

FDA's Final Rule on Sanitary Transportation of Human and Animal Food

Prepared for: The Seafood Products Association

March 2017



Agenda

- How We Got Here
- Overview and Key Changes from Proposed Rule
- Scope of the Rule
- Key Definitions
- General Requirements and Requirements by Role
- Specific Scenarios
- Recordkeeping
- Compliance Dates and Enforcement
- Questions and Answers



Overview

- Objective of the rule: 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
- 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
 - Does not apply to transportation on boats or airplanes
- Key provisions address:
 - Vehicles and transportation equipment
 - Transportation operations
 - Records
 - Training
 - Waivers
- Does not address food security/food defense



Key Takeaways

- FDA does not intend for companies that follow industry best practices to significantly alter their approach to sanitary food transportation
- Lots of flexibility
 - Specific practices will vary depending on the type of food that being transported and the type of transportation equipment being used
 - Less prescriptive temperature control requirements
 - Less prescriptive requirements for bulk vehicles
 - Ability to shift responsibilities between parties



Key Changes from the Proposed Rule

- Overall the regulation is less prescriptive and more GMP-like.
- Focus is on food safety—the agency has removed references and requirements that address quality or deterioration or spoilage issues.
- Exemption for food completely enclosed by a container, unless it requires temperature control for safety
- Primary responsibility placed on the shipper to determine what is needed for food safety and then make sure the necessary controls/practices are carried out. Shippers may rely on written contractual agreements to assign some of their responsibilities to other parties.

Who is Subject to the Rule? (§ 1.904)

- Shippers, loaders, carriers, and receivers engaged in “transportation operations” whether or not the food is being offered for or enters interstate commerce
- **Shipper:** the person who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially
- **Loader:** a person that loads food onto a motor or rail vehicle during transportation operations
- **Carrier:** a person who physically moves food by rail or motor vehicle in commerce in the U.S.
- **Receiver:** any person who receives food at a point in the U.S. after transportation

- A single entity can fill multiple roles
- Entities may reassign their responsibilities to another party subject to this rule

Who is Not Subject to this Rule? (§ 1.900)

- Shippers, loaders, receivers, or carriers:
 - With less than \$500,000 in average annual revenues over a 3 year period
 - When engaged in operations of food transshipped through the United States to another country
 - When engaged in operations of food imported for future export in accordance with FFDCA § 801(d)(3) that is not consumed or distributed in the United States
 - But note that food produced in the U.S. for export is covered
 - When engaged in operations of food when it is located in a facility that is regulated exclusively throughout the entire facility by USDA
- Farms performing transportation operations

What Foods Are Not Covered? (§ 1.904)

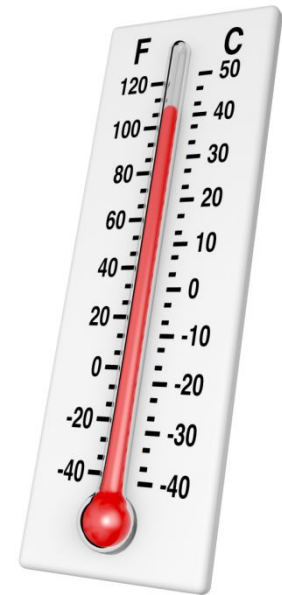
- Foods that are completely enclosed by a container (except foods that require temperature control for safety)
- Compressed food gases
- Food contact substances as defined in FFDCA § 409(h)(6)
 - Shipment and storage equipment that contacts food would be considered “transportation equipment” under the 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)
 - Human food byproducts that are used as an ingredient in manufactured food or are further processed are covered by the rule
- Live food animals (except molluscan shellfish)

General Requirements for Transportation Operations (§ 1.908(a))

- 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 and its production stage must be considered in determining the necessary conditions and controls for the transportation operation
 - e.g., animal feed, pet food, human food, raw material, ingredient, finished food

General Requirements, Continued (§ 1.908(a))

- If a shipper, loader, receiver, or carrier 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.
 - Qualified individual: “Whomever makes such a determination 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.” 81 FR at 20143.





Requirements for **Shippers** (§ 1.908(b))

- 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.
 - One-time notification is sufficient unless the requirements change
 - 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
 - Applies to all segments of a shipment's transit, no matter how many carriers
- The shipper of food that requires temperature control for safety must specify in writing to the carrier and, when necessary, the loader, an operating temperature for the transportation operation including, if necessary, the pre-cooling phase.
 - One-time notification is sufficient
 - Does not apply to a carrier who 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



Requirements for **Shippers**, Continued (§ 1.908(b))

- The shipper must develop and implement written procedures adequate to ensure that:
 1. Vehicles and equipment used in transportation operations are in appropriate sanitary condition to prevent the food from becoming unsafe during transportation
 2. A previous cargo does not make the food unsafe if food is transported in bulk 
 3. 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



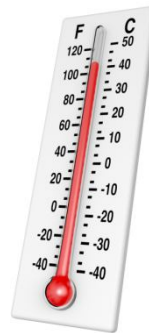
Requirements for **Loaders** (§ 1.908(c))

- Before loading food 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.



Requirements for **Loaders**, continued (§ 1.908(c))

- Before loading food that requires temperature control for safety, the loader must verify, as appropriate, 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** (§ 1.908(e))

- When the carrier and the shipper have a written agreement that the carrier is responsible, the carrier is responsible for the following as applicable per the agreement:
 - 1) Ensuring that vehicles and transportation equipment meet the shipper's specifications and are appropriate to prevent the food from becoming unsafe during transportation
 - 2) If requested by the shipper for food transported in a bulk vehicle, provide information to the shipper that identifies the previous cargo transported in the vehicle and/or the most recent cleaning of the bulk vehicle



Requirements for **Carriers**, continued (§ 1.908(e))

- 3) If requested by the receiver, providing the operating temperature specified by the shipper
- 4) If requested by the receiver or shipper, demonstrating that the carrier has maintained temperature conditions consistent with the operating temperature specified by the shipper
- 5) If requested by the shipper for food that requires temperature control for safety, pre-cool each mechanically refrigerated cold storage compartment



Requirements for Carriers, Continued (§ 1.908(e))

- 6) Develop and implement 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



Requirements for **Receivers** (§ 1.908(d))

- Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse
 - E.g., determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection (e.g., for off-odors).



Intra-Company Transportation Activities (§ 1.908(a)(5))

- Shippers, carriers, loaders, and receivers, which are under the ownership or operational control of a single legal entity can rely on compliance with common, integrated written procedures rather than develop written procedures as specified in the regulations
- Loaders, as appropriate, must continue to :
 - Determine that the vehicle and transportation equipment is in appropriate sanitary condition
 - Verify that refrigerated transportation vehicles and equipment are adequately prepared for the transportation of food that requires refrigeration for safety



Less Than Load Shipments

- Less than load shipments: 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; for example:
 - Adequate physical condition
 - Free of visible evidence of pest infestation
 - Previous cargo that could cause the food to become unsafe
- FDA expects that the shipper would generally instruct the loader on what to inspect the vehicle for



International Shipments

- The rule does not establish specific requirements for the transport of food before it reaches the U.S.
- Shipments of food destined for consumption in the U.S. remain subject to the general adulteration provisions of the statute
- The application of the rule starts at the origination of the truck or rail segment of transportation in the U.S.
 - 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.



Training Requirements for **Carriers** (§ 1.910)

- When the carrier and shipper have a written agreement that the carrier will be responsible, in whole or in part, for sanitary conditions during transportation, the carrier must provide training to personnel that covers:
 - Awareness of potential food safety problems that may occur;
 - Basic sanitary practices to address those problems
 - The responsibilities of the carrier under the rule
- Training must be provided upon hiring and as needed
- FDA expects training will take less than 1 hour and intends to provide a training course on its website



Recordkeeping Generally (§ 1.912)

- Generally records must be retained for 12 months after their use has been discontinued
- Records must be made available promptly to a duly authorized individual upon oral or written request
- Electronic records are exempt from compliance with Part 11
- Offsite storage is permitted if records can be retrieved and provided onsite within 24 hours of a request
 - Exception: 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
- Standard FOIA exemptions from disclosure apply

Records that Must Be Retained (§ 1.912)

- Shippers must retain records:
 - That demonstrate that they provide sanitary specifications for vehicles and equipment and operating temperatures to carriers
 - Of the 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
 - 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 the written procedures
- 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

Records that Must be Retained (§ 1.912)

- Carriers must retain records:
 - Of the 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 it has maintained temperature conditions
 - 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

Compliance Dates

- Large businesses: April 6, 2017 (one year)
- Small businesses: April 6, 2018 (two years)
 - A business with less than 500 full time equivalent employees
 - Determine by dividing total wage/salary hours paid to employees by 2,080
 - Motor vehicle carriers (if not also shippers and/or receivers) with less than \$27,500,000 in annual receipts



Enforcement

- Compliance encompasses all of the requirements in the regulations (including training and recordkeeping), but FDA will consider all circumstances surrounding a deviation before initiating enforcement action
- When responsibility is assigned by contract, 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 not covered by the rule, FDA will hold the party covered by the rule ultimately responsible for compliance.
- DOT has the authority to conduct inspections, but FDA will likely take lead on enforcement when violations arise

Conclusion

- This rule is not intended to require companies that have employed best practices for food transportation to significantly alter their approach
- FDA recognizes that the applicable sanitary transportation practices will vary depending on the type of food that being transported and the type of transportation equipment being used
- Although the regulation is focused only on transportation practices that could make food unsafe, the general statutory prohibitions on adulteration still apply
- Parties can shift responsibility through written agreements
- Temperature control requirements are important but flexible



Questions

