June 9, 2017

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 thank you and your colleagues for meeting on April 5, 2017 with us and representatives of the Association of American Railroads and the Agricultural Transporters Conference of the American Trucking Associations to discuss concerns of agricultural shippers and receivers about the Food and Drug Administration's (FDA) final rule regarding Sanitary Transportation of Human and Animal Food (21 CFR Part 1, Subpart O) (the "sanitary food transportation final rule"). We appreciate your continued collaboration as FDA implements the regulations required by the Sanitary Food Transportation Act of 2005 and the FDA Food Safety Modernization Act (FSMA).

As discussed during the meeting, we are proceeding to establish a joint working group with representatives of the rail and truck industries to facilitate safe transport of agricultural products and ingredients used in human and animal food. The goal of this group is to develop consensus regarding voluntary best practices that apportion shared responsibility among carriers and shippers for bulk transportation operations.

As we begin this work, it is necessary to create an atmosphere for discussion that is conducive to achieving a successful outcome. In that regard, it would be extremely useful if FDA would promptly respond in writing to this letter to confirm the general obligations and responsibilities that carriers and shippers alike have to engage in safe transportation operations under Section 402 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. §342]), as well as under the general applicability requirements in the sanitary food transportation final rule.

In particular, the FFDCA provides that food is adulterated if (among other reasons):

- "[I]t bears or contains any poisonous or deleterious substance which may render it injurious to health" (§ 401(a)(1));

- "[I]t bears or contains any added poisonous or added deleterious substance . . . that is unsafe within the meaning of section 406" (§ 402(a)(2)(A));

- "[I]t has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" (§ 402(a)(4)); or

- "[I]t is transported or offered for transportation by a shipper, carrier by motor vehicle or rail vehicle, receiving or any other person engaged in the transportation of food under conditions that are not in accordance with [the sanitary food transportation final rule]" (§ 402(i)).

Violation of any of the adulteration provisions is a "Prohibited Act" under section 301(b) of the FFDCA.

In addition, the sanitary food transportation final rule includes provisions that apply to (1) all vehicles and transportation equipment (§ 1.906) and (2) all transportation operations (§ 1.908(a)), regardless of whether there is a written agreement under § 1.908(e) to take responsibility. In particular:

- "Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, i.e., adulterated within the meaning of section 402(a)(1), (2), and (4) of the [FFDCA] during transportation operations" (§ 1.906(a));

- "Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations" (§ 1.906(b));

- "Vehicles and transportation equipment must be stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in food for which it will be used becoming unsafe during transportation operations" (§ 1.906(d));

- "All transportation operations must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations including: . . . (ii) Taking effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations. (§ 1.908(a)(3)(ii)); and

- "The type of food, *e.g.*, animal feed, pet food, human food, and its production stage, *e.g.*, raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation." (§ 1.908(a)(4)).

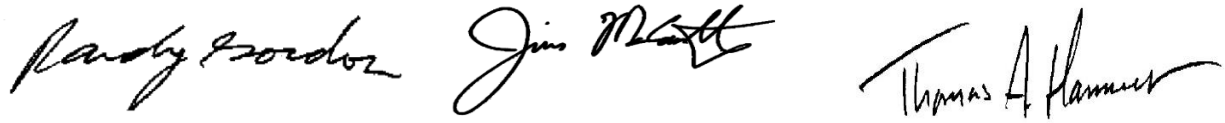
Of particular importance, we request that FDA emphasize in its written response that there are general requirements applicable to rail and truck carriers engaged in transportation operations, even in the absence of a written agreement between the shipper and carrier under § 1.908(e). We ask that FDA clearly articulate that carriers have obligations in lieu of written agreements under § 1.908(a)(3) (to utilize controls and observe operating conditions to prevent food from becoming unsafe during transport (including from cross-contamination or cross-contact with food allergens)), and § 1.908(4) (to consider the appropriateness of the conveyance given the type of food being hauled and its production stage (*e.g.*, human food, ingredients)).

In addition to explaining these general requirements, we request that FDA in its response articulate its views concerning the utility and importance of carriers' sharing previous load(s) hauled and clean-out information for bulk vehicles with shippers, upon request, to facilitate the objectives of the rule.

In conclusion, we enter these discussions with rail and truck carriers in good faith and with the intent of reaching a successful outcome based upon shared responsibilities to attain our mutual goal of facilitating the safe transport of human and animal food. However, if these discussions are unsuccessful, including if carriers erect economic or other barriers to accessing information needed by shippers to comply with their obligations under the rule, we reserve the right to request the agency's intervention. As discussed during our April 5 meeting with FDA, we are leaving open the possibility of asking FDA to consider our August 26, 2016 joint letter urging that the agency administratively stay the final rule's "written agreement" provisions and amend the rule to require carriers to provide information needed by shippers to comply with their obligations under the rule.

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

Sincerely,



Randall C. Gordon
President
National Grain and Feed Association
Feed Association

Jim McCarthy
President and CEO
North American
Millers' Association

Tom Hammer
President
National Oilseed
Processors Association