

DEPARTMENT OF TRANSPORTATION

**Research and Special Programs
Administration**

49 CFR Part 171

[Docket No. HM-181G; Amendment No.
171-124]

RIN 2137-AC38

**Infectious Substances; Extension of
Compliance Date**

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

ACTION: Final rule; extension of
compliance date.

SUMMARY: On March 3, 1993, RSPA published an advance notice of proposed rulemaking that asked questions and solicited comments on infectious substances and regulated medical waste (RMW) transportation issues. In this document, RSPA is extending the compliance date for classification, hazard communication, and packaging requirements applicable to infectious substances and RMW from January 1, 1994, to October 1, 1994, in order to provide additional time to

consider the issues raised in the advance notice and comments to it.

EFFECTIVE DATE: This amendment is effective on December 20, 1993.

FOR FURTHER INFORMATION CONTACT: Ms. Eileen Martin or Ms. Jennifer Posten, Office of Hazardous Materials Standards, Research and Special Programs Administration, 400 Seventh Street SW., Washington, DC 20590-0001, telephone: (202) 366-4488.

SUPPLEMENTARY INFORMATION: On December 21, 1990, RSPA issued a final rule under Docket HM-181 (55 FR 52402) which comprehensively revised the Hazardous Materials Regulations (HMR) with respect to classification, hazard communication, and packaging requirements. A document making editorial and substantive revisions to the December 1990 final rule was published on December 20, 1991 (56 FR 66124). The revisions contained in the latter document were primarily in response to over 250 petitions for reconsideration received on the December 21, 1990 final rule.

Following issuance of the December 1991 rule, RSPA received two additional petitions for reconsideration and numerous comments and requests for clarification concerning provisions applicable to infectious substances and regulated medical waste. On October 1, 1992 (57 FR 45442), 49 CFR 171.14(b) was revised to establish a compliance date of April 1, 1993, rather than October 1, 1992, for new requirements applicable to infectious substances. 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. Additionally, on March 3, 1993, under Docket HM-181 (58 FR 12182), RSPA extended the compliance date for provisions applicable to infectious substances from April 1, 1993, to January 1, 1994, to provide time to evaluate the comments received in response to the ANPRM. The advance notice 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 regulated medical wastes. Comments to the docket expressed a wide variety of opinions and recommendations, often conflicting.

that RSPA must analyze. There is insufficient time for RSPA to complete its evaluation prior to the January 1, 1994 compliance date. Therefore, in this document RSPA is revising 49 CFR 171.14 to extend the compliance date applicable to infectious substances to October 1, 1994.

During the transition period 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 § 171.14(c)(3) provides for limited intermixing of old and new requirements). If a material meets the new "infectious substance" definition but not the old "etiologic agent" definition, it may be shipped in accordance with the new requirements, but compliance is not mandatory until October 1, 1994.

Because the amendments adopted herein extend the compliance date of certain regulations, and impose no new regulatory burden on any person, notice and comment are unnecessary. For these same reasons, these amendments are being made effective without the usual 30-day delay following publication.

Rulemaking Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule is not considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, is not subject to review by the Office of Management and Budget. 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 a compliance date.

Executive Order 12612

This action has been analyzed in accordance with Executive Order 12612 on Federalism. It has no substantial direct effect on the States, the current Federal-State relationship, or the

current distribution of power and responsibilities among levels of government. Therefore, no Federalism Assessment is required.

Regulatory Flexibility Act

Based on information concerning the size and nature of entities likely to be affected by this rule, I certify that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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 continues to read as follows:

Authority: 49 App. U.S.C. 1802, 1803, 1804, 1805, 1806, 1818; 49 CFR part 1.

2. In § 171.14, paragraph (b)(5) is removed and reserved and paragraph (b)(6)(iii) is added to read as follows:

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

- * * *
- (b) * * *
- (5) (Reserved).
- (6) * * *

(iii) All applicable regulatory requirements, including those pertaining to classification, (see § 173.134 of this subchapter), hazard communication, and packaging for Division 6.2 materials (infectious substances, including regulated medical waste) are effective.

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Issued in Washington, DC on December 15, 1993, under authority delegated in 49 CFR part 1.

Rose A. McMurray,
Acting Administrator.

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