Introduction

Welcome to the Shipping Biological Substance,
Category B (BIO201) Course Material. This course is
required for anyone shipping samples considered a
Category B Biological Substance, Genetically
Modified Organism (GMO), or Exempt Human or
Animal Specimens.



Failure to properly pack and ship materials is a violation of the law and is punishable with fines or imprisonment.

Objectives

At the conclusion, participants should be able to:

- Identify and adequately classify samples considered a Category B Biological Substance, Genetically Modified Organisms (GMOs), or Exempt Human or Animal Specimens.
- 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 Category B Biological Substance, Genetically Modified Organisms (GMOs), or 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 Category B Biological Substance, Genetically Modified Organisms (GMOs), or Exempt Human or Animal Specimens, and Exempt Human or Animal Specimens, the University of Alabama at Birmingham (UAB) follows:

International Air Transportation Association Dangerous Goods Regulations (IATA-DGR)

• <u>United States Department of Transportation Hazardous Materials Title 49 Code of Federal</u>
Regulations Parts 171-180

Shipper Responsibilities

When shipping packages containing Category B Biological Substance, Genetically Modified Organisms (GMOs), or 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 an infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs). Use this Classification Flowchart to assist you. Keep in mind, professional judgement must be used to classify the biological material being shipped. If there is any doubt on how to classify a particular pathogen it must be shipped as a Category A Infectious Substance.

Note: Toxins from plant, animal or bacterial sources which do not contain any infectious substances or toxins that are not contained in substances which are infectious substances should be considered for classification in Division 6.1 and assigned to UN 3172 or UN 3462.

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 that have a minimal likelihood of containing pathogens, as determined by an expert.

Do not assume your sample is an Exempt Human or Animal Specimen. Professional judgment is also 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 a UAB Biosafety representative in Department of Environmental Health and Safety (EH&S) 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 (GMOs)

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

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Identification

UN and PSN

United Nation (UN) Number

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

- UN3373 Biological Substance, Category B
- UN3245 Genetically Modified Micro-Organisms (GMMOs) 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.



The words diagnostic specimen and clinical specimen are no longer allowed as Proper Shipping Names (PSN).

Packaging System

Selecting the Proper Packaging

Biological Substance, Category B

Packaging components for Biological Substance,
Category B must pass testing requirements as a
system. Mixing and matching packaging components
from different manufacturers is not allowed. For



Disposable components of a packaging system must be replaced by components from the same vendor tested and certified for that packaging system. Substituting alternative products is a violation of the law!

example, you cannot ship Biological Substance, Category B in an EXAKT-PAKTM secondary container, and a SAF-T-PAKTM 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 EH&S Biosafety at (205) 934-2487.

Inside Packaging

- Use Packing Instructions 650 (P.I. 650) when shipping Biological Substances, Category B.
- Exempt Human Specimens do not have designated Packaging Instructions, so they should be triple-packed (Primary



All packaging components for Biological Substances, Category B must be assembled per the manufacturer's closing instructions specific to the packaging system purchased.

Container→Secondary Container →Tertiary Container) to prevent any release or leak of substances in the shipment.

- Non-infectious Genetically Modified Organisms (GMOs) are packed using P.I. 959.
- Use triple package approved boxes only for any substances identified as UN3373.
- 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

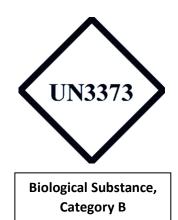
General Information

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 Substance, Category B

Biological Substance, Category B shipments require the following labels:

- Biological Substance, Category B Black & White Diamond-On-Point Label
- Proper Shipping Name and UN Number (which is "UN3373 Biological Substance, 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 UN3373 Diamond-on-Point Label. Remember to remove or completely cover any irrelevant marks or labels.





Genetically Modified Organisms (GMOs)

Genetically Modified Organisms (GMOs) 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 UN3245 Genetically Modified Organisms mark
- Remove or completely cover any irrelevant marks or labels



Note: COVID-19 vaccines containing GMOs or GMMOs, including those in clinical trials, are not subject to these Regulations.

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

Documentation

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

- UN Number
- Proper Shipping Name
- 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 are 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.

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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
 - o Potentially hazardous animal or plant products

<u>Plant Related:</u> USDA/APHIS Regulation 7 CFR Part 330 Federal Plant Pest Regulations covers the transport of plant pests.

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.



Before shipping anything internationally, please submit the UAB International Shipment Export Control Review

UAB International Shipment Export Control Review Form

Before You Ship Anything Internationally

Although UAB does not have an overall centralized shipping process for international or domestic shipments, there remain export control regulatory requirements for international shipping. All physical items, equipment, materials, commodities (including food and medicines), software and biologics (collectively "things") are subject to export control regulations and require some form of shipping documentation prior to shipping abroad. It is important to understand that everything that crosses the border is an export, even if the item is abroad only temporarily, or if it will be used for research.

Department of Commerce Export Licenses:

Exports of designated biological agents and toxins having the potential to pose a threat to human, animal, or plant life require 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 at exportcontrol@uab.edu, or (205) 996-2735, to conduct a separate review to determine if a BIS export license is required.

Export Control at UAB is mediated through the <u>Director</u> of Export Control & International Compliance, located within the Office of Research Regulatory Oversight. BIS may require a license for the export of:

- Designated human, animal and plant pathogens, zoonotic agents, 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 EH&S 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 Substance, Category B

Operator (or Carrier) Responsibilities

Not all couriers or carriers transport Biological Substance, Category B, and not all countries or states in the U.S. accept Biological Substance, 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 potentially infectious 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 EH&S and your courier.

Security

After preparing the package for shipment, the package must remain under the direct control of trained personnel until 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



If you suspect a package has been tampered with, notify EH&S immediately at (205) 934-2487.

over to the carrier for shipment, it is the shipper's responsibility to ensure all Federal and International Regulations are met. International shipments may require additional permits.

Receiver (or Consignee) Responsibilities

If you are expecting to receive packages containing Biological Substance, 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 Substance, Category B (BIO201) Course Material. You must now complete the Reality Check.

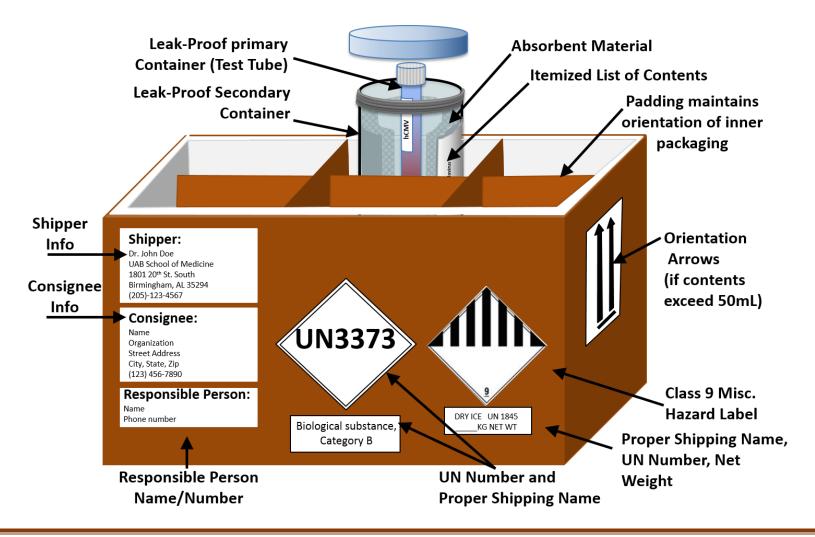
Other Training

- If you intend on shipping samples containing Dry Ice, you are also required to complete
 Shipping with Dry Ice (BIO200).
- If you intend on shipping samples considered Infectious Substances, Category A, you are also 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 are required to complete <u>Bloodborne Pathogens Training (BIO500)</u>.

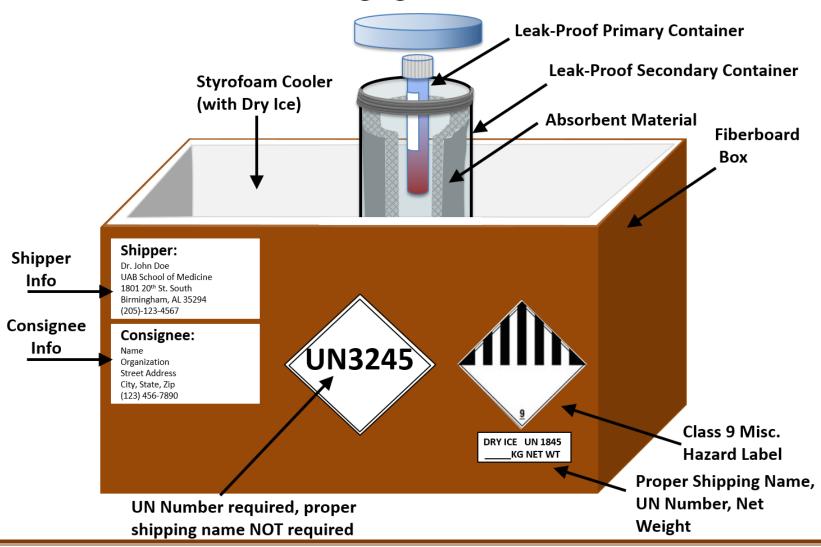
EH&S has many training courses available to all UAB active employees and students. A <u>decision tree</u> is available to assist you in choosing the right training courses to supplement the knowledge and skills you may need at work. If you have any questions or comments, contact EH&S at (205) 934-2487.

Appendix A: Shipping Label Requirements

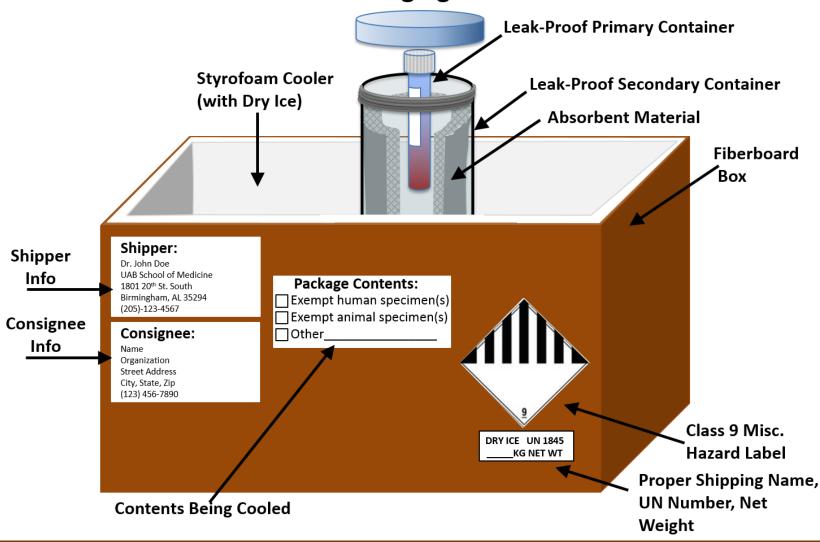
Shipping Biological Substances, Category B, on Dry Ice Follow Commercial System Instructions; IATA Packaging Instructions 650 & 954



Shipping Genetically Modified Organisms on Dry Ice Follow IATA Packaging Instructions 959 & 954



Shipping Nonhazardous or Exempt Specimens on Dry Ice Follow IATA Packaging Instruction 954



Appendix B: Examples of Waybill Information

UN3373 Biological Substances, Category B

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Exempt Human/Animal Specimens

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