



NAVIGATING THE FOOD SAFETY MODERNIZATION ACT (FSMA): A GUIDE TO TRANSPORTING FOOD SAFELY

The economic losses to industry, including farming, caused by foodborne illnesses in the United States are enormous, estimated at \$75 billion per year.¹

WHITE PAPER





RULE OVERVIEW

- > The rule becomes effective April 6, 2017.
- > Shippers (including freight brokers), loaders, carriers, and receivers play a role in implementation and compliance.
- > Rule establishes general training and compliance requirements.
- > Shippers will continue to hold primary responsibility for sanitary conditions of transport under this rule.
- > Vehicles and equipment acceptable for food transport use are clean, pest-free, food grade, and non-hazmat.
- > Stakeholders maintain records for 12 months.
- > Carriers with a food safety compliance program will be better equipped to comply with the rule.

Why respond to food contamination when you can take measures to prevent it? The U.S. Food and Drug Administration (FDA) asked this question in response to a rise in outbreaks of foodborne illnesses. The answer was the FDA Food Safety Modernization Act (FSMA). Since its passage in 2013, seven foundational rules of the FSMA have been finalized. These rules aim to prevent food safety problems versus reacting to them after they occur. Among the seven rules is the Sanitary Transportation of Human and Animal Food rule, also referenced as “the rule” in this white paper, which will become effective April 6, 2017. This rule will have a significant impact on the transportation of food-related products.

COMPLIANCE REQUIREMENTS

While most food contamination is believed to originate on farms, it can also occur during transport, packaging, and handling.² This is why, with some exclusions, shippers (including freight brokers), loaders, carriers, and receivers play a role in implementation and compliance of the rule. Larger businesses, defined as having 500+ full-time equivalent employees and more than \$27.5 million in USD revenue, as well as those who do not qualify for a waiver or exclusion, have until April 6, 2017, to comply. Other businesses falling below the employee count and revenue threshold have until April 6, 2018.

COMPLIANCE WAIVERS

Waiving the requirements of the rule will only be permitted occasionally, and only when the FDA determines that the food in question will not be transported under conditions that make it unsafe for human or animal health. For example, receivers, shippers, and carriers who hold valid permits for specific types of operations are exempt. This includes those that relinquish food to customers after the food is transported from an establishment (restaurants, supermarkets, and home delivery operations), as well as those subject to inspection and monitoring through the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety Program or the Retail Food Program.³

IMPLEMENTATION

The FSMA has been thorough in creating rules to protect public health. It has also attempted to make each rule as feasible as possible for the shippers, loaders, carriers, and receivers impacted. A food safety failure at any stage in transportation can have disastrous civil, regulatory, and criminal consequences.⁴ The rule establishes general requirements for vehicles and transportation equipment, transportation operations, training, and records. However, the primary responsibility for ensuring the FSMA requirements are properly achieved and maintained rests heavily on all parties involved and contractually obligated in the transportation chain.

EQUIPMENT DESIGN AND MAINTENANCE

To ensure food does not become contaminated or rendered unsafe during transport, vehicles and transportation equipment must be both suitable and cleanable. At the most basic level, vehicles and equipment acceptable for food transport use are clean, pest-free, food grade, and non-hazmat. Further precautions must be taken when products with special designations (organic, Kosher, and Halal) are involved.

In addition, vehicles and equipment should also be suitable for any stage of transport in the food supply chain. For example, trailers with temperature control capabilities should be equipped with a proper cooling apparatus and monitoring mechanisms to ensure temperatures are maintained during transit. However, the full benefit of food transport equipment, such as multi-temperature trailer bulkheads, can only be realized when equipment is correctly operated. The proper vehicles and equipment for food transport are only as effective as the personnel operating them.

TRAINING

Agreements between shippers and carriers should be specific to establish the requirements of each party. Companies should use industry best practices to create and implement relevant training programs and procedures, covering prevention and awareness training as well. At this time, the FDA does not plan to establish specific training requirements, aside from the requirement to maintain training documentation. Carriers that have a food safety compliance program will be better equipped to comply with the rule.

OPERATIONS

Beyond transporting food, sanitary and safe food transport practices extend to loading and unloading, too. As a result, shippers must ensure contamination does not occur during any phase of handling. Taking steps to review previous manifests and perform proper cleaning procedures to equipment and facilities involved in every stage of transportation and storage is recommended. The rule now requires procedures be created and implemented to address the following as well:

- > Monitor and record temperatures
- > Prevent contamination of ready-to-eat food from raw food with stacking order
- > Avoid contamination of non-food items with food items in same/previous load
- > Protect food and avoid unintentional cross-contact (e.g. food allergens)

RECORD KEEPING

To comply with the rule, documentation is critical. Food may be declared adulterated for record-keeping violations alone.⁵ Requirements for retaining records vary based on the type of record and timing in which the activity occurred, but retention periods are not to exceed 12 months.

NON-COMPLIANCE

The goal of the rule is to improve compliance rates through prevention and risk-based food safety standards. Shipper-defined requirements to keep food safe and unadulterated as defined by industry standards demand strict adherence. This is especially important now that criminal liabilities for food industry firms up and down the supply chain are part of FSMA.⁶ However, even these safeguards don't fully eliminate issues.

Food shipments can be declared unfit for consumption at any point in the supply chain. When this occurs, receiving facilities cannot accept the shipment, and it cannot be salvaged or sold on the secondary market.

RULE ENFORCEMENT

With implementation comes the question of rule enforcement. Collaboration is crucial between agencies at every level and is critical to ensure rules are enforced. For the rule to be successful, the FDA, Department of Transportation, United States Department of Agriculture, Federal Motor Carrier Safety Administration, Food Safety and Inspection Service, health departments, and other state or local agencies will collaborate to maintain public safety.

CONCLUSION

Working with a carrier that has expertise in food safety can help shippers navigate the regulatory environment and mitigate food safety risks in the supply chain.

FOODBORNE ILLNESSES

Despite having one of the safest food supplies in the world, foodborne illnesses do occur in the United States.

HISTORY OF OUTBREAKS IN THE US

1994

Salmonella Enteritidis outbreak found in ice cream that sickened 224,000 people nationwide after a tank carrying raw eggs was not properly washed between loads.⁷

2008/09

Salmonella Typhimurium outbreak in peanut products sickened over 700 people in 46 states and may have contributed to nine deaths.⁸

2010

More than 500 million eggs were recalled by an Iowa producer due to suspected Salmonella Enteritidis contamination sickening hundreds of people in multiple states.⁹

2012

Cantaloupe contaminated with Listeria sickened at least 147 and killed more than 30, making it one of the deadliest foodborne illness outbreaks in the nation's history.¹⁰

These high-profile outbreaks have prompted policy makers to create the FSMA, the first major overhaul in U.S. food safety practices since 1938.¹¹

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