

# Unregulated and Regulated Materials

This section provides information on which biological materials are or are not subject to DOT HMR and IATA DGR infectious substance and genetically modified organism shipping regulations. LBNL employees should use this information to assist in selecting or requesting appropriate modes of transport for their biological materials.

## Unregulated Biological Materials

The following materials are not subject to DOT and IATA infectious substance shipping regulations:

- Substances that do not contain infectious substances or that are unlikely to cause disease in humans or animals.
- Noninfectious biological materials from humans, animals, or plants. Examples include noninfectious cells, tissue culture, blood, or plasma from individuals not suspected of having an infectious disease, DNA, RNA, or other genetic elements.
- Substances containing microorganisms that are nonpathogenic to humans or animals.
- Substances that have been neutralized or inactivated so that they no longer pose a health risk.
- Environmental samples that are not considered to pose a significant risk of infection (e.g., food and water samples).
- Dried blood spots.
- Fecal occult blood screening tests.
- An infectious substance (other than a Category A infectious substance) contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment and prevention; or a biological product when such materials are being transported by a private carrier in a motor vehicle used exclusively to transport such materials.
- Blood or blood components that have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation.
- Tissues or organs intended for use in transplantation.
- A material with a low probability of containing an infectious disease, or where the concentration of the infectious substance is at a level that naturally occurs in the environment and cannot cause disease when exposure to it occurs. Examples of these materials include foodstuffs and environmental samples (e.g., samples of water, dust, or mold).
- A biological product, including an experimental or investigational product or component of a product, subject to federal approval, permit, review, or licensing requirements such as those required by the Food and Drug Administration (FDA) or U.S. Department of Agriculture (USDA).

## Regulated Biological Materials

The materials presented below are subject to DOT and IATA shipping regulations for infectious substances and genetically modified organisms:

**Infectious substances** are materials regulated for shipping. These materials are known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus,

microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion), or a recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal diseases are not subject to biological shipping regulations.

- **Category A infectious substances** are materials capable of causing permanent disability, or a life threatening or fatal disease in humans or animals when exposure to them occurs. Category A infectious substances are shipped as infectious substances affecting humans (UN2814) or infectious substances affecting animals (UN2900). Examples of Category A infectious substances are listed in a table in the [infectious substances section](#) of the [IATA Dangerous Goods Regulations](#).
- **Category B infectious substances** are materials that do not meet Category A criteria. Category B infectious substances are shipped as UN3373.

**Patient specimens or diagnostic specimens** are any human or animal materials including but not limited to excreta, secretions, blood, blood components, tissue, and tissue fluids being shipped for the purpose of diagnosis. Patient specimens that have a minimal likelihood of containing pathogens are regulated materials, but they are also exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and should be based on the patient's medical history, symptoms, local conditions, and individual circumstances. The outer package must be marked "Exempt human specimen" or "Exempt animal specimen." If there is more than a "minimal likelihood" that a patient specimen contains pathogens, it must be shipped as a Category A or Category B infectious substance.

**Biological products** are materials that are derived from living organisms and manufactured for use in the prevention, diagnosis, treatment, or cure of disease in humans or animals and are certified by the USDA, FDA, or other national authority. Examples of biological products include certain viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, and blood products. Biological products transported for final packaging, distribution, or use by medical professionals are not subject to biological shipping regulations. Biological products that do not meet these criteria must be shipped as UN2814, UN2900, or UN3373 when appropriate.

**Genetically Modified Organisms (GMO) or microorganisms (GMMO)** are organisms whose genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs and GMMOs that are not infectious but that can alter animals, plants, or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and are shipped as UN3245. GMOs and GMMOs that are infectious must be shipped as UN2814, UN2900, or UN3373.