

# Guide to Shipping Biological Materials

## Introduction

This manual is to aid in the shipment of biological materials from NC State University in compliance with the US Department of Transportation (DOT) and the International Air Transporters Association (IATA). This manual does not include agricultural and foreign customs restrictions.

Carrying biological materials on one's person onto an aircraft is prohibited. All biological materials must be properly packaged and checked as luggage or transported via a courier.

The steps to properly ship biological materials include:

- Classification
- Packaging
- Labeling
- Documentation

Anyone participating in any one of the previous steps must be trained and certified according to DOT and IATA regulations. Training can be scheduled at the Environmental Health and Safety Center by calling 515-2895.

Biological materials fall into the following categories:

- Infectious substances
  - Category A infectious substances
  - Category B infectious substances
- Diagnostic specimens
- Biological products
- Genetically modified organisms and micro-organisms
- Unregulated biological materials

Infectious substance shipping regulations do not apply if the biological material to be shipped cannot cause disease. Substances that have a low probability of containing infectious substances such as water samples or food are not subject to these requirements.

## Infectious Substances

Infectious substances are those substances known to contain, or reasonably expected to contain pathogens. Pathogens are defined as microorganisms or recombinant microorganisms that are known or reasonably expected to cause infectious disease in humans or animals. However, they are not subject to the provisions of shipping if they are unlikely to cause human or animal disease. Infectious substances are subject to the regulations only if they are capable of spreading disease when exposure to them occurs.

## **Category A Infectious Substances**

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease to humans or animals when exposure to them occurs. Category A infectious substances have two shipping names: “Infectious substances, affecting humans” (UN 2814) or “Infectious substances, affecting animals” (UN 2900). Examples of Category A substances can be found on page 10.

### Packaging

Category A infectious substances must be tripled packaged and compliant with IATA Packing Instruction 602 detailed in Figure 1. The maximum quantity of Category A infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum allowable quantity on passenger aircraft is 50 ml or 50 g.

### Labeling

The outer container of all Category A infectious substance packages must display the following on two opposite sides:

- Sender’s name and address
- Recipient’s name and address
- Infectious substance label
- Proper shipping name, UN number, and net quantity of infectious substance
- Name and telephone number of person responsible for shipment
- Cargo Aircraft Only label when shipping over 50 ml or 50 g
- Class 9 label, including UN 1845, and net weight if packaged with dry ice

## **Category B Infectious Substances**

Category B infectious substances are infectious but do not meet the criteria for Category A. Category B infectious substances have the proper shipping name “Biological Substance, Category B” and the identification number UN 3373.

### Packaging

Category B infectious substances must be tripled packaged and compliant with IATA Packing Instruction 650 detailed in Figure 2. The maximum quantity for a primary receptacle is 500 ml or 500g and outer packaging must not contain more than 4 L or 4 kg.

### Labeling

The outer container of all Category B infectious substance packages must display the following on two opposite sides:

- Sender’s name and address
- Recipient’s name and address
- The words “Biological Substance, Category B”

- UN 3373 label
- Class 9 label, including UN 1845, and net weight if packaged with dry ice

## **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

Diagnostic specimens must be assigned to UN3373 unless the source patient or animal has or may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly and for which effective treatment and preventable measures are not usually available in which case they must be assigned to UN2814 or UN 2900.

### Packaging

Diagnostic and clinical specimens must be triple packaged and compliant with IATA Packing Instruction 650 detailed in Figure 2. The maximum quantity for a primary receptacle is 500 ml or 500g and outer packaging must not contain more than 4 L or 4 kg.

### Labeling

The outer container of all diagnostic/clinical specimen packages must display the following on two opposite sides:

- Sender's name and address
- Recipient's name and address
- The words "Biological Substance, Category B"
- UN 3373 label
- Class 9 label, including UN 1845, and net weight if packaged with dry ice

## **Biological Products**

These are 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 human 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.

Biological products transported for final packaging, distribution, or uses by medical professionals are not subject to shipping regulations. Biological products that do not meet these requirements must be assigned to UN 2814, UN 2900, or UN 3373 as appropriate.

## **Genetically Modified Organisms and Micro-organisms**

These are microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. They are divided into the following categories:

1. Genetically modified microorganisms, which meet the definition of an infectious agent. they must be classified in division 6.2 and assigned un 2814 or UN 2900.
2. Animals, which contain or are contaminated with genetically, modified microorganisms or organisms that meet the definition of an infectious substance. They must not be transported by air unless exempted by the States concerned.
3. Genetically modified organisms, which are known or suspected to be dangerous to humans, animals or the environment. They must not be transported by air unless exempted by the States concerned.
4. Except when authorized for unconditional use by the states of origin, transit and destination, genetically modified microorganisms which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way which is not normally the result of natural reproduction must be classified in Class 9 and assigned to UN 3245.

Genetically modified organism and organisms which do not meet the definition of an infectious substance and which are not otherwise included under (a) to (d) above are not subject to these regulations.

### Packaging

These materials must be packaged in the same manner as category A infectious substances except there are no testing requirements for the packaging. The packing instructions are IATA Packing Instruction 913. If this packaging cannot be purchased, 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.

### Labeling

The outer container of a genetically modified organism assigned to UN 3245 must have the following labels:

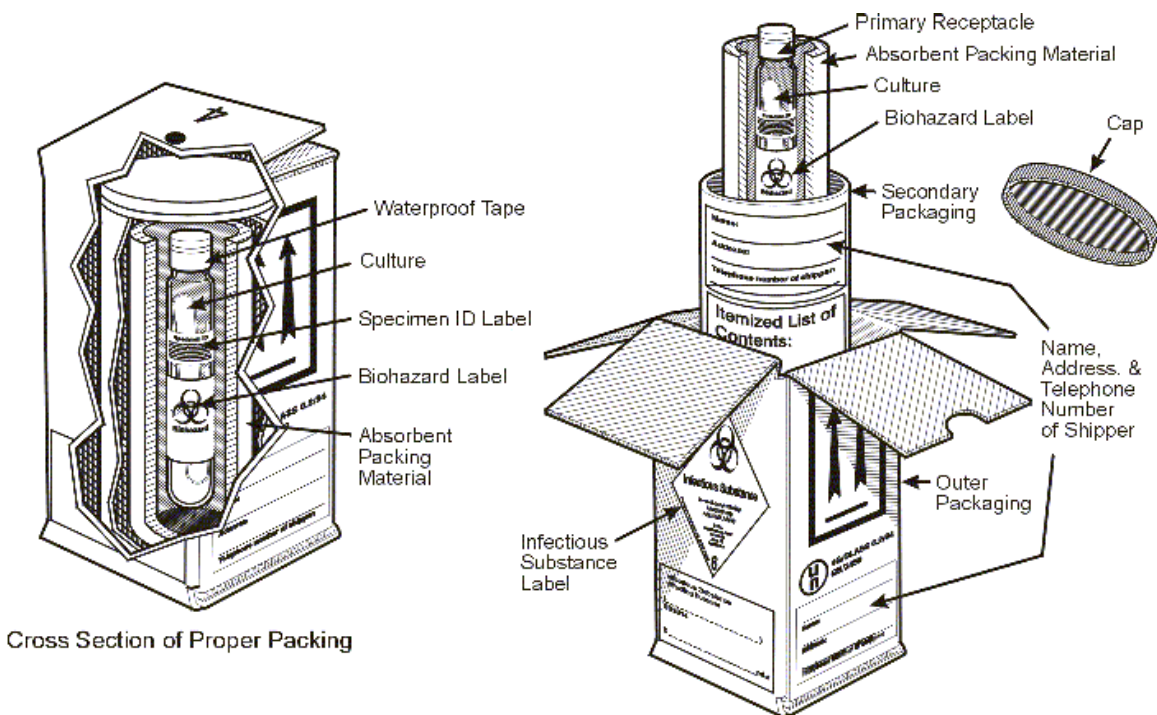
- Sender's name and address
- Recipient's name and address
- Class 9 label
- Genetically Modified micro-organisms, UN 3245

## Packaging Biological Materials

Potentially hazardous biological materials must be packaged to withstand content leakage, shocks, temperature changes, pressure changes, and other conditions that can occur during transport. When ordering, specify what category of materials you will be shipping: infectious substances, diagnostic specimens, dry ice, ice packs, etc. All biological materials must be triple packaged.

### Packing Instruction 602

Figure 1



## Packing and Labeling of Infectious Substances

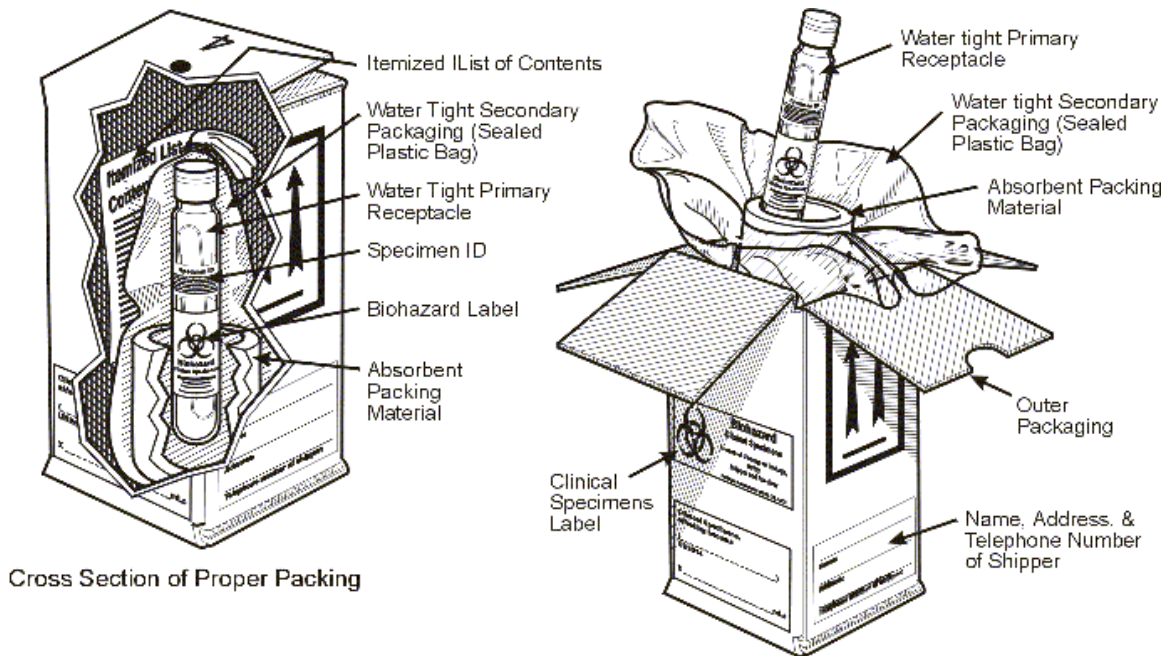
1. Packages must bear UN specification mark
2. Shipments must be prepared so they arrive in good condition and pose no hazard to humans or animals during transport
3. Triple packaging consisting of watertight primary receptacles, watertight secondary packaging and an outer packaging of sufficient strength to meet the design test types (9 meter drop test, puncture test)
4. Primary receptacle or secondary packaging capable of withstanding a 95Kpa internal pressure differential
5. Absorbent material sufficient to absorb the entire contents of the shipment
6. An itemized list of contents must be included between the secondary and outer packaging



7. Name and number of the person responsible for the shipment must appear on the package
8. Minimum dimension 100mm
9. See IATA 5.0 p418/419 for the complete document

Packing Instruction 650

Figure 2



## Packing and Labeling of Clinical Specimens

1. Packages must be of good quality, strong enough to withstand the rigors of transport
2. Triple packaging consisting of leak proof primary receptacles (for liquid shipments), silt proof primary receptacles (for solid shipments), leak proof secondary packaging, outer packaging of sufficient strength to meet the design type test (1.2 meter drop test)
3. For liquid shipments, primary receptacle or secondary packaging capable of withstanding a 95Kpa internal pressure differential
4. Absorbent material sufficient to absorb the entire contents of the shipment
5. An itemized list of contents must be included between the secondary and outer packaging
6. “Biological Substance, Category B” must appear on the package
7. Minimum dimension 100mm
8. See IATA 5.0 p451/452 for the complete document

## Labeling

Below are examples of labels required on biological material packages.



## Shipping Papers

A Shipper's Declaration for Dangerous Goods must be completed when shipping a Category A infectious substance or a Genetically Modified Organism or Micro-organism assigned to UN 3245. A declaration is not required for shipments in which dry ice is the only hazardous material. A declaration is not required for Category B infectious substances or diagnostic/clinical specimens assigned to UN 3373. All shipper's declarations must be in English, typed, and printed in color with red hatchings bordering the document. Three copies must be presented to the courier with a fourth copy retained by the shipper for at least 375 days. All shipper's declarations must conform to the following format:



Shipper  <b>A</b>	Air Waybill No.  Page      of      Pages Shipper's Reference Number <i>(optional)</i>
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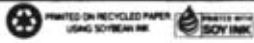
Consignee  <b>B</b>	
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<i>Two completed and signed copies of this Declaration must be handed to the operator</i>	<b>WARNING</b> Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, 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.										
<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left; padding: 2px;">TRANSPORT DETAILS</th> </tr> <tr> <td style="width:25%; padding: 2px;">                     This shipment is within the limitations prescribed for:  <i>(delete non-applicable)</i> </td> <td style="width:75%; padding: 2px;">                     Airport of Departure  <b>C</b> </td> </tr> <tr> <td style="padding: 2px;"> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; padding: 2px;">PASSENGER AND CARGO AIRCRAFT</td> <td style="width:50%; padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table> </td> <td style="padding: 2px;">                     Airport of Destination:                 </td> </tr> </table>	TRANSPORT DETAILS		This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>	Airport of Departure  <b>C</b>	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; padding: 2px;">PASSENGER AND CARGO AIRCRAFT</td> <td style="width:50%; padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table>	PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	Airport of Destination:	Shipment type: <i>(delete non-applicable)</i> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; padding: 2px;">NON-RADIOACTIVE</td> <td style="width:50%; padding: 2px;">RADIOACTIVE</td> </tr> </table>	NON-RADIOACTIVE	RADIOACTIVE
TRANSPORT DETAILS											
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PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY										
NON-RADIOACTIVE	RADIOACTIVE										

NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization
<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>	<b>H</b>	<b>I</b>	<b>J</b>	<b>K</b>

Additional Handling Information  <b>L</b>	<b>M</b>  24 hr. Emergency Contact Tel. No. _____
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I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.	Name/Title of Signatory  Place and Date  Signature <i>(see warning above)</i>
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- A. Name and address of shipper
- B. Name and address of recipient. When shipping infectious substances include the text “Person responsible for the shipment” and include your name and phone number.
- C. Cross out the type of shipment which does not apply (cargo vs. passenger aircraft)
- D. Proper shipping name
- E. Hazard class or division of biological to be shipped
- F. UN number of biological to be shipped
- G. Leave blank unless entry is dry ice (Packing Group III)
- H. Leave blank
- I. Enter net quantity of biological materials (in metric units); indicate number and type of packagings typically “One fibreboard box”
- J. Packing instruction used for each biological shipped
- K. Leave blank
- L. Enter “ICAO” as well as any additional instructions for recipients
- M. Should always read “**Chemtrec 1-800-424-9300**”
- N. Complete this section, sign, and date all copies of shippers declaration

Note: The words “Radioactive” should be crossed out. All radioactive shipments must be coordinated through NCSU Radiation Safety Office, which can be contacted at 515-2894.

### Summary of Shipping Information

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group	Packing Instruction	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 <i>(technical name)</i>	UN 2814	6.2		602	50 ml or 50 g	4 L or 4 kg
Category A infectious substance, affecting only animals (not humans)	Infectious substance, affecting animals <i>(technical name)</i>	Un 2900	6.2		602	50 ml or 50 g	4 L or 4 kg
Category B infectious substance	Biological Substance, Category B	Un 3373	6.2		650	4 L or 4 kg	4 L or 4 kg
Diagnostic Specimens	Biological Substance, Category B	Un 3373	6.2		650	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice	Un 1845	9	III	904	200 kg	200 kg
Non-infectious, transducing genetically modified organism or micro-organism	Genetically modified micro-organisms	UN 3245	9		913	No limit	No limit

## Examples of Category A Infectious Substances

### UN 2814 Infectious Substance Affecting Humans

- *Bacillus anthracis* cultures
- *Brucella abortus* cultures
- *Brucella melitensis* cultures
- *Burkholderia mallei* – *Pseudomonas mallei* – Glanders cultures
- *Burkholderia pseudomelli* – *Pseudomonas pseudomallei* cultures
- *Chlamydia psittaci* – avian strain 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
- Hantann virus
- Hantaviruses causing hantavirus pulmonary syndromw
- Hendra virus
- Hepatitis B 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
- *Rickettsia prowazekii* cultures
- *Rickettsia rickettsia* cultures
- Rift Valley fever virus
- Russian spring-summer encephalitis virus
- 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 horse sickness virus
- African swine fever virus
- Avian paramyxovirus Type 1 – Newcastle disease virus
- Bluetongue virus
- Classical swine fever virus
- Foot and mouth disease virus
- Lumpy skin disease virus
- *Mycoplasma mycoides* – Contagious bovine pleuropneumonia
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Goatpox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus

# Checklist for Dry Ice Shippers

This checklist should be used when shipping dry ice with non-hazardous materials. Do not ship your material if “NO” is checked for any of these entries.

Is the following correct for each entry?

YES

NO

## Air Waybill

The Air Waybill contains the following information in the “Nature and Quantity of Dangerous Goods.”

1. The words “Carbon dioxide, solid” or “Dry ice”
2. The Class number “9”
3. The UN number “UN 1845”The number of packages of dry ice
4. The net quantity of dry ice in kilograms

Note: The packing group “III” and packing instructions “904” are optional upon the particular air waybill being used.

## Quantity

5. The quantity of the dry ice per package is 200kg or less

## Packages and Overpacks

6. Outer packaging is UN approved and has corresponding signage
7. Packages are free from damage and in proper condition for carriage
8. The packaging conforms to packing instruction 904 and the package is vented to permit the release of gas.

## Markings

9. The words “Carbon dioxide, solid” or “Dry ice”
10. The UN number “UN 1845”
11. Full name and address of the shipper and consignee
12. The net quantity of dry ice within each package

## Labels

13. Class 9 label affixed
14. Irrelevant marks and labels removed