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Equipping Your Supply Chain for FSMA: Allocating Responsibilities under the FSMA Transportation Rule

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In the late 1980s, stories of garbage hauled in the same trucks regularly used to transport fruits and vegetables caused public outrage. Outbreaks of foodborne illnesses, including a salmonellosis outbreak that affected 224,000 consumers, have been attributed to contamination of transportation vehicles. Recently, a major U.S. foodservice distributor was penalized after its practice of storing seafood, milk and raw meat in unrefrigerated sheds was uncovered.

To mitigate the food safety risks associated with transportation practices, Congress passed the Sanitary Food Transportation Act of 2005 (“SFTA”) and again addressed food transportation practices in the Food Safety Modernization Act of 2011 (“FSMA”). Earlier this month, in one of the final rules issued to implement FSMA, the FDA released its final rule on Sanitary Transportation of Human and Animal Food (“**FSMA Transportation Rule**” or “**Rule**”). The final FSMA Transportation Rule reflects the FDA’s response to many of the industry’s concerns, in that the FDA refocused its efforts on transportation practices that cause food safety risk, rather than also addressing practices that might lead to quality defects or spoilage of food products.

Now is the time for food product manufacturers, processors, carriers, brokers, distribution centers, and others involved in food product and ingredient supply chains to determine what requirements apply to their business practices and to address how they will implement the FSMA Transportation Rule. After all, under the FSMA Transportation Rule, if transportation occurs under conditions that are not in compliance with the Rule, the food will likely be adulterated under the federal Food, Drug and Cosmetic Act. Responsible parties may be subject to fines and other liability. In addition, violations of the FSMA Transportation Rule may also support freight claims against carriers, or claims against other responsible parties in the supply chain alleging the negligence or other misconduct of a responsible party.

Businesses (other than small businesses) must comply with the Rule in 2017. Small businesses (those with fewer than 500 full time employees or carriers that are not also shippers and receivers with less than \$27.5 million in annual receipts) must comply with the Rule in 2018. Given the need to establish written procedures and update supply chain contracts, those affected by the Rule cannot afford to wait to begin implementing changes.

Many companies are likely to find that though current procedures may need to be incorporated into contracts or otherwise formalized, many of the Rule’s requirements are flexible enough to adapt to the food industry’s current strategies for ensuring food safety during transportation. But as recognized by the FDA, companies are likely to find that there are new responsibilities, and therefore new costs, such as those associated with training and recordkeeping.

What Activities are Covered?

Through the final Rule, the FDA has clarified the parties, operations, and products that are subject to the FSMA Transportation Rule. To fully understand the scope of what is covered by the FSMA Transportation Rule, interested parties should note which activities and products are or are *not* covered by the Rule.

Transportation operations are broadly defined under the FSMA Transportation Rule to include “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.” All transportation operations subject to the Rule must be conducted under such conditions and controls necessary to prevent the food from becoming unsafe. Conditions and controls necessary to prevent the food from becoming unsafe include segregation, isolation, or other protective measures to protect food:

- From cross-contact and contamination during transportation operations if transported in bulk vehicles or not completely enclosed by a container;
- From contamination by raw foods and nonfood items in the same load; and
- From unsafe temperature fluctuations.

The following transportation operations are *not* covered by the FSMA Transportation Rule:

- Transshipping of food through the U.S. to another country;
- Transporting food that is imported to the U.S. for future export, and not consumed or distributed in the U.S.; or
- Food that is located in food facilities regulated *only* by the U.S. Department of Agriculture (“**USDA**”) under the Federal Meat Inspection Act, Poultry Products Inspection Act, or the Egg Products Inspection Act.

Except for the above express exceptions, the requirements of the Rule apply whether or not the food is being offered for or enters interstate commerce. That is, food that is being transported from one processing facility to another for further processing would still be covered by the Rule.

What Food Products are Covered?

The Rule applies to *transportation operations of food not completely enclosed by a container*, which means “any food that is placed into a container in such a manner that it is partially open to the surrounding environment,” such as in an open wooden basket or crate, an open or vented cardboard box, or a vented plastic bag. The Rule also applies to food shipped in bulk, which comes into direct contact with the vehicle. The Rule’s requirements extended to food additives (except for food contact substances) and generally recognized as safe (“**GRAS**”) substances.

Importantly, under the Rule, transportation operations do not include any activities associated with the transportation of food that is completely enclosed by a container *unless* that food requires temperature control for safety. The Rule further does not apply to transportation operations that include the transportation of compressed food gases or food contact substances (*e.g.*, packaging materials). The FDA, noting that the temperature and time required for frozen food to become unsafe would result in significant quality issues before posing any safety risk, also stated that frozen food is not subject to the Rule.

The FDA stated that it considers a *completely enclosed container* “to be one that physically separates the food from the environment and functionally protects the food from environmental contamination during transportation.” However, the FDA would not consider items such as pallet wrap, which are primarily to facilitate

handling, to be food containers. Examples of enclosed containers include cans, bottles, or a sealed bag or box (including a paper bag or box that could be subject to moisture permeation under certain circumstances). However, much to the chagrin of the produce industry, the FDA declined to exclude food packaged in vented cardboard cartons from food completely enclosed in a container, on the basis that such food could be susceptible to environmental contamination. Boxes with flaps sealed by tape are considered to be a completely enclosed container.

Therefore, some parties, such as shippers and carriers of frozen or of shelf stable consumer packaged goods (*i.e.*, foods that can be stored under ambient temperature and humidity conditions), or retailers that receive primarily frozen or shelf stable consumer packaged goods, may have fewer obligations under the FSMA Transportation Rule than originally perceived. For example, the FDA noted that its final definition of transportation operations essentially excludes packaged alcoholic beverage products from coverage under the Rule.

Who is Covered?

Keeping in mind the excluded activities discussed above, the FSMA Transportation Rule defines responsibilities for:

- *Shippers* – a person, such as a manufacturer or freight broker or third party logistics provider, who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially. Notably, retailers with captive distribution facilities, as well as wholesalers, may be shippers subject to the Rule.
- *Carriers* – a person who physically moves food by rail or motor vehicle in commerce within the U.S. Importantly, in response to concerns that parcel delivery services may, if subject to the Rule, refuse to ship food products, the final Rule specifies that a carrier does not include the transportation of food by a parcel delivery service. A carrier is responsible for all functions assigned to a carrier even if they are performed by other persons, such as a driver that is contracted by a trucking firm. A carrier may also be a receiver or a shipper if performing those functions.
- *Loaders* – a person that loads food onto a motor or rail vehicle during transportation operations. The FDA added loaders as responsible parties under the Rule in response to concerns that shippers (who would not necessarily be present) would be responsible for inspecting vehicles prior to shipment. This will allow shippers to contractually assign certain duties to loaders (or the person responsible for hiring loaders, such as a carrier).
- *Receivers* – any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food (but not a consumer or person who holds food on behalf of a consumer and who is not also a party to the transaction and not in the business of distributing food). This applies to all receivers that are subject to the Rule, not just food bound for retail outlets.

Overview of Significant Duties of Shippers

The FDA stated in issuing the FSMA Transportation Rule that it has three major areas of focus, which are to provide assurance that:

- Vehicles and equipment used in transportation operations (of food not completely enclosed by a container) are in appropriate sanitary condition;
- For bulk cargo, a previous cargo does not make the food unsafe; and
- For foods that require refrigeration for safety, the food is transported under adequate temperature control.

Shippers have significant obligations under the FSMA Transportation Rule, and several different types of parties – manufacturers, brokers, third party logistics providers, and retailers – can be the “shipper,” depending on the circumstance. While it is sensible for manufacturers to specify requirements applicable to products, many freight brokers and third party logistics providers are not in a good position to understand or implement the responsibilities of a shipper under the FSMA Transportation Rule; and therefore, many expect that the inclusion of the brokers under the Rule will continue to be hotly debated. Shippers have the most responsibility under the FSMA Transportation Rule, and are expected to “know whether a food falls within the scope of the exclusion from the definition of ‘transportation operations’ applicable to food completely enclosed by a container and does not require temperature control for safety,” among other points.

Under the FSMA Transportation Rule, shippers are charged with developing and implementing written procedures to address how food safety will be assured compared to the three major focus areas. As a practical matter, shippers rely upon a network of service providers to move food products from the point of production to consumers. Therefore, through a patchwork of written procedures and contract terms, shippers will need to ensure that they are meeting the requirements of the FSMA Transportation Rule.

A shipper must:

- Ensure that vehicles and transportation equipment are in, and are maintained in, compliance with the Rule, or specify to the carrier and, when necessary, the loader, in writing, all necessary sanitary specifications for vehicles and transportation equipment;
- Specify to the carrier, and when necessary, the loader, in writing, an operating procedure for the transportation operation with respect to temperature requirements and temperature control. This may include a pre-cooling phase; and
- If shipping food in bulk, develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe. Note that the FDA is only requiring shippers to look back one cargo load – not three loads, as previously proposed.

Overview of Significant Duties of Loaders

Loaders engaged in transportation operations subject to the FSMA Transportation Rule must:

- Prior to loading food subject to the Rule, determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food; and
- Prior to loading food subject to the Rule that require temperature control for safety, verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food, including that it has been pre-cooled, if necessary.

Overview of Significant Duties of Receivers

Receivers engaged in transportation operations subject to the FSMA Transportation Rule must:

- As to products subject to temperature control for safety, assess that the food was not subjected to significant temperature abuse.

If a receiver (or other person subject to the Rule) learns that food has been transported under a temperature or other condition that may render the food unsafe (*i.e.*, not in accordance with the FSMA Transportation Rule), then the receiver must ensure that the food is not sold or further distributed pending review by a qualified individual. A qualified individual may then make a determination that the food is safe, in accordance with the Rule.

Overview of Significant Duties of Carriers

When a carrier and shipper have a written agreement that a carrier is responsible for sanitary conditions during the transportation operation that is subject to the FSMA Transportation Rule, the carrier must, as applicable per such agreement:

- Ensure that vehicles and transportation equipment meet the shipper’s specifications and are appropriate to prevent food from becoming unsafe;
- Provide the operating temperature specified by the shipper and, if requested by the shipper or receiver, demonstrate that it has maintained temperature conditions as required;
- Pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper;
- If requested by the shipper, provide information identifying the previous bulk cargo; and
- Develop and implement written procedures in compliance with the Rule’s records requirements, specifying cleaning and sanitizing procedures, describing inspections of vehicles and transportation equipment, describing compliance with temperature control requirements, and describing how such carrier will comply with provisions for the use of bulk vehicles that are prescribed under the Rule.

Importantly, the Rule also requires carriers to provide adequate training to personnel engaged in transportation operations regarding potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of carriers under the FSMA Transportation Rule. With respect to training, the FDA stated that:

- The training must be provided upon hiring and as needed thereafter; and
- The carrier must keep records of the date of training, the type of training, and the persons trained, which records will be subject to the records requirements of the Rule.

The FDA declined to otherwise prescribe the content, frequency, and length of the training, and noted that given the diversity of the industry, it did not intend to require everyone to use a single training approach. If existing industry training meets the requirements of the Rule, such training will continue to be acceptable, even though not specifically developed for or tailored to compliance with the Rule.

Allocating Duties by Contract and Establishing Policies

The FDA declined to exempt shippers, receivers, loaders, and carriers that are part of the same company from the requirements of the final FSMA Transportation Rule. As to shippers, receivers, loaders, and carriers that are under common ownership or operation control (of a single entity), some of the Rule's requirements may be met by conducting transportation operations in conformance with common, integrated written procedures.

In response to the FDA's proposed rule, many commenters noted that the FDA should also recognize that companies that have legal responsibility for compliance with the FSMA Transportation Rule are likely to reassign specific tasks to the specific party in the supply chain that actually handles the activity in question, or is in the best position to handle the activity in question.

The FDA, as part of the final FSMA Transportation Rule, acknowledged that industry practice is to alter, by contract, the tasks assigned by the Rule, and that such contractual assignment of duties is acceptable. Companies should note, however, that the Rule also subjects such contracts to the records requirements of the Rule. Therefore, it may be prudent for companies to plan ahead to protect sensitive information by including the allocation of responsibilities related to the FSMA Transportation Rule in a separate exhibit, short form of agreement, or policy or procedure. The FDA may request such records during an inspection, and it is best to work in advance to mitigate the risk that sensitive information which may be subject to a public records request, such as route information that lists customers, be inadvertently exposed.

With respect to contracts, the FDA will consider the terms of the contract in determining who is responsible for compliance. If a task is assigned via contract to a party that who is not covered by the Rule (e.g., a carrier contracting with a truck wash station to wash a bulk tanker, where the wash station is not covered by the Rule), then the FDA would hold the party who is covered by the Rule ultimately responsible for compliance, regardless of the contractual assignment of duties. Therefore, reliance upon contractual assignment of duties alone will not be sufficient to ensure compliance, and similar to other types of supplier verification, responsible parties should ensure that their service providers are adequately performing their assigned duties.

Companies responsible under the FSMA Transportation Rule should also be aware that to the extent feasible to maintain safety of food products (which may differ from quality), such companies should develop standards that are flexible, to avoid food being deemed adulterated or having to have a qualified individual review and justify why the food is not adulterated. For example, though optimal quality for a refrigerated item may be preserved at 35 degrees Fahrenheit, the product may not actually become unsafe until it reaches a temperature over 40 degrees Fahrenheit for a certain period of time. Therefore, the shipper's instructions would be best served to specify a temperature range, or the temperature and time frame at which the food becomes unsafe.

Finally, the FDA clarified in the final Rule that a shipper's one-time communication for a particular food product or procedure is sufficient under the FSMA Transportation Rule, unless a factor such as the food itself or conditions of shipment changes. Instructions may also be communicated in a bill of lading.

Importance of Records

The FSMA Transportation Rule contains significant new recordkeeping requirements.

Generally, any agreement that assigns tasks in compliance with the FSMA Transportation Rule must be retained for a period for 12 months beyond such agreement's expiration or earlier termination.

Shippers must establish and retain records demonstrating that they provide specifications and operating temperatures to carriers as required by the Rule. Shippers must also retain as records any written agreements relating to ensuring that vehicles and equipment are in appropriate sanitary condition, ensuring that previous cargo does not make food unsafe, and temperature control requirements.

As noted above, carriers must establish and retain records specifying cleaning and sanitizing procedures, describing inspections of vehicles and transportation equipment, outlining compliance with temperature control requirements, and describing how such carrier will comply with provisions for the use of bulk vehicles that are prescribed under the Rule.

The FDA noted in its earlier comments, during public meetings, that it is looking for the carrier to provide records demonstrating that they conduct the required information exchange with shippers and provide shippers with information regarding temperature control. The FDA attempted to tailor the recordkeeping provision to ensure the accountability of the carrier to demonstrate to shippers that they are transporting refrigerated foods in compliance with the Rule.

Records must generally be retained for a period of 12 months. Careful attention is required to the retention period for each *type* of record, as the date that the 12 months begins may be triggered by different circumstances, such as when a procedure is in use, or when an agreement terminates, or when a person who has undergone training stops performing the duties for which the training was provided.

The FDA clarified that records may be maintained offsite, but must be available promptly, which will generally mean within 24 hours.

Responsible parties should take note that the failure to maintain records in compliance with the recordkeeping requirements of the FSMA Transportation Rule could provide fodder for an enforcement action. Though the FDA stated that it “will consider all circumstances surrounding the deviation(s), e.g., the nature of the deviation, from these regulations,” the FDA also highlighted its view, based on the language of SFTA, “that Congress intended recordkeeping to be one of the requirements for maintaining sanitary food transportation practices.” Therefore, food for which records are not maintained in accordance with the FSMA Transportation Rule may be deemed adulterated.

Vehicle and Transportation Equipment Requirements

The final FSMA Transportation Rule requires that vehicles and transportation equipment used in transportation operations be designed to be suitable and adequately cleanable to prevent food from becoming unsafe. Such vehicles and transportation equipment must be maintained in such sanitary condition, and if needed, be designed, maintained, and equipped to provide adequate temperature control. Vehicles and transportation equipment must also be stored to prevent the harborage of pests or contamination.

Special Situations

In issuing the final FSMA Transportation Rule, the FDA responded to over 180 separate comment topics. The FDA’s responses are useful for particular industry participants to better understand their responsibilities. Though an exhaustive list is not possible, the following includes certain notable highlights:

- *Fresh Produce and PACA* – In response to concerns regarding the potential rejection of produce shipments under the Rule that are also subject to the Perishable Agricultural Commodities Act, the FDA

clarified that the Rule does not require a receiver to reject a shipment if the transportation conditions deviate from the Rule. Instead, the Rule precludes the sale or distribution of the food where there is an indication of a material failure of temperature control or other conditions during transportation that may render a food unsafe, unless a qualified individual determines that the deviation or condition did not render the food unsafe.

- *Ingredients* – The FDA clarified that ingredients can meet the definition of food that is completely enclosed by a container, and thus, if such ingredients are shelf stable and do not require temperature control, may not be subject to the Rule’s requirements, including if shipped in dedicated, enclosed bulk containers.
- *Food Banks* – A commenter asked that the FDA exempt food banks and related partners from certain of the Rule’s requirements. For example, the commenter asked that the FDA exempt from recordkeeping requirements certain food transportation operations that involve shipments of food from centralized charitable distribution centers that also act as shippers, and sometimes as carriers, to member food banks. The comment also asked for an exemption for shipments between food banks. Much as we have seen as a trend with respect to state governments and local municipalities, the FDA declined to exempt food banks and charitable food distribution centers from the Rule’s requirements.
- *Preemption* – To the extent that a more stringent state law may exist as to a specific point, the FDA has stated that such state law is not preempted by the FSMA Transportation Rule.
- *Conflicts between FSMA Rules* – The FDA noted pressure from some parties to re-issue all seven of the FSMA rules simultaneously for comment, but noted that due to deadlines under the consent decree, this would not be possible. Therefore, industry participants can expect the need to continue to clarify with the FDA, whether via public meetings or direct questions, any apparent inconsistencies or other questions involved when applying multiple FSMA Rules.
- *Adulterated Product Intended to be Shipped Outside of the United States* – One commenter asked whether cargo deemed adulterated under the FSMA Transportation Rule could then be shipped to a destination outside of the U.S. The FDA cited the principle that if a product has been found to be adulterated, it cannot legally be offered outside of the U.S., but also noted that the owner might consider other options, such as reconditioning the product or diverting it to non-food uses.

Conclusion: Adapt the FSMA Transportation Rule for Diverse Supply Chains

The FDA recognized the diversity in the parties and supply chains that are impacted by the final FSMA Transportation Rule, and noted its attempt to structure the Rule “so as not to restrict innovation in the parties covered by the rule,” while not developing a rule so fluid as to be unenforceable. The FDA emphasized its goal to know who is responsible when things go wrong, and to be able to hold them accountable. Ultimately, organizations implementing the Rule should determine which of their existing policies, procedures, and contracts should be adapted to the Rule’s requirements, and then implement new approaches when needed to establish compliance.

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