INTRODUCTION

Occasionally DRI employees need to ship biological materials. Several agencies regulate the shipment of biologicals, including the International Air Transport Association (IATA), the US Department of Transportation (DOT), the US Public Health Service (PHS), the Occupational Health and Safety Administration (OSHA) and the United States Postal Service (USPS). Other agency's regulations may need to be considered for export or import of these items. Also, at times biological materials being shipped will be preserved in ethanol or formaldehyde solutions, while in other instances the material may need to be shipped frozen on dry ice or in liquid nitrogen.

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. Carrying dangerous goods by hand, for example a vial in your pocket or in luggage is strictly prohibited. IATA and DOT regulations cover your checked luggage and materials you put in your carry on or on your person when you board a plane. Persons who violate regulations are subject to fines and criminal prosecution.

SCOPE

This guideline provides information on how to properly categorize your biological material for shipment, but does not provide detailed instructions on how to properly package your biological if it is not in the unregulated category. If you determine your biological material is captured in one of the regulated in transportation categories, please contact DRI EH&S for addition information on where to obtain the required packing materials and how to proceed.

REQUIRED TRAINING for HAZARDOUS MATERIALS/DANGEROUS GOODS SHIPPERS

All shippers of dangerous goods are required by law to have applicable training. Before shipping any hazardous material, please ensure you have completed the DRI hazardous material shipper’s training course and that your training is still current. (Training expires every 2 years.) This document serves only as a guideline and does not constitute training. To help ensure your package is prepared correctly, it is highly recommended that you have your package and paperwork reviewed by a trained DRI employee prior to tendering your package for shipment. To make those arrangements, complete the DRI Dangerous Goods Shipping Request Form, http://oldintranet.dri.edu/Services/Safety/Forms/shipping_request.php.

PENALTIES FOR NON-COMPLIANCE

Penalties for non-compliance with shipping regulations can be significant. In addition to potential public safety implications, each violation of the regulations may result in a civil penalty of up to $75,000 or in the case of death, serious illness or severe injury to any person or substantial destruction of property, $175,000. There is no minimum civil penalty except for violations related to training. When a violation continues for more than one day, each day constitutes a separate offense. In addition, persons who willfully violate the regulations may be subject to criminal prosecution with penalties of up to $500,000 and/or five years.
CLASSIFYING A BIOLOGICAL SHIPMENT

A shipment of biological material will fall into one of the following categories:

- **Unregulated biological material**
- **Infectious Substances**, which are known or are reasonably expected to contain pathogens which can cause disease in humans or animals. Infectious substances can be further classified as:
  - Category A Infectious Substances
  - Category B Infectious Substance
- **Biological Products** which are known or reasonably believed to contain an infectious substance
- **Cultures** which are generated from intentionally propagating a pathogen
- **Patient specimens**, generated directly from humans or animals being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention
- **Medical or clinical wastes** derived from the medical treatment of animals or humans or from bio-research
- **Genetically Modified Organisms (GMOs)**, which may or may not be infectious in nature

**BIO-SHIPMENT CLASSIFICATION DEFINITIONS**

1. **Unregulated Biological Materials**: Unregulated biological materials are not subject to IATA or DOT infectious substance shipping regulations; however, these materials may require a permit for shipment abroad and will be considered a dangerous goods shipment if they are shipped on dry ice or liquid nitrogen or are preserved in ethanol or formaldehyde solutions. Please check with EH&S if you have any question as to whether your shipment is unregulated. Some examples of unregulated biological materials include:
   - Substances which do not contain infectious agents and which should not cause disease in humans or animals. These include non-infectious cells or tissue cultures; blood, plasma, or sera from humans or animals not suspected of having an infectious disease;
   - DNA, RNA, or any other genetic elements that are not themselves infectious;
   - Patient specimens that are not presumed to be infectious
   - Microorganisms which are not pathogenic to humans, animals, or plants;
   - Substances that have been neutralized or inactivated such that they are no longer infectious;
   - Environmental samples that are not known, or thought to be, infectious;
   - A biological product manufactured and packaged in accordance with the requirements of appropriate national authorities for the purposes of final packaging or distribution and use for personal health care by medical professional or individuals, such as an antibody or drug.

2. **Category A Infectious Substances**: Category A infectious substances are capable of causing disease in humans or animals. The proper shipping name for Category A Infectious Substances is **Infectious substance affecting humans** (UN2814), or **Infectious substance affecting animals** (UN2900). These substances are classified as DOT hazard class 6.2 (infectious). Some examples of Category A infectious substances are:
UN2814--Infectious Substances Affecting Humans

- *Bacillus anthracis* (cultures only)
- *Brucella abortus* (cultures only)
- *Brucella melitensis* (cultures only)
- *Brucella suis* (cultures only)
- *Burkholderia mallei* – *Pseudomonas mallei* – Glanders (cultures only)
- *Burkholderia pseudomallei* – *Pseudomonas pseudomallei* (cultures only)
- *Chlamydia psittaci* – avian strains (cultures only)
- *Clostridium botulinum* (cultures only)
- *Coccidioides immitis* (cultures only)
- *Coxiella burnetii* (cultures only)
- Crimean-Congo hemorrhagic fever virus
- Dengue virus (cultures only)
- Eastern equine encephalitis virus (cultures only)
- *Escherichia coli*, verotoxigenic (cultures only)
- Ebola virus
- Flexal virus
- *Francisella tularensis* (cultures only)
- Guanarito virus
- Hantaan virus
- Hantavirus causing hemorrhagic fever with renal syndrome
- Hendra virus
- Hepatitis B virus (cultures only)
- Herpes B virus (cultures only)
- Human immunodeficiency virus (cultures only)
- Highly pathogenic avian influenza virus (cultures only)
- Japanese Encephalitis virus (cultures only)
- Junin virus
- Kyasanur Forest disease virus
- Lassa virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- *Mycobacterium tuberculosis* (cultures only)
- Nipah virus
- Omsk hemorrhagic fever virus
- Poliovirus (cultures only)
- Rabies virus (cultures only)
- *Rickettsia prowazekii* (cultures only)
- *Rickettsia rickettsii* (cultures only)
- Rift Valley fever virus (cultures only)
- Russian spring-summer encephalitis virus (cultures only)
- Sabia virus
- Shigella dysenteriae type 1 (cultures only)
- Tick-borne encephalitis virus (cultures only)
- Variola virus
- Venezuelan equine encephalitis virus (cultures only)
- West Nile virus (cultures only)
- Yellow fever virus (cultures only)
- *Yersinia pestis* (cultures only)
UN2900—Infectious Substances Affecting Animals

- African swine fever virus (cultures only)
- Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
- Classical swine fever virus (cultures only)
- Foot and mouth disease virus (cultures only)
- Goatpox virus (cultures only)
- Lumpy skin disease virus (cultures only)
- Mycoplasma mycoides – Contagious bovine pleuropneumonia (cultures only)
- Peste des petits ruminants virus (cultures only)
- Rinderpest virus (cultures only)
- Sheep-pox virus (cultures only)
- Swine vesicular disease virus (cultures only)
- Vesicular stomatitis virus (cultures only)

3. Category B Infectious Substances: Category B infectious substances are materials that are infectious, but do not meet the definition of Category A infectious substances. These substances are also classified as DOT 6.2 materials and include patient samples, tissue cultures, and cells that are presumed to contain, or have a reasonable probability of containing, a pathogenic organism (e.g., blood known to contain HIV). The proper shipping name for these substances is Biological substance, Category B (UN3373).

4. Genetically Modified Organisms (GMOs): Genetically modified organisms (GMOs) are organisms in which their genetic material has been altered through recombinant DNA techniques. If a GMO is non-infectious it is classified as a DOT class 9 (miscellaneous) hazard and is assigned to UN3245. The proper shipping name for non-infectious GMOs is Genetically modified micro-organisms or Genetically modified organisms, whichever is most applicable. If a GMO is potentially infectious, it must be assigned to UN2814, UN2900, or UN3373 and would fall under the proper shipping name for the UN number assigned.

A synopsis of the above information is included in the table in the Shipping section below.

SHIPPING

If the item you are shipping is an unregulated biological material, you should package following the guidelines below.

- If liquid, use a non-breakable inner container, leave head space for expansion and place container in zip lock bag or surround it with absorbent material capable of soaking up all the liquid should the inner container break or leak during transportation. Use a strong box for outer packaging ensuring there are two sets of up arrows on opposite sides of the box and if reusing a box, that all extraneous markings and labels have been removed or blacked out. If the biological material is preserved with a material that is considered a dangerous good or is transported on dry ice or in liquid nitrogen, the packaging, marking, labeling and paperwork must comply with the applicable transportation regulations for the dangerous good involved.

- For solid non-regulated biological material, the inner container should be of appropriate size and strength to contain the material without breaking/bursting. Inner cushioning
(peanuts, bubble wrap, etc.) should be used to keep the inner container from shifting in the box during transportation. Use a strong box for outer packaging ensuring that all extraneous markings and labels have been removed or blacked out if recycling a box. If the solid is transported on dry ice or in liquid nitrogen, the packaging, marking, labeling and paperwork must comply with the applicable transportation regulations for the dangerous good involved.

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. For regulated shipments of biological material, the packaging, marking, labeling and paperwork must comply with the applicable transportation regulations for the dangerous goods involved (i.e., both the biological and preservative and/or cooling agent.) Special packaging materials as well as marking, labeling and paperwork will likely be required.

Table 1-Summary of Shipping Information for Regulated Biological Materials

<table>
<thead>
<tr>
<th>Shipment Type</th>
<th>Proper Shipping Name</th>
<th>Un Number</th>
<th>Hazard Class</th>
<th>Packing Instruction</th>
<th>Max Net qty/pkg for Passenger Aircraft</th>
<th>Max Net qty/pkg for Cargo Aircraft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A infectious substances affecting humans and possibly animals</td>
<td>Infectious substances, affecting humans (technical name)</td>
<td>UN2814</td>
<td>6.2</td>
<td>620</td>
<td>50 ml or 50 gm</td>
<td>4L or 4 Kg</td>
</tr>
<tr>
<td>Category A infectious substances affecting only animals (not humans)</td>
<td>Infectious substances, affecting animals (technical name)</td>
<td>UN2900</td>
<td>6.2</td>
<td>620</td>
<td>50 ml or 50 gm</td>
<td>4L or 4 Kg</td>
</tr>
<tr>
<td>Category B infectious substance</td>
<td>Biological substance, Category B</td>
<td>UN3373</td>
<td>6.2</td>
<td>650</td>
<td>4L or 4Kg--See packing instruction for specific requirements</td>
<td>4L or 4Kg--See packing instruction for specific requirements</td>
</tr>
<tr>
<td>Diagnostic specimens</td>
<td>Biological substance, Category B</td>
<td>UN3373</td>
<td>6.2</td>
<td>650</td>
<td>4L or 4Kg--See packing instruction for specific requirements</td>
<td>4L or 4Kg--See packing instruction for specific requirements</td>
</tr>
<tr>
<td>Non-infectious, transducing genetically modified organism or micro-organism</td>
<td>Genetically modified organism or Generically modified micro-organism</td>
<td>UN3245</td>
<td>9</td>
<td>959</td>
<td>No limit</td>
<td>No limit</td>
</tr>
</tbody>
</table>

If you need to ship one of the regulated biological materials listed in the table above, it is highly recommended that you contact DRI EH&S for advice on how to proceed.

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1 Table information taken from the IATA Dangerous Goods Regulations, 56th edition, effective January 1 through December 31, 2015. Regulations are subject to change throughout the calendar year and new editions are published annually so you should always ensure you are shipping dangerous goods per the most current requirements.