Shipping Biological (Infectious and Potentially Infectious) Materials and Genetically Modified Microorganisms (GMMOs) - TC0507
This module provides Columbia University personnel with training to safely and legally ship the following Dangerous Goods (also known as hazardous materials or HAZMATS):

- Biological Substances, Category B;
- Genetically Modified Microorganisms (GMMO)

Please note – The terms “Dangerous Goods” and “HAZMATs” are used interchangeably throughout this presentation.

The law (49 CFR) define a hazardous materials employee as anyone who prepares hazardous materials for transportation. All persons involved in any aspect of the transport of Dangerous Goods including packing, labeling and preparing shipping documents, must receive training based on US and international regulations.

This training and certification course must be taken before any shipping is done and must be renewed every two years.
Training Requirements

- Personnel wishing to ship Biological Substances, Category B and/or Genetically Modified Microorganisms (GMMO) must complete separate Biosafety/Bloodborne Pathogens training (TC0509 or TC0025) in order to understand the hazards posed by these materials and the corresponding safety practices that must be used to reduce or eliminate those hazards.

- Following completion of this module, a short quiz must be satisfactorily completed in order to be authorized to prepare packages, sign shipping documents, or perform any other shipping function discussed in this module.

- Individuals viewing this presentation outside of RASCAL, if unable to complete the related quiz in RASCAL, must contact EH&S hazshipping@columbia.edu to obtain a hard copy of the quiz.

- Please note – certification to ship other dangerous goods requires separate training not satisfied by this module. To ship dry ice, exempt specimens, non-regulated material or fixed tissue take RASCAL course TC0076.
This training and certification course will cover the following areas:

- Classifying biological materials for shipment,
- Determining appropriate packing instructions,
- Selecting materials for packaging,
- Marking and labeling of packages,
- Completing documents,
- Securing packages prior to releasing them to a courier,
- International shipping
- Records retention and inspections
- Intercampus transport
A number of entities regulate shipment of biological materials that may be capable of transmitting infectious disease; the two with the most important roles are:

- **US Department of Transportation (DOT)** — rules apply for ground shipments only.
- **International Air Transportation Association (IATA)** — an organization of the world’s commercial air carriers, their regulations are based on UN requirements and are applicable for all air transport of Dangerous Goods.

Shipments by air are subject to more stringent regulation. Most couriers, including FedEx, ship by air. This training course will certify you to ship by air and meet these more stringent standards.

- **The Federal Aviation Authority (FAA)** — inspects packages at airports. Violations can result in up to $250,000 and up to a year jail for the individual shipper, and up to $500,000 per incident for the organization.
- Improperly shipped packages can elicit an FAA inspection of the shipper’s university. Such an event triggered an inspection at Columbia in June 2016.
General HAZMAT Awareness – Identifying Hazardous Materials

Examples of HAZMAT Communication and Signage – These placards may appear as placards on vehicles transporting HAZMATs and/or may appear as smaller labels on packages of HAZMATs, including infectious materials and genetically-modified microorganisms.
Following the sequence of steps below will ensure that your package is safe, secure and can be transported according to applicable laws:

- **Classification** – Does the product meet the definition of a Biological Substance, Category B or Genetically-modified microorganism?
- **Packaging** – The correct packaging must be used and the materials must be packaged properly to achieve the goal of risk reduction.
- **Marking & Labeling** – Appropriate hazard awareness information must be provided to those transporting the shipment
- **Shipping documentation** – Airway bills, commercial invoices, permits
- **Security** – Retaining package prior to shipment

Any and all these of functions must be performed by trained and certified personnel (“hazardous materials employee”). For example, it is not acceptable to have an untrained person complete the air waybill.

Shipping companies (e.g., FedEx, UPS) are legally required to refuse to transport any shipment that is improperly packaged, labeled, or accompanied by incorrect shipping documents.
DOT and IATA regulations define two groups of **Infectious Substances**, Categories A & B.

- **Category A Infectious Substances** (proper shipping name: ‘Infectious Substance, Affecting Humans, UN2814 ’ or Infectious Substance, Affecting Animals, UN2900 ’) are the highest risk microorganisms, or materials expected to contain them, and pose a significant hazard to humans or animals.

- Category A materials may **only** be shipped by EH&S. They will be discussed only in the context of distinguishing them from **Category B** materials.

- For a representative list of Category A organisms, see pages 12-15 in this DOT brochure: [http://ehs.columbia.edu/Transporting_Infectious_Substances_brochure.pdf](http://ehs.columbia.edu/Transporting_Infectious_Substances_brochure.pdf)
  - ‘Cultures’ following a name indicates that only if that organism has been purposely amplified (on a slant, in liquid media) will it require Category A designation. Otherwise, (when shipping a blood or tissue sample reasonably expected to contain the organism), “Biological Substance, Category B” rules will apply.
Biological Substance, Category B, UN3373 are infectious substances that do not meet the criteria for inclusion in Category A. They are in a form not generally capable of causing serious disease in humans or animals. They comprise low and moderate risk microorganisms, and materials reasonably expected to contain them.

Most Biological Substance, Category B materials require BSL-2 procedures in the laboratory. Always wear a lab coat, single use nitrile gloves and eye protection when splash potential exists.

Regulations require that “Biological Substance, Category B” be used on packages and shipping papers to replace the older terms “Diagnostic Specimen” and “Clinical Specimen,” which are no longer legally acceptable.
Genetically Modified Microorganisms (GMMO) are defined for shipping purposes as microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Infectious GMMOs must be shipped as Category A or B Infectious Substances if they contain, or are reasonably expected to contain, materials that fit into the Category A or B classification.

GMMOs must be handled at the biosafety level applicable to the wild type organism.
Viral vectors (e.g., adenovirus, adeno-associated virus and lentivirus) are genetically modified viruses that are rendered replication deficient and often express a foreign gene (e.g., replication-deficient adenovirus expressing Green Fluorescent Protein-GFP).

They can therefore technically be classified as Biological Substance, Category B or Genetically Modified Microorganisms.

Even though viral vectors do not meet the classical definition of an infectious (contagious) agent, following accidental exposure, expression of the transgene or integration into the host genome could have a disease-causing effect.

Given this potential, and since most viral vectors are handled in the laboratory at BSL-2, EH&S guidance is that viral vectors should be shipped as “Biological Substance, Category B”.
Exempt Specimen: Specimen for which there is minimal likelihood that pathogens are present. Material collected directly from humans or animals, including, but not limited to blood and its components, excreta, secreta, tissue and swabs, and body parts transported for research, diagnosis, investigational activities, disease treatment and prevention.

Material transported for testing related to the diagnosis of infectious disease may not be classified as exempt, but rather as Category A or B Infectious Materials.

Please take RASCAL course TC0076 if you intend to ship exempt specimens.
Non-regulated material: Substances which do not contain infectious substances or are unlikely to cause disease in humans or animals:

- Isolated nucleic acids, antibodies
- Microorganisms typically handled at BSL-1 which are non-pathogenic to humans or animals (e.g., E. coli K12)
- Substances containing pathogens that have been neutralized or inactivated so they do not pose a health risk (e.g., autoclaved material)
- Environmental samples (water, soil, food)
- Blood or blood components collected for transfusion, organs for transplantation, dried blood spots (newborn screening) and fecal occult blood tests (stool for colorectal cancer testing)

Please take RASCAL course TC0076 if you intend to ship non-regulated material.
The table below summarizes relevant information for shipping biological materials. Packaging materials must meet specified performance standards (Packing Instruction). Maximum allowable quantities per package are also shown.

<table>
<thead>
<tr>
<th>Proper Shipping Name</th>
<th>UN Number</th>
<th>Hazard Class</th>
<th>Packing Instruction (PI)</th>
<th>Max. qty. per primary receptacle</th>
<th>Max. Net qty./pkg. for Passenger Aircraft</th>
<th>Max. Net qty./pkg. for Cargo Aircraft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious substances, affecting humans</td>
<td>UN2814</td>
<td>6.2</td>
<td>620</td>
<td>4L or 4 kg</td>
<td>50 ml or 50 gm</td>
<td>4L or 4 kg</td>
</tr>
<tr>
<td>Infectious substances, affecting animals</td>
<td>UN2900</td>
<td>6.2</td>
<td>620</td>
<td>4L or 4 kg</td>
<td>50 ml or 50 gm</td>
<td>4L or 4 kg</td>
</tr>
<tr>
<td>Biological substance, Category B</td>
<td>UN3373</td>
<td>6.2</td>
<td>650</td>
<td>1L or 4 kg</td>
<td>4L or 4 kg</td>
<td>4L or 4 kg</td>
</tr>
<tr>
<td>Genetically modified micro-organism</td>
<td>UN3245</td>
<td>9</td>
<td>959</td>
<td>No limit</td>
<td>No limit</td>
<td>No limit</td>
</tr>
<tr>
<td>Dry ice</td>
<td>UN1845</td>
<td>9</td>
<td>954</td>
<td>N/A</td>
<td>200 Kg</td>
<td>200 Kg</td>
</tr>
<tr>
<td>Exempt specimens</td>
<td>None</td>
<td>None</td>
<td>Triple pack</td>
<td>No limit</td>
<td>No limit</td>
<td>No limit</td>
</tr>
<tr>
<td>Non-regulated material</td>
<td>None</td>
<td>None</td>
<td>Triple pack</td>
<td>No limit</td>
<td>No limit</td>
<td>No limit</td>
</tr>
</tbody>
</table>
Classification quiz . . .

**Question:** How is a blood sample sent for HIV testing classified?

**Answer:** “Biological Substance, Category B.” The testing exception would not apply because the testing is related to infectious disease diagnosis.

Note, that a culture obtained from this sample would be shipped under Category A Infectious Substance rules because of the amplification step.

**Note:** Specimens suspected of containing the highest risk microbes (e.g., Ebola virus, which does not have the ‘cultures’ designation – refer to DOT brochure) are always shipped as Category A Infectious Substances.
**General Packaging Information**

**All classifications** of material require packaging capable of protecting against accidental release – “Triple performance packaging” (see packing instructions).

1. **Primary Receptacle**
   - Leakproof (no petri plates)
   - Labeled with the name of the contents (Specimen ID Label)
   - Use Biohazard label when necessary
   - Individual cushioning - wrap multiple primary containers to prevent contact between them and prevent breakage

2. **Secondary Container**
   - Leakproof
   - Absorbent material enough to absorb ALL of the liquid from the primary receptacle(s).
   - An itemized list of contents placed between the secondary container and the outer packaging.

3. **Durable Outer Container**
   - Typically a fiberboard box
Packing Instruction 650 requires:

- Primary containers must have seals such as a screw top lid, which must be reinforced with tape. Glass vacutainer tubes with rubber stoppers are unsuitable receptacles.

- The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar/13.8 lbs/sq. in.) – No Ziploc bags.

- At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.

- The entire package must withstand a 1.2 meter drop test and other tests without damage to the contents. While individuals may perform such tests, it is more practical to purchase packaging systems from vendors who will certify that their products meet these criteria (see “Supplies” section).
Packaging Instruction 959 requires:

- Primary containers must have seals such as a screw top lid, which must be reinforced with tape or parafilm.
- Leakproof secondary container. Ziploc or specimen bags are acceptable.
- At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.
- Durable fiberboard outer packaging.
- A packaging system suitable for Biological Substance, Category B, UN3373 will meet all the performance requirement for shipping Genetically Modified Microorganisms, UN3245. Ensure that any pre-printed UN3373 package markings are obliterated or covered.
Placing several complete (primary, secondary & outer package) packages into one large container, an “overpack”, may be desirable to get several packages to a single destination. The overpack must then have all the package markings that the outer packages would have if they were being sent separately. It must be marked “overpack.”

FedEx provide such overpacks for UN3373 Biological Substance, Category B. It is acceptable to deposit such overpacks into a FedEx drop box.
Many Biological Substance, Category B shipments take place during the course of clinical trials where the sponsor provides the packaging. If material is reasonable expected to contain a pathogen or study involves testing for an infectious disease, those with shipping responsibilities must obtain from the sponsor documentation that the packaging complies with regulations regarding labeling, packaging strength, and containment ability.

Shippers at the trial site (Columbia) are responsible for assuring that sponsors have provided the properly marked and labeled packages and for compliance with all applicable shipping rules.
Marking and Labels

- Label must be self-adhesive, or pre-printed to the side of the outer package. Self-printed labels attached with clear tape are not acceptable.
- Label must be at least 2” x 2” in size. Letters and numbers must be at least 6 mm tall and the diamond lines must be at least 2 mm thick.
- Oriented “on point,” upright and in diamond orientation (square set at 45 degrees).
- When more than one label is needed (e.g. GMMO and dry ice), the labels should be adjacent and on the same side of the package.
- Shipping labels available at no cost from EH&S: email hazshipping@columbia.edu
- International biohazard symbol may be on the primary or secondary container if the shipment consists of human blood/body fluids, **BUT hazmat package exteriors should not be labeled with the biohazard symbol**. This is not a recognized hazmat shipping label or marking and its similarity to a Category A infectious material symbol may only serve to confuse the carrier and lead to return of packages that do not meet other Category A requirements.
Markings and Labels - Biological Substance, Category B

A – Ship to/from info
B – Responsible Person contact information
C – Proper Shipping Name ≥ 6 mm tall
D – UN3373 Label
   • Must be ≥ 2”x 2” in size
   • Use only pre-printed shipping labels
   • Package large enough for the label to fit on one side
E – Up Arrow Orientation
   Labels on opposite sides (if >50ml/primary)
Markings and Labels - Genetically Modified Microorganisms

A – Ship to/from info
B – UN3245 Label

- Must be ≥ 2” x 2” in size
- Use only pre-printed shipping labels
- Package large enough for the label to fit on one side

SHIPPER:
Jane Doe
Columbia University Med. Ctr.
601 W 168th St. Room 53
New York, NY 10032

CONSIGNEE:
John Doe
ABC Laboratories
123 Main Street
Detroit, MI 48203
Shipping Documents -
Biological Substance, Category B

- Itemized List of Contents (or Commercial Invoice; required for international shipments). Complete and enclose between secondary and outer packaging.

- Air shipments require an “Air Waybill.” See FedEx example in next slide.
  - In the lilac-colored box of this document, “Biological Substance, Category B” and “UN3373” must appear.
  - Next business day shipment is recommended for temperature-sensitive packages.
  - Packaging - Select “other”
  - On the FedEx waybill, where the question, “Does this shipment contain dangerous goods” appears, select “Yes, Shipper’s Declaration not required.”
  - Enter number of packages and total weight (lbs)
# FedEx Airwaybill - Biological Substance, Category B

## FedEx Domestic Air Waybill

<table>
<thead>
<tr>
<th>From</th>
<th>Date</th>
<th>Sender's FedEx Account Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>ZIP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>To</th>
<th>Recipient's Name</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Biological Substance, Category B, UN3373

**Package Information**

- **Service Options**
  - FedEx First Overnight
  - FedEx Priority Overnight
  - FedEx Standard Overnight
  - FedEx Express Saver

- **Packaging**
  - FedEx Envelope
  - FedEx Pak
  - FedEx Box
  - FedEx Tube
  - Other

- **Special Handling and Delivery Signature Options**
  - No Signature Required
  - No Direct Signature
  - Indirect Signature

- **Does this shipment contain dangerous goods?**
  - Yes
  - No

- **Total Packages** 1
  - **Total Weight** 4.4
  - **Total Declared Value** 6,440

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**Columbia University**

Environmental Health and Safety

[www.ehs.columbia.edu](http://www.ehs.columbia.edu)
Shipping Documents -
Genetically Modified Microorganisms (GMMO)

- Commercial Invoice. Required for international shipments.
- Air shipments require an “Air Waybill.” See FedEx example in next slide.
  - In the lilac-colored box of this document, “GMMO” and “UN3245” must appear.
  - Next business day shipment is recommended for temperature-sensitive packages.
  - Packaging - Select “other”
  - On the FedEx waybill, where the question, “Does this shipment contain dangerous goods” appears, select “Yes, Shipper’s Declaration not required.”
  - Enter number of packages and total weight (lbs)
FedEx Air waybill - Genetically Modified Microorganisms (GMMO)

FedEx Domestic Air Waybill

From: [Redacted]
Date: [Redacted]
Sender's Name: [Redacted]
Company: [Redacted]
Address: [Redacted]
City: [Redacted]

To: [Redacted]
Recipient's Name: [Redacted]
Company: [Redacted]
Address: [Redacted]
City: [Redacted]

Notes:
- FedEx First Overnight: [Redacted]
- FedEx Priority Overnight: [Redacted]
- FedEx Standard Overnight: [Redacted]
- FedEx Express Saver: [Redacted]

Packaging: [Redacted]
- FedEx Envelope
- FedEx Pak
- FedEx Box
- FedEx Tube
- Other

Does this shipment contain dangerous goods?: [Redacted]
- No
- Yes

Total Packages: 1
Total Weight: [Redacted]
Total Declared Value: [Redacted]

Biosafety
www.ehs.columbia.edu
HAZMAT Shipment Safety and Security

- Improperly handled HAZMATs have the potential to cause harm to human health and the environment in transit. Incidents involving HAZMATs in transit can affect the integrity of roads, bridges, tunnels, transportation routes and other vulnerable facilities. HAZMATs are often loaded onto passenger aircraft for transportation. Improperly prepared packages can endanger passengers and vehicles.

- Several areas of potential security vulnerability are important to consider when offering HAZMATs for shipment.
  - For example, shippers of hazardous materials must limit access to their packages to trained personnel only, and must ensure their package remains in their possession until it is transferred to the carrier (or secured in a designated mailroom).
  - Shippers must not leave packages containing hazardous materials at drop boxes.
  - Immediately report to Public Safety any suspicious persons or activity in your laboratory or in any area where hazardous materials may be present.
International Shipping

- Permits – import and export may be required


- FedEx Expanded Service International Air Waybill required.


- Enclose additional copies of all documents.

- Notify consignee of all shipping details.

- Customs broker services required in destination country.

Contact EH&S shipping manual for more details and for guidance: hazshipping@columbia.edu
Importing and Exporting

Permit Requirements:

- **US Dept. of Commerce** – Bureau of Industry and Security Commerce Control List (exports).
- **CDC** - etiologic agents/infectious substances (and materials that may include them) permit (imports, exports and interstate).
- **USDA** – required before transporting any animal agent or product/item that has been in contact with a USDA-covered animal (imports, exports and interstate).
- **APHIS** – required before transporting any plant pests, pathogens, noxious weeds, or related products (imports and exports)
- **US Fish and Wildlife** - Permits (imports and exports)

Notes:

1. Shipments to or from **foreign nationals** within the US is also regulated as importing and exporting.
2. Import permits are required to import any of these items into the USA – **Infectious biological agents**, infectious substances, vectors, animals, arthropods, snails, bats and **any tissue or sample from a non-human primate**.
3. Non-infectious imports require statement on institutional letterhead from shipper about nature of the material and its non-infectiousness.
Improperly shipped packages can elicit an FAA inspection of the shipper’s university. Such an event triggered an inspection at Columbia in June 2016. If the FAA inspect your operations, they will likely review shipping documents and training certificates.

Centrally maintain and keep all documents readily available.

- **Shipping documents (2 years)**
  - Commercial Invoices
  - FedEx Air Waybills
  - Applicable Import / Export Permits

- **Training Certificate (3 years)**
  - Can generate certificate in RASCAL (My RASCAL → My test history → Generate transcript)
Investigator-mediated transport of Biological Substance, Category B material between Columbia University campuses is **prohibited** by University Policy.

Investigator-mediated transport of Genetically Modified Microorganisms (GMMO) between Columbia University campuses is **permissible**, provided the following conditions are met.

- Materials are transported in a taxi cab, personal vehicle or University-operated vehicle including shuttle bus. Transport on mass transit (MTA bus or subway) is prohibited.
- Materials are triple performance packaged according to the directions in this training material.
- Transport must be direct from campus to campus (no stops or detours).
- Package must stay in custody of shipper throughout transport and delivered on the same day.
- Shipper must bring a pair of disposable nitrile or latex gloves in their pocket or bag. These are to be donned ONLY in the event that the package is compromised, e.g., leaks. They are NOT to be used to carry the package.
- Applicable training and certification course must be taken prior to transporting any materials between campuses.
Need More Help?

Need help with classification (or any other aspect of hazardous material shipping)?
Read the Columbia Biological Materials Shipping Manual:

Complete an “intent to ship” form:

Contact EH&S by email:
ha...
The following companies market packaging materials for the safe and legal transport of diagnostic specimens. This list is strictly informational; inclusion does not constitute an endorsement or recommendation by Columbia University.

<table>
<thead>
<tr>
<th>Company</th>
<th>Phone Number</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAF-T-PAK*</td>
<td>800-814-7484</td>
<td><a href="http://www.saftpak.com">http://www.saftpak.com</a></td>
</tr>
<tr>
<td>Inmark</td>
<td>800-646-6275</td>
<td><a href="http://www.inmarkinc.com">http://www.inmarkinc.com</a></td>
</tr>
<tr>
<td>Therapak Corp.</td>
<td>888-505-7377</td>
<td><a href="http://therapak.com">http://therapak.com</a></td>
</tr>
<tr>
<td>EXAKT Technol.</td>
<td>800-923-9123</td>
<td><a href="http://exaktpak.com">http://exaktpak.com</a></td>
</tr>
<tr>
<td>HazMatPak</td>
<td>800-347-7879</td>
<td><a href="http://www.hazmatpac.com">http://www.hazmatpac.com</a></td>
</tr>
<tr>
<td>ThermoSafe Brands</td>
<td>800-323-7442</td>
<td><a href="http://www.thermosafe.com">http://www.thermosafe.com</a></td>
</tr>
<tr>
<td>Air Sea Atlanta</td>
<td>404-351-8600</td>
<td><a href="http://airseaatlanta.com">http://airseaatlanta.com</a></td>
</tr>
<tr>
<td>Berlin Packaging</td>
<td>800-229-7546</td>
<td><a href="http://www.berlinpackaging.com">http://www.berlinpackaging.com</a></td>
</tr>
</tbody>
</table>
CONGRATULATIONS

You’ve come to the end of the course material. You can now take quiz. Good luck!