DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 171

[Docket No. HM–181G; Amendment No. 171–128]

RIN 2137–AC36

Infectious Substances; Extension of Compliance Dates

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule; extension of compliance dates.

SUMMARY: RSPA is extending the compliance dates for classification, hazard communication, and packaging requirements of the Hazardous Materials Regulations applicable to infectious substances, including regulated medical waste. The extension is intended to provide RSPA with time to evaluate the need for changes to regulatory requirements which had been scheduled to go into effect on October 1, 1994, and to continue coordination with other Federal agencies that have jurisdiction over infectious substances. The extension is responsive to the concerns of shippers and transporters that more interagency coordination is needed in order to avoid overlapping or inconsistent Federal requirements for infectious substances.

DATES: This amendment is effective on September 22, 1994. However, if RSPA receives comments by September 30, 1994, that illustrate that an extension of compliance dates is not in the public interest, RSPA will remove this final rule amendment and propose another date.

ADDRESSES: Address comments to the Dockets Unit (DHM–30), Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590–0001. Comments should identify the docket number HM–181G) and amendment number (171–128) and be submitted, when possible, in five copies. 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. Office hours are 8:30 a.m. to 5 p.m., Monday through Friday, except for public holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Eileen Martin or Ms. Jennifer Antonielli, Office of Hazardous Materials Standards, Research and Special Programs Administration, 400 Seventh St., SW., Washington, DC 20590–0001, telephone: (202) 366–8553.

SUPPLEMENTARY INFORMATION: On December 21, 1990, RSPA issued a final rule under Docket HM–181 (55 FR 52402) that comprehensively revised the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) with respect to classification, hazard communication, and packaging requirements of hazardous materials. In Docket HM–181, RSPA adopted standards based on United Nations (UN) recommendations, including replacing the term "etiologic agent" with the term "infectious substance" and expanding the definition to include additional agents having the potential to cause severe, disabling, or fatal disease. On January 3, 1991, RSPA issued a final rule under Docket HM–142A (56 FR 197), removing the previous exception from regulation for cultures and stocks of etiologic agents (infectious substances) of 50 milliliters or less total quantity in one outside package (the "50 milliliter exception").

On December 20, 1991, in response to a large number of petitions for reconsideration, RSPA published a final rule making editorial and substantive revisions to the December 1990 final rule (56 FR 66124). In response to one petition for reconsideration, RSPA identified a subcategory of Division 6.2 (infectious substances) materials described as "regulated medical waste" (RMW), and provided packaging requirements for RMW which were less rigorous than those for other infectious substances. Following issuance of the December 1991 rule, RSPA received additional petitions for reconsideration and numerous comments and requests for clarification concerning provisions applicable to infectious substances and RMW. Petitioners were concerned that RSPA had not adequately considered the costs and other ramifications of adopting requirements for RMW. Commenters were concerned over potential overlaps or inconsistencies with other Federal agencies that regulate infectious substances. In partial response to the petitions, RSPA extended the compliance date for infectious substances from October 1, 1992, to April 1, 1993 (October 1, 1992; 57 FR 45442). This extension and others which followed (March 3, 1993; 58 FR 12182 and December 20, 1993; 58 FR 66302) also applied to the 50 milliliter exception which was removed under Docket HM–142A.

On March 3, 1993, RSPA issued an advance notice of proposed rulemaking (ANPRM) and announced a public hearing under Docket HM–181G (58 FR 12207) concerning the need for additional regulatory changes pertaining to infectious substances. In order to provide time to evaluate the oral and written comments received in response to the ANPRM, RSPA also extended the compliance date (58 FR 12182) for provisions applicable to infectious substances from April 1, 1993, to January 1, 1994. The ANPRM addressed a number of complex issues, pertaining to scope of regulation, consistency with regulations of other agencies, the need for revised standards for non-bulk and bulk packagings, and defining criteria for infectious substances and RMW. Following issuance of the ANPRM, RSPA continued its efforts to gain information on other Federal agencies' regulatory requirements, and hosted and participated in a number of interagency meetings on this issue. Federal agencies that regulate infectious substances include the Occupational Safety and Health Administration of the Department of Labor, the Centers for Disease Control (CDC) and the Food and Drug Administration of the Department of Health and Human Services, the United States Postal Service and the Animal and Plant Health Inspection Service of the Department of Agriculture. On December 20, 1993 (58 FR 66302), RSPA again extended the compliance date for provisions applicable to infectious substances from January 1, 1994, to October 1, 1994, to provide additional time for resolving the issues of concern.

RSPA intends to issue a notice of proposed rulemaking (NPRM) in the near future. The NPRM will address those issues concerning infectious substances and RMW that must be addressed in the near term to ensure the safe transportation of these materials. The NPRM also will outline RSPA's intent to make a longer-term effort to harmonize requirements of the HMR with international regulations and with the regulations of the other Federal agencies, and identify and address gaps in regulation that may adversely impact transportation safety.

Based on the merits of comments and petitions, RSPA believes there may be undue adverse impacts if regulatory provisions for infectious substances go into effect on October 1, 1994 without change. Therefore, in this document, RSPA is revising 49 CFR 171.14(b) to extend the compliance dates. For regulatory requirements for RMW and for materials infectious to animals only, the compliance date is extended from October 1, 1994, to October 1, 1995. This time period should be adequate for RSPA to publish the NPRM, evaluate

comments received in response to the NPRM, and make any necessary changes to the HMR based on the merits of those comments. Without an extension of this compliance date, shippers and transporters of these materials would have to comply with regulations that are likely to be changed in the near future and, thereby, incur unnecessary costs.

For other infectious substances, i.e., for cultures and stocks of substances infectious to humans, the compliance date is extended from October 1, 1994, to January 1, 1995. The requirements for these materials generally were not at issue in comments or petitions to the December 1991 final rule. The principal impacts of the January 1, 1995 compliance date will be a nomenclature change from the old "etiologic agent" hazard class to the new "Division 6.2" classification, elimination of the 50 milliliter exception for cultures and stocks, and expansion of the definition of infectious substances to cover substances, such as the human immunodeficiency virus (HIV) and Lyme disease, which are not listed in the CDC regulations (42 CFR 72.3). The removal of the 50 milliliter exception and expansion of the definition of infectious substances originally were to have occurred on February 19, 1991 (Docket HM-142A; January 3, 1991; 56 FR 197). RSPA believes it is necessary to implement these requirements as quickly as possible to ensure public safety and end confusion as to the status of materials that were not regulated prior to 1990.

During the transition periods provided in § 171.14, a person may comply with either the applicable "old" requirements of the HMR (i.e., those which were in effect on September 30, 1991), or the current requirements adopted under HM-181. If a material is an etiologic agent under the old regulations and does not meet any of the old exceptions, it must conform to either the old requirements (i.e., must be described, labeled and packaged as an "etiologic agent") or the current requirements of the HMR for "infectious substances." (Note that Section 171.14(c)(3) provides for limited intermixing of old and new requirements).

RSPA is issuing this extension of the compliance dates without prior notice and comments because we view this as a noncontroversial and necessary amendment and do not anticipate any adverse comments. However, if RSPA receives comments by September 30, 1994, that illustrate that an extension of the compliance dates is not in the public interest, RSPA will remove this final rule and propose another date. If no such comments are received, RSPA will publish a document in the **Federal Register** confirming the compliance dates.

Rulemaking Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is exempted from review by the Office of Management and Budget under Executive Order 12866. Although the underlying rule was significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034), this action is not significant because it does not impose additional requirements and has the effect of extending compliance dates. A regulatory evaluation for the December 20, 1991 final rule is available for review in the docket.

Executive Order 12612

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 ("Federalism"). Federal law expressly preempts State, local, and Indian tribe requirements applicable to the transportation of hazardous material that cover certain subjects and are not substantively the same as Federal requirements. 49 U.S.C. 5125(b)(1). These subjects are:

(A) The designation, description, and classification of hazardous material;

(B) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(C) The preparation, execution, and use of shipping documents pertaining to hazardous material and requirements respecting the number, contents, and placement of those documents;

(D) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(E) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This final rule concerns classification, packaging, labeling, and marking of hazardous material. Therefore, this final rule preempts State, local, or Indian tribe requirements that are not substantively the same as Federal requirements on these subjects.

Section 5125(b)(2) of title 49 U.S.C. provides that when DOT issues a regulation concerning any of the covered subjects, after November 1990, DOT must determine and publish in the **Federal Register** the effective date of Federal preemption. That effective date may not be earlier than the 90th day following the date of issuance of the final rule and no later than two years after the date of issuance. RSPA has determined that the effective date of Federal preemption of this final rule will be April 3, 1995. Because RSPA lacks discretion in this area, preparation of a federalism assessment is not warranted.

Regulatory Flexibility Act

This rule affects shippers and carriers of infectious substances and regulated medical waste, some of whom may be small entities. The effect of the rule is to provide regulatory relief to these entities. Therefore, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This amendment does not impose information collection or recordkeeping requirements.

List of Subjects in 49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR Part 171 is amended as set forth below:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for Part 171 is revised to read as follows:

Authority: 49 U.S.C. 5101—5127; 49 CFR 1.53.

2. In § 171.14, paragraph (b)(6)(iii) is removed, paragraphs (b)(6) and (b)(7) are redesignated as paragraphs (b)(5) and (b)(8), respectively, and new paragraphs (b)(6) and (b)(7) are added to read as follows:

§ 171.14 Transitional provisions for implementing requirements based on the UN Recommendations.

* * * * *

(b) * * *

(6) *January 1, 1995.* On January 1, 1995, all applicable regulatory requirements, including those pertaining to classification (see § 173.134 of this subchapter), hazard communication, and packaging, are effective for Division 6.2 materials (infectious substances) other than regulated medical waste and infectious substances affecting animals only.

(7) *October 1, 1995.* On October 1, 1995, all applicable regulatory

requirements, including those pertaining to classification (see § 173.134 of this subchapter), hazard communication, and packaging are effective for regulated medical waste (Division 6.2) and infectious substances affecting animals only (Division 6.2).

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Issued in Washington, DC on September 20, 1994, under authority delegated in 49 CFR Part 1.

D.K. Sharma,

Administrator.

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