



November 2, 2017

Thomas Hammer, President
National Oilseed Processors Association
1300 L. Street, NW 1020
Washington, DC 20005
Email: thammer@nopa.org

Dear Mr. Hammer:

On June 9, 2017 National Grain and Feed Association (NGFA), the North American Millers Association (NAMA) and the National Oilseed Processors Association (NOPA) sent a letter requesting FDA confirm the general obligations and responsibilities that carriers and shippers 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 requirements in the Food and Drug Administration's Sanitary Transportation of Human and Animal Food Final Rule (Sanitary Transportation Rule).

This letter was sent in follow-up to previous face-to-face meetings and correspondence between FDA and regulated industry on issues related to the Sanitary Transportation Rule. During an April 2017 meeting with FDA, the representatives present committed to establish a working group to identify procedures for transporting food in bulk that are adequate to ensure that a previous cargo does not make the food unsafe. FDA is encouraged that agricultural shippers and receivers want to establish a joint working group with representatives of the rail and truck industries to develop consensus regarding voluntary best practices that apportion shared responsibility among carriers and shippers for bulk transportation operations. For the working group to be successful, it is important for all sides to understand the general obligations of those who transport food or offer it for transportation under the FFDCA and the Sanitary Transportation Rule.

The adulteration provisions of the FFDCA¹ are applicable to any food transported or offered for transportation in the United States, including by any shipper, loader, carrier by motor vehicle or rail vehicle, or receiver subject to the Sanitary Transportation Rule. Furthermore, it is a prohibited act in the FFDCA for a shipper, loader, carrier by motor vehicle or rail vehicle, or receiver subject to the Sanitary Transportation Rule fail to comply with the relevant provisions of the Sanitary Transportation Rule.² Even if a person is not subject to the Sanitary Transportation

¹ Relevant provisions of the FFDCA include, but are not limited to § 402(a)(1), § 402(a)(2)(A), § 402(a)(4) and § 402(i).

² FFDCA § 301(hh).

Rule, they could still be in violation of the FFDCA if they perform other prohibited acts such as adulterating a food in interstate commerce, or introducing adulterated food into interstate commerce.³

The provisions of § 1.906 of the Sanitary Transportation Rule (Vehicles and Equipment) apply to all covered vehicles and transportation equipment. These provisions apply regardless of whether there is a written agreement under which the carrier has agreed to be responsible, in whole or in part, for sanitary conditions during the transportation operation. These provisions include the following requirements:

- “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));

In addition, the provisions of § 1.908(a) of the Sanitary Transportation Rule (Transportation Operations/General Provisions) apply to all covered vehicles and transportation equipment, regardless of whether there is a written agreement between a shipper and a carrier as specified under § 1.908(e). These provisions include the following requirements:

- “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)).

The requirements outlined above are 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). These requirements include the responsibility to consider the necessary

³ See § 301 of the FFDCA for a complete list of prohibited acts and associated penalties.

transportation conditions given the type of food being hauled and its production stage.⁴ They also require that transportation operations are performed under conditions and controls necessary to prevent food from becoming unsafe during transport, including by cross-contamination or cross-contact with food allergens.

All parties subject to these general requirements of the Sanitary Transportation Rule should work together to establish best practices to achieve these requirements and to communicate food-safety related information about the food and condition of transportation vehicles as necessary to achieve these requirements and the transportation of safe food.

FDA remains interested in the progress made by joint working group. We recognize the challenge posed in developing information systems that will maintain a shared record of prior cargoes in bulk vehicles that are not owned and moved by a single carrier. We are encouraged by the ideas in the April meeting and we are hopeful that the workgroup can develop workable transportation procedures for shippers and carriers that result in the safe transportation of food and compliance by all parties with the Sanitary Transportation Rule.

This same letter has been sent to your co-signers.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Ostroff", written in a cursive style.

Stephen M. Ostroff, M.D.
Deputy Commissioner for Foods
and Veterinary Medicine

⁴ Examples include, but are not limited to, human food, animal food, raw ingredients, and finished products.