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

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The U.S. Food and Drug Administration (FDA) on April 6, 2016 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 requirements do not apply to transportation by water vessel or air because of legal 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.

With some exemptions (listed below), the final rule applies to shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, regardless of whether the food is offered for or enters interstate commerce. Significantly, a given entity may be subject to the rule's requirements in multiple capacities, e.g., the shipper may also be the loader and the carrier, if the entity also performs the functions of those respective parties as defined by the rule. In such cases, the entity is responsible for meeting the applicable requirements for each function performed.

The final rule also applies to: 1) persons (e.g., shippers) in other countries who ship food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the United States, if that food will be consumed or distributed in the United States; and 2) transportation activities associated with food intended for export until the shipment reaches a port or U.S. border.

Operations Exempted 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 (FFDCA), 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.”

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 that are performed by a farm.”

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 Code of Federal Regulations Part 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, given FDA’s definition of “transportation operations,” activities associated with transportation of food that is “completely enclosed in a container” that does not require temperature control for safety are exempt from the rule’s requirements. This exemption

extends to transportation activities for grain, grain byproducts, animal feed, pet food, human food and other food products that meet these criteria.

Within the preamble of the final rule, FDA says it considers a “completely enclosed container” to be one that physically separates the food from the [transportation] environment and functionally protects the food from environmental contamination during transportation. FDA says that examples of such containers include a metal can, a glass or plastic bottle, or a sealed bag or box. In contrast, if the food comes into contact with the bulk vehicle or transportation equipment (e.g., hopper trailer, rail car, or intermodal container), FDA does not consider the food to be protected from the transportation environment and does not consider the food to be “completely enclosed by a container.”

Further, “transportation operations” do not include any activities associated with the transportation of human food byproducts 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 byproducts 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.

Although the previously specified operations are exempt from the rule’s requirements, the adulteration provisions of the FFDCA are applicable to any food transported or offered for transportation in the United States, including by any shipper, loader, carrier by motor vehicle or rail vehicle, or receiver subject to FDA’s rule for Sanitary Transportation of Human and Animal Food.

General Requirements for Vehicles and Transportation Equipment: FDA defines “vehicle” and “transportation equipment” as follows within the rule:

- “Vehicle” means a land conveyance that is motorized, such as a motor vehicle, or that moves on rails, such as a railcar, which is used in food transportation operations.
- “Transportation equipment” means equipment used in food transportation operations and includes items such as bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. Transportation equipment also includes a railcar not attached to a locomotive or a trailer not attached to a tractor.

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 (e.g., sweeping, 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.

In addition, the rule does not prescribe the use of seals on vehicles and transportation equipment during transportation operations. FDA states in the preamble of the rule that establishing requirements for the use of seals is outside the scope of the regulation, since the purpose of the rule is to establish sanitary transportation practices, which is distinct from the issue of security of food transportation.

General Requirements for Transportation Operations: The general requirements for transportation operations established by the rule apply to all covered shippers, carriers, loaders and receivers engaged in transportation operations. However, a party subject to the rule may reassign in a written agreement its responsibilities under the rule to another entity that is subject to the rule.

The general requirements for transportation operations require that:

1. Competent supervisory personnel be assigned to ensure transportation operations are carried out in compliance with all requirements of the rule.
2. All transportation operations are to be conducted under such conditions and controls necessary to prevent the food from becoming unsafe during transportation operations. This includes 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 and allergen cross-contact during transportation operations, and ensuring that food that requires temperature control for safety is transported under adequate temperature control.

Significantly, FDA states that this provision does not require persons who handle animal feed or feed ingredients to 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.

In addition, FDA defines the term “allergen cross-contact” to mean the unintentional incorporation of a food allergen as defined in section 201(qq) of the FFDCFA into food, except animal food. Therefore, the rule does not require transportation operations to be conducted under conditions and controls to prevent allergen cross-contact in animal food.

3. 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 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.
4. The type of food, e.g., animal feed, pet food, human food, and its production stage, e.g., raw material, ingredient or finished food, is to be considered in determining the necessary conditions and controls for the transportation operation.

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 its 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."

In addition to the previously referenced general requirements that apply to all covered parties engaged in transportation operations, specific requirements established within the rule for shippers include:

1. Shippers, in all cases, are to develop and implement written procedures adequate to ensure that vehicles and equipment used in transportation operations are in appropriate sanitary condition for the transportation of the food, i.e., they will prevent the food from becoming unsafe during the transportation operation. The shipper may perform the measures to implement these procedures themselves, or they may be accomplished by the carrier or another party subject to the rule under a written agreement.
2. Unless the shipper itself implements written procedures adequate to ensure that vehicles and equipment used in transportation operations are in appropriate sanitary condition for the transportation of the food, shippers are to 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. A one-time notification is sufficient unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported, in which case shippers are to notify the carrier in writing before the shipment.

Significantly, FDA states in the preamble of the final rule that it expects the "default arrangement" shippers typically will use to comply with this requirement of the rule is for them to provide instructions to the carrier and, when necessary, the loader to ensure the vehicle and equipment meet appropriate sanitary conditions (i.e., a one-time notification that is updated when necessary), while also allowing for alternative arrangements whereby the shipper itself ensures that the specifications are met. In doing so, FDA says the latter option provides flexibility in situations when the shipper does not have a relationship with the carrier or another party to provide instructions relative to the necessary sanitary condition of the vehicles and equipment by allowing the shipper itself to ensure that necessary conditions are met. Accordingly, the requirement to specify to the carrier and, when necessary, the loader, in writing, all

necessary sanitary specifications for the carrier's vehicle and transportation equipment applies to shippers in the instance when the shipper itself does not perform the written procedures necessary to ensure that vehicles and equipment used in transportation operations are in appropriate sanitary condition.

Further, FDA states in the preamble of the rule that this requirement allows the shipper to use reasonable judgment in deciding what information must be communicated to a carrier to meet the requirements of the rule, and that the agency understands that a shipper could reasonably determine that it is not necessary to specify procedures that are already commonly understood by carriers.

3. If food is shipped in bulk, shippers are to develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. The shipper may perform the measures to implement these procedures themselves, or they may be accomplished by the carrier or another party subject to the rule under a written agreement.

Significantly, the rule does not require the shipper to identify the previous cargo(es) transported with the bulk vehicle or transportation equipment. Instead, the rule provides flexibility to shippers when developing written procedures adequate to ensure that a previous cargo does not make the food unsafe by allowing them to use any effective means to make such a determination.

In addition, in the preamble to the rule, FDA notes that its current good manufacturing practice regulations for human food and animal food already require that storage and transportation of food occur under conditions that protect against allergen cross-contact in human food, as well as against biological, chemical (including radiological) and physical contamination that would cause human or animal 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.”

In addition to the previously referenced general requirements that apply to all covered parties engaged in transportation operations, the rule establishes that loaders are to determine 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”) for the type

of food to be shipped prior to loading onto a vehicle or into transportation equipment considering, as appropriate, any specifications provided by the shipper, 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.”

In addition to the previously referenced general requirements that apply to all covered parties engaged in transportation operations, the rule establishes that receivers are 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: 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.”

The previously referenced provisions within the rule for vehicles and transportation equipment and general requirements for transportation operations apply to carriers. The requirements established by these provisions apply regardless of whether there is a written agreement under which the carrier has agreed to be responsible, in whole or in part, for sanitary conditions during the transportation operation.

However, the other specific requirements for carriers within the rule only apply to the carrier when the carrier and shipper have established a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation.

When a shipper-carrier agreement has been established, the carrier is responsible for the following functions as applicable under the 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.

Carriers that have a contract with the shipper to be responsible for any sanitary conditions during transportation are to provide adequate training for personnel involved in food transportation operations. The carrier training is to be provided when personnel for food transportation operations are hired and as necessary thereafter. The training content is to provide 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 the rule. Records are to be established and maintained to document the required training. To assist carriers in providing training to personnel, FDA has made available on its website a free [training module](#) that covers the required training elements.

Intra-Company Transportation Activities: Intra-company shipments 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. Significantly, the rule has a specific provision that loaders involved in intra-company shipments 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 as indicated in the following table.

Required Records	Description
Information provided by shippers to carriers.	Shipper records are to demonstrate that the shipper provided, as a regular part of transportation operations, specifications and operating temperatures to carriers.
Written agreements and the written procedures of a shipper.	The shipper’s written agreements and written procedures are to meet the rule’s requirements.
Written procedures of a carrier.	The carrier’s written procedures are to meet the rule’s requirements.
Any written agreements subject to the rule that are not otherwise noted.	Written agreements that assign tasks required by the rule to another person.
Records documenting required training by carriers.	The training records are to: 1) include the date of training, the type of training, and the persons trained; and 2) be established and maintained in accordance with other records requirements.
Written procedures of firms that operate in more than one capacity under the rule, under the ownership or operational control of a single legal entity, for example, as a shipper and a carrier.	The written procedures are to be common integrated procedures that ensure the sanitary transportation of food consistent with the requirements of the rule.

All required records are 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 rule are exempt from FDA's onerous Part 11 electronic records and signatures requirements.

Required records are to be retained as follows:

1. Records of written procedures and written agreements (except as described in the next paragraph) for a period of 12 months beyond when the procedures or agreements are in use for transportation operations.
2. Records of written agreements that assign tasks required by this rule to another party for a period of 12 months beyond the termination of the agreements.
3. Records that demonstrate that shippers provide specifications and operating temperatures to carriers as a regular part of their transportation operations for a period of 12 months beyond the termination of the agreements with the carriers.
4. Carriers training records for a period of 12 months beyond when the person identified in the record stops performing the duties for which the training was provided.

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

Compliance Dates: All covered parties were to be compliant with the rule on April 6, 2018.

Questions: NGFA members with questions may contact NGFA Senior Vice President David Fairfield at dfairfield@ngfa.org.