



FDA FINAL RULEMAKING ON THE SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD

I. Introduction

As part of the Food Safety Modernization Act (FSMA), signed into law January 2011, the Food and Drug Administration (FDA) has published a final rule on section 111 - the sanitary transportation of human and animal food. According to FDA, “the goal of the rule is to ensure that transportation practices do not create safety risks”. FDA hopes to address three areas: 1) ensuring food is properly refrigerated, 2) vehicles and equipment are properly cleaned and sanitized, and 3) ensuring food is properly protected during transportation. The rule is based on the Sanitary Transportation of Food Act of 2005 and current best industry practices. Significant changes were made from the proposed rule offering more flexibility to carriers and shippers to set industry specific guidelines, minimizing burdensome requirements. The rule goes into effect on June 5, 2016 with compliance beginning one year later. Small businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and having less than \$27.5 million in annual receipts would have to comply within two years after the final rule goes into effect.

II. Highlighted Revisions to the Final Rule

Recordkeeping

Industry was concerned that we were going to have to hold a “room full of records” to comply with the rule. In fact, the proposed rule leaned in that direction. However, FDA clarified their position to request records on carrier’s procedures that are in place to meet shipper and/or receiver requests. Ex. FDA is not asking for temperature monitoring records for the past twelve months, just the fact that you have SOP’s or guidelines in place on how to provide those records to the shipper/receiver if requested. This is true for previous loads, sanitization, etc.

Training

The proposed rule indicated that we need at least a half day of training for those handling food products. In the final rule FDA states that the length of training, if even necessary, will be left up to the shipper and carrier. FDA plans to provide a one hour web based (not mandatory) training seminar on the basics of the rule, not on the specifics of handling the products. This training will be accompanied by a certificate of completion, but will not preclude other companies, or internal, training. The certificate of completion is an example of meeting the recordkeeping requirements for training. If the training is internal then they are only requesting that a program is in place.

Adulteration/Increased cargo claim issue

Initially FDA had proposed that if the TCS product went outside of the contractual obligations with the shipper (i.e. temperature outside stated guidelines) the food could/would be deemed adulterated, effectively rendering it useless. We were concerned that this would severely increase cargo claims and food waste, as well as damage the secondary market. FDA agreed and modified the language to state if a person notices an issue (temperature fluctuation, faulty temp device, faulty or damaged equipment) they must alert someone and the food held until a determination can be made on its safety. Ex. If raw chicken goes outside its required temperature threshold then the receiver would be alerted and the quality control person would inspect the chicken for safety.

Temperature monitoring

An approach for more prescriptive monitoring devices and continuous monitoring of temperature was taken in the proposed rule, but the final rule has been modified to allow the shipper and the carrier to agree to a temperature monitoring mechanism, and the carrier is not required to demonstrate the temperature records unless requested by the shipper and/or carrier. FDA made this change because the submittal of records every time was unnecessary, in most cases, and providing records when an issue arises would be more practical. Note - This change does not preclude the shipper or receiver from contractually requiring the documentation.

Increased shipper liability

The final rule now places primary responsibility to the shipper to determine appropriate transportation operations (i.e. temp control for foods, relevant temp, proper clean out procedures, and whether previous cargo should be reported (no more 3 previous loads)). This shipper may assign some of this liability to the carrier through a written contract.

III. Background

The FSMA was enacted into law after several food borne related outbreaks, including salmonella and E. coli, were reported across the U.S. Many of these outbreaks have been traced back to the handling, processing and manufacturing of the food. Due to this recent history, the majority of the FSMA was directed at those sections of the food supply chain, and the sanitary transport of food section simply closes loopholes within that supply chain.

IV. Overview

The regulation implements section 416 of the FD&C Act (the 2005 Sanitary Food Transportation Act). The main focus of the rule is to ensure proper temperature is held throughout the movement of the product and that the products are transported in sanitary conditions. The rule establishes requirements for sanitary transportation practices applying to shippers, loaders, carriers (truck and rail), and receivers involved in transporting food. The topics addressed by the rule are:

- Vehicles and transportation equipment
- Transportation Operations
- Training
- Recordkeeping

- Waivers

Due to education from industry and the over 240 comments submitted on the initial proposal, FDA made several important revisions to their initial proposal that allow more flexibility for the industry to utilize current best practices to meet many of the requirements.

V. Who is Covered by the Rule

Shippers

Defined as a person who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. Examples to include manufacturers and freight brokers.

Carriers

Defined as any person who physically moves food by rail or motor vehicle in commerce within the United States. A carrier does not include any person who transports food while operating as a parcel delivery service.

Loader

Defined as any person that loads food onto a motor or rail vehicle during transportation operations.

Receivers

Defined as any person who receives food at a point in the United States after transportation, whether or not that person represents the final point of receipt for the food.

VI. What Food is Covered

- FDA-regulated human food including raw materials and ingredients
No exemption for foods subject to seafood and juice HACCP rules (although regulation strives to be consistent with such rules)
- Animal food, to include pet food

Exemptions

- Food completely enclosed by a container unless requiring Temperature Control for Safety (TCS)
- Compressed food gasses
- Grade A Milk
- Live animals
- Any transportation performed by a farm

*Note - Food not completely enclosed

- Any food that is placed into a container in such a manner that it is partially open to the surrounding environment.
 - Includes: open wooden basket/crate, open cardboard box, vented cardboard box with a top, vented plastic bag

- *FDA states this approach is consistent with how they addressed unexposed refrigerated packaged foods in the proposed preventive controls rules

VII. Definitions

Vehicle

Vehicles are subject to requirements under the regulations. A vehicle is a land conveyance that is motorized (e.g., a motor vehicle) or that moves on rails (e.g., a railcar) which is used in transportation operations.

A *trailer* is considered to be a vehicle when attached to a tractor and used for transportation (because it functions as part of the conveyance).

Railcars are considered vehicles when attached to locomotives.

Transportation Equipment

Transportation equipment is subject to requirements under the regulation.

Transportation equipment means equipment used in food transportation. For example, bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems and unloading systems. Definition also includes a railcar not attached to a locomotive or trailer not attached to a tractor.

Transportation Operations

Transportation operations are subject to requirements under the regulations.

Transportation operations means all activities associated with food transportation that may affect the sanitary condition of the food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment.

Transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container, compressed food gasses, grade A milk, food contact substances as defined in section 409(h)(6) of the FD&C Act, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish.

Small Businesses

A business that employs fewer than 500 full time equivalent employees, except for carriers by motor vehicle that are not also shippers and/or receivers, this term would mean that there are less than \$27,500,000 in annual receipts.

VIII. Cost/Benefit

The new rule estimates it will cover 83,609 firms, including carriers engaged in transporting food and food facilities that ship food. Total first year cost is estimated to be \$162.7 million, and total annual cost is estimated at \$93.5 million. Unfortunately, FDA “lacks the sufficient data to quantify the potential benefits of the proposed rule”. They further explain that there is not sufficient data to quantify the likelihood of food becoming adulterated during its transport.

IX. Established Requirements

The rule defines transportation as “any movement of food in commerce by motor vehicle or rail vehicle”. The rule will establish requirement for sanitary transportation for shippers, loaders, carriers, and receivers engaged in food transport operations. Specifically the rule establishes requirements for:

Vehicles and transportation equipment – Be *designed* and of such material and workmanship as to be adequately cleanable for their intended use to prevent the food from becoming unsafe during transportation operations, i.e., adulterated within the meaning of section 402(a)(1), (2), and (4) of the FD&C Act.

They must be *maintained* in such a sanitary condition as to prevent the food from becoming unsafe (cleaning pumps and hoses to remove allergens, disposing of damaged, jagged pallets etc.). Requiring temperature control for safety must be designed, maintained and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe.

The equipment must be *stored* in a manner as to prevent the vehicles or equipment from harboring pests, or to prevent the food from becoming unsafe.

Transportation operations - Responsibility for ensuring that transportation operations are carried out in compliance with all requirements of regulation must be assigned to competent supervisory personnel. And all transportation operations must be conducted under such conditions and controls necessary to prevent food from becoming unsafe including:

- Measures such as segregation or isolation to prevent contamination by raw food and non-food items in the same load.
- Measures such as segregation, isolation, or other protective measures, such as hand washing to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.
- Ensuring that food is transported in a manner (including temperature control) to prevent unsafe food.

*Note – packaging of the product can count as segregation or isolation, and does not necessarily mean location in a separate compartment.

Shippers

Shipper must specify to the carrier, and when necessary, the loader, in writing, all necessary sanitary requirements for the carrier’s vehicle and transportation equipment including specific design requirements and cleaning procedures. A onetime notification is sufficient unless there is a change in food being transported.

Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment provided by a carrier, must visually inspect vehicle/equipment for cleanliness and determine it is in appropriate sanitary condition (e.g. free of visible evidence of pest infestation and of debris, previous cargo, or dirt that could cause the food to be adulterated).

Shippers of food , whether TCS or non-TCS, must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature

conditions necessary during the transportation operation, including the pre-cooling phase to ensure adequate temperature control.

Before loading food, a shipper of food must verify that each refrigerated cold storage compartment or container has been pre-cooled in accordance with information submitted by shipper to carrier.

Shipper assumes the requirements applicable to the carrier with respect to demonstrating temperature control to receiver if written agreement that shipper is responsible for ensuring that food was held under acceptable temperature conditions. For example, shipper may, by agreement with the carrier, arrange to have their own temperature monitoring device placed aboard the vehicle and recover the device upon delivery of the food.

Shippers and Receivers

Must provide vehicle operators who are expected to handle food not completely enclosed by a container during unloading and loading with convenient access to a hand washing facility and must carry out loading and unloading operations under conditions that prevent unsafe food.

Carriers

Must supply vehicle and transportation equipment that meets any necessary sanitary requirements specified by the shipper under the regulation and is otherwise appropriate to prevent unsafe food. The carrier is only required to demonstrate the temperature conditions to the shipper and/or the receiver if requested. This can be done by any appropriate means agreeable to the shipper and carrier including presenting printouts of a time/temperature recording device or a log of temperature measures taken at various times during shipment.

Shipper is responsible for monitoring temperature conditions or otherwise ensuring that food was held under acceptable temperature conditions unless requested from the carrier under written contract. Carrier must provide to receiver or shipper only upon request.

Upon shipper's request, precooling (consistent with shippers direction) of cold storage units is required before offering vehicle or equipment for transportation of unsafe foods.

Carriers must develop and implement written procedures subject to the recordkeeping requirements of regulation that:

- Specify cleaning, sanitizing (if necessary) and inspection practices
- Describe how carrier will comply with temperature control requirements under the regulation
- Describe how carrier will comply with requirements for use of bulk vehicles in regulation

*Note – Carrier is not required by FDA to keep a “room full of records”, only that records be kept on the processes and procedures (SOPs) of the above bullet points. And that the carrier have the ability to access and provide specific records, if requested.

Information exchange - Procedures for exchange of information about prior cargos, cleaning of transportation equipment and temperature control between the shipper, carrier, loader, and receiver, as appropriate to the situation. For example, a carrier transporting bulk liquid non-dairy foods would want to ensure that vehicles that have previously hauled milk will not introduce allergens into non-dairy foods through cross contact.

Training - Carriers must provide training to personnel engaged in transportation operations when the carrier and shipper have agreed via written contract that the carrier is responsible for the transportation operations, to include: an awareness of potential food safety problems that may occur during transportation, basic sanitary transportation practices to address those potential problems and the responsibilities of the carrier under the regulation. Beyond the general requirements in 1.910, FDA is not prescribing details on frequency, length, or subject matter. The mandated training (1.910(a)) is intended to raise awareness and not set out carrier specific duties. FDA plans to develop a web based hour long training that would meet the requirement and then issue a certificate. The FDA option is not mandatory. Carriers must also establish and maintain records documenting the training, including the date and type of training and the persons trained.

Recordkeeping - Shippers must retain records that demonstrate they regularly provide information to carriers as required under regulation for a period of 12 months. Carriers must retain any written agreements between shipper and carrier for temperature control and required written procedures for cleaning, inspecting vehicles, temperature control and use of bulk vehicles for 12 months beyond when the agreements and written procedures are in effect. Carriers must also retain required training records for a period of 12 months beyond when such person identified in records continues to perform the duties for which the training was provided. Records are allowed to be stored offsite. Note – FDA does not require the carrier to keep records pertaining to previous loads, temp monitoring, and sanitization. They are requesting records to show that SOP's or procedures are in place to demonstrate the carrier's ability to produce specific records to shippers/receivers, if requested. Ex. If an employee is trained on the basic food safety requirements and then 5 months later is trained on hauling fresh chicken, then the update made to the records at the 5 month date only has to be the additional training acquired.

Waivers - FDA intends to separately publish waivers concurrently with the publication of the final regulation that would exempt:

- Shippers, carriers and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments Grade —A Milk Safety Program, only when engaged in transportation activities involving Grade A milk and milk products
- Food establishments holding valid permits (e.g. from state agency), only when engaged in transportation operations as receivers, or as shippers or carriers in operations in which food is relinquished to consumers after transportation from the establishment

- *Note – A waiver for intra company movements was not granted. FDA did not feel that companies that encompassed all movements of food along the supply chain would be unnecessarily burdened by the STF requirements.

FDA will waive any requirement of the regulations with respect to any class of persons, vehicles, food, or nonfood products, when FDA determines that:

- The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and
- The waiver will not be contrary to the public interest
- FDA will consider whether to waive a requirement on its own initiative or on the petition by any person who is subject to the regulation

Additional items of note

LTL – The inclusion of the definition of a “loader” covers the shipper in case of cross dock loading/unloading where the shipper is not present and should not be liable for following the requirements during this point in the supply chain. The loader however is now required to follow the STF requirements including visually inspecting the equipment and documenting those inspections (trailer cleanliness, proper refrigeration, segregation, etc.)

Parcel carriers – parcel carriers are not covered under the STF. Example – Anyone transporting Omaha steaks from shipper to consumer.

Brokers/3PL – Within the new definition of a “shipper”, brokerage companies and manufactures may constitute a shipper if they arrange for the shipment of the freight, and would subsequently be held to the shipper requirements under the STF.

X. Exemptions

- Transportation of food completely enclosed by a container unless requiring TCS;
- Shippers, receivers, loaders, or carriers with less than \$500,000 in total annual sales;
- Transportation activities performed by a farm;
- Food transshipped through the United States to another country; Food imported for future export that is not consumed or distributed in the United States;
- Transportation of compressed food gases; and
- Transportation of live food animals.

For additional information on the STF please contact AFTC Executive Director Jon Samson: jsamson@trucking.org.