

Chapter 23 Shipping Regulations

[Quick Reference](#)

[Summary of New Regulations](#)

[Importation & Exportation Issues](#)

[Exportation Issue](#)

[Importation Issue](#)

[Special Situation Permits](#)

[Resources for More Information and/or Material](#)

[Details](#)

[Dangerous Goods](#)

[General Requirements](#)

Inner Packaging Specifications

Outer Packaging Specifications

[Specific Requirements \(Physical Conditions\)](#)

Shipping At or Above Ambient Temperature

Shipping Substances In Refrigerated or Frozen Condition

Shipping in Liquid Nitrogen

Specifications for Lyophilized Substances

[Required United Nations Specification Markings](#)

[Special Handling Requirements](#)

[Shipping Recombinant Materials](#)

This chapter is divided into three units: Quick Reference information, Summary of the New Regulations and Details section.

Quick Reference

All biohazardous materials shipped off campus must be packed in special packaging which meets "UN 6.2" packaging standards. Call the IBC office for guidance and assistance. The appropriate packaging may be obtained from Fisher Scientific Customer Service 1-800-766-7000.

Summary of New Regulations

A. Importation & Exportation Issues

The specific package model must be tested and certified to meet DOT/UN packaging standards. The package must be imprinted by the manufacturer with appropriate markings of the United Nations Dangerous Goods shipping code. This type of packaging is available for sale from several vendors, a few of which are listed below (see item E).

B. Exportation Issue

A license may be required from the Department of Commerce.

C. Importation Issue

Importation permits and shipping labels are required. Packages originating in foreign locations must have an importation permit and shipping labels issued by the U.S. Public Health Service. Importation permits are issued only to the importer who must be located in the U.S. Shipping labels containing (1) the universal biohazard symbol, (2) the address of the importer, (3) the permit number and (4) the expiration date of the permit are also issued to the importer, along with the permit.

Items requiring permits are:

- etiologic agents
- biological materials
- animals
- insects
- snails
- bats

The importer must send these labels and one or more copies of the permit to the shipper.

The shipper must secure the label and attach a copy of the permit to the package.

D. Special Situation Permits

The United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) permits are required for importing infectious agents for livestock; and for biological materials containing animal material--particularly livestock, including fetal bovine serum.

The United States Department of Interior permits are required for certain live animals.

E. Resources for More Information and/or Material

Centers for Disease Control & Prevention.....(404) 633-5313

United States Department of Agriculture.....(301) 734-7760...FAX (301) 734-8226

United States Department of Interior.....(800) 358-2104

United States Department of Commerce.....(202) 482-0896

For a list of approved vendors of requisite packaging, contact Federal Express Dangerous Goods Administration at.....(901) 369-3854 or (901) 369-3856

Fisher Scientific Customer Service.....(800) 766-7000

Ambient Temperature Packs.....Fisher Catalog # 03-522-38

Frozen Packs--call Fisher Scientific for information update.....(800) 766-7000

Details

Dangerous Goods

The most current regulations affecting the transportation of Dangerous Goods went into effect January 1, 1995. For the purposes of the PI in a biomedical research setting, all potentially infectious substances come under the classification of Dangerous Goods. Carriers (such as FedEx and UPS) are legally bound to reject any packages that are not in compliance with these new regulations.

The specific requirements of the regulations are outlined in the International Civil Aviation Organization (ICAO) tariffs and the International Air Transport Association (IATA) tariffs. The following represents the relevant details of the regulations.

Infectious substances are assigned one of two UN numbers depending on the potential infectivity of the material.

Number 2814 is assigned to materials that may infect humans.

Number 2900 is assigned to materials that may infect animals ONLY.

If the material is to be shipped by passenger aircraft:

If it is liquid, maximum net quantity per package is 50 ml.

If it is solid, maximum net quantity per package is 50 g.

For greater unit quantities, the material must be shipped by cargo aircraft only, in which case:

For liquid material, maximum net quantity per package is 4 L.

For solid material, maximum net quantity per package is 4 kg.

General Requirements

Shippers of infectious substances must comply with these regulations and must ensure that shipments are prepared in such a manner that they arrive at their destination in good condition, and that they present no hazards to persons or animals during shipment.

The packaging must include both inner packaging and outer packaging.

Inner packaging specifications:

watertight primary receptacle(s)

a watertight secondary packaging

an absorbent material which must be placed between the primary receptacle(s) and the secondary receptacle

When multiple primary receptacles are placed within a single secondary packaging, each one of the primary receptacles must be individually wrapped in order to prevent contact between them.

The absorbent material must be sufficient to absorb the entire contents of all primary receptacles in the event of a leakage.

Outer packaging specifications:

packaging material must be of sufficient strength to meet the design type test standards

packages must be at least 100 mm (4 inches) in the smallest overall dimension

tested packaging must bear United Nations specification markings

an itemized list of contents must be enclosed between the secondary packaging and the outer packaging

all packages containing infectious substances must be marked durably and legibly on the outside of the package with the NAME and PHONE NUMBER of a person responsible for the shipment

Specific Requirements (Physical Conditions)

The physical conditions of shipped substances may be classified as follows:

- A. Substances shipped at, or above, ambient temperature
- B. Substances shipped refrigerated or frozen (i.e., with wet ice, dry ice, prefrozen packs, etc.)
- C. Substances shipped in liquid nitrogen
- D. Lyophilized substances

A. Specifications for shipping at or above ambient temperature

Primary receptacle may only be of glass, metal or plastic

Positive means of ensuring a leakproof seal must be provided (e.g., heat seal, skirted stopper or metal crimp seal)

If screw caps are used, they must be reinforced with adhesive tape

B. Specifications for shipping substances in refrigerated or frozen condition

Ice, wet or dry, must be placed OUTSIDE the secondary packaging.

Interior support must be in place to secure secondary packaging in its original position after the ice has dissipated.

If wet ice is used, packaging must be leakproof.

If dry-ice is used, the outer packaging must permit the release of carbon dioxide.

The primary and secondary portions must maintain containment integrity at the temperature of the refrigerant used, as well as at the temperature and pressure ranges of air transport to which the receptacle could be subjected if refrigeration is lost.

C. Specifications for Shipping in Liquid Nitrogen

Plastic primary receptacle capable of withstanding very low temperatures.

Secondary packaging must also withstand very low temperature and in most cases will be fitted over individual primary receptacles.

The primary receptacle must maintain containment integrity at temperature of refrigerant used, and temperature and pressure of air transport to which the receptacle may be subjected if refrigeration is lost.

D. Specifications for Lyophilized Substances

Primary receptacles must be either flame-sealed glass ampoules or rubber-stoppered glass vials with metal seals.

IBC Biosafety Handbook Revision 7/30/02 Chapter 23 Shipping Regulations Ver 3.0
Required United Nations Specification Markings

The shipping package must display markings that display United Nations specification symbol and alphanumeric code. The marking consists of five parts:

1. United Nations symbol
2. Characters denoting the Class of Dangerous Goods to which the particular package belongs. In the case of Infectious Substances, the required characters are "6.2" .
3. The last two digits of the year in which the packaging material was manufactured.
4. The country authorizing the marking.
5. The name of the package manufacturer or other ID specified by the appropriate authorities in the country of origin of the package.

Special Handling Requirements

Certain etiologic agents require special handling. Most of these agents are in Class 3 or Class 4. They must be shipped by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery. When this notice of receipt is not received within five days following anticipated delivery, the sender must immediately notify the CDC.

Questions pertaining to proper shipping and packaging of etiologic agents should be directed to the IBC Office, or the CDC Office of Health and Safety at (404) 639-3883.

Shipping Recombinant Materials

Recombinant materials should be shipped under the applicable regulations of the U.S. Postal Service (39 Code of Federal Regulations, Part 3); the Public Health Service (42 Code of Federal Regulations, Part 72); the U.S. Department of Agriculture (9 Code of Federal Regulations, Parts 171-179). See Appendix H of the NIH Recombinant DNA Guidelines for more information on Shipping recombinant materials.

APPENDIX

Shipping Biological and Infectious Substances

The interstate transportation of biohazardous substances is regulated by the U.S. Public Health Service (PHS) and the Department of Transportation (DOT). While these regulations apply to interstate transport by highway, rail, vessel, and air, the “Dangerous Goods Regulations” specified by the International Air Transport Association (IATA) are the guidelines followed by all Domestic and International air carriers. Knowledge and compliance with the IATA regulations ensures that those who ship (the consignees) regulated materials meet or exceed all PHS and DOT requirements.

The IATA Dangerous Goods Regulations are complicated and involved. Knowing how to properly classify, declare, pack, label, and handle biohazardous materials is mandatory and appropriate training must be documented. The following information provides the minimum guidance necessary to perform these activities. The Office of Environmental Health and Safety has a proprietary training module on compact disc which must be completed by any University employee whose job duties include routine shipment of biohazardous substances. Individuals who complete the program must print out the confirmation that they passed the final exam. Attaching the confirmation to this manual is acceptable evidence of technical competence.

IATA Definitions - 1999

3.6.2 Division 6.2 – Infectious Substances

3.6.2.1 Definition

Division 6.2 includes substances which are infectious to humans and/or animals and include genetically modified micro-organisms and organisms, biological products, diagnostic specimens and clinical and medical waste, as described in 3.6.2.1 to 3.6.2.5

3.6.2.1 Infectious Substances

Infectious substances are substances known to contain, or reasonably expected to contain, pathogens. Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) or recombinant micro-organisms (hybrid or mutant) that are known or reasonably expected to cause infectious disease in humans or animals. Infectious substances are not subject to the provisions of these Regulations for Division 6.2 if they are unlikely to cause human or animal disease. Infectious substances are, however, subject to the provisions of these Regulations for Division 6.2 if they are capable of spreading disease when exposure to them occurs.

Note: Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are contained in substances which are not infectious substance should be considered for classification in Division 6.1 and assignment to UN 3172.

3.6.1.3 Biological Products

These are those products derived from living organisms, that are manufactured and distributed in accordance with the requirements of national governmental authorities which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines and diagnostic products.

Note: Some licensed biological products may present a biohazard in certain parts of the world only. In that case competent authorities may require these biological products to comply with the requirements for infectious substances or may impose other restrictions.

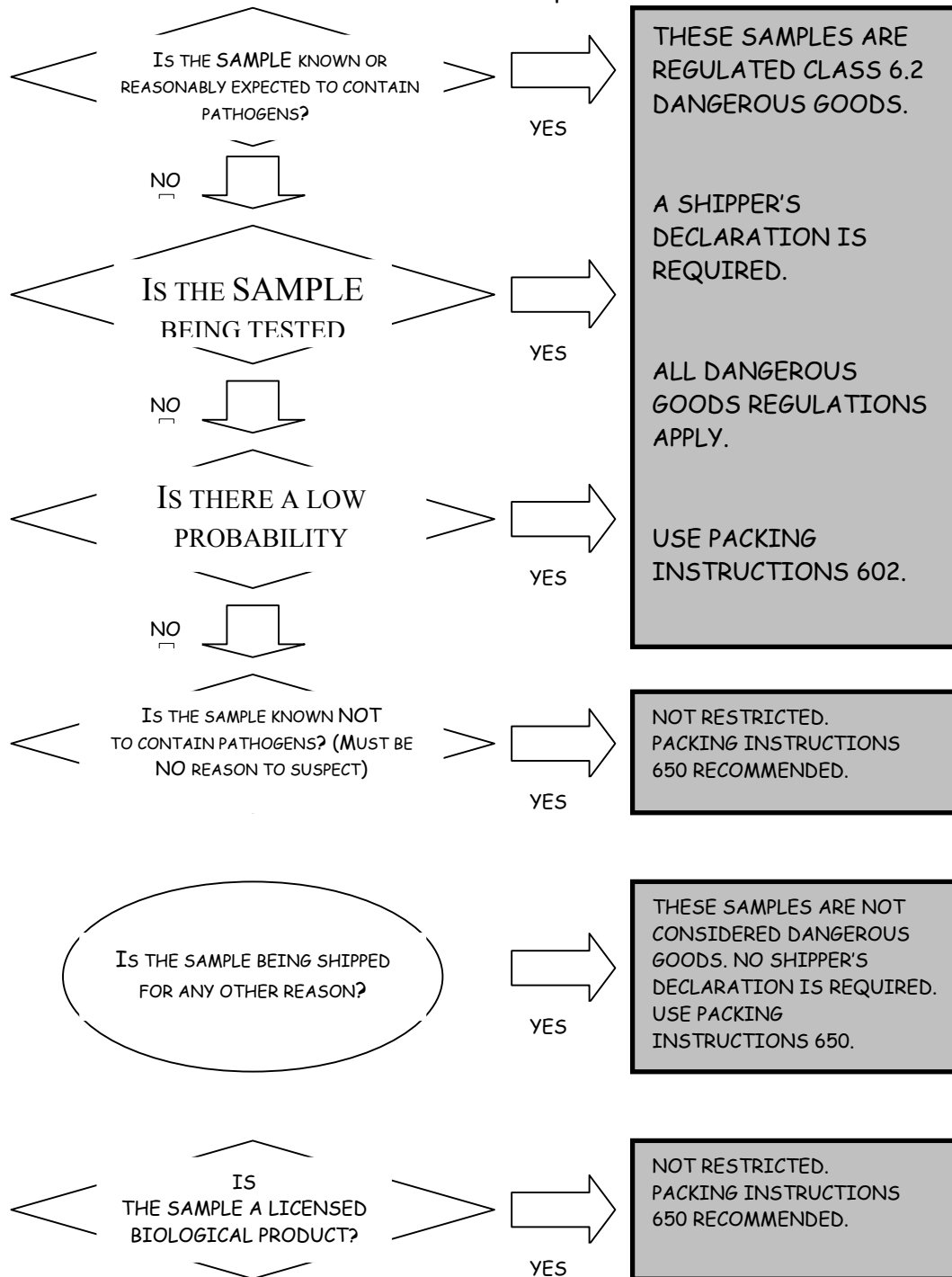
3.6.1.4 Diagnostic Specimens

Any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected animals.

Dangerous Goods Classification Flow Chart

Infectious Substances - Diagnostic Specimens - Biological Products

To be added compliments of Saf T Pak



Packing Instructions 602 **(Infectious Substance)**

Packaging

1. Watertight primary
2. Watertight secondary
3. Absorbent material
4. Specimens divided & separated
5. Outer packaging must meet stringent tests
UN specification mark
6. 4 inch minimum dimension
7. Itemized list
8. Primary or secondary capable of 95 kPa pressure differential (14 psi)
9. Name & phone # of responsible person
10. Prior arrangements with consignee required

Marking the Package

1. Proper shipping name
2. Technical name
3. UN ID #
4. Full address of shipper and consignee
5. Name and phone # of shipper and consignee

Labeling the Package

1. Use US label
2. Must be diamond on point, standard label
3. Only one label of each type

Shipper's Declaration

1. 3 copies
2. Keep on file at least 1 year
3. Carrier keeps one, consignee keeps one

Packing Instructions 650
(Diagnostic Specimen)

Packaging

1. Leakproof primary
2. Watertight secondary
3. Absorbent material
4. Specimens divided & separated
5. Outer packaging capable of passing 1.2 meter drop test
6. 4 inch minimum dimension
7. Itemized list
8. Primary or secondary capable of 95 kPa pressure differential (14 psi)
9. "Packed in Compliance with IATA Packing Instructions 650"

Marking the Package

Each package and the "nature & quantity of dangerous goods" box of the air waybill must show the text "BIOLOGICAL PRODUCTS" or "DIAGNOSTIC SPECIMENS" – PACKED IN COMPLIANCE WITH IATA PACKING INSTRUCTION 650.

Labeling the Package

If no other dangerous goods contained within, no labels are necessary.

Shipper's Declaration

Not required

Quiz

1. The US regulation that covers the shipment of Dangerous Goods as it applies to biohazardous substances is:
 - 49 CFR Department of Transportation
 - 29 CFR Department of Labor
 - TDGR Canadian Transportation of Dangerous Goods Regulation
 - None of the above
2. An Infectious Substance, Biological Product or Diagnostic Specimen are all treated equally in terms of shipping regulations.
 - True
 - False
3. A substance is considered a Regulated Class 6.2 Dangerous Good if:
 - The substance is known or reasonably expected to contain a pathogen in Risk Groups 2, 3, or 4.
 - The substance is being shipped to test for the presence of pathogens.
 - The substance does not have a low probability for Risk Group 4 pathogens being present in the sample.
 - All of the above.
4. If a substance meets the criteria as detailed in Question 3, the correct packaging and labeling standards to use would be:
 - Cardboard box with handwritten label on outside.
 - Packaging Instructions (PI) 602 .
 - Packaging Instructions (PI) 650.
 - None of the above.
5. The main parties involved with a shipment of a Dangerous Good are the:
 - Shipper.
 - Carrier.
 - Consignee.
 - All of the above.
6. Shipping with Dry Ice does not require any special labeling on the package.
 - True
 - False

7. The importation of plants, animals, animal containing material or other biological material from foreign countries requires a permit.
 - True
 - False
8. Depending on the nature of the imported plants, animals, animal containing material or other biological material, permits can be obtained from:
 - US Public Health Service.
 - US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS).
 - US Department of Commerce.
 - US Department of the Interior.
 - All of the above.
9. All shippers must be trained and show a record of training every 3 years under 49 CRF.
 - True
 - False
10. The University of Arizona of Arizona's training standard for shippers is:
 - Completion of the Department of Risk Management's training course on shipping of hazardous materials.
 - Completion of the Saf-T-Pak's 2002 (or current year) CD ROM Comprehensive Guide to Shipping Hazardous Substances
 - Working knowledge of University of Arizona Policy on Shipping Hazardous Materials.
 - All of the above.