



U.S. Department
of Transportation

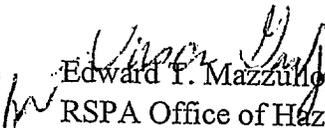
**Research and
Special Programs
Administration**

Memorandum

Date APR 9 2004

Reply to Attn of

Subject Definition of a Diagnostic Specimen

From  Edward T. Mazzullo, Director
RSPA Office of Hazardous Materials Safety

Reference No. 03-0208

To Bill Wilkening
Manager, ADG-1, FAA

This is in response to your memorandum requesting clarification on the definition of a diagnostic specimen under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). You stated under the Federal Aviation Administration's (FAA's) airworthiness requirements all diagnostic specimens are considered hazardous since some diagnostic specimens contain hazardous materials. You also stated certain air carriers are prevented from transporting hazardous materials under the FAA's airworthiness requirements. Your questions have been paraphrased and answered in the order provided.

- Q1: Are routine diagnostic specimens such as urine tests for drug screenings, blood tests for routine physicals, etc., taken from healthy individuals that are not suspected of containing a pathogen considered to be hazardous materials under the HMR?
- A1: The answer is no. Samples transported for routine testing and samples transported to investigate non-communicable diseases or conditions that are not known or suspected of being contaminated with an infectious substance do not meet the definition in § 173.134(a)(1) for a Division 6.2 (infectious) material and, therefore, are not regulated under the HMR.
- Q2: Is the wording "Diagnostic Specimen," as a regulated term of art, prohibited as a marking on shipments of specimens that are not classed as hazardous materials under § 172.303 or any other part of the HMR?
- A2: The answer is no. Section § 172.303(b)(3) permits a proper shipping name, such as "Diagnostic specimen," listed on the § 172.101 Table to be marked on a package containing a non-regulated material provided the marking does not include a UN or NA identification number. The intent of the provision is to provide shippers and transporters relief when using proper shipping names that also describe non-regulated materials.



U.S. Department
of Transportation
Federal Aviation
Administration

Edmonson
§ 173.134
Definition of Diagnostic Specimen
03-0208
Memorandum

Subject: Diagnostic Specimens

Date: August 15, 2003

From: FAA Office of Hazardous Materials

Reply to
Attn. of:

To: Ed Mazzullo
RSPA Office of Hazardous Materials Standards

Dear Mr. Mazzullo,

As you know, FAA airworthiness requirements prevent certain air operators from accepting hazardous materials. Therefore, we must clearly understand when a diagnostic specimen meets the definition of a hazardous material. Currently, because some diagnostic specimens contain hazardous materials, all diagnostic specimens are considered hazardous materials.

49 CFR 173.134(a)(4) of the HMR defines a diagnostic specimen as "...any human or animal material, including excreta, secret, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live animals." The definition goes on to explain that specimens suspected of containing a Risk Group 4 pathogen must be classed as div 6.2 and assigned UN 2814 or UN 2900.

Paragraph 173.134(b) makes the following clarification:

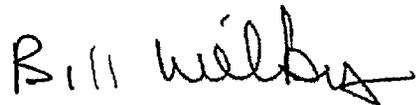
"The following are not subject to the requirements of this subchapter as division 6.2 materials: ... (2) A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 1, or that does not contain a pathogen, or a diagnostic specimen in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs."

Question 1 – Are routine diagnostic specimens from healthy individuals (e.g.; urine tests for drug screenings, blood tests for routine physicals, etc.) that are not suspected of containing a pathogen considered to be hazardous materials under the HMR?

Question 2 – Is the term "Diagnostic Specimens" (as a regulated term of art) prohibited as a marking on shipments of specimens that are not classed as hazardous materials under 172.303 or any other part of the HMR?

Question 3 – If a “non-hazardous” use of the term diagnostic specimen is not prohibited, how can air carriers identify the hazardous diagnostic specimens from the non-hazardous specimens?

Thank you for your assistance.

A handwritten signature in black ink that reads "Bill Wilkening". The signature is written in a cursive style with a long horizontal stroke at the end.

Bill Wilkening, Manager, ADG-1

portable tanks in § 172.514, to portable tanks having a capacity of less than 3,785 L (1,000 gallons). RSPA also is accepting petitions recommending revision of the cargo tank marking size to require a 50 mm (2 inch) marking. Accordingly, consistent with the 50 mm marking required for cargo tanks in § 172.328(b), paragraph (b)(3) is revised to specify a 50 mm (2 inch) mark for cargo tanks and other bulk packages.

In order to relieve some of the burden associated with remarking bulk packages due to minor changes in shipping names, RSPA is adding a new paragraph (f) stating that a bulk packaging marked with a proper shipping name prior to October 1, 1991, does not have to be remarked if the key words of the old mark are identical to those currently specified in the § 172.101 Table. For example, a tank car marked "ANHYDROUS AMMONIA" need not be remarked "ANHYDROUS AMMONIA, LIQUEFIED."

Section 172.303. Several petitioners stated that the requirements for prohibited marking in paragraph (a), as written, would prohibit the use of terms used generically, such as paint, ink or cotton, from being used in connection with a non-hazardous product, when the name is the same as the hazardous product. They suggested that the matter can easily be solved if "or" is replaced with "and" between the words "shipping name" and "identification number." The effect would be that a package containing a non-hazardous product, whose name is the same as a hazardous product, when not marked with a UN or NA identification number, would not be in violation of the prohibited marking provision. RSPA agrees in principle with petitioners. However, changing the conjunction to "and" would permit either the shipping name or the identification number, but not both to appear on a package. This could lead to confusion. Instead, RSPA is providing an additional exception in paragraph (b) for those shipping names which describe non-regulated materials.

Several petitioners objected, for different reasons, to the exceptions provided in paragraphs (b)(1) and (b)(2). One petitioner objected to allowing non-bulk packages, under certain conditions, to remain marked. The petitioner believes that the exceptions may lead to confusion on the part of carriers, inspectors, enforcement officers, and emergency responders, and stated that requiring removal of marking, or covering the marking would present no burden to industry. RSPA is not aware of problems caused by this exception,

which has been in the regulations, at § 173.29(d), for some time.

Another petitioner objected to the requirement to cover or obliterate the marking (§ 172.303(b)(2)) when moving an empty tank car from manufacturing facilities, or to or from cleaning or repair facilities. The petitioner said that, although the concept *not* to have the shipping name shown on a clean empty tank car is noteworthy, strict adherence on a tank car is a problem, recommending that RSPA permit empty, clean tank cars, moving from tank car manufacturing facilities, or to or from tank car cleaning or repair facilities, to remain marked with the hazardous material shipping name and identification number without securely covering or obliterating the marking. RSPA is denying this petition. As with the provision addressed in the previous paragraph, this is a long-standing provision previously found in § 173.29(d). RSPA believes covering of markings on empty bulk packagings is necessary to preclude confusion or unnecessary response on the part of emergency responders.

Section 172.312. Several petitioners recommended revision of requirements in paragraph (a)(2) for display of orientation markings on liquid hazardous materials in non-bulk packagings. They suggested that RSPA specify that the marking only "pictorially" conform to the ISO 780-1985 standard, to allow for commonly used methods of orientation markings on packages containing hazardous materials. They stated, for example, that the orientation marking shown in the ICAO Technical Instructions is widely used and readily recognized and understood. One petitioner recommended that two additional exceptions to the orientation marking requirements in paragraph (a) be included in paragraph (c) for manufactured articles and when the top closure is similar to the bottom closure or seal (e.g., a dry cell battery). The petitioner stated that in such cases the orientation of the inner package is either irrelevant or not applicable with respect to the closures of the inner packagings.

RSPA agrees. Therefore, in § 172.312, paragraph (a) is revised to require that the orientation marking only "pictorially" conform to the ISO 780-1985 standard, and exceptions are added in paragraph (c) for orientation markings for liquids in hermetically-sealed inner packagings and manufactured articles.

Section 172.313. RSPA is revising paragraph (a) to clarify package marking requirements for gases and liquids that

are materials poisonous by inhalation as defined in § 171.8. This revision addresses HMAC's request to eliminate the need in paragraph (a) for marking "Inhalation Hazard" on packages containing lesser hazard Division 6.1 liquids.

One petitioner stated that the location for marking the phrase "Inhalation Hazard" on tank cars, as specified in paragraph (a), for a Division 2.3 material or a poisonous liquid, is not appropriate. The petitioner recommended that instead of locating the marking in association with the labels or placards, the marking would better communicate the "inhalation hazard" to emergency response personnel if it were located "in association with the required shipping name." The petitioner stated that because the placard displays the pictorial representation of poison (i.e., symbol of the skull and crossbones), the placement of the required marking is redundant. RSPA believes that locating this warning in association with a proper shipping name, when one is required, is equally as visible as when located near labels or placards. Therefore, RSPA is revising paragraph (a) to permit either location. A petitioner questioned the need to permanently mark the word "POISON" on non-bulk plastic outer packagings, as specified in § 172.313(b), used as single or composite packaging for materials in Division 6.1. The petitioner stated that RSPA had no basis for extending this provision to materials with a relatively low degree of toxicity, and that the provision should be limited to materials in Division 6.1, Packing Groups I and II. RSPA disagrees. Currently, the HMR requires that each polyethylene packaging used as an outside packaging for materials meeting the definition of a poison be permanently marked with the word "POISON" (§ 173.24(d)(4)). RSPA believes that extension of the requirements to permanently mark the word "POISON" on non-bulk plastic outer packagings used as a single or composite packaging for materials in Division 6.1 is necessary. This requirement will help ensure that foodstuffs are not packed in the same drum or package with the poison material. Therefore, the requirements in § 172.313 will remain unchanged in the final rule.

Section 172.320. Several petitions were received regarding the requirement in § 172.320 to mark packages with the approval number (i.e., EX-number) of the explosive contained therein. Products that are not given EX-numbers and for those packages that are marked with national stock numbers or product codes

in § 173.115(c) of this subchapter), is not included in the proper shipping name for the material, the technical name shall be entered on the shipping paper in the manner prescribed in paragraph (k) of this section.

(3) For materials which are poisonous by inhalation (see § 171.8 of this subchapter), the words "Poison-Inhalation Hazard" and the words "Zone A", "Zone B", "Zone C", or "Zone D", for gases or "Zone A" or "Zone B" for liquids, as appropriate, shall be entered on the shipping paper immediately following the shipping description. The word "Poison" need not be repeated if it otherwise appears in the shipping description.

§ 172.203 [Amended]

37. In addition, in § 172.203, the following changes are made:

a. In paragraph (c)(2), in the second sentence, "3" is revised to read "6.1"; and "PG" is removed both places it appears.

b. In paragraph (k) introductory text, "PG" is removed both places it appears; and the last sentence is revised to read "For example, 'Organic peroxide type B, solid, 5.2, UN 3102 (dibenzoyl peroxide, 52-100%)' or 'Organic peroxide type E, solid, 5.2, UN 3108 (dibenzoyl peroxide, paste, <52%)'."

c. In paragraph (k)(1), in the second sentence, "compound" is revised to read "mixtures" both places it appears; and "PG" is removed both places it appears.

d. In paragraphs (k)(2) and (k)(4)(iii), "PG" is removed each place it appears.

e. In paragraph (k)(4)(ii), the reference "§ 172.101(c)(12)" is revised to read "§ 172.101(c)(11)".

f. In paragraph (k)(4)(iv), the last sentence is revised to read "For example: 'Carbamate pesticides, liquid, flammable, toxic, n.o.s., flash point less than 23°C (contains Xylene) 3, 6.1, UN 2758, II'."

38. In § 172.302, paragraphs (b)(2) and (b)(3) are revised, and a new paragraph (f) is added to read as follows:

§ 172.302 General marking requirements for bulk packagings.

* * * * *

(b) * * *

(1) * * *

(2) 25 mm (one inch) for portable tanks with capacities of less than 3,785 L (1,000 gallons); and

(3) 50 mm (2.0 inches) for cargo tanks and other bulk packagings.

* * * * *

(f) A bulk packaging marked prior to October 1, 1991, in conformance to the regulations of this subchapter in effect on September 30, 1991, need not be remarked if the key words of the proper

shipping name are identical to those currently specified in the § 172.101 Table. For example, a tank car marked "ANHYDROUS AMMONIA" need not be remarked "ANHYDROUS AMMONIA, LIQUEFIED".

39. In § 172.303, the introductory text of paragraph (b) is republished, and paragraph (b)(3) is added to read as follows:

§ 172.303 Prohibited marking.

* * * * *

(b) This section does not apply to—

(1) * * *

(2) * * *

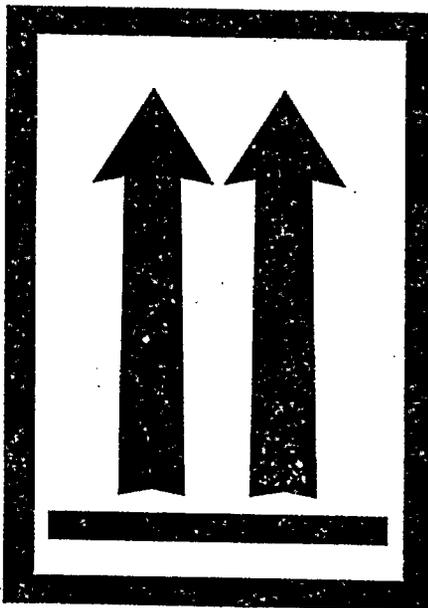
(3) The marking of a shipping name on a package when the name describes a material not regulated under this subchapter.

40. In § 172.312, paragraph (a)(2) is revised, and paragraphs (c)(4) and (c)(5) are added to read as follows:

§ 172.312 Liquid hazardous materials in non-bulk packagings.

(a) * * *

(2) Legibly marked, with package orientation markings that conform pictorially to ISO Standard 780-1985, on two opposite vertical sides of the package with the arrows pointing in the correct upright direction.



Package orientation

(b) * * *

(c) * * *

(4) Liquids contained in manufactured articles (e.g., alcohol or mercury in thermometers) which are leak-tight in all orientations.

(5) A non-bulk package with hermetically-sealed inner packagings.

41. In § 172.313, paragraph (a) is revised to read as follows:

§ 172.313 Poisonous hazardous materials.

(a) For materials poisonous by inhalation (see § 171.8 of this subchapter), the package shall be marked "Inhalation Hazard" in association with the required labels or placards, as appropriate, or shipping name, when required. (See § 172.302(b) of this subpart for size s.

* * * * *

42. In § 172.316, the section heading is revised to read as follows:

§ 172.316 Packagings containing materials classed as ORM-D.

43. Section 172.320 is revised to read as follows:

§ 172.320 Explosive hazardous materials.

(a) Except as otherwise provided in paragraphs (b), (c), (d) and (e) of this section, each package containing a Class 1 material must be marked with the EX-number for each substance, article or device contained therein.

(b) Except for fireworks approved in accordance with § 173.56(j) of this subchapter, a package of Class 1 materials may be marked, in lieu of the EX-number required by paragraph (a) of this section, with a national stock number issued by the Department of Defense or identifying information required by regulations for commercial explosives specified in 27 CFR part 55, if the national stock number or identifying information can be specifically associated with the EX-number assigned.

(c) When more than five different Class 1 materials are packed in the same package, the package may be marked with only five of the EX-numbers, national stock numbers, product codes, or combination thereof.

(d) The requirements of this section do not apply if the EX-number, product code or national stock number of each explosive item described under a proper shipping description is shown in association with the shipping description required by § 172.202(a) of this part. Product codes and national stock numbers must be traceable to the specific EX-number assigned by the Associate Administrator for Hazardous Materials Safety.

(e) The requirements of this section do not apply to the following Class 1 materials:

(1) Those being shipped to a testing agency in accordance with § 173.56(d) of this subchapter;