MEMORANDUM
Via Email

April 11, 2016

TO: Clients and Other Interested Parties

RE: Overview of FDA’s Final Rule to Establish Requirements for the Sanitary Transportation of Human and Animal Food

On April 6, 2016, the Food and Drug Administration (FDA) published its final rule to establish requirements for the sanitary transportation of human and animal food.¹ The final rule implements the Sanitary Food Transportation Act of 2005 (which created Section 416 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) and Section 111 of the FDA Food Safety Modernization Act (FSMA). FDA issued a proposed rule to implement the sanitary transportation provisions in February 2014.² The final rule creates a new subpart O in Part 1 of Title 21 of the Code of Federal Regulations (CFR). Although the final rule retains many essential features of the proposal, FDA has made a series of specific changes in response to stakeholder comments.

The final rule is effective June 6, 2016. Companies generally have 1 year from the date of publication to comply with the final rule, i.e., April 6, 2017. Small businesses (< 500 full-time equivalent employees) must comply within 2 years, i.e., April 6, 2018. Failure to comply with the applicable requirements once the compliance date has passed is a “prohibited act” under Section 301 of the FD&C Act.³

³ FD&C Act § 301(hh).
I. Key Differences Between Proposed Rule and Final Rule

Throughout the final rule – and as discussed in detail in the preamble to the rule – FDA has added revisions and clarifications to respond to specific stakeholder comments and concerns. Although the core components of the sanitary transportation requirements remain substantially similar to those in the proposal, a non-exhaustive description of key differences between the proposal and the final rule is provided below:

- **Exclusion of specific products from coverage of rule:** In response to stakeholder comments and in recognition of the low risks associated with the transportation of specific commodities, FDA revised the definition of “transportation operations” to exclude the transportation of: (1) food-contact substances (including coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging); (2) human food byproducts transported for use as animal food without further processing; and (3) food completely enclosed by a container, except food that requires temperature control for safety. The proposed rule had only excluded enclosed foods that were shelf-stable (safely stored at room temperature in a sealed container). The final exclusion applies to all enclosed foods that do not require temperature control for safety.

- **Express recognition that responsibilities may be reassigned by contract:** FDA has added language to the final rule to clarify that entities may reassign their responsibilities under the rule by reliance on written agreements. If responsibility is assigned via contract to another party covered by the rule, FDA will consider the terms of the contract in determining responsibility for compliance. If responsibility is assigned to a third party not otherwise subject to the rule (e.g., a truck wash station), FDA will hold the party covered by the rule ultimately responsible for compliance.

- **Assigning primary responsibility to the “shipper”:** Although the final rule still applies to multiple parties throughout the transportation chain, FDA has revised the rule to place primary responsibility for making determinations about appropriate transportation operations on the shipper. The shipper is permitted to rely on contractual agreements to assign responsibilities to other parties. However, FDA believes shippers are best-positioned to know the appropriate specifications for the transportation of their food.

- **Revisions to clarify relevance of food type and production stage:** FDA has made revisions throughout the rule to clarify that the type of food being transported (e.g., human food vs. animal feed vs. pet food) and the production stage (e.g., raw material vs. ingredient vs. finished food) are relevant to the determining the necessary conditions and controls for sanitary transportation.
• **Simplification of defined parties; newly defined term, “loader”:** FDA has simplified the definitions of the various parties engaged in transportation to focus on the activities that they perform. The Agency also has defined a “loader” as a new party to be covered by the rule – this is a person that loads food onto a motor or rail vehicle during transportation operations.

• **Clarification that rule addresses food safety, not spoilage/quality issues:** FDA clarified that the goal of the rule is to prevent food from becoming “unsafe” during transportation operations, rather than to address spoilage or quality defects.

• **Enhanced flexibility in temperature monitoring requirements:** FDA removed prescriptive requirements related to temperature monitoring devices, continuous monitoring of temperature during transport, and the requirement that the carrier demonstrate temperature control to the receiver for every shipment requiring temperature control. The final rule provides for a more flexible approach, permitting shippers, carriers, and receivers to agree on appropriate temperature monitoring and sharing of documentation.

• **New requirement for action in the event of known safety risks:** FDA imposes a new affirmative obligation on parties who become aware of potential material failures of temperature control or other conditions that may render the food unsafe during transport. Specifically, such parties must take appropriate action to ensure that the food is not sold or distributed unless a qualified individual determines that the temperature deviation or other risk did not render the food unsafe.

II. **Summary of Requirements in the Final Rule**

Although a detailed description of all requirements in the final rule is beyond the scope of this summary memo, below we provide a synopsis of key requirements and definitions intended to implement the rule.

The final rule establishes criteria for the sanitary transportation of food. With some exceptions, the rule applies to shippers, receivers, loaders, and carriers who transport food in the United States by motor or rail vehicle, or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle. The requirements do not apply to transportation by ship or air. The rule applies to activities that are intrastate in character.

Under the rule, a **shipper** means a person who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially. A **receiver** means any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food. A **loader** is newly defined to mean a person that loads food onto a motor or rail vehicle during transportation operations. A **carrier** means a person who physically moves food by rail or motor vehicle in commerce within the U.S. and does not include a person who transports food while operating as a parcel delivery service. 21 CFR § 1.904.
Exempt from the rule are transportation operations involving: (1) food that is transshipped through the U.S. to another country; (2) food that is imported for future export and that is neither consumed nor distributed in the U.S.; (3) food when it is located in food facilities exclusively regulated by the U.S. Department of Agriculture (USDA); (4) food transported by a “non-covered business,” defined to mean a shipper, loader, receiver, or carrier that has less than $500,000 in average annual revenues; (5) food completely enclosed by a container except food that requires temperature control for safety; (6) compressed food gases; (7) food-contact substances; (8) human food byproducts transported for use as animal food without further processing; (9) live food animals except molluscan shellfish; and (10) transportation activities performed by a farm. 21 CFR §§ 1.900, 1.904.

The rule establishes sanitary transportation practices for covered entities addressing: (1) vehicles and transportation equipment; (2) transportation operations; (3) training; (4) records; and (5) waivers. According to FDA, the rule will facilitate the transportation industry’s continued use of existing best practices that it has developed concerning cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment to ensure that food is transported under conditions and controls necessary to prevent adulteration linked to food safety. However, the Agency acknowledges that new costs and obligations are associated with the training and recordkeeping requirements.

A. Requirements for Vehicles and Transportation Equipment (21 CFR § 1.906)

The final rule requires vehicles and transportation equipment used for transportation operations to be: (a) designed and manufactured to be suitable and cleanable for their intended use; (b) maintained in a sanitary condition; (c) designed, maintained, and equipped as necessary to provide adequate temperature control, where needed; and (d) stored so as to prevent contamination by pests. Examples of compliance measures are: ensuring that coatings in vehicles maintain corrosion resistance and are free of defects under the intended conditions of use; not using wood containers for raw meat and poultry because the wood may retain contaminants and cause insanitary storage conditions; cleaning equipment between transportation of different food types (e.g., milk and juice); or not using damaged equipment.

B. Requirements for Transportation Operations (21 CFR § 1.908)

The final rule requires all shippers, carriers, loaders, and receivers to assign competent supervisory personnel and ensure that transportation operations effectively protect food from contamination or cross-contact, and to ensure adequate temperature conditions are maintained. Examples of compliance measures are: segregation of raw foods from non-food items, so as to prevent, for example, raw poultry dripping on fresh product; and protections for food in bulk vehicles, such as cleaning procedures.

Where a covered party becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed, and these persons must take appropriate follow-
up action to prevent sale or distribution unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

1. **Requirements Applicable to Shippers**

   The rule requires a shipper to provide a written document specifying the requirements that carriers (and loaders, where necessary) must meet in order to ensure food is maintained in sanitary conditions, such as design requirements, cleaning procedures, and temperature requirements (including pre-cooling), as applicable. Written temperature specifications are not required if the food is carried in a thermally insulated tank. One-time notification is sufficient absent factors that necessitate a change.

   The shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food. For food transported in bulk, the shipper must develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. For food that requires temperature control for safety, the shipper must develop and implement written procedures to ensure that the food is transported under adequate temperature control. Measures to implement food safety procedures may be accomplished by the shipper, the carrier, or another party covered by the rule under a written agreement.

2. **Requirements Applicable to Loaders**

   The rule requires a loader, prior to loading a food not completely enclosed by a container, to verify the sanitary condition of the vehicle or transportation equipment to be used to transport the food. This may be accomplished by reference to the shipper’s specifications, visual inspection, or other appropriate means. Before loading a food that requires temperature control for safety, the loader must verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary.

3. **Requirements Applicable to Receivers**

   The rule requires a receiver, upon receipt of food that requires temperature control for safety, to take steps to adequately assess that the food was not subjected to significant temperature abuse during shipment. This may include determining the food’s temperature or the ambient temperature of the vehicle, or conducting a sensory inspection, e.g., for off-odors.

4. **Requirements Applicable to Carriers**

   Where the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operations, the carrier must: (1) ensure that vehicles and/or transportation equipment meet the shipper’s requirements and will maintain food in a sanitary condition; (2) provide documentation related to temperature control to the shipper or receiver at the end of the transportation operation, if requested; (3) before
offering a vehicle or transportation equipment to transport food that requires temperature control for safety, pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper; (4) provide information to the shipper identifying the previous cargo transported in a bulk vehicle, if requested; (5) provide information to the shipper describing the most recent cleaning of a bulk vehicle, if requested; (6) develop and implement written procedures to: (i) specify appropriate practices for cleaning, sanitizing, and inspection of its vehicles and equipment; (ii) comply with any required temperature controls; and (iii) comply with the provisions for the use of bulk vehicles.

C. Training (21 CFR § 1.906)

Where the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operations, the carrier must provide adequate training to personnel engaged in transportation operations. Although no specific curriculum is prescribed, the training must provide an awareness of potential food safety problems that may occur during transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under this rule. Training must be provided upon hiring and as needed thereafter. Carriers must maintain records of the training.

D. Records (21 CFR § 1.912)

As a general matter, records required to implement this rule – e.g., the shipper’s written specifications and temperature control requirements for the carrier; the carrier’s training records – must be maintained for a period of 12 months beyond the last effective date of those records (e.g., 12 months beyond the termination of a shipper’s agreement with a carrier; 12 months beyond when the person identified in a carrier’s training records stops performing the duty for which the training was provided).

Records may be maintained electronically and must be made available to an authorized individual upon oral or written request. Except for a carrier’s written procedures, offsite storage is permitted if the records can be retrieved within 24 hours of such a request. These records would be subject to disclosure under the Freedom of Information Act.

E. Waivers (21 CFR §§ 1.914-1.934)

FDA will waive any requirement of the final regulations for any class of persons, vehicles, food, or nonfood products, if FDA determines that: (1) the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and (2) the waiver will not be contrary to the public interest.

A waiver must be requested in a citizen’s petition under 21 CFR § 10.30, and will be responded to in the manner prescribed by that regulation. Alternatively, FDA may, on its own initiative, determine that a waiver is appropriate. Waivers may be modified or revoked.
Consistent with the proposed rule, FDA has determined that it is appropriate to issue waivers for:

(1) Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products; and

(2) Food establishments holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment.

FDA intends to publish waivers in the Federal Register addressing these two classes of persons prior to the compliance date of the final rule.

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We will continue to monitor and report on FDA’s activities to implement the sanitary transportation requirements and other FSMA related activities.