Shipment and Transport of Biological Materials

Common Questions and Scenarios
Outline

- Importation and exportation of biological materials
  - We will not go over how to categorize shipments – this is in HTP online training

- Excepted quantities of preservatives

- Basics of local transport
How many of you are trained shippers?
Courses available to train you how to ship biological materials

- LAB104
- LAB114
- LAB109
Import / Receipt of Biological Material

- How many of you receive materials from international sources?
- Permits from federal or state agencies
- Institutional approval (COMS, etc.)
Salmonella Shortage

- A new postdoc joins your lab after completing her graduate studies in California. The new postdoc is starting a project in your lab that continues her previous research on *Salmonella enterica* Typhimurium.
- Your lab has never worked on Salmonella before.
- The postdoc needs to obtain some of the strains she used previously from her former lab.
What do you need to consider in order to receive these strains of *Salmonella*?

A. A permit may be needed to receive this zoonotic pathogen
B. Nothing – transport is within the US so no permits are needed
C. Nothing – *Salmonella* is commonly found poultry and reptiles
D. Nothing – the shipper is responsible for permits and proper shipment of the material
A permit is be needed to receive *Salmonella* from California

- Does this material contain or is it suspected of containing an infectious biological agent or other organism that is capable of causing disease in humans, plants, or animals?

  - YES

- Animal pathogen
- Human pathogen
If it could cause disease in:

<table>
<thead>
<tr>
<th>Agencies</th>
<th>Animals</th>
<th>Plants</th>
<th>Humans</th>
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<tbody>
<tr>
<td><strong>USDA</strong></td>
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Your lab is participating in a study to measure exposure to environmental pollutants.

Blood samples will be collected from subjects in Nigeria, centrifuged at the collection site, and the sera shipped to your lab.

Subjects should be healthy adults that will self-report any ailments/symptoms on a questionnaire at the time of blood draw.
Do you need a permit to import these blood samples?

A. Yes – they are human samples and all human samples require a permit
B. Maybe – I need more information
C. No – the participants in the study are healthy adults
What other information do you need?
What other information do you need?

- What infectious diseases are endemic in Nigeria?
- What specific questions are asked on the questionnaire?
- Will subjects have their temperature taken at the time of blood draw?
- Will the blood be screened in any way before shipment?
What other information do you need?

- What infectious diseases are endemic in Nigeria?
  - High prevalence of HIV – 15.2%
  - Lassa seroprevalence approximately 20%, many asymptomatic
- What specific questions are asked on the questionnaire?
  - None that will identify those infected with the above
- Will subjects have their temperature taken at the time of blood draw?
  - No
- Will the blood be screened in any way before shipment?
  - No

- CDC Import Permitting Tool
  https://www.selectagents.gov/resources/IPPetool/
What type of material(s) will you be importing into the U.S.?

Mouse over your choice, click to choose.

Animal or Human body fluids, tissues, body parts, blood/blood products and feces
- Bacterial isolates, viral isolates, fungal isolates, and prions
- Diagnostic or clinical samples (patient samples that will be tested for specific infectious biological agent(s))
- Environmental samples (air, water, soil, surfaces, etc.)
- Genomic material (DNA, RNA, genomic vectors i.e., plasmids)
- Hosts or vectors (flies, mosquitoes, snails, ticks, etc.)
- Human tissue/organs used for human transplants or grafts

- Human remains
- Vaccines/drugs/reagents
- Live animals
- Live bats
- Live non-human primates
- Materials from non-human primates
- All other live animals
- Isolates of select agent(s)
INFECTIONOUS BIOLOGICAL AGENTS

Does the material contain or is suspected of containing an infectious biological agent that is capable of causing disease in humans or is being tested for a specific biological agent?

- Yes
- No
- Don't Know
INFECTIONOUS BIOLOGICAL AGENTS

Does the material contain or is suspected of containing an infectious biological agent that is capable of causing disease in humans or is being tested for a specific biological agent?

- Yes
- No
- Don’t Know
YOU NEED AN IMPORT PERMIT!

Click here to complete a Permit to Import Biological Agents or Vectors of Human Disease.

Once the import permit has been obtained, refer to the following resources for shipping and packaging guidance:

- Click here for Shipping and Packing Regulations
- Click here for Shipping Infectious Substances
- Click to continue to non-human primate information
A British Bunny

- Your collaborator in the UK has made a custom antibody against your protein of interest. The antibody was made by immunizing a New Zealand White Rabbit in their AAALAC accredited animal facilities.
- After all scheduled boosters, the rabbit was bled and the serum collected.
- Your collaborator is now ready to ship the serum to you.
What do you need to consider in order to receive the serum?

A. A permit is needed to import animal products into the US because they may contain animal pathogens
B. Nothing – live animals but not animal products need a permit
C. Nothing – standard lab animals and lab animal products do not need a permit
A permit is NOT required, but ...

- There are recommended steps described by USDA for the shipper to take in order to reduce chance of delays at customs and facilitate a timely delivery.
- A document should accompany the shipment to clearly identify the material and that it is derived from a lab animal that was not housed in a facility where infectious disease work was ongoing.

- Take home message: Ask EH&S and we can provide this guidance.

- [http://www.ehs.harvard.edu/sites/ehs.harvard.edu/files/research_materials_import_export_requirements_0.pdf](http://www.ehs.harvard.edu/sites/ehs.harvard.edu/files/research_materials_import_export_requirements_0.pdf)
Shipping & Transporting Research Materials

EH&S assists laboratory researchers to manage shipments and transportation of dangerous goods, including chemicals, radioactive materials, and biological materials, by ground, air, or sea, in order to comply with the U.S. Department of Transportation (DOT) regulations, International Air Transport Association (IATA) guidelines and/or Maritime law. Shipping certain materials may require import/export permits or other documentation from federal agencies including, US Border Protection and Customs, FDA, USACHIPHS, Fish and Wildlife, and CDC.

Documents
- Biological Material Shipping Classification Table
- Change to Dry Ice Shipping Label
- Request to Ship Dangerous Goods
- Research Materials Import and Export Requirements

External References
- CDC Etiologic Agent Import Permit
- FDA Import Permits
- Fish & Wildlife Permit
These materials do not require a USDA import permit, but will be reviewed at the port of entry.

- **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
- **1107** Guidelines for Importation of Lactose and Lactose Derivatives
- **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
If it could cause disease in:

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If you think you need a permit

- Ask yourself: Does this material contain or is it suspected of containing an infectious biological agent or other organism that is capable of causing disease in humans, plants, or animals?

- If you don’t know, ask EH&S or get a permit.

- Give yourself enough time to complete the process
  - Obtaining a permit may include an inspection by USDA
  - Processing time varies by agency but try for at least 1 month lead time
  - Have your permit in place **BEFORE** the shipment is sent
    - Include all permit paperwork with the shipment

Transgenic quail from Australia – Yes you need a permit for this!
Questions on Importing
Exporting / Shipping Biological Materials Internationally or Interstate

- International
  - Harvard Export Control
  - Permits required by recipient country

- Interstate, intrastate
  - USDA permits needed for interstate and intrastate transport
Export Control

- Control the distribution to foreign nationals and foreign countries of items, services, technology, and software.
- Whether a license is required would depend on three factors:
  - the nature of the item;
  - the country of destination; and
  - the end user of the item.
- Nature of the item – may include information, software, technology microorganisms, chemicals or radioactive materials
- Export Control Contact for HMS
  - Suzanne Higgins, Associate Director Research Compliance
  - export_control@hms.harvard.edu
So long, cells, give my regards to S. Korea

- You need to ship some frozen murine cells to your collaborator in South Korea.
- The cells have been modified to express a chicken protein, ovalbumin.
How will you categorize this shipment?

A. Non regulated
B. Exempt animal specimen
C. GMO
D. Category B
Are you required to be trained to ship this?

A. Yes
B. No
Is a permit needed for this shipment?

A. No – these samples are from standard lab animals
B. No – only a copy of my COMS protocol is needed
C. Yes – they are genetically modified
D. I don’t know – it depends on the requirements of S. Korea
Exporting Biological Materials - Permits

- Permits associated with exporting biological materials is dependent on the country where the shipment will be received.
- Any time you send something internationally, you should ask your recipient to look into the local regulations.
- Your recipient should let you know if any documentation from their country needs to accompany the shipment.

- **WAIT** to send the material until you have this information from your recipient!
Questions on Exporting
Shipping biological material with preservatives
Microbiome sample collection

- You are part of a group of faculty who are applying grant to create a microbiome resource at the school. Part of this project includes collecting stool and oral samples from 35k women in the Nurses' Health Study – a domestic study.
- Each collection kit will contain 3 collection vials, 2 of the vials are made by DNA Genotek and contain about 1.5ml of a proprietary preservative each. The last vial will contain about 1.5ml of 95% ETOH.
- You would like to ship these as Exempt Human Specimens.
In addition to following all requirement to ship these packages as an Exempt Human Specimen, what else do you need to consider?

A. A CDC permit will be needed for the human samples
B. The ethanol must be put into 30 mL containers
C. The packaging will require labeling for an excepted quantity of ethanol
D. Nothing
Excepted quantities of preservatives

- Shipping Excepted Quantities: Flammables, Corrosives, and Common Fixatives
- (ID: LAB109)

- Break up larger volumes into smaller primary containers to use this exception
Questions on Shipping Excepted Quantities
Local Transport of Biological Materials
How does your lab move research materials around Boston/Cambridge?

Choose all that apply

A. Public Transit
B. Taxi
C. Uber/Lyft
D. Walking
E. Bicycle
F. Shuttle bus
G. Personal vehicle
H. Medical courier
I. Shipment via carrier (e.g. FedEx)
J. Other
Key points for local transport

- If the samples will be moved along a public roadway, they fall under Department Of Transportation (DOT) oversight and must be packaged and transported accordingly
  - You must be trained in the same manner as if you shipped via a carrier
  - Package them as you have been taught for a shipment via carrier
    - Triple layer packaging
    - Appropriate labels
  - Place entire package into shopping bag or other unmarked bag so as not to draw attention to it during transit
  - You must accompany your package

- If the samples are not moved along a public roadway (intra-campus), proper primary and secondary containers are required
Options for local transport

- Shipment via normal carrier (e.g. FedEx)
- Taxi (certain companies)
- Medical courier
- Walking
- Bike (discouraged)

DO NOT USE:
Public transit
Personal Vehicles

- Allowed but discouraged
  - Car insurance company may not cover accidents that occur while transporting hazardous materials
  - Dry ice can present a hazard for driver due to off-gassing. Package should be in the trunk or truck bed. If not in a trunk/truck bed, caution must be taken to allow for good ventilation in the car during transport.

- Category A shipments cannot be transported in a personal vehicle
Local Transport Guidance – coming soon

- Collaborative effort to create a unified approach among local institutions
  - Currently: Harvard, MIT, Ragon, Broad, Whitehead

- Guidance will be posted on EH&S website and discussed at future ROMs meeting

- Will include details about
  - University-specific shuttles
  - Recommended taxi companies
  - Uber/Lyft