

Guidelines for the Shipping and Receiving Biological Materials

I. Introduction

The shipping and receiving of biological materials is regulated by several government agencies. According to federal regulations:

"It is the responsibility of the shipper to ensure correct identification, classification, packaging, labeling, marking, and documentation for all shipments of infectious substances. In addition, the shipper must make advance arrangements with the recipient (consignee) and operator (carrier), including acquisition of any permits for the importation of infectious substances from foreign countries. Failure to comply with federal and international regulations can result in refusal of the shipment by the airline, penalties of fines, jail, or both. Hand carriage of infectious substances by air is strictly prohibited by law."

Applicable Transportation Regulations

- FedEx - General guidelines for packaging, marking and labeling clinical samples and biological substance, Category B, <http://www.fedex.com/us/services/packageshipment/index.html?CMP=PAC-GTS-VURL008> (see **Pack like a Pro** in menu bar)
- DOT regulates the shipment of Etiological Agents, <http://www.federalregister.gov/articles/2008/01/23/E8-1050/interstate-shipment-of-etiological-agents>
- IATA - Dangerous Goods Regulations (DEHS has copies of the regulations)
- WHO - Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens, 1997
- Postal Service Hazardous Materials Domestic Mail Regulation, <http://www.ups.com/content/us/en/resources/ship/hazardous/index.html>

Before requesting biological material to be shipped to you:

- Obtain any required permits, see Sections III & VI, and send copies to the shipper.
- If shipment is from a foreign country be sure they are aware of U.S. shipping regulations and that they have the correct labels, send labels to the foreign shipper if needed.
- Be sure you have current Institutional Biosafety Committee (IBC at <http://gero.nku.edu/research/rgc/irb/ibc.html>) approval to work with the material if it requires Biosafety Level 2 or higher precautions or is a biologically derived toxin.
- Arrange to have someone present to receive the material when it arrives.
- Get approval from academic department and dean to receive materials.

After receiving biological material:

- Notify the Biosafety Officer to have Biosafety Level 2 or higher organisms and biologically derived toxins added to the university's biological material inventory.

Before shipping biological material:

- Request a copy of Biological Safety Officer approval for pathogen possession/use from the receiver's institution; send a copy of the approval to Safety and Emergency Management.
- Determine if a Material Transfer Agreement is required. See Section III D.
- Determine the material's classification; see Section IV and the Classification Flow Chart. (Appendix 1)
- If the material is classified as a Category A or B Infectious Substance, or shipped on dry ice, or a toxin you must contact the Department of Biological Science Lab Manager who will supervise and sign off on all shipments. In the event the Lab Manger is not available, contact the Safety and Emergency Management Director.
- Obtain the correct type of packaging and labels for the material classification.
- If the receiver needs a permit, request a copy from them before shipping.
- If shipment is going to another country, see Section VI and include a customs courtesy letter.
- Arrange for the receiver to be available to take possession of the package when it arrives.

The information provided in these guidelines is an overview and not meant to be comprehensive. It may be necessary to contact applicable government agencies for clarification and updates regarding permit requirements.

II. Training Requirements

If you regularly ship Category A or B Infectious Substances (see Appendix 1 Infectious Substance Classification Flow Chart) or on dry ice or toxins as described in Section IV, you **must** receive initial and update training to fulfill the requirements of the U.S. Department of Transportation and the shipping companies. **Shipping training must be updated every two years or more frequently if regulations change.**

These guidelines are meant to supplement the above training and **are not** a substitute for the hazardous material shipping class.

Shipping biological materials listed as excluded from dangerous goods regulations in Section IV does not require training.

III. Permits to Receive Biological Materials

Federal permits are required to import/export disease-causing agents for humans and animals, vectors for those agents, animal products, plants, plant products, and plant pests. Permits may also be required for domestic transport of some agents. The recipient of the material must obtain any required permits. If you are the shipper, request a copy of any applicable permits from the recipient.

The U.S. receiver (importer) is responsible for the package being sent to them from a foreign country. The receiver must assure that the foreign shipper has packed and labeled the material according to U.S. Public Health Service and the International Air Transport Association (IATA) regulations. The importer must send the proper shipping labels and a copy of their import permit to

the shipper. Complying with foreign import regulations should prevent packages from being held at customs or denied entry. See Section VI for additional information.

Inquire to the proper government agency listed below for permit requirements and applications well before the material is needed as it may take several weeks to process a permit application.

A. USDA/APHIS Transport Permits

The USDA/APHIS (Animal and Plant Health Inspection Service) regulates transport of materials that could potentially harm U.S. agricultural products including livestock, poultry and crops. APHIS permits may be required for import, export, and interstate transport of animal or plant pathogens, pathogen vectors, animals, animal products, plants, plant products, and the introduction of genetically modified organisms into the environment.

1. Transportation of Infectious Substances

See Appendix 2

2. USDA Import Guidelines For Products That Do Not Require An Import Permit

See Appendix 3

- **1110** Microbially Produced Materials:
http://www.aphis.usda.gov/import_export/animals/animal_import/downloads/imicro.html
- **1114** Recombinant Microbes and Their Products:
http://www.aphis.usda.gov/import_export/animals/animal_import/downloads/irecom.html

3. Animal Related

USDA/ APHIS permits are required for imports/ exports and inter-state transport of:

- animal or plant pathogens including challenge material from the USDA
- specimens reasonably believed to contain animal or plant pathogens*
- vectors of animal or plant disease*
- potentially hazardous animal or plant products

*USDA/APHIS regulation 9 CFR Animals and Animal Products Parts 94, 95, and 122 covers transport of organisms or vectors that can cause infectious diseases of animals. The regulation defines material requiring a permit as, "(d) Organisms. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). (e) Vectors. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

http://www.access.gpo.gov/nara/cfr/waisidx_03/9cfrv1_03.html.

An Import/Transport permit:

- must be obtained by the intended receiver of the material before shipment is made
- is good for one year and is amendable/renewable
- application (VS Form 16-3) can be downloaded at:
http://www.aphis.usda.gov/import_export/animals/downloads/vs16_3.pdf
- form is for either foreign import or interstate transfer
- requires 6 to 8 weeks for processing

To determine if the material you wish to transport requires a permit, visit the APHIS: National Center for Import and Export (NCIE) Website at
http://www.aphis.usda.gov/import_export/index.shtml

NOTE: According to the USDA, "Generally, a USDA veterinary permit (VS-16-6) is needed for materials derived from animals or exposed to animal-source materials. Materials which require a permit include, animal tissues, blood, cells or cell lines of livestock or poultry origin, RNA/DNA extracts, hormones, enzymes, monoclonal antibodies for IN VIVO use in non-human species, certain polyclonal antibodies, antisera, bulk shipments of test kit reagents, and microorganisms including bacteria, viruses, protozoa, and fungi. Exceptions to this requirement are human and non-human primate tissues, serum, and blood."

4. Plant Related

USDA/APHIS regulation 7 CFR Part 330 Federal Plant Pest Regulations covers the transport of plant pests (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=d3893c775af403b08c654c1f15a669be&c=ecfr&tpl=/ecfrbrowse/Title07/7tab_02.tpl). For information on plant pest transport permits see http://www.aphis.usda.gov/permits/ppq_epermits.shtml. For information on plant and plant product transport permits see http://www.aphis.usda.gov/permits/ppq_epermits.shtml.

The intended receiver of plants and plant pests must obtain a permit for transport before shipment is made. Allow 6 to 8 weeks for processing.

Examples of some permit applications are:

- PPQ 526 Application for Permit to Move Live Plant Pests or Noxious Weeds
- PPQ 586 Application for Permit to Transit Plants and/or Plant Products Into or Through the United States
- PPQ 587(MD) Application for Permit to Import Plants or Plant Products
- PPQ 588 Application for Permit to Import Plants or Plant Products for Experimental Purposes
- Phytosanitary certificate: document required by many states and foreign countries see http://www.aphis.usda.gov/import_export/plants/plant_exports/pcit.shtml for description

Contact APHIS for clarification of which permit is required, instructions on how to obtain permit applications, and to determine if any changes have been made to the initial regulation. APHIS National Center for Import/Export Products (301 734-3277)
<http://www.aphis.usda.gov/lpa/about/welcome.html>

5. Genetically Modified Organisms (GMOs)

To determine if a permit is needed to import or transport a GMO, contact the APHIS Biotechnology permit branch via a letter of notification.

B. Centers for Disease Control (CDC)

The Department of Health and Human Services, through the CDC, regulates the transport of biological materials that could cause illness in humans, including pathogens and biological toxins.

Human infectious substances. In general, a permit is needed for any infectious agent known or suspected to cause disease in humans that you wish to import into the United States. In some cases subsequent distribution of an agent (i.e., SARS-CoV, select agents, viruses requiring BSL-4 containment) is prohibited within the United States and requires CDC authorization/permit prior to transfer to another location within the U.S. These permits may be obtained from the Centers of Disease Control and Prevention, Office of Health and Safety, Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/> or telephone (404) 498-1600 for further information.

Foreign imports of the following materials require a Permit to Import or Transport Agents or Vectors of Human Disease:

- any etiologic agent
- any arthropod or other animal host or vector of human disease
- any exotic living arthropod or other animal capable of being a host or vector of human disease
- Non-human primate material - all non-human primate material (e.g., blood, plasma, tissue, urine, feces) requires an import permit, unless it has been specifically treated and rendered non-infectious.

Domestic transport may or may not require a permit.

To determine if your shipment requires a permit:

- call 404-498-2260
- visit the CDC Web site at <http://www.cdc.gov/od/eaipp/>
- Go to the online form to submit a permit application <http://www.cdc.gov/od/eaipp/faq.htm>

Some microorganisms and cell lines purchased from ATCC require permits to be shipped domestically. For ATCC permit info see <http://www.atcc.org/Order/permits.cfm>.

C. Phytosanitary Certificate

A phytosanitary certificate is a document often required by many states and foreign countries for the import of nonprocessed, plant products,

http://www.aphis.usda.gov/import_export/plants/plant_exports/pcit.shtml

D. Material Transfer Agreement

Steps to ship a Select Agent:

- Contact the Department of Biological Sciences Lab Manager to coordinate shipment and CDC/USDA approval with the receiving entity.
- After CDC/USDA approval has been received to ship the material, the material will remain in the Biological Sciences Department for pick-up.
- Immediately update your inventory including the date sent and signature of the authorized individual who removed the material from storage. Send a copy to EHS Department.
- Notify EHS Department any time a request is received for a Select Agent even if you do not agree to ship the material.

Steps to receive a Select Agent:

- Call the Biosafety Officer to verify that the University's Certificate of Registration includes your lab and the desired Select Agent material. You will need to have an active NKU Biohazardous Agent Registration (BAR) before using the material. If there are no permits required from Homeland Security or CDC, then your package can be shipped. The location and approximate amounts of Biosafety Level 2 pathogens and select agents will be tracked by the Biosafety Officer and the Director of EHS.
- After the shipping entity receives CDC/USDA approval for the transfer, the Department of Biological Sciences Lab Manager will arrange for shipment. The shipment will be delivered to your department.
- Open the package in a biological safety cabinet, to examine the contents for damage.
- Update your inventory immediately including the date received, source of material, and any identifying characteristics. Sign the amended inventory log and send a copy to EHS Department.

The Office of Research, Grants and Contracts handles all **incoming** Material Transfer Agreements. Contact Mary Ucci for details.

IV. Classification of Hazardous Material

Biological materials that fall under the Dangerous Goods Regulations for shipping by air are classified in one of four different groups:

- Category A Infectious substances: Hazard Class 6.2, which are BSL-3 and BSL-4
- Category B Infectious Substance (previously called Diagnostic/Clinical specimens): Hazard Class 6.2
- Toxins: Hazard Class 6.1
- Some genetically modified organisms (GMOs) including microorganisms: Hazard Class 9 UN3245

These classifications are used to select the proper shipping procedures, see Section V. Shipping Category A & B Infectious Agents, Toxins, and some GMOs require attending a training session, see Section II.

See Appendix 1 Infectious Substance Classification Flow chart to help determine if a material falls under Category A or B Infectious Substances.

NOTE: If the material is also classified as a Select Agent, additional regulations apply, see Section E below.

The following materials are not classified as dangerous goods and are not subject to IATA regulations:

- Biological products which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals.
- Biological products which are certified by the USDA, FDA, or other national authority for use in the prevention, diagnosis, or treatment of disease in humans or animals, or for development, experimental or investigational purposes related thereto. **NOTE: If the product contains an infectious substance it must be shipped as Category A or B Infectious Substance.**
- Substances which do not contain infectious substances or substances that are unlikely to cause disease in humans or animals.
- Substances containing microorganisms which are non-pathogenic to humans or animals.
- Patient specimens for which there is minimal likelihood that pathogens are present.

Note: Patient specimens are material collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purpose such as research, diagnosis, investigational activities, disease treatment and prevention.

Note: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgement is required to determine if a substance is exempt. That judgement should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. If there is any reason to suspect that the specimen contains a pathogen, it cannot be shipped as exempt from Class 6.2 Hazardous Material.

- Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk.
- Environmental samples (including food and water samples) which are not considered to pose a significant risk of infection.
- Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests.
- Material collected for transfusion or transplantation.

- All human blood, human blood products and human cells must have a biohazard label (OSHA) on the sample on the primary containment but not on the outside of an "exempt human specimen".

Exempt substances do not require a Declaration of Dangerous Goods or hazardous material training. However, if the substance is shipped on dry ice the dangerous goods regulation for dry ice must be followed and training is still required.

USDA/APHIS permits may still be required even if IATA transportation regulations do not apply.

A. Category A Infectious Substances

Infectious substances are materials that are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (bacteria, viruses, rickettsiae, parasites, fungi) and other agents, such as prions, which can cause disease in humans or animals.

Category A Infectious Substances are agents which are transported in a form that, when exposure to it occurs, is capable of causing permanent disability or life threatening or fatal disease in otherwise healthy humans or animals. All material meeting these criteria **must** be shipped as Category A. See Appendix 6 for examples of Category A agents.

Note: Some of the materials on this list only need to be shipped as Category A if it is cultured. Cultures do not include patient samples. Patient samples are collected directly from the patient and are not propagated for diagnosis. When in doubt, ship as Category A

B. Biological Substances Category B (Previously Called Diagnostic/Clinical Specimens):

Category B Infectious Substances are biological materials that:

- do not meet criteria for inclusion in Category A
- are not exempt patient samples and are not included in the exemptions listed above

Category B substances are shipped under the proper shipping name: Biological Substance, Category B.

Any material listed in Appendix 6 cannot be shipped as Category B. This is a list of examples only and is not meant to include all materials forbidden as Category B. When in doubt, ship as Category A.

C. Non-infectious Exempt Patient Specimens

IATA (air transport) regulations allow for some patient specimens to be shipped as exempt from Dangerous Goods requirements. These regulations are adhered to by FedEx and can also be used for DHL/Airborne shipments.

Exempt patient specimens are those for which there is minimal likelihood that pathogens are present, but that does not mean these are not regulated.

Note: Patient specimens are material collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purpose such as research, diagnosis, investigational activities, disease treatment and prevention.

Note: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgement is required to determine if a substance is exempt. That judgement should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. If there is any reason to suspect that the specimen contains a pathogen, it cannot be shipped as exempt from Class 6.2 Hazardous Material.

Exempt substances do not require a Declaration of Dangerous Goods or hazardous material training. However, if the substance is shipped on dry ice the dangerous goods regulation for dry ice must be followed and training is still required.

Exempt patient specimens must be properly packaged.

D. Toxins

Toxins are material obtained from a plant, animal, fungal, or bacterial source that are toxic to humans or animals. Shipping of toxins falls under Hazardous Material regulations. If the toxin is contained in an infectious substance or if the toxin contains an infectious substance, it must be classified as an Infectious Substance, not a toxin. Packing Group (PG I, II, or III) criteria for toxins is based on severity of risk according to its LD₅₀. Shipping training is required. Toxins are Class 6.1.

E. Genetically Modified Organisms (GMOs)

Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Classifying GMOs for shipping:

- If a GMO meets the definition of a Category A or B Infectious Substance it must be classified as such.
- GMO/GMMOs, which do not meet the definition of infectious substances, must be assigned to class 9 UN3245 if shipped by air.

Individual countries have strict regulations regarding GMOs. Be sure to become informed of the receiving country's regulations.

F. Select Agents

The federal government regulates the use, handling, and transport of certain biological materials considered to be potential bioterrorism agents.

Select Agents are classified as either Infectious Substances or Toxins. Follow IATA packing and labeling instructions according to its classification. Transport of Select Agents is subject to the following additional regulations; The Department of Health and Human Services' Regulation 42 Part 73, Possession, Use, and Transfer of Select Agents and Toxins; Final Rule, http://www.cdc.gov/od/sap/pdfs/42_cfr_73_final_rule.pdf, the USDA's Agricultural Bioterrorism Protection Act, and university policy.

Notify the university's Biosafety Officer if you wish to ship, receive, or transfer any quantity of Select Agents. This includes on campus transfers. All infectious Select Agents and Select Agent toxins, in quantities above CDC exemption quantities, require DEHS and CDC or USDA approval **prior to shipping**. The Biosafety Officer is responsible for tracking all transfers of Select Agents both on and off campus, documenting and reporting transfers to CDC or the USDA, verifying that transfers are only made between registered facilities, maintaining an accurate Select Agent inventory, and notifying CDC or USDA of suspicious activity or requests regarding the transfer of Select Agents.

Federally Regulated Quantities of Select Agents

CDC or USDA must approve all shipments of Select Agents between entities. Both the receiving and the shipping entity must have a current Select Agent Certificate of Registration. The receiving entity is responsible for initiating the approval process. All documentation should be forwarded to Safety and Emergency Management.

Steps to ship a Select Agent:

- Contact the Department of Biological Sciences Lab Manager to coordinate shipment and CDC/USDA approval with the receiving entity.
- After CDC/USDA approval has been received to ship the material, the material will remain in the shipping department for pick-up.
- Immediately update your inventory including the date sent and signature of the authorized individual who removed the material from storage. Send a copy to Safety and Emergency Management.
- Notify Safety and Emergency Management any time a request is received for a Select Agent even if you do not agree to ship the material.

Steps to receive a Select Agent:

- Call the Biosafety Officer to verify that the university's Certificate of registration includes your lab and the desired Select Agent material. If it does not, you will need to fill out a Biohazardous Registration Form that will be reviewed by NLU's Biosafety Officer. If approved, and if there are no permits required from Homeland Security or CDC, then your package can be shipped. Level 2 pathogens and select agents will be tracked by the Biosafety Officer and the Director of Safety and emergency Management.
- After the shipping entity receives CDC/USDA approval for the transfer, the Department of Biological Sciences Lab Manager will arrange for shipment. The shipment will be delivered to your department.

- Open the package in a biological safety cabinet, to examine the contents for damage.
- Update your inventory immediately including the date received, source of material, and any identifying characteristics. Sign the amended inventory log and send a copy to Safety and Emergency Management.

Federally Exempt Quantities of Select Agent Toxins

Contact Safety and Emergency Management prior to shipping or receiving any quantity of Select Agent Toxins. Exempt quantities of Select Agent toxins do not require submission of Report of Transfer Form EA101 to CDC/USDA but are still tracked by the Biosafety Officer in order to keep the university's biological material inventory up-to-date. Report to Safety and Emergency Management how much toxin is shipped, when it was shipped, and to whom it was shipped.

On Campus Transfer of Select Agents

Follow all transfer of biological material guidelines in Section VIII. In addition:

- transfers can only be made between laboratories that are registered for that particular Select Agent
- only authorized individuals can make transfers between labs
- the receiving lab must have an authorized individual present to accept the material
- Document the transfer by submitting a Record of Transfer of Select Agent to the Biosafety Officer, copy Safety and Emergency Management.
- Both transferring and receiving labs must immediately update their inventory including the date of transfer and a signature of the authorized individual making the transfer.

V. Packing Instructions

The following information is an overview, not comprehensive instructions.

Hazard Class designations and packing groups are used to determine the packing instructions that must be followed for shipping. See Appendix 4 for a summary of shipment types, proper shipping names, UN numbers, hazard class, and packing instruction numbers.

[FedEx's Web site](#) gives instructions on filling out their U.S. Airbill required for all shipments.

Packages displaying UN markings referred to in the following packing instructions meet the United Nations (UN) packaging specifications and performance testing.

A. Category A Infectious Substances: Packing Instruction 620

Infectious substances require a Shipper's Declaration for Dangerous Goods. [FedEx's Web site](#), provides helpful information on filling out the Shipper's Declaration for Dangerous Goods.

General Requirements

- The Consignee section of the Shipper's Declaration for Dangerous Goods must include a name and phone number for the person responsible for the shipment.
- Proper shipping names must be indicated on the outside of the package; for UN 2814 - Infectious Substance Affecting Humans and for UN 2900 - Infectious Substance Affecting Animals.
- Technical names may be omitted from the proper shipping name on the outside of the package.
- If the technical name of the pathogen is not known, you may omit the technical name on the Shipper's Declaration for Dangerous Goods and place "Suspected Category A infectious Substance" in parenthesis following the proper shipping name.
- The Additional Handling Information box on the Shipper's Declaration for Dangerous Goods must include "Emergency Telephone Number 1-800-424-9300". (ChemTrec)
- A SDS sheet must be on file with ChemTrec prior to shipping
- Enclose an itemized list of contents between the secondary packaging and the outer packaging.
- If an overpack is used for dry ice, infectious substance markings need to go on the outer box along with the statement "Inner packages comply with prescribed specifications".

Inner Packaging Requirements

- Primary receptacles must be watertight.
- Secondary packaging must be watertight.
- An itemized list of the contents enclosed between the secondary packaging and the outer packaging
- Absorbent material must be placed between the primary receptacle(s) and secondary packaging and be of sufficient quantity to absorb the entire contents of the primary receptacle(s).

Outer Packaging Requirements

- Must be rigid
- Package must be at least four inches in the smallest overall external dimension.
- Package must be properly labeled.
- Package must pass required testing and be marked with UN marking for CLASS 6.2

B. Category B Infectious Substances (Previously Called Diagnostic/Clinical Specimens): Packing Instruction 650

Shipments of Category B Infectious Substances do not require a Dangerous Goods Declaration.

Packaging must be of good quality, strong enough to withstand normal transport conditions including manual or mechanical handling, vibration, changes in temperature, humidity, or pressure. Packaging must have a:

- a leak-proof primary receptacle not containing more than 1 liter or 4 kg

- a leak-proof secondary package
- a rigid outer package not containing more than 4 liters or 4 kg
- Outer package must have a diamond-shaped label with UN3373 in letters at least 6mm high and the proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" adjacent to the diamond-shaped label.
- Outer package must have one side with a minimum of 100mm X100mm.
- Include name, address, and telephone number of responsible party either on the air waybill or on the package.
- Package may include 30ml or less of substances in Classes 3, 8, or 9 if required to maintain the viability of the sample, preserve the sample, or reduce the hazard of the sample. Remember, these packing instructions are for air shipments only.

The completed package must be capable of passing a drop test of at least 1.2 meters. An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

C. Non-infectious Exempt Patient Specimens

- Use a leak-proof primary receptacle.
- When multiple fragile primary receptacles are placed in a single secondary package they must be either individually wrapped or otherwise separated to prevent contact between them.
- For liquid specimens, place sufficient absorbent material between the primary and secondary package to be able to absorb the entire volume.
- Use a leak-proof secondary receptacle.
- Use an outer package of adequate strength for its capacity, mass and intended use.
- The outer package must have at least one surface with minimum dimensions of 100mm x 100mm. If the outer package is smaller, place it in a shipping envelope.
- Mark the outer package "Exempt Human Specimen" or "Exempt Animal Specimen".
- For the FedEx Airbill question "Does shipment contain dangerous goods?" check no.

D. Toxins: Packing Instructions Vary

Biologically derived toxins that contain infectious substances or toxins that are contained in an infectious substance must be shipped as a Risk Class 6.2 Infectious Substances. All other biologically derived toxins fall under Risk Class 6.1. Risk Class designations and packing groups are used to determine the packing instructions that must be followed for shipping. Packing Group criteria for toxins is based on severity of risk according to LD₅₀.

Very small amounts of toxins in Risk Class 6.1 may be shipped as "Dangerous Goods in Excepted Quantities." "Excepted Quantities" are accepted from the marking, labeling, and documentation requirements for shipping Dangerous Goods. No toxic label or Shipper's Declaration for Dangerous Goods are needed. On the FedEx waybill, check the box marked "Yes, does not require declaration of dangerous goods." If shipped by ground, the outer packaging must have the marking: "This package conforms to 49 CFR 173.4." If shipped by air, package must have a special handling label for "Excepted Quantities" indicating the hazard class and UN number.

Any quantity of inhalation toxins in Packing Group I may not follow "Excepted Quantities" procedures.

All "Dangerous Goods in Excepted Quantities" must be considered material that is permitted for shipping on passenger aircraft. "Dangerous Goods in Excepted Quantities" cannot be transported in either checked or carry-on baggage or shipped via mail.

If shipping a quantity above the dangerous goods "Excepted Quantities", a shipper's Declaration for Dangerous Goods is required, toxic labels need to be attached, and package must be marked as meeting with UN performance requirements.

E. Genetically Modified Organisms: Packing Instruction 959

IATA regulated GMOs fall under Hazard Class 9, UN3245 and must follow Packing Instruction 959.

- Hazardous Material shipping training is required.
- Pack same as infectious materials (Packing Instruction 620) but package does not require testing.
- The maximum quantity in a primary receptacle must not exceed 100ml or 100g.

F. Dry Ice: Packing Instruction 954

- box must be able to release gas build-up
- indicate the dry ice weight in kg on both the waybill and on the box
- include the marking "Dry Ice, UN1845" on the box
- place a Class 9 label on the box

G. Liquid Nitrogen

Properly handled liquid nitrogen "dry shippers" can be transported without any additional regulations. Be sure that all the liquid nitrogen has been removed from the shipper before transport. Failure to do so can result in substantial fines. For further information, see [University of Washington EH&S "Tips for Dry Shipping"](#).

H. Transporting Infectious Substances Safely

FedEx - General guidelines for packaging, marking and labeling clinical samples and biological substance, Category B,
<http://www.fedex.com/us/services/packageshipment/index.html?CMP=PAC-GTS-VURL008> (see **Pack like a Pro** in menu bar)

VI. International Shipment Regulations and Permits

The following agencies may require a permit for international shipments. Expect to need more preparation time to send or receive foreign shipments in order to process the required paperwork.

The U.S. receiver (importer) is responsible for the package being sent to them from a foreign country. The receiver must assure that the foreign shipper has packed and labeled the material according to U.S. Public Health Service and IATA regulations. The importer must send the proper shipping labels and a copy of the import permit to the shipper.

Taking care to comply with foreign import regulations should prevent packages from being held at customs or denied entry. As an extra precaution, you may wish to find out what carrier the shipper will use and what day and at what port your package is expected to arrive. Contact the U.S. Customs Office at that port and inform them that a package will be arriving for you and what the contents will be. Ask them to contact you immediately if there are any questions

A. USDA/APHIS

Section III covered USDA and CDC permits required to ship/receive biological material both within the U.S. and from a foreign country.

Be aware that Genetically Modified (Engineered) Organisms that are not controlled, or subject to regulations, may be held by customs because of the similarity of the organism to other organisms that are regulated. To prevent an international shipment from being stopped at the port of entry:

- include a courtesy form letter in the shipment, see Appendix 5
- as another option, application may be made for a Courtesy Permit (APHIS Form 2000) <http://www.aphis.usda.gov/brs/pdf/2000.pdf>. Indicate on the form that the data is being submitted as a request for a courtesy permit. Include a statement explaining why you believe the organism or product does not come within the definition of a regulated article. The application must be submitted at least 60 days prior to the time the courtesy permit is sought.

B. Department of Commerce

Exports of designated biological agents and toxins that have the potential to pose a threat to human, animal or plant life may require a license from the U.S. Department of Commerce, Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than “select agents,” and **researchers must consult with the Director of Safety and Emergency management to conduct a separate review to determine if a BIS export license is required.**

BIS may require a license for the export of:

- Designated human, animal and plant pathogens, zoonoses and toxins
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with the pathogenicity of a controlled organism or that code for a controlled toxin
- Genetic material and products which might be used for culture of large amounts of agents

These regulations are chemical and biological weapon controls and generally require licenses for all locations other than Canada. (Canada requires the recipient to have an import permit, see E. below.)

Obtaining a license is a long process, and a license may be denied at the discretion of BIS.

Researchers should contact the Export Controls Officer as early as possible, should build in three (3) months' lead-time to initiate foreign shipments of material requiring a license, and should not commit to delivery prior to issuance of a license.

C. U.S. Fish and Wildlife

A permit may be required by the U.S. Fish and Wildlife to export/import non-agricultural biological samples, including artificially propagated plants and endangered species. Call 1-800-770-0150 or go to <http://www.fws.gov/permits/> to determine if your shipment needs a permit.

D. Food and Drug Administration (FDA)

The FDA controls most food and other products that enter the U.S. Foods (except for certain meats and poultry products), drugs (human, animal and biological), cosmetics, medical devices and radiation emitting devices, etc., offered for entry into the United States require a permit or registration. Go to <http://www.fda.gov/ora/import/> to determine if your request for shipment of one of these products from another country is regulated.

E. Canadian Import Regulations

Shipments of human, animal, or plant pathogens to Canada will require a Canadian import permit. You will need to allow sufficient lead-time for the Canadian recipient to obtain the proper permits.

Packaging of shipments will need to comply with the Canadian Transport of Dangerous Goods Regulations. See the Transport Canada Web site for details, <http://www.tc.gc.ca/eng/tdg/clear-tofc-211.htm>.

VII. Receipt of Leaking, Damaged, or Suspicious Packages

A. Leaking or Damaged Package

Departments/laboratories that regularly receive shipments of biological materials should have a written procedure for the receipt of leaking or damaged packages.

If you receive a biological material package that is leaking or has broken containers inside, call Safety and Emergency Management.

- consult on clean-up procedures
- determine if any outside agencies need to be notified
- advise on disposal of the box and its contents

If any material is spilled on a person, remove contaminated clothing and shoes, flush the skin for 15 minutes, and seek medical assistance immediately.

While waiting for help to arrive:

- do not touch or walk through spill area
- isolate the spill or leak area
- keep unauthorized personnel away
- obtain identity of the substance(s) involved

B. Suspicious Package

See the CDC Web site <http://www.bt.cdc.gov/DocumentsApp/HAN50.pdf> for guidelines on handling suspicious packages or envelopes.

VIII. Transporting Infectious Substances by Ground

When these materials are transported, Department of Transportation (DOT) Hazardous Materials Regulations (HMR) may apply and are extremely complex in nature. Laboratory personnel must properly package, transport, and handle any Infectious substances that are used in their research. Labeling using the universal biohazard symbol is also required for any infectious biological materials in order to prevent accidental exposure to unsuspecting personnel who may be exposed to the biological material (e.g., couriers, administrative staff, and janitors).

A. Packaging and Training Requirements

The following packaging requirements apply to **all ground transport** of infectious substances prepared for transport either on-grounds or off-grounds irrespective of the mode of transportation.

Category A: It is permissible to hand-carry between buildings. IATA/DOT Packing Instruction PI 620 must be followed. If the distance is too great for carrying by hand, materials must be shipped by air with a commercial carrier (e.g. FedEx, DHL). Cat.A material must **NEVER** be transported by ground in a motor vehicle.

Category B: must follow the IATA/DOT Packaging Instruction, PI 650.

Exempt Patient/Animal Specimens²:

- Triple-packaged (i.e., as in Category B with leak proof primary and secondary containers).
- Absorbent material for liquids, and a rigid outer container.
- If materials are human in origin, a biohazard symbol must be placed on either the secondary container or the outer container to meet OSHA compliance (29 CFR 1910.1030).

Dry Ice: Package must be labeled “Dry Ice” on two sides. No Training requirements for Ground.

B. Means of Transport

The following are means by which Infectious Substances may be legally transported within and around the University. The DOT Hazardous Material Regulations (49 CFR Parts 171-180) regulates

the movement of Division 6.2 Infectious Substances and are regulated when carriage is considered to be "in commerce".

Transport in Personal or University Vehicle

Under NO circumstances may public transportation be used for transport of Hazardous Materials.

In general, movement or ground transport of regulated materials is covered by the DOT's Hazardous Materials Regulations (HMR) only when they are considered to be "in commerce." If a Division 6.2 infectious substances is transported in a personal or university (i.e., government) vehicle for use in university activities (projects, research, etc.) it is generally not considered to be "in commerce." However, these personnel must

1. have a valid driver's license,
2. be authorized to use a University vehicle,
3. use the proper containment and packaging materials in-route and
4. Be trained and authorized to handle and transport hazardous materials within University property.
5. Should use a University vehicle when available.

***Note:** If using a personal vehicle to transport the individual should consult with his/her personal insurance policy regarding liability and coverage in this instance.

Transport by contracted carrier

Commercial or Private carriers (i.e., commercial transport companies) are subject to the HMR. These include companies such as FedEx, DHL as well as medical couriers etc. Transport of infectious substances to **other institutions or entities** such as another university, a waste disposal facility, or a return to the manufacturer should only be done by DOT licensed hazardous materials carriers to another location via a public thoroughfare. When Principal Investigators leave an institution, the research may be transferred to the new institution, which then becomes the owner; however, the original institution is legally responsible for the shipment to the new institution. Contact the Biological Science Lab Manager for consultation.

Category A and Category B Infectious Substance should be consigned by air (exempt human specimens are exempt but regulated). Assurance from the carrier must be given that DOT regulations are being met.

As of October 1, 2006 the DOT regulations state that Materials of Trade (MOTS) see 49 CFR §173.6 exceptions **only apply to patient specimens** or those samples that would be otherwise considered Category B that are contained in a human (patient) or animal sample (no cultures). Therefore personal or dedicated vehicle transport in addition to carrier transport can only use a MOTS exception for Patient Specimens.

Transport (hand-carry) between University labs or buildings through public areas

Infectious substances must be transported or moved between laboratories in way as to prevent spills and accidental exposure or release. Include the following:

- Provide your contact information: name, address, and phone on the outside of the package
- Place material in a primary (specimen) container that is leak-proof and secured with a tight-fitting cap, parafilm, or lab tape.
- Place sufficient absorbent material (diapers, absorbent towels, pads) around the primary containers to contain all the liquid if a breakage occurs.
- Place the primary containers in a secondary transport container that is also sealed and labeled with a biohazard symbol.
- Rigid outer package of good quality strong enough to withstand normal transport conditions.³
- If transporting on dry ice label the package "Dry Ice" on two sides.
- Materials packed in this way may be moved on a cart or other device between rooms or buildings.
- Lab coats and gloves are not appropriate attire for moving between buildings or transporting material in tunnels. Wear PPE that is appropriate for movement through public areas (e.g. lab coat and/or single-glove technique where appropriate -- it is not advisable to wear gloves when using public elevators, however, a single-glove technique may be employed when moving through laboratory floors).
- Leave the material with a known responsible individual in the receiving lab. Do not leave the material unattended or with an unknown individual.

References

1) The handling and movement of hazardous materials within a building between rooms is governed by:

29 CFR 1910.1030, Bloodborne Pathogens Standard

29 CFR Part 1910.1200, Hazard Communication

29 CFR Part 1910.1450, Occupational Exposure to Hazardous Materials in Laboratories

40 CFR Part 262, Standard Applicable to Generators of Hazardous Waste.

The ground (vehicle) transport of hazardous materials between buildings or off-site to other entities is governed by:

49 CFR Parts 171-180, Hazardous Materials Regulations 171.1 (d)

2) Functions not subject to the requirements of the HMR

The following are examples of activities to which the HMR do not apply:

- Transportation of a hazardous material in a motor vehicle, aircraft, or vessel operated by a Federal, state, or local government employee solely for noncommercial Federal, state, or local government purposes.
- Transportation of a hazardous material by an individual for non-commercial purposes in a private motor vehicle, including a leased or rented motor vehicle.

- Air transport is regulated by the IATA Dangerous Good Regulations, 49th Ed. 2008.

3) Important Shipping Information Links

[Federal Aviation Administration, Dangerous Goods Program](#)

[Federal Motor Carrier Safety Administration, US Department of Transportation](#)

[International Air Transport Association](#)

[Office of Research Services, National Institutes of Health - Shipping Hazardous Materials Safely](#)

[Research and Special Programs Administration, US Department of Transportation](#)

¹ The amount of Division 6.2 material in a combination packaging must conform to the following limitations: (A) one or more inner packaging, each of which may not contain more than 0.5 kg (1.1 lbs) or 0.5 L (17 ounces), and an outer packaging containing not more than 4 kg (8.8 lbs) or 4 L (1 gallon); or (B) A single inner packaging containing not more than 16 kg (35.2 lbs) or 16 L (4.2 gallons) in a single outer packaging.

² DOT's "Patient Specimen" definition and exemption differs from the IATA definition when materials are shipped by air. Contact EHS Biosafety for more information if shipping by air.

³ Pressure-tested (i.e., 95 kPa) secondary containers not required for ground transport

Adapted from the University of Minnesota website.

Appendix Index

Appendix 1 – Infections Substance Classification Flow Chart

Appendix 2 - Transportation of Infectious Substances/Import-Export

Appendix 3 - Animal and Animal Product Importation

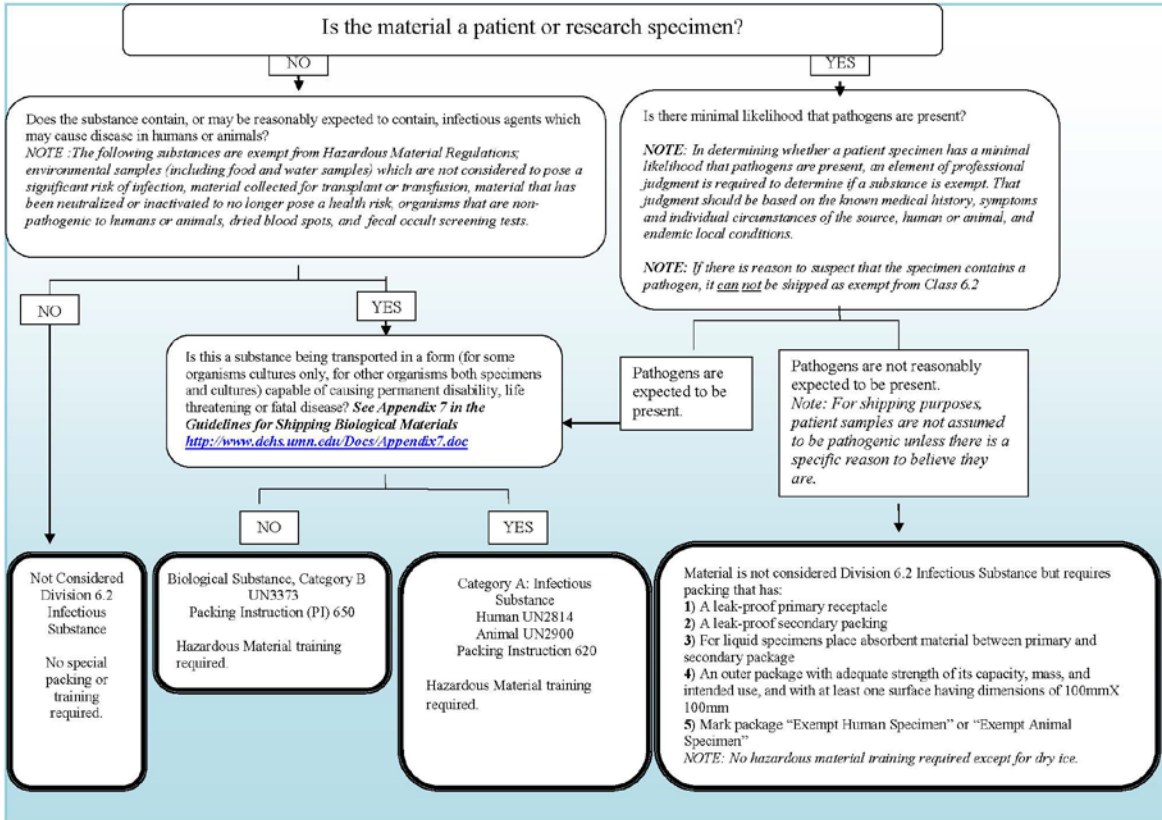
Appendix 4 - Summary of IATA (International Air Transport Association) Shipping Information

Appendix 5 – USDA BRS – APHIS Notification

Appendix 7 – Examples of Infectious Substances

Appendix 1

Shipping Classification Guide January 2015 Division 6.2 Infectious substances, GMOs and Dry Ice



Appendix 2

Transportation of Infectious Substances

An infectious substance is a material known to contain or reasonably expected to contain a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals. Infectious substances may exist as purified and concentrated cultures, but may also be present in a variety of materials, such as body fluids or tissues. Transportation of infectious substances and materials that are known or suspected to contain them are regulated as hazardous materials by the United State Department of Transportation (DOT), foreign governments, and the International Civil Aviation Organization, and their transportation is subject to regulatory controls. For transport purposes, the term “infectious substance” is understood to include the term “etiologic agent.”

Transportation Regulations

International and domestic transport regulations for infectious substances are designed to prevent the release of these materials in transit to protect the public, workers, property, and the environment from the harmful effects that may occur from exposure to these materials. Protection is achieved through rigorous packaging requirements and hazard communication. Packages must be designed to withstand rough handling and other forces experienced in transportation, such as changes in air pressure and temperature, vibration, stacking, and moisture. Hazard communication includes shipping papers, labels, markings on the outside of packagings, and other information necessary to enable transport workers and emergency response personnel to correctly identify the material and respond efficiently in an emergency situation. In addition, shippers and carriers must be trained on these regulations so they can properly prepare shipments and recognize and respond to the risks posed by these materials.

Select agents include infectious substances that have been identified by the CDC and the USDA as having the potential to pose a severe threat to public health and safety. Persons who offer for transportation or transport select agents in commerce in the United States must develop and implement security plans for such transportation. A security plan must include an assessment of the possible transportation security risks for materials covered by the security plan and specific measures to reduce or eliminate the assessed risks. At a minimum, a security plan must include measures to address those risks associated with personnel security, en route security, and unauthorized access.

Regulations

Department of Transportation. 49 CFR Part 171-180, Hazardous Materials Regulations. Applies to the shipment of infectious substances in commercial transportation within the United States. Information on these regulations is available at: <http://www.phmsa.dot.gov/hazmat>.

United States Postal Service (USPS). 39 CFR Part 20, International Postal Service (International Mail Manual), and Part 111, General Information on Postal Service (Domestic Mail Manual). Regulations on transporting infectious substances through the USPS are codified in Section 601.10.17 of the Domestic Mail Manual and Section 135 of the International Mail Manual. A copy of the Domestic and International Mail Manuals may be obtained from the U.S. Government Printing Office by calling Monday through Friday, 7:30 a.m. – 9:00 p.m. EST: (202) 512-1800; toll free (866) 512-1800; or at the USPS Web site: <http://bookstore.gpo.gov/>.

Occupational Health and Safety Administration (OSHA). 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens. These regulations provide minimal packaging and labeling for blood and body fluid when transported within a laboratory or outside of it. Information may be obtained from your local OSHA office or at the OSHA Web site: <http://www.osha.gov>.

Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions). International Civil Aviation Organization (ICAO). Applies to the shipment of infectious substances by air and is recognized in the United States and by most countries worldwide. A copy of these regulations may be obtained from the ICAO Document Sales Unit at (514) 954-8022, fax: (514) 954-6769; e-mail: sales_unit@icao.int; or from the ICAO Web site: <http://www.icao.int>.

Dangerous Goods Regulations. International Air Transport Association (IATA). These regulations are issued

by an airline association, are based on the ICAO Technical Instructions, and are followed by most airline carriers. A copy of these regulations is available at: <http://www.iata.org/index.htm> or <http://www.who.int/en/>; or by contacting the IATA Customer Care office at: telephone: +1 (514) 390 6726; fax: +1 (514) 874 9659; for Canada and USA (800) 716-6326 (toll free); Europe, Africa and Middle East +41 (22) 770 2751; fax: +41 (22) 770 2674; TTY: YMQTPXB, or e-mail: custserv@iata.org.

Transfers

Regulations governing the transfer of biological agents are designed to ensure that possession of these agents is in the best interest of the public and the nation. These regulations require documentation of personnel, facilities, justification of need and pre-approval of the transfer by a federal authority. The following regulations apply to this category:

Importation of Etiologic Agents of Human Disease. 42 CFR Part 71 Foreign Quarantine. Part 71.54 Etiological Agents, Hosts and Vectors. This regulation requires an import permit from the CDC for importation of etiologic agents, hosts or vectors of human disease. The regulation, application form, and additional guidance is available at the CDC Web site: <http://www.cdc.gov/od/eaipp>.

Completed application forms may be submitted to the CDC Etiologic Agent Import Permit Program by fax: (404) 718-2093, or by mail:

Centers for Disease Control and Prevention
Etiologic Agent Import Permit Program
1600 Clifton Road, N.E., Mailstop A-46
Atlanta, GA 30333

Importation of select agents or toxins into the U.S. also requires the intended recipient to be registered with the Select Agent Program and submit an APHIS/ CDC Form 2 to obtain approval to import the select agent or toxin prior to each importation event (see 42 CFR 73 and/or 9 CFR 121). More information regarding select agents and toxins is available at: www.selectagents.gov.

Importation of Etiologic Agents of Livestock, Poultry and Other Animal Diseases and Other Materials Derived from Livestock, Poultry or Other Animal. 9 CFR Parts 122. Organisms and Vectors. The USDA, APHIS, Veterinary Services (VS) requires that a permit be issued prior to the importation or domestic transfer (interstate movement) of etiologic disease agents of livestock, poultry, other animals. Information may be obtained at (301) 734-5960, or from the USDA Web site: http://www.aphis.usda.gov/animal_health. Completed permit applications may be submitted electronically at: http://www.aphis.usda.gov/permits/learn_epermits.shtml; or by fax to (301) 734-3652; or by mail to:

USDA APHIS VS
National Center for Import and Export 4700 River Road
Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737

Importation of select agents into the United States also requires the intended recipient to be registered with the Select Agent Program and submit an APHIS/ CDC Form 2 to obtain approval to import the select agent or toxin prior to each importation event (see 42 CFR 73 and/or 9 CFR 121). More information regarding select agents and toxins is available at: http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml.

Importation of Plant Pests 7 CFR Part 330. Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. This regulation requires a permit for movement into or through the United States, or interstate any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Information can be obtained by calling (877) 770-5990 or at the USDA Web site: <http://www.aphis.usda.gov/permits>.

Export of Etiologic Agents of Humans, Animals, Plants and Related Materials; Department of Commerce (DoC); 5 CFR Parts 730 to 799. This regulation requires that exporters of a wide variety of etiologic agents of human, plant and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents, will require an export license. Information may be obtained by calling the DoC Bureau of Export Administration

at (202) 482-4811, or at the DoC Web site: <http://www.ntis.gov/products/export-regs.aspx>; or at <http://www.access.gpo.gov/bis/index.html>; and <http://www.bis.doc.gov>.

Transfer of CDC Select Agents and Toxins. 42 CFR Part 73 Possession, Use, and Transfer of Select Agents and Toxins. The CDC regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. The CDC Select Agent Program registers all laboratories and other entities in the United States that possess, use, or transfer a select agent or toxin. Entities transferring or receiving select agents and toxins must be registered with the Select Agent Program and submit an APHIS/CDC Form 2 (see 42 CFR 73 and/or 9 CFR 121) to obtain approval prior to transfer of a select agent or toxin. The regulations, Select Agent Program forms, and additional guidance is available at the CDC Web site: www.selectagents.gov.

Transfer of USDA Select Agents and Toxins. 9 CFR Part 121 Possession, Use, and Transfer of Select Agents and Toxins. The USDA, APHIS, VS regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to animal health or animal products. The VS Select Agent Program oversees these activities and registers all laboratories and other entities in the U.S. that possess, use, or transfer a VS select agent or toxin. Entities transferring or receiving select agents and toxins must be registered with either the CDC or APHIS Select Agent Program, and submit an APHIS/CDC Form 2 (see 42 CFR 73 and/or 9 CFR 121) to obtain approval prior to transfer of a select agent or toxin. The regulations, Select Agent Program forms, and additional guidance is available at the APHIS Web site: http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml.

Transfer of USDA Plant Pests

The movement of Plant Pests is regulated under two distinct and separate regulations: (1) 7 CFR Part 331. Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; and (2) 7 CFR Part 330 Federal Plant Pest Regulations; General; Plant Pests; Soil; Stone and Quarry Products; Garbage. The regulation found at 7 CFR Part 331 requires an approved Transfer Form (APHIS/CDC Form 2) prior to importation, interstate, or intrastate movement of a Select Agent Plant Pest. In addition, under 7 CFR Part 330, the movement of a Plant Pest also requires a permit for movement into or through the United States, or interstate any plant pest or a regulated product, article, or means of conveyance in accordance with this part. Information can be obtained by calling (301) 734-5960 or at the USDA Web site: http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml.

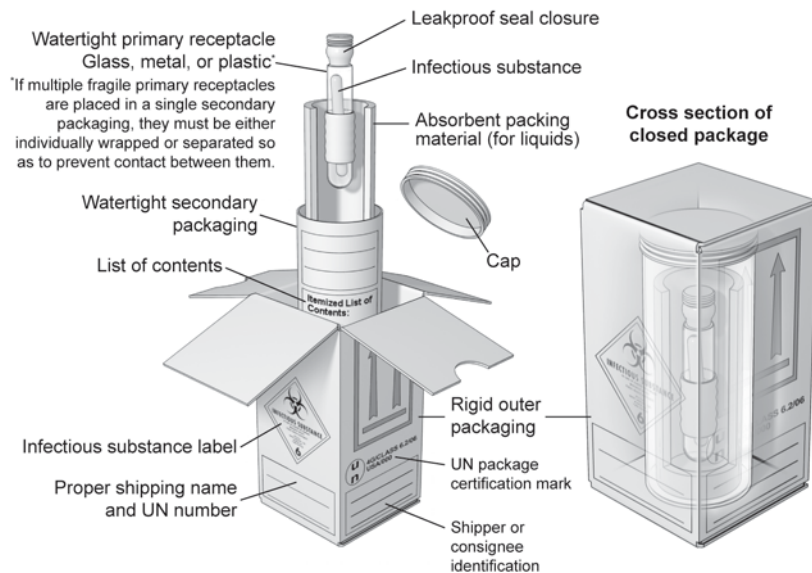
General DOT Packaging Requirements for Transport of Infectious Substances by Aircraft

The DOT packagings for transporting infectious substances by aircraft are required by domestic and international aircraft carriers, and are the basis for infectious substance packagings for motor vehicle, railcar, and vessel transport. The following is a summary of each packaging type and related transportation requirements.

Category A Infectious Substance (UN 2814 and UN 2900): Figure 1. A Category A material is an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Category A infectious substances are assigned to identification number “UN 2814” for substances that cause disease in humans or in both humans and animals, or “UN 2900” for substances that cause disease in animals only.

Figure 1 shows an example of the UN standard triple packaging system for materials known or suspected of being a Category A infectious substance. The package consists of a watertight primary receptacle or receptacles; a watertight secondary packaging; for liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles; and a rigid outer packaging of adequate strength for its capacity, mass, and intended use. Each surface of the external dimension of the packaging must be 100 mm (3.9 inches) or more. The completed package must pass specific performance tests, including a drop test and a water-spray test, and must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The completed package must also be capable of withstanding, without leakage, temperatures in the range of -40°C to +55°C (-40°F to 131°F). The completed package must be marked “Infectious substances, affecting humans, UN 2814” or “Infectious substances, affecting animals, UN 2900” and labeled with a Division 6.2 (infectious substance) label. In addition, the package must be accompanied by appropriate shipping documentation, including a shipping paper and emergency response information.

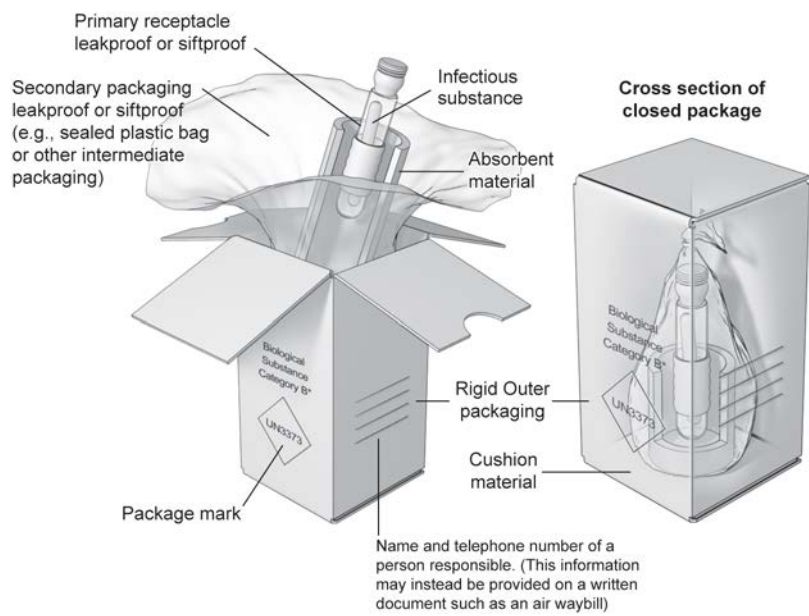
Figure 1. A Category A UN Standard Triple Packaging



Biological specimen, Category B (UN 3373): Figure 2. (previously known as Clinical specimen and Diagnostic Specimen). A Category B infectious substance is one that does not meet the criteria for inclusion in Category A. A Category B infectious substance does not cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. The proper shipping name for a Category B infectious substance, “Biological specimen, Category B,” is assigned to identification number “UN 3373.” The proper shipping names “Diagnostic specimen” and “Clinical specimen” may no longer be used (as of January 1, 2007).

Figure 2 shows an example of the triple packaging system for materials known or suspected of containing a Category B infectious substance. A Category B infectious substance must be placed in a packaging consisting of a leak proof primary receptacle, leak proof secondary packaging, and rigid outer packaging. At least one surface of the outer packaging must have a minimum dimension of 100 mm by 100 mm (3.9 inches). The packaging must be of good quality and strong enough to withstand the shocks and loadings normally encountered during transportation. For liquid materials, the secondary packaging must contain absorbent material in sufficient quantities to absorb the entire contents of all primary receptacles. The primary or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of 95 kPa. The package must be constructed and closed to prevent any loss of contents that might be caused under normal transportation conditions by vibration or changes in temperature, humidity, or pressure. The completed package must be capable of passing a 1.2-meter (3.9 feet) drop test. The package must be marked with a diamond-shaped marking containing the identification number “UN 3373” and with the proper shipping name “Biological substance, Category B.” In addition, the name, address, and telephone number of a person knowledgeable about the material must be provided on a written document, such as an air waybill, or on the package itself.

Figure 2. A Category B Non-specification Triple Packaging



Import Export

APHIS plays a vital role in ensuring the free flow of agricultural trade by keeping U.S. agricultural industries free from pests and diseases and certifying that the millions of U.S. agricultural and food products shipped to markets abroad meet the importing countries' entry requirements. APHIS makes sure that all imported agricultural products shipped to the United States from abroad meet the Agency's entry requirements to exclude pests and diseases of agriculture.

APHIS also keeps export markets open for American agricultural products by working to eliminate unjustified sanitary or phytosanitary (SPS) barriers - that is, concerns involving plant and animal health - raised by U.S. trading partners. APHIS' team of technical experts, based in the United States and abroad, includes scientists, veterinarians, pathologists, and entomologists that advocate on behalf of U.S. agriculture. They build relationships with their agricultural health and regulatory counterparts in other countries and use scientific principles to make the case for American agricultural exports, explaining to foreign officials why U.S. commodities are safe to import. APHIS played a direct role in opening new markets and retaining and expanding existing market access for U.S. agricultural products worth billions of dollars annually.

What are you **IMPORTING** into the United States?

- [Food and Agricultural Products](#) (Factsheet)
This factsheet is available in Amharic, Arabic, Burmese, Simplified Chinese, Traditional Chinese, Japanese, Korean, Lao, Polish, Russian, Spanish, Vietnamese >> [more](#).
- [Animal or Animal Product](#)
 - [State Regulations and Import Requirements](#)
- [Organism and Vectors](#)
- [Organism and Soil](#)
- [Plants or Plant Products](#)
 - [View Electronic Manuals](#)
This web site contains an alphabetized list of Plant Protection and Quarantine manuals in electronic format
- [Veterinary Service Forms](#)

What are you **EXPORTING** from the United States?

- [Animal or Animal Products](#)
 - [International Animal Export Regulations \(IREGs\)](#)
 - [International Products Export Regulations \(IREGs\)](#)
- [Plants or Plant Products](#)

Related Topics

[Biotechnology Import and Export Information](#)

APHIS' Biotechnology Regulatory Services (BRS) requires a permit or notification for the import of certain genetically engineered organisms.

[Phytosanitary Issues Management](#)

The Phytosanitary Issues Management (PIM) unit facilitates and negotiates, through the use of scientifically based processes, the safe export and import of agricultural commodities.

[APHIS Regulated Garbage Website](#)

APHIS collaborates with officials in U.S. Customs and Border Protection and Plant Protection and Quarantine personnel to ensure appropriate and consistent handling of regulated garbage at U.S. ports of entry and elsewhere.

[Trade](#)

The Animal and Plant Health Inspection Service (APHIS) plays a vital role in ensuring the free flow of agricultural trade ([learn more](#)).

Appendix 3

Animal and Animal Product Import

No Import Permit Required

These materials **do not require a USDA import permit**, but will be reviewed at the port of entry by USDA inspectors.

- 1100 Human Pharmaceuticals and Human Vaccines Containing Animal Components
- 1101 Human and 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
- 1120 Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)
- 1121 Test Kits
- 1122 Animal Feeds, Feed Supplements, and Pre-Mixes

Section B

B. Centers for Disease Control (CDC)

The Department of Health and Human Services, through the CDC, regulates the transport of biological materials that could cause illness in humans, including pathogens and biological toxins.

Human infectious substances. In general, a permit is needed for any infectious agent known or suspected to cause disease in humans that you wish to import into the United States. In some cases subsequent distribution of an agent (i.e., SARS-CoV, select agents, viruses requiring BSL-4 containment) is prohibited within the United States and requires CDC authorization/permit prior to transfer to another location within the U.S. These permits may be obtained from the Centers of Disease Control and Prevention, Office of Health and Safety, Etiologic Agent Import Permit Program at <http://www.cdc.gov/od/eaipp/> or telephone (404) 498-1600 for further information.

Foreign imports of the following materials require a Permit to Import or Transport Agents or Vectors of Human Disease:

- any etiologic agent
- any arthropod or other animal host or vector of human disease
- any exotic living arthropod or other animal capable of being a host or vector of human disease
- Non-human primate material - all non-human primate material (e.g., blood, plasma, tissue, urine, feces) requires an import permit, unless it has been specifically treated and rendered non-infectious.

Domestic transport may or may not require a permit.

To determine if your shipment requires a permit:

- call 404-498-2260
- visit the CDC Web site at <http://www.cdc.gov/od/eaipp/>
- Go to the online form to submit a permit application <http://www.cdc.gov/od/eaipp/faq.htm> or see Appendix 6 (permit application)

Some microorganisms and cell lines purchased from ATCC require permits to be shipped domestically. For ATCC permit info see <http://www.atcc.org/Order/permits.cfm>

Appendix 4

Appendix 9

Summary of IATA (International Air Transport Association) Shipping Information

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Max Qty On Passenger & Cargo	Max Qty On Cargo Only	Packing Instruction
Category A Infectious Substance Affecting Humans***	Infectious substance, affecting humans *	UN 2814	6.2	50ml or 50g	4L or 4Kg	620
Category A Infectious Substance Affecting Animals Only***	Infectious substance, affecting animals *	UN 2900	6.2	50ml or 50g	4L or 4Kg	620
Category B Biological Substance***	Biological Substance, Category B**	UN 3373	6.2	50ml or 50g	4L or 4Kg	650
Toxins ***	Toxins, extracted from living sources * (indicate solid or liquid)	UN 3172	6.1	Varies by Packing Group	Varies by Packing Group	Varies by Packing Group
Exempt human specimen	Patient specimens for which there is minimal likelihood they contain pathogens **	None	None	N/A		Similar to 650 no UN Label
Exempt animal specimen	Patient specimens for which there is minimal likelihood they contain pathogens **	None	None	N/A		Similar to 650 no UN Label
Dry Ice ***	Dry Ice or Carbon Dioxide, solid	UN1845	9	200Kg	200Kg	954
Non-infectious GMO***	Genetically Modified Organism	UN3245	9	Varies by Packing Group	Varies by Packing Group	959
Non-infectious and Non-transducing GMO***	Genetically Modified Organism	UN3245	9	N/A	N/A	959
GMO Known to be or Suspected to be Dangerous to Humans, Animals, or the Environment	Cannot be shipped by air	None	None	N/A	N/A	None
Animals Containing Infectious GMO	Cannot be shipped by air	None	None	N/A	N/A	None
70% Ethanol in Water **	Ethanol solution	UN1170	3	5L	60L	305/307
Formaldehyde 10%-25% **	Aviation regulated liquid, n.o.s.(Formaldehyde solution)	UN3334	9	100L	220L	906
Formaldehyde >25% **	Formaldehyde solution	UN2209	8	5L	60L	818/820

* Include technical name for specific microorganism, toxin, etc. in parentheses following the proper shipping name.

** Category B Biological substance packages may include 30ml or less of substances in Classes 3, 8, or 9 if required to maintain the viability of the sample, preserve the sample, or reduce the hazard of the sample. If 30ml or less you don't need to follow packing instructions for the compound.

*** Requires special training: shipping class every two years, topic specific

Appendix 5



United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services



This genetically engineered product(s) does not require an APHIS notification or permit for the following reason (check appropriate line or lines):

___ This **interstate movement or importation** is a plasmid(s) that does NOT contain the complete sequence of a virus or viroid.

___ This **interstate movement or importation** of this nonpropagative material does not require a biotechnology permit because the material has been rendered nonviable (e.g. by freezing) or is nonpropagative (e.g. cell cultures that whole plants cannot be regenerated from).

___ This **interstate movement** of *E. coli* (strain K-12 and its derivatives), sterile strains of *Saccharomyces cerevisiae*, or asporogenic strains of *Bacillus subtilis* containing plant pest sequences does not require a permit because it meets the following conditions: (i) The microorganisms are shipped in a container that meets the requirements of 7 CFR 340.8(b)(3); (ii) The cloned genetic material is maintained on a nonconjugation proficient plasmid and the host does not contain other conjugation proficient plasmids or generalized transducing phages; (iii) The cloned material does not include the complete infectious genome of a known plant pest; (iv) The cloned genes are not carried on an expression vector if the cloned genes code for: (A) A toxin to plants or plant products, or a toxin to organisms beneficial to plants; or (B) factors directly involved in eliciting plant disease (i.e., cell wall degrading enzymes); or (C) Substances acting as, or inhibitory to, plant growth regulators.

___ This **interstate movement** of *Arabidopsis thaliana* material because does not require a permit because: (i) the materials are shipped in a container that meets the requirements of 7 CFR 340.8(b),(1, (2), and (3); (ii) The cloned genetic material is stably integrated into the plant genome; and (iii) The cloned material does not include the complete infectious genome of a known plant pest.

___ The **interstate movement or importation** of this genetically engineered material does not require biotechnology permit because it was deregulated under petition number _____.

Name of Person (print) _____

Affiliation _____

Telephone number _____

Signature _____ Date _____

If you have questions about these exemptions, please call Mr. Juan A. Roman, USDA, APHIS, BRS at Area Code (301) 734-0029.

Enclose this form with the shipment of the genetically engineered product

Appendix 6

Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated

UN 2814 Infectious Substances Affecting Humans

Bacillus anthracis (cultures only)
Brucella abortus (cultures only)
Brucella melitensis (cultures only)
Brucella suis (cultures only)
Burkholderia mallei - *Pseudomonas mallei* – Glanders (cultures only)
Burkholderia pseudomallei – *Pseudomonas pseudomallei* (cultures only)
Chlamydia psittaci - avian strains (cultures only)
Clostridium botulinum (cultures only)
Coccidioides immitis (cultures only)
Coxiella burnetii (cultures only)
Crimean-Congo hemorrhagic fever virus
Dengue virus (cultures only)
Eastern equine encephalitis virus (cultures only)
Escherichia coli, verotoxigenic (cultures only)
Ebola virus
Flexal virus
Francisella tularensis (cultures only)
Guanarito virus
Hantaan virus
Hantaviruses causing hemorrhagic fever with renal syndrome
Hendra virus
Hepatitis B virus (cultures only)
Herpes B virus (cultures only)
Human immunodeficiency virus (cultures only)
Highly pathogenic avian influenza virus (cultures only)
Japanese Encephalitis virus (cultures only)
Junin virus
Kysanur Forest disease virus
Lassa virus
Machupo virus
Marburg virus
Monkeypox virus
Mycobacterium tuberculosis (cultures only)
Nipah virus
Omsk hemorrhagic fever virus
Poliovirus (cultures only)
Rabies virus (cultures only)
Rickettsia prowazekii (cultures only)
Rickettsia rickettsii (cultures only)
Rift Valley fever virus (cultures only)
Russian spring-summer encephalitis virus (cultures only)

Sabia virus
Shigella dysenteriae type 1 (cultures only)
Tick-borne encephalitis virus (cultures only)
Variola virus
Venezuelan equine encephalitis virus (cultures only)
West Nile virus (cultures only)
Yellow fever virus (cultures only)
Yersinia pestis (cultures only)

UN 2900 Infectious Substances Affecting Animals

African swine fever virus (cultures only)
Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
Classical swine fever virus (cultures only)
Foot and mouth disease virus (cultures only)
Lumpy skin disease virus (cultures only)
Mycoplasma mycoides - Contagious bovine pleuropneumonia (cultures only)
Peste des petits ruminants virus (cultures only)
Rinderpest virus (cultures only)
Sheep-pox virus (cultures only)
Goatpox virus (cultures only)
Swine vesicular disease virus (cultures only)
Vesicular stomatitis virus (cultures only)

NOTE 1: The following list is not exhaustive. Infectious substances, including those containing new or emerging pathogens, which do not appear in the following list but which meet the same criteria must not be transported as a diagnostic specimen. In addition, if there is doubt as to whether or not a pathogen falls within this category it must not be transported as a diagnostic specimen.

NOTE 2: In this table, the microorganisms indicated in italics are bacteria, mycoplasmas, rickettsiae, or fungi.

NOTE 3: Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include human or animal patient samples.

NOTE 4: If a health authority list is available that shows other pathogens regarded as Risk Group 4 this should also be taken into account and the substances should not be transported as diagnostic specimens.

