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

Impacts on the Grain and Feed Industry

July 7, 2016
Food Safety Modernization Act of 2011

- Signed into law on Jan. 4, 2011
- Greatly expands FDA’s authority to regulate the U.S. food supply
  - Mandates that FDA create a new prevention-based regulatory system to ensure the safety of food/feed products
  - Requires FDA to develop and issue more than 50 regulations and/or guidance documents
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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.
Exempted from Sanitary Transportation Rule

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
Exempted from Sanitary Transportation Rule

• “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
Farm means:

1) **Primary production farm.** A primary production farm is an operation **under one management** in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term “farm” includes operations that, in addition to these activities:

i) Pack or hold raw agricultural commodities;

ii) Pack or hold **processed** food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and

iii) Manufacture/process food, provided that:

A) All food used in such activities is consumed on that farm or another farm under the same **management**; or

B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

   (1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

   (2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

   (3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); OR
Farm means:

2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.
Exempted from Sanitary Transportation Rule

- Activities associated with the transportation of food that is completely enclosed by a container (e.g., a sealed bag or box), except for food that requires temperature control for safety, are exempt.
  - Examples: Bagged or containerized grains, oilseeds, animal feed and feed ingredients, and human foods that do not require temperature control for safety.
Exempted from Sanitary Transportation Rule

- Activities associated with the transportation of human food co-products transported for use as animal food without further processing are exempt
  - *Example*: Activities associated with transporting human food co-products used as animal food directly to a farm for consumption by animals
  - Exemption does **not** extend to human food co-products transported to an animal feed manufacturer where the co-product will be further processed
General Requirements

- **Vehicles and Transportation Equipment**
  - Designed of such material and workmanship so as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe
  - Sanitary condition is to be maintained to prevent food from becoming unsafe during transportation operations
  - Designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations
  - Stored to prevent harboring of pests or becoming contaminated in any other manner that could result in unsafe food
Transportation Operations

All shippers, carriers, loaders, and receivers engaged in transportation operations covered by rule are to:

- Assign competent supervisory personnel to ensure compliance with requirements
- Conduct transportation operations to prevent food from becoming unsafe
- Take **effective measures** to protect food from being contaminated by raw foods and nonfood items in the same load
  - Examples of measures: segregation, isolation or the use of packaging
- Take **effective measures** to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination during transportation operations
  - Examples of measures: segregation, isolation or other protective measures, such as hand washing
- Take **effective measures** to ensure that food requiring temperature control for safety is transported under adequate temperature control
Determining *Effective Measures*

- The type of food, e.g., animal feed, pet food, human food, and its production stage, e.g., raw material, ingredient or finished food, must be considered in determining the necessary conditions and controls for the transportation operation.
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 takes other measures in accordance with requirements (1.908 (b)(3)), the shipper must specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for the carrier’s vehicle and transportation equipment, including any specific design specifications and cleaning procedures.
  - One-time notification is sufficient unless the design requirements and cleaning procedures required for sanitary transport change
Requirements for Shippers

- Unless the shipper takes other measures in accordance with requirements (1.908 (b)(5)), the shipper must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase.

- One-time notification is sufficient unless a factor, e.g., the conditions of shipment, changes.
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 Shippers

• The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures to ensure that the food is transported under adequate temperature control.

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 Loaders

• Loaders must:
  • Before loading food that requires temperature control for safety, verify, considering, as appropriate, specifications provided by the shipper that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been properly pre-cooled, if necessary, and meets other sanitary conditions for food transportation
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 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 the operating temperature specified by the shipper and demonstrate that it has maintained temperature conditions during the transportation operation consistent with the operating temperature specified
Requirements for Carriers

• The carrier is responsible for the following functions as applicable per the written agreement:
  • Pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper
  • 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

• The carrier is responsible for the following functions as applicable per the written agreement:
  • Develop and implement written procedures that:
    • Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary condition as required
    • Describe how it will comply with the provisions for temperature control as required;
    • Describe how it will comply with the provisions for the use of bulk vehicles pertaining to prior loads and cleaning of the conveyance
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.
• 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
Record Requirements

- Any person subject to this rule must retain any other written agreements assigning tasks in compliance with the requirements for a period of 12 months beyond the termination of the agreements.

- Shippers, receivers, loaders, and carriers, which operate under the ownership or control of a single legal entity, must retain records of the written procedures for a period of 12 months beyond when the procedures are in use in their transportation operations.
Record Requirements

• All required records are required to be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records.

• Records established and maintained to satisfy requirements of the sanitary food transportation rule are exempt from FDA’s Part 11 electronic record requirements.
Record Requirements

- Required records are to be made available to a FDA investigator or other duly authorized individual promptly upon oral or written request.

- Except for written procedures established by a carrier that specify practices for cleaning, sanitizing, if necessary, and inspecting vehicles and transportation equipment, offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

- Electronic records are considered to be onsite if they are accessible from an onsite location.
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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