to non-intrusive inspection (X-ray)
- Advanced notification of shipment to CBP recommended
- Appropriate markings, required labels, and content description must be visible outside the package





# Passenger Environment

- Travelers are asked to declare prohibited agricultural and biological products
- Etiologic and bioagents packages are not opened; referrals are made to CDC or USDA/APHIS
- CBP POE have no facility to store biohazardous materials
- Seized prohibited materials are destroyed or transferred custody

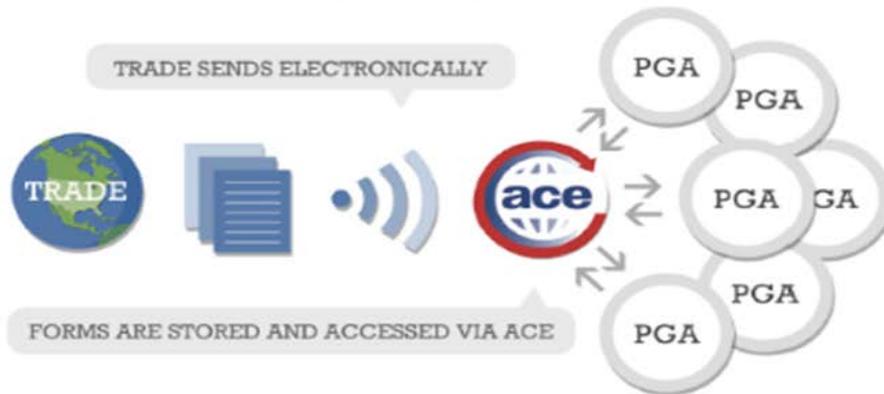


# What the Future Holds...

## ACE SINGLE WINDOW DOCUMENT IMAGE SYSTEM

The Automated Commercial Environment (ACE) will become the Single Window, the one system through which the international trade community submits import and export information and the Government determines admissibility. The Document Image System (DIS) is an ACE feature that eliminates the need to send paper forms to the Government in order to comply with import and export regulations.

### HOW DOES DIS WORK?



### WHAT FORMS CAN BE SENT VIA DIS?

- General forms not specific to any agency, such as invoices or packing lists
- CBP forms to support Cargo Release/Simplified Entry
- Ocean export manifests
- Specific forms for six initial Partner Government Agencies (PGAs)



# U.S. Customs and Border Protection

## Agriculture Programs and Trade Liaison

Questions?





# U.S. Customs and Border Protection



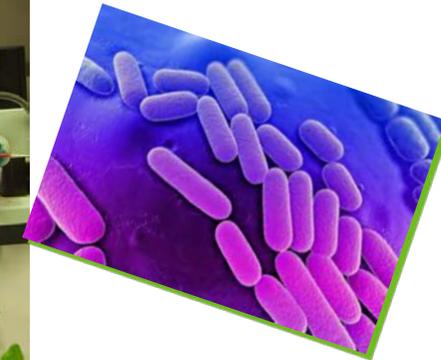
U.S. Customs and  
Border Protection

Field Operations



# Missions of CBP and APTL

- Facilitate legitimate trade and travel
- Agricultural pest and disease exclusion
- Prevent entry of terrorists and tools of agriculture and biological terrorisms



U.S. Customs and  
Border Protection

Field Operations

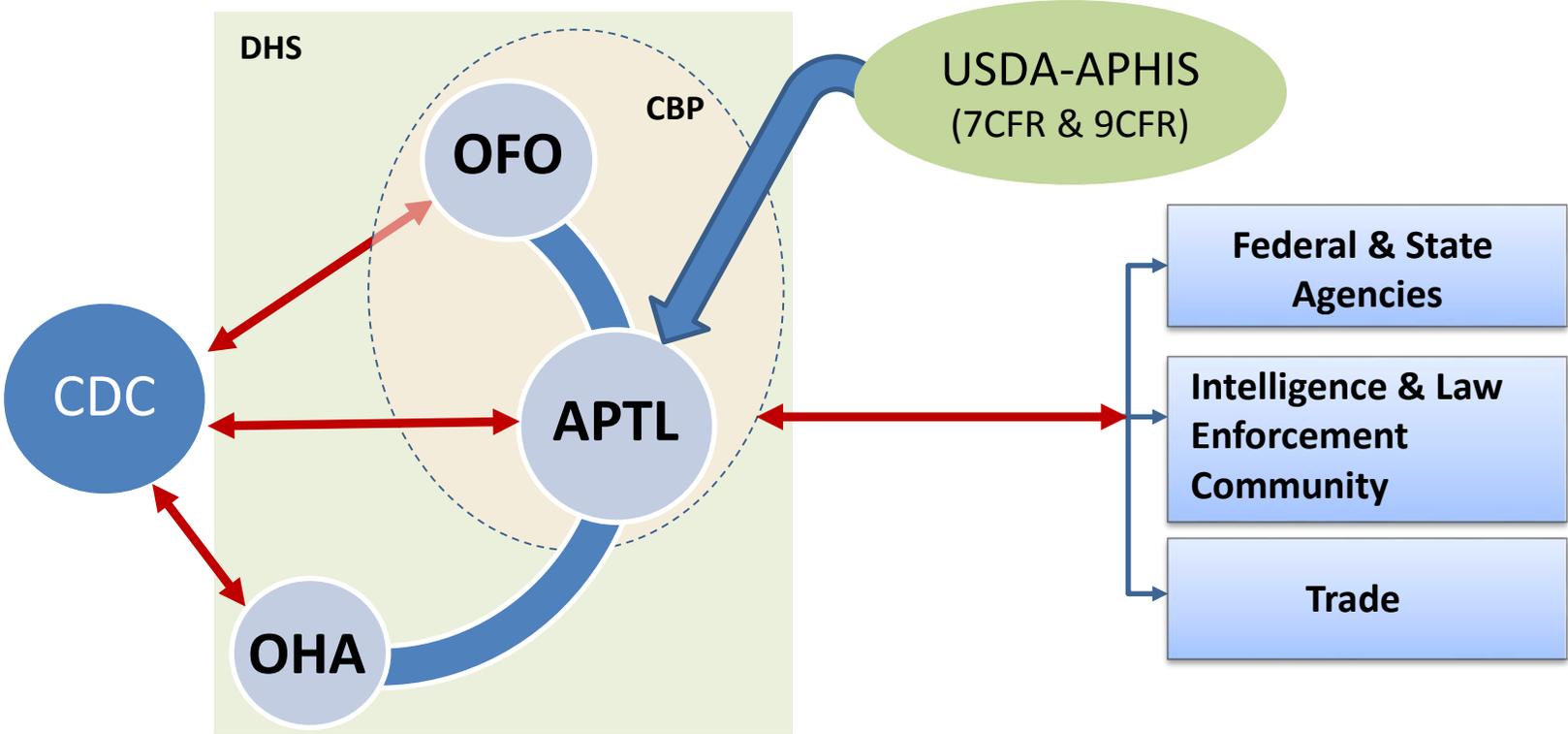


# U.S. CBP Ports of Entry (POE)

- Total POE – 328
- Pre-Clearance – 16
- Express Consignment Carrier Facility - 19
- POE Staffed by Agriculture Specialists -182
- Total CBPAS - 2,417



# CBP-APTL Collaborations



# How CBP Assist CDC Enforce its Regulations

## Screening Potentially Sick Travelers

### Operational Procedure:

- Assist “No boarding”
- Visual assessment for signs and symptoms
- Temperature checks (e.g., Ebola)
- Secure, isolate, referral of ill traveler to CDC Quarantine Station staff and public health officials



# Trade Compliance to Regulations

**Importation of bushmeat and carriers of pathogenic human diseases**

**Operational Procedure:**

- Referral/transfer custody of restricted products to CDC or Fish & Wildlife Services (FWS)



U.S. Customs and  
Border Protection

Field Operations

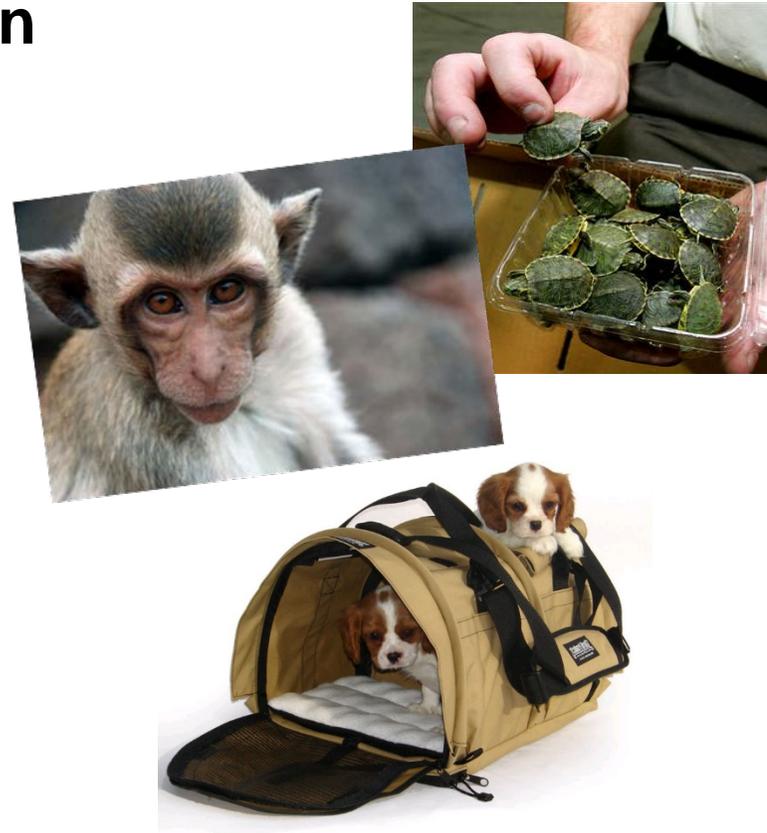


# Trade Compliance to Regulations

**Importation of live non-human primates, turtles, African rodents, and dogs**

**Operational Procedure:**

- Entry Verification
- Check Permit Compliance
- Notification to CDC Quarantine Station staff (or APHIS, FWS)



**U.S. Customs and  
Border Protection**

**Field Operations**



# Trade Compliance to Regulations

## Importation of etiologic agents and vectors

### Operational Procedure:

- Entry Verification
- Check Permit Compliance
- Notification to CDC  
Quarantine Station staff  
(or APHIS)



U.S. Customs and  
Border Protection

Field Operations

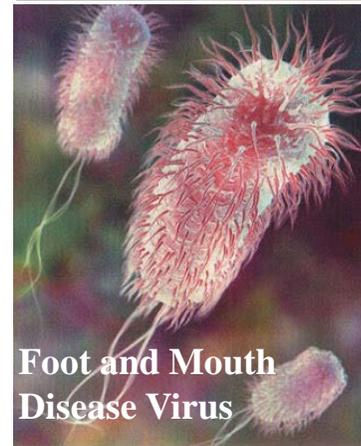


# Trade Compliance to Regulations

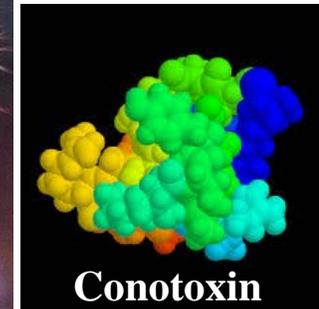
## Importation of select agents and toxins

### Operational Procedure:

- Entry Verification
- APHIS/CDC Form 2
- Letter of Authorization (APHIS)
- Referral to APHIS/AgSAS or CDC/DSAT for adjudication (with issues)



Foot and Mouth Disease Virus



Conotoxin



# International Garbage Compliance Agreement

- Joint USDA/CBP effort
- Regulated Garbage Handling
- Compliance Agreements
- Training, Handling, Destruction
- Monitoring and Inspection



U.S. Customs and  
Border Protection

Field Operations



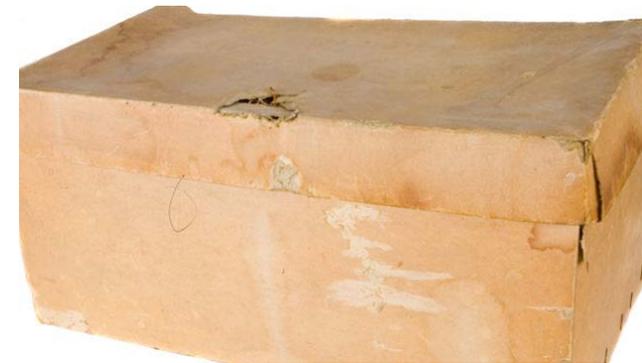
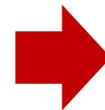
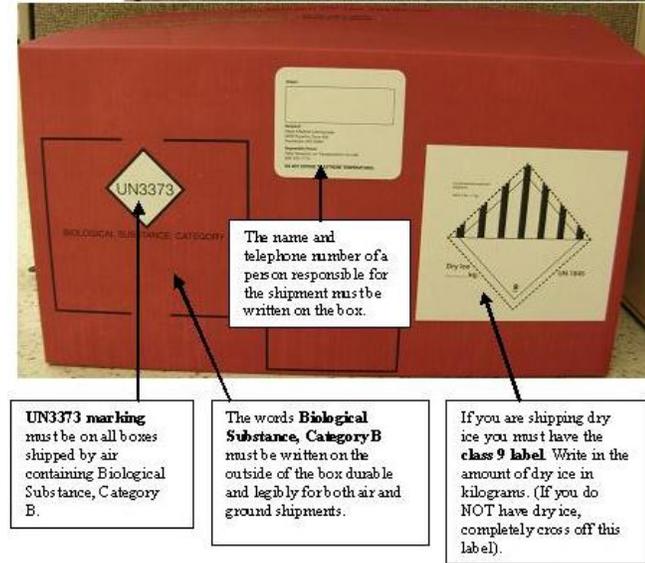
# Commercial Cargo Environment

- Entry examination includes:
  - Advanced screening of imports
  - Document review (only) at POE
- All packages and luggage referrals to CBP agriculture secondary are subject to non-intrusive inspection (X-ray)
- Advanced notification of shipment to CBP recommended
- Appropriate markings, required labels, and content description must be visible outside the package



# Packaging and Shipping

- Labels, biohazard sign, appropriate UN marking must be legible and clearly visible
- Quantity (weight) of dry ice must be clearly indicated
- Secure and isolate unmarked, damaged, and leaking packages - bound for destruction



# Passenger Environment

- Travelers are asked to declare prohibited agricultural and biological products
- Etiologic and bioagents packages are not opened; referrals are made to CDC or USDA/APHIS
- CBP POE have no facility to store biohazardous materials
- Seized prohibited materials are destroyed or transferred custody

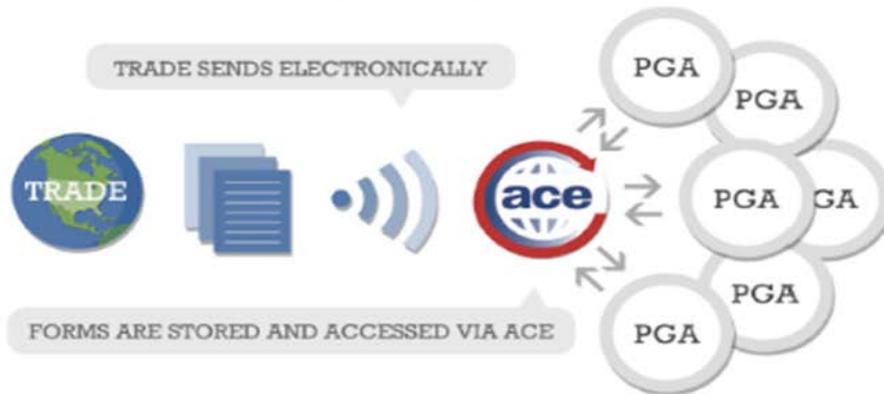


# What the Future Holds...

## ACE SINGLE WINDOW DOCUMENT IMAGE SYSTEM

The Automated Commercial Environment (ACE) will become the Single Window, the one system through which the international trade community submits import and export information and the Government determines admissibility. The Document Image System (DIS) is an ACE feature that eliminates the need to send paper forms to the Government in order to comply with import and export regulations.

### HOW DOES DIS WORK?



### WHAT FORMS CAN BE SENT VIA DIS?

- General forms not specific to any agency, such as invoices or packing lists
- CBP forms to support Cargo Release/Simplified Entry
- Ocean export manifests
- Specific forms for six initial Partner Government Agencies (PGAs)



# U.S. Customs and Border Protection Agriculture Programs and Trade Liaison Questions?



# U.S. Customs and Border Protection



## U.S. Customs and Border Protection



U.S. Customs and  
Border Protection

Field Operations



# Export Controls for Biological Materials



## FEDERAL PARTNERS IMPORT/EXPORT REGULATIONS WEBCAST

Kimberly Orr, DVM, PhD  
Chemical and Biological Controls Division  
Office of Nonproliferation and Treaty Compliance

# Department of Commerce Export Controls

- What needs a license
  - How to determine if a license is needed
  - Controlled items
  - License exceptions
- What about Genomic Material?
- Technology controls
  - Technology export
  - Deemed export
- Scenarios
- Regulation Update

# Department of Commerce Export Controls

- Dual-use biological material
  - Subject to BIS regulatory jurisdiction
  - Predominantly commercial/academic uses
  - Could also be used in military applications
  - Listed in Export Administration Regulations (EAR) by Export Control Classification Number (ECCN)
  - Commerce Control List (CCL)
- May require export license
- Other Controls to consider – USML (CAT XIV), OFAC

# Export Control Basics

- Part 732 of the EAR – Steps for using the EAR
  - What is the item
  - Where is it going (what country or countries)
  - Who will use it (ultimate consignee, end users)
  - What will they do with it (end use)
  - What else do the recipients do (red flags)
- Supplements 1 -3 of Part 732 of the EAR
  - Decision Tree - Is export license needed?
  - Decision Tree – Is item subject to the EAR?
  - Know your Customer Guidance/ Red flags

# What Might Need a License?

- Biological agents, toxins, and genetic elements (1C351,1C353,1C354) (Australia Group list plus Select Agents)(worldwide)
- Vaccines (ECCN 1C991) (limited destinations)
- Biological processing equipment (ECCN 2B352)
- Technology (Development, Production, Use)
  - ECCN 1E001, 2E001, 2E002, 2E301
- Foreign worker in US facility (deemed export)
- Re-exports

# Key Questions to Determine if License is needed

- Is it under Commerce Control ?
  - Commodity Jurisdiction if unsure (DDTC - STATE)
- What is the ECCN of the item to be exported?
  - Commodity Classification if unsure (DOC)
  - EAR99 usually No License Required (NLR)
    - Unless red flags on the end user? (entity list)
- Based on ECCN and destination
  - License required
  - No License required
  - License exception eligible

# License Exceptions

- **GOV (Government) EAR 740.11**
  - Agencies of Cooperating Governments
  - Country Group A:1 (see Supplement No. 1 to 740) and the national governments of Hong Kong, Singapore, and Taiwan
- **STA (Strategic Trade Authority) EAR 740.20**
  - Certain Toxins from ECCN 1C351
  - Has reporting requirements
  - Less than 100 mg, six or fewer shipments per CY
- **Read regulations carefully**

# Biological Agents/Toxins

- 1C351 and 1C354
  - Human, Animal and Plant Pathogens
    - Australia Group (AG) controlled -
    - Select Agents not on the AG list
    - Select Agent (SA) exempt strains ARE controlled for export
- 1C353
  - Genetic Elements for controlled agents
  - Subunits/units of controlled toxins
- 1C991
  - Vaccines against controlled agents
  - Medical toxins

# Commerce Control List

## Australia Group Pathogens and Select Agents

- No exemptions for quantity or attenuation
- AG Agents/Toxins listed/delisted via consensus
  - History of attempted use in biowarfare
  - Serious economic/public health potential
- Select Agent not AG listed (e.g.)
  - *Phoma glycinola*
  - Tick-borne encephalitis virus Siberian subtype
- AG controlled non Select Agents (e.g.)
  - Yellow Fever virus
  - *Tilletia indica*

# Genomic Material

- Controlled under 1C353 *if agent* on CCL
- What is controlled ?
- Genetic elements or GMOs that contain
  - nucleic acid sequences associated with the pathogenicity of controlled microorganisms
  - nucleic acid sequences coding for any controlled toxin or toxin sub-unit
  - for a virus, most sequences will be assumed associated with pathogenicity

# Genomic Material – Genetic Elements

- Genetic elements include and not limited to
  - Chromosomes
  - Genomes
  - Plasmids
  - Transposons
  - Vectors
- May be genetically modified or unmodified
- May be synthesized

# Genetic Elements

- Whole Nucleic acids – not controlled if
  - Certified non-infective and chemically treated to be non-recoverable
- Chimeric Viruses- controlled if
  - Based on a controlled virus
  - Has controlled virus element in non-controlled virus
- Plasmids - controlled if
  - Promoter present
  - Complete gene or Viral Particle
  - Replication competent

# Example: Chimeric Viruses

Ebolavirus



**Genetically modified Vesicular stomatitis virus  
(controlled as genetically modified VSV)**

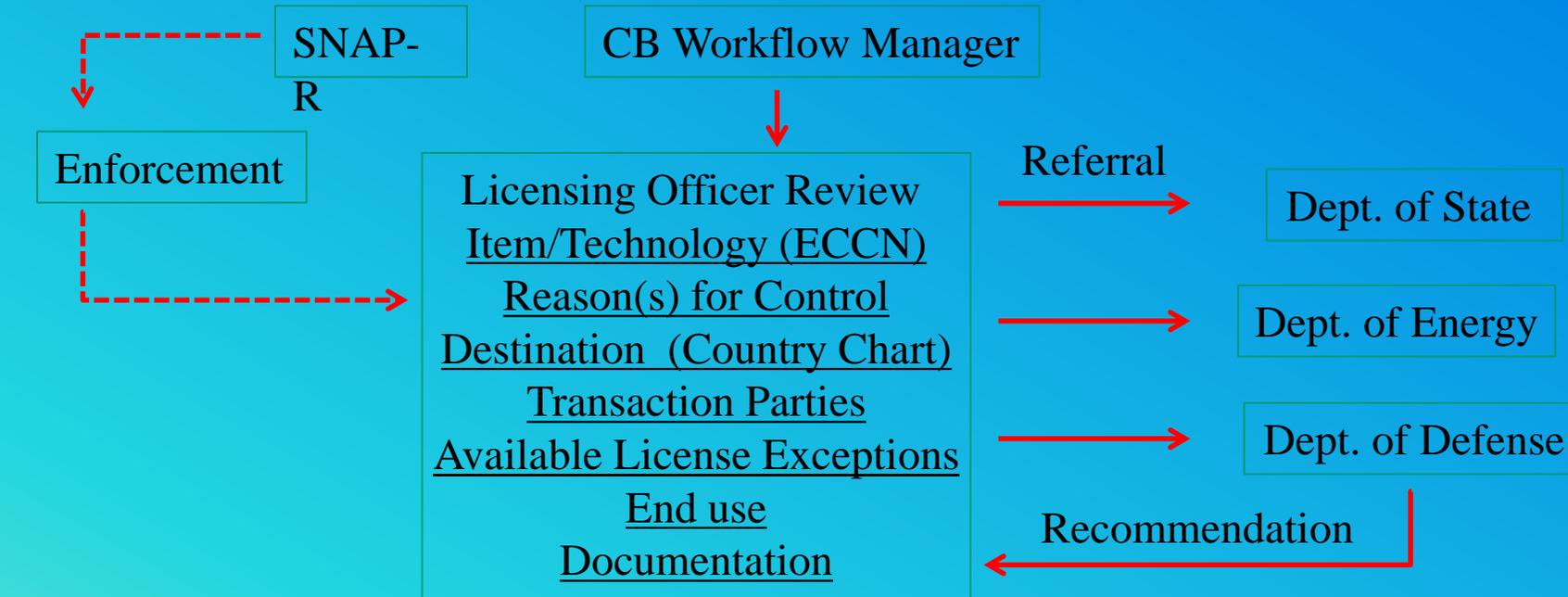


If the ebolavirus GP were incorporated into a non-controlled virus, this would be still controlled as a genetic element.

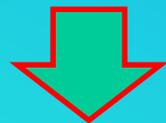
# Biological Material Export License Key Points

- Select Agent exempt material may need license
  - Small quantity and attenuation do not negate requirement
- Commerce Controlled biological items need license worldwide including Canada
- Recipient laboratory is ultimate consignee/end user
- Provide info on researcher, end use and biosafety level capability in additional information
- Provide shipment amounts and cost (\$1 minimum)
- Highlight any DURC or GOF activity
- Vaccine seed stock not considered vaccine

# License Application Review



May RWA at any point



Validated License or denial

# Sample License Application Review for CB

Commerce Country Chart Supplement 1 to Part 738

Item/Technology (ECCN)

50 mg Cholera toxin

Reason(s) for Control

CB1

Destination (Country Chart)

Iceland

License Exceptions (CB items)

GOV, STA (depending on the item)

**Commerce Country Chart**

**Reason for Control**

Countries	Chemical & Biological Weapons			Nuclear Nonproliferation		National Security		Missile Tech	Regional Stability		Firearms Convention	Crime Control			Anti-Terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
	Iceland <sup>3</sup>	X					X		X	X						
India <sup>7</sup>	X			X		X	X	X	X							
Indonesia	X	X		X		X	X	X	X	X		X		X		

# Technology Considerations

- Is the technology for controlled biological processing equipment?
  - “Development”
  - “Production”
  - “Use”
- Is the technology related to manipulation of controlled biologicals that is not public domain or fundamental research?
- Where is the transfer taking place?
  - Deemed export vs. tech transfer
- Consider Fundamental Research, Public Domain

# Technology NOT Subject to the EAR (734.3)

- “Publicly Available Technology and Software
- Already published or will be published (734.7)
- Arise during fundamental research (734.8)
- Educational (734.9)
- Included in certain patent applications (734.10)

# Is a License Required?

- Researcher working with Yellow Fever
- Exports strain to colleague in Kenya for use in vaccine production ??
- Foreign student in lab on different project
  - not working with pathogens ???
  - working with pathogen??
- Research generates a monovalent vaccine candidate no approval or IND #

# License Required?

- Researcher ships new YF strain to Kenya
  - 1C991 or 1C351/353 ??
- Foreign student (from Malaysia) pulled into research group
  - Deemed export ??
- Colleague in Kenya asks for unpublished methodology on increasing Yellow Fever virulence
  - Tech export??

# Recent Updates to the CCL

- CAT XIV effective Dec. 31, 2016 81FR 49517
- NEW ECCNS 1A-E607
  - Items moving off ITAR
- Implementation of 2015AG Decisions 81FR 36458
  - Additions
    - SARS-related coronavirus
    - Reconstructed 1918 influenza virus
  - Updated controls on bioprocessing equipment
    - Freeze dryers
    - Biosafety cabinets
    - Aerosol inhalation equipment

# Contact Info

- Kimberly Orr 202 482 4201
- [Kimberly.Orr@bis.doc.gov](mailto:Kimberly.Orr@bis.doc.gov)
- [www.bis.doc.gov](http://www.bis.doc.gov)
- [www.bis.doc.gov/licensing/index.htm](http://www.bis.doc.gov/licensing/index.htm)
- [www.bis.doc.gov/deemedexports](http://www.bis.doc.gov/deemedexports)
- [www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls](http://www.bis.doc.gov/index.php/policy-guidance/product-guidance/chemical-and-biological-controls)

U.S. Fish and Wildlife Service  
Office of Law Enforcement

**Import/Export Requirements**



# **FWS Mission Statement**

The Mission of the US Fish & Wildlife Service  
is to Conserve, Protect, and Enhance  
the Nations Fish and Wildlife and Their Habitats  
for the Continuing Benefit of People



# Legislation Regulating Imports and Exports of Wildlife

- Lacey Act
- Endangered Species Act
- Convention on International Trade in Endangered Species of Fauna and Flora (CITES)
- African Elephant Conservation Act
- Marine Mammal Protection Act
- Wild Exotic Bird Conservation Act
- Migratory Bird Treaty Act
- Rhino-Tiger Conservation Act
- Bald & Golden Eagle Protection Act



# Injurious Species Regulations

- It is unlawful to import live specimens deemed as injurious to native wildlife or habitat, without special permits
- Examples:  
Snakehead Fish,  
Mitten Crab  
Walking Catfish
- The full list can be found at [ecfr.gov](http://ecfr.gov) under 50 CFR Part 16
- Many of these are imported for human consumption and the pet trade



# WILDLIFE INSPECTION STAFFING

- Approximately 140 of Fish and Wildlife Service Wildlife Inspectors are located at 18 designated ports and 20 other locations (many along either the Nation's northern or southern border)
- Stationed at major international airports, ocean ports, and border crossings
- Work the passenger terminals at airports and conduct inspections at international mail facilities



# Wildlife Inspection Offices



# Wildlife Inspections

**PERSONAL  
BAGGAGE**



**CARGO FREIGHT**



**LIVE WILDLIFE**



**U.S MAIL  
(International  
mail)**



**FREIGHT  
CARRIERS**



**K9 Units**



# Inspector Work Locations



Ocean Cargo

International Passenger



Border Crossing



Air Cargo

International Mail



# Passenger Baggage

- Tourist and personal items (including hunting trophies)
- Live wildlife
- Scientific specimens
- Small commercial shipments
- Food



# Air Cargo Inspections

- Live and perishable wildlife
- Hunting Trophies
- Handicrafts
- Garments, footwear and other products



# Mail Facility

- Personal and tourist items
- Scientific specimens
- Small commercial shipments
- Express Mail carriers increasingly includes live wildlife



# Ocean/ Truck Cargo Inspections

- Large quantities of *perishable* and *non-perishable* commodities.
- Fashion Accessories, Garments, Foot Wear, Handicrafts, Antiques, Hunting Trophies (finished and unfinished), Frozen Meat, Frozen Frog Legs, Unfinished Furs and Skins



# Border Facility Inspections

- Passenger vehicles, commercial trucks, railroads and pedestrians all use border crossings



# Important Definition

## 50 CFR 14.4 - Definitions

”Import means to land on, bring into, or introduce into, or attempt to land on, bring into, or introduce into any place subject to the jurisdiction of the United States, whether or not such landing, bringing, or introduction constitutes an importation within the meaning of the tariff laws of the United States.”

# Import/Export License

The import/export license is required for all individuals or companies that engage in commercial trade as an importer or exporter of wildlife. This license, which is valid for one year, must be acquired before importing or exporting.

The license must be renewed each year as long as the commercial trade activity continues.



# Designated Ports

All CITES listed wildlife must be imported or exported through one of the following designated ports:

Anchorage, Alaska  
Baltimore, Maryland  
Chicago, Illinois  
Honolulu, Hawaii  
Los Angeles, California  
Memphis, Tennessee  
New Orleans, Louisiana  
Newark, New Jersey  
San Francisco, California

Atlanta, Georgia  
Boston, Massachusetts  
Dallas/Ft. Worth, Texas  
Houston, Texas  
Louisville, Kentucky  
Miami, Florida  
New York, New York  
Portland, Oregon  
Seattle, Washington



# Non-designated Ports

## Canadian Border Ports

Unless specific authorization is given, Canadian border ports may only be used for the import or export of wildlife that does not require a permit under certain wildlife laws, and whose country of origin is Canada or the United States. There are 23 FWS Canadian border ports but only nine are currently staffed.

<https://www.fws.gov/le/canadian-border-ports.html>



# Non-designated Ports

## Mexican Border Ports

Unless specific authorization is given, Mexican border ports may only be used for the import or export of wildlife that does not require a permit under certain wildlife laws and whose country of origin is Mexico or the United States. There are seven FWS Mexican border ports but only five are currently staffed.

<https://www.fws.gov/le/mexican-border-ports.html>



# Designated Port Exception Permit (DPEP)

An exemption to the required use of certain ports for wildlife import or export can be granted by this permit.

The DPEP, which is valid for no more than two years, must be acquired before importing or exporting.

A DPEP may be issued for single or multiple transactions and may be granted if applicants can demonstrate that the use of the port is for scientific purposes, will minimize deterioration or loss, or will alleviate undue economic hardship.

The final criterion that must be met for issuance of a DPEP is a determination that FWS staff is available.



# Prior Notification Process

The trade/importer must notify FWS 48 hours in advance of the import of a live or perishable shipment subject to FWS requirements.

The trade/exporter must notify FWS and make the shipment available 48 hours in advance of the export of any wildlife, whether perishable or not.

The trade/importer/exporter must also notify FWS a minimum of 48 hours in advance of the import or export of any commodity subject to FWS requirements when using a DPEP. This latter notification may require additional prior notification depending upon the port, species, and special conditions listed on the DPEP.

# Declaration Form 3-177

USFWS Form 3-177  
(Revised 03/10)  
O.M.B. No. 1018-0012  
Expiration Date: 04/30/2016

 **U.S. FISH AND WILDLIFE SERVICE**  
**DECLARATION FOR IMPORTATION**  
**OR EXPORTATION OF**  
**FISH OR WILDLIFE**

1. Date of Import/Export: (mm/dd/yyyy)		7. Name of Carrier:	
2. Import/Export License Number:		8. Air Waybill or Bill of Lading Number: Master: House:	
3. Indicate One: <input type="checkbox"/> Import <input type="checkbox"/> Export		9. Transportation Code: _____ License # _____ State or Province _____	
4. Port of Clearance:		10. Bonded Location for Inspection:	
5. Purpose Code: _____		11. Number of Cartons Containing Wildlife:	
6. Customs Document Number (s)		12. Markings on Cartons Containing Wildlife:	

13a. (Indicate One) (Complete name/U.S. address/telephone number/e-mail address) <input type="checkbox"/> U.S. Importer <input type="checkbox"/> U.S. Exporter Type Address Here		14a. (Indicate One) (Complete name/foreign address/telephone number/e-mail address) <input type="checkbox"/> Foreign Importer <input type="checkbox"/> Foreign Exporter Type Address Here		14b. Country Code _____	
13b. Identifier Number: _____ ID Type: _____		14c. Identifier Number: _____ ID Type: _____		15a. Customs Broker, Shipping Agent or Freight Forwarder: (Complete business name/address/telephone and fax number/e-mail address) Type Address Here	
		15b. Identifier Number: _____ ID Type: _____		15c. Contact Name: _____	

Species Code (Official Use Only)	16a. Scientific Name ----- 16b. Common Name	17a. Foreign CITES Permit Number ----- 17b. U.S. CITES Permit Number	18a. Description Code ----- 18b. Source Code	19a. Quantity/Unit ----- 19b. Total Monetary Value	20. Country of Species Origin Code (ISO Code)	21. Venomous Live Wildlife Indicator <input type="checkbox"/> (Check if yes)
						<input type="checkbox"/>
						<input type="checkbox"/>
						<input type="checkbox"/>
						<input type="checkbox"/>

Knowingly making a false statement in a Declaration for Importation or Exportation of Fish or Wildlife may subject the declarant to the penalty provided by 18 U.S.C. 1001 and 16 U.S.C. 3372(d)

22. I certify under penalty of perjury that the information furnished is true and correct:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Type or Print Name: \_\_\_\_\_

For Official Use Only  
Action/Comments:

Wildlife Declared: Yes No  
Wildlife Inspected: None / Partial / Full

See Reverse Side of this Form for Privacy Act Notice

- This form may be filed in paper or electronically in eDecs with the U.S. Fish and Wildlife Service

# CITIES form

FORM 5-2014 (1/97)		<b>CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES OF WILD FAUNA AND FLORA</b>		<input type="checkbox"/> EXPORT PERMIT <input checked="" type="checkbox"/> RE-EXPORT CERTIFICATE <input type="checkbox"/> OTHER CERTIFICATE (see block 9)	Page 1 of 1						
<b>3. Permittee (name and address, country)</b> SHARKNADO INC 1234 CORPORATION LANE ARLINGTON, VIRGINIA U.S.A.		<b>4. Consignee (name and address, country)</b> ACME DENTAL 777 FRONT ROW AVENUE UNITED KINGDOM		1. Original Permit/Certificate No. <b>14US12345A/9</b> 2. Valid until <b>02/26/2015</b>							
<b>5. Special Conditions</b> MUST COMPLY WITH ENCLOSED GENERAL PERMIT CONDITIONS.		<b>5a. Purpose of Transaction</b> T		<b>6. U.S. Management Authority</b> U.S. FISH AND WILDLIFE SERVICE DIVISION OF MANAGEMENT AUTHORITY BRANCH OF PERMITS, MS: 1A 5275 LEESBURG PIKE FALLS CHURCH VA 22041-3803  <b>08/27/2014</b> Issuing Date United States Management Authority AUTHORITY: Endangered Species Act of 1973 (16 USC 1531 et. seq.)							
<i>For live animals, only valid if the transport conditions comply with the CITES Guidelines for Transport of Live Animals or, in the case of air transport, with IATA Live Animals Regulations.</i>											
<b>7/B. Common Name and Scientific name (genus and species) of Animal or Plant</b>		<b>9. Description of Part or Derivative, including Identifying marks or numbers (age/sex if live)</b>		<b>10. Appendix No. and Source</b>							
<b>A. Common Name</b> GREAT WHITE SHARK  <b>Scientific Name</b> CARCHARODON CARCHARIAS		<b>9. RE-EXPORT: TEETH</b>		<b>10. 2 W</b> <b>11. Quantity (including units)</b> 200 NO <b>11a. Total Exported/Quota</b>							
<b>12. Country of Origin</b> AUSTRALIA	<b>Permit/Certificate No.</b> 2011-AU-123456	<b>Date of Issue</b> 01/25/2011	<b>12b. Breeding Operation No.</b>								
<b>12a. Country of Last Re-export</b> SINGAPORE	<b>Re-export Certificate No.</b> 11SG001234CR	<b>Date of Issue</b> 06/22/2011	<b>12c. Pre-Convention: Date of Acquisition</b>								
<b>B. Common Name</b> GREAT WHITE SHARK  <b>Scientific Name</b> CARCHARODON CARCHARIAS		<b>9. RE-EXPORT: JAWS</b>		<b>10. 2 W</b> <b>11. Quantity (including units)</b> 3 NO <b>11a. Total Exported/Quota</b>							
<b>12. Country of Origin</b> AUSTRALIA	<b>Permit/Certificate No.</b> 2011-AU-123456	<b>Date of Issue</b> 01/25/2011	<b>12b. Breeding Operation No.</b>								
<b>12a. Country of Last Re-export</b> SINGAPORE	<b>Re-export Certificate No.</b> 11SG001234CR	<b>Date of Issue</b> 06/22/2011	<b>12c. Pre-Convention: Date of Acquisition</b>								
<b>13. Export / Re-export Endorsement:</b> The official who inspects shipment upon exportation / re-exportation must enter the total quantities of specimens being exported / re-exported in this block.		<b>14. Bill of Lading/Air Way-Bill Number</b>  Port of Exportation / Re-exportation  Total No. of Shipping Containers		<b>15. This document valid only with inspecting official's ORIGINAL stamp, signature and date in this block.</b>							
<table border="1"> <thead> <tr> <th>See Block 7</th> <th>Quantity</th> </tr> </thead> <tbody> <tr> <td>A</td> <td></td> </tr> <tr> <td>B</td> <td></td> </tr> </tbody> </table>		See Block 7	Quantity	A		B		Inspecting Official's Stamp, Signature and Date			
See Block 7	Quantity										
A											
B											

# When in Doubt?

Please contact a FWS law enforcement office to clarify regulations, requirements, or procedures



**Questions?**



# Contact Information

**Senior Wildlife Inspector**

**Tamesha Woulard**

**Phone: 703-358-1949**

**Additional Information:**

**<https://www.fws.gov/le/>**

**[lawenforcement@fws.gov](mailto:lawenforcement@fws.gov)**

**[managementauthority@fws.gov](mailto:managementauthority@fws.gov)**

**<https://cites.org>**

