43812

RSPA Docket #
#98-3971-5

RSPA's Internet Public Meeting on Infectious Substances (Docket HM-226)

The purpose of this forum is to provide you with an easy and convenient way to submit your comments, to rebut or follow-up on others' comments, and to engage in an Internet dialogue on a proposed rule on the transportation of infectious substances which RSPA will publish in August, 1998.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

This forum will be available from 9:00 am September 14, 1998 to 12:OO noon (Eastern Time) on September 16, 1998. A Moderator will be periodically checking the forum between the hours of 9:00 am - 5:30 pm (Eastern Time) and will respond to messages, and if appropriate, add new discussion topics.

For help on reading and replying to messages use the Forum Help link below.

Any questions and/or comments concerning this forum (not the rulemaking) should be sent using the Forum Feedback link on the main Alta Vista page.

Note: Please use the navigation bar at the bottom to view additional discussion forums.

Entries

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12.	Forum Help		AltaVista Forum Administrator	09/03/98 09:35 AM
11.	Docket RSPA 98-3971 (HM-226)		AltaVista Forum Administrator	09/03/98 09:34 AM
10.	Other Related Comments/Concerns	(6)	AltaVista Forum Administrator	09/11/98 11:17 AM
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6.	Regulated Medical Waste	(17)	AltaVista Forum	09/11/98
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14. Small business impacts

Under the Regulatory Flexibility Act (5 USC 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 businesses and organizations. We believe that an NPRM that closely follows the proposals outlined in this ANPRM may have a significant economic impact on small businesses and on state and local governments.

RSPA seeks comments that will assist in determining the number of potentially affected small entities and in weighing the impact of various regulatory alternatives

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

14.1 Question1

How many small entities might potentially be affected by a proposed rule?

14.1.2 Reply (Dr. Mark D. Wood, Director, Scientific Affairs, AHI)

In AHI's previous reply to this question, the title text was apparently lost and the address format for listing each USDA/APHIS/VS/CVB Director (located at the end of our reply) was changed. In this case, the adjacent address columns were blended into one and the cited addresses were indistinguishable. Please accept the following as an addendum to our previous reply:

14.2 Question 2

Will any of these proposals affect the competitive position of small businesses in relation to larger businesses?

14.3 Question 3

How can these proposals be modified to minimize their impact on small entities?

14.4 Vapor Containment is the Issue

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future.

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This represents the primary personal danger and health risk that the employee's and passengers will be exposed to while handling and in transit.

We welcome your comments.

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President & CEO
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13. Exceptions from regulation as infectious substances

RSPA is proposing that a number of materials be excepted from the HMR requirements for infectious substances, including:

(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;

(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. (For proposed regulations text, see p. 46856.)

We are seeking comments on the appropriateness of these exceptions.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

13.1 Question 1

Should additional items/materials be excepted from the HMR?

13.2 Question 2

Should any items/materials currently excepted from the HMR be subject to some or all of the regulatory requirements because of the safety risks they pose?

13.2.1 Reply -- Exempted waste: B. Cunha

The exemption of household medical wastes in this regulation indicates a lack of understanding on current medical practices in the United States.

Many patients are administering their own medications well beyond simple injections. Currently, patients can do their own wound care, dialysis, chemotherapy, and a host of other medical practices that used to be restricted to hospitals.

Some of the chemotherapy agents that are generated a “Household wastes” are RCRA regulated hazardous wastes

New systems are being developed that allow households that generate used sharps to be sent through the mail and other carriers to specific places to be destroyed. As more and more States ban sharps and other household medical wastes from landfills, more shipping of these materials will be occurring.

It is a interesting paradox. Do we make it easy for the private citizen to properly dispose of their medical waste by not regulating the of disposing of it. Or do we protect the safety of the workers who will be exposed to improperly packaged and labeled hazards.?

Bruce E. Cunha

Cunhab@MFLDCLIN.EDU

13.3 Vapor Containment is the Issue

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future.

The packaging requirements must address the containers ability to fully and absolutely contain the

vapors being emitted by the hazardous/biological/pathological contents of the container.

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When they transit from high altitude to sea-level the individual packages suck in the mixed hazardous/pathological vapors of the cargo compartment into their containers without discriminating as to the dangers of chemically mixing the vapors.

This represents the primary personal danger and health risk that the employee's and passengers will be exposed to while handling and in transit.

We welcome your comments.

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10. Other Related Comments/Concerns

RSPA seeks comment on any other aspect of the ANPRM, including provisions proposed for:

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

10.1 Question 1

Revising the INFECTIOUS SUBSTANCE label with a 2-year delay until the revised labels must be used.

10.2 Question 2

Revising incident reporting requirements.

10.3 Question 3

Revising authorized packaging requirements and allowing use of IBCs for RMW.

10.4 Vapor Containment is the Issue

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10.5 Pressure testing 95 kPa requirement

One thing that has not been addressed in the proposed rule and is currently absent from the HMR is the test method used to determine whether or not a container meets the 95 kPa internal pressure required in 173.196 (f). Currently there are three test methods that I'm aware of available to determine whether a container meets this requirement. One is described in 178.604 using compressed air. Another can be found in 178.605 which outlines a hydrostatic pressure test. The third is a vacuum test. I believe that a standard method needs to be addressed.

Recently, I read an interpretation letter sent November 19, 1997 written by Hattie L. Mitchell of the Office of Hazardous Materials Standards. In the letter the question was asked if the following method is acceptable in determining whether a package is capable of withstanding 95 kPa without leakage:

1. The container is filled to 98% capacity and closures applied.
2. The container is placed in a vacuum chamber.
3. A vacuum of 95 kPa is drawn on the chamber and held for 5 minutes.
4. If no leakage is observed during that time period, the container passes.

The answer to the question was yes. However, such a method is only valid for empty rigid containers submerged in a vacuum container. Filled to 98% capacity with a liquid invalidates the procedure. Since liquid does not expand in a vacuum, the package will never achieve a 95 kPa internal pressure differential. In testing in our own laboratory, we put a pressure gauge on a sealed inner receptacle filled with liquid in a vacuum jar and evacuated the air to -95 kPa. The pressure in the inner receptacle never exceeded 10 kPa. I have used the exact method described above to test a ziplock sandwich bag and it passed.

Such an example demonstrates the need for a standard test method written into 178.609 for testing the primary or secondary containers. One suggestion would be to modify 178.609 (f) to the following:

(f) Packagings subject to this section are not subject to 178.503 or any other requirements of this subpart, except 178.608 and 178.604 except the pressure applied in (e) must not be less than 95 kPa..

Justification for using the air leakage test outlined in 178.604 is based on the following two reasons:

1) In the event of a transport mishap involving a package of Class 6.2 dangerous goods, not only is there concern of direct contact with an infectious substance, but one must also be wary of possible aerosilization. In fact some infectious agents, such as Mycobacterium tuberculosis, primary route of transmission is the inhalation of aerosolized particles. Packages must be designed to contain both the liquid and the air at pressure. The air pressure leakage test outlined in 178.604 best approaches this.

2) The air leakage test is consistent with international standards and the tests required for packaging of other dangerous goods such as poison by inhalation materials.

Setting a standard test method will help to clear up confusion and provide a standard to measure all infectious packaging against. This will also help to harmonize US regulations with UN, ICAO and other national regulations. The US is one of the few countries that does not designate a method for pressure testing the primary or secondary receptacles for infectious substance packaging.

10.7 Bulk Packaging Use of Roll Off Containers

As the operator of a Medical Waste firm in Pennsylvania I want to voice my concerns about using “bulk or Roll-Off containers for storage and disposal of RMW.

Storage and disposal or RMW poses a significant health threat to persons required to come into contact with the roll-off container - beginning with the hospital/clinic employee placing the waste into the container, through and to the persons (s) unloading by hand and assigned the task of decontaminating

and disinfecting the container. The proposed method of depositing the plastic bags filled with RMW indiscriminately into a roll-off container(s) will result in the piercing of the waste bags, thereby allowing pathogens to become airborne. Access to the containers will be through doors, which would have to be lockered and unlocked. After filling, the waste will require transportation to a disposal site, without protection from contamination through airborne pathogens. Any accidental opening or piercing of the containers will risk widespread contamination from the waste being transported.

Further, no provision is made for protection of workers at the disposal site from pierced medical waste bags. Last, and equally important, proper decontamination of the containers is virtually impossible because of the very nature, size and number of hinges and joints in the roll- off container.

If the regulations requiring bagging, boxing, taping and container maximums apply at all, they must apply to all persons engaged in the handling and management of medical wastes. A leak in a box of medical waste is easy to fix...

simply re-package the leaking box into a larger box with a fluid proof membrane or liner. Try stopping a leaking container. Impossible. Medical waste should not be shipped or packaged in such a manner that would allow airborne pathogens to escape that which contains them.

These pathogens are life threatening in some cases. I urge you to ban the use of roll-off containers in this country.

These containers are a threat to public health.

Perhaps CDC should be involved in this issue.

Respectfully,

Craig Sanford

President,

SMI-East Coast Medical Waste, Inc.

1307 South Pennsylvania Ave.,

Morrisville, Pennsylvania 19067

10.8 Composite Material Roll-Off Containers

We, Mini Mobile Systems, Inc manufacture a 45 cubic yard

fiberglass roll-on-roll-off approved and safe container for the handling and transportation of biohazardous waste. The unit has mechanical discharge, it has a sump should material spill and can be cleaned after each use, it is equipped with an ozone purifier and filtration system for sterilization purposes for reuse. The unit has exemption D.O.T. - E10837.

Because of our safety features we are able to handle thin bags.From experience steel bodies are not safe to carry medical waste.

Nathan Lubie

Mini Mobile Systems, Inc

1920 E. Hallandale Beach Blvd. #607

Hallandale, FL 33009

Tel: 954 455 0806

Fax: 954 455 8856

9. Segregation from Foodstuffs

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

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

9.1 Vapor Containment is the Issue

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9.2 Segregate

From: G.E. Sprenkle
Chairman, Dangerous Goods Committee
Airline Pilots Association
PO Box 1169

535 Herndon Parkway

Herndon. VA. 22070-l 169

It would appear to us that common knowledge/common sense should dictate that all infectious substances, as all poisons, must be segregated from all foodstuffs. This should not require supportive evidence but rather a basic knowledge of public health.

8. Petition for Rulemaking – Waste Cultures and Stocks

Cultures and stocks of infectious substances typically contain a high concentration of microorganisms and, therefore, require special handling. The Medical Waste Institute (MWI) requested in a petition for rulemaking that RSPA revise the HMR to allow contract and private motor carriers to transport discarded cultures and stocks of infectious substances in Packing Group II packagings if the carriers use dedicated vehicles. This practice is currently permitted under the terms of an exemption (E-l 1588). MWI asserts that current packaging requirements in the HMR for discarded cultures and stocks are onerous and expensive and lack a safety record that proves their actual health and safety benefits. (For preamble discussion, see pp. 46848 - 46849.)

RSPA seeks comments on whether an exception from the specification packaging requirements for waste cultures and stocks transported in dedicated vehicles provides an adequate level of safety in transportation.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

8.1 Question 1

Can waste cultures and stocks be transported safely in non-specification packagings if transported in dedicated vehicles?

8.1.1 Cultures and Stocks Transportation

Waste cultures and stocks are currently being transported safely throughout the country on a daily basis: as has been the case for years and years. Generators of RMW do not typically segregate or

distinguish most waste cultures and stocks from “other” RMW. These materials are co-mingled and packaged, then shipped offsite for treatment and disposal along with the rest of the medical waste. I believe data is readily available on the lack of incidents involving exposure to RMW due to traffic accidents. This should underscore the fact these materials most certainly can be transported safely and cost efficiently.

Peter Dyke

P.O. Box 17557

Chicago, IL. 60617

8.1.2 Bill Warder

Bill Warder

P. 0. Box 20104

Kansas City, MO 64 195

(816)243-5535

Yes

8.2 Question 2

Are there any alternative exceptions that should be considered for the transportation of waste cultures and stocks or are the risks posed by such materials severe enough that exceptions should be considered on a case-by-case basis only?

8.2.1 Bill Warder

Bill Warder

P. 0. Box 20104

Kansas City, MO 64195

(816)243-5535

No general exceptions. In fact, I object to the broad base relief found in DOT-E 11588. The parties to this exemption is a list of every garbologist in America.

8.3 Vapor Containment is the Issue

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We welcome your comments.

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7. Materials of Trade Exception

RSPA has adopted exceptions from most of the requirements of the HMR for hazardous materials that are transported as materials of trade. Materials of trade include certain hazardous materials carried by a private motor carrier to support a principal business other than transportation. Such businesses include lawn care, plumbing, welding, door-to-door sale of consumer goods, and farm operations. RSPA is considering an amendment that would permit entities such as home health care providers and clinical laboratories to transport biological products, diagnostic specimens and RMW as materials of trade. 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) would also be imposed. (For preamble discussion, see pp. 46847 - 46848; for section-by-section review, see p. 46849; for proposed regulations text, see p. 46855.)

RSPA requests comments on the appropriateness of a materials of trade exception for certain infectious substances.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

7.1 Question 1

Will an acceptable level of safety be achieved through a materials of trade exception for infectious substances, including those that are known or suspected of containing a Risk Group 4 pathogen?

7.1.1 Safety. Bruce Cunha

Blood and other potentially infectious materials are currently not regulated unless they are known to contain a biohazard.

Current proposed regulations would make it difficult for laborators that collect and transport specimens to their facilities, to not have to institute significant changes and additional costs into their system.

Because of the minimal hazard that blood (even category 4 blood) poses. These costs and changes should be exempt for facilities that offer this service as a part of their business.

If our couriers did not pick up lab specimens, these specimens would have to be shipped to our facility

through regular carriers. This would significantly increase the potential for leaking or spilling of blood due to the increased handling required by the shippers.

Costs would also increase for the shippers in dealing with leaks or spills of potentially infectious specimens. While spills do occur in our system. They are contained in our shipping containers and can be cleaned up by competently trained and experienced personnel. This would not be the case if all these specimens were to go by regular carrier.

Bruce E. Cunha MS

Cunhab@MFLDCLIN.EDU

7.1.1.1 Potentially Infectious Material

IATA/ICAO currently requires a packaging standard for potentially infectious materials under Packaging Instruction 650. You would not have the leaks you are currently experiencing if you used proper packaging. You comment confirms the need for the diagnostic packaging requirements proposed in this forum.

7.1.2 Bill Warder

Bill Warder

P.O. Box 20104

Kansas City, MO 64195

There should be no exception for materials of trade. A materials of trade exception would jeopardize the safety of an estimated 90% of all laboratory shipments that would otherwise be regulated in HM-226. Like class 7 materials, quantity is not the relevant issue since quantity does not necessarily relate to or communicate the level of hazard.

7.2 Question 2

Should Risk Group 4 materials be excluded from the materials of trade exception?

7.2.1 Risk 4 B. Cunha

Risk 4 category could cover HIV or Hepatitis C blood. Since we do not label specimens for these diseases (per the OSHA BBP standard, Standard (universal) precautions). It is never known if a tube of blood contains one of these hazards until the specimen it tested.

Since we know that a percentage of the specimens will contain one of these hazards. We treat every single specimen as if it were infectious.

When picking up specimens for lab analysis, there is no way of knowing which one may or may not contain a biohazard. This would almost force us to consider every shipment as a category 4. This would create significant increase in costs and problems for our system.

If a specimen were a hazard that could be spread by breathing it in. This would constitute a more significant hazard and possibly should require more specific labeling and packaging. Very few pathogens would meet this criteria. The added costs and problems of this type of change are not warranted from a safety prospective.

The wording of category 2, 3 and 4 is to vague to be used as a good guide as to what should be covered under that category.

Bruce E. Cunha
CunhaB@MFLDCLIN.EDU

7.2.1.1 Risk Categories

HIV and Hep-a/b/c are all risk group 2

7.2.2 Bill Warder

Bill Warder
P. 0. Box 20104
Kansas City, MO 64195
(816)243-5535
No exception for materials of trade - period.

7.3 Question 3

Should the quantity limits applicable to the materials of trade exception be reduced for infectious substances?

7.3.1 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64153
(816)243-5535
Reduced to "0" there should not be a materials of trade exception. period

7.4 Question 4

What, if any, hazard communication should be required for carriage of such materials?

7.4.1 Bill Warder

Bill Warder
P. 0. Box 20104
Kansas City, MO 64195
(816)243-5535
No exception for materials of trade.

7.4.2 Hazard Communication

Marking the combination packages required in 173.6 to communicate the risks involved should not provide any significant expense. There should be some sort of manifest and record keeping required, although it may not need to be as detailed as that required for conventional shipments. I also feed a hazard label to be mandatory.

7.5 Vapor Containment is the Issue

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7.6 Quantity Limits B. Cunha

No:

The quantity of a biohazard has little to do with how dangerous it is. 1 ml of hepatitis or HIV infected blood can contain millions of viral particles. Since there is no exposure limit for biohazard, the quantity of material transported is not going to make much difference. Is 1000 pounds more dangerous than 500 pounds?. No.

The hazard of blood and other infectious body fluids is limited to getting it into the body through a few, very specific ways. (direct puncture of the skin by a contaminated item, contact with non-intact skin and contact with mucus membranes) This factor needs to be constantly reinforced when talking about these substances. The hazardous properties are very limited and do not fit in to most of the traditional hazards associated with other materials.

Bruce E. Cunha

Cunhab@MFLDCLIN.EDU

7.7 Universal Precautions

There seems to be a thread of thought that the universal precautions will protect hazmat workers and the public in the event of a spill or discharge of infectious substance. Unfortunately this is not valid. Hazmat workers and the public are not trained in the UP and have no access to the necessary support materials (gloves hepa filters, fume cabinets, isolation areas etc. Is it practical to require the training of MILLIONS of people in the up for the transport of just one hazard class? I do not think so. Transport of hazmat is the venue of the DOT/RSPA and there is a well established and effective system in place and proven. If anything needs to be changed it may be the reinforcement of the requirement for incident reporting.

Art Rutledge

6. Regulated Medical Waste

RSPA is considering authorizing non-specification bulk packagings for transporting RMW. Such packagings are currently permitted only under the terms of approved exemptions. RSPA is considering revising the RMW packaging requirements to allow five types of packagings:

(1) non-bulk infectious substance triple packagings in accordance with § 173.196;

(2) non-bulk packagings conforming to § 173.197;

(3) packagings that conform to 29 CFR 1910.1030 (OSHA);

(4) non-specification bulk packagings currently authorized under exemption; and

(5) intermediate bulk containers.

RSPA is also considering whether to revise the quantity limitations in columns (9A) and (9B) of § 172.10 1 for RMW to read No Limit to reflect provisions of the ICAO Technical Instructions for maximum net quantity permitted per package. Consistent with ICAO, RSPA is considering whether to permit RMW to be placed in bulk packagings in modes of transportation other than air. (For preamble discussion, see p. 46847; for section-by-section review, see p. 46849, 46850; for proposed regulations text, see pp. 46852 - 46853, 46857 - 46858.)

RSPA requests comment on these proposals to revise the packaging requirements for RMW.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

6.3 Question 1

Should the HMR be revised to authorize non-specification bulk packagings as reusable outer packagings for RMW packaged in plastic film bags, as currently authorized by exemption? If so, what specifications and size limitations are appropriate for non-specification bulk packagings?

6.3.1 (no title)

The HMR should be revised to allow for large quantity generators, such as hospitals, to minimize labor costs and potential exposure incidents caused by packaging RMW into small containers. A container the size of a standard “laundry cart” is a very efficient vessel for such a generator to use, as it is easily maneuvered through the facility. The container should conform to the standards imposed by O.S.H.A.'s Bloodbome Pathogen Standard, i.e., of sufficient strength to prevent puncture and leak-proof on the

sides and bottom.

6.4 Question 2

If non-specification bulk packagings are authorized for transporting the transportation of 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?

6.5 Question 3

If authorized for reuse to transport RMW, should non-specification bulk packagings be decontaminated after each use?

6.5.1 Disinfecting reusable containers

All containers used to package RMW, whether bulk or non bulk, should be disinfected after each use. A generator must be assured that reusable containers supplied to them are clean and safe for their employees to handle. A policy of disinfecting only containers that are visibly soiled practically ensures that some containers will be distributed for reuse in an unsuitable condition.

6.6 Question 4

Should hospitals or clinics that use non-specification (combination) bulk packagings to transport RMW be required to register as shippers of bulk hazardous materials?

6.7 Question 5

Should non-specification bulk packagings be allowed only if they are mechanically unloaded, without the inner packaging being handled manually?

6.8 Question 6

Should there be a time limit on the period a bulk packaging loaded with RMW can remain at the generator's site before being required to be entered in transportation? Would such a requirement

reduce the risk of exposure to an infectious substance should a film bag be tom?

6.10 Vapor Containment is the Issue

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future.

The packaging requirements must address the containers ability to fully and absolutely contain the vapors being emitted by the hazardous/biological/pathological contents of the container.

This can only be achieved by using special materials and procedures that are currently available but relatively unknown to forwarders, shippers and transporters.

The BioSeal System, Our triple laminate, heat-sealed process creates a seamless metal container that feels like a paper bag but is actually a sealed metal box.

When these infectious packages transit from sea-level to high altitudes they exclude their vapors into the cargo compartment where they mix with all the other hazardous vapors emitted by all the other hazardous/infectious packaged commodities.

When they transit from high altitude to sea-level the individual packages suck in the mixed hazardous/pathological vapors of the cargo compartment into their containers without discriminating as to the dangers of chemically mixing the vapors.

This represents the primary personal danger and health risk that the employee's and passengers will be exposed to while handling and in transit.

We welcome your comments.

Edward L. McWilliams

President & CEO

Ageis Barrier Products

8 195 Ronson Rd. #D

San Diego, CA 92111

v# 619-569-9868

f# 6 19-569-9867

www.biosealsystem.com

6.11 re: mechanical unload of bulk material

It is very important to require that any bulk transport have mechanical rather than manual handling. I managed a medical waste processing facility that received bulk material that was manually unloaded and it was extremely prone to exposure incidences. The additional risk of manual handling is not worth the "ease" of using bulk transport.

6.11.1 bulk unloading

The comment regarding the need to require mechanical unloading of bulk medical waste was submitted by:

Rick Poll

RAPCO Inc

3390 - 60th ST

Caledonia MI 493 16

l-888-554-0445

I don't know how to identify myself as the author.

6.11.2 (no title)

I agree, the inner packaging should be mechanically unloaded. Without this requirement, the potential exposure to employees is too great.

6.13 173.197 RMW

173.197(a) Non-bulk packaging for RMW.

In my opinion, a UN 4G (fibreboard) packaging is unsuitable for bio-med waste unless a plastic film inner packaging is used. UN metal or plastic single packagings are suitable without an inner if, for solids packaging, the conditions in 173.197 (1) through (7) are applied.

Non-UN non-bulk packaging has been used in Canada for many years, under permit, for the transportation in dedicated vehicles, of infectious and non-infectious bio-med waste (there is no practical way to distinguish between the two).

The following specifications, based on that experience, are currently being proposed:

1. Fibreboard outer packaging: bursting or edgewise compressive strength are specified for particular gross weight and box dimensions, based on Uniform Freight Classification, Rule 41;

Plastic film inner packaging is required: tear, puncture and seal strength are specified (no min thickness).

2. Plastic, metal and fibreboard drums conforming to UFC Rules 40 and 54 are authorized;

173.197(b)Special Bulk Packaging

(l)(ii)Non-specification bulk packaging

(A)(2)The lower limit should be 250 L, since there are no available non-bulk packagings in the 250 - 450 L range, which is a desirable capacity for many reusable containers in waste handling systems;

(B)Requirement for being “capable” of passing 1.2 m drop test is not necessary, in my opinion. I suggest “designed for reuse”. That and the conditions (A) and (C) to (G) provide adequate controls.

(b)(2)Inner packagings

(ii)A specification for plastic film thickness will limit the types of plastic that can be used in this application. I suggest using a performance approach: film tear, puncture and seal strength.

6.14 173.197 RMW

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(b)(2)Inner packagings

(ii)A specification for plastic film thickness will limit the types of plastic that can be used in this application. I suggest using a performance approach: film tear, puncture and seal strength.

6.15 Non-Specification Bulk Packaging

Yes, non-specification bulk packaging should be authorized as reusable outer packagings for RMW packaged in plastic film bags.

The specifications contained in DOT-E-10821 provides for packaging that is safe and a cost effective way to store and transport RMW. In addition to these requirements, the interior of the roll-off container should be constructed such that the plastic film bags do not catch or tear on access door latches. This can be accomplished by moving the latching mechanism to the outside of the container or shielding the interior latches.

The container size should be limited to a 40 yard roll-off container, or equivalent. Yes, non-specification bulk packaging should be authorized as reusable outer packagings for RMW packaged in plastic film bags.

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6.16 Non-Specification Bulk Packaging

Yes, non-specification bulk packaging should be authorized as reusable outer packagings for RMW packaged in plastic film bags.

The specifications contained in DOT-E- 1082 1 provides for packaging that is safe and a cost effective way to store and transport RMW. In addition to these requirements, the interior of the roll-off container should be constructed such that the plastic film bags do not catch or tear on access door latches. This can be accomplished by moving the latching mechanism to the outside of the container or shielding the interior latches.

The container size should be limited to a 40 yard roll-off container, or equivalent.

6.17 Bag Specifications

These specifications are adequate as long as the plastic film bags are loaded into the non-specification bulk packaging without being “thrown” causing the bags to burst or tear. This can be accomplished by having multiple access doors on the bulk packaging so the bags can be laid into the bulk packaging. Also, the interior of the non-bulk packaging should be constructed such that the plastic film bags do not catch or tear on access door latches. This can be accomplished by moving the latching mechanism to the outside of the container or shielding the interior latches.

5. Hazard Communication

RSPA is considering several options with respect to marking or placarding shipments containing infectious substances, including regulated medical wastes (RMW). RSPA is considering whether to require 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. Also, RSPA is considering whether to require placarding for bulk packagings, freight containers, unit load devices, transport vehicles, or rail cars that contain infectious substances known or suspected of containing Risk

Group 2 or 3 pathogens, including RMW. Alternatively, RSPA is considering a requirement to mark bulk packagings, freight containers, transport vehicles or rail cars with the words REGULATED MEDICAL WASTE for domestic transportation of waste infectious substances other than those known or reasonably expected to contain a Risk Group 4 pathogen. RSPA is also considering revising the telephone number on its infectious substance label to reflect a toll free number currently in operation at CDC. (For preamble discussion, see pp. 46846 - 46847. The ANPRM does not include proposed regulatory text on placarding.)

RSPA requests comments on the feasibility of these hazard communication proposals.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

5.1 Question 1

Should placarding be required for any quantity of an infectious substance known or reasonably expected to contain a Risk Group 4 pathogen regardless of the quantity of material being transported or are the CDC regulations sufficient for hazard communication? How many shipments would be affected?

5.1.2 Placarding: B. Cunha Cunhab@MFLDCLIN.EDU

I do not believe that placarding of vehicles transporting blood products should be required regardless of the biohazard. The Occupational Health and Safety Administration already requires biohazard warnings on the outside of containers that hold blood and other infectious body fluids.

Infectious substances that can infect by air may require a more specific warning and placarding. Exposure to an infectious substance that is transmitted by air would pose a hazard to anyone approaching a open/damaged/leaking container. Material of this nature is very rare.

Blood and other infectious body fluids require a direct entry route into the body. That is puncture of the skin by a contaminated sharp object, contact with non-intact skin or contact with mucus membranes.

Universal precautions must be taken (according to the OSHA Bloodborne pathogen standard) for any expected exposure to blood or other potentially infectious body fluids.

Rescue units and other emergency response personnel should be following universal precautions when responding to any vehicle accident, since the potential for exposure to a

Bloodborne pathogen is always present in any accident.

Spills of blood or other potentially infectious body fluids have specific clean up requirements per the OSHA Bloodborne pathogen standard. No other actions are required and it is unclear what adding placarding for shipping of blood or other body fluids would add to this.

What placarding could do is make civilians less likely to assist an injured driver. Will the public (or emergency personnel for that matter) be less likely to assist in an accident if the vehicle that the driver was in is labeled Infectious substance or biohazard?

5.1.2.1 Placarding is unnecessary!!

29 CFR 1910.1030 OSHA Blood Borne Pathogen Standard already addresses concerns of proposed DOT RSPA placarding requirements for RMW.

What sense does it make that 88001bs of RMW is dangerous and requires placarding, but 8,799lbs does not? Why do bulk packages over 468 cubic ft. require placarding and hazmat registration, while 467 cubic ft. does not? Where do these numbers come from?

I agree completely with Cunhab@MFLDCLIN. Medical waste transporters are heavily regulated by the States in which they operate and more Federal regulation will do nothing to promote public safety (look at your own Federal DOT records for injuries from RMW- few injuries and zero deaths over an entire decade)! ! !

If DOT does decide to require placarding, all vehicles regardless of weight or bulk type, should be placarded (the generator nor the transporter knows what the weight is until we weigh it!!!) Also, full or empty vehicles dedicated for RMW transport should be allowed permanent placards to simplify driver responsibilities.

5.1.2.2. Placarding is unnecessary!!

29 CFR 19 10.1030 OSHA Blood Borne Pathogen Standard already addresses concerns of proposed DOT RSPA placarding requirements for RMW.

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5.1.3. Bill Warder

Bill Warder
P.O.Box 20104
Kansas City, MO 64 195
(816)243-5535

Infectious substances placards should be required for the transport of infectious substances. RSPA does not need to exhibit extraordinary concern for those substances that could be level 4 substances. A multitude of forms are required to possess or transport these substances. For example, CDC 0.753 Application for permit to import or transport agents or vectors of human disease, Form EA- 101, Transfer of Select Agents, The Biological Defense Safety Form (I can't locate that form number right now). A registry of persons or laboratories and records of transfers with ultimate disposition is already in place. The National Institutes of Health have no record of any transfers in 1998.

5.2. Question 2

Should placarding be required for a bulk packaging, freight container, transport vehicle or rail car that contains RMW? Should an optional marking, such as REGULATED MEDICAL WASTE or BIOHAZARD, be authorized in lieu of placards? How many shipments would be affected?

5.2.1 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195
(816)243-5535

Yes, too placarding No to substitute placarding

5.3. Question 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? How many shipments would be affected?

5.3.1. Level 2 - 3 placarding B. Cunha

Placarding of blood and other infectious body substances will not add any level of increased safety more than is already required.

Placarding is a way of letting responders to accidents and spills know what the hazard in the vehicle might be. Since blood and other potentially infectious agents do not pose a hazard unless they are gotten into a persons body.
The use of “standard precautions”, required by OSHA for all potential exposures to blood or other potentially infectious body fluids, would be in place in responding to the scene of a spill or accident.

5.4. Question 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?

5.4.1 Emergency Responders B. Cunba

Since it must be anticipated that there will be blood or other infectious body fluids at the scene of a vehicle accident, emergency responders are supposed to be taking “standard precautions” against exposure to blood or other infectious body fluids.

Would there be a difference in the risk factor of blood from a person in the vehicle or from the blood being transported in the cargo?

5.5. Question 5

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

5.5.1 Improved Safety? B. Cunha

Since blood and other potentially infectious body fluids do not create the same hazards as other materials listed in DOT regulations (fire, explosion, corrosive, radiological, toxic gas, etc), it is difficult to see how placarding the vehicle of transport will add to safety?

The basic principle of labeling the internal container with a biohazard sticker should provide all the warning that is needed by personnel responding to an emergency

5.5.1.1 Response to Mr. Cunha

Not that I think placarding is necessary but I can't help but respond to Mr. Cunha's statement:

"The basic principle of labeling the internal container with a biohazard sticker should provide all the warning that is needed by personnel responding to an emergency."

It is attitudes like this that jeopardize the safety of transportation workers and the public.

I assume Mr. Cunha has been trained in universal precautions. Most healthcare safety professionals are trained in the safe handling of infectious or potentially infectious material in the hospital or laboratory setting. Universal precautions and blood borne pathogen training, which have risen to prominence since the HIV epidemic, protect the healthcare worker who handles such material daily. Most facilities have taken their own regulatory measures to establish procedures and guidelines that meet or exceed national standards and regulations. While strenuous measures such as protective equipment and clothing, cleaning and disinfecting procedures, meticulous record keeping, etc., are taken in the lab or hospital to protect patients and employees and Mr. Cunha, what about Joe carrier, or Jane Public? Do universal precautions protect them? No.
This is the very reason why we have transportation regulations. Not to long ago in a Vancouver airport, a small package got caught in a cargo transfer belt. It was damaged. A worker there removed the package from the line. When he looked down, his hands were covered in blood. There were no markings on the outside of the package. Upon opening it, the internal containers were marked with a biohazard symbol and indicated that the blood was HIV positive.

Can we train the public and baggage handlers in universal precautions? Should everyone be trained in blood boume pathogens?
Alternatively, we can train the shippers to do it right and train the carriers to recognize and handle declared shipments of dangerous goods.
Please get trained Mr. Cunha, for everyone safety.

5.5.2 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195

It is the most significant means of visually communicating the risk. It certainly works in every other class and division.

5.6. Question 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?

5.6.1 Costs B. Cunha

This answer covers both question 5 and 6.

In our facility 35 drivers transport blood and other human and animal specimens to our laboratories from pickup sites throughout the state. Currently, these drivers are not required to carry CDL licenses since the vehicles are of the minivan type and unknown hazardous laboratory specimens are exempt.

If placarding were required for any category of biohazard. It would mandate that all of our vehicles be placarded and that all the drives be CDL certified. This would add the expense of 35 CDL physicals, drug screens, etc. plus the cost of administering these requirements.

We are also concerned about the needless worry that placarding vehicles that are not a hazard to the general public would bring. How would you feel if you went to a Mcdonalds and the vehicle parked next to you were placarded on all four sides with Infectious substance? How would the management react?

It is not unusual for our drivers to stop to get lunch at small food establishments on their routes.

Bruce E. Cunha
Cunhab@MFLDCLIN.EDU

5.6.2 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195
(816)243-5535

A single vinyl placard is $1 .OO. For a vehicle dedicated to the transport of these substances a fixed placard carrier is between $8.00 and $10.00. What could be cheaper?

5.7 Question 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?

5.7.1 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195
(816)243-5535
Every driver should have a CDL with a HM endorsement. No exception. Everyone

5.8 Question 8

RSPA is 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 current labels? If so, how long?

5.8.1 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64 195
(816)243-5535
I like 12 yrs (or until the vapor is gone)

5.9 Vapor Containment is the Issue

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future.

The packaging requirements must address the containers ability to fully and absolutely contain the vapors being emitted by the hazardous/biological/pathological contents of the container.

This can only be achieved by using special materials and procedures that are currently available but relatively unknown to forwarders, shippers and transporters.

The BioSeal System, Our triple laminate, heat-sealed process creates a seamless metal container that feels like a paper bag but is actually a sealed metal box.

When these infectious packages transit from sea-level to high altitudes they exclude their vapors into the cargo compartment where they mix with all the other hazardous vapors emitted by all the other hazardous/infectious packaged commodities.

When they transit from high altitude to sea-level the individual packages suck in the mixed hazardous/pathological vapors of the cargo compartment into their containers without discriminating as to the dangers of chemically mixing the vapors.

This represents the primary personal danger and health risk that the employee's and passengers will be exposed to while handling and in transit.

We welcome your comments.

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www.biosealsystem.com

5.10. Objection to alternative "Biohazard" or "Regulated Medical Waste" markings

I believe that a clear, consistent approach to the marking of vehicle exteriors will best facilitate the recognition of hazards by emergency responders.

DOT also recognizes the value of clarity and consistency, requiring that established placards not be obscured and that placard holders not contain other information that may be confused with an established hazard placard (such as a "Drive Safely" placard).

By allowing alternative “Biohazard” or “Regulated Medical Waste” markings, the DOT would allow for a variety of potentially inconsistent formats (in terms of color or layout) for the information, making the information less consistently presented to emergency responders. If these markings are to be allowed, I believe the DOT should specify their size and appearance, as they have done with established hazard placards.

On a related note, I believe DOT should work with other federal agencies (such as EPA and OSHA) to promote mark and label consistency between agencies. From my experience, placement of EPA PCB M(L) or M(S) labels on the exterior of hazardous waste hauling vehicles was always problematic because they could not be placed in placard holders. I would hate to see the creation of additional “Biohazard” or “Regulated Medical Waste” markings not amenable to use with placard holders, since I feel that on a day-to-day operational basis, it would make the attachment of such markings more difficult for all but vehicles dedicated to regulated medical waste or biohazardous materials hauling.

Michael G. Pirrello, CHMM
Team Leader
NC Hazardous Materials Regional Response Team #4
c/o Parkwood Volunteer Fire Department
1409 Seaton Road
Durham, NC 277 13
mpirrello@trimeris.com

5.11. Exempt!!??

“since the vehicles are of the minivan type and unknown hazardous laboratory specimens are exempt” Not according to the HMR!! It is the responsibility of the shipper to assess the risk and classify ALL shipments prior to shipping.

4. Genetically Modified Material

RSPA is considering whether to align the HMR with the UN Recommendations and ICAO Technical Instructions for genetically modified organisms and microorganisms. The international standards treat any genetically modified material that meets the definition of an infectious substance as an infectious substance. A genetically modified material that does not meet the definition of an infectious substance but is capable of altering animals, plants, or microbiological substances in a way not normally the result of reproduction is classified as a Class 9 material. (For preamble discussion, see pp. 46845 - 46846; for section-by-section review, see p. 46850; for proposed regulations text, see pp. 46852 - 46853, p. 46856.)

RSPA invites commenters to address whether RSPA should proceed with developing regulations for genetically modified organisms and microorganisms.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

4.1 Question 1

Are provisions for the safe transport of these substances adequately addressed in regulations of other agencie

4.1.1 Contain The Vapor

If a substance is considered to be hazardous then it should be shipped in a container that will absolutely contain all fluids and vapors associated with its contents. To do less is to discredit the classification.

4.1.2 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195
(816)243-5535
Genetically Modified Organisms and Micro-organisms should be treated the same as biological products.

4.2 Question 2

Are the exceptions considered in 173.140 for genetically modified microorganisms justifiable in terms of safety? Should RSPA consider additional exceptions? Should RSPA consider applying additional controls?

4.2.1. 173.140(d)(l) Exceptions (for GMOs)

HMAC 6.2 Subcommittee:
Although we are fairly certain that we understand the intent in this section, the text is a bit confusing. Specifically the phrase: "...authorized for final distribution and use by a U.S. Government agency...". We will certainly offer text to modify this section in our formal comments to RSPA, however, we believe something akin to: "...that is authorized by a U.S. Government agency for use..."

4.2.2 Contain The Vapor

Under what circumstances does exempting freight handling personnel from safety regulations

regarding known hazardous commodities make sense??

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www.biosealsystem.com

4.3. Vapor Containment is the Issue

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future.

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We welcome your comments.

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4.4. Question regarding Definition of GMOs

HMAC 6.2 Subcommittee.
There is some concern by members of our group that the definition of GMO is a bit confusing as to what is actually the “micro-organism or organism” and could be misinterpreted (e.g., When fruits, vegetables, grains, etc. are the product of a genetically altered plants, the fruit/vegetable/grain should not be a regulated material under this definition.).

3. Biological Products

Currently, the HMR except biological products from all regulatory requirements. RSPA is considering revising this exception so that it would apply to licensed biological products only. Licensed biological products would be defined as those that have been approved by FDA. Biological products known to contain an infectious substance would be treated as infectious substances. RSPA also is considering whether to add a new special provision in 172.102 (consistent with ICAO Technical Instructions Special Provision A81) to except blood and blood products from existing quantity limits by aircraft when the materials are packaged in accordance with 173.196, transported in primary receptacles that do not exceed 500 ml (17 ounces), and outer packagings not exceeding 4 L (1 gallon). (For preamble discussion, see p. 46845; for section-by-section review, see pp. 46849 - 46850; for proposed regulations text, see pp. 46852 - 46853, pp. 46855 - 46856.)

RSPA invites comments on its proposal to eliminate the blanket exception from the HMR for biological products.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

3.1. Question 1

Is an exception for licensed biological products justified?

3.1.1 (No-Title)

The Animal Health Institute (AHI) is the trade association that represents manufacturers of animal health care products. These products include veterinary drugs and biological products. Our licensed member companies produce the majority of all veterinary biological products here in the United States as well as servicing a significant segment of the world market.

Under the January 1, 1996 amendments to 49 CFR, biological products and diagnostic specimens were exempted from the Department of Transportation's (DOT) packaging and labeling requirements, unless they were being discarded. These regulations are currently in force and have served the industry well without notable consequence.

AH1 has been informed that the DOT is in the process of drafting stronger infectious substance regulations, i.e., Title 49 Code of Federal Regulations (49 CFR), Section 173.134. The pending regulations are predicted to remove biological products from their current exemption status. Obviously our members are concerned since these regulations may adversely affect the shipment and availability of United States Department of Agriculture (USDA) licensed veterinary biological products.

The cited basis for this initiative by the DOT was to support international harmonization efforts and not because these products have presented a significant safety risk to people and/or the environment. Since our industry has not been included in the DOT's international harmonization negotiations, we thought it very important to ask that the DOT know more about the current views of all United States stakeholders potentially impacted by these negotiations.

AH1 is aware that closed international harmonization negotiations can occur under the specter of "non-binding agreements". This enables negotiators to proceed without input from all affected parties. The process essentially bypasses the Administrative Procedures Act and the economic impact assessment requirements needed prior to proposed rulemaking. Once these non-binding agreements have international acceptance, regulatory change is inevitable. We certainly hope this is not the case with current efforts.

As of this date, we have contacted Mr. Edward Mazzullo, Director, DOT and other members of his staff, in an effort to acquaint them with our trade association and relay veterinary biological product industry concerns. Subsequent to our meeting with Mr. Mazzullo and staff, we also elected to contact Mr. Alan Roberts, Associate Administrator, RSPA.

As you are probably aware, USDAIAPHISNS- Center for Veterinary Biologics (CVB) regulates the veterinary biological product industry. The regulations for these products are located in Title 9, Code of Federal Regulations, Subchapter E, Parts 10 1 through 118. These regulations are also supplemented with a series of Veterinary Services memoranda and notices as well.

Every licensed veterinary biological product is thoroughly tested for sterility (purity and identity), safety (target animal, environmental, and human food when applicable), potency, and efficacy. Consequently, each veterinary biological product is thoroughly reviewed, characterized, and approved by the USDA prior to its licensure for sale and use. Once licensed, these products are not only shipped and handled by our customers but are administered to livestock and/or pets all over the world.

We believe a relevant and yet objective body of information exists which enables the DOT to justifiably support the current exemption for this class of materials. The inherent safety record of these

products, when in the hands of those that ship and/or administer these products, is quite recognized and well accepted. Consequently, the current USDA and DOT regulations have always been and should continue to be adequate for the shipment of these products.

If the past is a healthy indicator of the present, we do not anticipate any problems under the current regulations. We certainly hope that exaggerated or fear-driven possibility scenarios, especially those with either no or very low probabilities of actual occurrence, will not be cited as the basis for new product shipment regulations on all products--both domestically and foreign.

Pre-license seed and experimental materials for testing from USDA-licensed manufacturers have and continue to be reasonable candidates for exemption. Present USDA regulations, both from Animal and Plant Health Inspection Services (APHIS)/Veterinary Services/Center for Veterinary Biologics (CVB) and the Import and Export staff, require specific application, review, and permission by respective State and Federal authorities for movement and tracking of these materials. This involves the completion and review of preliminary testing, i.e., purity, identity, safety, back passage, environmental risk assessment, et cetera-when applicable. Once permission is granted, protocols for product destination, shipment, experimental design, and disposition of test animals must be approved by APHIS prior to shipment and use.

Finally, routine veterinary diagnostic specimens and materials might be less characterized and should be appropriately packaged and shipped under DOT rules. The current rules have been adequate for the shipment of these items to date; however, we can certainly understand the DOT's concern with shipping certain diagnostic specimens and materials. This same concern would probably apply to some medical wastes as well.

We were aware that the DOT has consulted with the APHIS-Import and Export staff regarding various import and export requirements. However, we strongly recommend that the DOT contact the CVB directors listed below for a more detailed account of the current licensing, policy development, inspection, and compliance regulations for all licensed veterinary biologicals.

Dr. David Espeseth Dr. Donald Randall
Director,LPD Director,IC
CVB CVB
USDAIAPHISNS USDAIAPHISNS
4700 River Road, Unit 148 5 10 South 17th St. Suite 104
Riverdale, MD 20737-123 1 Ames, IA 50010
Phone: 301-734-8245 Phone: 5 15-232-5785
Fax: 301-734-8910 Fax: 515-232-7120

As always, please feel free to contact me if you should have any questions regarding this matter.

Sincerely,
Mark D. Wood, DVM

3.1.1.1. Exemption for USDA-Licensed Veterinary Biologicals

Dear Sir or Madam:

MVP Laboratories, Inc., Ralston, NE, is a USDA-licensed manufacturer of veterinary vaccines. We are STRONGLY OPPOSED to the proposal to drop the exemption of USDA-licensed veterinary vaccines to DOT's packaging and labeling requirements.

This proposal has NO SCIENTIFIC MERIT:

USDA-licensed veterinary vaccines are not "infectious substances". They are prepared from either KILLED microorganisms or from live microorganisms which have been RENDERED INCAPABLE OF CAUSING DISEASE. These products
present no risk to PEOPLE, ANIMALS, or the ENVIRONMENT.

The development of USDA-licensed veterinary vaccines is monitored closely by USDA. Manufacturing, testing and distribution of these products can be initiated only after close scrutiny of all developmental data by USDA. USDA then
continues to monitor and perform confirmatory testing thereafter. USDA also performs unannounced inspections of each manufacturer on a routine basis to further ensure each USDA-licensed veterinary vaccine is prepared and tested to
written USDA-approved procedures and specifications for purity, safety and potency.

This proposal will have an ADVERSE ECONOMIC IMPART:

Costs to manufacture, package and distribute USDA-licensed veterinary vaccines will be significantly increased due to the need for specialized shipping containers and labeling, registration fees, higher shipping costs, increased paperwork, increased staff and training, etc. Some shipping firms will probably refuse to accept products labeled in such a way due to concerns about liability. This would be unfortunate since these products are safe.

Manufacturers who distribute USDA-licensed veterinary vaccines will have to pass on the increased costs that would result from this UNNEEDED proposal to their customers. The only people who will benefit from this proposal are transportation companies and manufacturers of specialized packaging materials. The losers will be pet owners and livestock producers.

The proposal to delete the exemption to USDA-licensed veterinary vaccines is a horrible example of IRRESPONSIBLE BUREAUCRATIC OVERREACHING. HYSTERIA should be no substitute for common sense.

Mary Lou Chapek
President
MVP Laboratories, Inc.

Jack D. McGonigle
QC/Regulatory Affairs Mgr.
MVP Laboratories, Inc.

3.1.1.1.1. Exemptions for USDA-Licensed Veterinary Biologicals

There appears to be some confusion as to the scope of the exception RSPA is proposing for licensed biological products. RSPA is proposing to limit the current exception from the Hazardous Materials Regulations (HMR) for biological products to licensed biological products only. Licensed biological products are defined as those that have successfully completed all screening and confirmatory tests required for licensing by FDA (for human use) or USDA (for animal use). Thus, licensed veterinary biological products would continue to be excepted from the requirements of the HMR. Please see the proposed regulatory text on p. 46855 of the ANPRM.

3.1.2. Maintaining Exemptions For Licensed Veterinary Biological Products

In AHI's previous reply to this question, the title text was apparently lost ("no title") and the address format for listing each USDA/APHIS/VS/CVB Director (located at the end of our reply) was changed. In this case, the adjacent address columns were blended into one and the cited addresses were indistinguishable. Please accept the following as an addendum to our previous reply:

Dr. David Espeseth
Director of Licensing & Policy Development
Center for Veterinary Biologics
USDA-APHIS-VS
4700 River Road, Unit 148
Riverdale, MD 20737- 123 1
Phone: 301-734-8245
Fax: 301-734-8910

Dr. Donald Randall
Director of Inspection & Compliance
Center for Veterinary Biologics
USDA-APHIS-VS
5 10 South 17th Street, Suite 104
Ames, IA 50010
Phone: 5 15-232-5785
Fax: 515-232-7120

3.1.3. Justification for exception for licensed biological products.

Colorado Serum Company, a manufacturer of licensed veterinary biological products and an AH1

member, would like to comment on the justification for exception for licensed biological products.

To begin with, these products have a long history of safety in animals, as well as safety in shipment. To our knowledge, none of our products have ever been broken and/or leaked while in shipment. If this were to occur, the products themselves would present no danger. We go to great lengths to insure our products arrive to the customer in satisfactory condition.

Second, these products are regulated by the USDA, so it is not as if these products do not fall under some U.S. government jurisdiction already.

Third, USDA requires a significant amount of data documenting the safety of these products prior to issuing a license for these products.

And finally, a change in DOT regulations would impose a significant and unnecessary paperwork and financial burden on manufacturers and shippers of licensed products. This cost will be borne in the end by the farmer, rancher and pet owner.

Thank you for considering these comments.

Sincerely,
David K. Camey
Vice-President
Colorado Serum Company

3.1.4. Ia exemption to licensed biologicals justified?

Yes! USDA-licensed veterinary Biologics are thoroughly regulated and tested to ensure they are safe and pose no significant threat to the environment.

Jack McGonigle
MVP Laboratories, Inc.

3.1.5 Bill Warder

Bill Warder
P.O.Box 20104
Kansas City, MO 64153
(816)243-5535

Biological Products as defined in HM-226 should not be subject to the hazardous materials transportation regulations.

3.2. Question 2

Should relief from quantity limits be extended to all biological products rather than limited to licensed biological products?

3.3 Question 3

Do the risks associated with the transportation of biological products warrant the granting of other exceptions while still providing for an adequate level of safety?

3.4 Question 4

Is it appropriate for RSPA to continue to defer to FDA and USDA regulations for these materials? Do the FDA and USDA regulations adequately protect against the hazards these materials may pose in transportation?

3.4.1 Deference to FDA and USDA

Yes. FDA and USDA have the governmental expertise with biologicals and they make risk assessments on a routine basis. Similar expertise in these matters probably does not reside within DOT.

3.5 Question 5

Currently, biological products for which a relatively low probability exists that a pathogen of risk groups 2 or 3 is present are subject to neither the HMR nor requirements of the CDC (42 CFR part 72). What additional costs for packaging, handling, transportation, etc., are shippers likely to incur in order to conform to the requirements proposed in 173.196? Are the exceptions contained in proposed 173.134(b)(1) for diagnostic specimens and 173.6(a)(4) (materials of trade) sufficient to allow shippers to avoid additional costs for packaging, handling, and transportation, while still achieving an adequate level of safety?

3.9 173.134(a)(3) Biological Products

HMAC 6.2 SUBCOMMITTEE:
As HMAC was the primary author of the text which currently appears in the UNCETDG Recommendations ("UN Orange Book"), we tend to agree with the comments of the AHI, however for different reasons.
AH1 has commented that RSPA is expanding the scope of "biological products" in the name of global harmonization without appropriate input from affected U.S. industry via the Administrative Procedures Act.
First, we believe that RSPA has made appropriate effort to include industry through its routine pre-UN and post-UN meetings and RSPA's publication of access to the United Nations website for

Transport of Dangerous Goods.
However, in our reading of this ANPRM it appears that RSPA has in fact gone beyond the text in the "model regulations" and thereby has not harmonized the proposed regulations in the Docket with current international regulations.
RSPA has stated in the text above (within this forum) that a biological product which contains an infectious substance is to be classified as an infectious substance. The UN model regulations actually state in 2.6.3.1.2(b) "those manufactured and packaged in accordance with the requirements of national governmental health authorities and transported...are not subject to the regulations applicable to Division 6.2;"
If RSPA intends to adopt the international regulations, we believe they should attempt, to the extent possible, to capture the language currently accepted on an international basis.
We believe that the removal of the current "exception" for biological products under 173.134(b) and subsequent adoption of the language in 2.6.3.1.2 of the UN Orange Book would allow the same provisions for movement of the properly approved biological products as are provided under the current U.S. exception.
We will attempt to address this issue in greater detail and clarity in our written comments to this Docket,

2. Diagnostic Specimens

Currently, the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-l 80) except diagnostic specimens from all regulatory requirements. RSPA is considering eliminating this exception. Instead, the regulations would differentiate between a diagnostic specimen known or suspected to contain an infectious substance and one that probably does not contain an infectious substance, such as a diagnostic specimen offered for transportation and transported for routine screening. A diagnostic specimen that is known or suspected to contain a pathogen in Risk Group 2, 3, or 4 would be treated as an infectious substance. A diagnostic specimen that probably does not contain a Risk Group 2 or 3 pathogen would be subject to reduced packaging and hazard communication requirements. (For preamble discussion, see p. 46845; for section-by-section review, see pp. 46849 - 46850; for proposed regulations text, see pp. 46854, 46855 - 46856, 46857.)

RSPA invites comments on its proposal to eliminate the blanket exception from the HMR for diagnostic specimens.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

2.1 Question 1

Will shippers be able to differentiate between diagnostic specimens that probably contain Risk Group 2, 3, and 4 pathogens and those that do not? If not, are shippers likely to ship all diagnostic specimens as infectious substances rather than take advantage of the regulatory exceptions proposed for packaging and hazard communication requirements?

2.1.1 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64153
(816)243-5535

The definition or "diagnostic" answers this question. The risk posed by diagnostic specimen materials shipped declared or undeclared pose the GREATEST risk for transportation workers. There is at least a million times greater exposure to injuries, illness and death caused by a frustrated diagnostic specimen and the subsequent wastes. This is and since 1972 has been the most important issue facing RSPA in infectious substance rulemaking. Diagnostic Specimens should be regulated as infectious substances. Infectious substances are infectious substances period.

2.2 Question 2

Currently, diagnostic specimens for which a relatively low probability exists that a pathogen of risk groups 2 or 3 is present are subject to neither the HMR nor requirements of the CDC (42 CFR part 72). What additional costs for packaging, handling, transportation, etc., are shippers likely to incur in order to conform to the requirements proposed in 173.196? Are the exceptions contained in proposed 173.196(c)(2) for diagnostic specimens and 173.6(a)(4) (materials of trade) sufficient to allow shippers to avoid additional costs for packaging, handling, and transportation, while still achieving an adequate level of safety?

2.2.1. Costs- Bruce E. Cunha Cunhab@mfldclin.edu

Our facility has both Medical and Veterinary laboratories. We ship and receive approximately 40 shipment of blood and other specimens in and out of our facility a day.

Current shipping requirements only require a hazard warning on products that would fit the category 4 classification. Our carriers charge between $15 and $25 for this additional labeling.

It is estimated that in one year, we ship or receive 11,600 specimens. It is impossible to determine which of these specimens fit under any of the listed categories since they are usual being send to us to determine a problem.

If, as expected, transporters require any unknown specimen to have a hazard warning, they will be able to charge for this.

For our facility and customers this will cost approximately $230,000 more per year in shipping costs (that is if the costs do not change).

2.2.1.1. Question to Cunha - Costs/Classification

You reference “category 4 classification” in your comments. Do you mean WHO Risk Group 4??

How are the majority of your samples shipped at present? By air or by highway? If by air, which transport regulations do you apply, if any?

2.2.1.1.1. Clarification B. Cunha

Yes. I was referring to Group 4 of the WHO list.

We currently ship primarily by carriers such as UPS, Airborne express and Federal Express. Both Air and Ground.

We have been advised by all these carriers that we will have to have persons trained to IATA standards for shipping purposes.

We do both shipping of specimens and receiving of specimens.

Bruce Cunha
Cunhab@MFLDCLIN.EDU

2.2.1.1.1.1. UPS

UPS prohibits the shipment of ANY class 6.2 hazmat on their system. Are you declaring your shipments?

P.S. CFR 49 172.700, 173.1, 175.20, 177.800 and 177.816 all require your people to be trained BEFORE any shipments.

2.2.2 Bill Warder

Bill Warder
P. 0. Box 20104
Kansas City, MO 64 195
(816)243-5535

Diagnostic specimen should not be a proper shipping name. Diagnostic specimen should be treated as infectious substances. There is no distinction in any other regulation and there doesn’t need to be one in transportation. This is the crux of the regulation.

2.2.2.1 Comment for Mr. Warder

I disagree with your comment that there need not be a distinction made between “diagnostic specimens” and “infectious substances”. My experience, limited as it is, would suggest that there are

many more samples - magnitudes more - which have a low probability of containing an infectious agent. As such, it would appear to me that requiring all these shipments to be packaged, marked, labeled, and documented as INFECTIOUS would be costly and irresponsible.

However, in the interest of safety of those workers in the transport arena, a minimal packaging requirement does seem appropriate.

2.2.3 Eric Cook

First, I believe the first statement of the question is somewhat misleading. While it may be true that 49 and 42 CFR do not require any special marking or hazard communication, 42 CFR does outline minimum packaging requirements for the transportation of diagnostic specimens and biological products which may possibly contain a pathogen. I refer to 42 CFR 72.2.
Second, in my experience, most shipments that are not covered by the MOT exception are shipped by air. As such IATA carriers require that these low probability diagnostic specimens be packaged according to their Packing Instruction 650. ICAO has basically the same requirements. The proposed packaging for such material as found in 173.196 (c) is similar to packing requirements found in ICAO and IATA which shippers have been following (or should have been following if using an IATA member carrier) for the past several years. As long as they are packaged properly, these packages are not considered dangerous goods and as far as I'm aware are not subject to the $15 - $25 dangerous goods surcharges mentioned by Mr. Cunha. As far as packaging is concerned, since the proposal does not require these specimens to be in a UN specification marked package, facilities can put together their own package with limited internal testing (which most are already doing now). Thus, I do not believe that packaging costs will be an issue either.

2.5. Vapor Containment is the Issue.

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future. The packaging requirements must address the containers ability to fully and absolutely contain the vapors being emitted by the pathological contents of the container. This can only be achieved by using special materials and procedures that are currently available but relatively unknown to forwarders.

2.6. Diagnostic Specimens

The requirements of the Occupational Health and Safety Administration (OSHA) Bloodborne Pathogen standard call for the use "Standard" precautions when handling all blood or other potentially infectious body fluids.. This is interpreted as treating every specimen as if it contains a pathogen. This is done because most of the diseases of concern (HIV, Hepatitis B, Hepatitis C) have varying periods of time where no visible symptoms of a disease exists.

Because of the "Standard Precautions" provision, OSHA has taken a negative view of labeling

specimens as containing Bloodborne pathogens. Our interpretation on this view is if the employee can take safer precautions for known pathogen specimens, they should be taking the same precautions for those not known to contain pathogens. The percent of specimens that contain pathogens is unknown. Therefor, most transporters would require the category 4 labeling.

For blood specimens, the pathogen must get into the body through open wounds, direct puncture by a contaminated object or contact with mucus membranes.

A simple warning such as the biohazard label that OSHA now requires should be sufficient to warn personnel to take “standard precautions”

An interesting question is what about the blood and other body fluids that occurs from routine traffic accidents. It would be very difficult to identify if this blood or other body fluids contained pathogens.

2.7 Eric Cook

I believe that the changes to the HMR in the proposed rule to eliminate the blanket exception go a long way to promote safety, harmonization and eliminate a great deal of confusion. Saf-T-Pak Inc., does a great deal of training specific for shipper’s of Class 6.2 dangerous goods in the US. In our training we discuss in detail the requirements of the Hazardous Materials Regulations (HMR) as well as the IATA/ICAO requirements for air shipments. A good portion of the training course deals with classification. In my experience, once a person has been properly trained, understanding the ICAO classification scheme for diagnostic specimens and infectious substances becomes very easy to understand and apply.
Those who have not been trained properly may ship all diagnostic specimens as infectious agents. The question to be answered is: Would we rather have someone who has not been properly trained sending a possible biohazardous material as an infectious substance with all the proper packaging marking and labeling or just not declare it and ship it unmarked and not properly packaged? Currently, the latter scenario happens thousands of times every day because of the broad exception in the HMR. Personally, I would rather see untrained shippers ship everything as infectious and let only those who have been through a proper hazmat training course take advantage of the regulatory exceptions proposed for packaging and hazard communication. Maybe this will provide more impetus to get trained.

2.8. Chairman, ALPA Dangerous Goods Committee

From: G.E. Sprenkle
Chairman, Dangerous Goods Committee
Airline Pilots Association
PO Box 1169
535 Herndon Parkway

Herndon, VA. 22070- 1169

ALPA is, and historically has been opposed to diagnostic specimens being excepted from the regulations. The reason is quite simple. Any specimen that is being transported for testing for an infectious substance must be assumed to be infectious until proven otherwise and all regulations governing the shipping of infectious substances should apply. We approach this proposal as a safety issue that could directly affect all personnel that are charged with handling these packages, and in the case of airborne pathogens, the passengers and flight crews. (This being due to the recirculation fans on newer aircraft that recirculate air exhausted from the cargo compartments back into the main cabin.) The cost of shipping these specimens as "regulated" is apparently an issue. Our response is that human safety must always come first and that the additional cost really amounts to inexpensive insurance toward this end. ALPA supports this proposal by the RSPA, including the use of the WHO/UN Risk Groups.
Thank you for the opportunity to comment.

2.8.1 Diagnostic Specimens

From: Art Rutledge, DITTO!!

2.9. Diagnostic Specimen Concerns

September 16, 1998

Ladies and Gentlemen,

Thank you for giving me the opportunity to respond to this ANPRM for HM-226.

My area of interest in this ANPRM is Diagnostic Specimens.

Some sort of minimal packaging standards needs to be made for all the Groups, 1 through 4. An FAA spokesman made the statement last month that the group of Dangerous Goods with the largest amount of spills from Latin America to the US was Diagnostic Specimens. This ANPRM alludes to this fact in its opening statement on page 46845 item B, Diagnostic Specimens.

This ANPRM proposes to do away with any packaging standard for Diagnostic Specimens in Group 1. Who makes this determination, and what safeguards are in place to ensure proper classification in Groups 1 through 4? Even Group 1 needs some sort of minimal packaging standard as an extra margin of safety in the event of misclassification.

There exists a potential for confusion in this ANPRM in its use of the term "Diagnostic Specimens". On one hand, it is proposed as a Proper Shipping Name with a UN Number, and on the other hand, Diagnostic Specimens in Group 1 are not regulated. Two different terms need to be used. A

suggestion would be to leave Diagnostic Specimens as the proper shipping name for Groups 2, 3, and 4, and Diagnostic Samples for Group 1. Substitute any terms you wish, but two different terms are needed here.

Sincerely,

Capt. G.T."Trent" Davis, III
Vice-Chairman Dangerous Goods Committee, Air Line Pilots Association
PO Box 610625
Dallas, TX. 75261-0625
214-361-9430

1. International Recommendations & Regulations/WHO Risk Groups

RSPA is considering revising the classification criteria for infectious substances to be consistent with the United Nations Recommendations on the Transport of Dangerous Goods and the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air (Technical Instructions). In particular, RSPA is considering adopting the risk groups and defining criteria developed by the World Health Organization (WHO) for these materials. RSPA will defer to the Centers for Disease Control and Prevention (CDC) for guidance in determining the risk group of specific materials. (For preamble discussion, see pp. 46844 - 46845; for section-by-section review, see pp. 46849 - 46850; for proposed regulations text, see p. 46855.)

RSPA seeks comments on how adoption of this risk-based classification criteria will affect the way shippers and carriers of infectious substances currently operate.

RSPA is requesting that you provide your name, address, and telephone number as part of your comments.

1.1 Question 1

Are the proposed criteria consistent with definitions of infectious substances in other federal or state regulations with which shippers and carriers must comply? To the extent that federal or state criteria differ, if at all, from this proposal, do the proposed criteria allow for greater flexibility in the application of risk-based requirements for packaging, handling and transportation?

1.1.1 Bill Warder

The "risk groups and defining criteria" developed by the World Health Organization (WHO) published in WHO/EMC/97.3 (Guidelines for the Safe Transport of Infectious Substances and diagnostic specimens, Geneva, 1997) is NOT a formal publication of WHO. By and large, this guideline was published at the request of the delegation from the United States.
Dr. Jonathan Y. Richond, Director, Office of Health and Safety, Centers for Disease Control and

Prevention in his presentation, "The 1,2,3's of Biosafety Levels indicates Biosafety levels are, "guidelines evolved as a means of protecting microbiological workers". Biosafety levels are specific to the healthcare disciplines. They have no meaning to transport workers and should not be considered in this rulemaking procedure.

1.1.2 Greater Flexibility

This requirement will give less flexibility in shipping biohazard. Because current requirements allow the shipper to determine only if a biohazard is known, most materials can be shipped without labeling since they are unknown.

From the category definitions, even a culture swab from a patient with a common cold could fit under a category 2 requirement.

This change is going to require that hundreds of thousands of specimens now transported without problem or incident will have to have labeling indicating they contain an infectious substance. This will significantly increase costs and will also cause larger problems for receiving facilities in that employees will experience increased and needless fears about the materials they are handling.

Bruce E. Cunha MS
Cunhab@MFLDCLIN.EDU

1.2 Question 2

Is it appropriate for RSPA to defer to either WHO or CDC concerning determinations of the risk group assignment of specific materials? Should we incorporate WHO materials by reference?

1.2.1 Bill Warder

Bill Warder
P. 0. Box 20104
Kansas City, MO 64195
(816)243-5535

It is totally inappropriate for RSPA to defer to either WH
0 or CDC. Except for public transportation workers, the safety guidelines for workers outside the healthcare environment is addressed in the Department of Labor (DOL) Standard 1910.1030 Bloodborne pathogens. The scope of the DOL standard applies to all occupational exposure to blood or other potentially infectious materials generally defined as, "any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids". This DOL recommended method of compliance with the 1910.1030 standard is "universal precautions".

1.3 Question 3

Will shippers have difficulty determining the risk groups of specific materials?

1.3.1. Determining risk groups

Since the Occupational Safety and Health Administration does not want different handling and treatment of biological specimens, they are not currently labeled as if they do or may contain a biohazard.

Because a specimen may be sent for testing other than for the exact disease the person or animal may have, it is impossible to say which specimens will or will not contain category 2,3,or 4 material.

This will mandate from the shippers that all unknown specimens be put at the highest category.

Bruce E. Cunha MS
Cunhab@MFLDCLIN.EDU

1.3.2 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195
For a hugh % of materials covered by this rulemaking shippers are trying to have the materials specifically identified as the primary cause for the transportation in the first place. Yes, shippers will have a difficult, no impossible, time determining a risk group. This is exactly the reason risk groups were not included in 1972. RSPA has never proposed rules to any class or division of hazardous material that subjects transportation workers to a compromise like the “Risk Group Table”.

1.4 Question 4

To what degree may persons who now perform the classification function require additional training in order to properly determine the risk group of an infectious substance? Please identify the new costs, if any, and provide comments on how RSPA may help to minimize those costs, especially on small businesses

1.4.1 Cost of Training

We need to be practical when it comes to these proposals. The transportation carrier is going to require that a classification 4 be added to any medical specimen that cannot be shown is not a hazard.

Currently specimens that are unknown do not have to be labeled as biohazard. It is impossible to test every lab specimen for the pathogens that could fit under a category 4 classification.

This addition will require minimal extra training, all you are going to have to do is say “I do not know”

and shippers will require the highest level of hazard.

Please remember, the shippers currently charge an extra 15 to 25 dollars for a specimen marked biohazard. This change will give the carrier an extra excuse to add this charge to every package now shipped as unknown. The financial incentive to the carriers will drive this requirement.

Bruce E. Cunha MS
Cunhab@MFLDCLIN.EDU

1.4.1.1 TRAINING

I have always heard that ignorance is bliss. Are YOU trained in the transportation of hazardous materials as required in 172.700?

14.2 Bill Warder

Bill Warder
P.O. Box 20104
Kansas City, MO 64195
(816)243-5535
Additional cost for training will be very small. Regardless of size, persons and institutions that handle blood are required by CLIA to have a safety plan and regular training. Persons outside the instructional setting are required to maintain ongoing education to stay current in their discipline. Continuing Education Units (CEU's) could be offered for specific transportation training.

1.7. Vapor Containment is the Issue

Barrier Products would like all those concerned with this issue to please advance your thinking to the future of hazmats transporting. The absolute and total containment of life/health threatening vapors is an issue that will confront all of us in the near future.

The packaging requirements must address the containers ability to fully and absolutely contain the vapors being emitted by the hazardous/biological/pathological contents of the container.

This can only be achieved by using special materials and procedures that are currently available but relatively unknown to forwarders, shippers and transporters.

The BioSeal System, Our triple laminate, heat-sealed process creates a seamless metal container that feels like a paper bag but is actually a sealed metal box.

When these infectious packages transit from sea-level to high altitudes they exclude their vapors into the cargo compartment where they mix with all the other hazardous vapors emitted by all the other hazardous/infectious packaged commodities.

When they transit from high altitude to sea-level the individual packages suck in the mixed hazardous/pathological vapors of the cargo compartment into their containers without discriminating as to the dangers of chemically mixing the vapors.

This represents the primary personal danger and health risk that the employee's and passengers will be exposed to while handling and in transit.

We welcome your comments.

Edward L. McWilliams
President & CEO
Ageis Barrier Products
8195 Ronson Rd. #D
San Diego, CA 92111
v# 61 9-569-9868
f# 619-569-9867
www.biosealsystem.com

1.7.1. Vapor barrier bag/box !!!!

When you reference the breath-in/breath-out process which occurs with the changes from sea level to high altitude and visa versa - are you saying that this is what your packaging does? The provisions for infectious substance packagings certainly don't allow for such activities. Reference IATA Packing Instruction 602.

1.7.2. Vapor Smapor

First of all, are you familiar with 173.196 (f) of 49 CFR? My guess is that you are not.

(f) 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 differential of not less than 95 kPa (14 psi) and temperatures in the range of -40 C to +55 C **(-40** F - +131 F)

95 kPa is about near vacuum and is approximately the pressure a closed rigid container will experience at 90,000 ft in an unpressurized cargo hold. If the infectious substance is properly packaged there should not be ANY escape (vapor or otherwise) from the package.

Secondly, as far as I'm aware, most modern aircraft cargo holds are pressurized. Or at least any dangerous goods should be placed in pressurized cargo holds. Only in the dire emergency of a cabin depressurization would any vapors be forced out(if they could. Besides if the container meets the 95 kPa requirement, I guarantee that if air can't get out at that pressure, no infectious agent can either.

And finally, when it comes to infectious substances, it is not the “vapors” that are dangerous. Yes it is conceivable that, certain infectious agents could become aerosolized in a transport accident and spread through the air. However, current regulations address this with pressure containment, triple packaging and leakproof containment requirements.

Are you bags up to the rigorous 95 kPa pressure differential requirement?

Have you put together a complete package? IE can it meet the 9m drop, and the impact testing outlined in 178.609. Do you include absorbent, etc.

1.8. International Recommendations

Standardization is always a better way of making things safer and easier. The problem that this question asks is “Do we have any input into what the standard is?”

The 4 hazard categories as listed in this proposal are very poorly worded and leave tremendous room for interpretation. When you issue standards that are up for interpretation, you create more confusion.

If shippers are confused about what category to put something in, two possibilities come up. Ship at the highest level to avoid any potential liability, or ship at a lesser level and hope your package is not damaged or leaks.

More specific category information is needed.

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1.9 Eric Cook

Saf-T-Pak Inc., does a great deal of training specific for shippers of Class 6.2 dangerous goods in the US. In this training we discuss in detail the requirements of the Hazardous Materials Regulations (HMR) as well as the IATA/ICAO requirements for air shipments. As such, we discuss the WHO Risk Groups as they relate to the IATA/ICAO classification structure. In my experience probably less than a quarter of participants have any knowledge of risk groups. These are doctors and lab professionals. It is not difficult to explain the criteria for assigning risk groups. However, to require shippers to determine the exact risk group based on these criteria can be challenging and in most cases unnecessary for the following reasons:

1. Consistency: two scientists or doctors using the same Risk Group Table found in the ANPRM could classify the same organism differently. A good example would be HIV. Based on that table and what we know of AIDS, one would probably put HIV in RG III. However, HIV is generally placed in RG II by the WHO. In order to maintain consistency, an exhaustive list must be published and

regularly updated for the thousands of infectious agents. Also, different strains of the same organism can have varying pathogenicity and will affect certain populations differently complicating things enormous
2. Whether the material contains a pathogen of Risk Group II, III, or IV, the proper shipping name, marking, labeling, packaging, etc. is all the same.
3. Risk Groups, as used in the proposed rule, only apply to 173.134 © Exceptions for diagnostic specimens. For many diagnostic specimens the exact micro-organism is unknown and therefore cannot be assigned to a risk group.
4. Risk Group I micro-organisms are unlikely to cause disease and therefore do not meet the definition of a pathogen, as defined by ICAO Technical Instructions 6.3.1 and in 173.134 (a)(2) of the proposed rule. Because RG I micro-organisms are not pathogens, substances containing only RG I micro-organisms should not be classed as infectious substances. As such, they do not require the specific exemption identified in Note 1. of paragraph 6.3.3 in the ICAO TI and 173.134 (c)(3) of the proposed rule.
5. The only other reference to risk groups is only in the instance where a diagnostic specimen has a low probability for pathogens of RG IV. These must be classed as Division 6.2 dangerous goods.
6. Although we have no numbers, in our training sessions, we have rarely trained anyone who has ever dealt with a RG IV pathogen.

It seems to me that a lot of effort is put into assigning risk groups for no purpose other than to include diagnostic specimens with a low probability of RG IV pathogens in Division 6.2 and to provide an exception for RG I micro-organisms which do not need it because by definition they are not pathogens and therefore not infectious substances. Instances in the regulations which state “pathogens in RG II, III, or IV” are redundant in that micro-organism in RG II, III, or IV are by definition pathogens. It would be the same as stating “pathogens which are pathogens.”
Specimens where there is even a low probability for RG IV should, in the interest of public safety, be fully regulated Class 6.2 dangerous goods. In fact, there are some RG III micro-organisms that probably should be handled the same way as well. I believe this can be accomplished without reference to risk groups by including those select agents identified by the CDC in their “Select Infectious Agent List” found in Appendix A of 42 CFR Part 72. The 1996 Anti-Terrorism and Death Penalty Act requires the CDC to create a List of Select Infectious Agents. This can be found in Appendix A to Part 72 of 42 CFR. Most risk group IV pathogens are on this list and if they are not maybe they should be by default. When transporting any agents on this list shippers are responsible to obtain specific permits and labs which handle this material must be registered with the CDC.

In order to reflect this, 49 CFR 173.134 (c) could be amended to the following:

(1) A diagnostic specimen that is known or reasonably expected to contain a pathogen (medium to high probability) or for which there is any probability that it contains a pathogen from the Select List of Agents in 42 CFR Part 72 Appendix A 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 there is a low probability for pathogens other than those listed in 42 CFR Part 72 Appendix A may be transported under the exceptions provided in 173.196(c).

(3) A diagnostic specimen that is known or reasonably expected to contain only non-pathogenic micro-organisms or is known not to contain a pathogen is not considered an infectious substance and is not subject to the requirements of the subchapter.
(4) same as proposed rule
(5) same as proposed rule

I believe harmonization with 42 CFR, less confusion, redundancy and ultimately better compliance and safety can be achieved by using the select agent list from 42 CFR rather than risk groups as proposed above.
An alternative to the 42 CFR list, would be to include a list of RG IV pathogens in the HMR; the list is small and if there is any probability that a pathogen from that list is present, include the substance in Class 6.2. Just a thought.