FDA’s Final Rule on Sanitary Transportation of Human and Animal Food

Impacts on the Grain and Feed Industry

Aug. 10, 2016
Final Rule for Sanitary Transportation of Human and Animal Food

- Establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting human and animal food to use sanitary practices to ensure the safety of the food
- Requirements do **not** apply to transportation by vessel or air because of limitations established by the Sanitary Food Transportation Act of 2005
- Requirements apply to both interstate and intrastate transportation of food
- Among the many operations covered by the rule are shippers, loaders, carriers and receivers involved with truck or rail vehicle transportation of raw agricultural commodities (e.g., grains and oilseeds), animal feed and feed ingredients, and human food and food ingredients
Requirements do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations of:

1. Food that is transshipped through the United States (e.g., from Canada or Mexico by truck or rail) to another foreign country; or
2. Food that is imported for future export, in accordance with the Federal Food, Drug and Cosmetic Act, and that is neither consumed nor distributed in the United States; or
3. Food when it is located in food facilities that are regulated exclusively by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.
“Non-Covered Businesses” are exempt

Definition: A shipper, loader, receiver, or carrier engaged in transportation operations that has less than $500,000, as adjusted for inflation, in average annual revenues, calculated on a rolling basis, during the three-year period preceding the applicable calendar year.

For the purpose of determining an entity’s three-year average revenue threshold as adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.
Exempted from Sanitary Transportation Rule

• Requirements apply to “transportation operations”
  • Definition: “All activities associated with food transportation that may affect the sanitary condition of 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, except a food that requires temperature control for safety, compressed food gases, food contact substances as defined in section 409(h)(6) of the Federal Food, Drug and Cosmetic Act, human food by-products transported for use as animal food without further processing, or live food animals except molluscan shellfish. In addition, transportation operations do not include any transportation activities...performed by a farm.”
Exempted from Sanitary Transportation Rule

• Activities performed by a “Farm” (as defined by 21 CFR Section 1.227) are exempt
  • Transportation activities performed by farms that transport commodities (e.g., grains and oilseeds) in their vehicles to storage or processing facilities are exempt
  • Non-farm carriers that transport commodities from the farm are subject to the rule, unless they are considered to be non-covered businesses
Situations That May Result In Unsafe Food

• If a shipper, loader, receiver, or carrier becomes aware of an indication of conditions that may render the food unsafe during transportation, the food is not to be sold or otherwise distributed, and appropriate actions are to be taken.
  • Actions are to include, 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 condition did not render the food unsafe.
Requirements for Shippers

- Final rule places most of the responsibility on the shipper for ensuring sanitary transportation of food and feed.
- Definition: "Shipper" means "a person, e.g., the manufacturer or a freight broker, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially"
Requirements for Shippers

• Unless the shipper itself develops and implements written procedures to ensure appropriate sanitary conditions, shippers must specify in writing to the carrier and, when necessary, to the loader, all sanitary specifications necessary for the carrier’s vehicle and transportation equipment pursuant to the product to be transported
Requirements for Shippers

- A shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., will prevent the food from becoming unsafe during the transportation operation.

Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement.
Requirements for Shippers

- A shipper of food transported in bulk must develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe.

Measures to ensure the safety of the food may be accomplished by the shipper or by the carrier or another party covered by this subpart under a written agreement.
Requirements for Loaders

• Definition: “Loader” means “a person that loads food onto a motor or rail vehicle during transportation operations”

• Loaders must:
  • Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment, determine, considering, as appropriate, specifications provided by the shipper that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food, e.g., it is in adequate physical condition, and free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation. This may be accomplished by any appropriate means.
Requirements for Receivers

• Definition: “Receiver” means “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.”

• Receivers must, for food that requires temperature control for safety under the conditions of shipment, take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food’s temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, e.g., for off-odors.
Requirements for Carriers

• Definition: “Carrier” means “a person who physically moves food by rail or motor vehicle in commerce within the United States. The term ‘carrier’ does not include any person who transports food while operating as a parcel delivery service.”

• Carrier requirements generally are limited to those established by a written agreement between the shipper and carrier.
Requirements for Carriers

• The carrier is responsible for the following functions as applicable per the written agreement:
  • Ensuring that vehicles and transportation equipment meet the shipper’s specifications and are otherwise appropriate to prevent the food from becoming unsafe
  • If requested, provide information to the shipper that identifies the previous cargo transported in the vehicle
  • If requested, provide information to the shipper that describes the most recent cleaning of the bulk vehicle
Requirements for Carriers

• 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, the carrier must:
  • Provide adequate training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier under this part. The training must be provided upon hiring and as needed thereafter
  • Establish and maintain records documenting the training in accordance with the rule’s record requirements
Intra-Company Transportation Activities

• Intra-company transfers of food are **not** exempt from the rule’s requirements

• However, shippers, carriers, loaders and receivers that are under the ownership or operational control of a single legal entity can rely on compliance with common, integrated written procedures for transportation activities as an alternative to developing written procedures and agreements as specified in the FDA regulations.
Transloading Operations

• An entity that only transfers food cargo from one mode of transportation to another, e.g., from a railcar to a truck, would be subject to the rule as a receiver of food arriving by rail vehicle and as a loader of food onto trucks.

• A transloading entity is not considered to be a shipper if it simply holds the food pending transport and does not arrange for its transport.
Record Requirements

- Shippers are to establish and maintain records:
  - That demonstrate that they provide specifications and operating temperatures to carriers as required for a period of 12 months beyond the termination of the agreements with the carriers
  - Of written agreements and the written procedures required to ensure adequate sanitation of transportation equipment, ensure that a previous cargo will not make the food unsafe, and use of necessary temperature controls for a period of 12 months beyond when the agreements and procedures are in use
Record Requirements

• Carriers are required to establish and maintain records of the written procedures per contractual agreements pertaining to:
  • Cleaning, sanitizing, if necessary, and inspecting vehicles
  • Maintaining temperature control
  • Previous cargos
  • Cleaning of bulk conveyances
  • Training of personnel
• Records are to be retained for a period of 12 months beyond when the agreements, procedures, documents are in use in their transportation operations
Compliance Dates

- **Small Businesses:** Businesses (other than motor carriers that are not also shippers and/or receivers) employing fewer than 500 persons and motor carriers having less than $27.5 million in annual receipts are to comply two years after the publication of the final rule – April 6, 2018.

- **Other Businesses:** A business that is not small and is not otherwise excluded from coverage under the rule is to comply one year after the publication of the final rule – April 6, 2017.
More Information

• FDA Guidance: Revision of the 2010 Guidance for Industry: Sanitary Transportation of Food
• FDA plans to develop an online course that would meet the training requirements of the rule
• NGFA Summary on FSMA Final Rule on Sanitary Transportation of Human and Animal Food
• FSMA Food Safety Technical Assistance Network
  • Source of information to support industry in understanding and implementing FSMA
  • Questions submitted online or by mail
Questions?

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