IMPORTATION OF BIOLOGICAL SUBSTANCES

Importation of Biological Materials Workshop
University of Michigan

November 30, 2016

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Materials provided at the Importation of Biological Materials Workshop at the University of Michigan are for official use only and are the property of the U. S. Government. Materials must not be disseminated without the prior written consent of U.S. Customs and Border Protection.
What are Biologicals?

- Plant, animal, or human diagnostic specimens, infectious substances, genetically modified organisms and microorganisms, cell and DNA/RNA cultures, tissue samples, and unregulated biologicals.

Presenter: Robyn Cotting
Importation of Biological Substances: Requirements for CBP Release

Cargo and Express Consignment Carrier Facilities (ECF) requirements.

- Must be properly manifested
  - Accurate description
  - Physical units and total weight.

- Must be accompanied with valid import documents, including but not limited to:
  - Permission letter or permit from the regulating U.S. government agencies
  - A signed certification statement of non-infectiousness on official letterhead, if applicable

- Will require a Formal Entry to meet CBP entry requirements
Cargo and ECF requirements (continued).

Example of documentation provided with a compliant shipment:

- **Cargo Description:**
  - DNA tubes
  - non-hazardous/non-infectious from exempt human cell lines
  - 0.9 g net weight.

- **Additional Statements:**
  - Toxic Substances Control Act (TSCA) Certification, negative certification
  - USDA Statement stating non-hazardous/non-infectious exempt human specimens – human cell lines. Material is not recombinant and not derived from livestock. Material is being sent for in lab testing (in vitro) only.
What is a Formal Entry?

A Formal Entry is the process of importing a commodity that is covered by an entry bond.

- How do I file a Formal Entry?
  - Contact a Customs Broker
    - CBP.gov>

- The shipment must have:
  - An accurate invoice
  - Packing list
  - Shipping documents
  - Required permits
How do I find a Broker?

CBP.gov > Trade > Basic Import and Export

Detroit Metropolitan Airport

Brokers: Brokers

Locate Port Information
CBP provides security and facilitation operations at 328 main ports of entry throughout the U.S.

Read More
Importation of Biological Substances: Requirements for CBP Release

Requirements for hand-carried shipments arriving on passenger aircraft.
Importation of Biologicals in Passenger Baggage

- Who is bringing biologicals into the U.S. in passenger baggage?
  - University and private researchers
  - Medical doctors
  - Veterinarians
  - Graduate students
  - Farmers
  - Medical patients
  - Couriers
Importation of Biologicals in Passenger Baggage

- What types of biologicals are being brought into the U.S. in passenger baggage?
  - Human tissue samples
  - DNA cell cultures
  - Monoclonal antibodies
  - Disease vectors
  - Viruses
  - Toxins
  - Reagents
  - Drugs
  - Vaccines
Importation of Biologicals in Passenger Baggage

- What determines the admissibility of a biological substance?
  - Was it declared?
  - Are valid permits present and being followed?
  - Is it properly labelled and packaged?
  - Has a formal entry been completed?
CBP Written Declaration Form

• Declare ‘yes’ to the category that best describes your biological importation.

• Write a more detailed description of the biological material on the back of the form under ‘Description of Articles’.

• Failure to declare may result in penalties or seizure.

U.S. Customs and Border Protection

Presenter: Robyn Cotting

November 30, 2016
How should biologicals be transported into the U.S. in passenger baggage?

- Checked or hand-carry bags
  - In accordance with proper importation guidelines, including:
    - Properly labeled and packaged
    - Notice given to airline if the material is potentially hazardous
    - A formal entry has been filed prior to arrival
  - Recommended that you make entry during the week during normal business hours to facilitate entry of your shipment.
Final outcome of the biological importation after inspection:

- Passenger is allowed to exit the Federal inspection area with the biologicals.
- Passenger is not allowed to exit with the biologicals.
  - The biologicals were not declared, do not meet the permit requirements, or lack any appropriate documentation.
    - Expect to be delayed up to several hours while information is collected and other agencies are contacted to determine the final disposition of the biological.
      - Biological held in bonded warehouse while awaiting supporting documentation or permit
      - Biological is destroyed at the importer’s cost
QUESTIONS?

Detroit Field Office Agriculture Operations
- Supervisory Program Manager Kimberly Nott
- Acting Agriculture Operations Manager Robyn Cotting
  - (313) 496-2155

Detroit Metropolitan Airport
- Supervisory Agriculture Specialist Adam Pitt
- Agriculture Specialist Steve Ashton
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Recent Importations of Biological Substances in the Detroit Field Office
CBP Intercepts Concealed Human Urine and Toenail Samples
CBP Intercepts Undocumented Cholera Samples in Passenger Baggage
CBP Intercepts Improperly Packaged Human Tissue Sample from a patient with known TB
CBP Intercepts Non-human Primate Urine and Feces from University Researcher
CBP Intercepts Illegal Basement Laboratory Supplies

Dengue Fever
Human papillomavirus
Hepatitis C
Mycoplasma pneumoniae
Chlamydia pneumoniae
Cytomegalovirus
Urea plasma
Hantavirus

Presenter: Adam Pitt

November 30, 2016
CBP Intercepts Human Proteins Isolated from Kidney Cells
IN THE NEWS...
Pasteur Institute breaches MERS Biosecurity rule

By Jung Min-ho

The Institut Pasteur Korea (IPK) committed serious biosecurity breaches, which could have resulted in the loss of many lives, and tried to cover it up, according to evidence obtained by The Korea Times.

An IPK virologist transported samples of the deadly Middle East Respiratory Syndrome (MERS) coronavirus to the Institut Pasteur in Paris on Oct. 11, 2015, without alerting the health authorities of any country.

Her actions, including transporting the hazardous materials in the cabin of a commercial airplane, are not only a violation of the U.N.'s Globally Harmonized System of Classification and Labelling of Chemicals (GHS) but also a violation of French laws on infectious disease control.

Christian Brechot, president of the Institut Pasteur that has 33 research institutions worldwide, was apparently aware of the incident. In his email to the virologist, he said, "You failed to alert both Korean and France authorities about transporting them on a commercial plane risking many lives."

Last year, 38 of 186 MERS patients in Korea died, despite the government's all-out efforts to contain the disease. Its fatality rate was 20.4 percent.

If the virologist's containers carrying the samples were ruptured, potentially the virus could have infected many passengers, as the confined space and re-circulated air of the cabin provides the right conditions for the virus to spread quickly.

"Her actions were a serious threat not only to the local public but also to global safety, and are an example of how safety is governed and managed in Korea," the whistleblower said.

IN THE NEWS…
Virginia executive pleads guilty to mislabeling monkey blood as human

NON-COMPLIANCE

- Seizure
- Destruction
- Fines (failure to declare and importation contrary to law)
- Penalties and/or Liquidated Damages from all agencies that have had laws and/or regulations violated.
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