DEPARTMENT OF TRANSPORTATION
HAZARDOUS MATERIALS REGULATIONS BOARD
WASHINGTON, D.C. 20590

[Docket No. HM-96, Amdts. 172-17 and 173-67]

PART 172—COMMODITY LIST OF HAZARDOUS MATERIALS CONTAINING THE SHIPPING NAME OR DESCRIPTION OF ALL ARTICLES SUBJECT TO PARTS 170-189 OF THIS CHAPTER

PART 173—SHIPPERS

Etiologic Agents

The purpose of this amendment to the Hazardous Materials Regulations of the Department of Transportation is to provide for the shipment of etiologic agents.

On December 29, 1971, the Hazardous Materials Regulations Board published a notice of proposed rule making, Docket No. HM-96; Notice No. 71-32 (36 F.R. 25163), which proposed these amendments. Interested persons were invited to give their views.

The International Air Transport Association (IATA) and the Air Transport Association (ATA), representatives for many aircraft operators, submitted several similar comments generally objecting to the use of the proposed label, to some of the requirements for better packaging than is now being used by the industry (there are no requirements in the present DOT regulations), and to the prohibition against the shipment of other than exempt etiologic agents via passenger-carrying aircraft.

They objected to the use of the symbol on the label. The proposed symbol was adopted and published as a national standard (USAS Z35.1-1968) by those persons most familiar with these materials and most interested in their safe handling. These comments were filed with the Department of Health, Education, and Welfare (HEW) and the Hazardous Materials Regulations Board, and considered before the publication of the new HEW label in 37 F.R. 12915. The Board cannot justify a requirement for two different labels on a shipping container for etiologic agents. The Department of Health, Education, and Welfare also advised the Board that the skull and crossbones symbol proposed by these commenters was unacceptable. The Board has determined that since a nationally acceptable symbol already exists, the transportation interests should undertake to educate themselves on its meaning and use rather than to develop another symbol.

The associations voiced serious reservations to some of the requirements for better packagings on the basis of past experience and the fact that the packaging would * * * "be difficult and expensive to manufacture and demonstrate" * * * for compliance with the regulations. The comment was not supported by data. They stated that this was primarily a matter for shippers to resolve. The Air Line Pilots Association (ALPA) stated that the * * * "testing procedures proposed are good, but they are the least that should be required for this type of commodity." Inasmuch as no person objected to the packaging requirements, and since the regulations are acceptable to an association which represents persons who must work in an environment involving these packages, the Board believes that the regulations are necessary.

Both IATA and ATA suggested that the proposed reduced pressure requirements did not provide an adequate safety margin under severe depressurization conditions. The requirements of 0.5 atmospheric (absolute) are based on existing performance criteria in the Hazardous Materials Regulations. This value is also consistent with present IAEA and IATA regulations. Before making any change the Board wants to evaluate the performance criteria as they presently exist for other materials and consider the need for change wherever the criteria are used. Also, additional consideration is being given by the Board to general pressure requirements for packaging. Regulations for solid carbon dioxide (dry ice) that will apply to air transportation will be covered in a future rule making notice.

The air carrier associations (IATA and ATA) and the representative for the pilots (ALPA) expressed opposing opinions regarding the presence of these materials on passenger aircraft. The carrier associations objected that * * * "very considerable hardship and transport difficulties" * * * would arise * * * "for research and medical facilities" * * * since there is much air freight traffic with these materials and * * * "many cities are not served by all-cargo aircraft." No data was furnished to support this position. The pilots' association (ALPA), in the opposite view, declared that * * * "we are reviewing the pos-

sibility of the association adopting a policy in strong opposition to the carriage of etiologic agents by public air transport." The Board received no other indication that its restriction against carriage on passenger-carrying aircraft would cause any hardship. In its deliberations, the Board's prime motivation must be the public interest. After weighing the curtailment of certain shipments in passenger-carrying aircraft against the lack of any demonstrated public interest need for such transportation, the Board concluded that the published regulations are in the best interest of the public.

Several other comments were received regarding definitions and scope of the proposed etiologic agent category. Since these comments related to technical matters with which the Department of Health, Education, and Welfare is more familiar, and since the Board is relying on that Department for adequate identification of what constitutes an etiologic agent and the degree of control necessary for each material, the Board has adopted the decisions of that Department as published in its regulations on June 30, 1972, in the FEDERAL REGISTER (37 F.R. 12915).

In consideration of the foregoing, 49 CFR Parts 172 and 173 are amended as follows:

I. (A) In § 172.4, paragraph (a) is amended by adding the following entry to the list of explanation of signs and abbreviations, as follows:

§ 172.4 Explanation of signs and abbreviations.

(a) * * *

Etio. Ag—Etiologic Agent

(B) In § 172.5(a) the list of hazardous materials is amended as follows:

§ 172.5 List of hazardous materials.

(a) * * *

Article	Classed as—	Exemptions and packing (see sec.)	Label required if not exempt	Maximum quantity in one outside container by rail express
* * *	* * *	* * *	* * *	* * *
Etiologic agent, n.o.s.	Etio. Ag	173.386, 173.387	Etiologic (§ 173.388)	4 liters.
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II. (A) In Part 173 Table of Contents, Subpart G is amended; §§ 173.386, 173.387, and 173.388 are added to read as follows:

Subpart G—Poisonous Materials, Etiologic Agents, and Radioactive Materials; Definition and Preparation

Sec.
173.386 Etiologic agents; definition and scope.
173.387 Packaging requirements for etiologic agents.
173.388 Labeling of packages containing etiologic agents.

(B) In § 173.119, paragraph (a) (22) is amended to read as follows:

§ 173.119 Flammable liquids not specifically provided for.

(a) * * *

(22) Specification 17H or 37A (§§ 178.118 and 178.131 of this subchapter). Metal drums with inside glass packagings not over 9 pints capacity each. Inside containers may contain biological materials if these materials are not etiologic agents, except that etiologic agents exempt by § 173.386(d) are authorized.

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(C) Subpart G is amended to read as follows:

Subpart G—Poisonous Materials, Etiologic Agents, and Radioactive Materials: Definition and Preparation

(D) Section 173.386 is added to read as follows:

§ 173.386 Etiologic agents; definition and scope.

(a) *Definition.* For the purpose of Parts 170–189 of this subchapter:

(1) An "etiologic agent" means a viable microorganism, or its toxin, which causes or may cause human disease, and is limited to those agents listed in 42 CFR 72.25(c) of the regulations of the Department of Health, Education, and Welfare.

(2) A "diagnostic specimen" means any human or animal material including, but not limited to, excreta, secreta, blood, and its components, tissue, and tissue fluids, being shipped for purposes of diagnosis.

(3) A "biological product" means a material prepared and manufactured in accordance with the provisions of 9 CFR Part 102 (licensed veterinary biological products), 42 CFR Part 73 (licensed human biological products), 21 CFR Part 130, § 130.3 (new drugs for investigational use in humans), 9 CFR Part 103 (biological products for experimental treatment of animals), or 21 CFR Part 130, § 130.3a (new drugs for investigational use in animals), and which in accordance with these provisions, may be shipped in interstate commerce.

(b) *Applicability.* Except as provided in paragraph (d), no person may ship any material, including a diagnostic specimen or a biological product, containing an etiologic agent unless this material is packaged and prepared for shipment in accordance with § 173.24 and the other applicable regulations of this subchapter.

(c) *General provisions.* The requirements of these regulations (Parts 170–189 of this subchapter) supplement the requirements of the Department of Health, Education, and Welfare's regulations contained in 42 CFR 72.25.

(d) *Exemptions.* The following substances are not subject to any requirements of this subchapter if the items as packaged do not contain any material otherwise subject to the requirements of Parts 170–189 of this subchapter:

(1) Diagnostic specimens; and
(2) Biological products.

(E) Section 173.387 is added to read as follows:

§ 173.387 Packaging requirements for etiologic agents.

(a) Except as provided in § 173.386(d) no person may ship a package containing over 4 liters gross volume of an etiologic agent.

(b) In addition to the requirements of 42 CFR 72.25(c), each package containing an etiologic agent must be designed and constructed so that, if it were subject to the environment and test conditions prescribed in this section, there would be no release of the contents to the environment, and the effectiveness of the packaging would not be significantly reduced.

(1) *Environmental conditions.* (i) Heat—direct sunlight in an ambient temperature of 130° F. in still air.

(ii) Cold—an ambient temperature of −40° F. in still air and shade.

(iii) Reduced pressure—ambient atmospheric pressure of 0.50 atmosphere (7.3 p.s.i.a.).

(iv) Vibration—vibration normally incident in the mode of transportation the package is to be shipped.

(2) *Test conditions.* (i) Water spray—a water spray heavy enough to keep the entire exposed surface of the package (except the bottom) continuously wet during a period of 30 minutes. Packages for which the outer layer consists of metal, wood, ceramic, or plastic, or combination thereof, are exempt from this test.

(ii) Freedrop—a freedrop through a distance of 30 feet onto a flat, essentially unyielding horizontal target surface, the package striking the surface in a position for which maximum damage is expected.

(iii) Penetration—impact of the hemispheric end of a steel cylinder 1.25 inches in diameter and weighing 15 pounds, dropped from a height of 40 inches on to the exposed surface of the package expected to be most vulnerable to puncture. The long axis of the cylinder must be perpendicular to the impacted surface. This test is not required for a package subject to subdivision (iv) of this subparagraph.

(iv) Penetration (required for packages exceeding 15 pounds gross weight only)—a freedrop of the package through a distance of 40 inches, striking the top end of a vertical cylindrical mild steel solid bar on an essentially unyielding surface, in a position for which maximum damage is expected. The bar must be 1.5 inches in diameter. The top of the bar must be horizontal, with its edge rounded to a radius not exceeding one-quarter inch. The bar must be of such length as to cause maximum damage to the package, but not less than 8 inches long. The long axis of the bar must be vertical to the unyielding horizontal impact surface of the package.

(3) *Testing procedure.* (i) At least one sample of each type package (maximum size and gross weight), filled with water, must be subjected to the water spray test unless exempted by subparagraph (2) (i) of this paragraph.

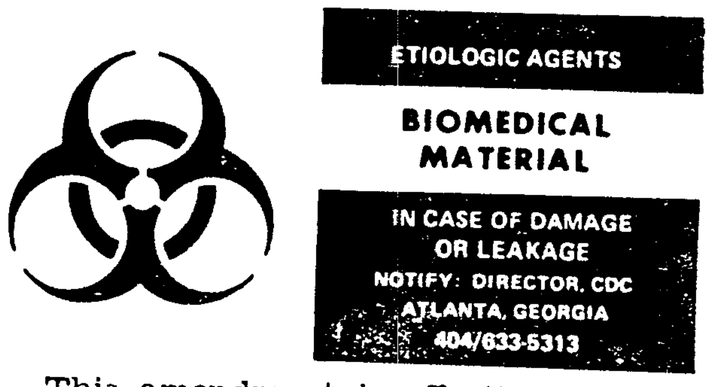
(ii) This sample package then must be given the freedrop and one of the penetration tests, as applicable. Separate wetted sample packages may be used for the freedrop and the penetration test.

(iii) If the sample package is exempted from the water spray test by subparagraph (2) (i) of this paragraph, at least one sample of each type package (maximum size and gross weight), filled with water, must be subjected consecutively to the freedrop and the penetration test.

(F) Section 173.388 is added to read as follows:

§ 173.388 Labeling of packages containing etiologic agents.

(a) Each package containing an etiologic agent, except a diagnostic specimen or a biological product, must be labeled as prescribed by the regulations of the Department of Health, Education, and Welfare, 42 CFR § 72.25(c) (4). For information, this label is required to be a rectangle measuring 51 mm. (2 inches) high and 102.5 mm. (4 inches) long, predominantly red printing on a white background, and appears as follows:



This amendment is effective December 30, 1972. However, compliance with the regulations, as amended herein is authorized immediately.

(Secs. 831–835, title 18, United States Code, sec. 9, Department of Transportation Act, 49 U.S.C. 1657, title VI; sec. 902(h), Federal Aviation Act of 1958, 49 U.S.C. 1421–1430, 1472(h))

Issued in Washington, D.C., on September 26, 1972.

G. H. READ,
Captain, Alternate Board Member for the United States Coast Guard.

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Board Member for the Federal Railroad Administration.

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