DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 172 and 173

[Docket No. HM-142A; Amdt. Nos. 172-124, 173-225]

RIN 2137-AB56

Etiologic Agents

AGENCY: Research and Special Programs Administration, DOT.

ACTION: Final rule.

SUMMARY: This final rule amends the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) by (1) Revising the definition of "etiologic agent" in 49 CFR 173.386(a)(1); (2) removing the "50 milliliter (1.666 fluid ounces) exception" for cultures of etiologic agents in § 173.386(d)(3); and (3) clarifying the "maximum net quantity in one package" limits for etiologic agents transported by aircraft as specified in Column 6 of the Hazardous Materials Table in § 172.101. This action is necessary to protect the health and safety of the public and to establish uniform requirements for all quantities of etiologic agents. The intended effect of these changes is to enhance the safe transportation of etiologic agents through the application of regulatory requirements for packaging and hazard communication.

EFFECTIVE DATE: These amendments are effective on February 19, 1991. However, compliance with the regulations, as amended herein, is authorized immediately.

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SUPPLEMENTARY INFORMATION:

I. Background

On November 10, 1988, the Research and Special Programs Administration (RSPA) published a notice of proposed rulemaking (NPRM) under Docket HM–142A, Notice No. 88–8 (53 FR 45525), to solicit comments on three proposals concerning etiologic agents. RSPA received 24 comments in response to the NPRM. These comments were from shippers, not-for-profit organizations, trade associations, and Federal and State agencies. The majority of the commenters expressed their support for the proposed rule. However, some commenters expressed concerns about the proposals. These comments are discussed in this final rule.

B. Etiologic Agent Definition

The first proposal concerns the definition of an "etiologic agent." As defined in 49 CFR 173.386(a)(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 72.3 of the regulations of the Department of Health and Human Services" (DHHS). RSPA has not previously developed objective criteria for the etiologic agent hazard class, and the DHHS's list of etiologic agents has not been revised since July 21, 1980 (45 FR 48626). RSPA proposed to broaden the definition of an etiologic agent to include those agents listed in 42 CFR 72.3 and "any agent that poses a degree of hazard similar to those agents." Therefore, the definition of an etiologic agent would include additional agents which may cause human disease, such as the acquired immune deficiency syndrome (AIDS) virus and Lyme disease. However, the proposed definition was 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), the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions) and the International Maritime Organization's International Maritime Dangerous Goods Code (IMDG Code). These international regulations define infectious substances as "those substances containing viable microorganisms or their toxins which are known, or suspected, to cause disease in animals or humans." This definition of an infectious substance includes agents that affect animals and appears to include some relatively innocuous substances such as cold viruses, yeasts, and fungi that may cause minor illnesses.

Several commenters agreed that RSPA's proposal to broaden the definition of an etiologic agent was justified because the DHHS has not updated its regulations. However, some commenters considered the proposed language too broad and vague. One commenter suggested substituting the wording "the Acquired Immune Deficiency Syndrome (AIDS) virus" for the wording "any agent that poses a degree of hazard similar to those agents." Two other commenters, the Air Transport Association of America (ATA) and the Air Line Pilots Association (ALPA), suggested the wording "any other agent that has the potential to cause severe, disabling or fatal disease." RSPA believes adding the AIDS virus to the definition in place of the phrase "any agent that poses a degree of hazard similar to those agents" would satisfy RSPA's effort to regulate the AIDS virus but would not cover other agents that may pose an unreasonable risk to health and safety and should be regulated during transportation. RSPA believes the wording suggested by the ATA and ALPA would clarify and more appropriately define the other types of agents that should be regulated as etiologic agents. Therefore, the definition is revised to incorporate a modified version of the wording suggested by the ATA and ALPA.

Several commenters had other concerns with the proposed definition. Three commenters involved in blood collection and supply programs were concerned that the proposed definition would adversely affect those programs. One commenter stated that some carriers are refusing to transport packages containing blood intended for transfusion unless the units of blood are packed based on DOT "guidelines for transport of hazardous materials." RSPA emphasizes that the HMR do not contain "guidelines" for transporting blood *per se*. Most blood and blood components intended for use in transfusions and prepared according to U.S. Food and Drug Administration (FDA) requirements are not subject to the HMR. However, those shipments of blood and blood components containing an etiologic agent or suspected of containing an etiologic agent are subject to the HMR.

Another commenter requested that RSPA exclude infectious wastes from regulation as etiologic agents, even though the wastes may contain pathogens. Pathogens are microorganisms or other agents that cause disease. The commenter stated that these wastes are regulated by the Environmental Protection Agency under the Medical Waste Tracking Act of 1988 and, therefore, should not be regulated under the HMR. The HMR currently contain no specific requirements for infectious waste generated by medical and health care facilities. RSPA believes most infectious waste is composed of material that does not contain etiologic

agents. In many cases, if an infectious waste is known or suspected to contain an etiologic agent, the infectious waste is treated on site to destroy the etiologic agent by using a method such as incineration, autoclave, or treatment with disinfectants. However, if infectious waste that contains an etiologic agent is offered for transportation, it must conform with the requirements in the HMR for etiologic agents.

RSPA published an NPRM under Docket HM-181, entitled "Performance Oriented Packaging Standards; Miscellaneous Proposals" (52 FR 16482; May 5, 1987), prior to the NPRM under Docket HM-142A. Among other numerous changes, Docket HM-181 proposed to replace the term "etiologic agent" with the term "infectious substance" and adopt the INFECTIOUS SUBSTANCE label. The term "infectious substance" is used in the UN Recommendations, the ICAO Technical Instructions, and the IMDG Code. The scope of changes proposed in Docket HM-181 was so extensive that RSPA could not be certain when, if ever, a final rule would be issued. The NPRM under Docket HM-142A was subsequently issued to request public comments specifically addressed to definitions and criteria for etiologic agents and to authorize, on an interim basis pending publication of a final rule under Docket HM-181, use of the term "infectious substance". It was originally planned to published the final rule under Docket HM-142A prior to publication of the final rule under Docket HM-181. However, the latter was published on December 21, 1990 (55 FR 52402). A number of the provisions in this final rule are included in that publication, except that comments to this docket which are discussed herein were used in the decisionmaking process for Docket HM-181, and the changes implemented herein take effect prior to the October 1, 1991 effective date of Docket HM-181. Since compliance with Docket HM-181 is authorized beginning January 1, 1991, it is recommended that shippers implement the Docket HM-181 provisions as soon as practicable, rather than the interim provisions contained herein.

B. 50-Milliliter Exception

The second proposal concerns the "50-milliliter" (ml) exception in § 173.386(d)(3). This exception provides that etiologic agents with a total quantity of 50 ml (1.666 fluid ounces) or less in one outside package are not subject to the requirements of the HMR if the items, as packaged, contain no material otherwise regulated under the HMR. RSPA believes etiologic agents pose certain health hazards and inherent safety considerations without regard to quantity. Therefore, RSPA proposed to remove the 50-ml exception.

Some commenters agreed with RSPA that small amounts of etiologic agents are as dangerous as larger amounts. One commenter, supporting removal of the 50-ml exception, stated that any implication that an etiologic agent poses less of a hazard in volumes under 50 ml than the same etiologic agent in volumes of 51 ml or more is medically and scientifically illogical. The commenter also noted that the existing exception allows an etiologic agent to be transported domestically with fewer restrictions than most air carriers impose on biological fluids containing no infectious material.

Several commenters opposing the removal of the 50-ml exception expressed concern that it may take longer for a regulated material to reach its destination if the exception is eliminated. A review of the historical files concerning § 173.386(d)(3) revealed that the 50-ml exception was added in the HMR to facilitate the transportation of etiologic agents aboard passenger-carrying aircraft. The exception was adopted based on requests from DHHS's Centers for Disease Control (CDC) and other petitioners that the provision would enhance public health by allowing these materials to be transported expeditiously for testing and processing. In 1973 when the 50-ml exception was adopted, the air transport system was not as efficient as it is today. Cargo transporter services can now provide overnight and next-day delivery to and from all areas in the United States. Therefore, RSPA is not aware of any reason why a shipment properly prepared in accordance with applicable requirements would take longer to reach its destination than an unregulated shipment.

A commenter claimed that the removal of the 50-ml exception would result in additional paperwork and processing costs for shipping medical samples. Most etiologic agents are transported by aircraft and are packaged, marked, labeled and described on the transport documents according to the ICAO Technical Instructions, which contain no exception for small quantities. Therefore, RSPA believes cost increases associated with hazard communication and packaging for shipments of previously unregulated ecologic agents will be minimal.

One commenter stated that only certain, but not all, etiologic agents in any quantity may present a public health hazard and should be regulated. However, the commenter did not offer a way to differentiate between these two types of etiologic agents. Another commenter stated that eliminating the 50-ml exception would be financially detrimental to not-for-profit organizations which provide proficiency-testing materials to laboratories, particularly if RSPA were to require a detailed list of each package's contents on shipping papers. The commenter stated that his company has transported proficiency-testing materials, some containing etiologic agents labeled and packaged according to DOT and DHHS rules, for 25 years by aircraft and through the mail without a single injury or illness. The commenter also said that the CDC testified before a Congressional subcommittee in 1988 stating that calls to the CDC on verified damaged packages containing etiologic agents have averaged three per year, over the past 9 years. Of that number of incidents, none resulted in a reported infection. The commenter requested that RSPA carefully examine the economic impact of eliminating the 50-ml exception for test specimens, particularly on the medical community. RSPA believes the potential risks involved in shipping etiologic agents in amounts of 50 ml or less justify the regulation of those shipments where shippers have not been subject to the regulations. In the event special situations do occur, RSPA believes they can be handled effectively under the terms of an exemption.

Other commenters opposing the removal of the 50-ml exception stated RSPA has provided no data to support the change. In particular, one commenter stated that RSPA should state the specific reasons why the exception should be removed and provide an opportunity for public comment. In the NPRM, RSPA stated that this proposal was based on reconsideration of the health hazards presented by etiologic agents. While the safety record for transporting these materials has been satisfactory, the number of shipments of etiologic agents has increased significantly in recent years. RSPA has received telephone calls from air transport workers concerning the handling of damaged packages of etiologic agents in quantities not regulated under the HMR. Because etiologic agents may pose an unreasonable health and safety risk when transported in commerce, RSPA believes all transport workers should be aware of the presence of these materials. RSPA believes the safety benefits gained by removing the 50-ml

exception should more than offset the minimal costs imposed on persons offering small quantities of etiologic agents for transportation that would be affected by this final rule. For these reasons, the 50-ml exception is removed as proposed.

C. Maximum Net Quantity in One Package Aboard Aircraft

The third proposal concerns the maximum net quantity in one package of etiologic agents permitted aboard a passenger-carrying aircraft or a cargo-only aircraft, as prescribed in columns (6)(a) and (6)(b) of the Hazardous Materials Table in § 172.101 (the Table). These current limits of etiologic agents are 50 ml per package by passenger-carrying aircraft and 4 liters per package by cargo-only aircraft. The proposal contained provisions to align the quantity limitations for etiologic agents in the HMR with those for infectious substances in the ICAO Technical Instructions. As such, the maximum net quantity in one package would be 50 ml or 50 grams when transported by passenger-carrying aircraft, and 4 liters or 4 kilograms when transported by cargo-aircraft only.

The three commenters who addressed the per package quantity limits for etiologic agents transported by aircraft expressed their support for the proposal. These limits for the maximum net quantity of etiologic agents permitted in one package are adopted as proposed.

II. Additional Considerations

A. Revision of 42 CFR Part 72

Some commenters stated that the DHHS's Public Health Service, through the CDC, has been charged with the responsibility for comprehensively reviewing and revising the regulations for the shipment of etiologic agents and that RSPA should withhold promulgation of further changes until the CDC completes its review. After publication of the NPRM under HM-142A, the CDC published a notice of proposed rulemaking concerning the interstate shipment of etiologic agents (March 2, 1990; 55 FR 7678). In the notice, CDC proposes to (1) Remove the list of etiologic agents in 42 CFR 72.3 and require "that all cultures or suspensions of etiologic agents be packaged, labeled and shipped according to the regulation"; (2) substitute the term "clinical specimen" for "diagnostic specimen"; (3) impose packaging and labeling requirements for all clinical specimens and for biological products that contain an etiologic agent; and (4) require labels on inner containers of etiologic agent preparations. Although the outcome of the CDC's proposed rule is indeterminable at this time, RSPA plans to continue working with the CDC to harmonize both agencies' requirements.

B. Revision of International Regulations

The UN Subcommittee of Experts on the Transport of Dangerous Goods (Subcommittee) has started work to revise their recommendations for infectious substances. A 2-year work cycle was completed in December 1988, and revised recommendations for infectious substances were published in the sixth revised edition of the UN Recommendations. The revised recommendations were adopted as regulatory requirements in the ICAO Technical Instructions and the IMDG Code. During the 1989–1990 work cycle, the Subcommittee continued its work on infectious substances. Among other issues, it (1) Is revising the definition of infectious substances to remove the word "toxins" on the basis that toxins should be included in Division 6.1—Poisonous (toxic) substances of Class 6—Poisonous (toxic) and infectious substances; (2) is reviewing the assignment of infectious substances to risk levels or risk groups tied to packing groups; (3) is developing recommendations for packaging and maximum net quantity in one package for diagnostic specimens and biological products whereby these packages would not be subject to further requirements; (4) has eliminated the proposal regarding the "dynamic crush test" for certain packages; and (5) is planning to discuss medical waste in the context of the overall recommendations and not as an adjunct to Division 6.2—Infectious substances.

In the meantime, RSPA is publishing this final rule to correct safety deficiencies in the current HMR. RSPA plans to continue working with the UN Subcommittee to improve the definition, classification, packaging, and operational controls for etiologic agents.

III. Review by Section

Section 172.101. In the Table, the entry "Etiologic agent, n.o.s." is amended to specify a maximum net quantity permitted in one package of 50 ml or 50 g when transported by passenger-carrying aircraft and 4 L or 4 kg when transported by cargo-only aircraft. The entry "Infectious substance, human, n.o.s. See Etiologic agent, n.o.s." is revised to read "Infectious substances, affecting humans See Etiologic agent, n.o.s." and the identification number "UN2814" is added in column (3A). The use of either proper shipping name ("Etiologic agent, n.o.s." or "Infectious substances, affecting humans") is acceptable. Any quantity of an etiologic agent must conform to the packing and shipping requirements and must be labeled etiologic agent. The exceptions granted for diagnostic specimens and biological products remain unchanged.

Section 172.203. In paragraph (k)(3), the proper shipping name "Infectious substance, human, n.o.s." is removed and replaced with "Infectious substances, affecting humans" in order to be consistent with international modal regulations.

Section 173.386. In paragraph (a)(1), the definition of "etiologic agent" is revised to include other agents that have the potential to cause severe, disabling or fatal diseases in humans in addition to the agents listed in 42 CFR 72.3 of the DHHS regulations. In paragraph (a)(3), the definition of "biological product" is revised to correct various CFR citations. Paragraph (d)(3), which grants an exception for cultures of etiologic agents of 50 ml or less, is removed.

Section 173.387. Paragraph (a) is revised to specify the maximum quantity of a solid containing an etiologic agent that may be packed in one package.

IV. Administrative Notices

A. Executive Order 12291 and Administrative Notices

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.

B. 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

C. Regulatory Flexibility Act

The changes in this final rule will affect persons involved in the transportation of etiologic agents by expanding the definition of an etiologic agent to include some agents not previously subject to the HMR, and by making all quantities of etiologic agents subject to the packaging and hazard communication requirements in the

HMR. Although there may be incremental costs associated with this amendment, the increase in safety outweighs the minimal cost impacts of this rule. Based on limited information concerning size and nature of entities likely affected by this final rule, I certify this regulation will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

The final rule imposes information collection requirements, for shipping papers, for certain previously unregulated shipments of etiologic agents. The information collection requirements for shipping papers contained in current 49 CFR part 172, subpart C, have been approved by the Office of Management and Budget under the provisions of 44 U.S.C. chapter 35 under OMB control number 2137–0034 (expiration date: 6/30/92).

E. Regulatory Information Number (RIN)

A regulatory information number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

In consideration of the foregoing, 49 CFR Parts 172 and 173 in effect on the date of this amendment are amended as follows:

PART 172—HAZARDOUS MATERIALS TABLES, HAZARDOUS MATERIALS COMMUNICATIONS REQUIREMENTS AND EMERGENCY RESPONSE INFORMATION REQUIREMENTS

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

Authority: 49 App. U.S.C. 1803, 1804, 1808; 49 CFR part 1.)

2. The Hazardous Materials Table in § 172.101 is amended by revising entries to read as follows:

§ 172.101 Purpose and use of hazardous materials table.

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§ 172.101 HAZARDOUS MATERIALS TABLE

(1)+/A/W	(2) Hazardous materials descriptions and proper shipping names	(3) Hazard Class	(3A) Identification number	(4) Label(s) required (if not excepted)	(5) Packaging		(6) Maximum net quantity in one package		(7) Water Shipments		
					(a) Exceptions	(b) Specific requirements	(a) Passenger carrying aircraft or railcar	(b) Cargo only aircraft	(a) Cargo vessel	(b) Passenger vessel	(c) Other Requirements
	REVISE 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.
	Infectious substances, affecting humans. *See* Etiologic agent, n.o.s.	.....	UN2814								

§ 172.203 [Amended]

3. In § 172.203, paragraph (k)(3) is amended by removing the proper shipping name "Infectious substance, human, n.o.s." and replacing it with "Infectious substances, affecting humans."

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

4. The authority citation for part 173 continues to read as follows:

Authority: 49 App. U.S.C. 1803, 1804, 1805, 1806, 1807, 1808; 49 CFR Part 1, unless otherwise noted.

§ 173.386 [Amended]

5. In § 173.386, paragraph (d)(3) is removed and paragraphs (a)(1) and (a)(3) are 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 is listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services or which causes or may cause severe, disabling or fatal human disease.

* * * * *

(3) A *biological product* means a material prepared and manufactured in accordance with the provisions of 9 CFR part 102 (Licensed Veterinary Biological Products), 9 CFR part 103 (Biological Products for Experimental Treatment of Animals), 9 CFR part 104 (Imported Biological Products), 21 CFR part 312 (Investigational New Drug Application), or 21 CFR parts 600 to 680 (Biologics), and which, in accordance with these provisions, may be shipped in interstate commerce.

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6. In § 173.387, paragraph (a) is revised to read as follows:

§ 173.387 Packaging requirement for etiologic agents.

(a) Except as provided in § 173.386(d), no person may ship a package

containing more than 4 liters of a liquid containing an etiologic agent or 4 kilograms net weight of a solid containing an etiologic agent.

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Issued in Washington, DC, on December 21, 1990, under authority delegated in 49 CFR part 1.

Travis P. Dungan,

Administrator, Research and Special Programs Administration.

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