

CDC Importation Regulations Restricted Materials



**Elizabeth Harton
Officer in Charge**

U.S. Centers for Disease Control Detroit Quarantine Station



DETROIT FIELD OFFICE

**IMPORTATION
OF BIOLOGICALS
WORKSHOP**

CDC IMPORTATION REGULATIONS

Restricted Materials

**Liz Harton, Officer in Charge | Public Health
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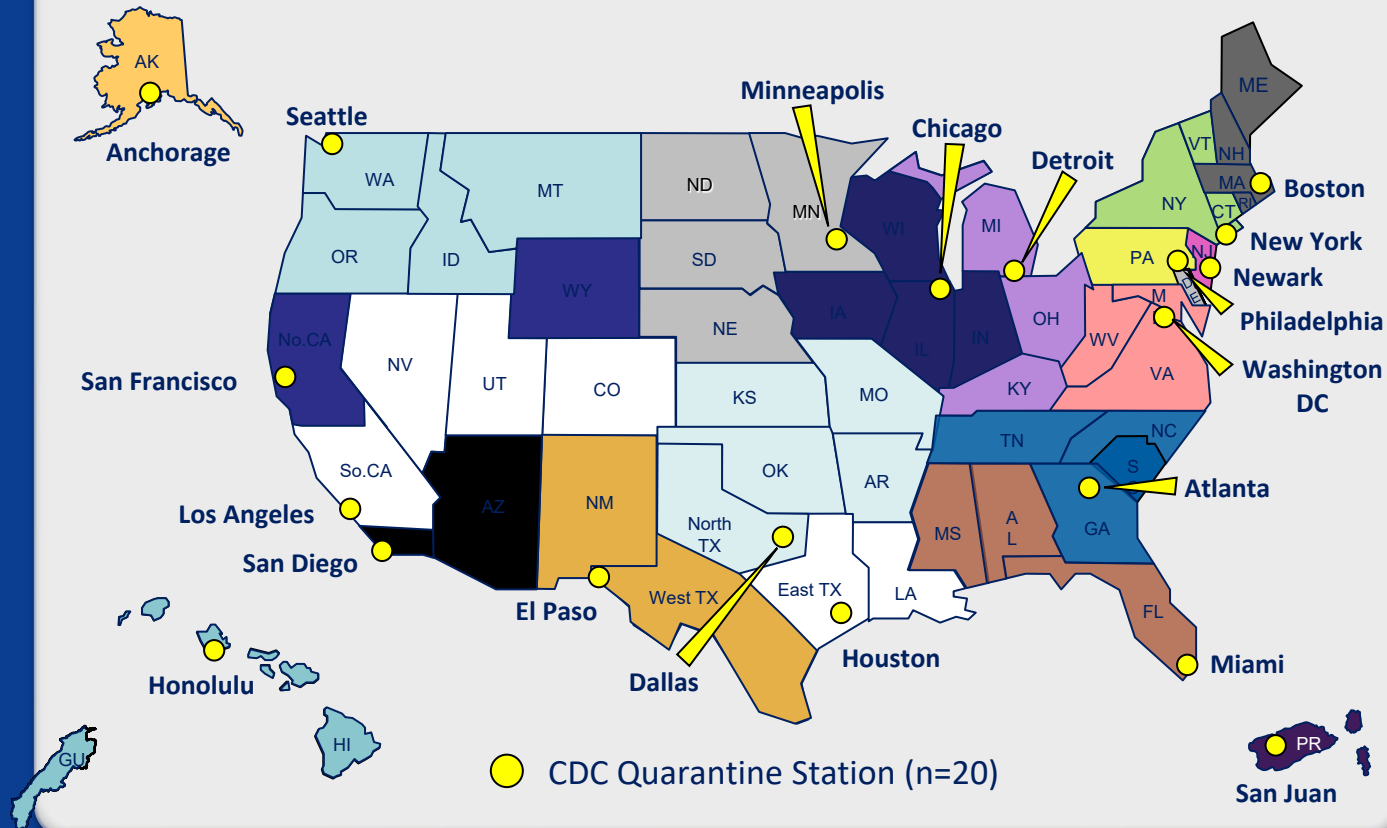
**CDC Detroit Quarantine Station
2021**



SAFER • HEALTHIER • PEOPLE™



CDC Quarantine Station Jurisdictions



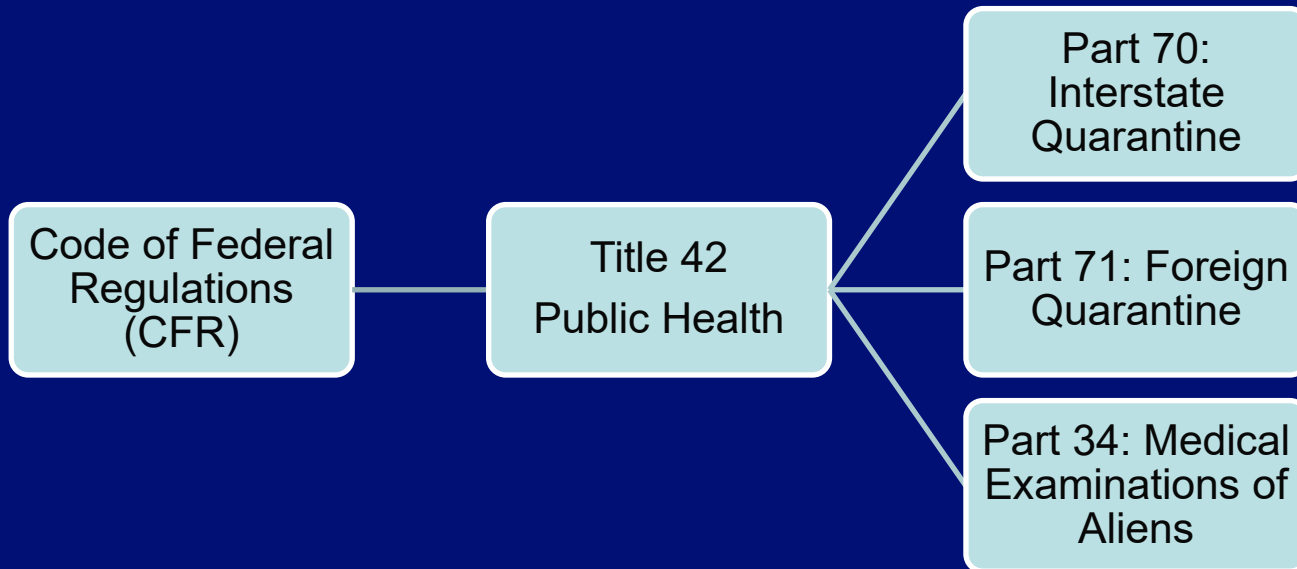
Quarantine and Border Health Services Branch Mission



To protect the health
of the public from
communicable
diseases at U.S.
borders and beyond



CDC's Regulatory Authorities



Quarantine

ENFORCEMENT OF CDC IMPORT REGULATIONS

- **CDC Quarantine Stations and Partnerships at U.S. Ports of Entry**
 - Division of Global Migration and Quarantine (DGMQ)
 - Division of Select Agents and Toxins (DSAT)
 - NIOSH
- Public Health Agency of Canada (PHAC)



Quarantine Executive Orders

Executive Orders

- **Federal isolation, quarantine, and conditional release only authorized for certain communicable diseases.**
 - **Diseases are specified by Executive Order of the president.**
 - **The president can revise the list by Executive Order, upon recommendation of the Secretary.**
- Cholera
 - Diphtheria
 - Infectious tuberculosis
 - Plague
 - Smallpox
 - Yellow fever
 - Viral hemorrhagic fevers
 - Severe acute respiratory syndromes
 - New or re-emerging types of flu (influenza) that could cause a pandemic



Other Communicable Diseases of Public Health Concern*

- Malaria
- Typhoid
- Varicella
- Rabies
- Measles
- Meningococcal disease
- Legionellosis
- Polio
- Dengue
- Zoonotic poxvirus
- Pertussis
- Mumps
- Rubella
- Infectious diarrhea

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



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



Importation of Items of Public Health Importance

Review & Initial Determination

- Paperwork reviewed
- Regardless of other agency permits, CDC requirements need to be met
- Item is declared?
- Determination is made
- May be released or
- May be denied entry

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.



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.)



Canines

- **New this year!**
- **Dogs arrives as pets or from rescue organizations cannot enter the US if they originated from a country with high risk for canine variant rabies.**



Inspection of Etiologic Agents

- **No threat posed → Statement of Non-infectiousness**
- **Potential or known threat → Apply for Import Permit**



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

Centers for Disease Control and Prevention (CDC)
National Center for Emerging and Zoonotic Infectious Diseases
Division of Global Migration and Quarantine

QARS # _____

Disposition Form for Baggage and Cargo

1. Port of Entry	2. Entry Date/Time (24hr)	3. Conveyance	4. CDC Quarantine Station	5. Quarantine Officer
6. CDC Notified by (Agency/Officer/Telephone/E-mail):			7. U.S. Customs and Border Protection (CBP) Form Attached (check all that apply): <input type="checkbox"/> Determination Notice (60510) <input type="checkbox"/> Re-Export (7512) <input type="checkbox"/> Entry (3481) <input type="checkbox"/> Seized Property (60510) <input type="checkbox"/> Mail Interdiction (187) <input type="checkbox"/> Other	
8. Name of Owner		9. Owner's Address Street/City/State: Zip Code/Country		10. Owner's Telephone/Facsimile
11. Passport Information/Country		12. Mastes/Vessel Wharf #		13. Item's Country of Origin
14. Broker Name/Address/Telephone/E-mail			15. Conveyance Representative's Name/Address/Telephone/E-mail	
16. Description of Items Held or Denied Entry			17. Reasons Held or Denied Entry (ref. 42 CFR Part 71)	
18. No. of Items			19. Items Declared to Customs? <input type="checkbox"/> Yes <input type="checkbox"/> No	
20. Quarantine Station Action/Disposition Status (check all that apply): <input type="checkbox"/> Requested post-entry <input type="checkbox"/> Awaiting permit <input type="checkbox"/> Requested other documents* <input type="checkbox"/> Requested hold <input type="checkbox"/> Denied entry <input type="checkbox"/> Abandoned by importer <input type="checkbox"/> Shipped in-bound to residence/other location (name/address)				
21. Quarantine Officer's Signature			22. Date	
23. Owner/Broker's Signature (only indicates receipt of CDC Form 75.42)			24. Date	
25. Final Disposition of Item(s)** (check all that apply): <input type="checkbox"/> Allowed entry to original importer <input type="checkbox"/> Allowed entry to another (not original) importer (write in R28 below) <input type="checkbox"/> Destroyed (write in R28 below) <input type="checkbox"/> Re-exported <input type="checkbox"/> Destroyed by (agency)				
26. Final Destination (Name/Address/Telephone/E-mail)			27. Date	
Acceptance/Chain of Custody				
Date	Name (Individual/ Agency/Organization)	Telephone	Item	Quantity

Form Instructions: Quarantine Station to complete if unable to enter a shipment (see Item/shipment) under CDC regulations immediately upon entry.
 * Transmittal certificate, documentation that item has been rendered non-infectious, retesting/relax test results, rabies vaccine certificate, etc.
 ** As agreed upon by importer (or agent), CBP, CDC and other agencies with authority over the item.
 CDC Form 75.42

CDPH: Quarantine Station



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.

Cat B = permit



Example

- Shipment arrives from Germany with a final destination of a “MD Logistics”
- What is MD Logistics?
 - ABOUT MD LOGISTICS
 - MD Logistics is a third party logistics (3PL) company specializing in customized supply chain solutions. Each opportunity represents unique, client-specific challenges that are evaluated utilizing proven strategic methodologies to deliver turnkey solutions. Our vertical markets include Freight Forwarding and Transportation, Retail and Consumer Goods Supply Chain Management, Life Sciences and Pharmaceuticals Cold Chain Management, as well as eCommerce and Omni-Channel Logistics.
 - In addition to cold chain storage and foreign trade zone warehousing, our services range from packaging, fulfillment and distribution, to global supply chain solutions, freight forwarding and freight management.
 - Located in Plainfield, Indiana, nine miles west of Indianapolis International Airport, and also Reno, Nevada, our combined facilities include nearly one million square feet of state of the art Pharmaceutical and Retail distribution space



What are they shipping?

- LOADED ON 20 US-PALLETS KCENTRA **DERIVED FROM HUMAN PLASMA ONLY.**
NON INFECTIOUS, NO ANIMAL DERIVATES ADDED, MANUFACTURED IN GERMANY
H:IE.MATERIAL CONTAINS NO ANIMAL OR NON HUMAN PRIMATE MATERIAL HS
CODE: 3002.12 TO BE CARRIED AT A TEMPERATURE OF: 15 DEGR CELS.
DEHUMIDIFICATION: 60% VENTS: CLOSED RISTO.TASHEV@US.DSV.COM
CSLOPERATIONS@MDLOGISTICS.COM AMLOG.OPERATIONS@CSLBEHRIN G.COM
BLXMSC012020FREIGHT PREPAID WOOD PACKAGING CLAUSE: SHIPPER
DECLARES THAT ANY APPLICABLE WOOD PACKAGING MATERIALS COMPLY WITH
ISPM15 REGULATIONS. FAILURE TO COMPLY WILL RESULT IN CONTAINERS BEING
RETURNED TO LOAD PORT OR CARGO DESTROYED - ALL COSTS/FINES/
PENALTIES WILL BE FOR SHIPPERS ACCOUNTS. Temp: 15.00 C Air Fresh
Vents(cbm/h): 0.00



What are we looking for?

- We know this is human product
- They have FDA approval
- CDC continues to look through the documentation and finds.....



THIS

For Intravenous Administration Only

Because Kcentra® is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. See package insert **Warnings and Precautions** section.

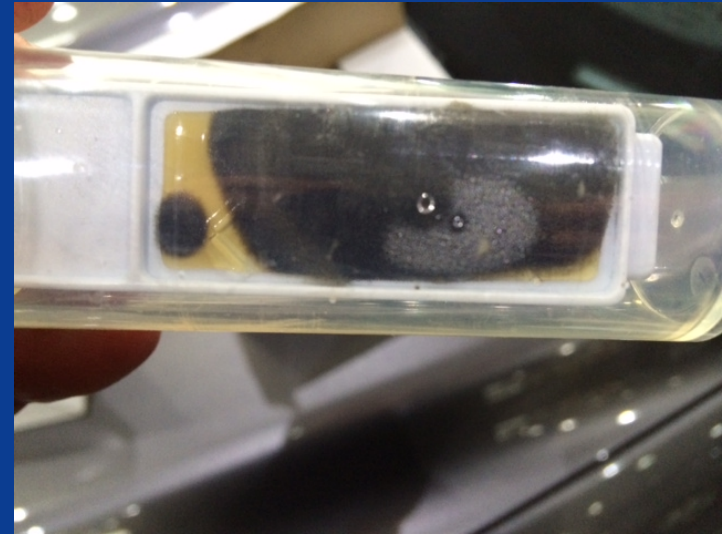
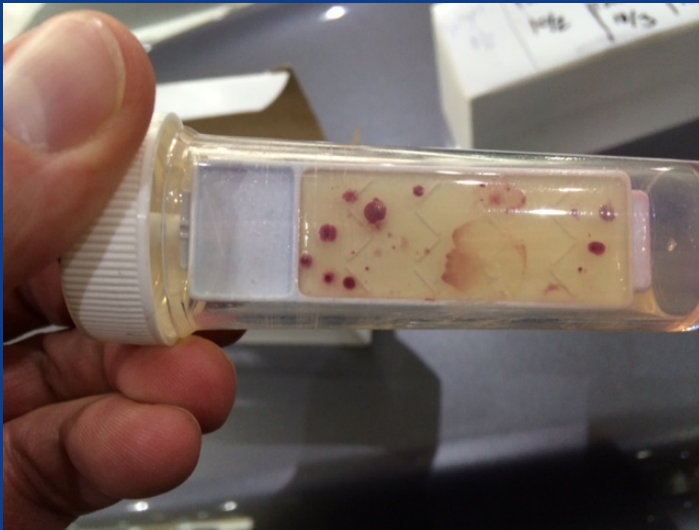


Next steps

- Shipper will be asked to apply for a permit through DSAT
- Material will be held in bond until / if appropriate documentation is provided



If you don't know what it is.....



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

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



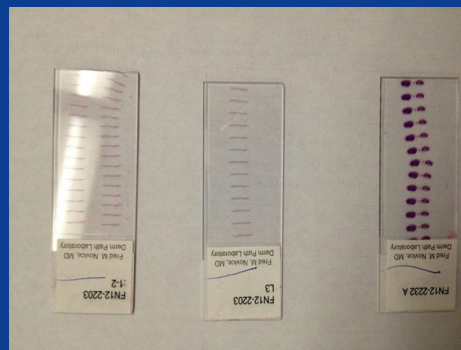
Human Tissues & Products

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



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

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/>



National Center for Emerging and Zoonotic Infectious Diseases

Division of Global Migration and Quarantine

Intermission

Thank you for attending “CDC Restricted Items”

We’ll be right back

Our next presentation, “Import Requirements”
will begin at 12:00 p.m. EDT.



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