DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, and 178

[Docket No. RSPA 98–3971 (HM–226)]

RIN 2137–AD13

Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-organisms

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

ACTION: Advance notice of proposed rulemaking (ANPRM); notice of public meeting.

SUMMARY: RSPA is considering revising the requirements for infectious substances, including regulated medical waste (RMW) to: adopt defining criteria, hazard communication and packaging requirements for Division 6.2 materials consistent with international standards; revise broad exceptions for diagnostic specimens and biological products; provide additional packagings for RMW; and make other changes to improve and clarify regulatory requirements and exceptions. These proposals are intended to ensure an acceptable level of safety in the transport of infectious substances, facilitate international transportation and make it easier to understand and comply with the regulations.

In order to enhance the opportunity to provide comments to RSPA concerning this notice, the public is invited to provide written or E-mail comments during the comment period and to participate in an electronic public meeting on the Internet on September 14, 15 and 16, 1998.

DATES: *Comment date:* Comments must be submitted on or before December 1, 1998.

Electronic public meeting date: The electronic public meeting will commence on September 14, 1998, at 9:00 a.m. and end on September 16, 1998 at 12 noon (Eastern Daylight Time).

ADDRESSES: Information on the electronic meeting, including the Internet address, is available under **SUPPLEMENTARY INFORMATION.** *Written comments:* Address written comments to the Dockets Management System, U.S. Department of Transportation, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590–0001. Comments should identify the docket number (Docket Number RSPA–98–3971). Persons wishing to receive confirmation of receipt of their comments should include a self-addressed, stamped postcard. Comments may also be submitted by E-mail to ''rules@rspa.dot.gov''.

Dockets Management System is located on the Plaza Level of the Nassif Building at the Department of Transportation at the above address. Public dockets may be reviewed there between the hours of 10:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. In addition, the public may also review comments by accessing the docket management system through the DOT home page (http://dms.dot.gov). An electronic copy of the document may be downloaded using a modem and suitable communications software from the Government Printing Office Electronic Bulletin Board Service at (202) 512–1661.

FOR FURTHER INFORMATION CONTACT: Eileen Mack, Office of Hazardous Materials Standards, (202) 366–8553, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION: *Electronic public meeting:* The electronic public meeting will be held at the conferences and public meetings section of RSPA's hazmat home page. The Universal Resource Locator (URL) address is ''http://hazmat.dot.gov/forum''. The electronic meeting will enable anyone with Internet access to participate in a near real-time electronic discussion of the rulemaking. This type of meeting may also increase the breadth of domestic and international participation in the commenting process. The message board will be posted on RSPA's hazmat web site and will be hot-linked to this advance notice of proposed rulemaking. A transcript of the electronic public meeting will be placed in the docket. The topics are as follows:

List of Topics

I. Background

On September 20, 1995, RSPA published a final rule (60 FR 48780) to revise the requirements for Division 6.2 materials (infectious substances). The rule clarified the scope of regulation for infectious substances, provided relief for certain shipments of regulated medical waste (RMW) that conform to other Federal agency regulations, allowed certain quantities of RMW to be transported by aircraft, and made other changes to clarify the regulatory provisions applicable to infectious substances. The final rule was intended to address critical, yet non-controversial, issues. RSPA stated in the final rule that other, more complex issues would be considered in a future rulemaking. This ANPRM seeks comment on RSPA's discussion of certain issues and solicits information to address the agency's concerns for safety in transportation of infectious substances and genetically modified micro-organisms and organisms.

II. Revisions Under Consideration

A. World Health Organization (WHO) Risk Groups/International Recommendations and Regulations

In this ANPRM, RSPA is considering revising the classification criteria for infectious substances consistent with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations) and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions). In particular, RSPA is considering adopting risk groups and defining criteria developed by the World Health Organization (WHO) for Division 6.2 materials. These risk groups are described in the following table:

RISK GROUP TABLE

Risk Group	Pathogen	Risk to individuals	Risk to the community
4	Usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available.	HIGH	HIGH.
3	Usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another and for which effective treatment and preventative measures are available.	HIGH	LOW.
2	Can cause human or animal disease but is unlikely to be a serious hazard and, while capable of causing serious infection on exposure, effective treatment and preventive measures are available and only a limited risk of spreading infection exists.	MODERATE.	LOW.
1	Micro-organisms that are unlikely to cause human or animal disease	NONE OR VERY LOW.	NONE OR VERY LOW.

Because the hazards posed by infectious substances vary greatly depending on the pathogenicity of the organism, mode and relative ease of transmission, and other factors, RSPA believes that classifying these materials based on the level of risk and applying requirements commensurate with the risk will ensure an adequate level of safety without imposing an undue burden on the regulated community. RSPA does not intend to provide a list of infectious substances that correlates with each risk group. Instead, RSPA would defer to the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC), Office of Public Health, for guidance in determining the risk group of a specific material. RSPA seeks comments on whetheradoption of this risk-based classification criteria will improve safety in the transportation of infectious substances.

B. Diagnostic Specimens

Currently, in § 173.134 of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180), RSPA defers to the CDC regulations in 42 CFR Part 72 for packaging, hazard communication, and handling in the transportation of diagnostic specimens. Based upon reports of undisclosed and improperly prepared shipments of diagnostic specimens, RSPA believes that many shipments of diagnostic specimens are not properly identified and lack adequate hazard communication. RSPA also is concerned that, in some instances, packagings for diagnostic specimens lack sufficient integrity to survive normal handling in transportation. RSPA's Hazardous Materials Information System (HMIS) database contains a number of reports on packages of these materials that were damaged in transportation, causing costly delays and posing risks to cargo handlers, flight crews, emergency responders, and others who may have been exposed to infectious substances.

At the same time, RSPA recognizes that thousands of shipments of diagnostic specimens are transported by highway without incident to and from clinics, households and laboratories by private or contract carriers. To ensure that diagnostic specimens are regulated consistent with the degree of risk posed by the material, RSPA is considering differentiating between a diagnostic specimen known or suspected to contain an infectious substance and a diagnostic specimen that is offered for transportation and transported for routine screening where there is a lower probability that a risk group 2 or 3 pathogen is present.

RSPA is considering requirements that would treat diagnostic specimens that are known or suspected to contain a Risk Group 2, 3 or 4 pathogen as an infectious substance. For diagnostic specimens transported for routine screening (i.e., materials with a low probability of containing a Risk Group 2 or 3 pathogen), RSPA is considering whether to apply reduced packaging and hazard communication requirements. Proposed § 173.196(c) specifies quantity limits for inner receptacles and for outer packagings, and requires that a packaging meet performance tests for non-bulk packagings in Subpart M of part 178 of the HMR except that the height for the drop test must be at least 1.2 meters (3.9 feet).

C. Biological Products

Under current provisions, biological products are excepted from the HMR provided they meet the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) regulations for the transfer of biological products specified in 9 CFR parts 102, 103, and 104 and 21 CFR parts 312 and 600–680. In this ANPRM, RSPA is considering whether to revise § 173.134(b) to except only licensed biological products. A licensed biological product is defined in this ANPRM as a material approved by FDA for human use as a drug in the diagnosis, cure, mitigation, treatment, or prevention of disease and that is derived from biological sources, e.g., blood plasma and/or platelets and products obtained from these materials. In the case of biological products known to contain infectious substances, RSPA proposes that they be treated as infectious substances. RSPA is interested in receiving information on whether the risks associated with the transportation of licensed biological products warrant the granting of these exceptions and whether there are any risks that have been overlooked. RSPA is also interested in information concerning whether it is appropriate for RSPA to continue to defer to FDA and USDA regulations regarding these materials.

In addition to the above, RSPA is considering whether to add a new special provision in § 172.102 (consistent with ICAO Technical Instruction Special Provision A81) to except blood and blood products from existing quantity limits by aircraft when the materials are packaged in accordance with proposed § 173.196, packaged in primary receptacles that do not exceed 500 ml (17 ounces), and contained in outer packagings not exceeding 4 L (1 gallon).

D. Genetically Modified Organisms and Micro-organisms

The UN Recommendations and the ICAO Technical Instructions treat any genetically modified material that meets the definition of Division 6.2 as an infectious substance. In addition, those international standards classify a genetically modified material that does not meet the definition of a Division 6.2 material, but is capable of altering animals, plants, or microbiological substances in a way not normally the result of natural reproduction, in hazard class 9 material. The UN Recommendations also contain a

provision that excludes from regulation genetically modified micro-organisms that are authorized and licensed for use by the government of the country of origin, transit, and destination.

RSPA is considering whether to align the HMR with the international provisions for genetically modified organisms and micro-organisms. RSPA invites commenters to address whether RSPA should proceed with developing regulations for genetically modified micro-organisms or whether provisions for the safe transport of these substances are adequately addressed in other agencies' regulations. Are the conditions specified in proposed § 173.140 that provide exceptions from the HMR for genetically modified micro-organisms and organisms justifiable in terms of safety and are they easily understood, or are there alternative safety controls that may be more appropriate?

E. Hazard Communication

RSPA is considering several options with respect to the marking or placarding of bulk packagings and transport vehicles containing infectious substances, including regulated medical waste (RMW), and is interested in receiving comments on those options. RSPA is considering requiring the display of an INFECTIOUS SUBSTANCE placard for any quantity of an infectious substance known or reasonably expected to contain a Risk Group 4 pathogen. RSPA seeks comment on whether a requirement to display placards on bulk packagings, freight containers, unit load devices, transport vehicles, or rail cars for shipments of infectious substances known or reasonably expected to contain a Risk Group 4 pathogen, regardless of the quantity of material, is necessary. RSPA is considering amending § 172.504(e), Table 1, column 1, to include 6.2 infectious substances known or reasonably expected to contain a Risk Group 4 pathogen, and to add the appropriate references to an INFECTIOUS SUBSTANCE placard in columns 2 and 3 of the Table. Additionally, a new ''INFECTIOUS SUBSTANCE'' placard would be proposed, as shown below:

BILLING CODE 4910-60-P

BILLING CODE 4910-60-C

RSPA is also considering whether placards should be required to be displayed for bulk packagings, freight containers, unit load devices, transport vehicles or rail cars that contain other infectious substances, including RMW. If placarding is considered necessary, Table 2 of § 172.504 would be revised to

require display of placards for these materials. Consistent with exceptions in § 172.504(c), transport vehicles or freight containers that contain less than 454 kg (1,001 pounds) aggregate gross weight of infectious substances would not be required to be placarded. Alternatively, RSPA is considering a requirement to mark bulk packagings, freight containers, transport vehicles or rail cars with a display similar to that required for units that have been fumigated. For example, a rectangular display with the words ''REGULATED MEDICAL WASTE'' could be prominently displayed so that it can be readily seen by any person attempting to enter the interior of the bulk packaging, freight container, transport vehicle, or rail car. This marking is being considered for domestic transportation of infectious substances, other than those known or reasonably expected to contain a Risk Group 4 pathogen (see discussion above).

RSPA requests comments on the following questions:

1. Should placarding be required for an infectious substance known or reasonably expected to contain a Risk Group 4 pathogen regardless of the quantity of material in the bulk packaging, freight container, transport vehicle or rail car?

2. For RMW, should placarding be required for a bulk packaging, freight container, transport vehicle or rail car which contains RMW? Alternatively, should an optional marking, such as ''REGULATED MEDICAL WASTE,'' be authorized in lieu of placards?

3. Should other infectious substances shipments (e.g., those known or reasonably expected to contain a Risk Group 2 or 3 pathogen) be required to display an INFECTIOUS SUBSTANCE placard? Should an optional marking, such as the term ''BIOHAZARD'' appearing in a rectangular display alongside the BIOHAZARD trefoil symbol, be authorized in lieu of placards?

4. Are placarding and marking proposals for infectious substances, as considered in this ANPRM, necessary and effective for communicating the infectious substance hazard to emergency responders?

5. Will transportation safety be significantly improved if placarding or identification number marking is required?

6. What costs would be incurred by shippers and carriers of infectious substances, including RMW, in fulfilling the proposed placarding requirements or the alternate marking requirements? Are there less costly alternatives to communicate the hazards of infectious substances, including RMW?

7. If placards are required, how many drivers would need to obtain a commercial drivers license (CDL) or a hazardous material (HM) endorsement to the CDL? What would be the associated impacts, including costs?

8. With respect to labels, RSPA is also considering revising the telephone number on its INFECTIOUS SUBSTANCE label to reflect the CDC's new toll free telephone number for reporting incidents involving infectious substances. Even though both CDC telephone numbers are currently in operation, should a transition period be provided to allow for use of existing inventories of currently required labels? If so, how long?

F. Regulated Medical Waste

RSPA is considering authorizing non-specification bulk packagings meeting conditions set forth in proposed § 173.197(b) for RMW. Currently, bulk packagings are only authorized under the terms of 18 exemptions. This proposal would incorporate the provisions of some of these exemptions into the HMR to allow the use of non-specification bulk packagings for RMW under specific conditions, thereby eliminating the need for exemptions. These bulk packagings would require inner packagings that are securely closed and leak-resistant to be placed inside fiberglass or plastic containers, bins, or carts. With certain exceptions, these packagings have demonstrated through the exemption process that they provide an acceptable level of safety in transportation.

RSPA is considering, also, whether to revise the quantity limitations in columns (9A) and (9B) of § 172.101 for RMW to read ''No Limit'' to reflect the language in the ICAO Technical Instructions for maximum net quantity permitted per non-bulk package. RSPA notes that the ICAO Technical Instructions in Packing Instruction 622 restrict infectious substances, such as RMW, to non-bulk packagings only. Consistent with ICAO Technical Instructions, RSPA is considering whether to limit RMW in bulk packagings to non-air modes (railcar, motor vehicle, vessel) only.

1. Should the HMR be revised to authorize caster carts as reusable outer packagings for RMW packaged in plastic film bags, as currently authorized by 12 exemptions? If so, what specifications and size limitations are appropriate for caster carts?

2. Should the HMR be revised to authorize roll-off bins as reusable outer packagings for RMW packaged in plastic film bags, as currently authorized by 7 exemptions? If so, what specifications and size limitations are appropriate for roll-off bins?

3. If caster carts or roll-off bins are authorized for transporting RMW in plastic film bags, should film bags be required to be single or multiple ply with a total film thickness of 3 mils, a volume not more than 46 gallons, and a weight not more than 22 pounds, or are there more appropriate specifications?

4. If authorized for reuse to transport RMW, should roll-off bins and caster carts be decontaminated with a disinfectant solution after each use?

5. Should hospitals or clinics that use roll-off bins to transport RMW be required to register as shippers of bulk hazardous materials?

6. Should there be a time limit on the period a bin may hold RMW at the generator's site, to prevent the waste from decomposing and possibly releasing high concentrations of infectious vapors should a film bag be torn?

7. Should roll-off bins be allowed only if they are mechanically unloaded, without the inner packaging being handled manually?

G. Materials of Trade Exception

Under Docket HM–200, Hazardous Materials in Intrastate Commerce (62 FR 1216, as amended at 62 FR 49566 and 62 FR 51560), RSPA adopted exceptions from most of the requirements of the HMR for hazardous materials when transported as materials of trade. Materials of trade include certain hazardous materials carried by a private motor carrier engaged in a principal business other than transportation, such as lawn care, plumbing, welding, door-to-door sale of consumer goods, and farm operations. Specific limitations (such as maximum gross weight of materials of trade that may be carried on a motor vehicle) and safety provisions (such as packaging and hazard communication) contained in current § 173.6 achieve an acceptable level of safety at a minimal cost to the carrier.

In this ANPRM, RSPA is inviting comments on whether to amend § 173.6 to permit certain biological products, diagnostic specimens and RMW in Division 6.2, to be transported by private carraige as materials of trade. Entities, such as home health care and diagnostic laboratories, that transport smaller amounts of infectious substances in direct support of a principal business other than transportation would be included.

RSPA requests comments on whether an acceptable level of safety would be

achieved, also, through a materials of trade exception for infectious substances. What, if any, hazard communication should be required for carriage of such materials? If so, what should the communication be?

Section 173.6 specifies quantity limits for the packaging and the motor vehicle, and minimal hazard communication, for materials transported by a private motor carrier engaged in a principal business other than the transportation of hazardous materials. RSPA invites comments on the costs and benefits associated with this proposal and whether special recognition should be given to private carriage by highway, including the transportation of risk group 4 pathogens.

H. Discussion of Petition for Rulemaking

On August 28, 1997, The Medical Waste Institute (MWI) submitted a petition for rulemaking (P–1350) requesting relief for the transportation of waste cultures and stocks that meet the definition for infectious substances. This petition and its enclosures have been entered as part of the public docket for this rulemaking and can be obtained by contacting the Department of Transportation Dockets Management System using the information provided in the address section at the beginning of this rule.

Specifically, MWI requested that RSPA revise the HMR to allow contract and private motor carriers to transport discarded cultures and stocks of infectious substances in non-specification packagings if the carriers use dedicated vehicles. The petitioners requested that this relief be authorized for Biosafety Level 1, 2, and 3 materials, as defined in Health and Human Services publication No. 93–8395. These biosafety levels are based on the same WHO risk groups as referenced in § 173.134(a) of the accompanying regulatory text. Currently, the HMR allows this type of transportation for RMW that does not contain a waste culture or stock of an infectious substance. The HMR require a waste culture or stock to be transported in a packaging meeting the performance criteria in § 178.609. Section 178.609 specifies requirements for a triple packaging that survives several rigorous performance tests, including a 9 m (30-foot) drop test and a 1 m (3-foot) puncture test. By comparison, § 173.197 currently requires that the packaging for RMW that does not contain a waste culture or stock of an infectious substance meet performance criteria of a UN specification packaging at the Packing Group II performance level contained in 49 CFR Part 178, Subpart M, except § 178.609. In addition, when packaging authorized in § 173.134 is used, RSPA currently requires that the material be transported in a dedicated vehicle by a private or contract carrier and conform to Biosafety Levels 1, 2, or 3.

MWI included with its petition for rulemaking DOT and State incident data on infectious substances from 1989 through March 1997. The petitioner stated that the information shows a relatively low number of hazardous materials incidents in the U.S. involving a release of RMW transported by highway. MWI further said that:

- The CDC reports hospital waste disposal practices have not resulted in epidemiologic evidence of disease in communities;
- Emergency responders take the same precautions with infectious substance releases as they do with RMW releases;
- Packing group II packagings are not justified for discarded cultures and stocks;
- Discarded cultures and stocks from non-health care settings pose the same level of risk as those from health care settings; and
- The HMR's general packaging requirements coupled with OSHA's bloodborne packaging standards have a proven safety record.

From these points, the MWI concluded that the current packagings required in the HMR for discarded cultures and stocks are not justified because they are onerous and expensive and lack a safety record that proves their actual public health and safety benefit. The MWI also enclosed an EPA press release announcing its medical waste incinerator program, and language that MWI suggests justifies discarded cultures and stocks to be defined as RMW when transported by private or contract motor carriers.

As a result of a provision in § 171.15(b) and the wording of the INFECTIOUS SUBSTANCE label in § 172.432, many releases of infectious substances are reported directly to CDC but not to RSPA. Section 171.15(b) allows carriers that report infectious substance (etiologic agent) incidents the option of reporting the event to the CDC or DOT. Although § 171.15(c) requires incident information reported to CDC to be reported to RSPA in the form of a written report, often this information is not provided to RSPA. This has resulted in an under-reporting of these events in RSPA's HMIS incident database. Further, pre-1996 HMR exceptions for packagings containing 50 ml (1.7 ounces) or less of an infectious substance (known then as an etiologic agent) were often misapplied and used to ship larger amounts of an infectious substance.

The § 171.15(b) exception, when properly applied, relieved carriers from immediate telephonic notification requirements of the HMR. It was intended to avoid duplication with CDC regulations because these materials were subject to CDC requirements in 42 CFR Part 72. Because a number of incidents involving infectious substances were not reported to DOT, RSPA is considering revising § 171.15 to clarify that any incident involving the release of an infectious substance be reported to RSPA, in addition to the CDC, in the form of an incident report.

Over the last few years, individuals and companies commenting on infectious substance rulemakings, or on their own initiative, reported to RSPA information concerning infectious substance releases. They have reported witnessing blood pouring from rolloffs and freight containers transporting RMW, the disposal of AIDS-contaminated blood in municipal waste cans, overturned vehicles that have released diagnostic specimens on the highways, leaking non-bulk packagings of RMW, ruptured packages containing diagnostic specimens being transported by aircraft, releases of treatment-resistant diseases from insufficient packaging, and used sharps that punctured inner packagings. As a result of information received from these sources, and through RSPA's own initiative and incident reporting system, RSPA is now considering whether to take a more conservative approach, on the side of safety, to the transportation of waste cultures and stocks.

Several commenters, responding to earlier NPRMs issued on this subject under Docket HM–181G, stated that a high concentration of micro-organisms exist in cultures and stocks of infectious substances. These micro-organisms have the potential to cause disease and, therefore, require special handling. CDC supported special handling of these materials in a October 24, 1996 final rule (61 FR 55190) and in response to RSPA's rulemaking actions on infectious substances issued under Docket HM–181G. In meetings and conversations with RSPA, CDC recommended more rigorous packagings for cultures and stocks of infectious substances. Therefore, RSPA did not base its current regulations for these materials solely on incident reports. In addition, RSPA recommends, through guidance provided in the 1996 North American Emergency Response Guidebook, that emergency responders treat infectious substances and RMW

the same since both are Division 6.2 materials.

RSPA finds, through experience gained under exemption DOT–E 11588, that Packing Group II packagings transported by a private or contract carrier in a dedicated vehicle provide an acceptable level of protection for waste cultures and stocks of infectious substances. Private and contract carriers that transport these materials have an increased level of knowledge from working with these materials. Moreover, use of dedicated vehicles limits exposure of these packagings to other packagings and assures that shipments are handled by experienced personnel. RSPA also finds that the general packaging requirements in §§ 173.24 and 173.24a coupled with OSHA's packaging requirements for bloodborne pathogens contained in 29 CFR 1910.1030 are adequate for less virulent infectious substances. RSPA seeks specific comments on the MWI petition for rulemaking.

I. Segregation from Foodstuffs

RSPA currently requires segregation of poisons from foodstuffs. Is there sufficient justification to support imposing similar restrictions on all or certain packages containing infectious substances?

III. Section-by-Section Review

This discussion is included to provide the reader with additional information to more fully explain potential approaches. RSPA seeks comments on these potential approaches and may publish an NPRM to further refine these approaches or to propose alternatives to these approaches based on comments we receive.

Section 171.14

Paragraph (f) would be added to establish a two-year transition period for the use of infectious substance labels that do not include the CDC's new toll-free telephone number for reporting infectious substance incidents.

Section 171.15

In paragraphs (a) (3) and (b), the term ''etiologic agents'' would be revised to read ''infectious substances.'' In paragraph (b), information would be added to clarify that a written report, DOT Form F 5800.1, is required for all infectious substance incidents, including those reported to the CDC.

Section 172.101

For the entry, ''Regulated medical waste'', the letter ''D'' in column (1) would be removed, in column (7) the reference to Special Provision A14 would be removed, and columns (9A) and (9B) would be amended to indicate ''No limit'' as opposed to ''Forbidden'' for quantity limitations. These changes would harmonize requirements in the HMR with those in the ICAO Technical Instructions and facilitate the transport of RMW in non-bulk packagings by aircraft. It should be noted that, although ''No limit'' would be specified for per-package quantity limits in the Hazardous Materials Table (the Table), Special Provision A13 would be revised to prohibit the use of bulk packagings aboard aircraft. Further, quantity limits may apply with regard to the types of packagings authorized for RMW in Part 173 and to air transportation under § 175.75. RSPA requests comments concerning the need, if any, for further limitations or relaxations on the quantities of RMW authorized for transportation by aircraft.

For the entries ''Infectious substances, affecting animals only'' and ''Infectious substances, affecting humans'' new special provisions would be added in Column (7). One, A81, would provide relief from quantity limits for the transport of blood or blood products known to contain or suspected of containing infectious substances when in primary receptacles not exceeding 500 ml (17 ounces) and in outer packagings not exceeding 4 L (1 gallon) and packaged in accordance with § 173.196. The second, A82, would provide relief from UN standard packaging for transporting body parts, whole organs, and whole bodies.

A new entry, ''Genetically modified micro-organisms'' would be added to the Table as a Class 9 (miscellaneous) material consistent with the entry in the UN Recommendations, the ICAO Technical Instructions and the IMDG Code.

Another new entry, ''Diagnostic Specimen'', would be added to the Table as a Division 6.2 material. However, this proper shipping name would be authorized only for diagnostic specimens excepted under proposed § 173.196(c). There would be no identification number, hazard warning label, or packing group assignment.

In order to eliminate any confusion and costs that could result from the use of several proper shipping names for the same material, the other proper shipping names for infectious waste that are authorized in the UN Recommendation and the ICAO Technical Instructions, ''Biomedical waste, n.o.s.'', ''Clinical waste, unspecified, n.o.s.'', and ''Medical waste, n.o.s.'', would not be added to § 172.101. RSPA believes the proper shipping name ''Regulated medical waste'' more accurately describes the material and is the preferable shipping name. Also, it is RSPA's understanding that the other names were added to satisfy requests from specific countries that were already using these shipping names. International shipments using these names would be authorized for transport to their final destinations under the import-export provisions in §§ 171.11, 171.12, and 171.12a.

Section 172.102

Special Provision A13 would be revised to prohibit the use of bulk packagings for RMW aboard aircraft, thus imposing a maximum gross mass of 400 kg or 450 L per package. Special Provision A14 would be removed.

Two new Special Provisions, A81 and A82, that are consistent with A81 in the ICAO Technical Instructions, would be added, as discussed earlier in this section-by-section review under § 172.101.

Section 172.432

The current telephone number, ''404–633–5313'', printed on the INFECTIOUS SUBSTANCE label for reporting infectious substance incidents would be changed at the request of CDC to reflect its new toll free phone number for this purpose, to ''800–232–0124''. A two-year transition period would be provided in § 171.14 to allow shippers to exhaust their label inventories.

Section 173.6

Paragraph (a)(4) would be redesignated as paragraph (a)(5) and a new paragraph (a)(4) would be added to permit certain biological products, diagnostic specimens and RMW in Division 6.2 to be transported by entities, such as home health care providers and diagnostic laboratories, that transport smaller amounts of infectious substances in direct support of a principal business other than the transportation of hazardous materials.

Section 173.134

The criteria for Division 6.2 materials specified in § 173.134 would be revised based on the UN Recommendations and the 1999–2000 edition of the ICAO Technical Instructions. This section would also be revised to incorporate certain domestic exceptions for transportation by highway. The current definition for infectious substances would be revised to remove the term ''viable microorganism'' and clarify the term ''pathogens.'' The defining criteria would exclude toxins, include the WHO risk groups, and except from Division 6.2 infectious substances that are unlikely to cause disease, i.e., risk group

1 pathogens. The definitions for the terms ''diagnostic specimen'' and ''biological product'' would be amended to include the WHO risk groups and be compatible with the ICAO Technical Instructions. Paragraph (b) would be amended to except licensed biological products from regulation under the HMR and, under certain conditions, except diagnostic specimens and biological products where a low probability exists that they contain a WHO risk group 2 or 3 pathogen.

RSPA is considering requiring that animals which contain or are contaminated with genetically modified micro-organisms or organisms (§ 173.140(d)(4)) that meet the criteria of an infectious substance (§ 173.134(c)(5)) be transported under terms and conditions approved by RSPA's Associate Administrator for Hazardous Materials Safety, consistent with standards specified in the UN Recommendations and ICAO Technical Instructions.

Section 173.140

New paragraphs (c) and (d) would be added to provide defining criteria and exceptions for a genetically modified micro-organism that does not meet the definition of a Division 6.2 material but has the potential to alter animals, plants, or the environment. These materials would be assigned to the Class 9 hazard class. A genetically modified micro-organism that meets the criteria for a Division 6.2 material would be classed and described as an infectious substance. A genetically modified micro-organism would be required to be packaged in accordance with § 173.196, except that the packagings need not be marked in accordance with § 178.503 or tested in accordance with § 178.609. In addition, the quantity in the primary receptacles would be limited to a maximum of 100 ml (3.4 ounces) or 100 g (4 ounces) for consistency with the ICAO Technical Instructions. A Class 9 genetically modified micro-organism and organism packages would not be assigned a packing group and would be excepted from all requirements in the HMR if authorized for final distribution and use by a U.S. Government agency.

Section 173.196

Existing paragraph (a) would be revised and redesignated as paragraph (b). New paragraph (a) would clarify that § 173.196 prescribes non-bulk packagings for infectious substances. Existing paragraphs (b), (c), (d), and (e) would be incorporated in new paragraph (b). New paragraph (b) would include an exception from requirements for an absorbent material for solid infectious substances, and other revisions to provide consistency with the ICAO Technical Instructions. These revisions would include package and overpack marking requirements and requirements to ensure the containment integrity of the packagings during air transport, including circumstances where the refrigerant is dissipated or lost. The existing text in paragraph (h) of this section excepting biological products and diagnostic specimens from regulation under the HMR would be deleted. New exceptions for diagnostic specimens and biological products would be relocated to § 173.134. A new paragraph (c) would be added to remove from regulation diagnostic specimens with a low probability of containing a risk group 2 or 3 pathogen when a limited amount of the material is placed in a non-specification packaging. A new paragraph (d) would be added to prescribe non-specification packaging provisions for body parts and certain diagnostic infectious substances. Former paragraph (g) would be renamed paragraph (e).

Section 173.197

RSPA is considering revising the RMW packaging requirements to allow five types of packagings: (1) infectious substances packaging in accordance with § 173.196; (2) RMW packaging in accordance with current § 173.197; (3) packagings that conform to 29 CFR 1910.1030; (4) non-specification bulk packagings currently authorized under exemptions; and (5) intermediate bulk containers (IBCs).

In addition, the provisions for RMW packaging meeting the criteria in § 173.197 would be revised to permit liquid materials to be placed in a packaging suitable for solids when the liquid can be fully absorbed by the absorbent material in the packaging, the packaging is capable of retaining liquids, and the packaging conforms to the OSHA bloodborne pathogen packaging standards in 29 CFR 1910.1030.

Existing paragraph (b) would be removed because the anniversary date for this provision is no longer applicable.

Several commenters to earlier rulemakings on RMW were unaware that the HMR allow the use of non-bulk, single packagings for RMW. This proposal would clarify that the packaging requirements in § 173.197 allow the shipper to use single or combination UN specification packagings if the performance standards are met.

Section 178.503

In § 178.503, a new paragraph (f) would be added to incorporate package markings consistent with those in the ICAO Technical Instructions and UN Recommendations for infectious substances.

Section 178.601

A sentence would be added to paragraph (c)(1) of this section to include the tests for infectious substance packaging in the definition for design qualification testing. As a result of this change, manufacturers of infectious substance packagings would be required to retain design qualification records, as required in § 178.601(l).

Section 178.609

Several amendments may be incorporated in this section to harmonize it with the UN Recommendations and the ICAO Technical Instructions. The section heading may be revised to remove the wording ''(etiologic agents)''. Paragraph (c) would be revised to permit the use of expanded plastics for inner packagings and require the packaging tests to be determined by the most fragile inner packaging. Paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv) would be revised for editorial purposes. Paragraph (e) would be revised to replace the current water immersion test with a water spray test that simulates exposure to rainfall consistent with the ICAO Technical Instructions. The last sentences in paragraphs (h)(1) and (h)(2) would be revised to clarify the requirements for conducting the penetration test. Specifically, the text would be revised to clearly indicate that penetration of the primary receptacle is not acceptable. Paragraph (i) would be revised to clarify that infectious substances are required to be marked in accordance with § 178.503 and redesignated as a new paragraph (l). New paragraphs (i), (j) and (k) would be added to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions. These provisions allow variations in the primary receptacles within the secondary packaging without further testing of the completed packaging if an equivalent level of performance is maintained.

IV. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This ANPRM is not a significant regulatory action under section 3(f) of Executive Order 12866, and was not

reviewed by the Office of Management and Budget. It is not a significant regulatory action under the regulatory policies and procedures of the Department of Transportation (44 FR 11034, March 1, 1979).

Any future NPRM on infectious substances may contain proposals that have substantial effects on hospitals (SIC 8062), nursing and personal care facilities (SIC 8059), medical and dental laboratories (SIC 807), home health care services (SIC 8082), offices and clinics of doctors of medicine (SIC 8011) and dentists (SIC 8021), and research, development and testing services (SIC 8731). The primary economic impact of a proposed rule along the lines of this ANPRM would be on persons who offer for transportation or transport diagnostic specimens and biological products, subclassifications of infectious substances that are currently excepted from all requirements of the HMR. At this time, RSPA has neither sufficient data in the form of reported incidents concerning fire, breakage, spillage, or suspected contamination involving shipments of diagnostic specimens and biological products with which it may assess actual risks in transportation. Also, RSPA does not have a thorough understanding of current distribution systems by which it may estimate costs that would result from a decision to apply requirements of the HMR to various modes of transportation and types of carriage (i.e., common, contract and private). A primary purpose of this ANPRM is for RSPA to gather additional information that will assist the agency in measuring the anticipated benefits to society, through increased safety in the transportation of these hazardous materials, against anticipated costs to society resulting from new rules and regulations. RSPA requests comments on costs and benefits that may result from any future rulemaking.

B. Executive Order 12612

This notice has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 (''Federalism''). Federal hazardous materials transportation law, 49 U.S.C. 5701–5127, contains an express preemption provision (49 U.S.C. 5125(b)) that preempts State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(i) the designation, description, and classification of hazardous material;

(ii) the packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(iii) the preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents;

(iv) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(v) the design, manufacturing, fabricating, marking, maintenance, reconditioning, repairing, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This advance notice of proposed rulemaking addresses covered subjects under items i–v above and, if adopted, would preempt State, local, or Indian tribe requirements not meeting the ''substantively the same'' standard. Federal hazardous materials transportation law provides at Sec. 5125(b)(2) that if RSPA issues a regulation concerning any of the covered subjects RSPA must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. Thus, RSPA lacks discretion in this area, and preparation of a federalism assessment is not warranted.

C. Executive Order 13084

This notice has not yet been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because revised rules and regulations evolving from this ANPRM are not expected to significantly or uniquely affect the communities of Indian tribal governments, the funding and consultation requirements of this Executive Order would not apply. Nevertheless, this ANPRM specifically requests comments from affected persons, including Indian tribal governments, as to its potential impact.

D. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), RSPA must consider whether a potential notice of proposed rulemaking would have a significant economic impact on a substantial number of small entities. Unless alternative definitions have been established by the agency in consultation with the Small Business Administration, the definition of ''small business'' has the same meaning as under the Small Business Act. Because RSPA has established no special definition, the agency employs thresholds published under criteria in 13 CFR 121.101, e.g., $5 million for facilities falling within major group 80 (health services) and 500 employees for commercial physical and biological research (SIC 8731).

Because it has not yet proposed any new requirements, RSPA cannot yet determine potential effects upon small entities. Accordingly, an Initial Regulatory Flexibility Assessment discussing the impact of this potential rulemaking on small entities has not been prepared. However, RSPA has determined that an NPRM that closely follows considerations in this ANPRM may have potential impacts on small businesses, and State and local governments. The agency expects that comments received on this ANPRM will assist it in determining the number of potentially affected small entities and in weighing the impact of various regulatory alternatives for the purpose of drafting revised rules and regulations.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. This ANPRM does not propose any new information collection burdens.

F. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

G. Unfunded Mandates Reform Act

This ANPRM imposes no mandates and thus does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labels, Markings, Packaging and containers, Reporting and record keeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers.

49 CFR Part 178

Hazardous materials transportation, Packaging and containers.

In consideration of the foregoing, 49 CFR parts 171, 172, 173, and 178 may be proposed to be amended as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citiation for part 171 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR part 1.

1a. Section 171.14 would be amended by adding paragraph (f) to read as follows:

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

* * * * *

(f) Until [TWO YEARS FROM THE EFFECTIVE DATE OF FINAL RULE], labels which conform to specifications in subpart E of part 172 contained in the 49 CFR, parts 100 to 185, edition revised as of October 1, 1998, for a Division 6.2 material may be used in place of the Division 6.2 labels currently specified in subpart E of Part 172 of this subchapter.

§ 171.15 [Amended]

2. In § 171.15, the following changes would be made:

a. Paragraph (a)(3) would be amended by removing the term ''(etiologic agents)''.

b. Paragraph (b) would be amended by removing the term ''etiologic agents'' and in its place adding the term ''infectious substances''.

c. Paragraph (b) would be amended by adding the wording ''; however, a written report is still required as stated in paragraph (c) of this section'' immediately after the number ''202–267–2675''.

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION AND TRAINING REQUIREMENTS

3. The authority citation for part 172 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

3. In § 172,101, the following proper shipping names would be added to or revised in the Hazardous Materials Table: following proper shipping names would be added to or revised in the Hazardous Materials Table:

§ 172.101 Hazardous Materials Table

* * * * *

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or Division	Identification Numbers	PG	Label codes	Special provisions	(8) Packaging (§ 173.***)			(9) Quantity limitations		(10) Vessel stowage	
							Exceptions	Nonbulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[ADD]												
	Diagnostic specimen	6.2				A82	134	196	None	4L or 4kg	4L or 4kg.		
	* * * * * * * * *												
	Genetically modified micro-organisms.	9	UN3245		9		140	140	None	No Limit	No Limit	B.	
	* * * * * * * * *												
	[REVISE]												
	Infectious substances, affecting animals, only.	6.2	UN2900		6.2	A81, A82	134	196	None	50 ml or 50 g.	4L or 4kg	B.	
	Infectious substances, affecting humans.	6.2	UN2814		6.2	A81, A82	134	196	None	50 ml or 50 g.	4L or 4kg	B.	
	* * * * * * * * *												
	Regulated medical waste	6.2	UN3291		6.2	A13	134	197	197	No Limit	No Limit	E.	
	* * * * * * * * *												

* * * * *

4. In § 172.102, in paragraph (c)(2), Special provision A14 would be removed, Special Provision A13 would be revised, and Special Provisions A81 and A82 would be added in alphanumeric order to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(2) * * *

A13 Bulk packagings are not authorized for transportation by aircraft.

* * * * *

A81 The quantity limits in column (9A) do not apply to blood or blood products known to contain or suspected of containing infectious substances when transported in primary receptacles not exceeding 500 ml (17 ounces) and in outer packagings not exceeding 4 L (1 gallon) and packaged in accordance with § 173.196.

A82 The quantity limits in columns (9A) and (9B) do not apply to body parts, whole organs or whole bodies known to contain or suspected of containing infectious substances; these materials must be packaged in accordance with § 173.134 of this subchapter or, alternatively, in a strong outer packaging in accordance with 173.196(c)(3) with leakproof inner receptacles or liners so as not to present a hazard to persons or animals during transport.

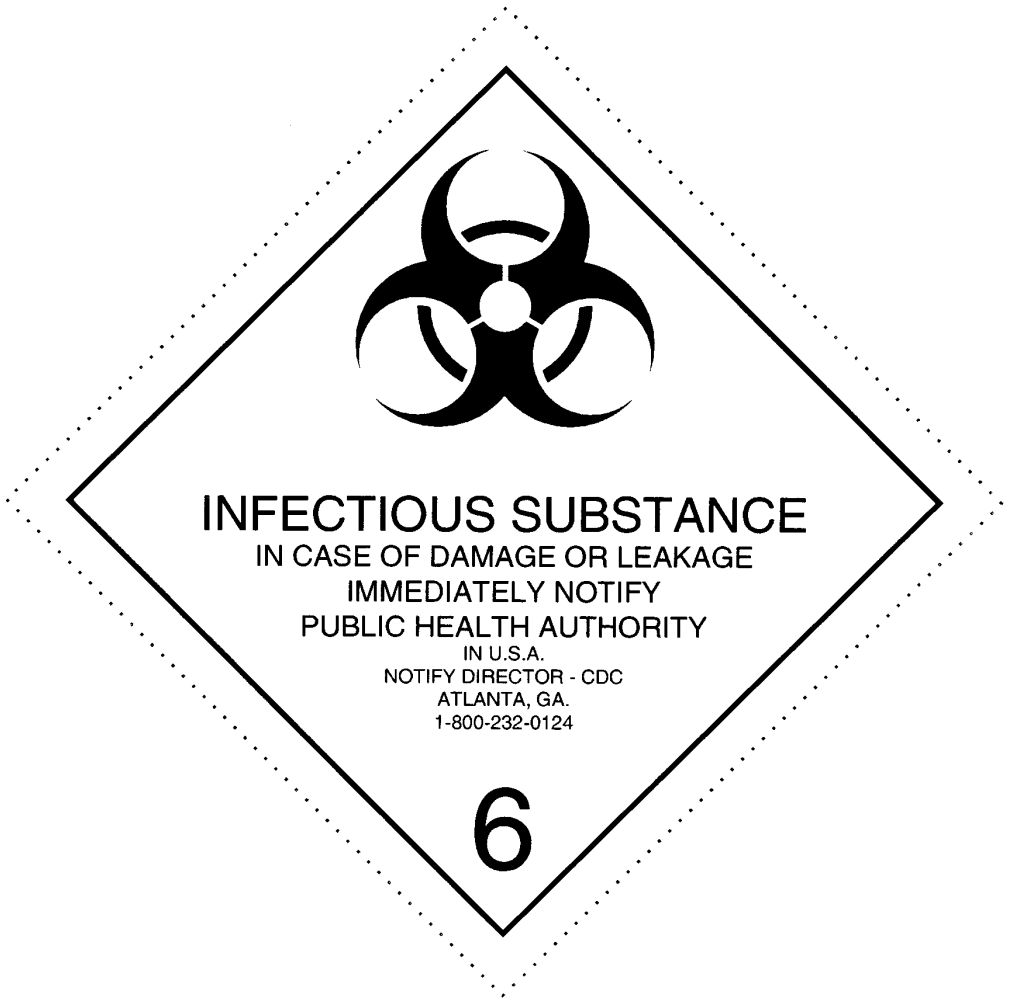
* * * * *

5. Section 172.432, the illustration in paragraph (a) and paragraph (b) would be revised to read as follows:

§ 172.432 INFECTIOUS SUBSTANCE label.

(a) * * *

BILLING CODE 4910–60–P



BILLING CODE 4910–60–c

(b) In addition to complying with § 172.407, the background on the INFECTIOUS SUBSTANCE label must be white.

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

5. The authority citation for part 173 would continue to read as follows:

Authority: 49 U.S.C. 51015127, 44701; 49 CFR 1.45, 1.53.

6. In § 173.6, paragraph (a)(1) introductory text would be amended by adding the term ''6.2'' immediately following the term ''6.1'', paragraph (a)(4) would be redesignated as paragraph (a)(5) and a new paragraph (a)(4) would be added to read as follows:

§ 173.6 Materials of trade exceptions.

* * * * *

(a) * * *

(4) A Division 6.2 material, other than a risk group 4 or a culture or stock, that is a diagnostic specimen, biological product or regulated medical waste contained in a combination packaging consisting of inner packagings having a gross mass or capacity not over 0.5 kg (1 pound), or 0.5 L (1 pint), and an outer packaging having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon).

* * * * *

7. Section 173.134 would be revised to read as follows:

§ 173.134 Class 6, Division 6.2—Definitions and exceptions.

(a) *Definitions.* For the purposes of this subchapter, the following terms pertain to Division 6.2 (infectious substances) materials:

(1) *Division 6.2 material* means a material containing an infectious substance subject to the requirements of this subchapter, including, but not limited to, a biological product, a diagnostic specimen, cultures and stocks of an infectious substance, and regulated medical waste.

(2) *Infectious substance* means a material known to contain, or reasonably expected to contain, pathogens. Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant micro-organisms (hybrid or mutant) that are known or reasonably expected to cause infectious disease in humans or animals. An infectious substance is assigned to a risk group based on its level of risk and is subject to the provisions of this subchapter as a Division 6.2 material if it has the potential to spread disease when exposure to it occurs.

(3) *Biological product* means a material derived from a living organism that is manufactured and distributed in accordance with the provisions of 9 CFR part 102 (Licenses for Biological Products), 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing), 9 CFR part 104 (Permits for Biological Products), 21 CFR part 312 (Investigational New Drug Application), or 21 CFR parts 600 to 680 (Biologics). A biological product is used for prevention, treatment, or diagnosis of disease in humans or animals, or for developmental, experimental, or investigational purposes related to these uses. This term includes, but is not limited to, a finished or unfinished product such as a vaccine; however, it does not include a diagnostic specimen.

(4) *Cultures and stocks* means material that contains a risk group 2, 3 or 4 pathogen for purpose of growth or storage.

(5) *Diagnostic specimen* means any human or animal material including, but not limited to, excreta, secreta, blood, blood and its components, tissue, and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live humans or animals. Exceptions are provided in paragraph (c)(4) of this section for Risk Group 2, 3, and 4 materials transported by private or contract motor carrier.

(6) *Regulated medical waste* means a waste or reusable material that contains or is suspected of containing an infectious substance in other than risk group 4 and is generated in—

(i) The diagnosis, treatment or immunization of human beings or animals;

(ii) Research pertaining to the diagnosis, treatment or immunization of human beings or animals; or

(iii) The production or testing of biological products.

(7) *Risk group* means a ranking based on level of risk using criteria developed by the World Health Organization (WHO). A risk group is characterized by the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. The criteria for each risk group according to the level of risk are as follows:

(i) *Risk group 4* means a pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventative measures are not usually available (i.e., high individual and community risk).

(ii) *Risk group 3* means a pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatment and preventative measures are available (i.e., high individual risk and low community risk).

(iii) *Risk group 2* means a pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatment and preventive measures available and the risk of spread of infection is limited (i.e., moderate individual risk and low community risk).

(iv) *Risk group 1* means a micro-organism that is unlikely to cause human or animal disease (i.e., no, or very low, individual or community risk). A material containing only such micro-organisms is not subject to the requirements of this subchapter.

(8) *Sharps* means any object that can penetrate the skin, including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires that may be contaminated with a pathogen.

(b) *Exceptions for biological products.* (1) A biological product which is known or reasonably expected to contain a pathogen in risk groups 2, 3, or 4 must be classified in Division 6.2 under UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(2) A biological product that has successfully completed all screening and confirmatory tests required by the Food and Drug Administration of the Department of Health and Human Services or the Department of Agriculture, as appropriate, to identify pathogens is not considered an infectious substance and is not subject to the requirements of this subchapter.

(c) *Exceptions for diagnostic specimens.* (1) A diagnostic specimen that is known or reasonably expected to contain a pathogen in risk group 2 or 3 (medium to high probability) or for which there is any probability that it contains a pathogen of risk group 4 must be classified in Division 6.2 under UN 2814 or UN 2900, as appropriate, unless otherwise excepted. A specimen transported for the purpose of initial or confirmatory testing for the presence of a pathogen falls within this group.

(2) A diagnostic specimen for which a relatively low probability exists that a pathogen of risk groups 2 or 3 is present may be transported under the exceptions provided in § 173.196(c).

(3) A diagnostic specimen that is known or reasonably expected to contain a pathogen in risk group 1 only or is known not to contain a pathogen is not considered an infectious substance and is not subject to the requirements of this subchapter.

(4) A diagnostic specimen which meets the provisions of paragraph (c)(1) or (c)(2) of this section is excepted from all other requirements of this subchapter when transported by a private or contract motor carrier not engaged in the transportation of passengers and the material is packaged and marked with the proper shipping name ''Diagnostic Specimen'' in accordance with the provisions for diagnostic specimens in § 173.196(c) of this subchapter.

(5) Animals which contain or are contaminated with an infectious substance must be transported under the terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(d) *Other exceptions.* (1) The following are not subject to the requirements of this subchapter as a Division 6.2 material:

(i) A living person;

(ii) Laundry or medical equipment that conforms to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030;

(iii) A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so that it no longer meets the definition of an infectious substance;

(iv) Any waste or recyclable material, other than regulated medical waste, including—

(A) Garbage and trash derived from hotels, motels, and households, including but not limited to single and multiple residences;

(B) Sanitary waste or sewage;

(C) Sewage sludge or compost; and

(D) Animal waste generated in animal husbandry or food production;

(E) Medical waste generated from households; or

(F) Corpses, remains, and anatomical parts that are intended for interment or cremation;

(v) Forensic material that is transported on behalf of, a Federal, State, local or Indian tribal government agency provided they are shipped in a packaging conforming to the provisions of § 173.24 of this subchapter. A package being shipped and transported under this provision must be marked ''Diagnostic Specimen''.

(2) [Reserved]

9. In § 173.140, paragraphs (c) and (d) would be added to read as follows:

§ 173.140 Class 9—Definitions.

* * * * *

(c) Any material that is a genetically modified micro-organism or organism.

(1) This includes micro-organisms and organisms in which:

(i) Genetic material has been purposely altered through genetic engineering in a way that does not occur naturally; and

(ii) The material does not meet the definition of an infectious substance, but has the potential to alter animals, plants or microbiological substances in a way not normally the result of natural reproduction.

(2) A genetically modified micro-organism or organism that meets the definition of an infectious substance in § 173.134 is subject to the requirements for a Division 6.2 material.

(d) Exceptions. (1) A genetically modified micro-organism or organism that is authorized for final distribution and use by a U.S. Government agency is not subject to requirements of this subchapter.

(2) Genetically modified micro-organisms or organisms that meet the definition of a Class 9 material are not assigned a packing group.

(3) Packaging requirements for genetically modified micro-organisms and organisms are specified in § 173.196(c).

(4) A genetically modified micro-organism or organism is excepted from all other requirements of this subchapter when transported by a private or contract motor carrier not engaged in the transportation of passengers, and the material is packaged and marked with the proper shipping name ''Genetically modified micro-organism,'' in accordance with the provisions in § 173.196(c)(4).

(5) Animals which contain or are contaminated with a genetically modified micro-organism must be transported under the terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

10. Section 173.196 would be revised to read as follows:

§ 173.196 Infectious substances.

(a) When § 172.101 of this subchapter specifies that an infectious substance be packaged under this section, only non-bulk packagings prescribed in this section may be used.

(1) An infectious substance must be classified and described under UN 2814 or UN 2900 and must be packaged in a Division 6.2 packaging meeting requirements of paragraph (b) of this section.

(2) An infectious substance that is authorized to be described under the proper shipping name ''Diagnostic Specimen'' must be packaged in accordance with paragraph (b) or (c) of this section. If the diagnostic specimen meets the requirements of § 173.134(c)(2) and is transported by highway only by a private or contract carrier, it may be packaged in conformance with provisions of paragraph (c) of this section.

(3) Body parts, organs or whole bodies must be packaged in a:

(i) Division 6.2 packaging meeting the requirements of paragraph (b) of this section;

(ii) Diagnostic specimen packaging meeting the requirements of paragraph (c) of this section, or

(iii) Non-specification packaging meeting the requirements of paragraph (d) of this section.

(b) *Division 6.2 packaging.* A Division 6.2 packaging must conform to a UN standard specified in subpart L of part 178 of this subchapter and meet the test standards of § 178.609 of this subchapter. The packaging must include:

(1) Inner packagings comprising:

(i) A watertight primary receptacle;

(ii) A watertight secondary packaging; and

(iii) Other than for a solid infectious substance, an absorbent material must be placed between the primary receptacle and the secondary packaging. If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped individually to ensure that contact between them is prevented. The absorbent material, such as cotton or wool, must be sufficient to absorb the entire contents of all primary receptacles.

(2) An outer packaging of adequate strength for its capacity, mass and intended use.

(3) The smallest overall external dimensions of the outer packaging must be at least 100 mm (3.9 inches).

(4) An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

(5) Based on their physical and chemical form, infectious substances must be packaged according to the following guidelines:

(i) *Lyophilized substances.* Primary receptacles must include flame-sealed glass ampules or rubber-stopped glass vials fitted with metal seals.

(ii) *Liquid or solid substances*—

(A) *Substances shipped at ambient temperatures or higher.* Authorized primary receptacles include those of glass, metal or plastic. Positive means of ensuring a leakproof seal, such as heat

seal, skirted stopper or metal crimp seal must be provided. If screw caps are used, they must be secured with adhesive tape.

(B) *Substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice or dry ice must be placed outside the secondary packagings. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the packaging must be leakproof. If dry ice is used, the outer packaging must permit the release of carbon dioxide gas and otherwise meet the provisions in § 173.217.

(C) *Substances shipped in liquid nitrogen.* Plastic primary receptacles capable of withstanding very low temperatures must be used. Secondary packaging must withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. For transportation of liquid nitrogen aboard aircraft, see § 171.11 of this subchapter.

(6) Whatever the intended temperature of shipment, the primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure which produces a pressure differential of not less than 95 kPa (14 psi) and temperatures in the range of −40°C to +55°C (−40°F to +131°F).

(c) *Diagnostic specimens and genetically modified micro-organisms and organisms.* (1) A diagnostic specimen that otherwise conforms to terms and conditions specified in § 173.134(c)(1) and (c)(4) must be packaged as specified in paragraph (b) of this section, except that the package need only be capable of meeting test standards of § 178.609 of this subchapter and at a drop test height of not less than 1.2 m (3.9 feet), rather than 9 m (30 feet).

(2) A diagnostic specimen that otherwise conforms to terms and conditions specified in § 173.134(c)(2) and (c)(4) must be packaged as follows:

(i) In a leakproof primary receptacle that does not contain more than 500 ml (17 ounces) or 500 mg (1.1 pounds).

(ii) In an outer packaging that does not contain more than 4 L (1 gallon) or 4 kg (8.8 pounds).

(iii) The packing conforms to requirements in § 173.196(b), but is not subject to the marking requirements in subpart L of part 178 of this subchapter or the performance tests in subpart M of part 178 of this subchapter. However, each completed package must be capable of successfully passing the drop test specified in § 178.603 of this subchapter. The height of the drop test must meet or exceed 1.2 m (3.9 feet).

(iv) For a solid diagnostic specimen, the primary receptacle and secondary packaging is excepted from requirements pertaining to their ability to withstand a pressure differential of not less than 95 kPa.

(3) Except as provided in paragraph (c)(4) of this section, a genetically modified micro-organism or organism must be packaged as specified in paragraph (b) of this section, except that the package need only be capable of meeting test standards of § 178.609 of this subchapter and at a drop test height of not less than 1.2 m (3.9 feet), rather than 9 m (30 feet).

(4) A genetically modified micro-organism or organism that otherwise conforms to terms and conditions specified in § 173.140(d)(4) must be packaged as follows:

(i) In a leakproof primary receptacle that does not contain more than 500 ml (17 ounces) or 500 mg (1.1 pounds).

(ii) In an outer packaging that does not contain more than 4 L (1 gallon) or 4 kg (8.8 pounds).

(iii) The packaging conforms to requirements in § 173.196(b), but is not subject to the marking requirements in subpart L of part 178 of this subchapter or the performance tests in subpart M of part 178 of this subchapter. However, each completed package must be capable of successfully passing the drop test specified in § 178.603 of this subchapter. The height of the drop test must meet or exceed 1.2 m (3.9 feet).

(iv) For a solid genetically modified micro-organism or organism, the primary receptacle and secondary packaging is excepted from requirements pertaining to their ability to withstand a pressure differential of not less than 95 kPa.

(d) *Non-specification packaging requirements.* This packaging consists of a non-bulk strong outer packaging and a leakproof inner packaging, such as a liner or receptacle, that conforms to the conditions specified in §§ 173.24 and 173.24a and the following additional requirements:

(1) When transported by aircraft, the packaging must conform to requirements specified in § 173.27;

(2) When transported with dry ice, the packaging must conform to requirements specified in paragraph (b)(5)(ii)(B) of this section; and

(3) When shipped in liquid nitrogen, the packaging must conform to requirements specified in paragraph (b)(5)(ii)(C) of this section.

(e) The requirements of this section are in addition to the requirements of the Department of Health and Human Services contained in 42 CFR part 72.

11. Section 173.197 would be revised to read as follows:

§ 173.197 Regulated medical waste.

(a) *Non-bulk packagings.* Non-bulk packagings conforming to the requirements of part 178 of this subchapter at the Packing Group II performance level are authorized for regulated medical waste as follows. The packagings must be:

(1) Rigid;

(2) Leak-resistant;

(3) Impervious to moisture;

(4) Of sufficient strength to prevent tearing or bursting under normal conditions of use and handling;

(5) Sealed to prevent leakage during transport;

(6) Puncture-resistant for sharps and sharps with residual fluids; and

(7) Break-resistant and tightly lidded or stoppered for fluids in quantities greater than 20 cubic centimeters.

(b) *Special bulk packagings.* Authorized packagings consist of one of the outer bulk packagings with multiple inner packagings, as described in this paragraph.

(1) *Outer packagings.* (i) *Intermediate bulk container (IBC) packaging.* Intermediate bulk containers are authorized as outer packagings subject to the conditions and limitations of this paragraph provided they conform to the requirements in subpart O of part 178 of this subchapter at the Packing Group II performance level, as follows:

(A) *Liquids or solids.* The following are authorized as outer packagings with inner packagings that contain liquids or solids:

(*1*) Composite: 31HZ1. The letter ''Z'' must be replaced with a capital letter which indicates the material of construction of the outer packaging (see § 178.702 of this subchapter);

(*2*) Metal: 31A, 31B, or 31N; or

(*3*) Rigid plastic: 31H1 or 31H2.

(B) *Solids only.* The following are authorized as outer packagings with inner packagings that contain solids only:

(*1*) Composite: 11HZ1 or 12HZ1. The letter ''Z'' must be replaced with a capital letter which indicates the material of construction of the outer packaging (see § 178.702 of this subchapter);

(*2*) Metal: 11A, 11B, 11N, 12A, 12B, or 12N; or (3) Rigid plastic: 11H1, 11H2, 21H1 or 21H2.

(C) *Additional provisions.* An IBC authorized for solids only, may be used for small quantities of liquids provided that sufficient absorbent material is used to absorb the entire amount of liquid

present. IBCs intended to carry sharps must be resistant to puncture and retain liquids under the performance tests of subpart O of part 178.

(ii) *Non-specification bulk packaging.* A non-specification packaging is authorized as an outer packaging subject to the conditions and limitations of this paragraph as follows:

(A) The packaging must be a metal or plastic bulk packaging of rigid, seamless construction, with the following features:

(*1*) A lid or closure that is closed, sealed and latched during transportation; and

(*2*) A maximum capacity greater than 450 L (119 gallons) but less than 1,000 L (264 gallons) as a receptacle for a liquid or a maximum net mass greater than 400 kg (882 pounds) but less than 1,000 kg (2,205 pounds) as a receptacle for a solid;

(B) Be capable of meeting the drop test requirements of § 178.810 and stacking test requirements of § 178.815, for the Packing Group II performance level for solids;

(C) Have an interior surface that is smooth, non-porous, and free of cracks and crevices that could obstruct decontamination operations;

(D) Be in dedicated service for the transportation of waste materials;

(E) Prior to reuse, be decontaminated; and

(F) The outer packaging must be maintained in an upright position during transportation.

(G) The package must be legibly marked with package orientation markings that conform pictorially to ISO Standard 780 on two opposite vertical sides of the package with the arrows pointing in the correct upright direction.

(2) *Inner packaging:* Inner packagings must conform to the following requirements to be authorized for use in special bulk packagings:

(i) A plastic film inner packaging may not exceed a volume of 175 L (46 gallons) and must have a film thickness of at least 0.076 cm (0.003 inches);

(ii) Sharps must be packaged in puncture-resistant containers that are not greater than 38 L (10 gallons) in volume;

(iii) Inner packagings for liquids must meet the non-bulk packaging standards for Packing Group II for liquids. Liquid materials are not authorized for transportation in inner packagings larger than 19 L (5 gallons); and

(iv) Inner packagings must be securely closed with a minimum of entrapped air and sealed with a positive sealing mechanism to prevent leakage.

PART 178—SPECIFICATIONS FOR PACKAGINGS

12. The authority citation for part 178 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

13. In § 178.503, paragraph (f) would be added to read as follows:

§ 178.503 Marking of packagings.

* * * * *

(f) A manufacturer must mark every UN specification package that is represented as manufactured to meet the requirements of § 178.609 for packaging of infectious substances with the marks specified in this section. The markings must be durable, legible and placed in a location and of such a size relative to the packaging as to be readily visible, as specified in § 178.3(a). An infectious substance packaging that successfully passes the tests conforming to the UN standard must be marked as follows:

(1) The United Nations symbol as illustrated in paragraph (e) of this section.

(2) The code designating the type of packaging and material of construction according to the identification codes for packagings specified in § 178.502 of this subpart.

(3) The text ''CLASS 6.2''.

(4) The last two digits of the year of manufacture of the packaging.

(5) The country authorizing the allocation of the mark. The letters ''USA'' indicate that the packaging is manufactured and marked in the United States in compliance with the provisions of this subchapter.

(6) The name and address or symbol of the manufacturer or the approval agency certifying compliance with subparts L and M of this part. Symbols, if used, must be registered with the Associate Administrator for Hazardous Materials Safety.

(7) For packagings meeting the requirements of § 178.609(k), the letter ''U'' must be inserted immediately following the marking designating the type of packaging and material required in paragraph (f)(2) of this section.

(8) Examples of markings for infectious substance packages include:

4G/CLASS 6.2/97/USA/ACME876

1A2/CLASS 6.2/97/USA/ACME CORP. 123 ELM ST DALLAS, TX 75230

1A2U/CLASS 6.2/97/USA/ACME CORP. 123 ELM ST DALLAS, TX 75230

14. In § 178.601, paragraph (c)(1) would be revised to read as follows:

§ 178.601 General requirements.

* * * * *

(c) * * *

(1) *Design qualification testing* is the performance of the tests prescribed in § 178.603, 178.604, 178.605, 178.606, 178.607, or 178.609, as applicable, for each new or different packaging, at the start of production of that packaging.

* * * * *

15. In § 178.609, paragraph (i) would be redesignated as paragraph (l), the section heading, paragraph (c) preceding the table, the undersignated sentence preceding paragraph (d)(1) introductory text, paragraphs (d)(1) introductory text, (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (e), (h)(1), (h)(2), and newly designated paragraph (l) would be revised, and new paragraphs (i), (j), and (k) would be added to read as follows:

§ 178.609 Test requirements for packagings for infectious substances.

* * * * *

(c) Packagings prepared for transport must be subjected to the tests in Table I of this paragraph, which, for test purposes, categorizes packagings according to their material characteristics. For outer packagings, the headings in Table I relate to fiberboard or similar materials whose performance may be rapidly affected by moisture; plastics, which may embrittle at low temperature; and other materials such as metal whose performance is not significantly affected by moisture or temperature. Where a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of more than one material, the material most likely to be damaged determines the appropriate test.

* * * * *

(d) * * *

The drops must be performed as follows:

(1) Where the samples are in the shape of a box, five must be dropped in sequence:

(i) Flat on the base;

(ii) * * *

(iii) Flat on the longest side;

(iv) Flat on the shortest side; and

* * * * *

(e) The samples must be subjected to a water spray that simulates exposure to rainfall of approximately 50 mm per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.

* * * * *

(h) * * *

(1) Samples must be placed on a level hard surface. A cylindrical steel rod with a mass of at least 7 kg (15 pounds), a diameter not exceeding 38 mm (1.5 inches) and the impact end edges a radius not exceeding 6 mm (0.2 inches), must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the impact end of the impact surface of the sample. One sample must be placed on its base. A second sample must be placed in an orientation perpendicular to that used for the first. In each instance the steel rod must be aimed to impact the primary receptacle(s). Following each impact, there shall be no leakage from the primary receptacle(s).

(2) Samples must be dropped onto the end of a cylindrical steel rod. The rod must be set vertically in a level hard surface. It must have a diameter of 38 mm (1.5 inches) and the edges of the upper end a radius not exceeding 6 mm (0.2 inches). The rod must protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm (7.9 inches). One sample must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the top of the steel rod. A second sample must be dropped from the same height in an orientation perpendicular to that used for the first. In each instance the packaging should be so orientated that the steel rod must be aimed to impact the primary receptacle(s). Following each impact, there shall be no leakage from the primary receptacle(s).

(i) Provided an equivalent level of performance is maintained, the following variations in the primary receptacles placed within the secondary packaging are allowed without additional testing of the completed package:

(1) Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided:

(i) The primary receptacles are of similar design to the tested primary receptacle (e.g., shape: round, rectangular, etc.);

(ii) The material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and a stacking force equal to or greater than that of the originally tested primary receptacle;

(iii) The primary receptacles have the same or smaller openings and the closure is of similar design (e.g., screw cap, friction lid, etc.);

(iv) Sufficient additional cushioning material is used to fill void spaces and to prevent significant movement of the primary receptacles; and

(v) Primary receptacles are oriented within the intermediate packaging in the same manner as in the tested package.

(2) [Reserved]

(j) A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in paragraph (i) of this section, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

(k) Primary receptacles of any type may be placed within a secondary packaging and shipped without testing in the outer packaging under the following conditions:

(1) The secondary/outer packaging combination must have been successfully tested in accordance with paragraphs (a) through (h) of this section with fragile (e.g., glass) inner receptacles;

(2) The total combined gross weight of inner receptacles must not exceed one-half the gross weight of inner receptacles used for the drop test in paragraph (d) of this section;

(3) The thickness of cushioning material between inner receptacles and between inner receptacles and the outside of the secondary packaging must not be reduced below the corresponding thicknesses in the originally tested packaging. If a single inner receptacle was used in the original test, the thickness of cushioning between the inner receptacles must not be less than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material must be used to fill the void;

(4) The outer packaging must have successfully passed the stacking test in § 178.606 of this subchapter while empty. The total weight of identical packages must be based on the combined mass of inner receptacles used in the drop test in paragraph (d) of this section;

(5) For inner receptacles containing liquids, an adequate quantity of absorbent material must be present to absorb the entire liquid contents of the inner receptacles; and

(6) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not siftproof, a means of containing any liquid or solid contents in the event of leakage must be provided in the form of a leak-proof liner, plastic bag or other equally effective means of containment.

(7) In addition, the marking required in § 178.503(f) of this subchapter must be followed by the letter ''U''.

(l) Packagings subject to this section are not subject to any other requirements of this subpart, except § 178.608.

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Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety.

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