

Interstate Shipment of Etiologic Agents 42 CFR Part 72

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Part 72-Interstate Shipment of Etiologic Agents ¹

Centers for Disease Control and Prevention

Office of Health and Safety

Biosafety Branch

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¹ The requirements of this part are in addition to and not in lieu of any other packaging or other requirements for the transportation of etiologic agents in interstate traffic prescribed by the Department of Transportation and other agencies of the Federal Government.

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Authority: Sec. 215, 58 Stat. 690, as amended. 42 U.S.C. 216; sec. 361, 58 Stat. 703, (42 U.S.C 264)

§72.1 Definitions

As used in this part: "Biological product" means a biological prepared and manufactured in accordance with the provisions of 9 CFR Parts 102-104 and 21 CFR Parts 312 and 600-680 and which, in accordance with such provisions, may be shipped in interstate traffic.

"Diagnostic specimen" means any human or animal material including, but not limited to, excreta, secretions, blood and its components, tissue, and tissue fluids being shipped for purposes of diagnosis.

"Etiologic agent" means a viable microorganism or its toxin which causes, or may cause, human disease.

"Interstate traffic" means the movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation which is entirely within a State or possessions, [a] from a point of origin in any State or possession to a point of destination in any other State or possession, or [b] between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

§72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.

No person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material including, but not limited to, diagnostic specimens and biological products which such person reasonably believe may contain an etiologic agent unless such material is packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

§72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.

Notwithstanding the provisions of §72.2, no person may knowingly transport or cause to be transported in interstate traffic, directly or indirectly, any material [other than biological products] known to contain, or reasonably believed by such person to contain, one or more of the following etiologic agents unless such material is packaged, labeled, and shipped in accordance with the requirements specified in paragraphs [a]-[f] of this section:

Bacterial Agents

<i>Acinetobacter calcoaceticus.</i>	<i>Leptospira interrogans</i> - all serovars.
<i>Actinobacillus</i> - all species.	<i>Listeria</i> - all species.
<i>Actinomycetaceae</i> - all members.	<i>Mimae polymorpha.</i>
<i>Aeromonas hydrophilia.</i>	<i>Moraxella</i> - all species.
<i>Arachnia propionica.</i>	<i>Mycobacterium</i> - all species.
<i>Arizona hinshawii</i> - all serotypes.	<i>Mycoplasma</i> - all species.
<i>Bacillus anthracis.</i>	<i>Neisseria gonorrhoeae, N. meningitidis.</i>
<i>Bacteroides spp.</i>	<i>Nocardia asteroides.</i>
<i>Bartonella</i> - all species.	<i>Pasteurella</i> - all species.
<i>Bordetella</i> - all species.	<i>Plesiomonas shigelloides.</i>
<i>Borrelia recurrentis, B. vincenti.</i>	<i>Proteus</i> - all species.
<i>Brucella</i> - all species.	<i>Pseudomonas mallei.</i>
<i>Campylobacter (Vibrio) foetus, C. (Vibrio) jejuni.</i>	<i>Pseudomonas pseudomallei.</i>
<i>Chlamydia psittaci, C. trachomatis.</i>	<i>Salmonella</i> - all species and all serotypes.
<i>Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani.</i>	<i>Shigella</i> - all species and all serotypes.
<i>Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C.</i>	<i>Sphaerophorus necrophorus.</i>

pyogenes, C. renale.

Edwardsiella tarda.

Erysipelothrix insidiosa.

Escherichia coli, all enteropathogenic serotypes.

Francisella [Pasteurella] Tularensis.

Haemophilus ducreyi, H. influenzae.

Klebsiella - all species and all serotypes.

Legionella - all species and all Legionella-like organisms.

Staphylococcus aureus.

Streptobacillus moniliformis.

Streptococcus pneumoniae.

Streptococcus pyogenes.

Treponema careteum, T. pallidum, and T. pertenue.

Vibrio cholerae, V. parahaemolyticus

Yersinia (Pasteurella) pestis, Y. enterocolitica.

Fungal Agents

Blastomyces dermatitidis.

Coccidioides immitis.

Cryptococcus neoformans.

Histoplasma capsulatum.

Paracoccidioides brasiliensis.

Viral and Rickettsial Agents

Adenoviruses - human - all types.

Arboviruses - all types.

Coxiella burnetii.

Coxsackie A and B viruses - all types.

Creutzfeldt - Jacob agent.

Cytomegaloviruses.

Dengue viruses - all types.

Ebola viruses.

Echoviruses - all types.

Encephalomyocarditis virus.

Hemorrhagic fever agents including , *but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.*

Hepatitis associated materials (hepatitis A, hepatitis B, hepatitis nonA-nonB).

Herpesvirus - all members.

Measles virus.

Mumps virus.

Parainfluenza viruses - all types.

Polioviruses - all types.

Rabies virus - all strains.

Reoviruses - all types.

Respiratory syncytial virus.

Rhinoviruses - all types.

Rickettsia - all species.

Rocha limaea quintana.

Rotaviruses - all types.

Rubella virus.

Simian virus 40.

Tick - borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.

Vaccinia virus.

Infectious bronchitis - like virus.	Varicella virus.
Influenza viruses - all types.	Variola major and Variola minor viruses
Kuru agent.	Vesicular stomatis viruses - all types
Lassa virus.	White pox viruses.
Lymphocytic choriomeningitis virus.	Yellow fever virus. ²
Marburg virus.	

² This list may be revised from time to time by Notice published in the Federal Register to identify additional agents which must be packaged in accordance with the requirements contained in this part.

[a] Volume not exceeding 50 ml.

Material should be placed in a securely closed, watertight container [primary container [test tube, vial, etc]] which shall be enclosed in a second, durable watertight container [secondary container]. Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers shall contain sufficient nonparticulate absorbent material [e.g. paper towel] to absorb the entire contents of the primary containers[s] in case of breakage or leakage. Each set of primary and secondary containers shall then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

[b] Volume greater than 50 ml.

Packaging of material in volumes of 50 ml or more shall comply with requirements specified in paragraph [a] of this section. In addition, a shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and the outer shipping container. single primary containers shall not contain more than 1,000 ml of material. However, two or more primary containers whose combined volumes do not exceed 1,000 ml may be place in a single, secondary container. The maximum amount of etiologic agent which may be enclosed within a single outer shipping container shall not exceed 4,000 ml.

[c] Dry ice.

If dry ice is used as a refrigerant, it must be place outside the secondary container[s]. If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material shall be place so that the secondary container does nor

become loose inside the outer shipping container as the dry ice sublimates.

[d]

[1] The outer shipping container of all materials containing etiologic agents transported in interstate traffic must bear a label as illustrated and described below:

[2] The color of material on which the label is printed must be white, symbol red, and the printing in red or white as illustrated.

[3] The label must be a rectangle measuring 51 millimeters (mm) [2 inches] by 10.25 mm [4 inches] long. 1

[4] The red symbol measuring 38 mm [1 1/2 inches] in diameter must be centered in a white square measuring 51 mm [2 inches] on each side.

[5] Type size of the letters of the label shall be as follows:

- Etiologic agents - 10 pt. rev.
- Biomedical material - 14 pt.
- In case of damage or leakage - 10 pt. rev.
- Notify Director CDC, Atlanta, Georgia - 8 pt.rev.
- (404) 633-5313 - 10 pt. rev

[e] Damaged packages.

The carrier shall promptly, upon discovery of evidence of leakage or any other damage to packages bearing Etiologic Agents/Biomedical Material label, isolate the package and notify the Director, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Atlanta,

Georgia 30333, by telephone (404) 633-5313. The carrier shall also notify the sender.

[f] Registered mail or equivalent system.

Transportation of the following etiologic agents shall be by registered mail or an equivalent system which requires or provides for the sending notification of receipt to the sender immediately upon delivery:

- *Coccidioides immitis*.
- Ebola virus.
- *Francisella (Pasteurella) tularensis*.
- Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses, and Korean hemorrhagic fever viruses.
- Herpesvirus simiae [B virus].
- *Histoplasma capsulatum*.
- Lassa virus.
- Marburg virus.
- *Pseudomonas mallei*.
- *Pseudomonas pseudomallei*.
- Tick-borne encephalitis virus complex including but not limited to Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses.
- Variola major and Variola minor and White pox viruses.
- *Yersinia (Pasteurella) pestis*

§72.4 Notice of delivery; failure to receive.

When notice of delivery of materials known to contain etiologic agents listed in 72.3[f] is not received by the sender within 5 days following the anticipated delivery of the package, the sender shall notify the Director, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., Atlanta, Georgia 30333, by telephone (404) 633-5313.

§72.5 Requirements; variations.

The Director, Centers for Disease Control and Prevention, may approve variations from the requirements of this section if, upon review and evaluation, it is found that such variations provide protection at least equivalent to that provided by compliance with the requirements specified in this section and such findings are made a matter of official record.

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