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July 7, 2003

VIA FEDERAL EXPRESS

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

Re: Proposed Rule Concerning Regulations for the Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket No. 02N-02777)

To Whom It May Concern:

On behalf of Horizon Lines, LLC, we are submitting comments on the proposed rule requiring the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. As a transportation service provider, Horizon Lines has several concerns about the implementation of this rule.

Horizon Lines (formerly CSX Lines, LLC) is based in Charlotte, N.C., with offices throughout the United States. Horizon Lines provides domestic ocean-liner service and operates 17 U.S.-flag vessels with 22,000 containers along six service routes between the continental United States and Alaska, Guam, Hawaii and Puerto Rico.

DISCUSSION

Horizon Lines appreciates the need to enhance the security of the global supply chain and the security of the U.S. food supply in particular. Horizon Lines also understands the need of the FDA to quickly investigate and address health threats to both humans and animals. As a voluntary participant in both the Customs-Trade Partnership Against Terrorism (C-TPAT) and the Super Carrier Initiative Agreement, the company is committed to helping the U.S. government secure the supply chain while maintaining the efficient flow of legitimate trade. Accordingly, Horizon Lines has some general observations on this proposed rule and several comments on specific sections.

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Requirement to Establish and Maintain Records for Subsidiaries and Affiliates

Horizon Lines, LLC has subsidiary and affiliated entities, which would be subject to the transporter requirements of this proposed rule. These entities provide transportation and related services both for Horizon Lines and other unrelated entities. Horizon Lines believes that the cost of implementing separate record keeping systems at each of its related entities would be economically burdensome. Therefore, the company recommends that the FDA's final rule permit transporters to establish and maintain the required records for their subsidiary and affiliated entities, should they so desire, especially where the parent and subsidiary and affiliates operate in an intermodal context.

Separating Food and Non-Food Shipment Data

Horizon Lines believes that the implementation of this rule as proposed would require the company to separate all food and non-food shipment data for the purposes of recording the required information on food shipments. Its existing databases do not have the ability to perform such segregation. In order to comply with the proposed rule using its current information systems, Horizon Lines would be forced to require all of its customers, including its non-food shipping customers to submit the required data elements. This presents a significant challenge since no regulations currently compel non-food shippers to provide such information. Additionally, when that information is received, Horizon Lines staff would face the burden of identifying food shipments in the database for the purposes of ensuring proper record retention.

Two Sets of Immediate Previous Sources and Immediate Subsequent Recipients

The proposed rule invites comments on whether requiring two sets of immediate previous sources and immediate subsequent recipients for non-transporters is a reasonable interpretation of section 414(b) of the Public Health Security and Bioterrorism Preparedness and Response Act. Horizon Lines does not believe that a reading of that section supports such an interpretation. Horizon Lines believes that the FDA does not need information on *two* sets of sources and recipients from each party in the supply chain in order "to identify the immediate previous sources and the immediate subsequent recipients of food," as required by the statute.

Furthermore, Horizon Lines disputes the FDA's claim that having two sets of sources and recipients would enhance its ability to investigate a food emergency. An effective investigation arguably should trace the source of contamination back along each point in the supply chain, ruling out each party before investigating the previous party. Horizon Lines believes that such an investigative approach does not sacrifice efficiency or speed, if each party promptly responds to its obligations to make its required records available as proposed. Keeping the requirement to the identification of the immediate previous source and immediate subsequent recipient of food will provide the most reliable information. Going beyond that to require two sets of immediate previous sources and immediate subsequent recipients will not yield quality information.

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Proposed Sections 1.352(a)(1) and (2)

Horizon Lines has concerns with the language in proposed sections 1.352(a)(1) and (2), specifically the requirements to collect and maintain certain data on persons at the “transporter’s immediate previous source” and the “transporter’s immediate subsequent recipient” as defined in proposed §1.328 and characterized by the FDA on pages 25197-25198 of the notice. In response to the FDA’s specific invitation for comments on whether the “individual responsible” should be an operator or one with overall responsibility for the food being transported, Horizon Lines strongly recommends the latter. The individual responsible should be a single contact (with a backup as appropriate) at the source or recipient company with management authority over the shipment of the food products in question. Such a contact is more likely to be available to the agency than someone at an operational level and would have the authority to organize any assistance necessary to an FDA investigation.

Notwithstanding this recommendation, Horizon Lines is generally concerned about the operational impact of this data collection requirement. The company currently has no method of capturing all of the proposed data elements through current sources of transaction documentation. Additionally, it does not always have access to the names, addresses, phone and fax numbers, and e-mail addresses of the specific individuals at the source or recipient company, especially for operational level employees such as warehouse personnel, truck drivers, or vessel operators.

Proposed Section 1.352(a)(3)

Horizon Lines also is concerned about the requirements in this proposed rule to provide brand and variety names of food products that it transports. Currently, there is no requirement compelling shippers to report that level of detail to transporters. Consequently, food shipments received and delivered by Horizon Lines typically are reported only in general terms, for example, “14 cartons of cheese.” Horizon Lines understands that the FDA may possess more specific information, and also is concerned about missed or inconsistent information references.

Horizon Lines urges the FDA to drop the requirement to provide specific brand or variety references. The company believes it will not be able to consistently obtain that information from shippers. Furthermore, such information is not necessary to trace a food product forward or backward through the supply chain. The remaining information elements are more than adequate for achieving that objective. Additionally, the potential inconsistencies in the way the same shipments are reported to the FDA by a shipper and by a transporter may only serve to hamper the FDA’s investigative efforts.

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Proposed Section 1.352(a)(4)

Horizon Lines suggests that the proposal to require the lot number or other code number is inadvisable. The company requests that the FDA clarify its purpose in asking transporters and non-transporters to record this information. Horizon Lines could record this information, however its databases currently do not have the capability to search for and retrieve shipment data using a lot number. Such access is possible only with the bill of lading number or for a limited time after the shipment, the container number or booking number. These identifiers would need to be added to the list of required data elements kept by non-transporters in order for the transporters to have a valid point of reference.

Proposed Section 1.352(a)(6)

The requirement that transporters identify “each and every mode of transportation” and responsible individual for the period in which a food item is under their custody is a concern for Horizon Lines. For any given shipment, the company may use several internal modes of transportation. For example, a truck at the loading port to move the container to the vessel, the vessel itself, the truck at the destination to park the load, and potentially its own road truck to deliver the shipment to the consignee. In addition, Horizon Lines frequently moves freight for its customers utilizing subsidiaries or affiliated entities that provide ocean transportation, trucking, and terminal operating services.

Maintaining records on each mode of transportation used and the operator for such intra-company movements would be overly burdensome. Horizon Lines handles some 1,100 containers each day. Complying with this proposed section would require the company to review the shipping documentation at each internal transfer to ascertain whether a container holds food items and then record both the mode used and the operator of that mode. The addition of these procedures would substantially slow the handling of both food and non-food freight and adversely affect the ability of the company to service its customers effectively.

For these reasons, Horizon Lines recommends that for each food shipment involving intra-company intermodal transfers (including transfers between a parent company and its subsidiaries and affiliates under a through bill of lading) transporters be permitted to record the name of a single responsible individual with operational management control. Consistent with our comments above regarding proposed sections 1.352(a)(1) and (2), Horizon feels that a single point of contact at the managerial rather than multiple points of contact at the operational level would facilitate the FDA’s investigation of a potential food emergency.

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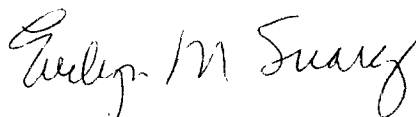
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Proposed Sections 1.360(f) and 1.363(a)

The proposed rule notes that maintenance of required records in electronic form is acceptable, and it further stipulates that regulated entities must permit access to or verification or copying of any required record. Horizon Lines requests further clarification of the requirements for retrieval and/or transmission of the required records for the FDA's review. In particular, Horizon Lines urges that the final rule permit companies to provide the FDA with any required records electronically as well.

Thank you for your consideration and the opportunity to provide these comments.

Respectfully submitted,



Evelyn M. Suarez