

DEPARTMENT OF TRANSPORTATION**Research and Special Programs
Administration****49 CFR Parts 172 and 173**

[Docket No. HM-142A; Notice No. 88-6]

RIN: 2137 AB56

Etiologic Agents

AGENCY: Office of Hazardous Materials Transportation, Research and Special Programs Administration (RSPA), DOT.
ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to amend the Hazardous Materials Regulations (HMR) by revising the definition of "etiologic agent" and removing the 50 milliliter (1.69 fluid ounces) exception in 49 CFR 173.386. This action is necessary to protect health and safety and to ensure that all quantities of etiologic agents are subject to the same requirements for packaging and hazard communication. The intended effect is to enhance the safe transportation of etiologic agents through application of regulatory requirements for packaging and hazard communication.

DATE: Comments must be received on or before January 18, 1989.

ADDRESS: Address comments to Dockets Unit, Office of Hazardous Materials Transportation, (DHM-30), U.S. Department of Transportation, Washington, DC 20590. Comments should be submitted, when possible, in five copies and should identify the docket number. Persons wishing to receive confirmation of receipt of their comments should include a self-addressed stamped postcard. The Dockets Unit is located in Room 8421 of the Nassif Building, 400 Seventh Street SW., Washington, DC 20590. Office hours are 8:30 a.m. to 5:00 p.m., Monday through Friday, except public holidays.

FOR FURTHER INFORMATION CONTACT: George Cushmac, (202) 366-4545, Technical Division, Office of Hazardous Materials Transportation, U.S. Department of Transportation, or Ann Boylan, (202) 366-4488, Standards Division, Office of Hazardous Materials Transportation, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: RSPA is proposing three amendments to the HMR with regard to etiologic agents. The first proposal concerns the definition of an etiologic agent and the

list of etiologic agents referenced in the regulations of the Department of the Health and Human Services (DHHS) in 42 CFR 72.3. Objective criteria for the etiologic agent hazard class have not been developed yet and the list of etiologic agents is difficult to keep current. Therefore, RSPA proposes to broaden the definition of an etiologic agent in 49 CFR 173.386(a)(1). The proposed definition would include those agents listed in 42 CFR 72.3, and "any agent that poses a degree of hazard similar to those agents". This proposed action would require pathogens not currently listed in the DHHS regulations to be shipped as etiologic agents, based on the shipper's knowledge that the agents present a substantial risk to health and safety. This would include the acquired immune deficiency syndrome (AIDS) virus.

The proposed definition is broader in scope than the current definition in § 173.386 because it applies to more agents than are currently regulated. However, it is not as broad as the definition for infectious substances (Division 6.2) contained in the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations) and international regulations based on the UN Recommendations such as the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions). These standards define infectious substances as "substances containing viable microorganisms or their toxins which are known, or suspected to cause disease in animals or humans". Under the international regulations, any quantity of an infectious substance is subject to requirements for shipping papers, marking, labeling and packaging. This definition of infectious substance includes substances which affect animals, and appears to include some relatively innocuous substances (e.g., cold viruses, yeasts and fungi which may cause minor illnesses). However, the scope of the definition is limited in this proposal to address the immediate problem.

A second proposal concerns the exception in 49 CFR 173.386(d)(3) under which cultures of etiologic agents of 50 ml or less total quantity in one outside package are not subject to any requirements of the HMR if the items are packaged do not contain a material otherwise subject to the HMR. After reconsideration of the health hazards presented by etiologic agents, it is RSPA's belief, based on safety

considerations, that etiologic agents in any quantity present a substantial public health hazard and should be subject to regulation. Therefore, RSPA proposes to regulate all quantities of etiologic agents by deletion of the exception for quantities of 50 ml or less.

A third proposal concerns the per package quantity limits of etiologic agents aboard aircraft. This proposal would align the HMR with quantity limitations for infectious substances in the ICAO Technical Instructions.

The proposals in this notice are the initial step in a comprehensive review of the requirements pertaining to the transportation of etiologic agents. In future rulemaking action, RSPA plans to focus attention on various issues concerning etiologic agents, including packaging, the exceptions for biological products and diagnostic specimens addressed in § 173.386(d)(1) and (2), the present exclusion of etiologic agents which only affect animals, and adoption of hazard communication provisions and the definition for infectious substances in the UN Recommendations.

Administrative Notices*Executive Order 12291*

The RSPA has determined that this rulemaking (1) is not "major" under Executive Order 12291; (2) is not "significant" under DOT's regulatory policies and procedures [44 FR 11034]; (3) will not affect not-for-profit enterprises or small governmental jurisdictions; and (4) does not require an environmental impact statement under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*). A regulatory evaluation is available for review in the Docket.

Executive Order 12612

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Impact on Small Entities

Based on limited information concerning size and nature of entities likely to be affected by this final rule, I certify that the regulations proposed herein would not, if adopted, have a significant economic impact on a substantial number of small entities.

List of Subjects*49 CFR Parts 172*

Hazardous materials transportation,
Hazardous materials table.

49 CFR Part 173

Hazardous materials transportation, Definition, Packaging, Etiologic agents.

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

PART 172—HAZARDOUS MATERIALS TABLES AND HAZARDOUS MATERIALS COMMUNICATIONS

1. The authority citation for Part 172 continues to read as follows:

Authority: 49 App. U.S.C. 1802, 1803, 1804, 1808; 49 CFR Part 1, unless otherwise noted.

§ 172.101 [Amended]

2. The Hazardous Materials Table would be amended by revising the entry for "Etiologic agent, n.o.s." to read as follows:

§ 172.101 Hazardous Materials Table

| + A W (1) | Hazardous materials descriptions and proper shipping names (2) | Hazard class (3) | Identifica- tion number (3a) | Label(s) required (if not excepted) (4) | Packaging | | Maximum net quantity in one package | | Water shipments | | |
|------------------|---|-------------------------|--|---|-----------------------------|---|---|------------------------------------|----------------------------------|--------------------------------------|---|
| | | | | | Excep- tions (5a) | Specific require- ments (5b) | Passenger carrying aircraft or railcar (6a) | Cargo only aircraft (6b) | Cargo ves- sel (7a) | Pas- senger vessel (7b) | Other requirements (7c) |
| | REVISED Etiologic agent, n.o.s. | Etiologic agent. | NA2814 | Etiologic agent. | 173.386 | 173.387 | 50 ml or 50 g. | 4 L or 4 Kg. | | | Not permitted except under specific conditions approved by the Department. |

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

3. The authority citation for Part 173 continues to read as follows:

Authority: 49 App. U.S.C. 1803, 1804, 1806, 1807, 1808; 49 CFR Part 1, unless otherwise noted.

4. In § 173.386, paragraph (d)(3) would be removed and paragraph (a)(1) would be revised to read as follows:

§ 173.386 Etiologic agents; definition and scope.

(a) * * *

(1) An "etiologic agent" means a viable microorganism, or its toxin, which causes or may cause human disease, and includes those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services and any agent that poses a degree of hazard similar to those agents.
* * * * *

Issued in Washington, DC, on November 7, 1968.

Alan I. Roberts,
Director, Office of Hazardous Materials
Transportation.

[FR Doc. 88-26132 Filed 11-9-88; 8:45 am]

(BILLING CODE 4910-60-M)