



ASSOCIATION OF AMERICAN RAILROADS

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July 8, 2003

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

Re: Docket No. 02N-0277; Establishment and Maintenance of
Records Under the Public Health Security and Bioterrorism
Preparedness and Response Act of 2002

Dear Sir/Madam:

Enclosed are the original and one copy of comments of the Association of
American Railroads in above-referenced Docket No. 02N-0277.

Very truly yours,

Enclosures

02N-0277

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BEFORE THE
FOOD AND DRUG ADMINISTRATION

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DOCKET NO. 02N-0277:
ESTABLISHMENT AND MAINTENANCE OF
RECORDS 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 in response to FDA's notice of proposed rulemaking concerning the keeping of records on the transportation of food.² The nation's railroads annually transport over 2 million carloads of food products and thus have a significant interest in this rulemaking proceeding.³

As background, FDA should be aware that transportation by rail is a safe and secure mode of transportation. Recently, the Departments of Homeland Security and Transportation considered the need for background checks for individuals transporting explosives and other hazardous materials. Unlike the case with other transportation workers, the Departments concluded that "the transportation of explosives via rail . . . does not pose a sufficient security risk warranting further regulation at this time."⁴ In reaching that conclusion, the Departments took note of the security measures undertaken by the railroad industry and observed that "the nature of

¹AAR 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.

²68 Fed. Reg. 25188 (May 9, 2003).

³See Association of American Railroads, *Railroad Facts*, p. 25 (October 2002).

⁴68 Fed. Reg. 34470, 34477 (June 9, 2003). Compare 68 Fed. Reg. 23844 (May 5, 2003) (background checks required for motor vehicle drivers).

railroad operations makes it difficult for an employee to have any realistic opportunity to gain access to, improperly use, or redirect the movement of the shipments."⁵

Turning to the notice of proposed rulemaking, FDA proposes to require a transporter to record, for each food shipment: 1) the "responsible individual" for the company (the shipper or previous transporter) who gave the food to the transporter and who received the food from the transporter (the consignee or subsequent transporter); 2) a specific description of the food shipped; and 3) the name of the company tendering the food to the transporter and certain information for the company (address, phone and fax numbers, e-mail address), and the same information for the company to which the transporter delivers the food.⁶ The first two requirements are particularly problematic.

FDA does not define "responsible individual," but in the preamble, FDA states that the

"individual responsible" should be the person within the transportation company who is responsible for that vehicle and the food being transported. FDA seeks comments on whether "individual responsible" should be the operator of the conveyance or whether it can be someone within the corporation who has overall responsibility for the vehicle and the food being transported.⁷

From a railroad standpoint, the identity of individuals involved in transportation does not have the relevance it may have for other modes of transport.

In contrast with motor vehicle transportation, no one individual is in control of a rail shipment. As a carload of food travels from origin to destination, the carload might move in several different trains, operated by multiple train crews with numerous dispatchers giving orders. For example, if a railroad picks up a rail car directly from a shipper, typically that will be accomplished by a "local" train crew that will take the car to a rail yard. At the yard, a "yard" switching crew will place the car in the correct train. A road crew will take the train onto the main line. The train will likely proceed to another yard where another yard crew will place the car in another train, unless it has reached its destination on the railroad. When the car finally reaches its destination, the car will be given to another transporter or the consignee by another "local" train crew.

Another difference between motor carrier and rail transportation is that railroads operate on fixed rights-of-way. As observed by the Departments of Homeland Security and Transportation, unlike drivers of motor vehicles, train crews do not have choices as to the routes

⁵68 Fed. Reg. 34477.

⁶Proposed 21 C.F.R. § 1.352.

⁷68 Fed. Reg. 25198.

they will follow. Consequently, for railroads no useful purpose would be served by identifying a specific "responsible individual" and, in any case, there is no practical way of doing so.

Rather than the name of a specific individual, it would appear that what FDA needs is a phone number for a company that it could call to get the information it seeks about a food shipment. AAR has no objection to requiring the railroads to have telephone information available and anticipates that many railroads would comply with the requirement to have telephone numbers for railroads and shippers, consignees, and other transporters by maintaining a readily accessible contact master list. In the event a food emergency occurred requiring FDA to track food shipments immediately, FDA would be able to obtain from the master contact list the information it needed to track the shipments.

With respect to recording other information about a shipment, including specific information identifying the commodity shipped, a railroad is totally dependent on the company tendering the shipment to the railroad. A railroad has no direct way of knowing if a shipment consists of "brand x cheddar cheese," to use one of FDA's examples.⁸ In fact, a railroad would not necessarily know a shipment contains food unless the company tendering the shipment identified the shipment as a food shipment. Railroad train crews do not load cars, as truck drivers sometimes do, and they never look inside cars to examine the contents.

Consequently, the transporters' obligation to record information should be limited to the information placed on the bill of lading. Transporters should not be held accountable or responsible for information that was never given to them. Railroads cannot even identify in every case the transportation company they receive goods from or the transportation company to whom they tender goods unless that information is specifically given to them. Railroads often contract with "third-party" companies to transport shipments that are actually transported to and from the railroad terminals by motor carriers hired by the third-party companies. When railroads receive bills of lading for these shipments, they have no way of identifying the motor carriers actually handling the shipments.

Another problem is that information for most shipments is transmitted electronically and the electronic transmissions do not identify the contents of shipments with the specificity sought by FDA. Railroads use a standard transportation commodity code (STCC) to identify on bills of lading a shipment's contents. STCC codes do not have the specificity FDA seeks for identification of food.

However, railroad shipments are easily traceable even if the railroads do not know, with the specificity FDA seeks, the contents of the shipments. Rail car numbers (container and trailer numbers in the case of intermodal shipments) or bill of lading numbers can be used to trace the movements of shipments. Armed with a rail car, container, trailer, or bill of lading number, FDA can easily trace a shipment back to the company tendering the shipment to a transporter and,

⁸See proposed 1.352(a)(3).

ultimately, to the shipper, who would possess the requisite specific information about the commodity shipped.

Therefore, FDA should permit transporters and their customers the option of using vehicle, package, or bill of lading numbers in lieu of commodity-specific information to trace food shipments. Those tendering shipments to a transporter should be required to ensure that a traceable system is being used. If the party tendering a shipment chooses to use vehicle, package, or bill of lading numbers for tracing, the party would be obliged to identify the shipments as a food shipment so that the transporter is aware of its recordkeeping obligations, but the party would not have to give the transporter commodity-specific information. If the party tendering the shipment chooses to use commodity-specific information to ensure traceability, then the party should be required to transmit that information to the transporter. A transporter's obligation to record information should be tied to the information actually given the transporter on the bill of lading.

Accordingly, AAR suggests that proposed section 1.352 be renumbered as 1.353 and amended as follows, and that a new 1.352 be inserted, as follows (additions italicized, deletions struck through):

Sec. 1.352 What information is required to be given to the next transporter?

(a) If you are a person and you tender food to a transporter, you must identify the shipment as a food shipment on the original bill of lading and place on the bill of lading the following information:

- (1) your name, address, phone number, fax number, if available, and e-mail address, unless the transporter already possess this information; and*
 - (2) either a vehicle, package (e.g., container or trailer), or bill of lading number that would enable FDA to trace the shipment to the person who had the food immediately after you or before you, or an adequate description of the food shipment, to the extent you have this information, including
 - (i) the brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);*
 - (ii) the lot or code number or other identifier of the food; and*
 - (iii) the quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle).**
- (b) Reserved.*

Sec. 1.353 What information is required in the transportation records?

(a) You must establish and maintain the following records for each food you transport:

- (1) The name ~~of the firm and responsible individual~~, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately before you, *if provided on the original bill of lading by the person**

who tendered the food to you for transport or if previously provided to you, and the date you received it from that person;

*(2) The name ~~of the firm and responsible individual~~, address, phone number and, if available, the fax number and e-mail address of the person who had the food immediately after you *if provided on the original bill of lading by the person who tendered the food to you for transport or if previously provided to you*, and the date you delivered it to that person;*

(3) Either a vehicle, package (e.g., container or trailer), or bill of lading number that would enable FDA to trace the shipment to the person who had the food immediately after you or before you, or ~~An~~ adequate description of the food shipment ~~type of food~~, to the extent provided on the original bill of lading by the person who tendered the food to you for transport, including

(i) brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(4ii) ~~The~~ lot or code number or other identifier of the food (to the extent this information exists); and

(5iii) ~~The~~ quantity and how the food is packaged (e.g., 6 ct. bunches, 25 lb carton, 12 oz bottle);

(64) Identification of each and every mode of transportation (e.g., company truck, private carrier, rail, air, etc.), ~~and the individual responsible~~, from the time you first received the food until the time you delivered it.

As a related matter, AAR urges FDA and other government agencies to coordinate their security programs. In addition to FDA's regulations, the railroad industry is potentially subject to security regulations issued by the Department of Transportation's Federal Railroad Administration and Research and Special Programs Administration, the Department of Homeland Security's Transportation Security Administration, Bureau of Customs and Border Protection, and Coast Guard, and the Nuclear Regulatory Commission, among other agencies. Disparate or even contradictory regulations on recordkeeping or other security matters issued by these agencies would adversely and unnecessarily affect the nation's economy by impairing the railroads' ability to

meet the needs of their customers. Recognizing the important responsibilities each of these agencies has, the railroad industry encourages FDA and the other agencies to work together to develop a coherent federal security program.

Respectfully submitted,

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

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