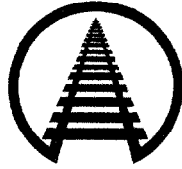


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ASSOCIATION OF AMERICAN RAILROADS

**Law Department
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December 11, 2003

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0276; Registration of Food Facilities under the
Public Health Security and Bioterrorism Preparedness and Response Act
of 2002

Dear Sir or Madam:

Enclosed are the original and one copy of the comments of the Association of
American Railroads for Docket No. 02N-0278.

Very truly yours,

Michael J. Rush

Enclosures

02N-0276

C173

BEFORE THE
FOOD AND DRUG ADMINISTRATION

DOCKET NO. 02N-0276:
REGISTRATION OF FOOD FACILITIES UNDER THE PUBLIC
HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS
AND RESPONSE ACT OF 2002

COMMENTS OF
THE ASSOCIATION OF AMERICAN RAILROADS

The Association of American Railroads (AAR),¹ on behalf of itself and its member railroads, submits the following comments on the Food and Drug Administration's (FDA) interim final rule governing registration of food facilities.² In these comments, AAR's member railroads seek clarification of the exemption for transportation.

The new registration regulations generally require that facilities which manufacture, process, pack, or hold food for consumption in the U.S. register with FDA. Transport vehicles are not considered "facilities if they hold food only in the usual course of business as carriers."³ A key issue for the railroad industry is the interpretation of the phrase "usual course of business."

One activity that takes place during intermodal transportation is the transloading of goods from tank car to tank truck, and vice versa. AAR understands that it is FDA's intent for facilities where the transloading of food products takes place to be registered, because during the transloading process food products are taken out of the package.

In contrast to transloading facilities are transportation facilities where food products may be held for some time in the normal course of transportation, but are kept in their original transportation package, such as in a tank car, boxcar, or intermodal container. For example, rail cars containing food products will be held in rail yards for relatively short periods of time during the normal course of transportation. It is also normal for rail cars containing food products to be

¹AAR is a trade association whose membership includes freight railroads that operate 76 percent of the line-haul mileage, employ 91 percent of the workers, and account for 94 percent of the freight revenue of all railroads in the United States; and passenger railroads that operate intercity passenger trains and provide commuter rail service.

²68 Fed. Reg. 58894 (Oct. 10, 2003).

³21 C.F.R. § 1.227(b)(2).

held for longer periods of time at rail yards or at mechanical shops if mechanical problems with the cars arise during transportation.

Another example of holding food during the usual course of transportation is the holding of shipments pursuant to Customs general orders, a common occurrence in the railroad industry. The length of time a shipment must be held pursuant to Customs orders, and the length of time a shipment would have to be held pursuant to an FDA order, is up to the government agency involved.

AAR understands that shipments held at rail yards as trains are made up and broken apart, shipments held for rail car repairs, and shipments held pursuant to government agency orders, including Customs general orders, are not within the scope of the registration requirement because they fall within the category of food held "in the usual course of business as carriers." Indeed, this view of the "usual course of business as carriers" is consistent with the Department of Transportation's view of activities that should be considered transportation activities. In a recent rulemaking proceeding, DOT's Research and Special Programs Administration (RSPA) defined transportation for the purposes of clarifying DOT's jurisdiction over the transportation of hazardous materials. RSPA defined transportation as including "the movement of property and . . . storage incidental to that movement."⁴

While FDA's intent regarding the registration of railroad yards and other facilities seems clear, there appears to be some confusion on the part of the Bureau of Customs and Border Protection (CBP). The enclosed statement from CBP's offices in Champlain, New York, erroneously states that carrier terminal facilities need to be registered. Consequently, FDA should reiterate that rail facilities where food is held in the usual course of business do not need to be registered.

Finally, AAR would like to take this opportunity to request that FDA establish a process to facilitate communication between FDA and the railroad industry concerning implementation of FDA's food security regulations. The food security program is a brand-new program that, of necessity, has been implemented on a fast-track basis. Undoubtedly, over the coming months unforeseen implementation issues will arise. The railroad industry is willing to do its part to ensure that the food security program is implemented as efficiently as possible. Accordingly, AAR suggests regular meetings between FDA and AAR. Another possibility is a designated FDA point of contact that the industry can communicate with on a periodic basis.

⁴49 C.F.R. § 171.8 (def. of "transportation"), 68 Fed. Reg. 61906, 61941 (Oct. 30, 2003).

Thank you for the opportunity to comment.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael J. Rush". The signature is written in a cursive style with a prominent initial "M".

Louis P. Warchot
Michael J. Rush
Counsel for the Association
of American Railroads
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(202) 639-2503

December 11, 2003



THE AREA PORT OF CHAMPLAIN, NY
INFORMATION Number: **04-FO-09**
NOTICE Date: **December 2, 2003**

Subject: Bioterrorism Act of 2002: Secure Facility Requirements

Distribution: Filers, importers, warehouse operators, carriers, interested parties

Public Law 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA), will go into effect on December 12, 2003.

This legislation provides that merchandise may be held in a secure facility pending the completion of satisfactory Prior Notice with the U.S. Food and Drug Administration (FDA). It requires that any facility where food is manufactured, processed or stored (whether foreign or domestic) be registered with FDA by this date.

If a party wants its facility designated as a secure facility, the owner of the facility must meet the following criteria: (1) register the facility with FDA; (2) file a valid custodial bond with U.S. Customs and Border Protection (CBP); *and* (3) may not be the owner, importer or the consignee of the goods being held.

Facilities that must register to be considered as secure facilities for purposes of the BTA include but are not limited to Terminal Facilities of bonded carriers, General Order Warehouses, Container Freight Stations and Container Examination Stations.

Registration forms and related information may be downloaded from the Internet at www.fda.gov. Electronic registration at that location is encouraged. Additional information on the BTA may be found on the CBP website at www.cbp.gov (search: BTA).

Questions concerning these requirements may be addressed to Import Specialist Linda Gonyo at (518) 298-8381 or LINDA.Gonyo@dhs.gov.

Mark Kollinger
Assistant Port Director
Trade Operations

Note: This Notice is provided for the convenience of the public, but due to the nature of this medium, only the latest printed version of a law, regulation or **Federal Register** notice should be considered official.