

Sanitary
Transportation
Final

Final Rule for Sanitary Transportation

**FDA FOOD SAFETY
MODERNIZATION ACT**

THE FUTURE IS NOW



Background

- Proposed Rule: February 5, 2014
- Public Comments: More than 200
- Final Rule: On Display April 5, 2016
- Builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act (SFTA).

Who is Covered by SFTA?

- 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.

Who is Covered by SFTA?

- The final rule also applies to persons, e.g., shippers, who ship food into the U.S.:
 - Directly by motor or rail vehicle (Canada or Mexico); and
 - By ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the U.S., if that food will be consumed or distributed in the U.S. (only the motor or rail portion).

Not Covered by SFTA

- Shippers, receivers, or carriers with transportation operations with less than \$500,000 in average annual revenue
- Transportation activities performed by a farm
- Trans-shipments of food through the U.S.
- Food not consumed in the U.S. (import for export)

Not Covered by SFTA

- Transportation of:
 - Food fully enclosed by a container (except if requiring temperature control)
 - Live food animals, except molluscan shellfish
 - Compressed food gases and food contact substances
 - Human food byproducts for use as animal food without further processing

Examples of Types of Food Subject to Final Rule

- Foods transported in bulk, e.g., juice, animal feed
- Packaged foods not fully enclosed by a container, e.g., fresh produce
- Foods that require temperature control for safety

Key Requirements

- Vehicles and Transportation Equipment
 - Design, maintenance, and storage must be appropriate to prevent the food from becoming unsafe during transportation operations.
 - For food requiring temperature control, vehicles and transportation equipment must be equipped, as necessary, to provide adequate temperature control.

Key Requirements

- Transportation operations must be conducted to prevent food from becoming unsafe during transport, including:
 - Ensuring adequate temperature controls
 - Preventing contamination of food by contact with raw food or non food items
 - Protection from cross-contact, i.e., food allergens
 - Protection of food transported in bulk

Key Requirements

- Transportation Operations
 - A person may be subject to transportation operation requirements in multiple capacities, e.g., shipper may also be the loader and the carrier.
 - General responsibilities are applicable to all.
 - Designated responsibilities may be reassigned, in a written agreement, to another party subject to the rule.

Key Requirements

- If a shipper, loader, receiver or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food shall not be sold or otherwise distributed...

Key Requirements

- ... and these persons must take appropriate action including, as necessary, communication with other parties, to ensure that the food is not sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.

Key Requirements

- A shipper must develop and implement written procedures, subject to the records requirements, adequate to ensure:
 - Vehicles and equipment are in appropriate sanitary condition
 - A previous cargo does not make food transported in bulk unsafe
 - Food requiring temperature control for safety is transported under adequate temperature control

Key Requirements

- Responsibilities for:
 - Loaders: inspection at loading, e.g., vehicle cleanliness and pre-cooling
 - Receivers: on receipt, assess food for temperature abuse
 - Carriers: (upon request, if agreed to by contract) demonstrate that shipper's operating temperature requirements have been met and disclose identity of most recent prior bulk cargo and cleaning information

Key Requirements

- Training
 - When the carrier and shipper have agreed in a written contract that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, carrier personnel must be provided with adequate and documented training on sanitary transportation practices and awareness of potential food safety problems that may occur during food transportation.

Key Requirements

- Records - shippers
 - Records that demonstrate that the shipper provides information to carriers about the necessary sanitary requirements for a vehicle, and the necessary temperature conditions for a temperature-controlled food, as appropriate

Key Requirements

- Records - carriers
 - Carrier must develop written standard operating procedures (SOPs) for cleaning and inspection of vehicles and that describe how it will meet requirements to provide information to shippers about temperature conditions and bulk cargo protection, as appropriate
 - Training records

Waivers

- The Agency may waive the requirements of the rule if it determines that the waiver will not result in transportation of food under conditions that would be unsafe to humans or animals.
 - Prior to the compliance date, the Agency intends to publish waivers in the Federal Register, as announced in the proposed rule.

Waivers

- Shippers, carriers and receivers holding valid permits under the NCIMS Grade A Milk Program, when transporting Grade A milk and products.
 - Controls already exist under the NCIMS program, with State enforcement and FDA oversight.

Waivers

- Food establishments, e.g., retail stores, restaurants, and home grocery delivery, holding valid permits, when acting as receivers, shippers, or carriers delivering food to consumers
 - Controls already exist under the Retail Food Program, with state, territorial, tribal and local enforcement, and FDA oversight.

Waivers

- Commenters also asked for a waiver for molluscan shellfish for entities holding valid state permits under the National Shellfish Sanitation Program.
 - The agency will shortly issue a notice describing its thinking on the two proposed waivers, as well as this request.

Changes from Proposed Rule

- Focus is on practices that create safety risks, not spoilage or quality issues
- “Loaders” have been added as a covered party.
 - Loader must determine that the transportation equipment is in appropriate sanitary condition; and, if applicable, adequately prepared for refrigerated transportation.

Changes from Proposed Rule

- Comments stated that rail operators often do not own, prepare or operate equipment, e.g., refrigeration units, in the railcars they transport and do not have the ability to ensure temperature control and sanitary conditions are met.
 - Shipper or loader responsible for sanitary conditions (e.g., inspecting railcar) unless reassigned in written agreement.

Compliance Dates

- Small businesses: 2 years
 - Businesses employing fewer than 500 FTE employees, except carriers by motor vehicle that are not also shippers and/or receivers
 - Motor vehicle carriers that are not also shippers and/or receivers having less than \$27.5 million in annual receipts
- Other businesses: 1 year
 - Not small and not otherwise excluded

Planned Guidances

- Small Entity Compliance Guide
- Revision of the 2010 Guidance for Industry: Sanitary Transportation of Food

Training & Technical Assistance

- FDA plans to develop an online course that would meet the training requirements of this rule.
- FSMA Food Safety Technical Assistance Network
 - Source of information to support industry in understanding and implementing FSMA
 - Questions submitted online or by mail will be answered by information specialists or SMEs.

For More Information

- Web site: <http://www.fda.gov/fsma>
- Subscription feature available
- To contact FDA about FSMA and find the online form for submitting questions:
<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>