DEPARTMENT OF TRANSPORTATION

Hazardous Materials Regulations Board

[49 CFR Parts 170–189]

[Docket No. HM–51]

CLASSIFICATION OF CERTAIN HAZARDOUS MATERIALS ON BASIS OF THEIR HEALTH HAZARDS

Advance Notice of Proposed Rule Making

On August 21, 1968 (33 F.R. 11862), the Hazardous Materials Regulations Board announced a plan to revise the regulations governing the transportation of hazardous materials. That document announced the intention to issue notices of proposed rule making in at least four areas, including, "classification and labels", and invited public help in developing the basic regulartory principles to guide the Board in revising the regulations.

The Board is planning to consider, in the near future, a proposal for classification tests for poisonous materials. To assist the Board in that consideration, the public is invited to express its views on the health hazard classification tests proposed herein. This document is not a proposal to change the regulations. It is an effort to get public participation early in the rule-making process.

The present definitions of poisonous materials contain specific testing criteria only in the case of class B poisons. There are no criteria now provided for class A poisons or irritating materials (including tear gases). As a result, the public cannot practically rely upon those definitions to determine when the Federal regulations apply. In order to correct that situation, the Department proposes to adopt testing criteria for those latter two categories.

The National Research Council-National Academy of Sciences assisted the Department in developing these test criteria. In addition, the testing procedures and benchmarks used by the Departments of Agriculture and Health, Education, and Welfare have also been considered to ensure harmony between the regulatory standards of the several Federal agencies having jurisdiction in this area (see, for example, § 191.1 of the regulations of the Department of Health, Education, and Welfare, 21 CFR Part 191, and § 362.116 of the regulations of the Department of Agriculture, 7 CFR Part 362).

Types of health hazards. The health hazards of materials being transported are characterized by their acute effects on human health. Hazards to be considered are:

Systemic hazards.
Contact hazards.
Irritant hazards.

Systemic hazards exist when materials are capable of causing harmful effects through inhalation, ingestion, or absorption through the skin. Contact hazards exist when materials are capable of causing destruction of living tissue or tissue reaction by thermal or chemical action at the site of contact. Irritant hazards exist when the materials are capable of causing local irritating effects on eyes, nose, or throat, or are capable of causing severe lachrimation.

Hazard degrees. Degrees of hazard are ranked according to the potential severity of the hazard to people. The establishment of hazard degrees is necessary in order to establish packaging criteria reflecting the potential severity of the damage if a product should escape from its packaging during transportation. This potential must be taken into account in the design and integrity of packaging used in the shipment of the toxic products. The major categories and criteria are as follows:

Extremely dangerous poisons. Materials would be classified as extremely dangerous poisons if, on short exposure, they could cause deaths or major residual injury to humans. In the absence of adequate data on human toxicity, a material would be presumed to be extremely poisonous to humans if it falls within any one of the following categories when tested on laboratory animals:

(1) *Ingestion (oral).* Any material that has a single dose LD_{50}[1] of 5 milligrams or less per kilogram of body weight when administered orally to both male and female rats, each weighing between 200 and 300 grams, and which have been fasted for a period of 24 hours.

(2) *Inhalation.* Any material that has an LC_{50}[1] of 75 parts per million by volume or less or 0.75 milligrams per liter by volume or less of vapor, mist or dust when administered by continuous inhalation for 1 hour or less to both male and female rats, each weighing between 200 and 300 grams. If the material is administered to the animals as a dust or mist, more than 90 percent of the particles available for inhalation in the test must have a diameter of 10 microns or less.

[1] LD_{50}, LC_{50}: That dose (LD) or concentration (LC) which will cause death within 14 days to at least one-half of the test animals.

(3) *Skin contact.* Any material that has an LC_{50} of 100 milligrams or lower per kilogram of body weight when administered by continuous contact for 1 hour with the bare skin of rabbits, each weighing between 2.3 and 3.0 kilograms, according to test procedures described in § 191.10 of the regulations of the Department of Health, Education, and Welfare (21 CFR Part 191). (This test procedure is also listed in NAS-NRC Publication 1138, "Principles and Procedures for Establishing the Toxicity of Household Substances", available from the Printing and Publishing Office, National Academy of Sciences, Washington, D.C. 20408 at $1.50.)

Toxic materials. Materials would be classified as toxic if on short exposure they could cause serious temporary or residual injury to humans. In the absence of adequate data on human toxicity, a material would be presumed to be toxic to humans if it falls within any one of the following categories when tested on laboratory animals:

(1) *Ingestion (oral).* Any material that has a single dose LD_{50} of more than 5 milligrams but not more than 50 milligrams per kilogram of body weight when orally administered to both male and female rats, each weighing between 200 and 300 grams, and which have been fasted for a period of 24 hours.

(2) *Inhalation.* Any material that has an LC_{50} of more than 75 parts per million by volume but not more than 200 parts per million or more than 0.75 milligram but not more than 2 milligrams per liter of vapor, mist, or dust when administered by continuous inhalation for 1 hour or less to both male and female rats, each weighing between 200 and 300 grams. If the product is administered to the animals as a dust or mist, more than 90 percent of the particles available for inhalation in the test must have a diameter of 10 microns or less.

(3) *Skin contact.* Any material that has an LD_{50} of greater than 100 milligrams but not more than 200 milligrams per kilogram of body weight when administered by continuous contact for 1 hour with the bare skin of rabbits, each weighing between 2.3 and 3.0 kilograms, according to the test procedure described in § 191.10 of 21 CFR Part 191.

Irritating materials. Materials would be classified as irritants if they would cause reversible local irritant effects on eyes, nose, or throat, or cause slight irritation to the skin of humans. In the absence of adequate data on human reaction, they would be presumed to be irritating if they fall within either of the following categories:

(1) *Skin irritation.* Any material with an average irritation score of 4 or more, but less than 6, according to the test procedures described in § 191.11 of 21 CFR Part 191. (If the score is 6 or more, the material would be classified as corrosive.)

(2) *Eye irritation.* Any material which exhibits a reaction with an average score of 2 or more according to the test for eye irritants described in § 191.12 of 21 CFR Part 191, and the "Illustrated Guide for Grading Eye Irritation by Hazardous Substances" prepared by the U.S. Department of Health, Education, and Welfare, and available from the U.S. Government Printing Office, Washington, D.C.

If human experience or other data indicate that the hazard of a given material that may be encountered during an accidental exposure in transportation is greater or lesser than indicated by the data from the specified animal tests, the classification for that specific material would be revised upward or downward.

If these classifications are adopted, appropriate changes will be required in the labels required to be applied to packages.

Interested persons are invited to give their views as to whether this approach is a reasonable and practical one. Alternative approaches, along with supporting data, will be welcome. Comments (identifying the docket number) should be submitted prior to September 4, 1970, in duplicate to the Secretary, Hazardous Materials Regulations Board, Department of Transportation, 400 Sixth Street SW., Washington, D.C. 20590. 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.

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