

Transporting Biological Materials

Researchers at the University of Arkansas often collaborate with researchers from institutions throughout the state and surrounding states as well. The Office of Environmental Health and Safety (EH&S) has the responsibility of ensuring that biological materials are transported safely and responsibly by individuals affiliated with the university. This document outlines unregulated and regulated biological materials as well as proper packaging and handling procedures for biological materials. Once a researcher determines whether the biological material to be transported is unregulated or regulated, then he/she must follow the correct procedures and/or notify EH&S if warranted. If the biological material for transport falls under the category of unregulated biological materials, then proceed to the packing and transport sections. However, if the biological material for transport falls under the category of regulated biological materials, contact EH&S at 575-5448 for proper shipping instructions. If there is a question or concern about the proper category for a particular biological material, contact EH&S for clarification.

Unregulated and Regulated Materials

This section provides information on which biological materials are or are not subject to DOT HMR (U.S. Department of Transportation's 49 CFR "Hazardous Materials Regulations") and IATA DGR (International Air Transport Association's "Dangerous Goods Regulations") infectious substance and genetically modified organism shipping regulations.

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, secreta, 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.

Source: Lawrence Berkeley National Laboratory (Berkeley Lab), a Department of Energy (DOE) Office of Science lab

Packaging Unregulated Biological Material

- Guidelines for Packaging and Transporting Biological Materials
Packages must be clearly labeled as to the contents and constructed of materials to protect the specimen and prevent leakage. Additionally, the OSHA Bloodborne Pathogens Standard requires all packages containing blood/blood products be labeled with the biohazard label.

- Recommended Packaging for Biological Materials
Primary container (innermost container):
 - Use a vial, tube, or plate made of glass, metal, plastic or other medium suitable for transportation of the material being transported.
 - Clearly identify the contents and avoid abbreviations (e.g. write out *E. coli* K-12 – DH1 rather than just DH1).
 - Wrap the primary container tightly e.g. using Parafilm to ensure that there will be no leakage.
Secondary container:
 - Use a watertight/leak proof container (e.g. Ziploc bag) and reinforce with an adhesive tape as necessary to contain the contents.
 - Affix a label with a complete list of the contents including the scientific name and the amount in ml for liquids.
 - Surround each primary container with sufficient absorbent packing material to completely absorb the contents should the primary container break.

Transport of Unregulated Biological Material

Transporting container (if necessary):

- Use a container made of sufficient strength to protect the specimen.
 - Affix a proper label to identify the contents.
 - Affix an accurate address label with the complete address and phone number for both the shipper and the recipient.
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- Transport of Biological Materials in Personal or University Vehicle
Note: University vehicles are preferred.
Personnel transporting biological materials must:
 - 1) have a valid driver's license;
 - 2) be authorized to use a University of Arkansas vehicle;
 - 3) should use a University of Arkansas vehicle when available;
 - 4) use the proper containment and packaging materials en route;
 - 5) notify the Office of Environmental Health and Safety at 575-5448 before transporting material.

A spill kit containing absorbent material, a chlorine disinfectant, a leak-proof waste container, and personal protective equipment (gloves and eye protection) should be available in the transport vehicle.

The transport boxes need to be secured in the transport vehicle, and traveling should be directly from the location of origin to the drop-off location. During transportation the vehicle should only

be used for that purpose and there is to be no passenger or food transport. EH&S encourages the use of university-owned vehicles rather than personal vehicles when transporting materials off campus to/from another facility or collaborator.

In the event of a motor vehicle accident, the transporter should follow the steps below:

- Call for emergency assistance, if needed.
- Let all emergency responders know that you are transporting potential biohazards.
- Notify recipient of sample(s) status.
- Arrange for alternate transportation if you are unable to reach your destination.

If a personal vehicle is used for transport, the transporter must have the following:

- 1) Liability insurance and
- 2) Proof of insurance inside the vehicle

Under no circumstances may public transportation (taxis, buses, etc.) be used for transport of work-related biological materials.

****When transporting dry ice in a vehicle, the box should not be placed inside the passenger compartment to prevent carbon dioxide accumulation within the vehicle.**

Sources: University of Texas Arlington and Georgia Regents University

Pertinent Definitions:

Biological Agents- Biological agents include bacteria, viruses, fungi, other microorganisms and their associated toxins. They have the ability to adversely affect human health in a variety of ways, ranging from relatively mild, allergic reactions to serious medical conditions, even death. These organisms are widespread in the natural environment; they are found in water, soil, plants, and animals. Because many microbes reproduce rapidly and require minimal resources for survival, they are a potential danger in a wide variety of occupational settings. (U.S. Department of Labor, Occupational Safety & Health Administration)

Biological Product- A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals. (*Transporting Infectious Substances Safely, Guide To Changes*, U. S. Department of Transportation, 2006).

Culture- An infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen. (*Transporting Infectious Substances Safely, Guide To Changes*, U. S. Department of Transportation, 2006).

Patient Specimen- Human or animal materials collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Patient specimen includes excreta, secreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (e.g., transwabs, culture media, and blood culture

bottles). (*Transporting Infectious Substances Safely, Guide To Changes*, U. S. Department of Transportation, 2006).