

Supply Chains Make Final Preparations as FSMA Transportation Rule Goes Into Effect

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Only one day before the compliance date for the FDA's final Rule on Sanitary Transportation of Human and Animal Food (the "FSMA Transportation Rule"), the FDA issued long awaited waivers that clarify the scope of exemptions to the Rule. The waivers reflect the FDA's response to industry concerns that retail food establishments would be required to comply with additional regulations even though they are already subject to rigorous regulatory oversight by state and local authorities. While some entities are exempt, others involved in the transportation cycle remain subject to the Rule in order to address transportation practices that cause food safety risks.

Food manufacturers, carriers, brokers, and others involved in food product and ingredient supply chains have had over a year to prepare for the Rule's implementation in order to determine what requirements apply to their business practices under the new Rule. If a business that engages in activities that are subject to the Rule fails to comply with such party's obligations under the Rule, such violation may cause the FDA to deem food products that such party handles to be adulterated under the federal Food, Drug and Cosmetic Act. Additionally, businesses may be subject to claims alleging negligence or other misconduct of a responsible party.

The Rule applies broadly to transportation operations and includes "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." In order to reduce the likelihood of food contamination or cross-contact, the Rule addresses (1) temperature fluctuations; (2) food transportation in bulk vehicles or not completely enclosed by a container; and (3) raw food and non-food items in the same load whether or not the food is offered for or enters interstate commerce.

The following foods are covered by the Rule: food not completely enclosed by a container, such as in an open wooden basket or crate, an open or vented cardboard box, or a vented plastic bag; and food that requires temperature control for safety, but is completely enclosed by a container. The FDA expressly excluded all other food enclosed by a container.

Persons Covered

Persons covered under the new Rule include shippers, loaders, carriers, and receivers. All definitions are activity based, meaning an entity may be both a shipper and carrier, or shipper and receiver depending on the action. Responsibility primarily lies with the shipper, but can be contractually assigned to other parties. The FDA will consider the terms of the contract in determining who is responsible for compliance.

Loaders and carriers have significant roles as well. Primary responsibilities include ensuring sanitization and maintenance of transportation vehicles and adherence to required temperature controls. Carriers must also provide food safety training to personnel and maintain records in accordance with the Rule. Records must be retained for a period of 12 months. All persons (*i.e.*,

loaders, shippers, carriers, and receivers) must ensure that any food that has been transported under a temperature or other condition that may render the food unsafe is not sold or further distributed pending review by a qualified individual.

Waivers

After much anticipation, the FDA published three waivers effective the same day as the final Rule. The waivers apply to the following class of persons:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade “A” milk and milk products;
- 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; and
- Businesses that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference’s National Shellfish Sanitation Program (NSSP), only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.

The food establishment waiver is applicable to retail food establishments e.g., grocery stores, convenience stores, and certain farm-operated businesses selling food directly to consumers as their primary function. While retail food establishments may be exempt as the receiver, if the same entity performs other activities that would result in classification as a shipper, loader, or carrier, that entity is still required to comply with the new Rule. However, if a retail establishment, e.g., a grocery store, operates a food delivery service direct to consumers, it is not considered a shipper and is therefore excluded under the waiver.

Conclusion

With compliance and enforcement dates now in effect, businesses (other than small businesses) should ensure that they have written procedures and updated supply chain contracts in place in order to comply with the Sanitary Transportation Rule. However, major hurdles to implementation may include the negotiation of contractual agreements with each business connected through the supply chain. Again, the shipper has the ultimate responsibility for transportation operations, but may assign its duties. Careful negotiation and scrutiny of agreements, proper record retention, and personnel training are important to insure that all parties will adhere to the new Rule and be prepared for enforcement by the FDA.