



# Shipment of Biological Materials Manual

*Many thanks and credit to:  
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## Introduction

The Georgia State University Office of Research Integrity (ORI) implemented 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 non-compliance 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.

## 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 certification requirements outlined below.

1. **Read this manual.** This manual will provide familiarity with the general provisions relating to the regulations and detailed training in the requirements applicable to shipping biological materials and dry ice.
2. **Have a current bloodborne pathogen training certification.** This training ensures that you are familiar with hazards presented by infectious materials, proper handling and emergency response procedures. The training can be completed online at: [www.usg.edu/ehs/training/pathogens](http://www.usg.edu/ehs/training/pathogens)
3. **Submit to ORI an Intent to Ship Hazardous Materials form** (Appendix E). ORI will review this form with you and, upon successful completion, will certify you to ship only those materials that are listed on your Intent form.

Shipping regulations change frequently so it is necessary to repeat training certification every two years. Training sessions reviewing the material in this manual are available from ORI. Call ORI at 404-413-3510 to schedule training or to ask questions regarding the shipment of biological materials and dry ice.

## Shipping Overview

Follow these steps when shipping biological materials and dry ice.

1. Classify your materials for shipment. See Section IV.
2. Package, mark, and label your material(s) appropriately. See Section V.
3. Fill out the Shipper's Declaration for Dangerous Goods form. See Section VI.
4. If you are shipping Select Agents, special regulations apply. Consult Section VII.
5. If you plan on importing or exporting biological materials, permits may be required. Consult Section IX.

## Shipment Type

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

- Unregulated biological material;
- Category A infectious substances;
- Category B biological substances;
- Patient specimens; or
- 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 XII). Refer to the classification guide to assist with classification of materials, Figure 6. **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.

### A. 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. Please check with the Office of Legal Affairs at 404-413-0500 if you have any questions about these materials. 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); or
- 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 XII.

## **B. 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.

### **1. 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: Chem-Tel 1-800-255-3924";
- 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 (Figure 3).

Figure 1.



Figure 2.

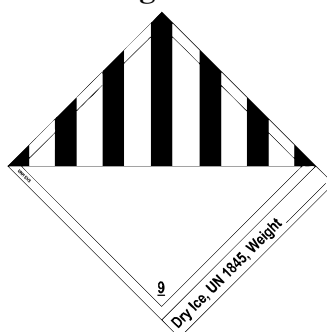


Figure 3.



## 2. Category B Biological Substances

Category B biological 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 biological 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 biological 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.

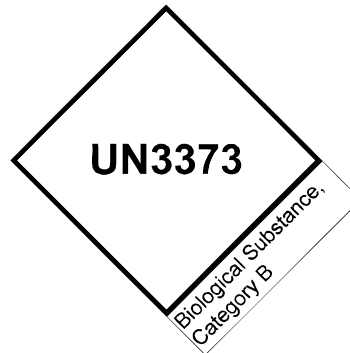
### b. Labeling

The outer container of a Category B biological 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: Chem-Tel 1-800-255-3924”; and
- Class 9 label (Figure 2), if packaged with dry ice.

**Figure 4.**



### **C. 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:

#### **1. 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.

#### **2. Labeling**

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

### **D. 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.

## **E. 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.

### **1. 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.

### **2. 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 (Figure 2); and
- Genetically modified microorganisms, UN3245, and net quantity.

## **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 biological substances*, etc. Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

## **F. 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. An example of triple packaging is illustrated in Figure 5.

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 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.

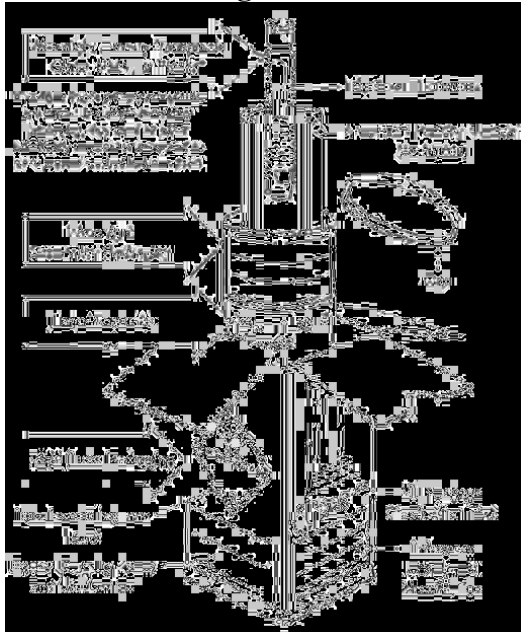
## G. Other Packaging Requirements

**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. For more information, please refer to the "Georgia State University Guide to Shipping with Dry Ice".

**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 ORI at 404-413-3510 if you need to ship materials with liquid nitrogen.

**Figure 5.**



Source: Transporting Infectious Substances Safely, US DOT Document PHH50-0079-0706.

### **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 UN2900 or 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.*

Refer to the Shipper's Declaration for Dangerous Goods in Appendix C for an explanation of each section:

- H. Shipper:** Enter your full name, address and telephone number.
- I. Consignee:** Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible: Peter Farina, 404-227-7472."
- J. Transport Details:** Indicate here if your shipment is restricted to cargo aircraft only (if it is more than 50 ml or 50 g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.
- K. Shipment Type:** Cross out "radioactive" to indicate you are shipping a non-radioactive substance.
- L. UN or ID Number:** Enter appropriate UN number as found in Table 1.
- M. Proper Shipping Name:** Enter the proper shipping name exactly as it appears in Table 1.
- N. Class or Division:** Enter appropriate hazard class as found in Table 1.
- O. Packing Group:** For dry ice, enter "III" in this column. Biological materials are not assigned packing groups.

- P. Quantity and Type of Packaging:** Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages used (usually, “All packed in one fibreboard box.”) If using an overpack, indicate here with “Overpack Used.”
- Q. Packing Instructions:** Enter appropriate packing instruction number. Refer to Table 1.
- R. Authorization:** Leave this column blank.
- S. Additional Handling Instructions:** The statement “Emergency Contact: Peter Farina, 404-227-7472” must be indicated.
- T.** This section is self-explanatory. Sign and date each copy of your Shipper’s Declaration.

Please note the following:

- 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**.

A completed sample declaration can be found in Appendix D. Contact ORI with any questions regarding the Shipper’s Declaration.

**Table 1. Summary of Shipping Information.**

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group (PG)	Packing Instruction (PI)	Max. qty. per primary receptacle	Max. Net qty./pkg. for Passenger Aircraft	Max. Net qty./pkg. for Cargo Aircraft
Category A infectious substance, affecting humans and possibly animals	Infectious substance, affecting humans	UN2814	6.2	-	602	Liquids: 4 L Solids: 4 kg	50 ml or 50 g	4 L or 4 kg
Category A infectious substance, affecting only animals (not humans)	Infectious substance, affecting animals	UN2900	6.2	-	602	Liquids: 4 L Solids: 4 kg	50 ml or 50 g	4 L or 4 kg
Category B infectious substance	Biological substance, Category B	UN3373	6.2	-	650	Liquids: 1 L Solids: 4 kg	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice or Carbon Dioxide, solid	UN1845	9	III	904	N/A	200 kg	200 kg
Non-infectious, transducing genetically modified organism or microorganism	Genetically modified microorganisms	UN3245	9	-	913	No Limit	No limit	No limit

## CDC Select Agents

The U.S. Department of Health and Human Services has developed a list of biological agents (see Appendix F) 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 GSU Institutional Biosafety Committee and the Centers for Disease Control and Prevention. If you are planning to, or currently work with, any of the select agents listed in Appendix F and have not registered, contact Dr. Bob Curry, Acting University Biosafety Officer and Alternate Responsible Official, at 404-413-3510. Specific shipping restrictions apply to these agents which are not discussed in this document.

## 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.

## 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

[\[http://aphisweb.aphis.usda.gov/ppq/permits/\]](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

[\[http://www.cdc.gov/od/ohs/biosfty/impptper.htm\]](http://www.cdc.gov/od/ohs/biosfty/impptper.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*

#### **Toxins**

- 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)

#### **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

#### **Rickettsiae**

- *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

## Commerce Department – Bureau of Industry and Security (BIS) - CONTINUED

[\[http://www.bis.doc.gov/index.htm\]](http://www.bis.doc.gov/index.htm)

### 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**

- *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*.

#### **Fungi**

- *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

[\[http://www.fda.gov/ora/import/\]](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

[\[http://international.fws.gov/permits/permits.html\]](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

## 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. For more information on whether your shipment requires an export permit, please contact the GSU Office of Legal Affairs at 404-413-0500.

**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.

## 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.

## 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 is limited to 500 mL or 500 g;
- Outer packaging must be 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.

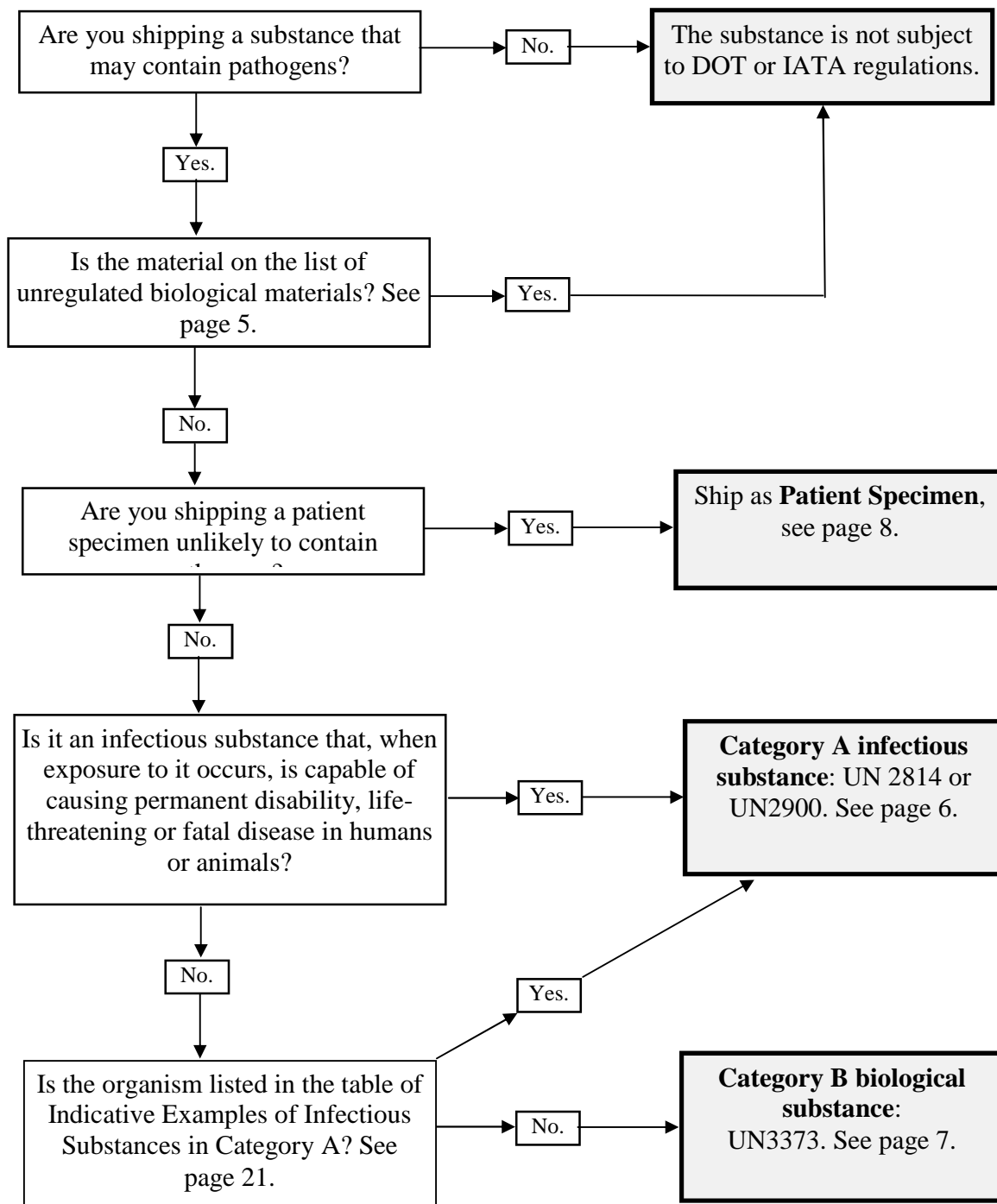
**2. Non-Regulated Liquid Substance, Exceeding 50 ml**

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.

Figure 6 - Classification Guide for Infectious Substances.



**Note:** Chemical, radiological or other hazards are not covered in this flow chart.

## Appendix A – Indicative Examples of Category A Infectious Substances

UN # and Proper Shipping Name	Microorganism
<b>UN 2814</b> Infectious substance affecting humans	<ul style="list-style-type: none"> <li>- <i>Bacillus anthracis</i> cultures</li> <li>- <i>Brucella abortus</i> cultures</li> <li>- <i>Brucella melitensis</i> cultures</li> <li>- <i>Brucella suis</i> cultures</li> <li>- <i>Burkholderia mallei</i> - <i>Pseudomonas mallei</i> - Glanders cultures</li> <li>- <i>Burkholderia pseudomallei</i> - <i>Pseudomonas pseudomallei</i> cultures</li> <li>- <i>Chlamydia psittaci</i> - avian strains cultures</li> <li>- <i>Clostridium botulinum</i> cultures</li> <li>- <i>Coccidioides immitis</i> cultures</li> <li>- <i>Coxiella burnetii</i> cultures</li> <li>- Crimean-Congo hemorrhagic fever virus</li> <li>- Dengue virus cultures</li> <li>- Eastern equine encephalitis virus cultures</li> <li>- <i>Escherichia coli</i>, verotoxigenic cultures</li> <li>- Ebola virus</li> <li>- Flexal virus</li> <li>- <i>Francisella tularensis</i> cultures</li> <li>- Guanarito virus</li> <li>- Hantaan virus</li> <li>- Hantavirus causing hemorrhagic fever with renal syndrome</li> <li>- Hendra virus</li> <li>- Hepatitis B virus cultures</li> <li>- Herpes B virus cultures</li> <li>- Human immunodeficiency virus cultures</li> <li>- Highly pathogenic avian influenza virus cultures</li> <li>- Japanese Encephalitis virus cultures</li> <li>- Junin virus</li> <li>- Kyasanur Forest disease virus</li> <li>- Lassa virus</li> <li>- Machupo virus</li> <li>- Marburg virus</li> <li>- Monkeypox virus</li> <li>- <i>Mycobacterium tuberculosis</i> cultures</li> <li>- Nipah virus</li> <li>- Omsk hemorrhagic fever virus</li> <li>- Poliovirus cultures</li> <li>- Rabies virus cultures</li> <li>- <i>Rickettsia prowazekii</i> cultures</li> <li>- <i>Rickettsia rickettsia</i> cultures</li> <li>- Rift Valley fever virus</li> <li>- Russian spring-summer encephalitis virus cultures</li> <li>- Sabia virus</li> <li>- <i>Shigella dysenteriae</i> type 1 cultures</li> <li>- Tick-borne encephalitis virus cultures</li> <li>- Variola virus</li> <li>- Venezuelan equine encephalitis virus</li> <li>- West Nile virus cultures</li> <li>- Yellow fever virus cultures</li> <li>- <i>Yersinia pestis</i> cultures</li> </ul>
<b>UN 2900</b> Infectious substance affecting animals	<ul style="list-style-type: none"> <li>- African swine fever virus cultures</li> <li>- Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus cultures</li> <li>- Classical swine fever virus cultures</li> <li>- Foot and mouth disease virus cultures</li> <li>- Lumpy skin disease virus cultures</li> <li>- <i>Mycoplasma mycoides</i> - Contagious bovine pleuropneumonia cultures</li> <li>- Peste des petits ruminants virus cultures</li> <li>- Rinderpest virus cultures</li> <li>- Sheep pox virus cultures</li> <li>- Goatpox virus cultures</li> <li>- Swine vesicular disease virus cultures</li> <li>- Vesicular stomatitis virus cultures</li> </ul>

\* 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.jitcertified.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 – Blank Shipper’s Declaration for Dangerous Goods

### SHIPPER'S DECLARATION FOR DANGEROUS GOODS

<b>Shipper</b>				Air Waybill No.			
				Page _____ of _____ pages			
				Shipper's Reference Number <i>(optional)</i> :			
<b>Consignee</b>				<i>Area for optional use for company logo name and address</i>			
Two completed and signed copies of this Declaration must be handed to <i>the operator</i>				<p><b>WARNING</b></p> <p>Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.</p>			
<b>TRANSPORT DETAILS</b>							
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure					
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY						
<b>Airport of Destination:</b>				<i>Shipment type: (delete non-applicable)</i> <input type="checkbox"/> NON-RADIOACTIVE <input type="checkbox"/> RADIOACTIVE			
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>							
Dangerous Goods Identification					Quantity and type of packing	Packing Inst.	Authorization
Proper Shipping Name	Class or Division	UN or ID No.	Pack-ing Group	Subsidiary Risk			
<b>Additional Handling Information:</b>							
<b>Emergency Telephone Number:</b>							
I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name, and are classified, packaged, marked, and labeled/placarded, and are in all respects in the proper condition for transport according to the applicable international and national governmental regulations.					<b>Name/Title of Signatory</b>		
					<b>Place and Date</b>		
					<b>Signature</b>		
					<i>(see warning above)</i>		

## Appendix D – Example Shipper’s Declaration for Dangerous Goods

### SHIPPER'S DECLARATION FOR DANGEROUS GOODS

<b>Shipper</b> Dr. Joe Germ 123 Science Building Georgia State University Atlanta, GA 30303				Air Waybill No.  Page <u>1</u> of <u>1</u> pages  Shipper's Reference Number (optional):			
<b>Consignee</b> Dr. Jane Infection 987 Research Building Anytown University Anywhere, USA				<i>Area for optional use for company logo name and address</i>			
Two completed and signed copies of this Declaration must be handed to <i>the operator</i>				<b>WARNING</b>  Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.			
<b>TRANSPORT DETAILS</b>							
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		<b>Airport of Departure</b>  ATL					
PASSENGER AND CARGO AIRCRAFT	<del>CARGO AIRCRAFT ONLY</del>			Shipment type: <i>(delete non-applicable)</i> <input checked="" type="checkbox"/> NON-RADIOACTIVE <del><input type="checkbox"/> RADIOACTIVE</del>			
<b>Airport of Destination:</b> ANY							
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b>							
Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Pack- ing Group	Subsi- diary Risk	Quantity and type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Hepatitis B virus)	6.2	UN2814			50 ml	602	
Dry Ice	9	UN1845	III		3 kg	904	
<b>Additional Handling Information:</b> Prepared according to ICAO/IATA; prior arrangements as required by IATA Dangerous Goods Regulations 1.3.3.1 have been made.							
<b>Emergency Telephone Number:</b> Peter Farina404-227-7472							
I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name, and are classified, packaged, marked, and labeled/placarded, and are in all respects in the proper condition for transport according to the applicable international and national governmental regulations.				<b>Name/Title of Signatory:</b> Dr. Joe Germ, Professor  <b>Place and Date:</b> Atlanta, GA 01/23/04  <b>Signature</b>  <i>(see warning above)</i>			

## Appendix E – Intent to Ship Hazardous Materials

After reading the *GSU Shipment of Biological Materials and Dry Ice Manual*, fill out this form to qualify to ship dangerous materials at GSU. The BSO 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
  - Cargo Aircraft label
  - Dry ice, UN 1845, net weight \_\_\_\_\_ kg
  - Infectious substance, affecting humans (*technical name*), UN 2814, net quantity \_\_\_\_\_
  - Infectious substance, affecting animals (*technical name*), UN 2900, net quantity \_\_\_\_\_
  - Name, Address and Phone Number of Shipper
  - Name and Address of Consignee
  - Name and Phone Number of Person Responsible for Shipment
  - “Inner Packages Comply with Prescribed Specifications.”
  - Genetically modified micro-organisms, UN 3245, net quantity \_\_\_\_\_
  - “Diagnostic Specimen Packed in Compliance with IATA Packing Instruction 650”
4. Fill out attached Declaration for Dangerous Goods form (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.

<b>Print name:</b>	
<b>Signature:</b>	
<b>Date:</b>	
<b>Please return to GSU Biosafety – Fax: (404) 413-3504; campus mail: PO Box 3999; in person: Alumni Hall, Suite 215</b>	

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

### Viruses

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

### Prion

1. Bovine spongiform encephalopathy agent <sup>3</sup>

### Toxins

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

### Bacteria

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

### Fungi

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

### Exemptions

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

- <http://www.cdc.gov/od/sap/sap/exclusion.htm>
- [http://www.aphis.usda.gov/programs/ag\\_selectagent/](http://www.aphis.usda.gov/programs/ag_selectagent/)

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 LD<sub>50</sub> < 100 ng/kg body weight.

<sup>1</sup> APHIS Plant Pathogen    <sup>2</sup> HHS Select Infectious Agent    <sup>3</sup> USDA High Consequence Livestock Pathogen or Toxin    <sup>4</sup> USDA-HHS Overlap Agent