

Guidance for Shipping and Receiving Infectious Agents

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Shipping of infectious agents is regulated by the Department of Transportation (49 CFR 171-180) and by the International Air Transport Association (IATA) as Dangerous Goods. In addition, some international shipments may require a license from the U. S. Department of Commerce; the need for a license depends on what is being shipped and the destination country.

Receipt of packages containing infectious agents may require import or transport permits from either the U. S. Department of Agriculture or the Centers for Disease Control and Prevention. The need for a permit depends on what is being received and where the shipment originates. This website is intended to guide OSU researchers to help clarify these complex rules and identify where additional information can be obtained. It is not intended to be an exhaustive resource. Support for the packaging and shipping of Dangerous Goods is provided by Printing and Mailing located behind the EH&S Annex on the OSU Campus near 35th Street. Technical questions about shipping infectious agents can be directed to the OSU Biological Safety Officer.

Shipping of research materials originating in OSU laboratories that may have commercial value will likely require a Material Transfer Agreement (MTA). Please contact Oregon State University Advantage in the Research Office for guidance on MTAs.

Shipping Materials that are Not Regulated as Dangerous Goods

In general, pathogenic microorganisms are regulated as Dangerous Goods, while non-pathogenic organisms, environmental specimens, and other biological materials that are unlikely to be hazardous are not. Even though not regulated as Dangerous Goods, there are requirements for packaging and labeling as described below.

Specifically, the following materials are **not** regulated as Dangerous Goods:

- Patient or animal specimens that are not likely to contain a pathogen (specific criteria must be satisfied to meet the exempt status, based on known patient medical history, symptoms, and individual circumstances of the source).
- Biological products derived from living organisms that are manufactured and distributed in accordance with the requirements of appropriate national authorities (USDA or FDA), and are applicable to the prevention, treatment, or cure of a disease or condition of humans or animals.
- Used medical devices or products being returned to the manufacturer for repair, sterilization, or evaluation that have **not** been in contact with a Category A infectious substance (see below).
- Substances that do not contain infectious agents or are unlikely to cause disease.
- Non-pathogenic microorganisms.
- Substances in which pathogens have been neutralized or inactivated and the inactivation has been verified.
- Environmental samples that do not pose a significant risk of infection.
- Dried blood spots or fecal occult samples.
- Blood products (where no pathogens are known or presumed present) to be used for research or transfusion; tissues and organs for research or transplantation.

Examples: extracted DNA/RNA, water or soil samples, cultures of non-pathogenic environmental organisms, lab strains of *Escherichia coli* that do not contain recombinant nucleic acids, tissue specimens from healthy humans or animals, etc.

Note: any of the above materials may be subject to shipping regulations when shipped on dry ice or with preservatives from other classes of dangerous goods. If shipping with dry ice, do not tape the lid of the cooler closed so that gas evolved can escape the package.

Note: biological materials, even those exempt from shipping regulations are prohibited in passenger carry-on or checked baggage. Always ship these materials rather than trying to transport them with you on passenger airliners.

How to Package Unregulated Biological Materials

Patient or Animal Specimens. Patient specimens for which there is minimal likelihood that pathogens are present are not subject to shipping regulations if the specimen is transported in a packaging that will prevent any leakage and which is marked with the words “Exempt human specimen” or “Exempt animal specimen”, as appropriate. The packaging must **triple packaged** to meet the following conditions:

- 1) The packaging must consist of three components:
 - a) a leak-proof primary receptacle(s)
 - b) a leak-proof secondary packaging
 - c) An outer packaging of adequate strength for its capacity, mass, and intended use (i.e., a sturdy cardboard box) and with at least one surface having minimum dimensions of 100mm x 100mm (4in X 4in).
- 2) For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material.
- 3) When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.
- 4) Quantities allowed for passenger and cargo: The primary receptacle must not exceed 500ml or 500g. The outer packaging must not contain greater than 4L or 4kg.

Other Unregulated Materials. Other unregulated research biological materials have no specific packaging requirements, but should be packaged in *triple packaging* in such a way as to prevent spills or leaks. If liquid, sufficient absorbent to absorb the entire volume should be included with absorbent placed between the primary and secondary packaging. Primary containers must not exceed 500 mL or 500 g; total package volume must not exceed 4 L or 4 kg. The outer packaging must be rigid. Label primary or secondary containers with a biohazard symbol, but not the outer package. Unregulated materials may be mailed using USPS, if shipped Priority, First Class, or Express mail; or these can be shipped by commercial carriers UPS and FedEx.

It is advisable to include a detailed written description of the materials being shipped on departmental letterhead that includes contact information of the sender and recipient, in case the package is opened or compromised during shipping. State the material is not infectious.

Dangerous Goods: Shipping Biological Materials and Infectious Agents

The materials described in this section must be packaged and labeled by an individual with current training in shipping infectious materials. The OSU [EH&S hazardous shipping](#) office provides this support to the main campus in Corvallis.

Generally, cultures of pathogens of humans, animals, and plants must be shipped as Dangerous Goods. There are two categories of these goods for shipping purposes: Category A and Category B. Most of the pathogens shipped from or received by OSU researchers can be shipped as Category B, but some must be shipped as Category A. Both are discussed below.

Category A. Category A shipments are generally pure or mixed cultures or specimens known or suspected to contain microbial pathogens that are capable of causing severe, debilitating, or fatal diseases in humans or animals. A few examples are below:

- Hemorrhagic fever viruses
- Monkeypox virus
- Hantaviruses
- SARS-CoV-2 (coronavirus or COVID-19)
- Rabies virus
- HIV, hepatitis B virus, hepatitis C virus
- All Select Agents
- Enterohemorrhagic strains of *Escherichia coli*
- Pathogenic strains of *Vibrio cholerae*
- Most encephalitis viruses (West Nile, Japanese, tick-borne, etc.)
- Polio virus

This is not an exhaustive list, but it gives an idea of the types of pathogens that must be shipped as Category A. If you need assistance in determining the shipping category for infectious agents, please contact the OSU Biological Safety Officer.

Packaging Requirements for Category A Infectious Substances

A new (not previously used or recycled) shipping container that conforms to the requirements of Packing Instruction 602 (diagram below) must be used. The basic design of the three-layer packaging system is:

- A **primary receptacle** that holds the actual sample in a watertight and leak-proof container, with absorbent material to protect against spills.
- A **secondary receptacle** that holds one or more primary receptacles in another watertight and leak-proof container surrounded by absorbent material.
- An **outer shipping package** that protects the secondary receptacle and protects it from breakage and water.

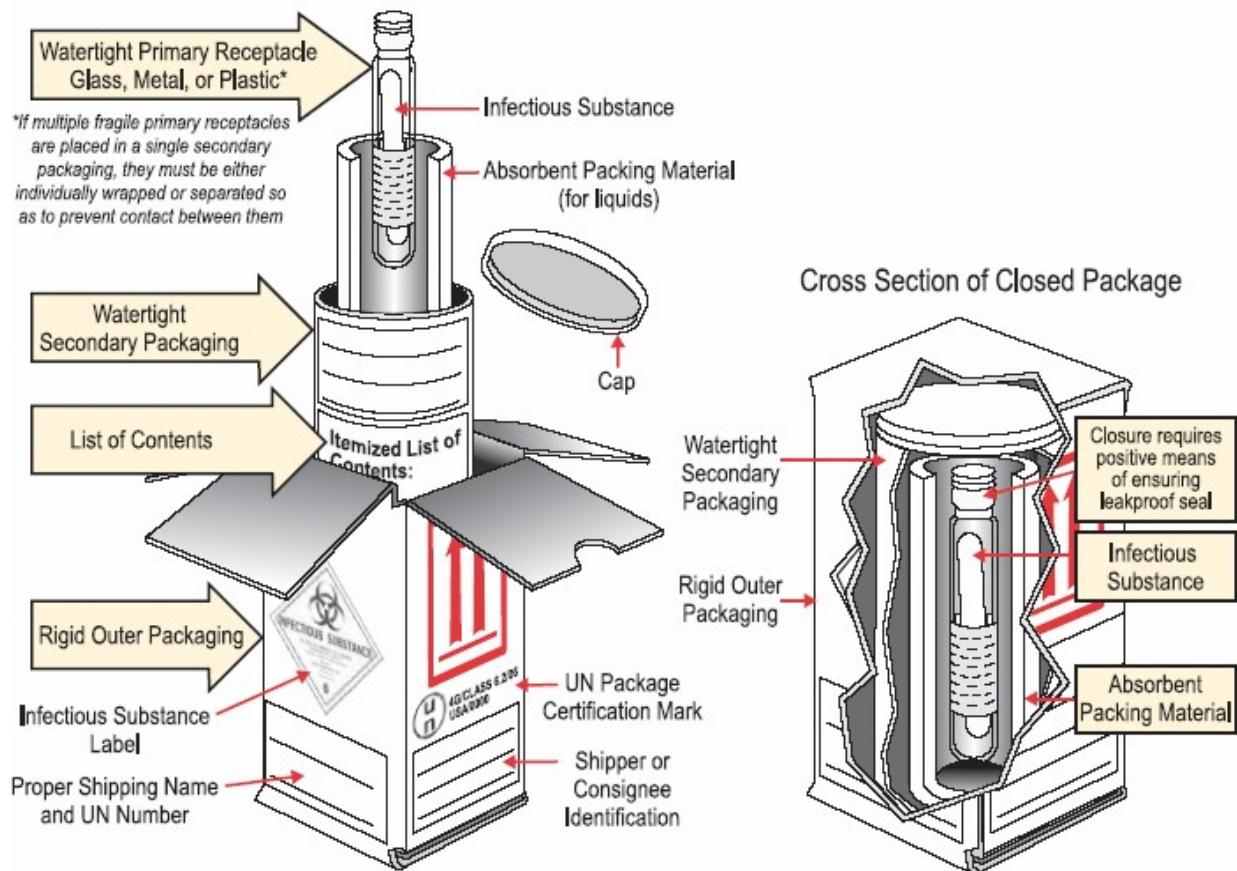
Several vendors sell appropriate containers. The maximum quantity that can be shipped by air in one package is 4 L or 4 kg. The maximum allowable quantity shipped on a *passenger aircraft* is 50 mL or 50 g.

Category A shipments must be labeled with stickers that indicate “Infectious substance, affecting humans” (UN 2814), or, “Infectious substance, affecting animals” (UN 2900). If the agent infects both humans and animals, label it as UN 2814. A Shippers Declaration is required.

Labeling of the outer container must display the following on two opposite sides of the box:

- Sender’s name and address
- Recipient’s name and address
- Infectious substance label (UN hazard class 6 warning label)
- Proper shipping name of what is being shipped, UN number, and the net quantity of infectious substance
- Name and telephone number of the person responsible for the shipment
- (conditional) Cargo Aircraft Only label when shipping over 50 mL or 50 g
- (conditional) Class 9 label, including UN 1845, and net weight if packaged with dry ice

The diagram below shows the proper way to assemble the shipping containers for a Category A substance.



Category B. Infectious materials that do not rise to the risk level of Category A can be shipped as Category B. All Category B shipments must be labeled “Biological Substance, Category B” and with the identification number UN 3373. Examples of materials that can be shipped as Category B:

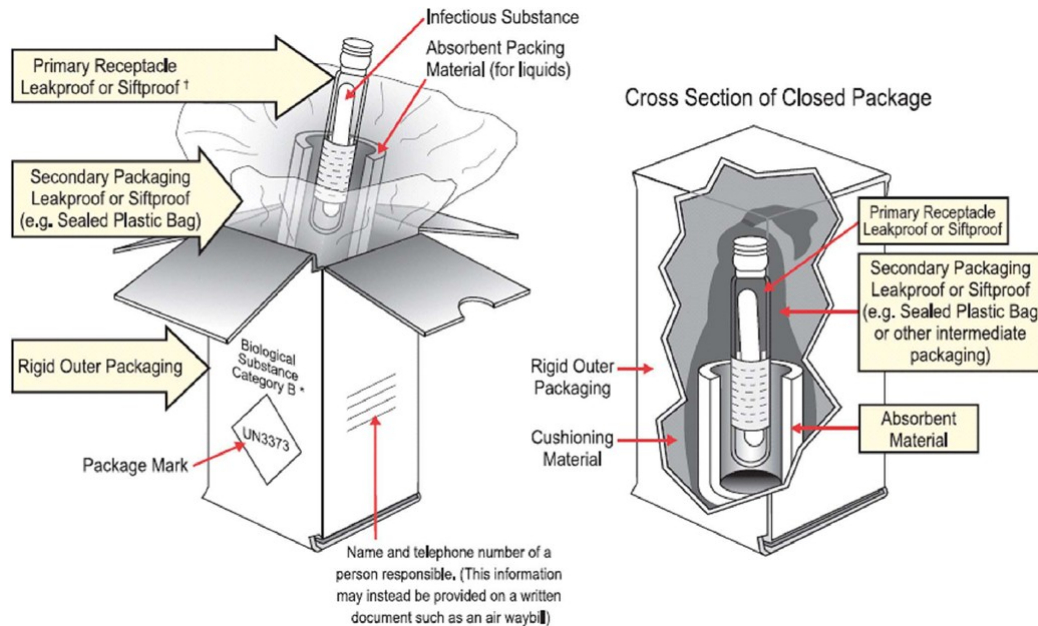
- Cultures and stocks of pathogens that do not cause life-threatening illness in healthy persons or animals, such as:
 - Most influenza viruses, except highly pathogenic avian strains and certain other strains (Contact OSU Biological Safety Officer for guidance)
 - Non-tuberculous mycobacteria (*M. avian* complex, *M. lepre*, etc.)
 - *Pseudomonas aeruginosa*, *Staphylococcus spp.* and other opportunistic pathogens
 - Most common *Enterobacteriaceae*
 - Viruses that cause the common cold, gastroenteritis, or other generally self-limiting infections
 - Non-enterohemorrhagic clinical strains of *E. coli*
 - *Chlamydia* spp. except *C. psittaci*
 - Non-typhoid strains of *Salmonella*
 - most plant pathogens, except Select Agents
- Human or animal diagnostic specimens being sent for culture that are not thought to harbor agents that would be considered Category A may be shipped as Category B

Packaging Requirements for Category B Infectious Substances

New or recycled shipping containers (in good condition) may be used for shipping Category B materials. Shippers must use Packing Instruction 650, which is shown in the diagram below. The maximum quantities for a primary receptacle is 500 mL or 500 g, and the outer packaging must not contain more than 4 L or 4 kg. A Shippers Declaration is not required.

Category B Packages must be labeled on two opposite sides with the following:

- Sender’s name and address
- Recipient’s name and address
- “Biological Substance, Category B” and a UN 3373 label
- (Conditional) Class 9 label, including UN 1845, and net weight if packaged with dry ice



Permits. Researchers who ship or receive infectious agents may need a permit or an export license. Generally, it is the **recipient** who must acquire the permit before the shipment, but a copy of the permit should be included inside the package by the **shipper**. Materials that require an import or transport permit are described below in the section on Receiving Biological Materials.

Export License. It is the shipper who must obtain an export license from the U.S. Department of Commerce if shipping biological materials out of the U.S. that are listed on the [Commerce Control List](#). Few of the infectious agents in use at OSU are on the Commerce Control List, but it is necessary to check if you wish to ship an infectious agent out of the country. The list is large, complex, and daunting. Microorganisms and toxins are listed by following the link for Category 1 [on this page](#), and found in section 1C351 of the PDF document.

For assistance in obtaining an export license if you are planning to ship a microorganism or toxin listed on the Commerce Control List out of the U.S., contact the [Export Control and International Compliance Officer](#) in the Research Office.

For most countries, the recipient will also need an import permit from their government to receive infectious agents. This paperwork should be included in the shipping documents.

Genetically Modified Organisms or Microorganisms

Genetically modified organisms (GMO) or microorganisms (GMMO) are genetically modified organisms or microorganisms where the genetic information has been purposely altered in ways that do not naturally occur through genetic manipulations such as recombinant DNA, CRISPR / Cas9, or similar technologies. If GMOs or GMMOs do not meet the definition of Category A or Category B, then they are assigned the category Genetically Modified Organisms or Genetically Modified Microorganisms are assigned to UN 3245. This is required for **international shipments only**; inside the U. S. GMOs and

GMMOs that are not Category A or B may be shipped as unregulated biological materials as described above.

Packaging Requirements for GMO and GMMO International Shipments

Use Packing Instruction 959. International shipments of GMOs and GMMOs require triple packaging, but only the primary layer and not the secondary layer needs to be leak-proof. There are no specific quantity restrictions.

The package needs to be labeled UN 3245 and Genetically Modified Organisms or Genetically Modified Microorganisms, as applicable, and the number of packages unless there is only one package in the shipment. A Shipper's Declaration for Dangerous Goods is not required.

Receiving Biological Materials

Researchers who receive infectious agents or other biological materials from another institution or entity may need to obtain various permits as described below, depending on the materials being received and the place of origin. This resource is not exhaustive and does not discuss some agencies that require import permits for biological materials, such as Food and Drug Administration or the U. S. Fish and Wildlife Service.

USDA / APHIS Permits. Importation from other countries or transport from one U.S. state to another is regulated for many types of materials by several different divisions of APHIS: Biotechnology Regulatory Services (BRS), Plant Protection and Quarantine (PPQ), and Veterinary Services (VS). The types of biological materials regulated are arthropods, animals, plants and plant pathogens, genetically modified plants, infectious agents of livestock or poultry, animal products, vaccines, and various experimental biological materials. Generally, once a material in any of these categories is licensed for commercial use it no longer requires a permit.

Regulated materials do not require an APHIS permit for shipment or movement within the boundaries of a single state, but those same materials will require a permit to cross state lines. Importation of regulated infectious agents or biological materials that may harbor livestock pathogens (for example, soil or fetal bovine serum) from other countries always requires an import permit.

A good place to start when determining if your material will require a permit is by visiting the [USDA / APHIS Import and Export website](#) and following the relevant links. Animal pathogens are under the link for "**Organism and Vectors.**" Links for other types of biological materials, including plant pathogens, can be found on the [APHIS Permits web page](#). There is a cost associated with obtaining APHIS permits, and this is the responsibility of the investigator or department. Permits are generally valid for 3 years, and generally prohibit secondary distribution of regulated materials to other researchers.

At the discretion of APHIS, an inspection will generally be required. APHIS will schedule an inspection to look at the facilities where the regulated material will be handled and scrutinize handling procedures and containment practices. Written SOPs for handling the materials will usually be required, as will secure (locked) storage location for regulated materials. It is a good idea to contact the OSU Biological Safety Officer, who can provide guidance in advance of and during inspections by APHIS.

CDC Import Permits. Importation of infectious agents of humans from outside the U.S. will require an import permit from CDC. The mandate is to insure that the importation of these agents is monitored and that facilities receiving permits have appropriate biosafety measures in place to work with the agents. Currently, there is no fee for obtaining a CDC import permit.

At the discretion of the CDC, an inspection of the laboratory facilities may be required before the issuance of the permit. If you are notified that your lab will be inspected, please contact the OSU Biological Safety Officer for guidance and a pre-inspection to ensure that the lab meets the necessary benchmarks ahead of the arrival of the CDC inspection team.

The [CDC Import Permit Program website](#) has additional information.

Select Agents and Toxins. Shipping of Select Agents and Toxins requires advance planning, active oversight, and pre-approval by federal as well as local authorities, and full compliance with the regulatory requirements. OSU currently does not have an active Select Agent Program, so at this time Select Agents and Toxins **may not be shipped to OSU**. The exception is the shipment of select toxins under the regulatory threshold amounts. For information and allowable toxin limits, see the [Federal Select Agent Program website](#).