IBRDSC Policy

Shipment of Biological Materials

Before you begin, in order to conserve your efforts, notify/contact Don Michael Hooks, Office of Environmental Health & Safety (EHS), 225-578-8498.

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Introduction

The Office of Environmental Health and Safety (EHS) developed this manual to assist in the shipment of biological materials and dry ice. This document includes information about how to properly classify, package, mark and label your shipment. This manual also describes the training requirements necessary to ship biological materials and dry ice.

Shipped biological specimens, infectious agents and other biological materials are regulated by governmental and non-governmental, consensus development organizations. Penalties for noncompliance with the rules are significant and could result in the following fines:

- Up to $250,000 and up to a year jail sentence for individuals.
- Up to $500,000 per incident for organizations.

Several agencies regulate the shipment of biological materials including:

- International Air Transport Association (IATA).
- US Department of Transportation (DOT).
- US Public Health Service (PHS).
- Occupational Health and Safety Administration (OSHA).
- United States Postal Service (USPS).

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. Carrying dangerous goods by hand, for example in a vial in your pocket or in luggage, is strictly prohibited. IATA and DOT regulations cover your checked luggage, materials

you carry on, or materials you carry in your pockets when you board an airplane. Persons who violate regulations are subject to fines and criminal prosecution. IATA regulations are commonly encountered since they regulate materials transported by air and are generally the most restrictive. For these reasons, this guide pays special attention to IATA protocols.

I. Training Requirements

Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training.

If you intend to package biological materials or dry ice for shipment or fill out a Shipper's Declaration for Dangerous Goods you must follow the training requirements as set forth by the regulating agencies.

Please contact EHS if you require training.

II. Shipping Overview

Follow these steps when shipping biological materials and dry ice.

1. Classify your materials for shipment.

2. Package, mark, and label your material(s) appropriately.

3. Fill out the Shipper's Declaration for Dangerous Goods form. Consult Section V.

4. If you are shipping Select Agents, special regulations apply. Consult Section VI.

5. If you plan on importing or exporting biological materials, permits may be required. Consult Sections IX and X.

III. Shipment Type

For shipment purposes, biological material will fit into one of the following categories:

1. Unregulated biological material;

2. Category A infectious substances;
3. Category B infectious substances;
4. Patient specimens;
5. Biological Products;
6. Genetically modified organisms and microorganisms.

Read each material section carefully to determine how to classify a material. If you are shipping a biological material that *cannot cause disease*, infectious substance regulations do not apply, unless sent by mail (see Section XI). Refer to the classification guide to assist with classification of materials.

Note: All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see Other Packaging Requirements). All samples preserved with flammable or corrosive materials, such as ethanol or formalin, must be shipped appropriately.

1. Unregulated Biological Material

The materials listed below are not subject to IATA or DOT infectious substance shipping regulations. However, these materials may require a permit for shipment abroad. All shipments of blood and blood products **must** be labeled with a biohazard symbol.

- Substances which do not contain infectious substances or which are unlikely to cause disease in humans or animals;

- Non-infectious biological materials from humans, animals or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA, or other genetic elements;

- Substances containing microorganisms, which are non-pathogenic to humans or animals;

- Substances that have been neutralized or inactivated such that they no longer pose a health risk;

- Environmental samples which are not considered to pose a significant risk of infection;

- Dried blood spots*;

- Fecal occult blood screening tests*;

• An infectious substance, other than a Category A infectious substance, contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment and prevention, or a biological product, when such materials are being transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials;

• Blood or blood components which have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation*;

• Tissues or organs intended for use in transplantation*;

• A material with a low probability of containing an infectious disease or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include foodstuffs and environmental samples (such as water or a sample of dust or mold);

• A biological product, including an experimental or investigational product or component of a product, subject to federal approval, permit, review or licensing requirements such as those required by the Food and Drug Administration or the US Department of Agriculture*.

* When mailing these items with the USPS, follow packaging guidelines for non-regulated items. See Section XI.

Infectious Substances

Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.

2. Category A Infectious Substances

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease in humans or animals when

exposure to them occurs. Category A infectious substances are shipped as infectious substances, affecting humans (UN2814), or infectious substances affecting animals (UN2900). Indicative examples of Category A infectious substances are listed in Appendix A.

a. Packaging

The triple packaging concept (explained in Section V) applies to Category A infectious substances. Purchase packaging compliant with IATA Packing Instruction 602. See Appendix B for a list of packaging suppliers. Make sure to specify if you are shipping a refrigerated sample (ice packs or dry ice). The maximum quantity of infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum quantity that may be shipped via passenger aircraft is 50 mL or 50 g.

b. Labeling

The outer container of a Category A infectious substance shipment must display the following information:

- Sender and recipient's full name and address;
- Infectious substance label (Figure 1);
- "UN2814, Infectious substance, affecting humans" and net quantity Or "UN2900, Infectious substance, affecting animals" and net quantity;
- The text "Person responsible: (a 24/7 phone number)";
- Class 9 label (Figure 2), including UN1845 and net weight, if packaged with dry ice; and
- Cargo Aircraft Label, when shipping over 50 mL or 50 g

3. Category B Infectious Substances

Category B infectious substances are materials that are infectious, but do not meet the standard for inclusion in Category A. Category B infectious substances are assigned to UN3373.

a. Packaging

The basic triple packaging concept applies to Category B infectious substances. Purchase packaging that complies with IATA Packing Instruction 650. See Appendix B for a list of some packaging suppliers. Be sure to specify if the shipment is a refrigerated sample (e.g., ice packs or dry ice). For Category B infectious substances, the maximum quantity of liquid per primary receptacle is 1 liter and outer packaging must not contain more than 4 L or 4 kg.

b. Labeling

The outer container of a Category B infectious substance shipment must display the following information:

- The sender and recipient's full name and address;
- The words "Biological Substance, Category B";
- UN3373 label (Figure 4);
- The text "Person responsible: (24/7 phone number); and
- Class 9 label (Figure 2), if packaged with dry ice.

4. Patient Specimens

Patient specimens that have a minimal likelihood of containing pathogens are exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and should be based on the patient's medical history, symptoms, local conditions and individual circumstances. If there is more than a "minimal likelihood" that a patient specimen contains pathogens, it must be shipped as a Category A infectious substance (UN2814 or UN2900) or a Category B infectious substance (UN3373). Patient specimens unlikely to contain pathogens must be prepared for shipment as follows:

a. Packaging

- Leak-proof primary container;
- Leak-proof secondary packaging;

• Fragile primary containers must be wrapped or separated to prevent breakage;

• Absorbent material must be placed between the primary and secondary containers to absorb entire contents so that no liquid release will reach the outer packaging; and
• Outer packaging must be durable enough for its intended use with at least one side 100 X 100 mm or more.

b. Labeling

The outer package must be marked with "Exempt human specimen," or "Exempt animal specimen."

5. Biological Products

Biological products are derived from living organisms and manufactured for use in the prevention, diagnosis, treatment or cure of diseases in humans or animals and are certified by the USDA, FDA or other national authority. Examples of biological products include certain viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, and blood products. Biological products transported for final packaging, distribution, or use by medical professionals are not subject to biological shipping regulations. Biological products that do not meet these criteria must be assigned to UN2814, UN2900 or UN3373, as appropriate.

6. Genetically Modified Organisms or Microorganisms

Genetically modified organisms (GMO) or microorganisms (GMMO) are organisms and microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs and GMMOs that are not infectious but that can alter animals, plants or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and are assigned to UN3245. GMOs and GMMOs that are infectious must be assigned to UN2814, UN2900 or UN3373.

a. Packaging

These materials are packed for shipment in the same way as Category A infectious substances, except there are no testing requirements for the packaging; this packaging variation is IATA Packing Instruction 913. Packages designed for Packing Instruction 913 may not be available from most vendors. In this

case, use packages compliant with Packing Instruction 602. The maximum allowable quantity per primary receptacle is 100 mL or 100 g. There is no maximum net quantity per package.

b. Labeling

The outer container of a GMO or GMMO assigned to UN3245 must display the following information:

- The sender and recipient's full name and address;
- Class 9 label and
- Genetically modified microorganisms, UN3245, and net quantity.

IV. Packaging Biological Materials

Potentially hazardous biological materials must be packaged to withstand leakage of contents, shocks, temperature, pressure changes and other conditions that can occur during ordinary handling in transportation. Packaging your material(s) appropriately is accomplished by purchasing certified packaging. Refer to Appendix B for vendors that can supply certified packaging for biological materials. When ordering, specify what type of material(s) you will be shipping: *Category A infectious substances, Category B infectious substances,* etc. Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

A. Triple Packaging

Biological materials must be packaged according to the triple packaging principle. The three elements of triple packaging include: *primary receptacle, leak-proof secondary container,* and *durable outer container*. Infectious substances in Category A and B, patient specimens and genetically modified microorganisms must be packaged in this way, with slight variations.

The **primary container** holds the biological material; it must be leak-proof. It must be labeled with the name of the contents. A leak-proof seal, such as a heat seal, skirted stopper or metal crimp, is required. If the container has a threaded lid, it must be secured with waterproof tape (e.g. Parafilm, etc.). Petri plates cannot be used as primary receptacles. Lyophilized substances can only be shipped in flame sealed glass ampoules or rubber stopped glass vials with metal seals.

Packaging purchased for shipping infectious substances usually does not include the primary container.

The **secondary container** holds one or more primary containers, and must also be leak-proof. Secondary containers for all Category A and liquid Category B infectious substances must meet specific pressure test standards when shipping liquids. Containers purchased from commercial vendors are designed to meet the necessary standards. If you are shipping any liquid, there must be enough absorbent material in the secondary container to absorb *all* of the liquid in the primary receptacle(s). If multiple primary containers are used, they must be wrapped to prevent contact between them so they do not break during transport. The **outer container** must be rigid and have one side that is at least 100 mm X 100 mm, in order for required markings and labels to fit. The outer package must be of adequate strength for its capacity, mass, and intended use. An **itemized list** of package contents must be included between the outer and secondary container. The outer package should be marked to identify hazardous contents, including the proper shipping name, UN number and net quantity for each substance, if required.

B. Other Packaging Requirements

Overpacks. An overpack can be used to combine several triple packages into one large package. This may be done to save on shipping charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within including hazard labels and proper shipping names. The outer container of the overpack must also be marked with the word, "Overpack."

Dry Ice. If a shipment includes dry ice the outer packaging must allow for the release of carbon dioxide gas when the solid sublimates. Dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary container as the refrigerant sublimates. Dry ice is considered a miscellaneous hazard (Class 9). Packages containing dry ice must bear a Class 9 label and be marked with the proper shipping name, UN number, and net quantity, (e.g., Dry Ice, UN1845, 3 kg). Packages designed for dry ice often are pre-labeled and marked. A Shipper's Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material. Dry ice is included on declarations for

shipments that include other hazardous materials such as infectious substances.

Liquid Nitrogen. Biological materials can be shipped refrigerated with liquid nitrogen in dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material. Special packing regulations apply to shipments containing nitrogen. Contact EHS at 8-5640 if you need to ship materials with liquid nitrogen.

V. Shipper's Declaration for Dangerous Goods

A Shipper's Declaration for Dangerous Goods must be completed when shipping a Category A infectious substance assigned to UN2814 or UN2900or a GMO or GMMO assigned to UN3245. A declaration is not required for shipments in which dry ice is the only hazardous material. A declaration is not required for shipments of Category B infectious substances assigned to UN3373. *Improperly completed declarations are the most common cause of package refusal.*

Contact EHS at 8-5640 before completing or signing the Shipper's Declaration for Dangerous Goods.

- Declarations must be typewritten or computer-generated; handwritten declarations will not be accepted.
- Declarations must be printed in color to display the red-striped border.
- Always print at least **four** copies: provide three to the carrier and keep one for your records.
- Remember to sign and date each copy.
- Regulations require that you must retain your copy for **2 years**.

VI. CDC Select Agents

The U.S. Department of Health and Human Services has developed a list of biological agents (see Appendix G) that have the potential to pose a severe threat to public health. Special regulations apply to the use and transfer of these materials, including registration with the LSU Inter-Institutional

Biological & Recombinant DNA Safety Committee (IBRDSC) and the Centers for Disease Control and Prevention. If you are planning to, or currently work with, any select agents and have not registered, contact Dr. Gregory Hayes at 8-5640. Specific shipping restrictions apply to these agents which are not discussed in this document.

VII. Shipping Company Restrictions

Some shipping companies may have requirements that are more restrictive than those discussed in this document. Consider the following information before planning a shipment.

DHL. DHL will accept shipments made according to IATA or DOT regulations. Shipments made according to instructions in this manual will be acceptable to DHL.

FedEx. FedEx Express and FedEx Ground will accept shipments prepared according to instructions in this manual. FedEx will not accept any material considered to be in Risk Group 4. A Risk Group 4 pathogen is one that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.

United States Postal Service (USPS). The USPS has highly restrictive regulations concerning the shipment of hazardous materials by mail. Category A materials may not be mailed with the USPS. USPS will accept shipments of UN3373 and exempt patient specimens. For more information, refer to Section XII.

UPS. UPS will not accept shipments of Category A materials. UPS will accept shipments of UN3373 and exempt patient specimens.

VIII. International Shipments

Shipping and receiving animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms may require the approval of federal agencies, both domestic and foreign. Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture. Packages shipped internationally generally require increased preparation time due to the additional paperwork required for such packages. An import/export permit may be required when shipping biological materials

internationally. Check the following U.S. governmental agencies for permits and additional information.

APHIS Agricultural Permits
[http://aphisweb.aphis.usda.gov/ppq/permits/**]**
Telephone: 1-877-770-5990
APHIS permits are required to import or domestically transfer a plant pest, plant biological agent, or other material listed below.

EXPORT/IMPORT

- Arthropods (insects and mites)
- Arthropods inhabiting dung or of medical/veterinary significance
- Bees and bee related articles
- Biological materials containing animal material
- Butterflies
- Cell cultures of bovine or other livestock origins
- Cut flowers
- Earthworms
- Endangered species
- Endangered species of wild fauna and flora
- Entomopathogens
- Farm animals
- Foreign cotton and covers
- Fruits and vegetables
- High consequence livestock pathogens and toxins
- Indian corn or maize, broomcorn and related plants
- Infectious agents of livestock
- Khapra beetle products
- Live arthropods for display or educational purpose
- Livestock
- Moths
- Noxious weeds
- Nursery stocks (including seeds)
- Parasitic plants
- Plant pathogens
- Predators and parasitoids of arthropods
- Prohibited material for research purposes
- Rice and rice related articles
- Seeds
- Snails and slugs
- Soil
- Sugarcane products and by-products (including parts of the

sugarcane plant)
- Tissue culture materials of bovine or other livestock origins
- Weed biocontrol
- Wildlife
- Wood products

CDC Permit to Import or Transport Agents or Vectors of Human Disease

[http://www.cdc.gov/od/ohs/biosfty/imprtper.htm**]**
Telephone: 1-404-498-2260
CDC permits are required when shipping any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids), or biological vectors of infectious animals, bats, insects, arthropods and snails.

INFECTIOUS SUBSTANCES

- It is impractical to list all of the several hundred species of infectious substances. In general, an import permit is needed for any infectious substance known or suspected to cause disease in man.

BIOLOGICAL MATERIALS

- Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious agent requires a permit in order to be imported.

VECTORS

- **Animals**: Any animal known or suspected of being infected with an organism capable of causing disease transmissible to man may require a CDC permit. Importation of live turtles of less than 4 inches in shell length and all nonhuman primates requires an importation permit issued by the Division of Quarantine.

- **Bats:** All live bats require an import permit from the CDC and the U.S. Department of Interior, Fish and Wildlife Services.

• **Insects or Arthropods:** All live fleas, flies, lice, mites, mosquitoes, or ticks require a CDC import permit, regardless of infection status. Permits are required for adult forms, as well as eggs, larvae, pupae, and nymph stages. Any other living insect or arthropod, known or suspected of being infected with any disease transmissible to man requires a CDC import permit.

• **Snails:** Any snail species capable of transmitting a human pathogen require a permit from the Centers for Disease Control.

Commerce Department – Bureau of Industry and Security (BIS)
[http://www.bis.doc.gov/index.htm**]**
A permit may be required from the Commerce Department, when exporting infectious agents of human, plant, and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents (Commerce Control List Supplement No. 1 to Part 774 Category 1, pages 54 - 59)

HUMAN PATHOGENS and TOXINS

Bacteria

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (*Pseudomonas mallei*)
- *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*)
- *Chlamydia psittaci*
- *Clostridium botulinum*
- *Clostridium perfringens,* epsilon toxin producing types
- Enterohaemorrhagic *Escherichia coli,* serotype O157 and other verotoxin producing serotypes
- *Francisella tularensis*
- *Salmonella typhi*
- *Shigella dysenteriae*
- *Vibrio cholerae*
- *Yersinia pestis*

Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Eastern equine encephalitis virus
- Ebola virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Japanese encephalitis virus
- Junin virus
- Kyasanur Forest virus
- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Monkey pox virus
- Murray Valley encephalitis virus
- Nipah Virus
- Omsk haemorrhagic fever virus
- Oropouche virus
- Powassan virus
- Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- Rabies virus cultures
- Rift Valley fever virus cultures
- Rocio virus
- South American haemorrhagic fever virus (Sabia, Flexal, Guanarito)
- St. Louis encephalitis virus
- Tick-borne encephalitis virus (Russian Spring-Summer Encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus cultures
- Western equine encephalitis virus
- White pox
- Yellow fever virus

Toxins and Rickettsia

- Abrin
- Aflatoxins

- Botulinum toxins
- Cholera toxin
- *Clostridium perfringens* toxins
- Conotoxin
- Diacetoxyscirpenol toxin
- HT-2 toxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- *Staphylococcal aureus* toxins
- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum Album Lectin 1 (Viscumin)
- *Bartonella quintana* (*Rochalimea quintana*, *Rickettsia quintana*)
- *Coxiella burnetii*
- *Rickettsia prowasecki*
- *Rickettsia rickettsii*

ANIMAL PATHOGENS and TOXINS

Bacteria

- Mycoplasma mycoides

Viruses

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (certain highly pathogenic strains – see the Export Administration Regulations for more information)
- Bluetongue virus
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Lassa virus
- Newcastle disease virus
- Peste des petits ruminants virus

- Porcine enterovirus type 9 (swine vesicular disease virus)
- Porcine herpes virus (Aujeszky's disease)
- Rinderpest virus
- Sheep pox virus
- Swine fever virus (Hog cholera virus)
- Teschen disease virus
- Vesicular stomatitis virus

GENETIC ELEMENTS/GENETICALLY MODIFIED ORGANISMS

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.

- Genetic elements that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins."

Technical Note: Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.

- Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.

- Genetically modified organisms that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins."

PLANT PATHOGENS

Bacteria Fungi

- *Xanthomonas albilineans*
- *Xanthomonas campestris* pv. citri including strains referred to as *Xanthomonas campestris* pv. *citri* types A,B,C,D,E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv., *Aurantifolia* or *Xanthomonas campestris* pv., *Citrumelo.*

- *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*)
- *Cochliobolus miyabeanus* (*Helminthosporium oryzae*)
- *Magnaporthe grisea* (*pyricularia grisea/pyricularia oryzae*)
- *Microcyclus ulei* (*Dothidella ulei*)
- *Puccinia graminis* (*Puccinia graminis* f. sp. *tritici*)
- *Puccinia striiformis* (*Puccinia glumarum*)

FDA Import Permits
[http://www.fda.gov/ora/import/**]**
All food (except most meat and poultry), drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation require a permit or registration before importation into the United States.

Fish and Wildlife Service Permit Station
[http://international.fws.gov/permits/permits.html**]**
Telephone: 1-800-770-0150
A permit may be required for transporting fish, wildlife, endangered species, or materials found in the list below.

EXPORT

- African elephant ivory
- Animals
- Artificially propagated plants
- Asian elephant ivory
- Biological samples
- Captive-born export
- Circuses/traveling animal exhibitions
- Goldenseal
- Ginseng
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Raptors
- Trophies by taxidermist
- Wildlife

IMPORT

- African elephant
- African elephant ivory
- African leopard
- Argali
- Asian elephant ivory
- Biological samples
- Birds
- Bontebok
- Circuses/traveling animal exhibitions
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Polar bears
- Scientific and zoological breeding or display
- Sport hunted trophy
- White rhinoceros
- Wildlife

IX. Exporting from the United States

Depending on the nature of the shipment, a U.S. export permit may be required when sending your package. Additionally, an import permit may be required in the country where the package is being shipped. If your shipment requires an export permit, it must be completed and approved by the appropriate government agency prior to shipment. **Note:** Packages may be opened and inspected when leaving the United States or at any time by any inspection service provided by other countries. In order to assure that your package is safely delivered to its intended destination, always consider the following:

1. If necessary, obtain an export permit from the appropriate governmental organization prior to shipment.

2. Package and label the material according to the guidelines listed in this manual.

3. Include a courtesy letter with the shipment describing the contents in detail including information about whether the material is infectious.

X. Importing into the United States

All shipments entering the United States are processed by the U.S. Bureau of Customs and Border Protection. An import permit may be required to deliver the package even if a permit is not required by the originating country. Check with the appropriate governmental organization prior to shipment of the material. **Note:** Packages may be opened and inspected upon entry into the United States. In order to assure that your package is safely delivered to its intended destination, always consider the following: If necessary, obtain an import permit from the appropriate governmental organization prior to shipment.

1. Package and label the material according to the guidelines listed in this manual.

2. Consider including a courtesy letter with the shipment. The **importer** is legally responsible for assuring that foreign personnel package, label, and ship the infectious materials according to USPHS and IATA regulations. Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date are also issued to the **importer** with the permit. The **importer** must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U.S. Customs and Border Protection and U.S. Division of Quarantine personnel of the package contents.

XI. United States Postal Service Mailings

The United States Postal Service (USPS) does not allow Category A infectious substances to be mailed. Follow the procedures below when mailing Category B substances, exempt patient specimens and non-regulated items.

A. Mailing Category B Substances

Follow packaging and labeling requirements listed in Section IV(B)(2) and note the following variations:

- Shipments of both liquid and solid substances must be packaged in a pressure tested primary or secondary container; and

- Category B substances may be mailed as First-Class, Priority, or Express mail.

B. Mailing Exempt Human and Animal Specimens

Follow packaging and labeling requirements listed in Section IV(C) and note the following variations:

- Inner containers and the total volume per package are limited to 500 mL or 500 g;
- Outer packaging must me rigid; and
- Exempt specimens must be mailed as First-Class, Priority, Express, or Package Services mail.

C. Mailing Non-Regulated Materials

According to USPS regulations, specific packing instructions apply when mailing non-regulated materials. The following are examples of non-regulated biological materials:

- Biological products not containing Category A or Category B substances;
- Blood or blood products collected for transfusion or preparation of blood products;
- Tissues or organs intended for transplantation;
- Dried blood spots; and
- Dried specimens for fecal occult blood detection.

Quantity limits and form of substance (liquid or solid) determine the packaging requirements for non-regulated materials. Refer to the appropriate category below to determine how to package you material.

1. Non-Regulated Liquid Substance, Not Exceeding 50 ml

Primary container and total package contents may not exceed 50 ml. Primary receptacle must be leak-proof and properly sealed. Include cushioning and enough absorbent to absorb entire contents of liquid. Enclose the primary container(s) in a leak-proof secondary container (e.g. plastic bag). Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

2. Non-Regulated Liquid Substance, Exceeding 50 ml
Primary container must not exceed 50 ml; total package may not exceed 500 ml. Package in triple packaging. Include cushioning and enough absorbent to absorb entire contents of liquid. Label primary or secondary container with a biohazard symbol. No other labeling is required.

3. Non-Regulated Dry Substance
Primary container must be sift-proof and must be enclosed in a sift-proof secondary container. Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

Appendix A - Indicative Examples of Category A Infectious Substances

UN # and Proper Shipping Name Microorganism

UN 2814

Infectious substance affecting humans

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

- Rabies virus cultures
- *Rickettsia prowazekii* cultures
- *Rickettsia rickettsia* cultures
- Rift Valley fever virus
- Russian spring-summer encephalitis virus cultures
- Sabia virus
- *Shigella dysenteriae* type 1 cultures
- Tick-borne encephalitis virus cultures
- Variola virus
- Venezuelan equine encephalitis virus
- West Nile virus cultures
- Yellow fever virus cultures
- *Yersinia pestis* cultures

UN 2900 – Infectious substance affecting animals

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

* This list is not exhaustive. New or emerging pathogens not on the list may meet the criteria to be included in Category A.

Appendix B – Manufacturers of Shipping Containers for Infectious Substances and Dry Ice

Air Sea Atlanta
1234 Logan Circle
Atlanta GA 30318
Phone: 404-351-8600
http://www.airseaatlanta.com

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017
Phone: 800-245-2283
http://www.all-pak.com

CARGOpak Corporation
3215-A Wellington Court
Raleigh, NC 27615
Phone: 800-266-0652
http://www.cargopak.com

DG Supplies, Inc.
5 Boxal Drive
Cranbury, NJ 08512
Phone: 800-347-7879
http://www.dgsupplies.com

EXAKT Technologies, Inc.
7416 N Broadway Ext., Suite E
Oklahoma City, OK 73116
Phone: 800-923-9123
http://www.exaktpak.com

HAZMATPAC, Inc.
5301 Polk St., Bldg. 18
Houston, TX 77023
Phone: 800-347-7879
http://www.hazmatpac.com

Inmark, Inc.
220 Fisk Drive S.W.
Atlanta, GA 30336-0309
Phone: 800-646-6275

http://www.inmarkinc.com

JIT Certified, Inc.
1740 Fenpark Drive
Fenton, MO 63026
Phone: 800-962-8636
http://www.jitcertifed.com

Polyfoam Packers Corporation
2320 S. Foster Avenue
Wheeling, IL 60090
Phone: 888-765-9362
http://www.polyfoam.com

SAF-T-PAK, Inc.
10807 - 182 Street Edmonton,
Alberta, Canada, T5S 1J5
Phone: 800-814-7484
http://www.saftpak.com
Source Packaging of New
England, Inc.
405 Kilvert St.
Warwick, RI 02886
Phone: 800-200-0366
http://www.sourcepak.com

Therapak Corporation
1440 Arrow Highway, Unit A
Irwindale, California 91706
Phone: 888-505-7377
http://www.therapak.com

Appendix C – Intent to Ship Hazardous Materials

After reading *Shipment of Biological Materials Manual*, fill out this form to qualify to ship dangerous materials at LSU. EHS will review this completed form and upon successful completion and demonstration of knowledge of applicable regulations you will be certified to ship those materials designated on this form.

1. What regulated material(s) might you ship via mail or courier service? List all hazardous materials that you intend to ship. Also, list the mailing service you intend to use.

2. What packaging will you use to ship your material(s)? Include company name and product number for chosen packaging for each material you intend to ship.

3. Check those that should appear on your package:

Class 6.2 label
Class 9 label
UN3373 label
Cargo Aircraft label
Dry ice, UN1845, net weight _____ kg
Infectious substance, affecting humans, UN2814, net quantity
Infectious substance, affecting animals, UN2900, net quantity
Name, Address and Phone Number of Shipper
Name and Address of Consignee
Person Responsible: 24 hour telephone number
Overpack
"Exempt Human Specimen," or "Exempt Animal Specimen."
Genetically modified microorganisms, UN3245, net quantity
Diagnostic Specimens

4. Fill out a Shipper's Declaration for Dangerous Goods (if your shipments require one). An example of each material you intend to ship must be included in the "Nature and Quantity of Dangerous Goods" section.

I understand the hazards associated with the materials noted above. Also, I understand the shipping requirements for those materials, as outlined in this manual.

Print name:
Signature:

Date:
Please return, in campus mail, to EHS –.

Appendix D – APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins

Viruses

1. African horse sickness virus 3
2. African swine fever virus 3
3. Akabane virus 3
4. Avian influenza virus (highly pathogenic) 3
5. Bluetongue virus (exotic) 3
6. Camel pox virus 3
7. Cercopithecine herpes virus (Herpes B virus) 2
8. Classical swine fever virus 3
9. Crimean-Congo haemorrhagic fever virus 2
10. Eastern equine encephalitis virus 4
11. Ebola viruses 2
12. Foot and mouth disease virus 3
13. Goat pox virus 3
14. Hendra virus 4
15. Japanese encephalitis virus 3
16. Lassa fever virus 2
17. Lumpy skin disease virus 3
18. Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1) 3
19. Marburg virus 2
20. Menangle virus 3
21. Monkeypox virus 2
22. Newcastle disease virus (velogenic) 3
23. Nipah virus 4
24. Peste des petits ruminants virus 3
25. Rift Valley fever virus 4
26. Rinderpest virus 3
27. Sheep pox virus 3
28. South American haemorrhagic fever viruses [(Junin, Machupo, Sabia, Flexal, Guanarito)] 2
29. Swine vesicular disease virus 3
30. Tick-borne encephalitis complex (flavi) viruses [Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)] 2
31. Variola major virus (Smallpox virus) and Variola minor Alastrim) 2
32. Venezuelan equine encephalitis virus 4
33. Vesicular stomatitis virus (exotic) 3

Prion

1. Bovine spongiform encephalopathy agent

3 **Toxins**

1. Abrin 2
2. Botulinum neurotoxins 4
3. Clostridium perfringens epsilon toxin 4
4. Conotoxins 2
5. Diacetoxyscirpenol 2
6. Ricin 2
7. Saxitoxin 2
8. Shigatoxin and Shiga-like ribosome inactivating proteins 4
9. Staphylococcal enterotoxins 4
10. Tetrodotoxin 2
11. T-2 toxin 4

Bacteria

1. *Bacillus anthracis* 4
2. Botulinum neurotoxin producing strains of *Clostridium* 4
3. *Brucella abortus* 4
4. *Brucella melitensis* 4
5. *Brucella suis* 4
6. *Burkholderia mallei* 4
7. *Burkholderia pseudomallei* 4
8. *Candidatus* Liberobacter africanus1
9. *Candidatus* Liberobacter asiaticus1
10. *Coxiella burnetii* 4
11. *Cowdria Ruminantium* (Heartwater) 3
12. *Francisella tularensis* 4
13. *Liberobacter africanus, Liberobacter asiaticus* 1
14. *Mycoplasma capricolu/M.* F38/*M. mycoides capri* (contagious caprine pleuropneumonia) 3
15. *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia) 3
16. *Ralstonia solanacearum* race 3 biovar 2 1
17. *Rickettsia prowazekii* 2
18. *Rickettsia rickettsii* 2
19. *Xanthomonas oryzae* pv. oryzicola 1
20. *Xylella fastidiosa* (citrus variegated chlorosis strain) 1
21. *Yersinia pestis* 2

Fungi

1. *Coccidioides immitis* 4
2. *Coccidioides posadasii* 2
3. *Peronosclerospora philippinensis* 1
4. *Sclerophthora rayssiae var zeae* 1
5. *Synchytrium endobioticum* 1

1 APHIS Plant Pathogen

2 HHS Select Infectious Agent

3 USDA High Consequence Livestock Pathogen or Toxin

4 USDA-HHS Overlap Agent

Exemptions

Exemptions to these rules can be found on the following websites:

http://www.cdc.gov/od/sap/sap/exclusion.htm

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/sa_ag_select_agent/ct_ag_bioterr_toxinlist

In addition, the following select agents or toxins are exempt:

1. Any select agent or toxin that is in its naturally-occurring environment provided it has not been intentionally introduced, cultivated, collected or otherwise extracted from its natural source.

2. Non-viable select agent organisms or nonfunctional toxins.

3. Toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts:

- 100 mg of abrin
- 0.5 mg of botulinum neurotoxins
- 100 mg of *Clostridium perfringens* epsilon toxin
- 100 mg of conotoxins
- 1,000 mg of diacetoxyscirpenol
- 100 mg of ricin

- 100 mg of saxitoxin
- 100 mg of shigatoxin
- 5 mg of staphylococcal enterotoxins
- 100 mg of shiga-like ribosome inactivating proteins
- 100 mg of tetrodotoxin
- 1,000 mg of T–2 toxin

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Nucleic acids that can produce infectious forms of any of the select agent viruses.

2. Recombinant nucleic acids that encode for the functional form(s) of any of the select agent toxins if the nucleic acids:
a) can be expressed *in vivo* or *in vitro*; or
b) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

3. Select agents that have been genetically modified.

Restricted Experiments

1. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine or agriculture.

2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.