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

[Docket No. HM-96; Notice 72-13]

ETIOLOGIC AGENTS

Shipment on Passenger-Carrying Aircraft

On September 30, 1972, the Hazardous Materials Regulations Board published Amendments 172-17 and 173-67 in Docket No. HM-96 establishing requirements for the shipment of etiologic agents.

The regulation permits the shipment of diagnostic specimens and biological products on passenger-carrying aircraft. However, it does not permit the shipment of cultures of etiologic agents on such aircraft. These cultures are presently being transported on passenger-carrying aircraft and prior to the above amendment they were not prohibited.

The Board has received many petitions for reconsideration indicating that the proposed change in transportation conditions would seriously and detrimentally affect the timely response and diagnostic capability of many laboratories involved in the protection of the public health. This position was expressed to the Board by numerous State health agencies, by the American Society of Clinical Pathologists, the American Type Culture Collection, the College of American Pathologists, the Association of State and Territorial Laboratory Directors, The Mycological Society of America, the Institute for Medical Research, The American Association of Immunologists, the American Society for Medical Technology, the American Society for Microbiology, the Infectious Diseases Society of America, the Association of Schools of Public Health, Inc., the American Association of Bioanalysts, a large number of hospitals, clinics, Federal health agencies, and several individual members of the medical profession.

One commenter, the Center for Disease Control, Health Services and Mental Health Administration, U.S. Department of Health, Education, and Welfare, summarized part of the problem by stating that "* * * [a]s an example, the physicians who live in areas not served by cargo-only carriers will be forced to rely on surface transportation to carry cultures to laboratories for determination of antibiotic resistance of cultured bacterial isolates—knowledge which is essential for correct treatment. Loss of time due to slower surface transportation delays the treatment of the patient. In addition, some agents are so sensitive that they may perish if their arrival is delayed in any way. Other problems such as changes in the required degree of acidity, etc., which already cause difficulties in the shipment of microbiologic cultures, will be increased as time between shipment and receipt is lengthened. * * *" This type of concern and statements that the level of protection for public health would be seriously affected permeated the dozens of comments received by the Board.

The Center for Disease Control petitioned that the regulations be amended to permit cultures of etiologic agents in volumes of less than 50 milliliters (1.666 fluid ounces) to be transported on passenger-carrying aircraft. They stated that "* * * [b]ased on our past experience with over 100,000 shipments of etiologic agents annually, our scientific knowledge of these agents, and the public health need for their rapid movement, you are assured that undelayed shipments of cultures of etiologic agents in quantities less than 50 ml. are in the interest of public health, and that the hazard to passengers or crews of aircraft is infinitesimal. * * *"

Throughout this proceeding, the Board has relied on information supplied by the Center for Disease Control because of its expertise in the knowledge and handling of these agents. Based on the information it now has, the Board proposes to modify its regulations and to adopt the proposal of the U.S. Health Services and Mental Health Department. This action would have no effect on the present Department of Health, Education, and Welfare regulations on etiologic agents which continue to apply to the packaging of these substances.

In consideration of the foregoing, 49 CFR Part 173 would be amended as follows:

Paragraph (d) in § 173.386 would be amended by adding paragraph (3) to read as follows:

§ 173.386 Etiologic agents; definition and scope.

* * * * *

(d) * * *

(3) Cultures of etiologic agents of less than 50 milliliters (1.666 fluid ounces) total quantity in one outside package.

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Interested persons are invited to give their views on this proposal. Communications should identify the docket number and be submitted in duplicate to the Secretary, Hazardous Materials Regulations Board, Department of Transportation, 400 Sixth Street SW., Washington, DC 20590. Communications received on or before January 23, 1973 will be considered before final action is taken on the proposal. All comments received will be available for examination by interested persons at the Office of the Secretary, Hazardous Materials Regulations Board, both before and after the closing date for comments.

This proposal is made under the authority of sections 831-835 of Title 18, United States Code, section 9 of the Department of Transportation (49 U.S.C. 1657), and Title VI and section 902(h) of the Federal Aviation Act of 1958 (49 U.S.C. 1421-1430 and 1472(h), 1655(c)).

Issued in Washington, D.C. on November 24, 1972.

W. J. BURNS,
Director,
Office of Hazardous Materials.

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