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FDA Publishes Final Rule on Sanitary Transportation of Human and Animal Food

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Food & Drug

Yesterday, FDA published in the Federal Register its final rule establishing sanitary transportation requirements for both human and animal food.[1] The rule is intended to ensure that food transportation practices do not create food safety risks. FDA provides a flexible, risk-based approach that largely aims to allow the transportation industry to continue to use industry best practices that are likely already in place concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment to satisfy the requirements in the final rule. These requirements also align in part with the hazard analysis and risk-based preventive controls requirements for food facilities that were established in FDA's preventive control final rules for human food and animal food released earlier this year.[2]

Under the final rule, shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of human and animal food must use sanitary transportation practices to ensure the safety of the food that they transport. The rule's requirements apply to vehicles and transportation equipment, transportation operations, training, and recordkeeping. Of particular note, the final rule focuses specifically on transportation practices that will prevent food from becoming unsafe. The rule's requirements generally do not require practices to prevent spoilage or other marketability concerns.

This alert provides a high-level summary of the final rule, highlights key differences between the proposed rule and final rule, and discusses major points of interest to industry stakeholders. FDA has provided additional information about the final rule on its FSMA website.[3]

Scope of the Final Rule and Key Exemptions

The final rule's requirements apply to shippers, receivers, loaders, and carriers engaged in transportation operations, whether or not the food is being offered for or enters interstate commerce.

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[1] 81 Fed. Reg. 20092 (Apr. 6, 2016). This final rule implements the statutory requirements set forth in the Food Safety Modernization Act (FSMA) and the Sanitary Food Transportation Act of 2005 (SFTA), which added section 416 to the Federal Food, Drug, and Cosmetic Act (FDCA).

[2] See our prior client alerts on the Final Rules for Preventive Controls for Human Food (September 17, 2015) and Animal Food (September 18, 2015).

[3] *See* FSMA Final Rule on Sanitary Transportation of Human and Animal Food on FDA's website.

Entities Subject to the Final Rule

One key change from the proposed rule to the final rule is in how FDA defines the entities subject to the final rule's requirements. Specifically, FDA has revised the definition of "shipper" and defined a new regulated entity, "loader," in response to many industry comments conveying that FDA's proposed definitions did not adequately reflect the complexity of the food supply chain.

FDA now defines "shipper" as the person who arranges for the transportation of a food by a carrier or multiple carriers sequentially. FDA explains that the "shipper" is best suited to perform required activities that take place before transportation occurs based on that entity's food safety and product-specific knowledge, and could be, for example, a manufacturer or a freight broker, depending on the circumstances under which transportation is arranged.[4]

The final rule also includes a newly defined entity, "loader," which is the person that loads food onto a motor or rail vehicle during transportation operations. FDA added this definition to acknowledge that many of the activities that FDA attributed to "shippers" in the proposed rule are, in practice, often performed by an entirely separate entity at the time food is loaded for transport. FDA also designated certain requirements under the final rule as specific to loaders. The final definitions of "carrier" and "receiver" did not substantively change from the proposed rule. A "carrier" is a person who physically moves food by rail or motor vehicle and a "receiver" is a person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

The final rule explicitly acknowledges that a person may be subject to requirements in multiple capacities, e.g., a shipper may also be the loader and the carrier, or a carrier also may be the receiver. In addition, any of the entities covered by the final rule may reassign, in a written agreement, its sanitary transportation-related responsibilities to another party subject to the final rule, and any such written agreement is subject to the recordkeeping requirements set forth in the final rule.[5]

Food and Operations Subject to the Final Rule

The final rule applies to entities engaged in "transportation operations" of human and animal food. However, the scope of its requirements is limited by FDA's definition of "transportation operations,"[6] which means all activities associated with food transportation that may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment, except for when such activities are associated with the transportation of the following types of food:

- Food completely enclosed by a container except a food that requires temperature control for safety;
- Compressed food gases;
- Food contact substances as defined in the FDCA;

[4] 81 Fed. Reg. at 20121.
[5] 21 C.F.R. 1.908(a).
[6] 21 C.F.R. 1.904.

- Human food byproducts transported for use as animal food without further processing; and
- Live food animals except for molluscan shellfish.

In addition, this definition excludes any transportation activities that are performed by a farm.

The final definition of "transportation operations" excludes a larger scope of food and activities than FDA initially proposed. For example, the proposed rule would have excluded the transportation of fully packaged shelf-stable foods, which FDA has expanded to include all food completely enclosed by a container so long as that food does not require temperature control for safety. However, FDA declined requests in comments to additionally exempt food in vented cardboard cartons, because FDA concluded that such food is at more risk for environmental contamination.

The final definition now also excludes certain human food byproducts intended for use as animal food without further processing -- for example, byproducts that move directly from a human food manufacturer to the farm, where they are fed directly to livestock by spreading on the ground. This does not exclude, however, human food byproducts that are transported to a business to be used as an ingredient in a manufactured animal food or rendered in the production of animal feed, though FDA received multiple requests to exclude these activities from the final rule's requirements. FDA concluded that the risk of contamination during these types of operations necessitated certain sanitary transportation requirements; however, as discussed in more detail below, FDA revised the final rule to make it clear that the type of food being transported is relevant in determining the applicable sanitary transportation requirements.[7]

The final rule also does not apply to "non-covered businesses," which FDA defines to mean an entity engaged in transportation operations that has less than $500,000 in average annual revenues during the three year period preceding the applicable calendar year.[8] Further, the requirements of the final rule do not apply to the transportation operations of:

- Food that is transshipped through the United States to another country;
- Food that is imported for future export in accordance with the FDCA's import for export provisions and is neither consumed nor distributed in the United States; and
- Food that is located in food facilities that are regulated exclusively, throughout the entire facility, by the US Department of Agriculture.[9]

Key Requirements of the Final Rule

The requirements of the final rule focus primarily on food safety concerns, and not concerns related to spoilage or quality defects, and thus are intended to ensure that food does not become *unsafe* during transportation operations. This is a significant change from the proposed

[7] 81 Fed. Reg. at 20124.
[8] 21 C.F.R. 1.900(a).
[9] 21 C.F.R. 1.900(b).

rule, where FDA would have also imposed requirements to prevent food from becoming unfit for consumption during transportation, and therefore adulterated, even if the food did not become unsafe.

Vehicles and Transportation Equipment (§ 1.906)

Vehicles and equipment used in transportation operations must be designed, adequately cleanable, and maintained for their intended use to prevent the food they transport from becoming unsafe. This means that the required sanitary practices depend on the food being transported and the intended use of that food. For example, FDA explains that a transportation vehicle used to haul materials destined for rendering wouldn't be operating under insanitary conditions if it was not refrigerated because those materials would undergo further processing to make them suitable for animal consumption (though such a vehicle could be subject to cleaning or other requirements to avoid cross-contamination).[10]

If vehicles or equipment are used to transport food requiring a temperature control for safety, the final rule requires them to be equipped as necessary to provide adequate temperature control, though FDA acknowledges that this could be accomplished through a variety of mechanisms, including the use of ice, dry ice, or insulated coolers.[11] Notably, FDA removed its proposed requirement that vehicles used to transport food must be equipped with some type of temperature monitoring device, concluding that there are a number of effective methods for monitoring temperature control that don't require the permanent installation of a monitoring device.[12]

Transportation Operations (§ 1.908)

The final rule requires all transportation operations (all activities associated with food transportation that may affect the sanitary condition of food) to be conducted under such conditions and controls necessary to prevent food from becoming unsafe. The shipper is primarily responsible for determining the appropriate transportation operations for a given food, though the shipper may contractually assign this responsibility to another party. These conditions and controls include segregation, isolation, or the use of packaging to protect food from contamination by other items in the same load or to protect food transported in bulk vehicles from contamination or cross-contact during transport; and taking effective measures to ensure that food that requires temperature control for safety is transported under adequate temperature conditions. FDA specifically concluded, however, that "if temperature control is not required to prevent the food from becoming unsafe during transportation, the temperature control provisions of this rule do not apply to those transportation operations," even if temperature control is necessary for maintaining certain other product attributes.[13]

In the final rule, FDA also clarified three aspects of requirements related to transportation operations in response to comments. First, the rule now explicitly states 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

[10] 81 Fed. Reg. 20128.
[11] 81 Fed. Reg. 20131.
[12] *Id*.
[13] 81 Fed. Reg. 20137.

transportation operations.[14] Second, the final rule provides some flexibility for transportation entities that are under the ownership or control of a single legal entity; as an alternative to complying with the requirements of § 1.908, such entities may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food.[15] Third, the rule requires that if a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render food unsafe during transportation, the person(s) must take appropriate action to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the food was not rendered unsafe.[16]

Training (§ 1.910)

The final rule imposes specific training obligations on carriers engaged in transportation operations, because carriers would generally not be subject to the training provisions in other human and animal food safety regulations. If a carrier is responsible, in whole or in part, for sanitary conditions during transportation operations through contractual agreement with the shipper, the carrier must provide adequate training to its personnel about potential food safety problems that might occur during transportation and basic practices to address those problems. Carriers must also maintain records documenting such training.

Records (§ 1.912)

Shippers, carriers, loaders, and receivers all must maintain records required under the final rule and make such records available to FDA upon request. These records include the specifications that a shipper provides to a carrier, required written procedures, and written agreements assigning responsibility among parties in the transportation chain.

Waivers (§ 1.914)

The final rule sets forth processes and procedures for FDA to waive any requirement of the rule with respect to any class of persons, vehicles, food, or nonfood products, when FDA determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to public interest. In the proposed rule, FDA tentatively concluded that it would be appropriate to waive the requirements of the final rule with respect to two classes of persons: (1) shippers, carriers, and receivers who hold valid permits under the National Conference on Interstate Milk Shipments (NCIMS) Grade "A" Milk Safety Program when engaged in transportation operations involving Grade A milk and milk products; and (2) food establishments, i.e., retail and food service operations, holding valid permits, when engaged in transportation operations as receivers or as shippers and carriers when food is relinquished to consumers after transportation. FDA is still considering comments received in response to this tentative conclusion, and intends to post its final decision related to these proposed waivers and additional requested waivers (including for transportation operations for molluscan shellfish by entities that hold certain state permits) as soon as possible.[17]

[14] 21 C.F.R. 1.908(a)(4).
[15] 21 C.F.R. 1.908(a)(5).
[16] 21 C.F.R. 1.908(a)(6).
[17] 81 Fed. Reg. at 20106.

Compliance Dates

Businesses other than "small businesses" must come into compliance with the requirements of this final rule by April 6, 2017 (one year after the final rule was published in the Federal Register). Small businesses, which the final rule defines to mean a business employing fewer than 500 full-time equivalent employees, or, for carriers by motor vehicle that are not also shippers or receivers, a business having less than $27,500,000 in annual receipts, must come into compliance by April 6, 2018.

Covington & Burling LLP continues to monitor FDA's implementation of FSMA and to advise clients on relevant developments. If you have any questions concerning FSMA or other food regulatory matters, please contact any of the following attorneys of our Food & Drug Practice Group or visit our food and beverage practice website:

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