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

NGFA's Guide to Most Important Provisions

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The U.S. Food and Drug Administration (FDA) on April 6 published [final regulations](#) mandated under the Food Safety Modernization Act (FSMA) that establish requirements for shippers, loaders, carriers, and receivers engaged in the transportation of human and animal food by truck or rail to use sanitary transportation practices to ensure food and feed safety.

The new regulation is the sixth of the seven major foundational rules to be issued by FDA under authority provided by FSMA. In addition to this rule, FDA already has issued regulations for produce safety, current good manufacturing practices and preventive controls for human food, current good manufacturing practice and preventive controls for food for animals, foreign supplier verification programs, and accreditation of third-party auditors. FDA's seventh and final rule – intentional adulteration of food – was issued May 27, 2016.

Overview of FDA's Final Rule for Sanitary Transportation of Human and Animal Food:

FDA's final rule 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. The requirements do not apply to transportation by vessel or air because of limitations established by the Sanitary Food Transportation Act of 2005.

Among the many operations covered by the rule are shippers, loaders, carriers and receivers involved with motor or rail vehicle transportation of raw agricultural commodities (e.g., grains and oilseeds), animal feed and feed ingredients, and human food and food ingredients.

Exemptions from the Rule: The requirements of the rule do *not* apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations of:

- Food that is transshipped through the United States (e.g., from Canada or Mexico by truck or rail) to another foreign country; or
- 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

- 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” also are exempt from the rule’s requirements. FDA’s rule defines a “non-covered business” as “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.”

In addition, the rule defines “transportation operations” to mean “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 byproducts 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.”

Significantly, as established by the definition, “transportation operations” do *not* include transportation activities performed by a farm. Therefore, transportation operations performed by a farm (defined by 21 CFR Section 1.227) are exempt from the rule’s requirements. As such, farms that transport commodities (e.g., grains and oilseeds) in their vehicles to storage or processing facilities are exempt. By contrast, non-farm carriers that transport commodities from the farm are subject to the rule, unless they are considered to be non-covered businesses.

In addition, “transportation operations” do *not* include any 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. Therefore, transportation activities associated with bagged or containerized grains, oilseeds, and animal feed and feed ingredients that do not require temperature control for safety are *exempt* from the rule because they are foods completely enclosed by a container.

Further, “transportation operations” do *not* include any activities associated with the transportation of human food coproducts transported for use as animal food *without further processing*. Therefore, transportation activities associated with such products are exempt from the rule’s requirements. However, this exemption does *not* extend to human food coproducts transported to an animal feed manufacturer where it is to be used as an ingredient in a manufactured animal food or to be further processed.

Vehicles and Transportation Equipment: FDA’s final rule establishes requirements that vehicles and transportation equipment used in transportation operations are to be 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. In addition, the sanitary condition of vehicles and transportation equipment is to be maintained to prevent food from becoming unsafe during transportation operations. Further, vehicles and transportation equipment are to be

stored in a manner that prevents it from harboring pests or becoming contaminated in any other manner that could result in unsafe food.

Significantly, the rule does *not* prescribe how the sanitary condition of vehicles and transportation equipment is to be maintained. For instance, FDA does not prescribe methods (such as washouts) for the cleaning and maintenance of vehicles and equipment. Nor does the agency establish required intervals for cleaning operations. Instead, FDA states that firms may employ any cleaning procedures and intervals that satisfy the requirements of the rule.

Transportation Operations: The rule requires that competent supervisory personnel be assigned to ensure transportation operations are conducted under conditions and controls necessary to prevent the food from becoming unsafe, including:

- Taking effective measures, such as segregation, isolation or the use of packaging, to protect food from being contaminated by raw foods and nonfood items in the same load.
- Taking effective 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 during transportation operations.

Significantly, FDA states that this provision does *not* require that persons who handle animal feed or raw feed ingredients always wear gloves and/or wash their hands. Instead, FDA states the rule provides flexibility to determine which measures are necessary to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination during transportation operations.

Further, the rule specifies that 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 that these persons are to take appropriate action. These 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: FDA's final rule places most of the responsibility on the shipper for ensuring sanitary transportation of food and feed. In the preamble to the rule, FDA states it's belief that shippers should be charged with developing and implementing written procedures that address how the safety of food they ship will be assured relative to the "three major focus areas" of the rule: 1) assurance that the vehicles and equipment used in the shipper's transportation operations are in appropriate sanitary condition; 2) assurance that, for bulk cargo, a previous cargo does not make the food unsafe; and 3) assurance that, for foods that require refrigeration for safety, the food is transported under adequate temperature control.

As defined within FDA's rule, a "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." Responsibilities for shippers established by the rule include requirements that the shipper 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, unless the shipper itself develops and implements written procedures to ensure appropriate sanitary conditions. The rule provides that a one-time notification from the

shipper to the carrier is sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported. If such changes occur, the rule requires the shipper to notify the carrier in writing before the shipment.

Further, shippers are required to develop, implement and maintain records of written procedures adequate to ensure that vehicles and equipment used in its transportation operations “are in appropriate sanitary condition” for the product to be moved. Measures to implement these procedures “may be accompanied by the shipper or by the carrier or another party covered by the rule under a written agreement” subject to records-retention.

Further, shippers are required to develop, implement and maintain records of written procedures that ensure that a previous cargo does not make the food unsafe. In the preamble to the rule, FDA notes that its current good manufacturing practice regulations already require that storage and transportation of food occur under conditions that protect against allergen cross-contact, as well as against biological, chemical (including radiological) and physical contamination that would cause the food to become unsafe.

Requirements for Loaders: The rule defines a “loader” as “a person that loads food onto a motor or rail vehicle during transportation operations.” The rule’s requirements for loaders include determining that the vehicle or transportation equipment is “in appropriate sanitary condition for the transport” (e.g., “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”) of the type of food to be shipped prior to loading onto a vehicle or into transportation equipment, except in instances where the food is completely enclosed by a container. The rule provides that this determination may be accomplished by any appropriate means.

Requirements for Receivers: A “receiver,” as defined by the rule, 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.” The rule requires receivers to take steps to adequately assess that food requiring temperature control for safety under the conditions of shipment was not subjected to significant temperature abuse during transport.

Requirements for Carriers: Importantly, FDA largely exempts rail carriers and truckers from the rule’s requirements unless the shipper and carrier have a written agreement (e.g., contractual arrangement) making the carrier or another party responsible, in whole or in part, for sanitary conditions during the transportation operation. The rule defines a “carrier” to mean “a person who physically moves food by rail or motor vehicle in commerce within the United States,” excluding persons who transport food while operating as a parcel delivery service.

If, but only if, a carrier has agreed in writing with the shipper that it (the carrier) is responsible, in whole or in part, for sanitary conditions during the transportation operation, does the rule provide that the carrier is responsible for the following functions as applicable per the written agreement:

- A carrier is to ensure that vehicles and transportation equipment meet the shipper’s specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.

- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation is to provide information to the shipper that identifies the previous cargo transported in the vehicle.
- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation is to provide information to the shipper that describes the most recent cleaning of the bulk vehicle.
- A carrier is to develop and implement written procedures and maintain records 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.
 - Describe how it will comply with the provisions for the use of bulk vehicles pertaining to identifying the previous cargo transported in the vehicle and describing the most recent cleaning of the vehicle.

In addition, training of carrier personnel in sanitary transportation practices and records documenting the training is required only if and when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.

In the preamble to the final rule, FDA states that shippers or loaders generally are responsible for inspecting a railcar to ensure it is suitable for the particular food cargo to be transported, regardless of which party owns the car. FDA also asserts that rail carriers “generally do not clean the cars they provide and do not maintain documented cleaning procedures. Further, the agency states that the use of railcars in interchange service “would likely mean that the railroad operator would not be able to provide information about the identity of a bulk vehicle’s previous cargoes and its most recent cleaning if requested by the shipper.” While the agency concedes that motor carriers generally do own the vehicles they provide for transport and “are directly involved in transportation operations, such as the loading and unloading of the trailers that they haul, and therefore can comply” with the rules. Yet, the agency decided to exempt motor carriers, as well, from the requirement to comply with the rules unless they are assigned to perform certain functions through written agreement with the shipper.

The agency concludes with this statement in its preamble discussion of this issue: “...[W]e have concluded that the appropriate solution with regard to the definition and the overall carrier regulatory requirements is: 1) a simplified definition of carrier that ties it to the movement of the food; 2) removal from the carrier definition of any assignment of duties; and 3) **a default assignment of responsibility to the shipper for the activities assigned to carriers in the proposed rule, unless a written contract between the shipper and carrier assigns them to the carrier (or another party covered by this regulation, as may be the case)...Therefore, linking responsibility for the carrier to perform such functions to the existence of a contract with the shipper, in which such functions are specified, seems appropriate and consistent with current industry best practice.**” *[Emphasis added.]*

Importantly, the NGFA has expressed major concerns to FDA that the way the final rule is written and structured, rail and truck carriers may be unwilling to enter into written

agreements with shippers to assume responsibility for the aforementioned sanitary food transportation functions, even those that have become relatively routine practice (such as identifying the immediate previous load hauled or most recent cleaning of bulk vehicles), given the compliance obligations such agreements would create. The NGFA is engaged in active discussions with the agency in attempting to address these significant shortcomings in the final rule.

Intra-Company Transportation Activities: 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. However, FDA in the preamble to its rule stated it was declining to establish a “blanket exemption” from the rules requirements for food transportation operations conducted between shippers, loaders, carriers and/or receivers that are part of the same corporate/legal entity. “We conclude that the fact that shippers, loaders, carriers and/or receivers may be operating within a unified corporate/legal entity or sanitary food transportation system does not necessarily ensure that all of the involved parties are operating in compliance....”

In addition, loaders must continue to ensure that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food.

Transloading Operations: Within the preamble of the final rule, FDA clarifies how the rule’s requirements apply to transloading operations. FDA states that 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. The entity would *not* be considered to be a shipper if it simply holds the food pending truck transport and does not arrange for its transport by the trucking firm.

Record Requirements: Shippers, receivers, loaders and carriers are to establish and maintain required records associated with written procedures, agreements and training required of carriers. The required retention time for these records depends upon the type of record and when the covered activity occurred, but is not to exceed 12 months.

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. Significantly, records established and maintained to satisfy requirements of the sanitary food transportation rule are exempt from FDA’s onerous Part 11 electronic record requirements.

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

Compliance Dates: Compliance dates for the rule’s requirements are based upon business size as follows:

- **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 – on or about April 5, 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 – thus on or about April 5, 2017.

NGFA-Grain Journal Webinar: The NGFA and *Grain Journal* have scheduled a July 7 webinar a 2 p.m. Central time to provide more information to the industry and respond to questions on the sanitary food transportation final rule. You may register for the webinar by [clicking here](#).

NGFA members with questions also may contact NGFA Senior Vice President for Feed Services David Fairfield at dfairfield@ngfa.org or (712) 243-4035.