Food Safety Modernization Act
Sanitary Food Transportation Act
Proposed Rule

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Background

• During the late 1980s, there were a number of press reports that trucks that hauled garbage from NY/NJ were subsequently used to carry meat, poultry and produce.

• GAO looked into the matter and could not find any conclusive evidence that this was a common practice.

• In spite of this, after receiving the report, Congress enacted the Sanitary Food Transportation Act in 1990.
The Sanitary Food Transportation Act directed the Dept. of Transportation to prescribe regulations regarding the transportation of food and food additives in motor and rail vehicles that are used to transport nonfood products that would make food/additives unsafe.

DOT issued a proposed rule in 1993.

In 1998, DOT’s OIG determined the agency did not have the expertise to implement the law and FDA did have it.

In 2005 Congress amended the law and directed FDA to implement it, but no deadline until FSMA.
When is Compliance Required?

• The proposed effective date is 60 days after the date of publication of the final rule in the Federal Register

• Compliance is required:
  – 1 year after effective date generally
  – 2 years after effective date for small businesses
    – Small business=fewer than 500 employees company-wide; but for carriers that are also not shippers and/or receivers, less than $25.5 million in annual revenues
Criminal Penalties

• Violating regulation is prohibited act under the Food, Drug and Cosmetic Act—21 USC 331(hh)

• Under U.S. v. Park, CEO and other corporate officers can be held criminally liable for misdemeanor violations without engaging in or having actual knowledge of violation
Criminal Penalties (contd)

- Criminal penalties:
  - Prohibited act under 21 U.S.C. 331(hh)

  §333. Penalties
  (a) Violation of section 331 of this title; second violation; intent to defraud or mislead
  (1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
  (2) Notwithstanding the provisions of paragraph (1) of this section,1 if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

- Fines can be up to $250k per violation for individual or $500k for organization under 18 U.S.C. 3571
Applicability

• Food is deemed adulterated if it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulation
Who is Subject to the Rule?

- Shippers of food
- Carriers of food
- Receivers of food

Rule does not apply to shippers, receivers, or carriers when they are engaged in transportation operations of food that is:
  - Transshipped through the U.S. to another country
  - Food that is imported for future export
Who is a Shipper?

• A person who initiates a shipment of food by motor or rail vehicle
  – The shipper is responsible for functions assigned to a shipper pursuant to the rule even if they are performed by other persons, such as a person who only holds food and physically transfers it onto a vehicle arranged for by the shipper
Who is a Shipper? (contd)

– For example, a produce distributor may initiate a shipment of food by arranging for a carrier to pick up a shipment of fresh produce at a holding facility for transport by truck to a produce distribution facility (owned by an unrelated entity). Employees of the holding facility who are not employed by the distributor may load the produce onto the truck

• Under the rule, the produce distributor is responsible (e.g. though contractual arrangements) for ensuring that the employees of the holding facility visually inspect the vehicle for cleanliness (and that all other applicable requirements of proposed rule are met)
Who is a Shipper? (contd)

- A shipper may also be a carrier or a receiver if the shipper also performs the functions of those persons (e.g. a supermarket chain may arrange for the shipment of fresh produce to be received at its distribution center)

- FDA states that as the initiator of a transportation operation, they expect the shipper to be knowledgeable about all factors concerning the food
Shippers: Foreign Exporters

- Foreign exporters are considered shippers under the proposed rule if they ship food to the U.S. in an international freight container by ship or in an air freight container and arrange for the transfer of the intact container in the U.S. onto a motor vehicle or rail vehicle for transportation in U.S. commerce, if that food will be consumed or distributed in the U.S.
Shippers: Foreign Exporters (contd)

• What does intact mean?
  – Not repacked
  – Container arriving into port via ship/aircraft, placed onto trailer/railcar and entered into commerce into the U.S.
  – Ex: Container of frozen shrimp arrives into port, entered through customs, not opened/repacked, placed on a truck and taken to a seafood distribution warehouse in the U.S.
Who is a Receiver?

- Any person who receives food after transportation, whether or not that person represents the final point of receipt for the food
  - Does not include an individual consumer or a person who receives or holds food on behalf of an individual consumer and who is not also a party to the transaction and who is not in the business of distributing food (e.g. a hotel concierge or apartment building reception desk)
Who is a Receiver? (contd)

• Receivers can also be shippers and carriers under the regulation

• All persons who receive food after transportation, not just the ultimate consignee, are subject to the requirements applicable to receivers in the regulation
Who is a Carrier?

• A carrier is a person who owns, leases, or is otherwise ultimately responsible for the use of a motor vehicle or rail vehicle to transport food

• The carrier is responsible for all functions assigned to a carrier in the regulation even if they are performed by other persons, such as a driver that is employed or contracted by a trucking firm

• A carrier may also be a receiver or a shipper if the person also performs those functions as defined in the rule
Examples

• A manufacturing facility that does not have its own private truck fleet, drivers or contracted drivers may enter into a contract of carriage with a trucking company to physically transport a food shipment using the trucking company’s vehicle to another facility designated in the contract
  – The trucking company is the entity ultimately responsible for the use of the vehicle that transports the food and is thus the carrier
Who is a Carrier? (contd)

• A distributor who is in possession of food in a holding facility operates leased vehicles to deliver food to his customers
  – The distributor is the carrier
  – The distributor may also be considered the shipper due to its operation of the holding facility
Who is a Carrier? (contd)

• The carrier is responsible for all functions assigned to them under the rule, even if they are performed by other persons (e.g. a driver employed or contracted by the carrier)
  – The carrier would be responsible for ensuring that a driver operating the vehicle functions in a manner that enables the carrier to comply with the regulations (e.g. ensure that the driver is providing temperature logs to shippers)

• Definition of carrier acknowledges distinction between the carrier and the operator of the motor vehicle
Non-covered Businesses

• Shippers, receivers and carriers engaged in transportation operations that have less than $500,000 in total annual sales are exempt from the regulations
What Food is Covered?

• FDA-regulated human food including raw materials and ingredients
  – No exemption for foods subject to seafood and juice HACCP rules (although regulation strives to be consistent with such rules)

• Animal food

• USDA-regulated meat, poultry and egg products
What Food is Exempt?

- Shelf-stable food completely enclosed by a container (no vents)
- Compressed food gasses
- Live food animals
- Transportation for RACs that are performed by a farm
What is food not completely enclosed by a container?

• Any food that is placed into a container in such a manner that it is partially open to the surrounding environment
  – Includes: open wooden basket/crate, open cardboard box, vented cardboard box with a top, vented plastic bag
  – FDA states this approach is consistent with how they addressed unexposed refrigerated packaged foods in the proposed preventive controls rules
What is a Vehicle?

• Vehicles are subject to requirements under the regulations
• A vehicle is a land conveyance that is motorized (e.g. a motor vehicle) or that moves on rails (e.g. a railcar) which is used in transportation operations
  - A trailer is considered to be a vehicle when attached to a tractor and used for transportation (because it functions as part of the conveyance)
  - Railcars are considered vehicles when attached to locomotives
What is Transportation Equipment?

• Transportation equipment is subject to requirements under the regulation
• Transportation equipment means equipment used in food transportation other than vehicles
  – E.g. bulk and non-bulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems and unloading systems
  – Also includes a railcar not attached to a locomotive or trailer not attached to a tractor
What are Transportation Operations?

- Transportation operations are subject to requirements under the regulations.
- Transportation operations means all activities associated with food transportation that may affect the sanitary condition of the food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment.
What are Transportation Operations? (contd)

- Transportation operations do not include any activities associated with the transportation solely of shelf stable food that is completely enclosed by a container, compressed food gasses or live food animals. Transportation operations do not include transportation activities for RACs that are performed by a farm.
Farm Exemption

• Farm is a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term farm includes facilities that pack or hold food, regardless of whether all food used in such activities is grown, raised or consumed on that farm or another farm under the same ownership.

• Definition of farm is broader than definition under food facility registration rules:
  – Includes farms conduct transportation operations for RACs that were grown/raised or consumed on farms under different ownership.
Farm Exemption (contd)

• Exclusion applies to the activities of farms regardless of whether they are serving in the role of shipper, carrier or receiver
• FDA requesting comment on whether exemption should apply to time/temperature control for safety (TCS) RACs (sprouts, raw molluscan shellfish)
Vehicle and Equipment Requirements

- Vehicles and transportation equipment must be:
  - Designed and of such material and workmanship as to be adequately cleanable for their intended use to prevent food from becoming filthy, putrid, decomposed or otherwise unfit, or being rendered injurious to health from any source during transportation operations (FPDUR)
Vehicle and Equipment Requirements (contd)

• Vehicles and transportation equipment:
  – Must be maintained in such a sanitary condition as to prevent FPDUR (cleaning pumps and hoses to remove allergens, disposing of damaged, jagged pallets etc.)
  – If transporting food that can support the rapid growth of undesirable microorganisms in the absence of temperature control (RGUM), must be designed, maintained and equipped to maintain food under temperature conditions that will prevent the rapid growth of undesirable microorganisms.
Vehicle and Equipment
Requirements: Microorganisms

- Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance (i.e. L. monocytogenes)

- The term undesirable microorganisms includes microorganisms that are of public health significance, and also that subject food to decomposition, that indicate food is contaminated with filth, or that otherwise may cause food to be adulterated
Vehicle and Equipment Requirements (contd)

- Each freezer and mechanically refrigerated cold storage compartment in vehicles or transportation equipment used to transport RGUM food, must be equipped with an indicating thermometer, temperature-measuring device, or temperature recording device installed to show the temperature accurately within the compartment.
Vehicle and Equipment Requirements (contd)

• Vehicles and transportation equipment must be stored in a manner as to prevent the vehicles or equipment from harboring pests, or becoming contaminated in any other manner that could result in food becoming FPDUR
Transportation Requirements

• Responsibility for ensuring that transportation operations are carried out in compliance with all requirements of regulation must be assigned to competent supervisory personnel.
Transportation Requirements (contd)

• All transportation operations must be conducted under such conditions and controls necessary to prevent food from becoming FPDUR including:
  – Measures such as segregation or isolation to prevent contamination by raw food and non-food items in the same load (FDA acknowledged and affirmed our previous comments that supermarket industry practices are adequate)
  – 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 cross-contact during transportation operations
  – Ensuring that RGUM food is transported in a manner (including temperature control) to prevent FPDUR
Transportation Requirements: Shippers

- Shipper must specify to carrier, in writing, all necessary sanitary requirements for the carrier’s vehicle and transportation equipment including specific design requirements and cleaning procedures (information is subject to records requirements)
Transportation Requirements: Shippers (contd)

- Before loading food not completely enclosed by a container onto a vehicle or into transportation equipment provided by a carrier, must visually inspect vehicle/equipment for cleanliness and determine it is in appropriate sanitary condition (e.g. free of visible evidence of pest infestation and of debris, pervious cargo, or dirt that could cause the food to be adulterated)
Transportation Requirements: Shippers (contd)

• Shippers of food that can support RGUM, whether TCS or non-TCS, must specify in writing to the carrier, except a carrier who transports the food in a thermally insulated tank, the temperature conditions necessary during the transportation operation, including the pre-cooling phase to ensure adequate temperature control (subject to recordkeeping requirements)
Transportation Requirements: Shippers (contd)

- Before loading food, a shipper of RGUM food must verify that each freezer and refrigerated cold storage compartment or container has been pre-cooled in accordance with information submitted by shipper to carrier.
Transportation Requirements: Shippers (contd)

- Shipper assumes the requirements applicable to the carrier with respect to demonstrating temperature control to receiver if written agreement that shipper is responsible for ensuring that food was held under acceptable temperature conditions
  - E.g. shipper may by agreement with carrier arrange to have their own temperature monitoring device placed aboard the vehicle and recover the device upon delivery of the food
Transportation Requirements: Shippers and Receivers

• Must provide vehicle operators who are expected to handle food not completely enclosed by a container during unloading and loading with convenient access to a hand washing facility

• Must carry out loading and unloading operations under conditions that prevent microbial growth for RGUM foods
Transportation Requirements: Carriers

• Must supply vehicle and transportation equipment that meets any necessary sanitary requirements specified by the shipper under the regulation and is otherwise appropriate to prevent FPDUR

• Once transportation operation is complete, must demonstrate to shipper and if requested, to the receiver, that it has maintained proper temperature conditions
  – Can be done by any appropriate means agreeable to the shipper and carrier including presenting printouts of a time/temperature recording device or a log of temperature measures taken at various times during shipment
Transportation Requirements: Carriers (contd)

• If carrier and shipper agree in writing before transportation operations that shipper is responsible for monitoring temperature conditions or otherwise ensuring that food was held under acceptable temperature conditions then above bullets do not apply; however, carrier must provide to receiver upon request

• Agreement is subject to recordkeeping requirements
Transportation Requirements:  
Carriers (contd)

• Precooling (consistent with shippers direction) of freezers and cold storage units is required before offering vehicle or equipment for transportation of RGUM foods

• Carrier offering bulk vehicle for food transportation must provide information to shipper that identifies the three previous cargoes unless otherwise agreed to in writing and adequate procedures in place (e.g. only hauls a single type of product)
  – Subject to recordkeeping requirements
Transportation Requirements: Carriers (contd)

- A carrier that offers a bulk vehicle for food transportation must provide information to the shipper that describes the most recent cleaning of the bulk vehicle unless otherwise agreed to in writing and adequate procedures in place (e.g. contractual agreement for specified cleaning intervals and methods)
  - Subject to recordkeeping requirements
Transportation Requirements: Carriers (contd)

• Carriers must develop and implement written procedures subject to the recordkeeping requirements of regulation that:
  – Specify cleaning, sanitizing (if necessary) and inspection practices
  – Describe how carrier will comply with temperature control requirements under the regulation
  – Describe how carrier will comply with requirements for use of bulk vehicles in regulation
Training Requirements

- Carriers must provide training to personnel engaged in transportation operations that provides an awareness of potential food safety problems that may occur during transportation, basic sanitary transportation practices to address those potential problems and the responsibilities of the carrier under the regulation
  - Must be provided upon hiring and as needed thereafter
Training Requirements (contd)

- Carriers must establish and maintain records documenting the training including the date and type of training and the persons trained
  - Subject to recordkeeping requirements
Recordkeeping

• Shippers must retain records that demonstrate they regularly provide information to carriers as required under regulation for a period of 12 months.

• Carriers must retain any written agreements between shipper and carrier for temperature control and required written procedures for cleaning, inspecting vehicles, temperature control and use of bulk vehicles for 12 months beyond when the agreements and written procedures are in effect.
• Carriers must retain required training records for a period of 12 months beyond when such person identified in records continues to perform the duties for which the training was provided
• All required records must be kept as original records, true copies (i.e. photocopies, scans) or electronic records which must be kept in accordance with part 11
• Offsite storage of records is permitted after 6 months following the date the record was made provided it can be retrieved within 24 hours of request for official review
• All records are subject to disclosure under part 20 (FDA FOIA rules)
Waivers

• FDA intends to separately publish waivers concurrently with the publication of the final regulation that would exempt:
  – Shippers, carriers and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments Grade “A” Milk Safety Program, only when engaged in transportation activities involving Grade A milk and milk products
Waivers (contd)

– Food establishments holding valid permits (e.g. from state agency), only when engaged in transportation operations as receivers, or as shippers or carriers in operations in which food is relinquished to consumers after transportation from the establishment

• E.g. home delivery of grocery products, restaurant takeout orders, or delivery service that is provided by common carriers
Waivers (contd)

- FDA will waive any requirement of the regulations with respect to any class of persons, vehicles, food, or nonfood products, when FDA determines that:
  - The waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health; and
  - The waiver will not be contrary to the public interest
- FDA will consider whether to waive a requirement on its own initiative or on the petition by any person who is subject to the regulation
Questions?

Thank you!

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