

FDA's Rule on Sanitary Transportation of Human and Animal Food

A. Horror Stories

There have been horror stories of food contamination and spoilage of food being delivered to grocery stores and restaurants which were not being kept in refrigerated trailers (or trailers that had the refrigerated units turned off or not in good working order), and food that was shipped in tankers that had previously hauled garbage or other products that could make food unsafe and were never cleaned before hauling other food products. These stories led to the introduction of the:

- 2005 Sanitary Food Transportation Act (SFTA)
- 2010 Guidance for Industry: Sanitary Transportation of Food
- FDA Food Safety Modernization Act (FSMA) signed into law by President Obama on January 4, 2011.

B. From Reactive to Proactive:

Rather than continue in a reactive mode the FDA proposed a more proactive preventive program in the Food Safety Modernization Act. This Act gives the FDA more enforcement powers to achieve higher rates of compliance with risk-based, prevention-oriented safety standards.

C. Seven foundational Rules:

FDA has published what they refer to as Seven Foundational Rules for Implementation of FSMA. The seventh Foundational Rule was published on Feb. 5, 2014 and is the Sanitary Transportation of Human and Animal Food.

D. What transportation modes are affected by the rule?

By definition transportation pertains to the movement of food in commerce by motor vehicle or rail vehicle. So this rule does not apply to the movement of food by air or ship.

II. Not all foods are covered by SFTA:

A. Foods not covered:

- Food fully enclosed by a container unless it requires 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
- Milk shippers, carriers and receivers holding a valid permit under the NCIMS (National Conference on Interstate Milk Shipments) Grade A Milk Program, when transporting Grade A milk products.
- Frozen food

B. Foods that are covered:

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

C. Not all shipments of food products are covered:

- Mexican and Canadian firms shipping food through the U.S. not entering food distribution within the U.S.
- U.S. companies exporting food are covered by the rule until the shipment reaches a port or U.S. border
- All transportation activities performed by a farm; although farms are still subject to FD&C Act's provisions that prohibit the holding of food under unsanitary conditions

III. Compliance dates:

A. April, 2017

- For large shippers and carriers, those that employ more than 500 full time employees and those motor carriers that are also shippers and/or receivers.
- Motor carriers that are also shippers and/or receivers having more than \$27.5 million in annual revenue.

B. April, 2018

- For all other shippers and carriers (Small business)
- Realistically many shippers will not use a carrier after April of 2017 without that carrier being in compliance with the rule regardless of their status as a business. This has been verified by C.H. Robinson one of the largest brokers for the food industry, they will not be offering these loads to any carriers that have not met the requirements of the Act.

IV. New Requirements

The rule creates new requirements for the sanitary transportation of human and animal food by motor carrier and rail to ensure that transportation practices do not create food safety risks. Note that the final rule is concerned with food safety and not focused on spoilage as was the original rule. The rule establishes requirements for shippers, loaders (added in the final rule), carriers and receivers involved in transporting human and animal food.

A. Shippers:

- The definition of shipper is different in this rule than in most rules, as the shipper is the person who arranges for the transportation of the food. The biggest difference in this definition is that now brokers are considered shippers by definition and must follow the requirements for shippers and will be held accountable by the FDA. The primary responsibility of the shipper is to provide the requirements and developing and implementing written procedures for the sanitary transportation of the food.
- This information should be gathered from the growers and manufactures of the food product.
- Develop written procedures to ensure:
 1. equipment and vehicles are in appropriate sanitary condition, which would include cleaning requirements for trailers and repair of any damage within the trailer body
 2. food transported in bulk must develop and have written procedures to ensure that a previous cargo does not make food unsafe
 3. food that requires temperature control for safety must have written procedures to ensure that food is transported under adequate temperature control. The final rule allows more flexibility for temperature controlled food safety in that the shipper and carrier can agree on alternative methods for temperature control information. In addition carriers only need to demonstrate they maintained requested temperature conditions only upon request.

B. Carriers: defined as the person who physically moves the food.

- Carriers will have to work closely with the shippers and meet the requirements of the shipper in order to move the load.
- This training will be awareness training and must be provided to drivers upon hiring and as needed thereafter.
- Training must be documented providing the: a.) date of training; b.) type of training and; c.) the person(s) trained
- There are three focus areas for carriers that must be assured: a.) assurance that vehicles and equipment in the transportation operation are in appropriate sanitary

condition; b.) assurance that , for bulk cargo, a previous cargo does not make the food unsafe; and c.) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control

- Carriers must have written procedures that specify cleaning, sanitizing and inspecting equipment.
- Carriers must develop and implement procedures that describe how they will comply with provisions for temperature control
- Carriers will work with shippers in how this information will be given to the shippers and receivers
- Drivers will have to have proof of training on temperature management and reporting requirements. (this would include knowing how to load, stack and keep vents open and airflow moving)
- Temperature records for each shipment must be retained for each shipment for one full year
- While shippers have the primary responsibility for the safe shipment of food it may under the rule assign some of the responsibility to other parties such as the carrier or loader by written contract. (I suspect most shippers especially brokers will attempt to have such a written contract and will only give that load to those carriers that agree to the contract)

C. Loader: The person that loads food onto a motor vehicle during transportation operations

- This was a new entity added to the chain of responsibility or food safety
- The loader must determine that the transportation equipment is in appropriate sanitary condition
- Before loading temperature controlled food the loader must determine that each mechanically refrigerated cold storage compartment is adequately prepared for refrigerated transportation, including precooling, if necessary.

D. Receivers: The person that receives the food

- Upon receipt of a food requiring temperature control for safety, receivers must take steps to adequately assess that the food was not subject to significant temperature abuse by
 - a) determining the food's temperature;
 - b) checking the ambient temperature of the vehicle; and
 - c) smelling for off-odors among other factors.

It should be noted that one person may have multiple responsibilities such that a carrier that loads the truck may have responsibilities as the carrier and the loader and if there is a written agreement with the shipper those added responsibilities also.

The rule requires that if a person subject to this rule 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 person must take appropriate action, 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.

E. Record Keeping:

- **Shippers:** Generally speaking all records must be kept for 12 months (This will include all contracts with carriers concerning who maintains responsibility for the shipment.)
- **Carriers:** Generally speaking all records must be kept for 12 months
- **Loaders:** Generally speaking all records must be kept for 12 months
- **Receivers:** Generally speaking all records must be kept for 12 months

All records required by this mandate must be made available to a duly authorized individual promptly upon oral or written request. Except for the written procedures required (carriers written procedures that specify practices for cleaning, sanitizing ,and inspecting vehicles; how the carrier plans to comply with temperature control requirements and/or how it will comply with the provisions for use of bulk vehicles), off site storage of records is permitted if such records can be retrieved and provided within 24 hours of request for official review.

F. Waivers:

It is possible to get a waiver from these requirements but there is a procedure that must be followed.

- The request for waiver must show that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health
- The waiver will not be contrary to the public interest
- If seeking a waiver a petition must be submitted that:
 1. Describe the waiver requested including the persons, vehicles, food or nonfood product(s) to which the waiver would apply and the requirements of the subpart to which the waiver would apply.
 2. Present information demonstrating that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to public interest.
- The petition will be published in the Federal Register requesting information and views on the filed petition.
- If the waiver is granted it too will be published in the Federal Register setting forth any waiver and the reasons for such waiver.

- If denied the petitioner will receive a written response explaining why it was denied.