Transporting Infectious Substances Safely

FEDERAL REGISTER
Hazardous Materials: Infectious Substances; Harmonization With the United Nations Recommendations
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WHY ARE INFECTIOUS SUBSTANCES REGULATED IN TRANSPORTATION?
An infectious substance is regulated as a hazardous material under the U.S. Department of Transportation’s (DOT’s) Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). The HMR apply to any material DOT determines is capable of posing an unreasonable risk to health, safety, and property when transported in commerce. An infectious substance must conform to all applicable HMR requirements when offered for transportation or transported by air, highway, rail, or water.

NEW TRANSPORTATION REQUIREMENTS FOR INFECTIOUS SUBSTANCES
DOT’s Pipeline and Hazardous Materials Safety Administration (PHMSA) published a final rule on June 1, 2006, revising the requirements in the HMR applicable to the transportation of infectious substances. The new requirements are effective October 1, 2006.

CHANGES UNDER THE NEW RULE APPLY TO PARTS 171, 172, 173, AND 175 OF THE HMR
- New classification system
  - New and revised definitions
- Revised marking requirements
- Revised packaging requirements
- New shipping paper requirements
- New security plan requirements
- New carriage by aircraft requirements
New classification criteria and packaging requirements are now consistent with international standards and help clarify existing requirements to promote compliance. These revisions will ensure an acceptable level of safety for the transportation of infectious substances and facilitate domestic and international transportation.

The new classifications are based on criteria developed by the UN Committee of Experts working with the World Health Organization (WHO), the U.S. Centers for Disease Control and Prevention (CDC), medical professionals, microbiologists, transportation professionals, and packaging technical experts. They are consistent with the requirements contained in the 13th and 14th editions of the United Nations Recommendations for the Transport of Dangerous Goods (UN Recommendations), the 2005-2006 edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), and the International Maritime Organization (IMO) Dangerous Goods Code.

The new HMR requirements establish a two-tiered classification system for infectious substances—Category A and Category B.
 DIVISION 6.2 (INFECTIOUS SUBSTANCE): A material known or reasonably expected to contain a pathogen. A pathogen is a micro-organism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion), that can cause disease in humans or animals.

CATEGORY A: An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. Category A poses a higher degree of risk than Category B.

Infectious substances, affecting animals, UN2900
Infectious substances, affecting humans, UN2814

CATEGORY B: An infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes.

PROPER SHIPPING NAME AND IDENTIFICATION NUMBER:
Biological substance, Category B, UN3373
(The proper shipping names “Diagnostic Specimen” or “Clinical Specimen” may be used in place of “Biological substance, Category B” until January 1, 2007.)
New and Revised Definitions

Part 173—General Requirements for Shipments and Packagings
In addition to Category A and Category B, there are other new and revised definitions in §173.134.

BIOLOGICAL PRODUCT: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsenamine or derivative of arsenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals.

CULTURE: an infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen as defined below.

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).

EXCEPTIONS: A complete listing of materials excepted from regulation as Division 6.2 materials under the HMR is found in §173.134(b).
Classification Process

- Is it known NOT to contain an infectious substance?
- Are any micro-organisms present non-pathogenic to humans and animals?
- Have the pathogens possibly been neutralized or inactivated so they no longer pose a health risk?
- Is it an environmental sample (e.g., food or water) that is not considered to pose a significant health risk?
- Is it a biological product or a biological material (e.g., blood product, tissue, or organ) subject to U.S. Department of Health and Human Services or U.S. Department of Agriculture regulation?
- Is it a dried bloodspot on a used medical glove?
- Is it a drug or medical equipment, or a used healthcare product that conforms to 29 CFR 1910.1030?
- Is it forensic material that complies with U.S., state, local, or Indian tribal government regulations?
- Is it an agricultural product or food defined under the federal Food, Drug, and Cosmetics Act?
- Is it intended for transport/transfusion?

- Does it meet the definition of a Category A substance?
- Is it a patient specimen that is unlikely to cause disease in humans or animals or for which there is only a minimal likelihood that pathogens are present, or is it a patient sample transported by private or contract carrier in a motor vehicle used exclusively for these materials?

UN2814 Infectious substance, affecting humans, or UN3920 Infectious substance, affecting animals (as appropriate)

UN2793 Biological substance, Category B

Not subject to the requirements as Division 6.2 material
### Examples of Category A Infectious Substances: UN2814, Infectious Substances Affecting Humans

#### Micro-Organism

<table>
<thead>
<tr>
<th>Micro-Organism</th>
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<tbody>
<tr>
<td>Bacillus anthracis (cultures only)</td>
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<td>Brucella abortus (cultures only)</td>
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<td>Brucella melitensis (cultures only)</td>
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<td>Brucella suis (cultures only)</td>
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<td>Burkholderia mallei—Pseudomonas mallei—Glanders (cultures only)</td>
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<td>Burkholderia pseudomallei—Pseudomonas pseudomallei (cultures only)</td>
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<td>Chlamydia psittaci—avian strains (cultures only)</td>
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<td>Clostridium botulinum (cultures only)</td>
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<td>Coccidioides immitis (cultures only)</td>
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<td>Coxiella burnetii (cultures only)</td>
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<td>Crimean-Congo hemorrhagic fever virus (cultures only)</td>
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<td>Dengue virus (cultures only)</td>
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<td>Eastern equine encephalitis virus (cultures only)</td>
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<td>Escherichia coli, veroxigenic (cultures only)</td>
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<td>Ebola virus (cultures only)</td>
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<td>Flexal virus (cultures only)</td>
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<td>Francisella tularensis (cultures only)</td>
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<td>Guanaro virus (cultures only)</td>
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<td>Hantaan virus (cultures only)</td>
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<td>Hantaviruses causing hemorrhagic fever with renal syndrome (cultures only)</td>
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<td>Hendra virus (cultures only)</td>
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<td>Herpes B virus (cultures only)</td>
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<td>Human immunodeficiency virus (cultures only)</td>
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<td>Highly pathogenic avian influenza virus (cultures only)</td>
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<td>Japanese Encephalitis virus (cultures only)</td>
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<td>Junin virus (cultures only)</td>
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<td>Kyasanur forest disease virus (cultures only)</td>
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<td>Lassa virus (cultures only)</td>
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<td>Machupo virus (cultures only)</td>
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<td>Marburg virus (cultures only)</td>
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<td>Monkeypox virus (cultures only)</td>
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<td>Mycobacterium tuberculosis (cultures only)</td>
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<td>Nipah virus (cultures only)</td>
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<td>Omak hemorrhagic fever virus (cultures only)</td>
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<td>Poliovirus (cultures only)</td>
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<td>Rabies and other lyssaviruses (cultures only)</td>
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<td>Rickettsia prowazekii (cultures only)</td>
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<td>Rickettsia rickettsia (cultures only)</td>
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<td>Rift Valley fever virus (cultures only)</td>
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<td>Russian spring-summer encephalitis virus (cultures only)</td>
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<td>Saba virus (cultures only)</td>
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<td>Shigella dysenteriae type I (cultures only)</td>
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<td>Tick-borne encephalitis virus (cultures only)</td>
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<td>Variola virus (cultures only)</td>
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<td>Venezuelan equine encephalitis virus (cultures only)</td>
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<td>Vesicular stomatitis virus (cultures only)</td>
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<td>West Nile virus (cultures only)</td>
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<td>Yellow fever virus (cultures only)</td>
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<td>Yersinia pestis (cultures only)</td>
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*List provided as guidance only

*List is NOT all inclusive*
Examples of Category A Infectious UN2900, Infectious Substances Affecting Animals Only

**Substances:**

**MICRO-ORGANISM**
- 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)

List provided as guidance only

List is NOT all inclusive
Classification Scenarios

**SCENARIO 1**
Appropriate classification: Infectious Substance, affecting humans, UN2814

- A blood sample known or reasonably suspected to contain **Ebola Virus**

  - [See bulleted questions pg. 11]

  - No

- Does it meet the definition of a Category A Substance?

  - Yes

- Infectious Substance, affecting humans, UN2814

**SCENARIO 2**
Appropriate classification: Infectious Substance, affecting animals, UN2900

- A culture of **Foot and Mouth Disease**

  - [See bulleted questions pg. 11]

  - No

- Does it meet the definition of a Category A Substance?

  - Yes

- Infectious Substance, affecting animals, UN2900

**SCENARIO 3**
Appropriate classification: Biological Substance, Category B, UN3373 (unless transported by private or contract carrier by motor vehicle)

- A blood sample taken from a patient known or suspected to have a Category B pathogen, such as **Hepatitis B or HIV**

  - [See bulleted questions pg. 11]

  - No

  - Is it a patient sample transported by private or contract carrier in a motor vehicle used exclusively for these materials?

    - Yes

    - Biological Substance, Category B, UN3373

    - No

    - Not subject to the requirements as Division 6.2 material

**SCENARIO 4**
Appropriate classification: Not subject to the Hazardous Materials Regulations

- A blood sample taken from a patient known or reasonably suspected to contain **Ebola Virus**

  - [See bulleted questions pg. 11]

  - No

  - Does it meet the definition of a Category A Substance?

    - Yes

    - Not subject to the requirements as Division 6.2 material

  - No

  - Does it meet the definition of a Category A or Category B Substance?

    - No

    - Not subject to the requirements as Division 6.2 material

  - Yes

Photos: Courtesy CDC and NIH
Paragraph D. Exceptions for Certain Shipments
Specimen packages marked as “Exempt human specimen” or “Exempt animal specimen” according to the ICAO Technical Instructions are not regulated under the HMR. In the United States, the mark “Exempt Human/Animal Specimen” is an indication that there is no infectious substance in the package. Packages bearing these marks may be accepted by an air carrier that has made a business decision not to accept hazardous materials.

§171.15 and §171.16 Incident reporting.
You must report any release of an infectious substance (Category A or B) in any mode of transportation to the Department of Transportation. See §171.15 for telephonic and §171.16 for written report requirements.
§172.101 Hazardous materials table.

- **Removed**: "Diagnostic specimen"
- **Added**: "Biological substance, Category B"
- **Revised**: "Infectious substances, affecting animals only"
  - "Infectious substances, affecting humans"
  - "Toxins, extracted from living sources, liquid, n.o.s."
  - "Toxins, extracted from living sources, solid, n.o.s."
§172.102 Special provisions.

Removed Special provision A81 pertaining to quantity limits (see §173.199) §172.200(b)(4) and §172.203(k)

Shipping Papers.

Revised Applicability

Added Technical name “Suspected Category A” for unknown substances using UN2814 or UN2900

§172.301 Marking.

Revised No technical name on outer package

Subparts C and D of Part 172 revisions and additions
$172.800$ Purpose and Applicability.

Revised Persons who offer for transportation or transport select agents and toxins regulated by the CDC under 42 CFR Part 73 or USDA under 9 CFR Part 121 must develop and implement security plans in accordance with Subpart I of Part 172 of the HMR.
Includes changes pertaining to:

§173.6 Materials of trade (MOT)
§173.24a Non-bulk packagings
§173.134 Definitions—see page 8
§173.134(b) Exceptions
§173.199 Category B infectious substances

§173.196 Category A infectious substances.
Added Category A infectious substances
Packing and Labeling of Category A Infectious Substances

PACKAGING FOR A CATEGORY A INFECTIOUS SUBSTANCE
- Must meet the test standards of §178.609 and must be marked in conformance with §178.503(f)
- Is a triple packaging consisting of
  - Primary watertight receptacle
  - Watertight secondary packaging
  - Rigid outer packaging

SAMPLE OF UN PACKAGE CERTIFICATION MARK

Note 1: The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)
Note 2: The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa
Note 3: Follow package manufacturer’s closure instructions

Additional packaging requirements can be found in §173.196(b)
Packing and Marking of Category B Infectious Substances

§173.199 Category B infectious substances.
Revised Required marking on outer package of Category B infectious substance adjacent to proper shipping name "Biological substances, Category B"

UN3373

Additional packaging requirements can be found in §173.199

* The proper shipping names "Biological Substance, Category B"; "Clinical Specimen"; and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.
† If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact.
§175.630 Special requirements for Division 6.1 (poisonous) material and Division 6.2 (infectious substances) materials.

Added Paragraph (c) requirement to inspect each package, overpack, pallet, or unit load device containing a 6.2 material for signs of leakage. If evidence of leakage is found, the cargo compartment hold where the 6.2 material was stowed is required to be disinfected by any means that makes the release of the 6.2 material ineffective at transmitting disease.
For information about other Hazmat Publications

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