

E-ALERT | Food & Drug

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FDA PUBLISHES PROPOSED RULE ON SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD UNDER FSMA

Today, FDA published in the Federal Register a proposed rule regarding sanitary transportation of human and animal food, as required by the Food Safety Modernization Act (FSMA).¹ With this proposed rule, which is the seventh issued to implement that Act,² FDA seeks to prevent transportation practices that may create food safety risks, such as inadequate temperature control and failure to protect food properly during transportation. Although FDA acknowledged that the risk of contamination from the transportation of food is low, the agency noted that it continues to receive reports of food transported under unsanitary conditions, and that addressing food transportation is part of FDA's implementation of a comprehensive regulatory framework for prevention of food safety risks. FDA seeks comments on the proposed rule by May 31, 2014.

SCOPE OF THE PROPOSED RULE

The proposed rule on sanitary transportation covers domestic and foreign entities, although 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 requirements under the rule, even if the food does not enter interstate commerce. Exporters outside of 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 proposed rule would exempt 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. The rule would do so by excluding the transportation of these articles from the definition of "transportation operations" subject to the rule. The proposed rule also would exempt entities engaged in food transportation operations with less than \$500,000 in annual sales. Additionally, FDA would allow entities who would otherwise be subject to the rule to request waivers if they can show that the agency's grant of this waiver would not result in the transportation of food under conditions that would be unsafe for human and animal health and would not be "contrary to the public interest."

HIGHLIGHTS OF THE PROPOSED RULE

Like the rest of the FSMA framework, the proposed rule on sanitary transportation applies a risk-based approach to focus on the transportation of food that is at the greatest risk for contamination during transport. FDA's examples of these greater risks include the transportation of food that is not

¹ The full text of the proposed rule is available [here](#).

² For Covington & Burling's client alerts on each of the other proposed rules, see [here](#), [here](#), [here](#), [here](#), and [here](#).

completely enclosed by its container (such as fresh produce in vented boxes) and foods that require time or temperature control to ensure their safety (such as meat, poultry, or seafood) or to prevent microbial spoilage (such as pasteurized juice). FDA explains that the proposed rule “otherwise would allow the transportation industry to continue to use best practices concerning cleaning, inspection, maintenance, loading and unloading of, and operation of vehicles and transportation equipment that it has developed” to ensure the sanitary transportation of human and animal food.

Some of the requirements that would be established by the proposed rule include:

- **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 allow the sanitary transport of food. This provision extends to the maintenance of these vehicles and transportation equipment to prevent food from becoming unfit for consumption or rendered injurious to health. 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 would 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 noted 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: first, 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; second, taking “effective measures,” such as hand washing to protect food transported in bulk vehicles or food that is not completely enclosed by a container from contamination and cross-contact; and third, ensuring the proper temperature control for food that can support the growth of undesirable microorganisms under inappropriate temperature conditions.
- **Information exchange.** The proposed rule sets out a number of specific provisions for shippers and carriers to exchange 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 and the temperature conditions necessary for transporting food that can support the rapid growth of undesirable microorganisms in the absence of temperature control. The carrier must also demonstrate its satisfaction 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 transportation practices to address these risks, and the carrier’s responsibilities under the final rule. Carriers must also maintain records of these trainings.
- **Records.** Shippers and carriers will need to retain records of, among other things, the information exchanged with each other and their written agreements.

Covington & Burling LLP would be happy to provide additional information regarding this proposed rule. We continue to monitor FDA's implementation of FSMA and will keep our clients updated regarding developments and next steps.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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