



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

MAR 08 2013

Alan G. Woodard, Ph.D.
Bureau of Permitting and Planning
Division of Materials Management
New York State Department of Environmental Conservation
625 Broadway
Albany, NY 12233-7258

Reference No. 12-0243

Dear Mr. Woodard:

This is in response to your October 26, 2012 e-mail, and October 4 and 26, 2012 telephone conversations with a member of my staff requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the transportation of waste "agricultural clearance material" (e.g., food, table and galley refuse, packaging, passenger waste, etc.), as this term is defined and regulated by the U.S. Department of Agriculture's Animal Plant Health Inspection Service (APHIS).

In your letter, you state these wastes typically are not contaminated with an infectious substance but some have been found to contain botulism, bacillus anthracis, and foreign biological agents. You also state APHIS requires these materials to be removed from any means of conveyance during interstate or international transportation and destroyed in the same manner as "UN 3271, Regulated medical waste, n.o.s., 6.2 (infectious), PG II" (RMW), to minimize introducing plant pests and animal diseases in the United States. You asked in your telephone conversation if agricultural clearance material may be excepted from regulation as a Division 6.2 material in conformance with § 173.134(b)(16), when it is described as "agricultural products" and/or "food," and offered, transported, and treated for disposal in the same manner as RMW.

The answer is yes provided the agricultural clearance materials 1) are "agricultural products" or "food" as these terms are generally defined by the Food and Drug Administration under the Federal Food, Drug, and Cosmetics Act (FFDCA; 21 U.S.C. 301 et. seq.), or 2) comply with an exception PHMSA added in 2011 under 49 CFR 173.134(c)(2). Section 173.134(b)(16) states material known or suspected of being contaminated with a Division 6.2 material that also meets the definitions in 21 U.S.C. § 332 et. seq. of the FFDCA for either "agricultural products" or "food" is excepted from regulation under the HMR. By excepting agricultural products and food contaminated with Division 6.2 material from regulation under the HMR, this Office intended to avoid unnecessary duplication of existing Department of Health and Human Services' Food and Drug Administration (FDA) regulations for managing and transporting these materials (see Docket No. PHMSA-2004-16895 (HM-226A); 70 FR 29170 and 71 FR 32244). The

Pipeline and Hazardous Materials Safety Administration (PHMSA) recently learned that the Federal Food, Drug, and Cosmetics Act (FFDCA; 21 U.S.C. 301 et. seq.) does not define “agricultural products” or “food” in 21 U.S.C. 332; therefore, the reference in § 173.134(b)(16) to these FFDCA terms is in error (this section refers to injunction proceedings only). PHMSA will make necessary corrections in a future rulemaking.

The exception prescribed in § 173.134(c)(2) permits the following materials to be offered for transportation and transported as RMW when packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030, and transported by a private or contract carrier in a vehicle used exclusively to transport RMW:

- 1) waste stock or culture of a Category B infectious substance;
- 2) plant and animal waste regulated by the APHIS;
- 3) waste pharmaceutical materials;
- 4) laboratory and recyclable wastes;
- 5) infectious substances that have been treated to eliminate or neutralize pathogens;
- 6) forensic materials being transported for final destruction;
- 7) rejected or recalled health care products;
- 8) documents intended for destruction in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements; and
- 9) medical or clinical equipment and laboratory products provided they are properly packaged and secured against exposure or contamination (see Docket No. PHMSA-2009-0151 (HM-218F), July 20, 2011 (76 FR 43530)).

If APHIS considers “agricultural clearance material” to be included in its definitions for plant and animal waste, the shippers transporting this material may wish to use the § 173.134(c)(2) exception. This exception also requires sharps containers to be securely closed to prevent leaks or punctures. In addition, § 172.202(e) permits a non-hazardous material to be described on a shipping paper with a proper shipping name from the Hazardous Materials Table (§ 172.101 Table) provided the hazard class number and identification number are not included. If none of these exceptions are satisfactory, the HMR prescribes that only materials known or suspected of being contaminated with a Category B, Division 6.2 material may be described and transported in commerce as “Regulated medical waste” (see § 171.2(k)).

I hope this satisfies your request.

Sincerely,



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

Drakeford, Carolyn (PHMSA)

Edmonson
§ 173.134(b)(16)
Exceptions
12-0243

From: Edmonson, Eileen (PHMSA)
Sent: Friday, October 26, 2012 1:05 PM
To: Drakeford, Carolyn (PHMSA)
Cc: Foster, Glenn (PHMSA)
Subject: FW: Agricultural Clearance Material/Regulated Garbage

Hi Carolyn,

Can you please log this letter in the system.

Thanks,

Eileen Edmonson
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From: Alan Woodard [<mailto:agwoodar@gw.dec.state.ny.us>]
Sent: Friday, October 26, 2012 1:02 PM
To: Edmonson, Eileen (PHMSA)
Subject: Re: Agricultural Clearance Material/Regulated Garbage

Hello Eileen:

Still working on the pharmaceutical waste issue which eventually we will discuss with you. Another nuance has surfaced. APHIS requires "Agricultural Clearance Material" removed from any means of conveyance during international or interstate movements that is comprised of food, table refuse, galley refuse, packaging, passenger waste, etc., to be placed in specific packaging, labeled as regulated garbage, and transported and treated before disposal as though it is a medical waste. Although there have been incidents of garbage containing food contaminated with botulism or foreign biological agents, animal skins contaminated with B. anthracis, etc., typically the material is not contaminated. APHIS requires that it be removed in this manner to prevent the introduction and spread of exotic plant pests and diseases. Regulated medical waste (RMW) handlers/transporters collect this material for processing. Stericycle obtains quantities of the material in New York State and ships it with RMW to their commercial autoclaves for treatment and eventual disposal. My understanding is it is being shipped in this manner in other locations throughout the U.S. USDOT regulations except agricultural products and food contaminated with infectious substances but does not address APHIS regulated garbage specifically. Does this exception apply to regulated garbage? We believe that since this type of garbage being transported for treatment as though it were potentially infectious or capable of causing public health or environmental harm, it should be packaged and labeled as RMW. Does PHMSA agree? If not, what is your opinion on how it should be regulated/excepted under the HMR? Thanks

Alan

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