August 19, 2016

Dr. Michael Kashtock
Division of Plant Products and Beverages
Office of Food Safety
Center for Food Safety and Applied Nutrition (HFS-317)
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Kashtock:

The undersigned organizations and our representatives appreciated the opportunity to meet with you and your colleagues on July 6, 2016 to discuss our serious concerns over the unintended consequences of several provisions of the Food and Drug Administration's (FDA) final rule implementing the Sanitary Food Transportation Act of 2005 and the Food Safety Modernization Act of 2011 (FSMA).

As discussed, we believe that FDA should reconsider several provisions of the final rule that we believe will have the unintended effect of disrupting current, widely observed prudent practices that exist between shippers, receivers and carriers in obtaining information on the condition and suitability of vehicles and transportation equipment used to transport human and animal food, and thereby ultimately be counterproductive to food safety.

We commend FDA for making several significant improvements in the final rule compared to the proposed rule, particularly in terms of adopting a more practical and performance-oriented approach focused on transport practices truly important to food safety, and in better reflecting trade practices that have been implemented for many years in fostering the safe transport of human and animal food. But we are concerned that the final rule created a significant imbalance by shifting to shippers and loaders the lion's share of the responsibility for ensuring the safe transport of food, while largely absolving rail and truck carriers – absent a formal written agreement with each individual shipper – from having a shared responsibility to fulfill their prudent and appropriate legal and business obligation to provide vehicles and transportation equipment suitable for safe transportation of human and animal food or to provide important previous-load-hauled and conveyance clean-out information.

The three problematic provisions of the final rule are found in Section 1.908(e), which, in a significant departure from the proposed rule, eliminate any requirements for truck and rail

carriers to share in the responsibility for engaging in certain prudent sanitary food transportation practices widely followed today unless they enter into a formal written agreement with each given shipper to assume legal and regulatory responsibility for such practices. While we believe all types and sizes of shippers will be affected adversely by this requirement, small companies with comparatively smaller shipping volumes likely will have a particularly, and likely disproportionately, difficult time in negotiating and obtaining the written agreements from rail and truck carriers required under the FDA final rule to secure this necessary information.

We believe these provisions in the final rule that exempt rail carriers and truckers from certain requirements unless the shipper and carrier have a written agreement will have the unintended effect of disincentivizing the exchange of information that is necessary to facilitate the safe and cost-effective transportation of human and animal food and place untenable and costly burdens on shippers forced to operate in the absence of such information. As explained during our meeting, we have little to no expectation that carriers – particularly Class I railroads – will be willing to enter into formal written agreements with shippers under which they would willingly become subject to FDA regulatory oversight for compliance with FSMA's sanitary food transportation rules. Several Class I rail carriers have indicated that this matter is under active internal legal review.

We therefore respectfully request that FDA administratively stay the enforcement of the "written agreement" requirement of these three provisions and reopen and amend the final rule to require carriers to provide such information upon request from either the shipper or receiver, with no stipulation that a written agreement exist with the carrier.

The three provisions, which truck and rail carriers are required to meet ***only if they have a written agreement with the shipper conveying responsibility, in whole or in part, to the carrier*** are as follows:

- Section 1.908(e)(1), under which the carrier is to ensure that vehicles and transportation equipment meet the shipper's specifications and "are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation…." With this provision, the final rule creates a paradox. On the one hand, it requires under Section 1.908(b)(1) that shippers engaged in transportation operations provide a one-time written notification to the carrier about "any specific design specifications and cleaning procedures" required to prevent food from becoming unsafe." Yet, the final rule does not obligate the carrier to comply with the contents of the shipper's written notification unless it commits to signing a formal written agreement assuming such responsibility. Requiring the existence of such a written agreement as a precondition before carriers are held responsible for providing suitable transportation conveyances and equipment under the final rule creates a significant obstacle to shipper compliance, and undercuts the long-standing common-carrier obligation of rail carriers under the Interstate Commerce Act to provide suitable transportation upon reasonable request. *[49 U.S.C. 11101(a)]*.

- Section 1.908(e)(4), under which a truck or rail carrier that offers a bulk vehicle for food transportation is to provide information to the shipper that identifies the previous cargo transported in the vehicle. Under FDA's recordkeeping rules implementing the Bioterrorism Act of 2002, rail carriers and truckers already are required to keep records containing the

names of the immediate previous source and immediate subsequent recipient of each commercial load hauled, as well as: 1) the physical location of the origin and destination points; 2) the date(s) the shipment is received and released; 3) the "number of packages" (e.g., quantity) transported; 4) a description of the freight (e.g., commodity); 5) the route of the movement during transport; and 6) the locations of any transfer point(s) through which the shipment moved. For rail shipments, the FDA Bioterrorism recordkeeping rule requires that records contain the following information required by the Surface Transportation Board: 1) date received; 2) received from (e.g., shipper); 3) consigned to (e.g., receiver); 4) destination; 5) the state and county of the destination; 6) the route of the shipment; 7) the delivering carrier; 8) the car initial and number; 9) the number of "packages"; and 10) a description of the cargo transported. For grain shipments, the records need to be retained for one year after the date the transporter receives or releases the commodity. Thus, truck and rail carriers already are required to have access to this information.

Further, the waybill data maintained by each rail carrier contains content information for the load, regardless of whether the equipment being used is carrier-owned, shipper-owned or leased.

Yet, despite the availability of such last-load-hauled information that heretofore customarily has been shared voluntarily with shippers, carriers now perceive there will be regulatory and compliance obligation associated with signing written agreements, as established under the final rule. In so doing, this regulatory framework creates a disincentive for carriers to identify previous cargos or provide other information to the shipper, because doing so imposes a regulatory obligation and FDA oversight on the carrier. Further, this provision impedes shippers and loaders from complying with their obligation for food transported in bulk to develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe [Section 1.908(b)(4).]

- Section 1.908(e)(5) and (6), under which a carrier that offers a bulk vehicle for food transportation, upon request of the shipper, is to provide information on the most recent cleaning of the bulk vehicle and develop and implement written procedures subject to the records requirements of Section 1.912(b) that specify practices for cleaning, sanitizing if necessary, and inspecting bulk vehicles and transportation equipment provided for transportation of food. Again, this basic informational obligation of truck and rail carriers would be made conditional and contingent upon there being a written agreement between the carrier and each shipper under the final rule. As explained by shipper representatives during our meeting, if carriers that have access to such information are unwilling to enter into such written agreements, shippers and/or loaders will face the untenable and costly choice of either rejecting carrier-provided rail cars or trucks because of their unknown cleaning history (along with the associated marketplace risk as to whether or when those conveyances will be replaced) or incurring the operational disruptions and significant costs for cleaning such conveyances (*assuming* cleaning facilities are available, an increasingly difficult proposition given environmental regulatory restrictions associated with such cleaning and weather conditions that may make cleaning impractical or infeasible during certain times of the year).

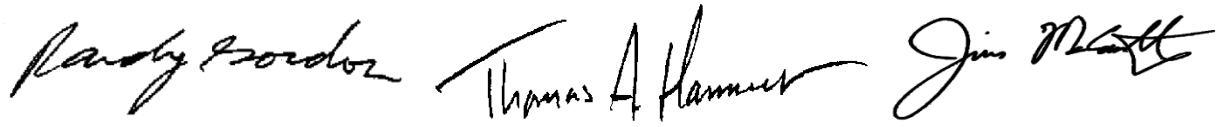
To recap, in the past, carriers commonly have shared information voluntarily with shippers on previous-cargo-hauled to assist in the safe transportation of food. Now, however, carriers perceive that under FDA's final rule, there is a regulatory liability associated with providing information about previous cargoes hauled, as well as in providing information on recent clean-outs. Even the common-carrier obligation to provide conveyances suitable to transport the type of food being hauled is put in question. Further, the final rule gives carriers an easily accessible "escape clause" by stating they have no obligation to provide previous cargo information, clean-out information or suitable conveyances unless they enter into a written contractual agreement with the shipper obligating that they do so. And finally, FDA's requirement to obtain written agreements from each truck and rail carrier imposes a significant burden on shippers.

We believe the net effect of the provisions in the final rule that largely exempt rail carriers and truckers from requirements unless the shipper and carrier have a written agreement will be to impede the exchange of information that is necessary to facilitate the efficient and safe transport of food.

For these reasons, we respectfully request that FDA administratively stay the requirement that there be a written agreement between the carrier and the shipper before the carrier is required to provide to the shipper or receiver: 1) vehicles and transportation equipment suitable to meet the shipper's written specifications to the carrier; 2) information identifying the previous cargo transported in the vehicle, upon request from the shipper, loader or receiver; and 3) information documenting and describing the most recent cleaning of the bulk vehicle if such information is requested by the shipper, loader or receiver and is available to the carrier. It is important that loaders be included in the informational loop, as there are numerous situations in the reseller market and the cross-country merchandising of all commodities in which railcars are placed for loading before the sale is consummated or the shipper and/or receiver identified. Further, we respectfully urge that FDA reopen and amend the final rule to require carriers to make this information available to shippers or receivers upon request, with no stipulation that a written agreement exist between these parties as a precondition for providing such information.

We appreciate your expedited consideration of this request, and would be pleased to respond to any questions you or your staff may have.

Sincerely,



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