



FDA's Proposed Rule on Sanitary Transportation of Human and Animal Food

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On February 5, 2014, the Food and Drug Administration published in the *Federal Register* a proposed rule¹ regarding sanitary transportation of human and animal food, as called for by the Food Safety Modernization Act (FSMA), which became law on January 4, 2011. FSMA requires FDA to issue regulations requiring shippers, carriers by motor or rail vehicles, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices to prevent food from being transported under conditions that may render the food adulterated.

Consequently, the goal of the proposed rule, which is the seventh rule issued to implement FSMA, is to ensure that transportation practices do not create food safety risks. Although acknowledging that the risk of contamination from the transportation of food is low, FDA noted that it continues to receive reports of practices that result in food safety risks, including failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and neglect in protecting foods during transportation by motor or rail vehicles.

Coverage of the Proposed Rule

The proposed rule on sanitary transportation applies to domestic and foreign entities, but the scope of the rule is not the same for both. Shippers, receivers, and carriers who transport food in the United States by motor or rail vehicle are subject to the requirements under the rule, even if the food does not enter interstate commerce. Exporters of food to the United States are also subject to the new rule if they (1) ship food to the United States in an international freight container by oceangoing vessel or in an air freight container, (2) arrange for the transfer of the intact container in the United States onto a motor or rail vehicle for transportation in US commerce, and (3) if the food will be consumed or distributed in the United States. The scope of the proposed rule applies both to finished food, raw materials, and ingredients subject to the jurisdiction of both FDA and the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. FSIS has issued guidance for the safe transportation and distribution of meat, poultry, and egg products, but does not have requirements that directly address transportation for these foods. FDA notes that this rulemaking will complement FSIS's efforts to promote the application of sanitary food transportation practices, and FDA intends to work together with FSIS to facilitate this shared objective while carrying out the agencies' respective regulatory programs.

The proposed rule has some exemptions. The transportation of fully packaged shelf-stable foods, compressed food gases (such as carbon dioxide used for carbonating beverages), live food animals, and raw agricultural commodities (RACs) when the RACs are transported by farms are excluding from the definition of "transportation operations" subject to the rule. The proposed rule also exempts entities engaged in food transportation operations with less than \$500,000 in annual sales. Finally, the proposed rule allows entities who would otherwise be subject to the rule to request waivers from FDA if certain conditions are met.

¹ 79 Fed. Reg. 7005 (Feb. 5, 2014), which can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-02-05/pdf/2014-02188.pdf>

Overview of the Proposed Rule

Consistent with the other FSMA rules proposed by FDA, the proposed rule on sanitary transportation builds on current safe food transport practices and focuses on ensuring that persons engaged in the transportation of food that is at the highest risk for contamination follow adequate sanitary transportation practices. Such risks include the transportation of food that is not completely enclosed by its container (e.g., fresh produce in vented boxes), foods that require time or temperature control to ensure their safety (e.g., meat, poultry, or seafood), and foods subject to potential microbial spoilage (e.g. pasteurized juice). FDA states that this risk-based approach will complement the industry's current best practices concerning cleaning, inspection, maintenance, loading and unloading of and operation of vehicles and transportation equipment, such as bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, and loading and unloading systems.

Specifically, the proposed rule establishes requirements for:

- **Vehicles and transportation equipment.** The proposed rule would require that the design of vehicles and transportation equipment used in transportation operations, the materials used in their manufacture, and their workmanship be “suitable” and “adequately cleanable” for their intended use to prevent the food they transport from becoming filthy, putrid, decomposed or otherwise unfit for food or being rendered injurious to health from any source during transportation operations. Although FDA recognizes that vehicles and transportation equipment are generally manufactured to meet certain standards, the agency cited surface coatings on vehicles or transportation equipment that are flaking or chipping and wood containers used to hold raw meat or poultry as examples that pose a risk of contamination.
- **Transportation operations.** The proposed rule defines “transportation operations” as “all activities associated with food transportation that may affect the sanitary condition of food,” subject to the exemptions specified above. These activities include cleaning, inspection, maintenance, loading and unloading, and the operation of vehicles and transportation equipment. The proposed rule requires that transportation operations be conducted “under such conditions and controls necessary” to prevent the food from becoming unfit for food or rendered injurious to health from any source. FDA provides three examples of conditions and controls that may be implemented: (1) taking “effective measures” to protect food from contamination by raw foods and non-food items in the same load, such as through segregation or isolation; (2) taking “effective measures,” such as hand washing and segregation to protect food transported in bulk vehicles or food that is not completely enclosed by a container from contamination and cross-contact; and (3) ensuring the proper temperature control for food that can support the rapid growth of undesirable microorganisms under inappropriate temperature conditions. This latter requirement will require that each freezer and mechanically refrigerated cold storage compartment in vehicles be equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device. Responsibility for ensuring compliance with these transportation operations must be assigned to “competent supervisory personnel.”
- **Knowledge exchanges between shippers and carriers.** The proposed rule sets out a number of specific provisions for shippers and carriers to exchange key information to maintain the sanitary condition of food. These provisions include, for example, requiring the shipper to specify to the carrier “all necessary sanitary requirements for the carrier’s vehicle and transportation equipment,” including any specific design requirements and cleaning procedures. In turn, a carrier must supply a vehicle that meets any requirements necessary to ensure the safe transport of the food. Additionally, before loading food not completely enclosed by a container onto a vehicle provided by a carrier, the shipper must visually inspect the vehicle for the absence of visible evidence of pest infestation, debris, previous cargo, or dirt that could cause the food to become adulterated and must provide vehicle operators with access to hand washing facilities. A shipper of food that can support the rapid growth of undesirable microorganisms in the absence of temperature control must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature conditions necessary during the transportation operation. Likewise, before loading such a food, the shipper must verify that each freezer and mechanically refrigerated cold storage compartment or container has been pre-cooled in accordance with the instructions

mentioned above. The carrier must also demonstrate its observance of these requirements to the shipper and meet other obligations under the rule, such as providing information to the shipper that identifies the three previous cargoes transported in the carrier's vehicle.

- **Training.** The proposed rule would require carriers to provide training to employees about food safety issues that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the carrier's responsibilities under the rule. Carriers must also establish and maintain records documenting this training.
- **Records.** Shippers and carriers will need to retain records of, among other things, the information exchanged with each other and their written agreements.
- **Waivers.** The proposed rule allows FDA to consider whether to waive a requirement of the rule on FDA's own initiative or on a citizen petition filed pursuant to 21 C.F.R. § 10.30. A waiver with respect to any class of persons, vehicles, food, or nonfood products, will be allowed when 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, or (2) the waiver will not be contrary to the public interest. Any waiver issued may subsequently be modified or revoked should FDA conclude that the waiver could result in the unsafe transportation of food or the waiver is no longer in the public interest.

Written comments on the proposed rule may be filed with FDA by May 31, 2014. The rules proposed to implement other provisions of FSMA have drawn significant comments from industry, consumer groups, and other interested parties, which has complicated FDA's ability to issue final rules. The proposed rule on sanitary transportation of human and animal food will likely add to this broad discussion of appropriate preventive measures to improve food safety.

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