



ASSOCIATION OF AMERICAN RAILROADS
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Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Dear Sir or Madam:

Enclosed are the original and four copies of the comments of the Association of American Railroads for Docket No. 02N-0278, "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

Respectfully submitted,

Michael J. Rush

2002 N-0278

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BEFORE THE
FOOD AND DRUG ADMINISTRATION

DOCKET NO. 02N-0278:
PRIOR NOTICE OF IMPORTED FOOD 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 prior notice for shipments of food entering the U.S. or being exported from the U.S.² AAR suggests revising the requirement that FDA be given between four hours and five days notice of imported shipments of food. AAR also suggests that FDA provide carriers with confirmation of prior notice when a confirmation number is issued.

The Prior Notice Window Should Be Between Two Hours and Ten Days

FDA's requirement to provide four-hours advance notice of shipments of food is inconsistent with the Bureau of Customs and Border Protection's (CBP) requirement that two hours advance notice be provided for imports of all cargo.³ There is no logic for the two agencies to have different advance notice requirements. There is no basis for concluding that more time is needed for food shipments than for other shipments.

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. 58975 (Oct. 10, 2003).

³*Compare* FDA's four-hour requirement at 21 C.F.R. § 1.279(a)(2) with CBP's two-hour requirement at 19 C.F.R. § 123.91(a), 68 Fed. Reg. 68140, 68173 (Dec. 5, 2003).

CBP's determination that two hours advance notice is sufficient should apply to all shipments, particularly since FDA intends to rely heavily on CBP to enforce FDA's advance notice requirements.⁴ CBP's determination that two hours is sufficient is persuasive, given the agency's long experience monitoring import shipments.

Turning to FDA's requirement that advance notice be provided no more than five days in advance, the five-day limit is problematic for certain rail shipments which are not time-sensitive.⁵ For example, some grain shipments from western Canada take longer than five days to reach the border. Similarly, beer shipments from the Gulf Coast of Mexico can take more than five days to reach our southern border. The brokers providing the advance notices for these shipments have no way of knowing precisely how much time it will take for the shipments to reach the border. Since the shipments are not time-sensitive, often the railroads will not have precise target dates for when the shipments will reach the border, even after transportation has commenced.

If a maximum advance notice period is necessary, AAR requests a ten-day period for providing advance notice. Ten days would be sufficient for most, although not all, shipments. The railroads would need to establish special procedures for shipments taking longer than ten days to reach the border, but far fewer shipments would be problematic if the advance notice period were ten days instead of five.

FDA Should Provide Carriers With Confirmation of Prior Notice

FDA has made no provision to provide carriers with confirmation that prior notice has been issued for a shipment. Instead, FDA commits only to providing the submitter of prior notice with confirmation that prior notice has been transmitted.⁶ Normally, the submitter will be a broker. AAR urges FDA to also provide carriers with confirmation of prior notice.

Providing carriers with confirmation of prior notice will facilitate compliance and avoid border problems. If carriers are routinely provided confirmation of prior notice and a situation occurs where a carrier is not provided with confirmation, the carrier will be able to react accordingly. Without routine confirmation, problems with prior notice will have to be addressed when shipments arrive at the border. The rail transportation system will be disrupted as trains containing problem shipments are, at a minimum, delayed. In all likelihood, problem shipments will need to be removed from trains and

⁴See FDA's news release at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00988.html>, in which FDA states it is commissioning thousands of CBP officers to enforce FDA's requirements.

⁵21 C.F.R. § 1.279(b).

⁶21 C.F.R. § 1.279(d).

diverted to locations where the shipments can be held pending resolution of the issue of compliance with FDA's prior notice requirements.

It should not be difficult to provide carriers with confirmation that prior notice has been filed. CBP's automated manifest system (AMS) is a system already in place that can be used to transmit a message to rail carriers that prior notice has been filed. Indeed, while there is an efficient, automated mechanism in place for communicating messages between CBP and the carriers, no such system exists for communications between railroads and brokers. Nor would it be feasible to develop such a system given the multitude of carriers and brokers. AMS would be the most efficient method of transmitting information concerning prior notice to the railroads.

Finally, as discussed in its comments on FDA's registration rules, AAR believes FDA and the railroads should establish a process to facilitate communication between FDA and the railroad industry concerning implementation of FDA's food security regulations. AAR suggested regular meetings between FDA and AAR and/or a designated FDA point of contact that the industry can communicate with on a periodic basis. AAR continues to believe that it is desirable to establish a formal mechanism for FDA and the railroads to communicate to facilitate implementation of FDA's new food security program.

Thank you for the opportunity to comment.

Respectfully submitted,



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