

Regulations Update—Shipping Biological Materials Infectious Substances and Diagnostic or Research Specimens

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- ✚ Questions may be addressed to the Health and Safety Division, Biosafety Office, UCDHSC, 303-724-0235.
- ✚ UCDHSC personnel shipping infectious substances, human or animal diagnostic specimens or any other biological substances must be in compliance with the applicable regulations for shipping these materials by any ground or air carrier.
- ✚ U.S. Postal regulations restrict what you may send through the U.S. Mail. You may **not** mail Category A materials. USPS will accept Category B, Biological Substances and Exempt Patient Specimens in U. S. Mail, per the Domestic Mail Manual.
- ✚ Any persons preparing shipping documents, packages or labels for shipping these materials must be trained. Training [is available](#) through the University Blackboard On-line Learning system.
- ✚ Training must be done at least every 24 months.
- ✚ Shipping papers must be retained by shippers for **2 years**.
- ✚ Infectious substances are **NO LONGER CATEGORIZED BY RISK GROUP**. The regulatory agencies have adopted a simplified system of classification. Please review and institute appropriate changes immediately.
- ✚ If using Dry Ice, it may need to be declared as a Dangerous Good, with the appropriate paperwork and labels on packages, i.e.: UN 1845, Dry Ice, **if** it is included in a shipment that contains other hazardous (infectious) materials.
- ✚ **Biological materials**, are now categorized in the following manner, for shipping purposes:
- ✚ **Category A, Infectious Substances** (see Packing Instruction 602 for proper leakproof, triple packaging requirements)

A Shipper's Declaration of Dangerous Goods is required. [Be sure you notify the Biosafety Office prior to shipping these materials.](#) Be sure you are using our 24 hour notification number information.

Category A infectious substances are those human or animal pathogens which cause serious disease in humans and animals, (UN2814) and those agents that cause serious disease in animals only (UN2900).

Category A material is an infectious substance that is in a form that is capable of causing permanent disability or life threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs.

Typically these will be the Risk Group 3 and 4 organisms (NIH, WHO classifications).

See Table 1 (below) for examples of infectious materials that are Category A infectious substances shipped under UN 2814.

Animal pathogens will need to be checked against USDA-APHIS Veterinary Services lists.

See Table 2 (below) for examples of infectious materials that are Category A infectious substances shipped under UN 2900.

Proper Shipping Name & UN ID number

UN 2814, Infectious Substance affecting humans, (*specify scientific name of organism and specify if liquid or solid*), 6.2

UN2900, Infectious Substance affecting animals, (*specify scientific name of organism and specify if liquid or solid*), 6.2

Category B, Biological Substances (see Packing Instruction 650 for proper leakproof, triple packaging requirements)

Category B includes those infectious substances which do not typically cause permanent disability or life threatening or fatal disease to humans or animals when exposure to it occurs, and those diagnostic or research specimens, from humans or animals, which are known to or suspected of having one of these infectious agents.

Typically these will be the Risk Group 2 organisms (NIH, WHO classifications).
These are assigned the UN ID number, UN3373.

Patient cultures, such as swabs, that are collected for diagnosis because of a suspected or known infectious disease, which are not Category A materials, are considered Category B Biological Substances.

A Shipper's Declaration of Dangerous Goods is **not** required, **but you must include the following information on your Air Waybill.**

UN3373, Biological Substance, Category B, (*specify if liquid or solid*)

Packing Instruction 650

All such packages must now include:

- The name, address, and telephone number of the responsible party is required, either as a label on the outside of each package, or included on the Air-Bill.
- Each package going by an air carrier must also be marked "Air Eligible"
- A diamond shaped label printed "UN3373" is required Each label must include a solid black border that is at least 2mm in diameter with the letters and numbers-- UN3373-- at least 6mm in height. This new label must be placed adjacent to the marking " Biological substances, Category B" on the outer packaging in letters that are at least 6 mm (0.24 inches) high.

Exempt Patient Specimens

This category of specimens, exempted from shipping regulations, are those human or animal materials collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention and for which, in the professional judgment of the shipper, there is minimal likelihood of an infectious agent or pathogen being present.

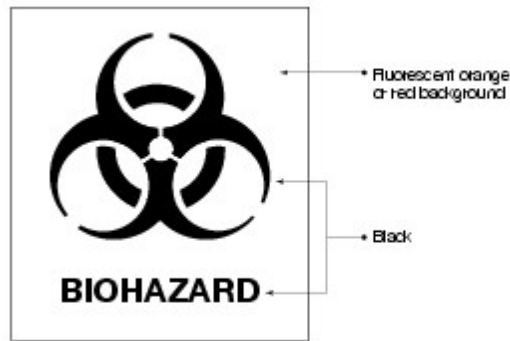
Examples include excreta, secreta, blood and its components, tissue and tissue swabs, from humans or animals being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.

Exempt patient specimens must still have leakproof triple packaging and should be marked as "Exempt human specimen" or "Exempt animal specimen" as appropriate.

U. S. Mail

The U. S. Postal Service has harmonized its classification of infectious substances with the U. S. Dept. of Transportation and international agency definitions. In accordance with the [U. S. Domestic Mail Manual](#), as of November, 2006:

1. **NO Category A** materials may be sent by U.S. mail.
2. **Category B, Biological Substances**, may be sent by U.S. Mail when the following regulations are met.
 - Must be triple-packaged and leakproof, essentially meeting the packaging requirements of Packaging Instruction 650, the primary and secondary packaging must be enclosed in a rigid outer shipping container
 - A single primary receptacle must not contain more than 1 liter (34 ounces) of a liquid specimen or 4 kg (8.8 pounds) of a solid specimen
 - Must be sent as First-Class Mail, Priority Mail, or Express Mail.
 - The secondary container must be marked with the international biohazard symbol



3. **Exempt Human or Animal Specimens** are not subject to regulation as hazardous materials but when presented for mailing must be:

- Must be triple-packaged and leakproof, essentially meeting the packaging requirements of Packaging Instruction 650, the primary and secondary packaging must be enclosed in a rigid outer shipping container
- A single primary receptacle must not contain more than 500 ml of a liquid specimen or 500 grams of a solid specimen.
- Must be sent as First-Class Mail, Priority Mail, or Express Mail.
- The secondary container must be marked with the international biohazard symbol
- The outer shipping container must be marked on the address side with the words "Exempt human specimen" or "Exempt animal specimen," as appropriate. In addition, at least one surface of the outer packaging must have a minimum dimension of 3.9 inches x 3.9 inches (100 mm x 100 mm).
- Exempt human and animal specimens are mailable as First-Class Mail, Priority Mail, Express Mail, or Package Services mail.

NOTE 1: The Category A and B designations developed for purposes of transportation are different from the Category A and B designations for agents of bioterrorism developed by the CDC and the NIH.

NOTE 2: Toxins—from plant, animal or bacterial sources, which do not contain any infectious substance, or toxins that are not contained in substances which are infectious substances, should be classified in Division 6.1 and assigned to UN3172 for shipping.

Table 1

Category A infectious substances/micro-organisms UN 2814—Infectious substances affecting humans and animals
Includes but is not limited to:
All Risk Group 4 infectious (viral) agents or specimens from patients suspected or known to be infected with RG 4 agents. <ul style="list-style-type: none">• Herpes B virus (cultures only).• Russian spring-summer encephalitis virus (cultures only)• Tick-borne encephalitis virus (cultures only).• Any Hemorrhagic fever agents and viruses as yet undefined
<i>Bacillus anthracis</i> (cultures only).
<i>Brucella abortus</i> (cultures only).
<i>Brucella melitensis</i> (cultures only).
<i>Brucella suis</i> (cultures only).
<i>Burkholderia mallei</i> — <i>Pseudomonas mallei</i> —Glanders (cultures only).
<i>Burkholderia pseudomallei</i> — <i>Pseudomonas pseudomallei</i> (cultures only).
<i>Chlamydia psittaci</i> —avian strains (cultures only).
<i>Clostridium botulinum</i> (cultures only).
<i>Coccidioides immitis</i> (cultures only).
<i>Coxiella burnetti</i> (cultures only).
Dengue virus (cultures only).
Eastern equine encephalitis virus (cultures only).
<i>Escherichia coli</i> , verotoxigenic (cultures only).
Flexal virus.
<i>Francisella tularensis</i> (cultures only).
Hantaan virus.
Hantaviruses causing hemorrhagic fever with renal syndrome.
Hendra virus.
Human immunodeficiency virus (cultures only).
Highly pathogenic avian influenza virus (cultures only).
Japanese Encephalitis virus (cultures only).
Monkeypox virus.
<i>Mycobacterium tuberculosis</i> (cultures only).
Nipah virus
Poliovirus (cultures only).
Rabies and other lyssaviruses (cultures only).
<i>Rickettsia prowazekii</i> (cultures only).
<i>Rickettsia rickettsia</i> (cultures only).
Rift Valley fever virus (cultures only).
<i>Shigella dysenteriae</i> type I (cultures only).
Variola virus.
Venezuelan equine encephalitis virus (cultures only).
Vesicular stomatitis virus (cultures only).
West Nile virus (cultures only).
Yellow fever virus (cultures only).
<i>Yersinia pestis</i> (cultures only)

Table 2

Category A infectious substances /micro-organisms
UN 2900—Infectious substances affecting animals only
Includes but is not limited to:
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). 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). Goatpox virus (cultures only). Swine vesicular disease virus (cultures only).