





FSMA Major Rules Series

Sanitary Transportation of Human and Animal Food Rule

Welcome and let's continue with the penultimate of our major rules factsheets under the Food Safety Modernization Act (FSMA): Rule on Sanitary Transportation of Human and Animal Food¹. This rule plays a critical role in safeguarding the transportation and security of our food supply. Let's delve into what the rule entails and why it is vital for the food industry.

Summary Requirements

The Sanitary Transportation rule under FSMA was published in the Federal Register on April 6, 2016. It became effective on June 6, 2016. However, small businesses had an additional year to comply, with the compliance date set for April 6, 2017. Given the length of time this rule has been in place, it should now be well implemented and understood. The rule itself establishes requirements for shippers, carriers and receivers who transport food by motor or rail vehicle to prevent practices that may result in food safety risks during transportation.

Key requirements²:

1 Vehicles and Transportation Equipment:

This rule mandates that vehicles and transportation equipment used for transporting food must be designed, maintained and operated to prevent contamination. This encompasses various aspects, including the construction

materials of the vehicles, the cleanliness of their surfaces and the effectiveness of sanitation procedures. For instance, tanker trucks used to transport liquid food products must be constructed of food-grade materials that are resistant to corrosion and easily sanitized. Regular cleaning and sanitization protocols must be implemented, with documented procedures to ensure compliance.

Example: a company specializes in transporting bulk liquid food products, such as vegetable oils or fruit juices. To comply with this rule, the company invests in stainless steel tanker trucks equipped with automated cleaning systems. These trucks undergo thorough cleaning and sanitization after each use, with documented records maintained to track the process. By prioritizing the hygiene and integrity of their transportation equipment, the company ensures the safe and sanitary transport of food products to their destination.

1 eCFR:21 CFR Part 1 Subpart O -- Sanitary Transportation of Human and Animal Food

2 FSMA Final Rule on Sanitary Transportation of Human and Animal Food | FDA



2 Temperature Controls:

Maintaining appropriate temperatures during transportation is critical to preventing the growth of harmful microorganisms and preserving the safety and quality of food products. This rule establishes requirements for monitoring and maintaining temperature controls throughout the transportation process, especially for perishable goods. This includes proper calibration of temperature-monitoring devices, regular checks during transit and immediate corrective action in case of deviations from the prescribed temperature ranges.

Example: a seafood distributor transports fresh fish fillets from a processing facility to retail stores. To comply with this rule, the distributor invests in refrigerated trucks equipped with state-of-the-art temperature monitoring systems. Throughout the journey, temperature sensors continuously monitor the conditions inside the truck, alerting the driver and the dispatch center in case of any fluctuations. Additionally, the truck is equipped with backup refrigeration units to ensure temperature stability even in the event of mechanical failures or power outages.

3. Cross-Contamination Prevention:

Preventing cross-contamination is paramount to ensuring the safety of food during transportation. This rule mandates measures to segregate different types of food, utilize protective barriers and prevent contact with non-food items that may pose contamination risks. This includes proper packaging, labelling and loading procedures to minimize the risk of cross-contact between allergens or pathogens.

Example: a logistics company specializes in transporting both fresh produce and packaged goods. To comply with this rule, the company implements strict protocols to prevent cross-contamination between different types of products. For example, fresh fruits and vegetables are segregated from raw meat products, with dedicated compartments and storage areas in the refrigerated trucks. Additionally, disposable protective barriers, such as plastic liners or pallet wraps, are used to create physical barriers between different types of cargo, minimizing the risk of cross-contact during transit.

4. Training and Records Keeping:

Ensuring that personnel involved in food transportation receive adequate training is essential to maintaining compliance with this rule. Training programs should cover topics such as proper handling procedures, sanitation

practices and emergency response protocols. Furthermore, records of training, written procedures and temperature monitoring must be kept for a specified period to demonstrate regulatory compliance and facilitate traceability in case of incidents or inspections.

Example: a transportation company specializes in delivering frozen food products to grocery stores and restaurants. To comply with this rule, the company provides comprehensive training to its drivers and warehouse staff on topics such as food safety regulations, proper loading and unloading procedures and emergency response protocols. Training sessions include handson demonstrations, interactive modules and regular assessments to ensure comprehension and retention of the material. Additionally, the company maintains detailed records of employee training, temperature logs and sanitation inspections, which are readily accessible for auditing purposes.

5. Waivers:

While This rule establishes strict requirements for the sanitary transportation of food, certain transportation operations may be eligible for waivers under specific circumstances. For example, the transportation of live animals or raw agricultural commodities may be granted waivers from certain requirements of the rule, provided they meet predefined criteria and pose minimal risks to food safety. However, obtaining a waiver does not exempt stakeholders from their obligation to ensure the safe and sanitary transport of food products.

Example: a family-owned farm specializes in the transportation of fresh produce to local farmers' markets. While the farm primarily transports fruits and vegetables covered by this rule, it occasionally transports live poultry for breeding purposes. To comply with regulatory requirements, the farm applies for a waiver from certain temperature control provisions of this rule for its poultry transportation operations. The waiver application includes detailed documentation of the farm's transportation practices, including biosecurity measures, ventilation systems and journey management plans, to demonstrate compliance with alternative safety measures. Upon approval of the waiver, the farm continues to uphold stringent hygiene and sanitation standards to ensure the welfare and safety of both the animals and the food products.



Summary Requirements

In essence, this Major Rule of the Food Safety Modernization Act encompasses a comprehensive framework for ensuring the safe and sanitary transportation of food products throughout the supply chain. This rule plays a pivotal role in safeguarding public health and maintaining consumer confidence in the integrity of our food system. Compliance not only mitigates the risk of foodborne illnesses but also fosters a culture of accountability, transparency and continuous improvement within the food industry.

In conclusion, the directives within the Major Rule on Sanitary Transportation of Human and Animal Food are critical to the success of FSMA and aim to further ensure the safety and security of our food even when outside the direct controls of the manufacturers or retailers.



Perigon clients can obtain funding towards RQA's services as part of a Contaminated Products Insurance policy.



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