

**DEPARTMENT OF TRANSPORTATION
Research and Special Programs
Administration**

49 CFR Part 107

[Docket No. NM-194; Amdt. No. 107-13]

**Designation of Testing Agencies;
United Nations Packagings**

AGENCY: Materials Transportation Bureau (MTB), Research and Special Programs Administration, DOT.

ACTION: Final Rule.

SUMMARY: This final rule adopts a procedure by which MTB may designate third-party packaging testing agencies, for the purpose of certifying conformance of packaging designs with United Nations (U.N.) standards. Third-party testing is adopted as a means through which shippers and container manufacturers may voluntarily demonstrate the adequacy of their packagings, and possibly enhance acceptance of their use in international transportation. This procedure may help to eliminate delays of, or impositions against, U.S. exports transported in packagings not specifically approved by the Materials Transportation Bureau (acting as the National Competent Authority).

EFFECTIVE DATE: July 1, 1985. However, compliance with the regulations as amended herein is authorized as of March 13, 1985.

FOR FURTHER INFORMATION CONTACT: Thomas J. Charlton, Chief, Standards Division, Office of Hazardous Materials Regulation, Materials Transportation Bureau, Department of Transportation, Washington, D.C. 20590, telephone (202) 426-2075.

SUPPLEMENTARY INFORMATION:

Background

On October 12, 1984, MTB published a notice of proposed rulemaking (Notice No. 84-13) in the Federal Register (49 FR 40056). That notice proposed the adoption of a procedure by which MTB may designate third-party packaging testing agencies for the purpose of certifying conformance of packaging designs to U.N. standards. This final rule contains amendments to the Hazardous Materials Regulations (HMR) based on the proposals in Notice 84-13 and the merits of comments filed in response to that notice. Interested persons should refer to Notice 84-13 for additional background information.

In response to Notice 84-13, MTB received 35 written comments. The respondents include international exporters of hazardous materials, packaging manufacturers and packaging

testing organizations. Of those commenters expressing an opinion on the overall merits of the proposal, 28 are in favor, two gave conditional support and one commenter strongly opposed the idea. The two commenters giving conditional support fail to see a need for implementing the proposed procedure. However, they indicated a willingness to support a procedure which is not keyed to "third-parties". Numerous commenters requested that the rule also permit the designation of "in-house" laboratories.

Clarification

The title of this docket is revised by replacing the word "Laboratories" with the word "Agencies" since the qualifications of a person performing the certification function is the prime factor in accomplishing the purpose of this rulemaking. Obviously, one qualification in the ability to determine the adequacy of test equipment for performance of a necessary function in his own facility (laboratory) or, for example, in the facility of a packaging manufacturer.

Acknowledgement of Problem

The comments do not reflect a universal agreement that the regulatory requirements for international road and rail transport within Europe (ADR and RID, respectively) will require that packagings conforming to U.N. standards be certified by MTB or a designated approval agency. Some commenters are convinced this will occur. Other commenters contend the ADR/RID countries will come to recognize that self-certification of performance-oriented packagings standards is just as reliable as the long-accepted policy for self-certification of specification packagings.

One company which sees the ADR/RID requirement as a serious threat is Monsanto. Currently, Monsanto is having containers tested in Europe. The commenter complains "this procedure is time consuming and expensive and results in an adverse effect on exports". Another company, Olin Chemicals, takes the position that it must assume the status quo of the ADR/RID package testing requirements and, therefore, supports the proposal as a short term solution. However, Olin is one of several commenters who believe, in the long term, ADR/RID countries can be convinced that self-certification is an acceptable alternative.

The principal argument raised by commenters who fail to recognize the ADR/RID requirements as a problem for U.S. shippers centers on Paragraph 9.7.1.1. of Chapter 9 of the U.N. Recommendations. That Paragraph

essentially leaves testing procedures to the discretion of the competent authority. Thus, PPG Industries, Inc. (PPG) and others contend ADR/RID countries must respect the determination of the U.S. Competent Authority on whichever system is selected.

Like most commenters to the Docket, MTB must assume that requirements promulgated by the ADR/RID countries will be fully implemented on the effective date of May 1, 1985, and it would not be appropriate to presume that U.S. shippers enjoy some privilege regarding compliance with these amendments not accorded ADR/RID member states after May 1, 1985. Consequently, the MTB believes a potential problem exists, and a positive step should be taken to minimize the negative impacts should this potential problem be realized.

Adequacy of the Proposal

Most commenters viewed the proposal as an acceptable response to the potential problem. It is characterized as a straightforward approach to a clearly defined problem; i.e., ADR/RID countries require that tests be performed by a person independent of the packaging manufacturer and the proposal provides that inspections may be conducted by third-party inspection agencies approved by the Associate Director for HMR. While some commenters argue that a non-governmental inspection agency will nevertheless be unacceptable, other commenters see evidence that this concept is taking hold in some ADR/RID countries.

Writing in opposition to the proposed rule, PPG expresses doubt that ADR/RID countries will accept the findings of approved agencies. To PPG, it is obvious that MTB can satisfy the ADR/RID countries only by testing and approving packagings in its own right.

Several other commenters cite evidence that suggests a willingness by the ADR/RID countries to accept certifications which are not issued by the national competent authority directly. For instance, although The Netherlands maintains its own national testing laboratories, it recently set a precedent by conferring authorization to conduct tests leading to packaging approval on TOPA, an independent government-approved laboratory. Similarly, the competent authority of the United Kingdom authorizes bodies qualified under the National Testing Laboratory Accreditation Scheme to undertake tests leading to packaging approval.

There is a diversity of opinion on how a packaging approval system should operate. Most commenters emphasize that the self-certification process used in the U.S. today should continue, and that whichever method develops for international traffic it should not prejudice certifications for domestic traffic. However, Natico, Inc., a drum manufacturer, concluded its comments by stating "(t)hird party testing and certification for the transportation of hazardous materials should be made mandatory."

While the Notice was specific to designation of independent third-party testing laboratories, there was some discussion of other possibilities. The National Bureau of Standards (NBS) advised MTB of its National Voluntary Laboratory Accreditation Program (NVLAP) and suggested this alternative is better than developing a separate system. NBS currently recognizes a series of nine different laboratory accreditation programs (LAP). Some of these cover the testing of insulating materials, concrete, carpeting, and paint and paper products. Accreditation is established through a demonstration, to technical experts working for NBS, of the applicant laboratory's proficiency. As each LAP looks more to the competency of a laboratory than its independence, there are many in-house testing laboratories which enjoy accreditation and apparent recognition by certain countries belonging to the International Laboratory Accreditation Conference. Thus, the concept of self-certification is given greater credibility through the accreditation program.

The NVLAP program was only recently brought to the attention of MTB and did not receive consideration prior to development of the notice of proposed rulemaking for this docket. However, the design of the NVLAP system appears to satisfy several interests. In its position as a facilitator, NBS would relieve MTB of most of the day-to-day functions necessary in the administration of an approvals program for testing agencies. Also, as the accreditation in existing LAP's includes many "in-house" laboratories, the request of numerous commenters to drop the "third-party" provision from the applicant's qualifications statement might be satisfied. The NVLAP system, however, goes considerably beyond the scope of Notice 84-13 and MTB doubts that any rulemaking would be necessary for implementation of such a program since self-certification is already permitted by the HMR.

Use of In-House Testing Facilities

Some shippers, who wish to maintain the status of their own testing laboratories, contend they meet MTB's objectivity test when testing packaging materials produced for them by an unrelated packaging manufacturer. To them, this is a form of quality assurance that adds another dimension to packaging integrity. For instance, when it wishes to ship materials in steel drums, 3M believes it can test drums made by any number of manufacturers with the same degree of objectivity as a third-party testing laboratory, but at a considerable savings of time and money. Packaging manufacturers who wish to maintain the status of their testing facilities argue very convincingly about the competency of their personnel and equipment, but their objectivity is not as apparent as that of a shipper testing a manufacturer's packaging.

It seems that a large number of commenters wrongly interpreted the requirement of § 107.402(b)(5). While that requirement specifies the agency must perform its functions independent of the manufacturers and owners of the packaging concerned, it does not prevent the agency from witnessing physical tests at a shipper or packaging manufacturer's facility. In fact, the requirements of § 107.402 were first applicable to the certification of specification intermodal portable tanks, and § 173.32a(b)(3) clearly indicates that witnessing a manufacturer's or owner's testing of tanks is acceptable. Nothing in today's final rule intends to modify that practice. Consequently, each in-house testing facility which possesses the necessary equipment and personnel may conduct the required tests, but the packaging certification must be issued under authority of a third-party designated for that purpose by the Associate Director for HMR.

Qualifications for Approval Agencies

Wyle Laboratories took exception to the proposed rule's absence of detailed criteria by which testing laboratories must operate. The commenter suggested quality-control criteria, such as traceability of calibration standards, calibration frequency and documentation, and standardization of procedures, would assure conformance to the packaging's certified level of performance.

Testing required by the U.N. Recommendations is very basic and may be adequately conducted with basic instruments. Currently, most packaging testing is performed by manufacturers and, to this date, there are no indications their instruments

(pressure gauges, micrometers, scales, etc.) are so poorly maintained that MTB should establish specific requirements which assure greater accuracy. It is doubtful that independent agencies are any less competent in their knowledge or equipment.

Economic Impact

Mallinckrodt, Inc., while supporting the proposed rule only as a necessary means to avoid frustration of its export shipments, complained manufacturers and shippers of small packages (bottles inside fiberboard boxes) will bear a disproportionate burden of costs resulting from this rulemaking. Whereas steel drums are limited to a relatively small number of designs and capacities, the number of different packaging consisting of fiberboard boxes with inside glass or plastic bottles is extremely large. Thus, a greater amount of time and money is required to demonstrate that each packaging conforms to the performance standard. Due to the shortness of time available for filing comments, the commenter was unable to present data supporting this claim; however, MTB does not challenge its validity except to note that there are provisions in the U.N. Recommendations that allow the selective testing of packaging that differ only in minor respects from a tested type, and specifically provide some relief for the use of various inner packaging in a combination packaging without requiring retesting of the completed packaging. Another point Mallinckrodt wished to make is that testing would have to be performed twice; first to the satisfaction of the shipper or manufacturer developing the package, and secondly to the satisfaction of the designated certification agency. This also results in increased costs of time and money. To preclude what it considers unnecessary costs, Mallinckrodt requested that MTB push for acceptance by the ADR/RID countries of the self-certification process currently used in the U.S.

There is no disputing the commenter's statement. However, if MTB were to do nothing, international shippers would be in the even worse position of possibly having to incur additional costs by having their packaging approved in a foreign country. As indicated by other commenters, that option is probably the most undesirable.

Major Rulemaking

One commenter, PPG, took exception to MTB's determination that this is not a major rule. The commenter states:

First, this proposal could have significant economic impact on PPG and other shippers. PPG has approximately 350 detailed packaging specifications that, if this proposal were adopted, may have to be "voluntarily tested to demonstrate adequacy." The cost of this testing could easily reach one million dollars. Secondly, this proposal, if adopted, would completely change the packaging approval process in the United States. It would become apparent to ADR/RID countries that the U.S. approves of third party certification of packaging, and it would be required for all shipments to these countries.

The MTB made it quite clear the Notice represents a possible solution to a problem that will likely affect many shippers, including PPG. An overwhelming amount of support for that proposal came from the regulated community. In addition, MTB clearly indicated in the Notice that the requirements in the HMR pertaining to U.N. performance-oriented packaging standards (§ 171.2 and § 178.0-3) can be met through self-certification. Consequently, affected persons are free to choose the option which they believe is most appropriate to their circumstances. MTB emphasizes that the result of the adoption of changes to procedural rules by this amendment does not impose a new mandatory burden on any person.

One of the criteria specified in Executive Order 12291 regarding a "major rule" refers to a regulation that is likely to result in "(s)ignificant adverse effects on . . . the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets." The MTB believes this rule may facilitate the ability of U.S.-based enterprises to compete in export markets.

Summary of Amendments

Section 107.401 is revised to expand its scope to include certifications issued for packagings conforming to standards appearing in the UN Recommendations on the Transport of Dangerous Goods. Paragraph (b) is added to clearly indicate that designated agencies share authority with MTE. Accordingly, packaging manufacturers and shippers may ask the Associate Director for HMR to provide a packaging certification. In addition, the affected party may appeal to the Associate Director for HMR an adverse determination made by a designated agency.

Section 107.402 is amended in paragraphs (b)(3), (b)(4)(ii) and (b)(6) by expanding the scope of packagings covered in this section to include packagings conforming to U.N. Recommendations.

Section 107.404 is amended to indicate a designated agency issues a

certification, rather than an approval certificate which is appropriate only to serially numbered intermodal portable tanks.

Subpart E, with the amendments discussed above and other conforming changes, is presented in its entirety for clarity.

OMB Control Number: 2137-0008

Paperwork Reduction Act

Reporting requirements contained in this regulation (§ 107.402) have been approved by the Office of Management and Budget under provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) and assigned OMB Control Number 2137-0008.

List of Subjects in 49 CFR Part 107

Hazardous materials transportation, Administrative practice and procedure.

In consideration of the foregoing, Subpart E of 49 CFR Part 107 is revised to read as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

Subpart E—Designation of Approval and Certification Agencies

Subpart E—Designation of Approval and Certification Agencies

Sec.

107.401 Purpose and scope.

107.402 Application for designation as an approval or certification agency.

107.403 Designation of approval agencies.

107.404 Conditions of designation.

107.405 Termination of designation.

Authority: 49 U.S.C. 1804, 1805, 1808; 49 CFR 1.53; App. A to Part 1.

§ 107.401 Purpose and scope.

(a) This subpart establishes procedures for the designation of agencies to issue approval certificates and certifications for types of packagings designed, manufactured, tested, or maintained in conformance with the requirements of this subchapter. Subchapter C of this chapter, and standards set forth in the United Nations (U.N.) Recommendations (Transport of Dangerous Goods), except for certifications of compliance with U.N. packaging standards, this subpart does not apply unless made applicable by a rule in Subchapter C of this chapter.

(b) The Associate Director for HMR may issue approval certificates and certifications addressed in paragraph (a) of this section.

§ 107.402 Application for designation as an approval or certification agency.

(a) Any organization or person seeking designation as an approval or

certification agency shall apply in writing to the Associate Director for Hazardous Materials Regulation (DMT-20), Department of Transportation, 400 Seventh Street, SW., Washington D.C. 20590. Each application must be signed and certified to be correct by the applicant or, if the applicant is an organization, by an authorized officer or official representative of the organization. Any false statement or representation, or the knowing and willful concealment of a material fact, may subject the applicant to prosecution under the provisions of 18 U.S.C. 1001, result in the denial or termination of a designation.

(b) Each application for designation must be in English and include the following information:

(1) Name and address of the applicant, including place of incorporation if a corporation. In addition, if the applicant is not a resident of the United States, the name and address of a permanent resident of the United States designated in accordance with § 107.7 to serve as agent for service of process.

(2) If the applicant's principal place of business is in a country other than the United States, a copy of the designation from the Competent Authority of that country delegating to the applicant an approval or designated agency authority for the type of packaging for which a DOT designation is sought, and a statement that the Competent Authority also delegates similar authority to U.S. Citizens or organizations having designations under this subpart from the MTB.

(3) A listing, by DOT specification (or exemption) number, or UN designation, of the types of packagings for which approval authority is sought.

(4) A personnel qualifications plan listing the qualifications that the applicant will require of each person to be used in the performance of each packaging approval or certification function. As a minimum, these qualifications must include—

(i) The ability to review and evaluate design drawings, design and stress calculations;

(ii) A knowledge of the applicable regulations of Subchapter C of this chapter and, when applicable, U.N. standards; and

(iii) The ability to review and evaluate the qualification of materials and fabrication procedures.

(5) A statement that the applicant will perform its functions independent of the manufacturers and owners of the packagings concerned.

(6) A statement that the applicant will allow the Associate Director for HMR or his representative to inspect its records and facilities in so far as they relate to the approval or certification of specification packagings and shall cooperate in the conduct of such inspections.

(c) The applicant shall furnish any additional information relevant to the applicant's qualifications, if requested by the Associate Director for HMR.

§ 107.403 Designation of approval agencies.

(a) If the Associate Director for HMR determines that an application contains all the required information, the applicant is sent a letter of designation and assigned an identification code.

(b) If the Associate Director for HMR determines that an application does not contain all the required information, the application is denied and the applicant is sent a written notice containing all the reasons for the denial.

(c) Within 30 days of an initial denial of an application under paragraph (b) of this section, the applicant may file an amended application. If after considering the amended application, the Associate Director determines that it should be denied, he notifies the applicant, and the denial constitutes the final action of the Associate Director on the application. Within 60 days of receipt of the final denial the applicant may appeal the denial to the Director, MTB, setting forth in writing where the Associate Director erred in this determination.

§ 107.404 Conditions of designation.

(a) Each designation made under this subpart contains the following conditions:

(1) The designated approval or certification agency may use only testing equipment that it has determined, through personal inspection, to be suitable for the purpose.

(2) Each approval certificate and certification issued by the designated approval agency must contain the name and identification code of the approval agency.

(3) Each approval certificate and certification must be in a format acceptable to the Associate Director for HMR.

(b) The designated approval agency shall notify the Associate Director for HMR within 20 days after the date there is any change in the information submitted under § 107.402.

(c) The designated approval agency shall comply with all of the terms and conditions stated in its letter of designation under the subpart.

(d) Nothing in this part relieves a manufacturer or owner of a packaging of responsibility for compliance with any of the applicable requirements of this title.

§ 107.405 Termination of designation.

(a) Any designation issued under § 107.403 of this subchapter may be suspended or terminated if the Associate Director for HMR determines that:

(1) The application for designation contained a misrepresentation, or the

applicant willfully concealed a material fact.

(2) The approval agency failed to comply with a term or condition stated in the agency's letter of designation.

(3) The Competent Authority of an approval agency of a country outside the United States has failed to initiate, maintain or recognize a qualified U.S. approval agency.

(b) Before a designation is suspended or terminated, the Associate Director for HMR shall give to the approval agency:

(1) Written notice of the facts or conduct believed to warrant suspension or termination of the designation.

(2) Sixty days in which to show in writing why the designation should not be suspended or terminated.

(49 U.S.C. 1804, 1805, 1808; 49 CFR 1.53; App. A to Part 1)

Note.—Because the requirements in this final rule relate to (a) agency practices and procedures and (b) clarifications of existing regulations and policies, the Materials Transportation Bureau determined that this final rule—(1) is not "major" under Executive Order 12291; (2) is not "significant" under DOT Regulatory Policies and Procedures (44 FR 11034; Feb. 28, 1979); and (3) does not require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321 *et seq.*). For these same reasons, I certify this final rule, as promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Washington, D.C. on March 8, 1985.

L. D. Santman,

Director, Materials Transportation Bureau.

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