

TRANSPORTATION, AGRIBUSINESS & HOSPITALITY INDUSTRY ALERT

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FDA new food safety rule spans stakeholders from farm to fork



On April 6, 2016, the U.S. Food and Drug Administration (FDA) published a new food safety rule governing the "Sanitary Transportation of Human and Animal Food." The new regulations are promulgated under the Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, 2011, and are considered part of a broader effort to focus on prevention of food safety problems throughout the "farm to fork" continuum.

The FDA's stated goal is to require all companies and individuals engaged in the transportation of food to use sanitary practices to "ensure that food is not transported under conditions that may render the food adulterated." In furtherance of this goal, the rule imposes a broad array of new regulatory requirements that apply to shippers, receivers, loaders and carriers by motor vehicle and rail engaged in the transportation of food, whether or not the food is offered for or enters interstate commerce. The core provisions impose new requirements relating to vehicles and equipment, formalized quality assurance operations, required training programs for employees and a host of new record-keeping and reporting requirements. All companies involved in manufacturing, processing and transporting food are well advised to be proactive in identifying and addressing the risks and opportunities created by the new regulations.

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The rule outlines new operational, procedural and record-keeping and reporting requirements, including:

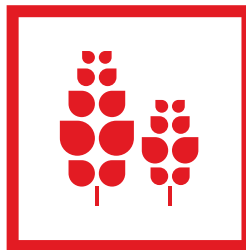
- New requirements for vehicles and transportation equipment
- New requirements for transportation operations for shippers, receivers, carriers and loaders
- New paperwork and documentation requirements including implementation of written procedures by shippers and carriers
- New requirements on what information a shipper must provide to a carrier and, in some cases, loaders, in the course of transportation operations
- New requirements covering what a shipper, loader, receiver or carrier must do when aware of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation
- New requirements mandating that loaders engaged in transportation operations determine, before loading, whether a vehicle is in appropriate sanitary condition for the transport of food
- New requirements mandating that receivers engaged in transportation operations take steps to determine that the food was not subjected to "significant temperature abuse," such as determining the food's temperature, the ambient temperature of the vehicle, and a sensory inspection (i.e. smell and touch)
- New requirement that a carrier must ensure that its equipment meets the shipper's specifications and is "otherwise appropriate to prevent the food from becoming unsafe" during transport
- New requirements for training of employees of carriers engaged in transportation operations
- New requirement that carriers create and retain written procedures that address practices for cleaning and sanitizing, inspecting their equipment, and describing how the carrier will comply with certain requirements in the rule
- New recordkeeping requirements for shippers (including freight brokers), receivers and carriers involved in transportation operations

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What types of shipments do the new regulations cover?

The new regulations apply broadly to all shipments of food that move in commerce in the United States, unless exempted. Shipments need not move in interstate commerce in order to be covered by the rule. In fact, the rule does not set a minimum distance that a shipment must travel to be subject to the regulations, suggesting even local deliveries of food may be impacted.

The regulations also generally apply to shippers in other countries who transport food to the United States directly and arrange for further transportation within the United States, if that food will be consumed or distributed within the United States. Companies involved in transporting food intended for export are covered by the rule until the shipment reaches a port or U.S. border.



The new regulations are considered part of a broader effort to focus on prevention of food safety problems throughout the “farm to fork” continuum.

The FDA also issued new rules governing “transportation operations,” which are defined broadly, to include “all activities associated with food transportation that may affect the sanitary condition of food.” Examples cited by the rule include cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment.

While the rule applies broadly, certain businesses and activities are exempt from compliance. Key examples include:

- Shippers, receivers or carriers engaged in food transportation operations that have less than \$500,000 in average annual revenue
- Transportation of food that is completely enclosed within a container except for food that requires temperature control for safety
- Transportation activities performed by a farm

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- Transportation of food that is transshipped through the United States to another country
- Transportation of food that is imported for future export that is neither consumed nor distributed in the United States
- Transportation of meat, poultry and egg product activities that occur within processing facilities regulated exclusively by the U.S. Department of Agriculture (USDA).

New duties for shippers of food products

The FDA explicitly states that the aim of the rule is to place on the shipper the primary responsibility to determine and communicate what is needed to keep food safe during transportation. The term "shipper" is defined broadly, covering **any person or business** who arranges for the transportation of food in the United States by a carrier, or multiple carriers sequentially.

The rule states that 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. Examples include whether food needs temperature control for safety, the relevant operating temperature and mode of temperature monitoring, whether particular clean-out products are needed and whether previous cargo must be identified.

In addition to the communication requirements, a shipper must implement various new written procedures to ensure sanitary conditions. The new procedures must cover vehicles and equipment used, ensuring appropriate temperature control and ensuring that previous cargo moved in the vehicle does not make the food unsafe. All of these written documents are subject to new record-keeping requirements. In most cases the rule requires documents to be retained for a period of 12 months beyond when the procedures were last in use in transportation operations. Shippers must be prepared to make all records required by the rule available to a "duly authorized individual promptly upon oral or written request."

New duties for freight brokers and other third-party logistics providers

Over the objections of many in the logistics community, the rule explicitly states that freight brokers are considered "shippers" for purposes of

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the rule when the broker “arranges for the transportation of food in the United States.” Industry advocates argued against this definition during the regulatory review process, pointing out that brokers typically do not touch the freight and do not exercise control over the carrier. Nevertheless, under the new rule, brokers and other third-party logistics providers who arrange for the transportation of food by a carrier have, in many circumstances, all the duties and functions of a shipper that must be completed before transportation occurs. Brokers always had a practical business incentive to ensure that the loader and carrier understood and met the necessary sanitary specifications for the food product. But under the new rule, brokers must know and effectively communicate all pertinent information to the carrier, unless others agree in writing to assume those responsibilities.

Critically, the rule provides that shippers, brokers and carriers in the farm to fork continuum may deliberately assign duties and responsibilities in written transportation contracts. Given the changing legal landscape, brokers involved in the transportation of food are well advised to be proactive in evaluating the new roles and resultant responsibilities created by the new regulation, and to modify their broker-carrier agreements accordingly where possible.

In addition, the rule imposes a range of new operational and document retention requirements that apply to freight brokers. Failure to comply with requirements is considered a “prohibited act” under the Federal Food, Drug, and Cosmetic Act, subject to potential criminal prosecution.

New duties for motor carriers and carriers by rail that transport food products

Carriers are also subject to new operational, procedural, training and document retention and reporting requirements. Well-advised shippers and freight brokers may respond to the new regulations by structuring their transportation contracts to reflect that the carrier accepts responsibility to ensure sanitary conditions during transport. Carriers, in turn, are well-advised to be mindful of the language in transportation contracts offered by brokers and shippers.

Under the new regulations, when the carrier and shipper agree that the carrier is responsible, in whole or in part, for the sanitary conditions during transportation operations, the carrier must provide adequate training to

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all of its involved personnel. Consequently, carriers must be prepared to develop and implement appropriate training programs for all employees involved in transportation operations. The training must be provided "upon hiring and as needed thereafter." Carriers must also prepare and implement written procedures relating to the required employee training, as well as written procedures relating to cleaning, sanitizing and inspecting vehicles and equipment.

The new rule also requires carriers to provide certain information to shippers upon request, including information relating to previous cargo transported in the vehicle and the most recent cleaning of the vehicle. Carriers must develop written procedures describing how they will comply with this requirement.

In most cases the rule requires all the aforementioned documents to be retained for a period of 12 months beyond when the procedures were last in use in transportation operations. Like shippers, carriers must be prepared to make all records required by the rule available to a "duly authorized individual promptly upon oral or written request."

Carriers may also note that the FDA plans to work with the Department of Transportation (DOT) to enforce the rule, raising the prospect that roadside DOT inspections may also now include investigation of potential food safety issues.

Loaders of vehicles have food safety duties under the new rule

The FDA also created new requirements for loaders, defined as "a person who loads food onto a motor vehicle or rail vehicle during transportation operations." Loaders are required to determine, before loading the food, whether the vehicle is appropriately sanitary to transport food. Loaders are also required to verify, as appropriate, that refrigerated storage compartments are "adequately prepared," including pre-cooled, if necessary.

New duties for receivers of food products

Receivers are required under the new rule to take steps to appropriately determine whether the food was transported under conditions that may give rise to safety concerns. The term "receiver" is defined broadly, meaning "any person who receives food at a point in the United States after transportation, whether or not that person represents the final point

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of receipt for the food.” Receivers must proceed cautiously if they become aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation.

So, the receiver rejected the shipment. Can we still sell the load for salvage?

Under the new regulations, receivers and others involved in transporting food should think twice before selling a potentially adulterated load for salvage, unless a “qualified individual” agrees. The new rule provides that if a shipper, loader, receiver or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render the food unsafe during transportation, the food “**shall not be sold or otherwise distributed**” unless a “qualified individual” determines that the temperature deviation or other condition did not render the food unsafe. Individuals and businesses with knowledge of the potential concern also must take appropriate action including, as necessary, communicating with other parties to ensure that the food is not sold or otherwise distributed.

The rule does not specifically define the term “qualified individual,” which could give rise to a host of practical issues and questions. What qualifications are required? Who determines whether or not an individual is “qualified?” The regulations are silent on these issues, so effective counsel and planning are essential.

Various commenters on the rule raised concerns about how this requirement may interact with the rules set forth by the Perishable Agricultural Commodities Act (PACA), which provides that receivers must accept produce that is damaged and decayed, up to a certain percentage, depending on the product’s grade standards. The FDA’s response attempts to downplay the apparent conflict in these requirements, but shippers and receivers subject to both regulations may still be uncertain of their specific duties and responsibilities.

When does my company have to be in compliance?

The FDA, recognizing that some businesses may need more time to comply, established a two-tiered timeline for full implementation of the rule. “Small businesses” must be in full compliance within two years after the publication of the final rule. A “small business” is defined as a businesses that employ fewer than 500 persons, except for motor carriers

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(that are not also shippers and/or receivers). For motor carriers, “small business” means a business having less than \$27.5 million in annual receipts. All other businesses must be in full compliance within one year.

Make sure your transportation contracts are in order

Critically, parties affected by the rule are permitted to reassign their responsibilities to other parties subject to the rule by written agreement. Consequently, shippers, brokers and carriers should be particularly mindful of how they define and allocate their duties, risks and potential downstream liabilities when they enter into written agreements for the transportation of food.

Conclusion

The broad nature of this new rule will likely create ripple effects well beyond transportation and logistics and agribusiness. Whether you are manufacturing, processing, handling, loading, or transporting food in the food chain or simply accepting delivery of product, the new requirements imposed are likely going to impact your operations and those of your partners. All stakeholders - from hospitality to healthcare, restaurants to retail - are wise to consider how current operations need to be adjusted to ensure compliance.

For more information, please contact [Brian Augustine](#) or [Phil Calabrese](#).