

## Importing Biological Materials Guidelines and Regulations

In order to safely ship biological agents and materials between locations, several US Government agencies, the UN-World Health Organization and several transportation organizations have developed guidelines and regulations that specify the proper packaging and labeling procedures to follow. In several instances, permits or registrations must be obtained **before you can legally** send or obtain biological materials, especially from or to overseas points.

The guidance offered here will serve to acquaint you with the appropriate agencies, their websites and their specific requirements. Specific documents will not be provided, since these links change sporadically within the home page site.

### REGULATIONS

These are enforceable laws, some carrying fines if not complied with by an offering individual. The following agencies have jurisdiction over biological materials:

US Customs and Border Patrol	<a href="https://www.cbp.gov/">https://www.cbp.gov/</a>
US Department of Agriculture Animal & Plant Health Inspection Service	<a href="http://www.usda.gov/">http://www.usda.gov/</a> <a href="http://www.aphis.usda.gov/">http://www.aphis.usda.gov/</a>
US Department of Commerce	<a href="https://www.bis.doc.gov/">https://www.bis.doc.gov/</a>
US Department of Transportation	<a href="http://www.dot.gov/">http://www.dot.gov/</a>
US Postal Service	<a href="http://www.usps.com/">http://www.usps.com/</a>
Centers for Disease Control CDC Import Permit Program	<a href="https://www.cdc.gov/biosafety/">https://www.cdc.gov/biosafety/</a> <a href="https://www.cdc.gov/phpr/ipp/index.htm">https://www.cdc.gov/phpr/ipp/index.htm</a>
Food and Drug Administration (FDA)	<a href="http://www.fda.gov/">http://www.fda.gov/</a>
World Health Organization	<a href="http://www.who.int/">http://www.who.int/</a>

## CARRIER SHIPPING GUIDELINES

These documents *are not* laws, but often refer to laws issued by the agencies above. Also, individual carriers can refuse to take your package and ship it if they believe it violates the WHO, US Gov't laws, carrier's guidelines, or association guidelines.

International Air Transport Association	<a href="http://www.iata.org/">http://www.iata.org/</a>
FedEx	<a href="http://www.fedex.com/us/">http://www.fedex.com/us/</a>
DHL (International ONLY)	<a href="http://www.dhl.com/">http://www.dhl.com/</a>
World Courier	<a href="http://www.worldcourier.com/">http://www.worldcourier.com/</a>
United Parcel Service	<a href="http://www.ups.com">http://www.ups.com</a>
International Civil Aviation Organization	<a href="http://www.icao.int/">http://www.icao.int/</a>

## EVALUATING AGENCY JURISDICTION

There is substantial interplay between various agencies and their respective requirements for importing biological materials; some of the agencies cite other agency regulations applying the requirements contained within those regulations or guidelines to their practices. The following guidance is found on the US Customs website and is used as an example of the complexity of regulations governing the importation of biological materials from outside the United States:

### “Biological Materials [ Importation ]

Unsterilized specimens of human and animal tissue (including blood, bodily discharges and excretions); cultures of living bacteria, viruses or similar organisms; animals suspected of being infected with a disease transmissible to humans; and insects, snails, and bats may require an import permit from the [Centers for Disease Control and Prevention](#). Write to the Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, GA 30333, USA.

Biological materials produced from animals or animal products may require an additional permit from the [Animal and Plant Health Inspection Service](#) (APHIS) of the U.S. Department of Agriculture (USDA). Please write to USDA'S Import-Export Products Staff, APHIS, 4700 River Road, Riverdale, MD 20737 USA, for further information and an application for an import permit.

In order to export biological material **outside** the United States, the U.S. Department of Commerce may require you to obtain an export license or at least file the material using an Export Classification and Control Number (ECCN) prior to shipping your specimens overseas. This practice serves to limit exporting materials to restricted countries or controlling "dual use" materials and preventing them from reaching the wrong hands. Remember it may not be the material **but the destination** that is going require a license to export. All exports must be reviewed by [UNMC Export Control Officer](#) .

Some of these permit or license applications have very long lag times and you should count on a **minimum** of 6-8 weeks turn-around time before you have the document in hand. Apply for them well in advance of anticipated need.

To make the process somewhat easier, the following considerations have to be made before taking any action:

- |                                                               |                        |
|---------------------------------------------------------------|------------------------|
| 1. Does the material I am receiving contain a pathogen?       | See: CDC; APHIS; WHO   |
| 2. Is the material I am receiving a pathogen?                 | See: CDC; APHIS; WHO   |
| 3. Is the material <b>on the Select Agent List?</b> *         | See: CDC- SAP, APHIS   |
| 4. Is the material a Restricted Animal Pathogen?              | See: APHIS; CDC        |
| 5. Is the material a Human Specimen?                          | See: CDC               |
| 6. Is the material an Animal Specimen?                        | See: APHIS; CDC; WHO;  |
| 7. Is the material an Animal?                                 | See: APHIS; US Customs |
| 8. Is the material on a restricted country / individual list? | See: DOC, BIS          |

\* <https://www.cdc.gov/phpr/dsat.htm> All imports of Select Agents must be reviewed by UNMC Biosafety Officer

Once you have the answers to these questions, and you have all of the required permits / licenses you can select the appropriate packaging and labels required for your shipment, and select the carrier you will use for your shipment. Your carrier may recommend packaging in their guidance materials. Many carriers restrict what you can ship through their service so check with them first (UPS does not handle highly pathogenic material!).

If you are receiving a package from a colleague overseas, it is **strongly advised**, that you discuss packaging, labeling, and carrier use *before* they send the material to the United States – it should conform to IATA / WHO requirements. It is also advised that you contact the carrier and find out what day and what airport the package will arrive at. Have a list of package contents ready for each package to forward to US Customs and Border Patrol, just in case your package is impounded.

Once this information is known, you should contact the US Customs Service Office at that port and inform the agents there that your package is coming to their port and contains whatever the contents are that are being shipped to you. You should have all appropriate permits, registrations and licenses in your possession on this side of the process *before arranging* the shipment.

**If you are not prepared** your package could sit in quarantine, and become damaged while US Customs and Border Patrol tries to find you, or clear the package for shipment to you. As stated earlier, you may even discover that you have subjected yourself to a fine / penalty if you have violated quarantine or shipping rules.

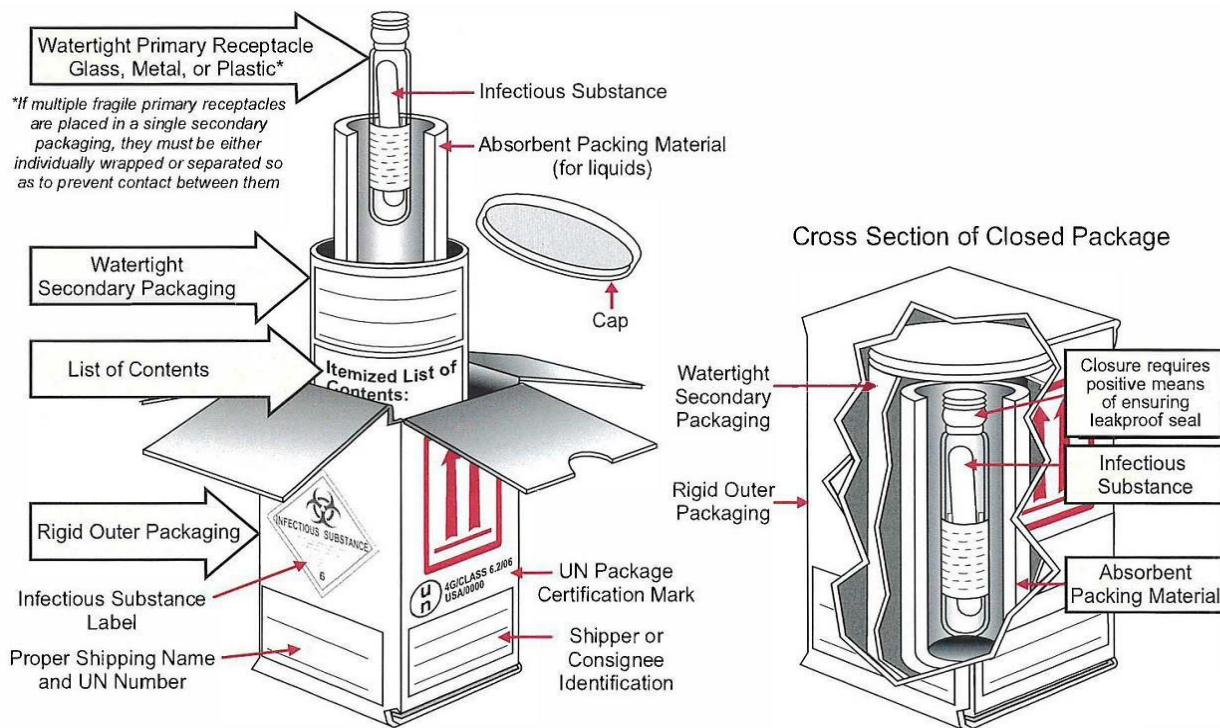
## **PACKAGING**

There are very specific requirements for the packaging of biohazardous material, which ensure that the shipment will arrive safely at its destination. The best site for information on small packages is the CDC's Office of Health and Safety, <http://www.cdc.gov> under the heading "Biosafety Information". The "Biosafety in Microbiological and Biomedical Laboratories, 5th Edition" book located there has a thorough description of packaging in "Appendix C". <https://www.cdc.gov/biosafety/publications/bmb15/index.htm>

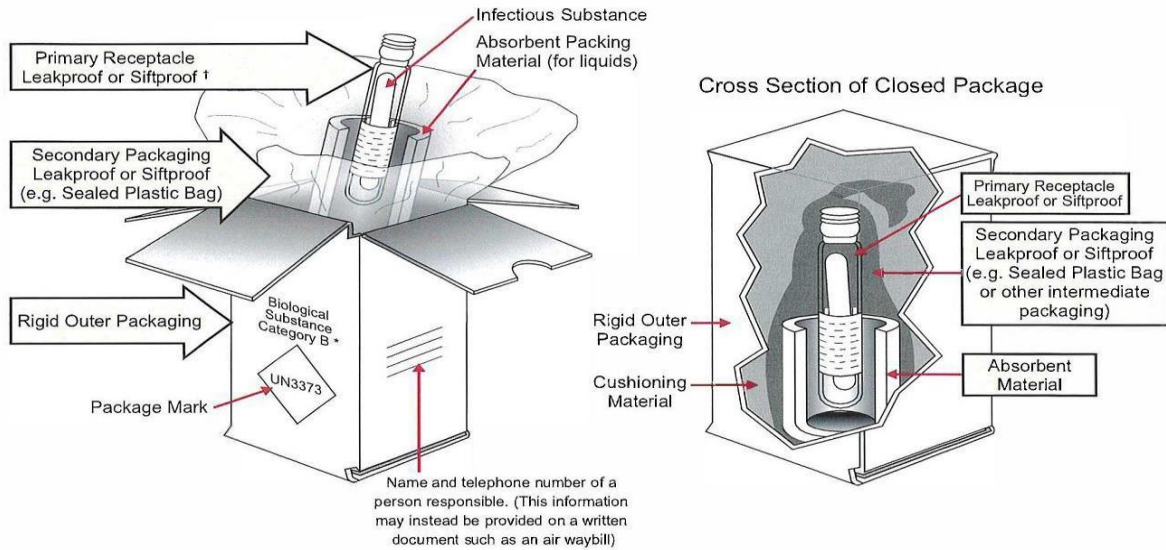
Many of the laboratory equipment vendors such as Fisher Scientific, SAF-T-PAK, AIR SEA CONTAINERS Inc, etc. have kits with all of the required items already assembled for your use. This type of packaging does not come on the inexpensive side, but unless you duplicate the packaging **exactly**, according to IATA (and DOT) Shipping Packaging instructions 620 and 650, your shipment may be in violation of carrier rules/government agency laws. **The issue of selecting the proper containers cannot be stressed enough**, since many carriers will reject containers that do not meet their requirements. Additionally, you may be responsible for any clean-up / decontamination of equipment, **airplanes** or surface vehicles contaminated by an improperly prepared package that leaks in transit.

Refer to the following figures as a guide to what the proper shipping container should look like. **DO NOT deviate** from these diagrams, or remove items from a shipping kit -they are all required by regulations to be in the kit and used accordingly. If you have questions, contact the Environmental Health & Safety Department at 402-559-6356.

**Fig. 1: Category A "Infectious Substances affecting Humans (UN 2814)" or "Infectious Substances affecting Animals (UN 2900)"**



**Fig.2: Clinical Specimens are now designated "Infectious Substances, Category B (UN 3373)"**



\* The proper shipping names "Biological Substance, Category B"; "Clinical Specimen"; and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.

† If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact

**Note:** Follow package manufacturer's closure instructions

## CHECKLISTS

A checklist for import has been attached to this document to assist you in getting your package ready for shipment. **IT IS EXTREMELY IMPORTANT** that you cover every detail, and get the necessary licenses /permits before sending a package. If you are receiving a package from overseas, get as much information as you can from the shipper and include it into your documentation. Failure to do this may result in your package **being delayed** in a quarantine impound.

## LEAKING PACKAGES

If you receive a leaking package, or a package that contains broken containers within, notify UNMC Security at 402-559-5444 immediately. Obtain assistance from UNMC Biosafety Officer (402-559-7774) as to which agencies may require notification, before notifying any external agency.

If any of the packaging contents is spilled or leaks on you, treat the incident similar to a blood borne pathogen incident, wash the site with soap and water, and obtain medical assistance immediately by going to the Employee Health or the Nebraska Medicine Emergency Department.

If you are unsure about any of the issues mentioned in this document, please contact Export Control Officer at 402-559-4518. If you need assistance in acquiring any of the documents or permits/registrations/licenses required for your shipment, contact the Export Control Officer at 402-559-4518.

## **Appendix A: Common Laboratory Specimens Offered for Transport**

### **Materials Requiring a Hazardous Materials (Dangerous Goods) Declaration**

- Infectious substance, affecting humans (UN 2814) Solid or Liquid
- Infectious substance, affecting animals (UN 2900) Solid or Liquid

### **Materials *Not* Requiring a Hazardous Materials (Dangerous Goods) Declaration**

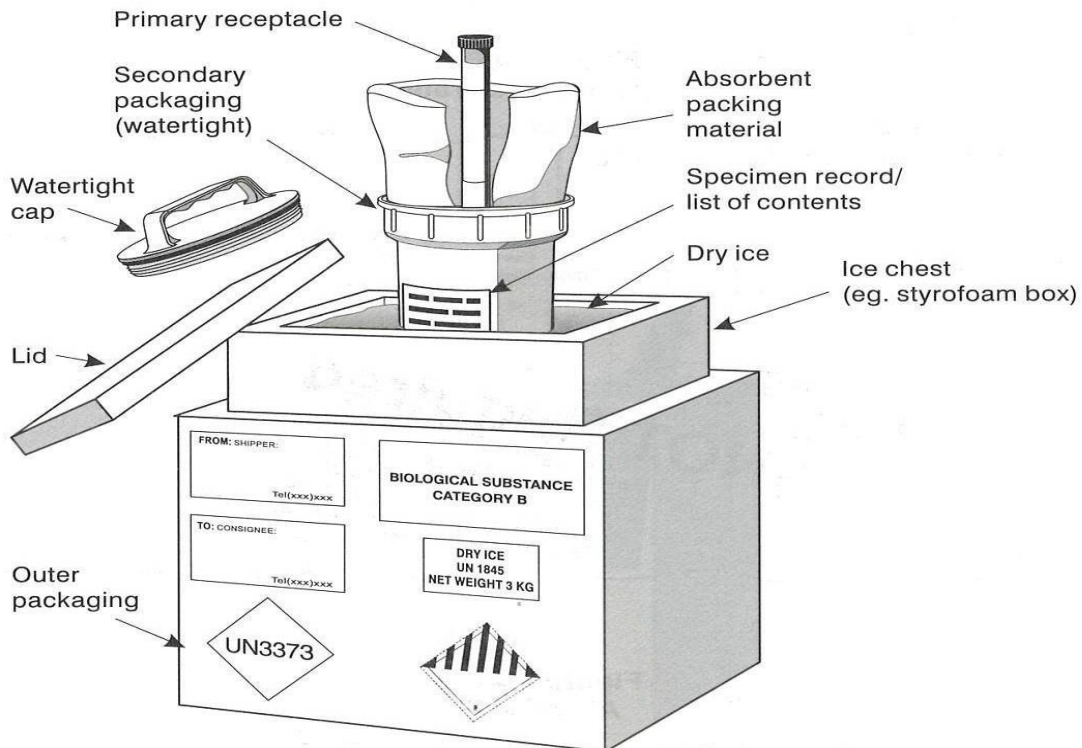
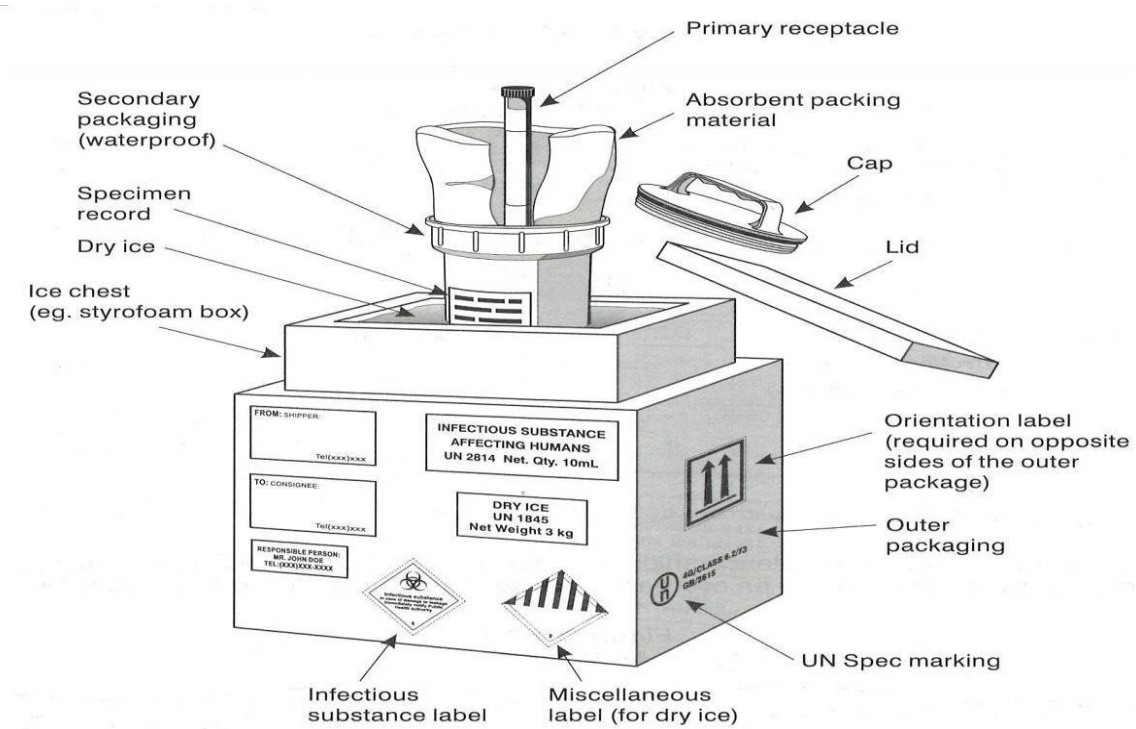
- Patient Specimens (Exempt Human or animal specimens)
- Clinical Specimens (UN 3373)
- Biological Substance, Category B (UN 3373)
- Genetically Modified micro-organisms (UN 3245) (Gets a Class 9 Sticker!!)

### **Other Hazardous Materials Offered along with Primary Contents Requiring a Hazardous Materials (Dangerous Goods) Declaration**

- Nitrogen, refrigerated liquid (as a cryopreservative) (UN1977)
- Formaldehyde solution (aka Formalin, 10%) (UN 2209)
- Ethyl Alcohol solution (Ethanol) (UN1170)
- Isopropyl Alcohol (Isopropanol) (UN 1219)

**Appendix B:**

**Outer Shipping Box Examples – Basic Schema for Marking Boxes**



**University of Nebraska Medical Center  
Sample Import Checklist**

**Type of Material to be imported**

- Human     Animal     Bacterial     Viral     GMO  
 Other \_\_\_\_\_

**Characterization of Material**

**Harmonized Code#:** \_\_\_\_\_

- Pure Form     Formulation

- Medical     Genetic     Infectious     Non-Infectious     Non-Radioactive  
 Non-Toxic     Not for Human use     Not for animal use     Other \_\_\_\_\_  
 UN 2814 Category A-Human     UN 2900 Category A-Animal     UN 3373 Category B

**Purpose of Material:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Quantity per tube /container / packet**

\_\_\_\_\_ mls    \_\_\_\_\_ µls    \_\_\_\_\_ gms    \_\_\_\_\_ mgs    Other \_\_\_\_\_

**Total Quantity**

\_\_\_\_\_ mls    \_\_\_\_\_ µls    \_\_\_\_\_ gms    \_\_\_\_\_ mgs    Other \_\_\_\_\_

**Total Number of Containers / Packages in Shipment:** \_\_\_\_\_

**Sample Origin (From)**

Institution: \_\_\_\_\_  
 PI. \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Phone#: \_\_\_\_\_

**Sample Origin (To)**

**University of Nebraska Medical Center**  
 PI. \_\_\_\_\_  
 Bldg: \_\_\_\_\_ Rm# \_\_\_\_\_

Phone#: \_\_\_\_\_

Transporter / Courier: \_\_\_\_\_  
 Tracking Number \_\_\_\_\_  
 Declared Value \_\_\_\_\_

Phone # \_\_\_\_\_  
**Manifest #** \_\_\_\_\_

**Port of Entry\*\***

- Air     Sea     Ground (Border Crossing Can, Mex)  
 JFK International     New York / Newark     Other \_\_\_\_\_

**Permit(s) required (Attach a copy to this document!)**

- USDA     CDC     DOC/BIS     FDA     Other: \_\_\_\_\_

I affirm that this information is correct based on information supplied to me and to the limit of my ability to verify.

**Print name:** \_\_\_\_\_

\_\_\_\_\_    \_\_\_\_\_    \_\_\_\_\_  
 Signed name    title    date