Introduction

Welcome to the Shipping Biological Substances, Category B (BIO201) Course Material. This course is required for anyone shipping samples considered Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animals Specimens.

Objectives

At the conclusion, participants should be able to:

1. Identify and adequately classify Biological Substances, Category B, Genetically Modified Organisms (GMO), and Exempt Human or Animal Specimens intended for shipment.
2. Pack samples with the appropriate primary and secondary containment.
3. Mark and label shipping packages.
4. Complete the appropriate shipping documents or permits.
5. Follow necessary safety guidelines avoiding any accidents, injuries, or spills.

Overview

When shipping Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, you are bound by regulations coming from several International and National Agencies. These regulatory bodies ensure infectious substances or materials are transported as safely as possible, most notably, by air.

Regarding the shipping and receiving of Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, the University of Alabama at Birmingham (UAB) follows:

- [International Air Transportation Association Dangerous Goods Regulations (IATA-DGR)]
- [United States Department of Transportation Hazardous Materials Title 49 Code of Federal Regulations Parts 171-180]
Shipper Responsibilities

When shipping packages containing Biological Substances, Category B, Genetically Modified Organisms (GMOs), and Exempt Human or Animal Specimens, from UAB, your responsibilities are:

- Classifying and identifying the substance or material
- Selecting the appropriate packaging system
- Marking, labeling, and packing the substance or material

Classification

Classification of an item to be shipped is used to identify the actual hazard and not the substance itself. Classification is necessary to follow both International and National regulations.

Biological Substances, Category B

Samples not meeting the criteria for Infectious Substances, Category A may qualify for classification as Biological Substances, Category B (meaning your specimen is not known or reasonably expected to contain pathogens. Use this Classification Flowchart to assist you).

Exempt Human or Animal Specimens

If your sample is not Category A or B, it may fall under the definition of an Exempt Human or Animal Specimens. These Exempt Human or Animal Specimens are those who have a minimal likelihood of pathogens being present.
Do not assume your sample is an Exempt Human or Animal Specimens. Professional judgment is required to determine if a substance is exempt. Base any professional judgment on known medical history, symptoms, and the likelihood of pathogens present in the local population from which the sample was obtained. If the professional judgment is not available, the specimen must not be shipped as Exempt Human or Animal Specimen. If you have questions, call UAB’s Department of Environmental Health and Safety (EHS) at (205) 934-2487.

Examples of Exempt Human or Animal Specimens often include blood or urine to monitor (i.e., cholesterol levels, blood glucose, hormone levels), biopsies to detect cancer, and testing specimens monitoring organ function in humans and animals with non-infectious diseases.

**Genetically Modified Organisms (GMO)**

Genetically Modified Organisms not meeting the definition of Category A or B Infectious Substances are assigned to Class 9 (Miscellaneous Hazard). Check with your carrier if you are unsure or have questions.

### Identification

**UN and PSN**

**United Nation (UN) Number**

The United Nations (UN) Numbers are taken from the List of Dangerous Goods and used to identify a substance or group of substances. The UN Number always precedes the Proper Shipping Name (PSN):

- UN 3373 Biological Substances, Category B
- UN 3245 Genetically Modified Micro-Organisms or Genetically Modified Organisms (GMOs)
- Exempt Human or Animal Specimens do not have a UN Number
Proper Shipping Name (PSN)

The Proper Shipping Name (PSN), is assigned by IATA, ICAO, or 49 CFR, and is the name used on shipping documents to describe substances.

Packaging System

Selecting the Proper Packaging

Biological Substances, Category B

Packaging components for Biological Substances, Category B must pass testing requirements as a system. Mixing and matching packaging components from different manufacturers is not allowed. For example, you cannot ship Biological Substances, Category B in an EXAKT-PAKT™ secondary container, and a SAF-T-PAKT™ outer container (fiberboard box).

Outside Packaging

The recommended outside packaging must be sturdy, rigid, corrugated fiberboard, and the appropriate size for the intended content. The box also serves as a surface for displaying clear marks, labels, and other relevant information. Always use boxes meeting approved standards and look for the UN mark. The UN Mark indicates the box has been tested and meets standards. If you have questions about which boxes are approved, contact EHS at (205) 934-2487.
Inside Packaging

- Use Packing Instructions 650 (PI 650) when shipping Biological Substances, Category B.
- Exempt Human Specimens do not have designated Packaging Instructions, so they should be triple-packed (Primary Container → Secondary Container → Tertiary Container) to prevent any release or leak of a substance.
- Non-infectious Genetically Modified Organisms (GMOs) are packed using PI 959.
- Use Triple package approved boxes only for any substances identified as UN 3373.
- Shipping liquids are of particular concern when traveling by air due to air pressure changes occurring during a flight. If the shipment is liquid, then the primary or secondary container must be able to withstand air pressure changes without leakage. Documentation of testing is available from the manufacturer.

Marks and Labels

General Information

Marks and labels provide information about the contents of the package, the nature of the hazard, and any special handling requirements. All marks and labels should be durable, placed so that they are completely visible (i.e., all on the same face of the package), and not obscured by any other labels or markings.
Biological Substances, Category B

Biological Substances, Category B shipments require the following labels:

- Biological Substances, Category B Black & White Diamond-On-Point Label
- Proper Shipping Name and UN Number (which is “UN3373 Biological Substances, Category B”)
- Complete name and address of the Shipper and Consignee (Receiver)
- Name and telephone number of a responsible, reliable, and trustworthy person that will answer the phone (no voicemail and no answering machines). They should be able to answer any questions about the content, shipper, recipient details, and permit inquiries.

Exempt Human or Animal Specimens

Exempt Human or Animal Specimen shipments require the following:

- Packed to prevent leakage
- Include the complete name and address of the Shipper and Consignee
- Marked with the Proper Shipping Name

Do not use a UN 3373 Diamond-on-Point Label. Remember to remove or completely cover any irrelevant marks or labels.
Genetically Modified Organisms (GMO)

Genetically Modified Organisms (GMO) shipments require the following:

- The complete name and address of the Shipper and Consignee (Receiver)
- The name and telephone number of a responsible person
- The UN 3245 Genetically Modified Organisms mark
- Remove or completely cover any irrelevant marks or labels

If you have any questions about the appropriate required marks and labels, contact EHS at (205) 934-2487.

Documentation

No Shipper’s Declaration is required for Biological Substances, Category B. You must include the following information on the waybill:

- UN Number
- Proper Shipping Name
- The Class or Division Number: 9
- The number of packages
- The Net Weight of the Dry Ice in each package (if appropriate)

Appendix B, at the end of this course material, has examples of Waybill information.

Permits

Additional documentation (i.e., permits or certificates) may be required when shipping any biological substances, particularly those designated Infectious Substances. Federal permits are required to import and export disease-causing agents for humans and animals, vectors for those agents, animal products, plants, plant products, and plant pests. Chemically inactivated agents are exempt from Dangerous Good Regulations, but may still require permits for receipt or transfer. Permits may also be required for the domestic transport of some agents. The recipient of the material must obtain any required permits.
If you are the shipper, request a copy of any applicable permits from the recipient and include a copy of the permit with the shipping documents.

The U.S. receiver (importer) is responsible for the package being sent to them from a foreign country. The receiver assures that the foreign shipper has packed and labeled the material according to U.S. Public Health Service and IATA Regulations. The importer must send the proper shipping labels and a copy of their import permit to the shipper. Complying with import regulations should prevent packages from being held at customs or denied entry.

**USDA/APHIS Import and Transport Permits**

The USDA/APHIS (Animal and Plant Health Inspection Service) regulates the transport of materials that potentially harm U.S. agricultural products, including livestock, poultry, and crops. APHIS permits may be required for import, export, and interstate transport of animal or plant pathogens, pathogen vectors, animals, animal products, plants, plant products, and the introduction of genetically modified organisms into the environment. For more information, see [Import and Export](#).

USDA/APHIS Import and Transport permits must be obtained by the intended receiver of the material before shipment is made and good for one year, amendable, and renewable. The application can be found [here](#). The application form is for foreign import or interstate transfer. This application requires 6 to 8 weeks for processing.
Animal-Related:

- USDA/ADPHIS permits are required for imports and exports and interstate transport of:
  - Animal or plant pathogens including challenge material from the USDA
  - Specimens reasonable believed to contain animal or plant pathogens¹
  - Vectors of animal or plant disease¹
  - Potentially hazardous animal or plant products


Genetically Modified Organisms (GMOs): To determine if a permit is needed to import or transport a GMO, contact the APHIS Biotechnology permit branch via a letter of notification.

Centers for Disease Control (CDC) Import and Transport Permits: The Department of Health and Human Services, through the CDC, regulates the transport of biological materials that could cause illness in humans (including pathogens and biological toxins). In general, a permit is needed for any infectious agent known or suspected to cause disease in humans that you wish to import into the United States. In some cases, acquisition or subsequent distribution of an agent (e.g., viruses requiring BSL-3 or BSL-4 containment) is prohibited within the United States, requires CDC authorization, and permits before transfer to another location within the United States. Select Agent permits may only be obtained through UAB’s Responsible Official, in coordination with the Federal Select Agent Program. A list of Select Agents and Toxins can be found [here](#). Domestic transport may or may not require a permit. To determine if your shipment requires a permit, see the CDC Import Permit Program.

¹ USDA/APHIS regulation 9 CFR Animals and Animal Products Parts 94, 95, and 122 covers transport of organisms or vectors that can cause infectious diseases of animals. The regulation defines material requiring a permit as, "(d) Organisms. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry). (e) Vectors. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease."
Foreign imports of the following materials require a permit to import and transport agents or vectors of human disease:

- Etiologic agent
- Arthropod or other animal host or vector of human disease
- Exotic living arthropod or another animal capable of being a host or vector or human disease
- Non-human primate material (e.g., blood, plasma, tissue, urine, and feces) requires an import permit unless it has been specifically treated and rendered non-infectious.

**Department of Commerce Export Permits:**

Exports of designated biological agents and toxins having the potential to pose a threat to human, animal, or plant life requiring a license from the U.S. Department of Commerce Bureau of Industry and Security (BIS). The scope of items subject to this licensing requirement is broader than “select agents,” and researchers must consult with the University’s Export Controls Officer to conduct a separate review to determine if a BIS export license is required.

Export Control at UAB is mediated through the [University Compliance Office](#). BIS may require a license for the export of:

- Designated human, animal and plant pathogens, zoonoses, and toxins
- Genetically Modified Microorganisms or genetic elements containing nucleic acid sequences associated with the pathogenicity of controlled organisms or that code for a controlled toxin
- Genetic material and products which might be used for the culture of large amounts of agents.

For further guidance on whether or not the agents you are shipping or receiving require permits, contact EHS at (205) 934-2487.
**Example**

Appendix A at the end of this document contains pictures showing the correct shipping label requirements for each one below:

- Shipping Nonhazardous or Exempt Specimens
- Shipping Genetically Modified Organisms
- Shipping Biological Substances, Category B

**Operator (or Carrier) Responsibilities**

Not all couriers or carriers transport Biological Substances, Category B, and not all countries or states in the U.S. accept Biological Substances, Category B. Where there are variations (restrictions) by state, country, courier, or carrier, they may be more restrictive than the IATA DGR or ICAO TI, but never less restrictive.

**Commercial Courier**

The airline industry is very strict about transporting biological materials. You cannot carry these materials or samples onto a passenger plane no matter how it is packaged. You must use commercial couriers such as UPS, USPS, FedEx, or DHL. There are quantity limitations, depending on the samples being shipped, and on the courier’s method of transport. For more information, check with EHS and your courier.

**Security**

After preparing the package for shipment, the package must remain under the direct control of trained personnel until it is handed over to the carrier. This reduces the chances of tampering, theft, destruction, invalidation of the shipper’s signature, and signifying the package was prepared by 49 CFR/IATA Regulations. Before handing the package over to the carrier for shipment, it is the shipper’s responsibility ensuring all Federal and International Regulations are met. International shipments may require additional permits.

If you suspect a package has been tampered with, notify EHS immediately at (205) 934-2487.
Receiver (or Consignee) Responsibilities

If you are expecting to receive packages containing Biological Substances, Category B at UAB, your responsibilities are:

- Inspecting documents and packages
- Obtaining import permits if necessary
- Reporting damages to the shipper and UAB Biosafety
- Notifying the sender of package arrival
- Keeping all shipping documents for a minimum of three years

Conclusion

This section concludes the Shipping Biological Substances, Category B (BIO201) Course Material. You must now complete the Reality Check.

Other Training

- If you intend on shipping samples containing Dry Ice, it is required to complete Shipping with Dry Ice (BIO200).
- If you intend on shipping samples considered Infectious Substances, Category A, it is required to complete Shipping Infectious Substances, Category A (BIO202).
- UAB Campus Employees whose job duties put them at increased risk for exposure to bloodborne pathogens, it is required to complete Bloodborne Pathogens Training (BIO500).

EHS has many training courses available to all UAB active employees and students. A decision tree is available to assist you in choosing the right training courses to supplement the knowledge and skills you may need at work. If you have any questions or comments, contact EHS at (205) 934-2487.
Appendix A: Shipping Label Requirements

Shipping Biological Substances, Category B, on Dry Ice
Follow Commercial System Instructions; IATA Packaging Instructions 650 & 954

- Leak-Proof primary Container (Test Tube)
- Leak-Proof Secondary Container
- Absorbent Material
- Itemized List of Contents
- Padding maintains orientation of inner packaging
- Orientation Arrows (if contents exceed 50mL)
- Class 9 Misc. Hazard Label
- Proper Shipping Name, UN Number, Net Weight

UN3373

Shipper: Dr. John Doe
UAB School of Medicine
1801 20th St. South
Birmingham, AL 35294
(205) 123-4567

Consignee: Name
Organization
Street Address
City, State, Zip
(123) 456-7890

Responsible Person: Name
Phone number

Biological substance, Category B

UN Number and Proper Shipping Name
Shipping Genetically Modified Organisms on Dry Ice
Follow IATA Packaging Instructions 959 & 954

- **Styrofoam Cooler (with Dry Ice)**
- **Leak-Proof Primary Container**
- **Leak-Proof Secondary Container**
- **Absorbent Material**
- **Fiberboard Box**

**Shipper:**
Dr. John Doe  
UA School of Medicine  
1801 20th St. South  
Birmingham, AL 35294  
(205)-123-4567

**Consignee:**
Name  
Organization  
Street Address  
City, State, Zip  
(123) 456-7890

**UN3245**

UN Number required, proper shipping name NOT required

**Class 9 Misc. Hazard Label**

**Proper Shipping Name, UN Number, Net Weight**

**DRY ICE UN 1845 **

**KG NET WT**
Shipping Nonhazardous or Exempt Specimens on Dry Ice
Follow IATA Packaging Instruction 954

Leak-Proof Primary Container

Leak-Proof Secondary Container

Absorbent Material

Fiberboard Box

Styrofoam Cooler (with Dry Ice)

Contents Being Cooled

Package Contents:
- Exempt human specimen(s)
- Exempt animal specimen(s)
- Other

Shipper:
Dr. John Doe
UAB School of Medicine
1801 20th St. South
Birmingham, AL 35294
(205) 123-4567

Consignee:
Name
Organization
Street Address
City, State, Zip
(123) 456-7890

Class 9 Misc. Hazard Label

Proper Shipping Name, UN Number, Net Weight
Appendix B: Examples of Waybill Information

UN3373 Biological Substances, Category B

Does this shipment contain dangerous goods?

- No
- Yes

One box must be checked

- Yes As per attached Shipper’s Declaration
- Yes Shipper’s Declaration not required
- Dry Ice
  - Dry Ice, 8, UN 1845 1 x 1.2 kg
  - Cargo Aircraft Only

Total Packages: 1
Total Weight: 
Total Declared Value: $0.00
UN3245 Genetically Modified Organism

<table>
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<th>Total Packages</th>
<th>Total Weight</th>
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**Does this shipment contain dangerous goods?**

- [ ] No
- [ ] Yes
- [X] Yes

**As per attached Shipper's Declaration**

- [ ] Yes
- [ ] No

**Shipper's Declaration not required**

- [ ] Yes
- [ ] No

**Shipper's Declaration**

- [ ] Yes
- [ ] No

**Dry Ice**

- [X] Dry Ice

| UN 1845 | 1 | 1.2 kg |

**Dry Ice, 9, UN 1845**

- [ ] Cargo Aircraft Only
- [ ] No
- [ ] Yes
Exempt Human/Animal Specimens

FedEx US Airbill

From: Angelise Esilegna
Company: UAB
Address: 1720 2nd Ave S
City: 1720 2nd Ave S

To: John Doe
Company: ACME Bio
Address: 1234 Main S.
City: Mayberry

Date: 5/19/17
Account Number: 1234-5678-00123
Phone: (567) 890-1234

Oncology BMX 34
State: AL
Zip: 35294

Total Packages: 1
Total Weight: 1.2 kg
Total Declared Value: $0.00

Does this shipment contain dangerous goods?

- No
- Yes

As per attached Shipper’s Declaration

Dry Ice, 9, UN 1845

1 x 1.2 kg

Cargo Aircraft Only