

BEFORE THE  
FOOD AND DRUG ADMINISTRATION

~~1700-03 APR -4 P3:43~~

DKT. NO. 02N-0276:  
REGISTRATION OF FOOD FACILITIES

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COMMENTS OF THE  
ASSOCIATION OF AMERICAN RAILROADS

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The Association of American Railroads (AAR),<sup>1</sup> on behalf of itself and its member railroads, submits the following comments in response to the notice of proposed rulemaking concerning the registration of facilities that manufacture, process, pack, or hold food for human or animal consumption ("food facilities").<sup>2</sup> AAR's member railroads transport food products and seek clarification that this rulemaking proceeding will not encompass certain transportation activities.

The purpose of this rulemaking proceeding is to implement Congress' mandate that food facilities register with FDA.<sup>3</sup> In FDA's words, registration of food facilities "will enable FDA to

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<sup>1</sup>AAR is a trade association whose membership includes freight railroads that operate 77 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. However, these comments do not address whether the registration program should or would apply to facilities that prepare food products for passenger railroads.

<sup>2</sup>See 68 Fed. Reg. 5378 (Feb. 3, 2003).

<sup>3</sup>Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 305, 116 Stat. 594. In this regard, FDA might want to clarify the obligation to register. Proposed subsections 1.225(a) and (b) state that "the owner, operator, or agent in charge" of a facility must register, implying that all three entities must register. It appears that FDA intended to state that the facility must be registered and that all three of those entities are obliged to ensure that registration occurs, but that the entities themselves do not have to register. FDA can make its intent clear by rewording subsection (a) to state: "If you are the owner, operator, or agent in charge of either a domestic or foreign facility, as defined in this subpart, that is engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States, you must ensure that the facility is registered, unless it qualifies for one of the exemptions in § 1.226." Similarly, subsection (b) could be clarified by rewording it to state: "An owner, operator or agent in charge of a domestic facility must ensure the facility is registered, whether or not the food from the facility enters interstate commerce."

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act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or to other food-related emergencies."<sup>4</sup> It appears that the activity of transporting rail cars containing food products from origin to destination, including periods when the rail cars are temporarily not moving, is not covered by the proposed rule. As explained more fully below, AAR requests that FDA clearly state that is the case.

Congress mandated the registration of facilities that engage in the "holding" of food. FDA proposes to define holding as follows:

*Holding* means storage of food. Holding facilities include, but are not limited to, warehouses, cold storage facilities, storage silos, grain elevators, or liquid storage tanks.<sup>5</sup>

AAR is concerned that certain railroad activities could be interpreted as "holding" if the word is interpreted literally and out of context, even though these railroad activities are not encompassed by FDA's specific list of activities constituting holding and nothing in the preamble indicates FDA intends to regulate these railroad activities. More specifically, AAR is concerned that if FDA fails to state explicitly that railroads are not subject to the registration requirement when food products are in rail cars, at a later point in time the question may be raised whether railroads are engaged in the "storage" of food.

AAR is particularly concerned that a question might be raised whether railroads are storing food products when rail cars containing food products come to a stop during transportation. All rail cars come to a stop at some point during transportation. For example, rail cars will come to a stop in rail yards as cars are moved from one train to another. Rail cars are stopped at yards near their destination, waiting for the consignee to accept their delivery. Rail cars are also stopped if mechanical problems develop. None of these events would be considered to constitute storage by the transportation or food industries.

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<sup>4</sup>68 Fed. Reg. 5379.

<sup>5</sup>Proposed 21 C.F.R. § 1.227 (c)(5).

Registration of railroads would not serve any purpose. There is no reason to believe that registration of railroad facilities would enhance security or that Congress contemplated that railroads would be covered by the registration requirement. AAR urges FDA to clarify that railroads do not need to register.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Michael J. Rush". The signature is written in a cursive style with a prominent initial "M".

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# ASSOCIATION OF AMERICAN RAILROADS

## FACSIMILIE

Urgent

For Review

Please Reply

Date: April 4, 2003 Pages: 1 of 4  
From: Mike Bush  
To: Rockets Management Fax: 301-827-6870  
Subject: DKT NO. O2N-0276

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