



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

1200 New Jersey Avenue, SE  
Washington, D.C. 20590

**OCT 15 2014**

Paul J. Meechan, Ph.D., MPH  
Director, Environment, Health  
and Safety Compliance Office  
Centers for Disease Control and Prevention  
Building 20, Room 2211, M/S F-05  
1600 Clifton Road  
Atlanta, GA 30329

Reference No. 14-0140

Dear Dr. Meechan:

This is in response to your April 25, 2014 letter requesting clarification of the U.S. Department of Transportation (DOT) regulations applicable to transporting select agents under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask if "Suspected Category A Infectious Substance" may be used as the proper shipping name to describe all Division 6.2 (infectious) select agents under the HMR. Ms. Lori Bane, Associate Director for Policy, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services, forwarded your letter to us on July 16, 2014. We have no past record of receiving your letter. We apologize for the delay in responding and any inconvenience this may have caused.

You state your agency and the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) have issued guidance in the past in support of using "Suspected Category A Infectious Substance" as the technical name as part of the proper shipping description for an infectious substance, even when the name of the agent is known, to encourage the safe transport of these materials through a "lost in the crowd" concept. However, you state since 2009 DOT and other inspectors have increasingly cited packages described in this manner as failing to use an authorized technical name under the HMR. You recommend using this technical name as the proper shipping name to reduce the chance of these packages becoming frustrated in transit while still supporting the "lost in the crowd" concept.

Under § 172.203(k), a Division 6.2 material assigned identification number UN 2814 or UN 2900 that is suspected to contain an unknown Category A infectious substance must have the words "suspected Category A infectious substance" entered in parentheses in place of the "technical name" as part of the proper shipping description. When the identity of the pathogen contained in an infectious substance is known, the technical name (see § 171.8), which can be a recognized chemical name or microbiological name or generic group, or for proficiency testing a generic microbiological description, of the pathogen must be indicated in parentheses in association with the basic description on a shipping paper as prescribed in § 172.203(k).

If you wish to transport the select agent materials in the manner you described, you have the following options. A "person," as this term is defined in § 171.8, may petition PHMSA to add or amend the HMR to include this wording as a proper shipping name through a rulemaking action in conformance with the procedures prescribed in 49 CFR 106.95 through 106.130. Proper shipping names are part of a uniform system of internationally accepted words and images designed to provide transportation workers and emergency responders with sufficient information to properly prepare the material for transport and to respond appropriately to contain risks that may be present if the material is released.

PHMSA designs and revises hazardous material proper shipping names, coded numbers, and images as needed in consultation with the specialized agencies of United Nations (UN) Economic and Social Council and other federal and international agencies, including the CDC and APHIS. We believe this system of hazard communication supports the CDC/APHIS "lost in the crowd" concept in that it is also designed to attract minimal attention from the general public. However, if additional changes are needed to ensure the safe transportation of select agent materials, we welcome discussing this matter with you.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Glenn Foster". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

T. Glenn Foster  
Chief, Regulatory Review and Reinvention Branch  
Standards and Rulemaking Division



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Edmonson §172.101  
§172.203(k)  
Proper shipping name

Public Health Service

14-0140

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

U.S. Department of Transportation  
PHMSA Office of Hazardous Materials Standards  
Attn: PHH-10  
East Building  
1200 New Jersey Avenue, SE.  
Washington, DC 20590-0001

Centers for Disease Control  
and Prevention  
1600 Clifton Road  
Bldg 20, Room 2211  
M/S F-05  
Atlanta, GA 30329

25 April 2014

Subject: Request for Interpretation of 49 CFR 172.101 and 172.202 and Technical name requirements for Select Agents (42 CFR part 73, 9 CFR part 121, and 7 CFR part 331).

Dear Sir or Madam:

I am writing to request an interpretation from the Department of Transportation (DOT) Hazardous Materials regulations (49 C.F.R. Parts 171-180) concerning the completion of the Shipper's Declaration for Dangerous Goods (Declaration) for shipments of biological agents and toxins listed in 42 C.F.R. §§ 73.3,4 and 9 C.F.R. §§ 121.3, 4. (select agents and toxins).

As we read them, the DOT Hazardous Materials regulations currently require entities that ship infectious materials, such select agents and toxins, enter "INFECTIOUS SUBSTANCE, AFFECTING HUMANS" or "INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY" in the Declaration's "Proper Shipping Name" block followed by the specific technical name such as "Ebola virus" or "Foot and Mouth disease virus."

However, we have received guidance from the Centers for Disease Control and Prevention's Division of Select Agent and Toxins (DSAT) and the Animal and Plant Health Inspection Service's Agriculture Select Agent Services (AgSAS) that, for security purposes, entities shipping select agents and toxins should use a "lost in the crowd" concept. Specifically, DSAT guidance is that in filling out the Declaration, an entity should enter "INFECTIOUS SUBSTANCE, AFFECTING HUMANS" followed by "SUSPECTED CATEGORY A INFECTIOUS SUBSTANCE" in the "Proper Shipping Name" block even when the entity knows the technical name of the infectious substance, such as "Ebola virus." AgSAS guidance is that in filling out the Declaration, an entity should enter "INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY" and "SUSPECTED CATEGORY A INFECTIOUS SUBSTANCE" in the "Proper Shipping Name" block even when the entity knows the technical name of the infectious substance, such as "Foot and Mouth disease virus." The DSAT and

AgSAS guidance states that the "DOT recommends the use of 'lost in the crowd' for all shipments of a select agent and toxin."

We were implementing the "lost in the crowd" concept until we were cited by DOT inspectors in 2009 for failing to use an agent's technical name in filling out the Declaration. I am requesting a DOT interpretation whether the term "Suspected Category A Infectious Substance" can be used as the proper shipping name for all Select Agents.

Thank you for your assistance in this matter. If you have additional questions, please contact me either via email at [pmeechan@cdc.gov](mailto:pmeechan@cdc.gov) or at 404-639-3147.

Sincerely,

Paul J. Meechan, Ph.D., MPH  
Director, Environment, Health and Safety Compliance Office  
Centers for Disease Control and Prevention

Edmonson  
173.134  
Definitions  
14-0140

**Dodd, Alice (PHMSA)**

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**From:** Edmonson, Eileen (PHMSA)  
**Sent:** Thursday, July 17, 2014 10:26 AM  
**To:** Dodd, Alice (PHMSA); Goodall, Shante CTR (PHMSA)  
**Subject:** FW: Interpretation for CDC  
**Attachments:** DOT LETTER.DOCX

Alice and Shante,

Please log the attached letter into Filemaker and assign it to me. I just received it yesterday.

Thanks,

Eileen Edmonson  
USDOT/PHMSA  
(202) 366-4481 (w)  
(202) 366-7041 (f)  
[eileen.edmonson@dot.gov](mailto:eileen.edmonson@dot.gov) (e-mail)  
<http://www.phmsa.dot.gov/hazmat> (website)  
[infocntr@dot.gov](mailto:infocntr@dot.gov) (Hazmat Info Center E-mail)

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**From:** Bane, Lori (CDC/OPHPR/DSAT) [<mailto:zoz1@cdc.gov>]  
**Sent:** Wednesday, July 16, 2014 4:58 PM  
**To:** Edmonson, Eileen (PHMSA)  
**Cc:** Stevens, William (PHMSA); Foster, Glenn (PHMSA)  
**Subject:** RE: Interpretation for CDC

Eileen,

I apologize for not being cleared. Please find attached the letter from the registered entity, CDC.

Thanks,

Lori J. Bane  
Associate Director for Policy  
CDC.Division of Select Agents and Toxins  
1600 Clifton Road MS A-46  
Atlanta, GA 30333  
404-718-2006  
Fax: 404-718-2096  
[zoz1@cdc.gov](mailto:zoz1@cdc.gov)  
<http://www.selectagents.gov/>

DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins.

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**From:** [eileen.edmonson@dot.gov](mailto:eileen.edmonson@dot.gov) [mailto:[eileen.edmonson@dot.gov](mailto:eileen.edmonson@dot.gov)]  
**Sent:** Wednesday, July 16, 2014 3:32 PM  
**To:** Bane, Lori (CDC/OPHPR/DSAT)  
**Cc:** [William.Stevens@dot.gov](mailto:William.Stevens@dot.gov); [Glenn.Foster@dot.gov](mailto:Glenn.Foster@dot.gov)  
**Subject:** RE: Interpretation for CDC

Hello Lori,

Are you referring to the document I provided edits to you on July 3<sup>rd</sup> (see e-mails below and the attachment)?

I searched my office's catalogue of the requests its received for letters of clarification on my agency's regulations and cannot find a recent one from the CDC. If the attached e-mail is not what you seek, can you tell me the topic of the request and who it came from?

Sincerely,

Eileen Edmonson  
USDOT/PHMSA  
(202) 366-4481 (w)  
(202) 366-7041 (f)  
[eileen.edmonson@dot.gov](mailto:eileen.edmonson@dot.gov) (e-mail)  
<http://www.phmsa.dot.gov/hazmat> (website)  
[infocntr@dot.gov](mailto:infocntr@dot.gov) (Hazmat Info Center E-mail)

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**From:** Bane, Lori (CDC/OPHPR/DSAT) [mailto:[zoz1@cdc.gov](mailto:zoz1@cdc.gov)]  
**Sent:** Wednesday, July 16, 2014 12:35 PM  
**To:** Edmonson, Eileen (PHMSA)  
**Cc:** Stevens, William (PHMSA)  
**Subject:** Interpretation for CDC

Eileen,

Can I get the status on the letter for interpretation for CDC?

Thanks,

Lori J. Bane  
Associate Director for Policy  
CDC Division of Select Agents and Toxins  
1600 Clifton Road MS A-46  
Atlanta, GA 30333  
404-718-2006  
Fax: 404-718-2096  
[zoz1@cdc.gov](mailto:zoz1@cdc.gov)  
<http://www.selectagents.gov/>

DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins.

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