

MEMORANDUM

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Re: **FDA Issues Final Rule Addressing Sanitary Transportation of Food Under FSMA**

The Food and Drug Administration (FDA) recently published a final rule addressing Sanitary Transportation of Human and Animal Food (STHAF). ^{1/} This is the sixth major final rule FDA has issued under the FDA Food Safety Modernization Act (FSMA). The final rule generally takes a more flexible approach than the proposal, aiming to codify current industry best practices with the hope that many companies will not have to significantly alter their approach in order to come into compliance. Accordingly, the compliance date for larger businesses is April 6, 2017 (1 year from the date of publication). This memorandum first provides an overview of the regulation, highlighting changes from the proposed rule, and then summarizes the requirements of the final rule. We also provide an appendix that summarizes the provisions related to temperature control.

Overview and Key Changes from Proposed Rule

The purpose of the STHAF rule is to prevent practices during transportation that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food. To accomplish this goal, the 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 that food. Due to statutory limitations, the rule does not apply to transportation on boats or airplanes and is limited to transportation operations within the United States. It also does not address food security/defense issues.

In response to industry comments, FDA made a number of significant changes to the proposed rule that overall result in a final rule that is more flexible. Instead of prescriptive requirements, the regulations set forth general requirements and expectations – a goal-based approach that is more like the agency's current Good Manufacturing Practices (cGMP) regulations. Key changes from the proposed rule include:

- FDA has limited the focus of the rule to ensuring food is safe. The agency has removed references and requirements that address quality, deterioration, or spoilage issues. Nonetheless, although the regulation is focused only on transportation practices that could

^{1/} 81 Fed. Reg. 20092 (Apr. 6, 2016).

make food unsafe, the broad statutory prohibitions on adulteration still apply to transportation operations. 2/

- The final rule clarifies that the intended use of the vehicle or equipment (e.g., transporting animal feed versus human food) and the production stage of the food being transported (e.g., raw materials versus finished products) are relevant to determining sanitary transportation requirements.
- FDA has changed the definitions of the parties involved in transportation operations – shippers, carriers, and receivers – and has added a new term (loader) to account for the various roles and activities during transportation operations.
- Primary responsibility is placed on the shipper to determine what is needed for food safety and then make sure the necessary controls/practices are implemented. Shippers may rely on written contractual agreements to assign some of their responsibilities to other parties.
- There is a new provision stating that if a covered person or company at any point in the transportation chain becomes aware of a possible failure of temperature control or any other condition that may render a food unsafe, that food must not be sold or distributed until a determination of safety is made by a qualified individual. Notably, however, temperature deviations alone do not trigger this provision – the food must be potentially unsafe for this obligation to apply.
- Temperature control requirements are important but more flexible. For example, the shipper and carrier can agree to a temperature monitoring mechanism for foods that require temperature control for safety. (The original proposal specified that a compartment must be equipped with a thermometer, temperature measuring device, or temperature recording device, but those specifics have been removed.) The agency also agreed with commenters that carriers need to demonstrate they maintained requested temperature conditions only upon request, rather than as a requirement for every shipment, as previously proposed. This can be done by any agreeable means, including temperature monitoring at loading/unloading. Importantly, continuous temperature monitoring is not required. The provisions of the rule regarding temperature control are explained throughout this memorandum and in an appendix.
- The scope of foods covered by the rule is narrower. Food completely enclosed by a container is exempt from coverage, unless the food requires temperature control for safety. The original proposal specified that the enclosed foods must be shelf-stable (safely stored at room temperature in a sealed container) in order to be exempt. Thus, frozen foods and packaged foods that are refrigerated for quality reasons are not covered by the rule.

Background

In 2005, Congress amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by creating section 416 (21 U.S.C. § 350e), which directs FDA to establish regulations prescribing sanitary transportation practices to be followed by shippers, carriers by motor vehicle or rail vehicle, and receivers engaged in the transportation of food. The 2005 Sanitary Food Transportation Act (SFTA)

2/ For example, food is deemed adulterated if it (i) bears or contains any poisonous or deleterious substance which may render it injurious to health, (ii) consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food, or (iii) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. FFDCA § 402(a) (21 U.S.C. § 342(a).

also created new sections of the FFDCa providing that failure to comply with the sanitary food transportation regulations renders the transported food adulterated and is a prohibited act. Additionally, the law provided FDA with authority to access and copy all records required by the SFTA regulations.

FDA initiated efforts to promulgate regulations to implement the 2005 SFTA by publishing guidance on the topic and publishing an advance notice of proposed rulemaking in 2010. In FSMA, which was enacted in January 2011, Congress directed FDA to promulgate the regulations required by the 2005 SFTA, but did not modify the preexisting statutory requirements. Accordingly, the STHAF rule only addresses motor and rail vehicle transportation (i.e., not transportation by boat or airplane) and in general reflects the need to fulfill a statutory mandate to issue regulations, rather than to address a significant food safety issue.

Scope of the Rule

The regulation covers shippers, loaders, carriers, and receivers engaged in “transportation operations” unless they or the food they transport are specifically exempted. These terms are defined as follows:

- *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.
- *Loader* means a person that loads food onto a motor or rail vehicle during transportation operations.
- *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.
- *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.

Note that a person can be subject to these requirements in multiple capacities (e.g., the shipper may also be the loader and the carrier). Entities subject to the rule can use a written agreement to reassign their responsibilities to another party that is subject to the rule.

The rule specifically exempts shippers, loaders, carriers, and receivers when they:

- Have less than \$500,000 in average annual revenues from transportation operations over a 3-year period;
- Are engaged in transportation of food that is transshipped through the United States to another country;
- Are engaged in transportation of food imported for future export, in accordance with section 801(d)(3) of the FFDCa, and that is neither consumed nor distributed in the United States; or
- Are engaged in transportation of food located in food facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act.

In addition, transportation activities performed by a farm are exempt from the rule.

Additionally, transportation operations associated with the following types of food also are not covered by the rule:

- Food that is completely enclosed by a container except for food that requires temperature control for safety—and note that food is not considered to be completely enclosed by a container if it is partially open to the surrounding environment (e.g., open wooden basket or crate; open cardboard box; vented cardboard box with a top; vented plastic bag; food wrapped in pallet wrap);
- Compressed food gases;
- Food contact substances, as defined in FFDC A § 409(h)(6)—but note that shipment and storage equipment that contacts food is covered by the rule;
- Human food byproducts transported for use as animal food that will not be subject to further processing (i.e., feed moved directly to the farm where it will be fed directly to livestock)—thus, human food byproducts that are used as an ingredient in manufactured food or are further processed are covered by the rule; and
- Live food animals (except molluscan shellfish).

Requirements for Vehicles and Transportation Equipment

The regulation establishes requirements that apply to vehicles and transportation equipment used in association with food transportation. “Transportation equipment” includes bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems, and unloading systems. These items must be:

- Designed and of such a material and workmanship to be suitable and adequately cleanable for the intended use to prevent the food from becoming adulterated;
- Maintained in such a sanitary condition for their intended use as to prevent the food from becoming unsafe during transportation operations;
- Stored in a manner to prevent harborage of pests or contamination that could result in food becoming unsafe during transportation operations; and
- If applicable, designed, maintained, and equipped as necessary to provide adequate temperature control to prevent food requiring temperature control for safety from becoming unsafe during transportation operations.

General Requirements for Shippers, Carriers, Loaders, and Receivers

The regulation establishes general requirements that apply to all shippers, loaders, carriers, and receivers engaged in transportation covered by the rule. As noted above, a person may be subject to these requirements in multiple capacities (e.g., the shipper may also be the loader and the carrier). Additionally, entities subject to the regulation may reassign their responsibilities to another party subject to the rule through a written agreement.

The rule establishes the following general requirements:

- Responsibility for ensuring that transportation operations are carried out in compliance with the regulation must be assigned to competent supervisory personnel.

- All transportation operations must be conducted under appropriate conditions and controls to prevent the food from becoming unsafe during transportation operations, including taking measures:
 - (i) Such as segregation, isolation, or the use of packaging to protect food from contamination by raw foods and nonfood items in the same load.
 - (ii) 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 cross-contact during transportation operations.
 - (iii) To ensure that food that requires temperature control for safety is transported under adequate temperature control.
- The type of food (e.g., animal feed, pet food, human food) and its production stage (e.g., raw material, ingredient, finished food) must be considered in determining the necessary conditions and controls for the transportation operation.

Additionally, if a shipper, loader, carrier, or receiver becomes aware of a possible material failure of temperature control or other conditions that may render the food unsafe, the food cannot be sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe. FDA explains in the preamble that in this context a qualified individual “should be qualified by training or experience to make such a determination, i.e., he should have a scientific understanding of how the temperature deviation could affect the growth of pathogens or production of toxins in the food.”

Requirements for Shippers

Shippers 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. A one-time notification is sufficient unless the requirements change based upon the type of food being transported. The shipper also can make alternative arrangements (e.g., personally ensuring that the specifications are met or by contracting with another covered party) to implement these measures. This requirement applies to all segments of a shipment’s transit, no matter how many carriers are involved.

The shipper of food that requires temperature control for safety must specify in writing to the carrier and, when necessary, to the loader, an operating temperature for the transportation operation. If necessary, the shipper also must specify requirements for pre-cooling. A one-time notification is sufficient unless a factor changes that necessitates a change in the operating temperature (e.g., the conditions of shipment change). These requirements do not apply if the carrier transports food in a thermally insulated tank. The shipper also can make alternative arrangements (e.g., personally ensuring that the temperature requirements are met or by contracting with another covered party) to implement these measures.

The shipper must develop and implement written procedures adequate to ensure that:

- Vehicles and equipment used in transportation operations are in appropriate sanitary condition to prevent the food from becoming unsafe during transportation;
- A previous cargo does not make the food unsafe if food is transported in bulk; and
- Food that requires temperature control for safety is transported under adequate temperature control.

Measures to implement these procedures may be accomplished by the shipper or by the carrier or another party covered by this regulation under a written agreement.

Requirements for Loaders

The only requirements for loaders apply when they load food that is not completely enclosed by a container or food requiring temperature control for safety:

- Before loading food that is not completely enclosed by a container, the loader must determine (considering, as appropriate, the specifications provided by the shipper) that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food. For example, the loader must confirm that the equipment is in adequate physical condition, free of visible evidence of pest infestation, and free of previous cargo that could cause the food to become unsafe during transportation.
- Before loading food that requires temperature control for safety, the loader must verify (considering, as appropriate, the 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.

Requirements for Carriers

The requirements for carriers only apply when the carrier and the shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during transportation operations. In such situations, the carrier is responsible for the following, as applicable, per the agreement:

- Ensuring that vehicles and transportation equipment meet the shipper's specifications and are appropriate to prevent the food from becoming unsafe during transportation.
- If requested by the shipper for food transported in a bulk vehicle, providing information to the shipper that identifies the previous cargo transported in the vehicle and/or the most recent cleaning of the bulk vehicle.
- If requested by the shipper for food that requires temperature control for safety, pre-cooling each mechanically refrigerated cold storage compartment.
- If requested by the receiver, providing the operating temperature specified by the shipper.
- If requested by the receiver or shipper, demonstrating that the carrier has maintained temperature conditions consistent with the operating temperature specified by the shipper. Note that such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.
- Developing and implementing written procedures that:
 - Specify practices for cleaning, sanitizing if necessary, and inspecting vehicles and transportation equipment that the carrier provides for use in food transportation to maintain appropriate sanitary condition;
 - Describe how the carrier will comply with the provisions for demonstrating temperature control; and
 - Describe how the carrier will comply with the provisions for identifying previous cargo and the most recent cleaning for bulk vehicles.

- Providing training to personnel (upon hiring and as needed) that covers:
 - Awareness of potential food safety problems that may occur;
 - Basic sanitary practices to address those problems; and
 - The responsibilities of the carrier under the rule.
 - Note that FDA expects training will take less than 1 hour and intends to provide an online training course on its website.

Requirements for Receivers

The requirements for receivers only apply for receipt of food that requires temperature control for safety under the conditions of shipment. For such food, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse. For example, the receiver may determine the food's temperature, determine the ambient temperature of the vehicle and its temperature setting, or conduct a sensory inspection for off-odors.

Specific Types of Transportation Operations

The regulation and preamble also address several specific types of transportation operations that were highlighted by comments on the proposed 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 rather than developing written procedures and agreements as specified in the regulations. Loaders (considering, as appropriate, specifications provided by the shipper) must continue to meet their obligations explained above (i.e., determine conditions are appropriate when food is not completely enclosed by a container or requires temperature control for safety).

Less Than Load (LTL) Shipments

LTL shipments are those in which additional loads are added to a partially loaded truck. Under the final rule, the loader (not the shipper or receiver) is responsible for making sure that the vehicle is in a sanitary condition and is appropriate for transporting the food (e.g., that it is free of visible evidence of pest infestation). FDA expects that the shipper would generally instruct the loader about the issues requiring inspection.

Concurrent Transportation of Food and Non-Food

The statute directs FDA to establish a list of nonfood products that may render food simultaneously or subsequently transported in the same vehicle to be adulterated. FDA decided not to develop such a list because the likelihood of adulteration from food and non-food cargos is very situation specific. FDA notes that packaging, segregation, and isolation can be effective means of protecting food from contamination by non-food items. FDA also intends to develop guidance on this issue.

International Shipments

Application of the regulation starts at the origination of the truck or rail segment of transportation in the United States. For example, if a closed container is shipped into the United States by ocean-going vessel and then is transferred, unopened, at the U.S. port of entry onto a truck, the container becomes subject to the rule at the origination of the truck segment in the United States. Although the rule does not establish specific requirements for the transport of food before it reaches the

United States, shipments remain subject to the general adulteration provisions of the statute if they are destined for U.S. consumption.

Recordkeeping

Records must be made available promptly to a duly authorized individual upon oral or written request for review and copying. Records generally must be retained for 12 months after their use has been discontinued. Offsite storage is permitted if records can be retrieved and provided onsite within 24 hours of a request—except that carriers' written procedures for cleaning, sanitizing, and inspecting vehicles and transportation equipment must remain onsite. Electronic records are considered onsite if they are accessible from an onsite location. FDA did not finalize a proposal to subject electronic records to 21 CFR Part 11, so records are exempt from Part 11 as under the other FSMA rules (unless there is a pre-existing obligation to comply with Part 11). The standard Freedom of Information Act exemptions from disclosure (e.g., for trade secrets and confidential commercial information) apply.

The scope of records that need to be maintained is significantly narrower than under the other FSMA regulations. FDA emphasizes in the preamble that there is no requirement to maintain records of each individual shipment, and the agency is not looking for companies to “fill up a room” with transportation records. Rather, the recordkeeping requirements mostly encompass specifications and written procedures.

Shippers must retain records (as applicable):

- Demonstrating that they provide sanitary specifications for vehicles and equipment and operating temperatures to carriers.
- Of their written procedures:
 - To ensure that vehicles and transportation equipment are in appropriate sanitary condition;
 - For food transported in bulk, to ensure that a previous cargo does not make the food unsafe; and
 - For food that requires temperature control for safety, to ensure the food is transported under adequate temperature control.
- Of written agreements to have another party implement their written procedures.

Carriers must retain records (as applicable):

- Of their written procedures for:
 - Cleaning, sanitizing, and inspecting vehicles and transportation equipment;
 - Providing the operating temperature specified by the shipper to the receiver, if requested;
 - Demonstrating that the carrier has maintained temperature conditions; and
 - Providing information on previous cargo transported in a bulk vehicle and the most recent cleaning of the bulk vehicle.
- Of employee training (date, type of training, person trained) when the carrier has agreed in writing to assume responsibility for sanitary conditions during transportation.

Shippers, loaders, carriers, and receivers must retain records of agreements that assign tasks under the rule. Shippers, loaders, carriers, and receivers that operate under the ownership or control of a single legal entity must retain records of written procedures for transportation activities.

Waivers

The statute permits FDA to waive any of the SFT requirements “with respect to any class of persons, vehicles, food, or nonfood products” if the agency determines that the waiver will not (1) result in transportation of food under unsafe conditions and (2) be contrary to the public interest. FDA is required to publish any waivers and the reason for the waiver in the Federal Register. The final rule outlines the process for submitting and FDA’s review of a petition requesting a waiver.

FDA proposed establishing waivers to address:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety Program, only when engaged in transportation operations involving Grade A milk and milk products; and
- Food establishments, i.e., retail and food service operations, holding valid permits, only when engaged in transportation operations as receivers, or as shippers and carriers in operations in which food is relinquished to consumers after transportation from the establishment.

The agency currently is evaluating comments on these waivers to determine whether either should be modified from what was proposed. The agency will post a notice on its website regarding its reasoning regarding the scope of these prospective waivers at the soonest possible date. The agency will publish the final waivers in the Federal Register prior to the compliance date for the final rule.

Compliance Dates and Enforcement

Like the other FSMA final rules, the compliance dates are staggered based on the size of the business. The general compliance date is April 6, 2017 (1 year from the date of publication). For small businesses, the compliance date is April 6, 2018 (2 years from the date of publication). A small business is defined as a business with less than 500 full-time equivalent employees, except that for motor vehicle carriers (if they are not also shippers and/or receivers), a small business is defined as a business with less than \$27,500,000 in annual receipts.

Under the 2005 SFTA, the Department of Transportation (DOT) is responsible for notifying FDA of any instances of potential food contamination or adulteration of a food identified during DOT transportation safety inspections. FDA plans to work with DOT to support its inspection efforts. However, although DOT has the authority to conduct transportation safety inspections, FDA states that it likely will take lead on enforcement when violations arise.

In the preamble to the final rule, FDA also explains that before initiating enforcement action it will consider all circumstances surrounding a deviation. Thus, the agency suggests that noncompliance with the recordkeeping or training provisions of the rule alone is unlikely to be a basis for enforcement action, even though legally such a violation renders the food adulterated. FDA also explains that when responsibility is assigned by contract, FDA will consider the terms of the contract in determining who is responsible for compliance. However, if a task is assigned via contract to a party who is not covered by the rule, FDA will hold the party covered by the rule ultimately responsible for compliance.

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We will continue to monitor FDA’s implementation of FSMA. Should you have any questions, please do not hesitate to contact us.

APPENDIX

Temperature Control Provisions in the Sanitary Transportation of Human and Animal Food Rule

If food that requires temperature control for safety is being transported, the following requirements apply:

- Vehicles and transportation equipment must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe during transportation operations.
- Transportation operations must be conducted under appropriate conditions and controls to prevent the food from becoming unsafe during transportation operations.
- The shipper must:
 - Specify in writing to the carrier and, when necessary, to the loader, an operating temperature for the transportation operation. If necessary, the shipper also must specify requirements for pre-cooling.
 - These requirements do not apply if the carrier transports food in a thermally insulated tank.
 - Develop and implement written procedures adequate to ensure that the food is transported under adequate temperature control.
 - Retain records demonstrating that they provide operating temperatures to carriers and records of their written procedures to ensure the food is transported under adequate temperature control.
- Before loading such food, the loader must verify (considering, as appropriate, the 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.
- The carrier must:
 - If requested by the shipper for such food, pre-cool each mechanically refrigerated cold storage compartment;
 - If requested by the receiver, provide the operating temperature specified by the shipper.
 - If requested by the receiver or shipper, demonstrate that the carrier has maintained temperature conditions consistent with the operating temperature specified by the shipper. Note that such demonstration may be accomplished by any appropriate means agreeable to the carrier and shipper, such as the carrier presenting measurements of the ambient temperature upon loading and unloading or time/temperature data taken during the shipment.
 - Develop and implement written procedures that describe how the carrier will comply with the provisions for demonstrating temperature control.
 - Train employees in relevant responsibilities related to temperature control activities.
 - Retain records of: (1) their written procedures for providing the operating temperature specified by the shipper to the receiver, if requested, and demonstrating that the carrier has maintained temperature conditions and; (2) of employee training.
- The receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse. For example, the receiver may determine the food's temperature, determine the ambient temperature of the vehicle and its temperature setting, or conduct a sensory inspection for off-odors.
- If a shipper, loader, carrier, or receiver becomes aware of a possible material failure of temperature control that may render the food unsafe, the food cannot be sold or otherwise distributed unless a determination is made by a qualified individual that the temperature deviation or other condition did not render the food unsafe.