CDC INTERNATIONAL IMPORT REGULATIONS

Liz Harton, Officer in Charge | Public Health Advisor
CDC Detroit Quarantine Station
November 30, 2016
ENFORCEMENT OF CDC IMPORT REGULATIONS

• CDC Quarantine Stations and Partnerships at U.S. Ports of Entry
  - Division of Global Migration and Quarantine
  - Division of Select Agents and Toxins
  - NIOSH

  ▪ Public Health Agency of Canada (PHAC)
Quarantine and Border Health Services Branch

Mission

To protect the health of the public from communicable diseases through science, partnerships, and response at U.S. ports
CDC Quarantine Station Jurisdictions

CDC Quarantine Station (n=20)
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
- 71.54 – Import Regulations
- 71.56 – African rodents

Subpart D – Health Measures at U.S. Ports

- 71.32(b) – Persons, carriers, things
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.
Infectious Importation Criteria

- A researcher 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 AND a copy of the permit is affixed to the outer most packaging of the shipment.
  - The “Notice to Carrier” label with the Permit # must be affixed to the outer container
  - 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 (IATA, for example)
Importation of Items of Public Health Importance

Review & Initial Determination

- Paperwork reviewed
- Item is declared?
- Determination is made
- May be released or
- May be denied

Possible Outcomes

- If paperwork is not in order, importer may need to provide additional information
- If all documents are available and known to the passenger, materials will be released.
- Formal Entry may be required.
The Basics

- 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)
Federally Quarantinable Communicable Diseases in the U.S.

Presidental Executive Order 13295, April 2005

- Cholera
- Diphtheria
- Infectious Tuberculosis
- Plague
- Smallpox
- Yellow Fever

- Viral Hemorrhagic Fevers
- Severe acute respiratory syndrome (SARS)
- Novel or reemerging influenza causing or with potential to cause a pandemic
Other Communicable Diseases of Public Health Concern*

<table>
<thead>
<tr>
<th>Malaria</th>
<th>Polio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Typhoid</td>
<td>Dengue</td>
</tr>
<tr>
<td>Varicella</td>
<td>Zoonotic poxvirus</td>
</tr>
<tr>
<td>Rabies</td>
<td>Pertussis</td>
</tr>
<tr>
<td>Measles</td>
<td>Mumps</td>
</tr>
<tr>
<td>Meningococcal disease</td>
<td>Rubella</td>
</tr>
<tr>
<td>Legionellosis</td>
<td>Infectious diarrhea</td>
</tr>
</tbody>
</table>

* Based on their ability to spread and cause significant illness or death
Importations

Inspect imported animal and human products that may pose a threat to human health

- Cats, dogs, & other domestic pets (rabbits, ferrets, etc.)
- Animals (bats, rodents, etc.)
- Animal products (trophies, skins, skulls, goatskin drums)
- Turtles, turtle eggs, tortoises, terrapins
- Nonhuman primates (monkeys, baboons, tamarins, etc.)
- Human remains
- Human products (stem cells, bone marrow, blood, serum, etc.)
- Cultures of living bacteria, virus or similar material
- Living insects (mosquitoes, ticks, fleas, lice, mites, maggots, etc.)
Inspection of Etiologic Agents

• No threat posed → Statement of Non-infectiousness

• Potential or known threat → Apply for Import Permit
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
Importation of Items of Public Health Significance

- May detain or destroy item
- Complete “CDC Denied Entry Form”
- Additional actions required are at the importer’s expense
Permit Sticker

DO NOT OPEN INTRANSIT

BIOMEDICAL MATERIALS
ETOLOGICAL AGENTS OR VECTORS

NOTICE TO CARRIER: If inspection on arrival in U.S. reveals evidence of damage, leakage, or suspected contamination involving an infectious substance, immediately notify: DOT National Response Center 1-800-424-8802.

IMPORTATION OR TRANSFER AUTHORIZED BY

PHS Permit No. ________
Expiration Date ________

TO:
Carry-on or Checked Luggage

- “Checked luggage” is NOT THE SAME as “Cargo”

- Some items may NOT be imported in checked or carried on bags, such as NHP feces
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.
Emerging Agents/Outbreaks

- Applications expedited – 24 hour release
  - Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
  - Avian influenza A virus (H7N9) or any novel influenza virus
  - Ebola surge outbreak
  - Material suspected to contain the Ebola virus
  - Cholera
  - Zika virus – (currently in expedite status)
APPLICATION FOR PERMIT TO IMPORT

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

• SECTION H - Signatures
Inspections

- By the CDC Import Program and/or NIOSH
- Conducted to verify:
  - Accuracy of the IP application (e.g., lab rooms, Safety levels, agents)
  - Importer has implemented adequate biosafety measures.

- Website has inspection checklists:
Criteria used to determine if an inspection may be required

- Biological safety level where work will be conducted
- Report of possible documentation tampering
- Report of packaging issues
- Risk of the agent and work conducted
- May not be inspected if the laboratory has been inspected by the Federal Select Agent Program
Import Permit Inspection Program

- Common descriptions of work associated with Import Permit Inspections:
  - Human diagnostic testing
  - Susceptibility testing
  - Animal studies
  - Exempt human specimens
  - Molecular biology research
Land Border – 11/08/2013

- CBP at Detroit-Windsor Tunnel notified Detroit QS 2 boxes of plastic containers containing "general bacteria samples" as described by traveler.
- The traveler stated that his employer (a water treatment company) ordered the samples, and he is bringing them home to “read them to find out how much bacteria is in the system.”
- Inspection photos show organism growth (and perhaps mold growth as well) on agar in these containers.
If you don’t know what it is…….
Guinea 10/30/2014 at UPS

AWB

• Package addressed to private home in NJ with contents labeled as “cotton”
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](http://www.cdc.gov/importation/animal-products.html)

- **Permission letter application process**
  - Entry allowed only for science, education or exhibition
  - Submit request to [CDCAnimalImports@cdc.gov](mailto:CDCAnimalImports@cdc.gov)
Human Remains (Whole or Parts)

- Death certificate required to determine cause of death

- If cause of death is communicable disease:
  - Human remains permit required
  - Body must be:
    - In a hermetically sealed casket OR
    - Embalmed or Cremated
    - Packaged per IATA
Human Tissues & Products

Medical, research, or educational
- Permit to import
- Rendered non-infectious
- No human pathogens and/or preserved tissue
- Leak-proof container

Commercial, collectible, or ceremonial
- Not contaminated
- Clean, dried
- Leak-proof and puncture proof
Example: Denied Entry Human Remains

- Improper documentation
- Contaminated specimens
- Not properly sealed
Thank You

• For more information, please contact:

  • Detroit Quarantine Station
  • Michigan | Ohio | Kentucky
  • Telephone: 734-955-6197
  • http://www.cdc.gov/quarantine/stations/detroit.html
  • Email: QS-Detroit@cdc.gov
Contact information for the CDC Import Program

- Import permit website is https://www.cdc.gov/od/eaipp/
  - FAQ
  - Import Permit Regulations
  - Inspection Checklist
  - Import Permit Applications
  - Guide for Shipping Infectious Substances
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
Web: http://www.cdc.gov/importation/