



## Sanitary Transportation Rule: Implementation

The first compliance date for the Sanitary Transportation of Human and Animal Food rule was April 6, 2017. The rule was mandated by the Sanitary Food Transport Act (SFTA) to prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food. Implementation of the SFTA provisions was included in the FDA Food Safety Modernization Act (FSMA). Consistent with our “educate before and while we regulate” approach to FSMA implementation, the agency is focusing on supporting compliance through education in these initial months.

So what do you need to know? And what is the FDA doing to implement this rule?

### First: Am I covered by the rule?

- With some exceptions, the final rule applies to shippers, receivers, loaders, and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. It also applies to:
  - Persons, e.g., shippers, in other countries who ship food into the U.S. directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the United States.
- Companies involved in the transportation of food intended for export are covered by the rule until the shipment reaches a port or U.S. border.
- Exemptions:
  - Shippers, receivers, loaders or carriers engaged in food transportation operations that have less than \$500,000 in average annual revenue
  - Transportation activities performed by a farm
  - Transportation of food that is transshipped through the United States to another country
  - Transportation of food that is imported for future export and that is neither consumed or distributed in the United States
  - Transportation of compressed food gases (e.g. cylinders of carbon dioxide, nitrogen used in food and beverage products), and food contact substances
  - Transportation of human food byproducts for use as animal food without further processing
  - Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety
  - Transportation of live food animals, except molluscan shellfish

### Do I have to comply now or do I have more time?

- For larger businesses subject to the rule, the compliance date is April 6, 2017.
- Small businesses motor carriers who are not also shippers and/ or receivers having less than \$27.5 million in annual receipts, and all other businesses employing fewer than 500 persons– have an additional year to comply.

### What is FDA doing to prepare for implementation of these new requirements?

The agency is preparing investigators for the work ahead and developing a free training module for carriers.

- Inspections:
  - The FDA expects to begin inspections later this year to ensure that shippers, receivers, loaders and carriers covered by the rule are complying with the requirements.
  - The FDA’s ultimate goal is compliance and so the objective of the first round of inspections will be to assess the industry’s level of readiness and, if deficiencies are found, to provide firms with the information they need to achieve compliance.
  - The FDA is in the process of training investigators to inspect firms for compliance with this rule.
- Carrier training:
  - Shippers will hold the primary responsibility for ensuring that the requirements of this rule are met. Carriers are required to provide training to personnel and to show documentation of that training when the carrier and shipper agree that the carrier is responsible, in whole or part, for the sanitary conditions during transport.

- The FDA is developing a free training module for carriers which will be available in the next few months.
- Carriers may also elect to train their own personnel or to acquire training through third party training vendors. The FDA does not require training courses offered by a company or third party to be approved by FDA or that their instructors be certified.
- The FDA acknowledges that carriers may find it difficult to acquire and provide documentation of training until the FDA training becomes available. The FDA encourages shippers to work with carriers to ensure that carriers are aware of the applicable provisions of the rule, and that food is transported in a safe and sanitary manner.

### **I have to comply with the rule- what are my requirements?**

- **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports to become unsafe.
- **Transportation operations:** The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food by raw food, protection from food contamination by non-food items in the same load or a previous load on the vehicle, and the protection of food from cross-contact, i.e., the unintentional incorporation of a food allergen.
- **Training:** Training of carrier personnel in the awareness of potential food safety problems and basic sanitary transportation practices required by the rule, and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible in whole or part, for sanitary conditions during transport.
- **Records:** Maintain records of shipper-to-carrier communication, written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but except for training documentation, does not exceed 12 months.

### **Am I subject to a waiver?**

In April 2017, the FDA published three waivers for businesses whose transportation operations are subject to Federal-State or local controls. They include:

- Businesses that 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 bulk and finished Grade "A" milk and milk products.
- Businesses that are permitted or otherwise authorized by the regulatory authority to operate a food establishment that provides food directly to consumers (including restaurants, retail food establishments, and nonprofit food establishments, as defined in 21 CFR 1.227), only when engaged in transportation operations as:
  - Receivers, whether the food is received at the establishment itself or at a location where the authorized establishment receives and immediately transports the food to the food establishment;
  - Shippers and carriers in operations in which food is transported from the establishment as part of the normal business operations of a retail establishment, such as:
    - delivery of the food directly to the consumer(s) by the authorized establishment or a third-party delivery service or;
    - delivery of the food to another location operated by the authorized establishment or an affiliated establishment where the food is to be sold or served directly to the consumer(s).
- 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.

### **Will FDA be publishing guidance to help industry comply?**

- FDA intends to publish a Small Entity Compliance Guide for the rule later this year.

### **For more information:**

- Learn more about the final rule on Sanitary Transportation of Human and Animal Food (Fact Sheet): <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM494118.pdf>
- Sanitary Transportation Rule Q&A: [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#Sanitary\\_Transportation](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#Sanitary_Transportation)

**Have a question?** Contact the FSMA Technical Assistance Network:

<https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm>