

Sanitary Food Transportation Under the FSMA

by Practical Law Commercial Transactions

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A Practice Note discussing how the Food and Drug Administration (FDA) regulates the sanitary transportation of food for humans and animals sold in the US under the Sanitary Food Transportation Act of 2005 (SFTA 2005) and the Food Safety Modernization Act (FSMA) to ensure that food is safe for human consumption. This Note discusses federal requirements and best practices for sanitary transport of food by shippers, loaders, carriers, and receivers under the Sanitary Transport Rule, including requirements for maintenance of vehicles and equipment, establishing sanitary procedures, establishing "cold chain" procedures, training personnel, and maintaining records.

The [Food Safety Modernization Act](#) (FSMA) modernized the [Food and Drug Administration's](#) (FDA) food safety regulations with a focus on prevention practices for those growing, processing, transporting, and storing food for human and animals. As a result, entities engaged in food transportation must now take effective measures to protect food during all stages of transport. These measures must be properly documented for inspection. This Note discusses the requirements and best practices for sanitary transport of food, including temperature control, personnel training, and record-keeping.

Food Transport Under Federal Law

Federal law requires that human and animal food are handled and transported in a manner that ensures they are not adulterated. The FDA, acting under the authority of the Food, Drug, and Cosmetic Act (FDCA) is charged with enforcing matters related to the safety of the US food supply. The FDA has the authority to regulate food transport under the following laws:

- The FSMA, which requires the FDA to develop rules to address core food safety and supply issues ([21 C.F.R. §§ 117.1 to 117.475](#)).
- The Sanitary Food Transportation Act of 2005 (SFTA), which requires the FDA to develop transportation practices that are sanitary and will not adulterate food ([Pub. L. No. 109-59](#), [119 Stat. 1911](#)).
- The FSMA Final Rule on Sanitary Transport of Human and Animal Food (Sanitary Transport Rule), which aims to prevent food safety hazards during food transportation by motor or rail vehicle ([21 C.F.R. §§ 1.900 to 1.934](#)).

The Sanitary Transport Rule

The Sanitary Transport Rule applies to shippers, receivers, loaders, and carriers that transport human and animal food in the US by motor or rail vehicle.

The Sanitary Transport Rule contains requirements for:

- Maintaining vehicles and transportation equipment engaged in food transport.
- Transportation operations.
- Training individuals involved in food transport.

- Maintaining records of sanitary transportation compliance.
- Obtaining waivers for certain requirements under the rule.

The rule does not set out many specific procedures for maintenance, operations, or training. Instead, covered entities must develop procedures based on industry standards and best practices. The rule focuses instead on ensuring covered entities are developing, following, and maintaining records regarding their sanitary transport procedures.

Covered Entities

The following entities fall under the Sanitary Transport Rule:

- **Shippers.** Shippers are entities that arrange for the transportation of food for distribution in the US by motor or rail carriers, including:
 - freight brokers; and
 - persons arranging for the transport of imported food by motor or rail carrier.
- **Loaders.** Loaders are entities that load food onto motor or rail vehicles during transportation operations.
- **Carriers.** Carriers are entities that physically move food by rail or motor vehicle in commerce within the US.
- **Receivers.** Receivers are entities that receive food at a point in the US after transportation, regardless of whether or not that person represents the final point of transport. Receivers do not include consumers accepting delivery of food parcels.
- **Importers.** Importers are entities that are responsible for the shipment of food into the US. They are covered by the Sanitary Transport Rule if they meet the following parameters:
 - the importer arranges for transfer of an intact container of food onto a motor or rail vehicle for transportation within the US; and
 - the food will be consumed or distributed within the US.
- **Exporters.** Exporters are entities involved in the transportation of food intended for export. The Sanitary Transport Rule applies to exporters of food shipments until the shipment either:
 - reaches a port; or
 - crosses a US border.

(21 C.F.R. § 1.900.)

An entity's responsibilities under the rule depend on both its specific role and any written agreements it may have with other covered entities (see [Entity-Specific Requirements](#)).

Covered Vehicles and Equipment

The Sanitary Transport Rule applies to vehicles and equipment used in food transportation operations, including:

- Motorized vehicles.
- Trailers not attached to a tractor.
- Railcars, including railcars not attached to a locomotive.
- Bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems.

(21 C.F.R. § 1.900.)

Covered Activities

The Sanitary Transport Rule applies to all activities associated with food transportation that may affect the sanitary condition of food, including:

- Cleaning.
- Inspection.

- Maintenance.
- Loading and unloading.
- Operation of vehicles and transportation equipment.

(21 C.F.R. § 1.900.)

Exempted Entities and Facilities

The Sanitary Transport Rule does not apply to:

- Shippers, receivers, or carriers with less than \$500,000 in annual revenues, calculated on a rolling basis, during the three-year period preceding the applicable calendar year, adjusted for inflation using 2011 as the baseline.
- Farms, defined as food facilities regulated exclusively by the [Department of Agriculture \(USDA\)](#) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act (21 C.F.R. § 1.227).
- Transportation of food by a means other than motor or rail (for example, ship, barge, or plane).
- Transportation of food that originates outside the US and is then shipped through the US to another country.
- Transportation of food completely enclosed in the container, except when temperature control safety requirements apply (see [Cold Chain Requirements](#)).
- Transportation of compressed gases, such as the carbon dioxide used in carbonated soda and other food contact substances.
- Transportation of human food byproducts transported for use as animal food without further processing.
- Transportation of live food animals, except molluscan shellfish. When the FDA published the Sanitary Transport Rule, the agency indicated that it may issue a waiver for molluscan shellfish in the future using the Sanitary Transport Rules' waiver procedures (see [Waivers](#)), but has not done so yet.

(21 C.F.R. § 1.904.)

General Requirements of the Sanitary Transport Rule

The Sanitary Transport Rule requires covered entities to exercise sufficient control over transportation conditions to prevent food from becoming adulterated during the transport process. Adulteration is extensively defined by the FDCA, but the definition includes food rendered injurious to health due to, for example:

- Contamination by a foreign substance, such as filth or harmful chemical substances.
- Unsanitary conditions.
- Putridity or decomposition (see [Cold Chain Requirements](#)).
- Disease.

(21 U.S.C. § 342.)

The Sanitary Transport Rule was designed to be flexible enough to encompass the food transport industry's best practices for food safety and to allow for diverse measures to be implemented depending on situational factors, such as the type of food being transported and items with which the food is transported. For example, specific measures related to the type of food being transported may include:

- Segregation of raw food from other foods, or unpackaged foods from one another, or food from non-food items.
- Isolation of food items.
- Packaging of items to prevent contamination and cross-contact when transported with other items.
- Hand washing by personnel directly handling food during transport.

An entity may be subject to these requirements in multiple capacities (as a shipper, loader, carrier, and so on). If a single entity performs all responsibilities associated with food transport, it is eligible for alternative compliance procedures (see [Alternative Compliance for Single-Entity Control](#)).

Whether the covered entity is performing one or more capacities of food transport, the responsibility for compliance must be assigned to competent supervisory personnel ([21 C.F.R. § 1.908\(a\)](#)).

Vehicle and Equipment Design, Maintenance, and Storage

Vehicles and equipment used for food transport must be designed, maintained, and stored in a manner that protects the food they carry. Specifically, all vehicles and equipment must be:

- Designed to be suitable for food transport. Suitability factors include:
 - the ability to be adequately cleaned for their intended use; and
 - capable of maintaining temperatures necessary for safe transport.
- Made from materials and workmanship of sufficient quality to prevent food from becoming unsafe.
- Maintained in a sanitary condition.
- Stored in a manner that prevents them from harboring pests or becoming otherwise contaminated.
- Capable of providing adequate temperature control, if the vehicles or equipment are to be used for food requiring temperature control for safety.

([21 C.F.R. § 1.906](#).)

Response to Unsafe Conditions

If a covered entity becomes aware of conditions that would render food unsafe during transport, including a possible failure in temperature control, the entity must:

- Not sell or distribute the food.
- Communicate with other parties to ensure the food is not sold or distributed to consumers.

The food must be held from distribution or sale until a qualified individual determines that the food is not unsafe. ([21 C.F.R. § 1.908\(a\)\(6\)](#).)

Entity-Specific Requirements

The Sanitary Transport Rule requirements for the following entities vary depending on the entity's role or roles in the transportation process:

- Shippers (see [Shippers](#)).
- Loaders (see [Loaders](#)).
- Carriers (see [Carriers](#)).
- Receivers (see [Receivers](#)).

Shippers bear the bulk of responsibility for setting appropriate procedures and ensuring those procedures are followed by loaders, carriers, and receivers, but certain responsibilities may be shifted to the carrier through a written contract.

An entity that fulfills all food transport roles (shipper, loader, carrier, and receiver) may choose to follow either:

- The specific requirements for each role.
- The single-entity control requirements (see [Alternative Compliance for Single-Entity Control](#)).

([21 C.F.R. § 1.908](#).)

Shippers

Shippers must ensure that their vehicles and equipment are in appropriate sanitary condition for the transport of food. The rule does not define appropriate sanitary conditions, but shippers should consider the following factors when selecting and maintaining vehicles and equipment for food transport:

- The cleanliness of any surface that might come into contact with food.
- The internal temperature of vessels that will contain food, particularly food that requires cold storage (see [Cold Chain Requirements](#)).
- The potential for bacteria or other contaminants to adhere to surfaces.

To meet this requirement, shippers must:

- **Develop and implement written procedures to ensure proper sanitary conditions.** These written procedures must include procedures for:
 - ensuring vehicles and equipment are in appropriate sanitary condition for the transportation of food;
 - cold chain procedures (see [Cold Chain Requirements](#)); and
 - bulk food shipments (defined as shipments in which food comes into direct contact with the vehicle) adequate to ensure that previous cargo does not make food unsafe through contamination or otherwise unsanitary conditions.
- **Notify carriers and loaders of sanitary procedures.** Shippers notify carriers and, if necessary, loaders at least once in writing of:
 - specific equipment design requirements and cleaning procedures necessary to maintain sanitary conditions during shipment; and
 - any changes to design requirements or cleaning procedures based on the type of food being shipped or other factors.
- **Maintain records of sanitary specifications and notification under the records requirements of 21 C.F.R. Section 1.912(a)** (see [Food Transport Records Requirements](#)).

(21 C.F.R. § 1.908(b).)

Loaders

Loaders must:

- Determine that the vehicle or transportation equipment onto which they are loading food is in appropriate sanitary condition before loading food that is not completely enclosed in a container, considering:
 - the specifications provided by the shipper;
 - the physical condition of the vehicles or equipment;
 - any visible evidence of pest infestation; and
 - any visible evidence of previous cargo.
- Verify that the shipper's cold chain procedures are followed, including specifications for pre-cooling any mechanically refrigerated cold storage compartment or container (see [Cold Chain Requirements](#)).

(21 C.F.R. § 1.908(c).)

Carriers

Carriers are not automatically responsible for sanitary transportation of food under the Sanitary Transport Rule. The primary responsibility belongs to shippers. However, shippers may contractually shift some of their responsibility for compliance onto carriers with a written agreement.

If the carrier and the shipper have a written agreement making the carrier responsible for sanitary conditions, in whole or in part, the carrier must fulfill the following requirements:

- **Ensure the shipper's specifications are met.** Under a written contract with a shipper, carriers must ensure that:
 - vehicles and equipment meet the shipper's specifications and are otherwise appropriate for food transport; and

- the shipper's cold chain procedures are properly followed and demonstrate maintenance of the proper operating temperature (see [Cold Chain Requirements](#)).
- **Provide information regarding bulk vehicle transport.** Because bulk vehicles, defined as vehicles used for shipment of food in which food comes into direct contact with the vehicle, present greater risks of contamination, a carrier offering a bulk vehicle for food transportation must, at the shipper's request:
 - identify the previous cargo transported in the bulk vehicle; and
 - describe the most recent cleaning of the bulk vehicle.
- **Develop and implement written compliance measures.** These measures must:
 - specify practices for cleaning, sanitizing, and inspecting vehicles and equipment provided by the carrier to maintain proper sanitary conditions;
 - describe how the carrier will comply with provisions for temperature control (see [Cold Chain Requirements](#)); and
 - describe how the carrier will comply with requirements for bulk vehicle transport.

(21 C.F.R. § 1.908(e).)

Receivers

Receivers must ensure that cold chain procedures are followed (see [Cold Chain Requirements](#)) (21 C.F.R. § 1.908(d)).

Alternative Compliance for Single-Entity Control

If a single legal entity performs all of the shipping roles involved in food transport, including shipping, loading, carrying, and receiving, that entity may choose, as an alternative to compliance with the requirements for independent entities, to conduct transportation operations:

- Conforming with common, integrated, written procedures for all operations.
- That ensure sanitary transportation of food consistent with the general requirements of the Sanitary Transport Rules (see [General Requirements of the Sanitary Transport Rule](#)).
- Subject to the records requirement of [21 C.F.R. Section 1.912\(e\)](#) (see [Food Transport Records Requirements](#)).

(21 C.F.R. § 1.908(a)(5).)

Cold Chain Requirements

Certain foods require temperature control to ensure that they are safe for consumption. For example, the following foods will spoil, develop dangerous bacteria (including Listeria and E-coli), or begin to decompose if stored above certain temperatures:

- Raw, cooked, or cured meats and fish.
- Eggs and certain food products containing eggs.

These foods require additional care to ensure that adequate temperature controls are in place during transport. While shippers are responsible for creating proper cold chain procedures, all covered entities must take steps to ensure maintenance of the cold chain throughout shipment.

Shipper Cold Chain Requirements

Shippers must ensure adequate temperature control for safety by:

- Notifying the carrier in writing of the operating temperature for the transportation operation including the pre-cooling phase.
- Notifying the carrier in writing of any changes in the operating temperature.
- Maintaining records of their temperature control procedures, including notifications to the carrier, according to the records requirements of [21 C.F.R. Section 1.912\(a\)](#) (see [Food Transport Records Requirements](#)).

(21 C.F.R. § 1.908(b).)

Loader Cold Chain Requirements

Loaders must follow shipper's cold chain procedures, including those for pre-cooling any mechanically refrigerated cold storage compartment or container before loading any food (21 C.F.R. § 1.908(c); see [Shippers Cold Chain Requirements](#)).

Carrier Cold Chain Requirements

Carriers that have a written contract with the shipper making the carrier responsible for sanitary conditions must:

- Pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper.
- On the receiver's request, provide the operating temperature specified by the shipper.
- On the shipper's or receiver's request, demonstrate by any appropriate means (for example, presenting measurements of ambient temperature on loading or unloading) that the carrier has maintained temperature conditions during transport consistent with the cold chain procedures specified by the shipper.

(21 C.F.R. § 1.908(e).)

Receiver Cold Chain Requirements

Receivers must, when receiving food requiring temperature control for safety, take steps to assess that the food was not subject to significant temperature abuse such as:

- Determining the food's temperature.
- Determining the ambient temperature of the vehicle and its temperature setting.
- Conducting a sensory inspection for signs of temperature abuse such as odors.

(21 C.F.R. § 1.908(d).)

Training Requirements

The Sanitary Transport Rule has relatively narrow training requirements, focusing on requirements for carriers that have contracted with a shipper to take responsibility for sanitary transport conditions.

Carriers to Provide Personnel Training

If a carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for sanitary transport conditions, the carrier must:

- Provide training, at hiring and as needed afterwards, to transportation operations personnel. The training must adequately provide awareness of:
 - potential food safety problems that may occur during food transport;
 - basic sanitary transportation practices that address potential food safety problems; and
 - the carrier's responsibilities regarding sanitary transport.
- Establish and maintain records documenting the training (see [Food Transport Records Requirements](#)).

(21 C.F.R. § 1.910.)

Training for Shippers, Loaders, and Receivers Not Specified

The Sanitary Transport Rule does not specify training requirements for shippers, loaders, or receivers. However, these entities should provide any training necessary to ensure that personnel follow proper procedures, including cold chain procedures, under the rule.

Food Transport Records Requirements

The Sanitary Transport Rule requires covered entities to retain records associated with food transport, including written procedures, agreements, and other evidence of compliance. Records must be retained for 12 months after they are no longer in effect. For example, a shipper's written agreement with a carrier assigning certain sanitary transport responsibilities must be retained for the duration of the agreement and for 12 months after its termination.

Shippers must retain the following records:

- Written agreements and procedures for sanitary transport, including procedures for:
 - maintaining vehicles and equipment;
 - bulk transport; and
 - temperature control.
- Written agreements assigning certain responsibility over sanitary transport conditions to carriers.
- Evidence of compliance with the cold chain procedure requirements, including written notifications to carriers of temperature control procedures (see [Shippers Cold Chain Requirements](#)).

Carriers that have a written contract with a shipper that shifts certain responsibilities under the Sanitary Transport Rule to the carrier (see [Carriers](#)), must retain records of:

- Written procedures for sanitary transport.
- Training provided to personnel.

All entities covered by the Sanitary Transport Rule must retain written agreements that assign tasks for compliance. This applies not only to agreements between shippers and carriers, but to any written agreement signed by a covered entity concerning compliance with the rules. ([21 C.F.R. § 1.912](#).)

Single-Entity Control

If a single legal entity owns or controls the entire chain of shippers, loaders, carriers, and receivers involved in food transport, and chooses to operate under the alternate regulations for single-entity control, the entity must retain records of its written procedures ([21 C.F.R. § 1.908\(a\)\(5\)](#); see [Alternative Compliance for Single-Entity Control](#)).

Requirements for Storing Records

Records may be retained in any of the following ways:

- Original records.
- True copies (for example, photocopies, pictures, scanned copies, or other accurate reproductions).
- Electronic records.

Most records may be stored off-site, provided they can be accessed within 24 hours.

The only records that must be stored on-site are carrier practices for cleaning, sanitizing, and inspecting vehicles and equipment used for food transport, where the carrier has a written agreement with a shipper assigning the maintenance of vehicles and equipment to the carrier.

If an individual authorized by the FDA or related agency requests orally or in writing to see the records covered by this rule, covered entities must produce the records promptly. Though the rule does not define "promptly" in this context, the requirements regarding off-site storage of records indicate that entities should be able to produce records within 24 hours of the request. ([21 C.F.R. § 1.912](#).)

Waivers

When the FDA announced the Sanitary Transport Rule, the agency also announced plans to waive its requirements for two groups that were identified during the comment period:

- **National Conference on Interstate Milk Shipments (NCIMS) waivers.** Shippers, carriers, and receivers holding valid permits and inspected under the NCIMS Grade A Milk Safety program will receive a waiver for transportation for Grade A milk and milk products. NCIMS already regulates the transportation of these products with enforcements by the states and oversight by the FDA.
- **Food delivery waivers.** Restaurants, supermarkets, home grocery delivery operations, and similar food establishments receive a waiver for food deliveries in which food is relinquished to customers after being transported from the establishment. The FDA's Voluntary National Retail Food Regulatory Program and state and local enforcement agencies already regulate food delivery services.

([21 C.F.R. § 1.914.](#))

The FDA has not yet issued these waivers, but intends to issue them before the rule takes effect (see [Compliance Deadlines](#)).

Petitions for Waiver

In addition to the planned waivers already announced, covered entities may apply for a waiver by following the rules for citizen petitions in [21 C.F.R. Section 10.30](#). Petitions for waiver must include in their Statement of Grounds:

- A description of the people, vehicles, food, or nonfood products to which the waiver would apply.
- A description of the specific rule or rules to be waived.
- Current information demonstrating that the waiver will not result in unsafe food conditions or otherwise be contrary to the public interest.

([21 C.F.R. § 1.914](#) to [1.934.](#))

Compliance Deadlines

The Sanitary Transport Rule went into effect on June 6, 2016. Compliance deadlines depend on whether a covered entity is a small business within the rule's definition, which is:

- A business employing fewer than 500 full-time equivalent employees, excluding motor carriers that are not also shippers or receivers, or both.
- A motor carrier that is not also a shipper or receiver, or both, with less than \$27.5 million in annual receipts.

([21 C.F.R. § 1.904.](#))

Small businesses have until April 6, 2018 to comply. All other businesses must comply by April 6, 2017.

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