



Full Speed Ahead!

President Trump's Executive Order Will Not Affect Compliance with the Sanitary Transportation of Human and Animal Food Rule

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April 6th, 2017 is the deadline for many covered transportation companies to come into compliance with the Food and Drug Administration (FDA) Final Rule on the Sanitary Transportation of Human and Animal Food (the "STF Rule"). Although President Donald Trump issued an Executive Order freezing the application of pending regulations, apparently compliance with the STF Rule will not be stayed. The STF Rule was published on April 6, 2016 and went into effect on June 6, 2016, long before the Executive Order. Small businesses that employ fewer than 500 full-time equivalent employees and motor carriers that are not also shippers

and/or receivers, with less than \$27.5M in annual receipts, have until April 6, 2018 to comply with the STF Rule.

Covered transportation companies include shippers, rail and motor carriers, loaders and receivers, freight intermediaries including freight forwarders, brokers, and indirect air carriers, ("3PLs"), that arrange transportation of covered food in the United States by a carrier or multiple carriers sequentially. All must comply unless they fall within the small operations exemption (operations that have less than \$500,000 in average annual revenue). If a 3PL arranges the U.S. land-based transportation leg of a foreign shipment, the freight forwarder is legally

deemed a "shipper" for purposes of the STF Rule and is subject to the STF Rule requirements. This includes the requirement to specify to the carrier the conditions necessary to ensure the safe transport of the food, e.g., an operating temperature for transportation of temperature-controlled food, including the temperature of a pre-cooling phase, if any.

What Kind of Food Shipments are Governed by the STF Rule?

Generally speaking, unless exempted or subject to an FDA waiver, all human and animal foods, additives, and dietary supplements are covered by the STF Rule. In addition to the small operations

exemption, other notable exemptions from the Rule's application include: (1) food that is completely enclosed by a container, unless the food requires refrigeration for safety ("Completely Enclosed Container Exemption"); (2) compressed food gases; (3) human food byproducts for use as animal food; and (4) live food animals (except mollusks and shellfish).

Are Frozen Foods Covered?

A point of confusion related to the completely enclosed container exemption is whether frozen foods are covered by the STF Rule. The confusion arose because these foods are generally completely enclosed by a container and require temperature control. While frozen foods are not referenced in the regulations themselves, the FDA explained in the comment section of the STF Rule that frozen foods are not covered because "the temperature and time required for a frozen food to become unsafe if not maintained in the frozen state would result in significant quality issues for the food before posing any safety risk." Nonetheless, treating frozen foods as covered foods would be the most prudent course of action and likely makes operational sense, too. For short haul moves, if the shipper or 3PL has determined that temperature control is unnecessary to prevent the food shipment from becoming adulterated or unsafe during transportation, it would not have to instruct the motor or rail carrier regarding an operating or pre-cooling temperature.

What Does the STF Rule Require?

STF Rules concern the design and maintenance of transportation equipment so as to prevent food from becoming adulterated during transport. They mandate that operational measures be taken to prevent food from becoming unsafe during transportation. There are also training and record-keeping

provisions, e.g., those requiring written procedures addressing how the company will comply with the STF Rule, training documentation, and agreements dictating the parties' responsibilities for compliance be maintained for at least twelve months.

The STF Rule requires that covered transportation companies take measures to prevent the adulteration of food shipments during transportation. Such measures might include isolation, segregation, and use of proper packaging. Covered entities must ensure that food that requires temperature control for safety is transported under adequate temperature control mechanisms.

A transportation company subject to the STF Rule may fit into more than one category of covered entity, depending upon the company's function at any given time. Companies may allocate certain responsibilities between them vis-a-vis a written agreement. However, to avoid unanticipated liability, be very careful about assigning responsibilities to other covered entities.

If there has been a possible temperature control failure, the food cannot be distributed or further released into the food supply chain until a safety determination has been made by a "qualified individual." Failure to comply with the Final Rule could lead to civil and criminal penalties for covered transportation companies if the food becomes adulterated while in transit.

A. Shipper/Freight Broker Responsibilities

The STF Rule requires that shippers (including 3PLs) communicate to the carrier in writing the necessary specifications for maintaining sanitary conditions in the transportation equipment.

Shippers must implement a written procedure to ensure that vehicles used, including bulk vehicles, are appropriate and sanitary, and must specify in writing

an operating temperature, including any necessary pre-cooling, for shipments that require temperature control for safety.

Shippers must retain records showing that the shipper provided the required specifications (concerning temperature and equipment) to carriers, as well as any written agreements allocating responsibility.

B. Loader Responsibilities

Loaders are required to determine, in accordance with the shipper's instructions, that the transportation equipment provided is in an appropriate sanitary condition for transporting food. They must also confirm that food shipments being transported are in adequate physical condition, free from visible evidence of pest infestation, and that previous cargo hauled in bulk vehicles would not cause the food to become unsafe during transport.

For food shipments requiring temperature control, loaders must verify, taking into consideration the shipper's instructions, that each mechanically refrigerated storage compartment or container has been adequately prepared to transport temperature controlled food and, when necessary, that it has been properly pre-cooled. Any failure of the loader to fulfill these obligations could be considered an act or default of the shipper and a defense to any cargo claim resulting from the condition of the trailer.

C. Receiver Responsibilities

Upon receipt of food that requires temperature control for safety, receivers are required by the STF Rule to take steps to adequately assess that the food was not subjected to significant temperature abuse, including determining the: (1) food's temperature; (2) ambient temperature of the vehicle; (3) vehicle's temperature setting; and (4) conducting a sensory inspection, e.g., for off-odors.



D. Carrier Responsibilities

If assumed by contract, the STF Rule requires carriers to: (1) ensure that transportation equipment meets shipper specifications; (2) demonstrate that it has maintained temperature conditions consistent with the operating temperature provided by the shipper; (3) pre-cool equipment as necessary; (4) upon request, provide information on prior cargos (bulk transport only); and (5) implement written procedures addressing: equipment sanitation, compliance with temperature control requirements, and training of personnel.

Does the STF Rule Apply Alike to International and Domestic Shipments?

The STF Rule applies to both domestic and international shipments involving rail and/or motor carriage. International shippers or 3PLs that export food to the U.S. by air or ocean transportation must comply if the food is: (1) shipped in an intact container, (2) transshipped on a motor or rail carrier, (3) transported in interstate commerce, or (4) eaten or distributed in the U.S. Although the air and ocean carriage portions of an intermodal move would not be covered by the STF Rule, the surface transportation both prior and subsequent to the ocean or air carriage would be covered if the food being transported by motor or rail carriage did not fall within one of the enumerated exemptions, e.g., the Completely Enclosed Container Exemption.

What are the Takeaways for Compliance and Limiting Liability?

3PLs can and should contractually assign their responsibilities under the Final Rule to other covered parties, e.g., a receiver, loader, and/or carrier. 3PLs should consider revising their agreements with rail and motor carriers to go beyond

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the minimum that is required under the Final Rule, and to contractually specify that if the carrier does not follow the shipper's or 3PL's instructions, the shipment will be considered adulterated, and the carrier will be held liable for such adulteration. This would alleviate the problem encountered when receivers refuse a shipment due to a broken seal or a temperature deviation. If the contract between the 3PL and the carriers specifies that a shipment will be considered adulterated and the carrier will be liable if the shipper's or 3PL's instructions are not followed, then the carrier can be held liable, even if under the Final Rule, the carrier would not necessarily be held liable. Careful due diligence in selecting carriers is important for many reasons, including the fact that if a carrier does not have insurance to cover this liability, collecting from them could be a problem.

To help ensure compliance with the Final Rule, consider the following:

- (1) identify shipments covered by the new legislation, and ensure that you do not agree to burdensome and unreasonable requirements for commodities that the Final Rule does not cover.
- (2) do not accept shipper requirements that would be difficult to meet reliably;

- (3) reassign responsibilities to entities in the best position to ensure compliance with the Final Rule;
- (4) pay close attention to your and the carriers' rules publications, terms and conditions, rate confirmations, and credit applications;
- (5) consider the use of a questionnaire for carriers to confirm compliance with the food safety laws;
- (6) address procedures to be followed if you or those with whom you contract become aware of any possible failure of temperature control or of other conditions that may render the food shipment unsafe;
- (7) address who is the qualified individual and how he/she will determine "adulteration";
- (8) address each party's duty to mitigate damages and the procedure to follow if a food shipment arrives with a broken or missing seal or there is food temperature variance during transport; and
- (9) memorialize industry and/or your best practices in written procedures required by the STF Rule and contractual arrangements. ✈️