



Sanitary Transportation Rule: A Guide for Industry

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What is the Sanitary Transportation Rule?

The Sanitary Transportation of Human and Animal Food Rule, often simply referred to as the Sanitary Transportation Rule, is enforced by the Food and Drug Administration (FDA) with the goal of protecting food during transport. This rule is one of the seven foundational rules of the FDA Food Safety Modernization Act. Contamination can occur at any point in the food supply chain, and actions must be taken to reduce these risks at all stages, including transport. Because of this, the Sanitary Transportation Rule contains transportation requirements to avoid potential food safety risks that may occur.

Why is this Rule Important?

While other guidance does exist for the transportation of specific food commodities, The Sanitary Transportation Rule provides all sectors (e.g., meat, dairy, produce) of the food industry with broadly applicable recommendations. Previously, there have been incidents of food contamination and incidents in which food could become contaminated during transport, signifying the need for implementation of this rule. Examples of key food safety events are highlighted in Figure 1.

Who is Covered?

The rule applies to shippers, receivers, loaders, and carriers who transport food in or to the United States by motor or rail vehicle (train cars, including boxcar, coil, flatcar, gondola, hopper, refrigerator, specialty, tanker, or others as appropriate). However, there are some exceptions and waivers to the rule. Refer to the FSMA FDA Final Rule on Sanitary Transportation of Human and Animal Food for more information.

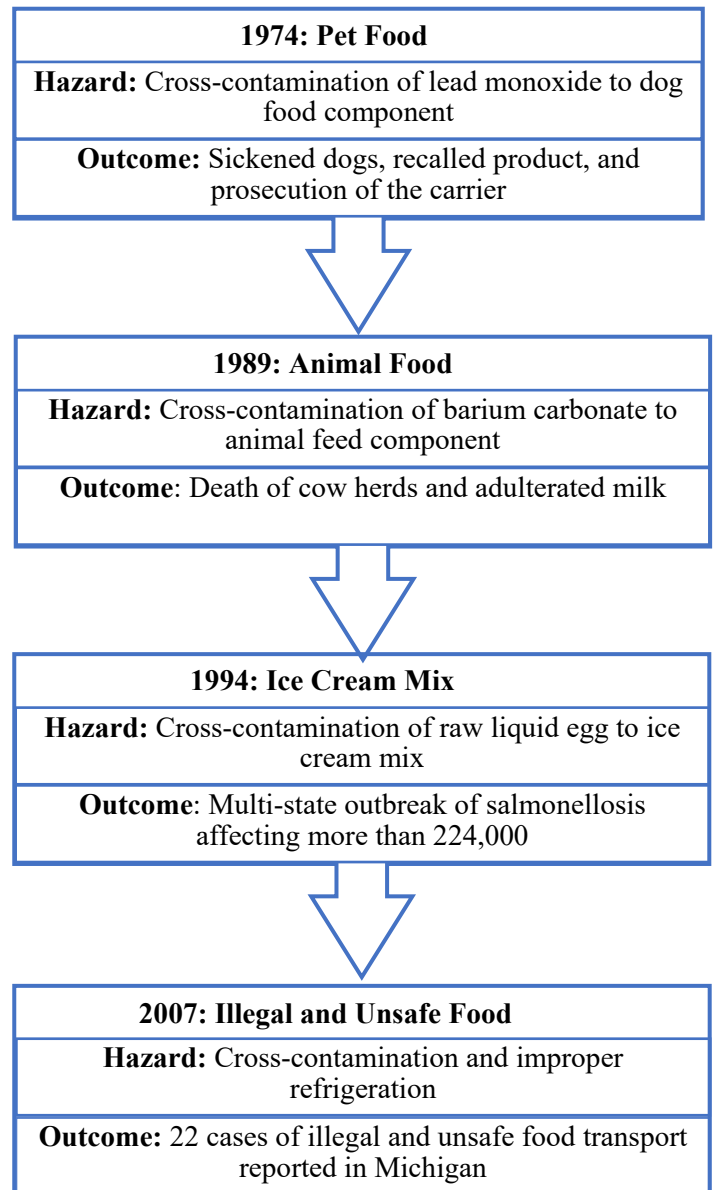


Figure 1. Examples of historical transportation of human and animal food safety incidents.

What Food is Covered?

Food and animal food are covered by this requirement. Food at all production stages, raw materials, ingredients, and finished food, for human or animal consumption may be covered. For example, foods that require temperature control for safety, bulk food products, and/or food not fully enclosed in a container are covered under this rule. Animal food specifically includes pet food, animal feed, raw materials, and ingredients intended for animal consumption. However, select foods are exempt from this rule, such as foods fully enclosed in a container that does not require temperature control. Certain foods may be easily identified as covered, while others may not be.

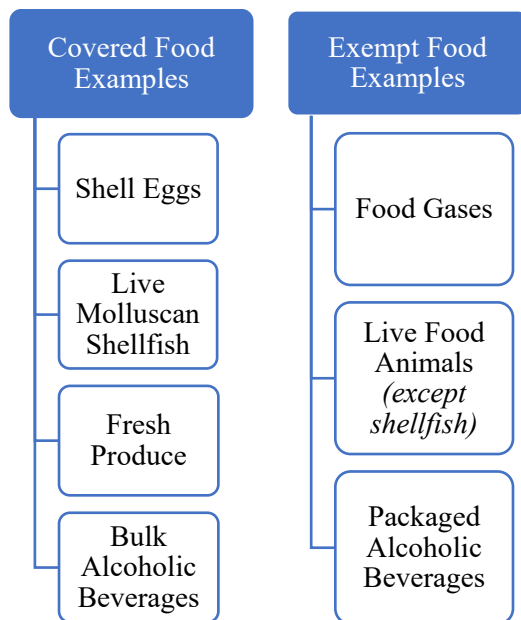


Figure 2. Examples of foods covered by or exempt from the Sanitary Transportation of Human and Animal Food Rule.

Key Rule Requirements

For shippers, receivers, etc. that handle covered foods, the requirements of the rule focus on four main areas:

- Vehicles and Transportation Equipment
- Transportation Operations
- Training
- Records

Vehicles and Transportation Equipment

The vehicle and transportation equipment's design and maintenance must not cause the food to become unsafe during transport. Examples of how this requirement

could be carried out include the vehicle design must be adequately cleanable, temperature-controlled products must have adequate temperature control, and pest prevention during vehicle storage.

Transportation Operations

During transportation, actions need to be taken to ensure safe food transport. This includes but is not limited to preventing cross-contamination between ready-to-eat and raw foods, foods and their environment, cross-contact of food allergens, and any other contamination that may occur.

Training

Carrier training is required for all personnel involved in transportation operations when the carrier is responsible for the sanitary conditions of the load (such as maintaining temperature control when shipping refrigerated or frozen foods). Carriers and shippers should discuss responsibility designations before transporting.

Records

Written procedures, agreements, and training must be kept for the required time. Required times vary based on the record; however, the mandatory time does not exceed 12 months. Shippers, receivers, loaders, and carriers have different record requirements, as discussed in both the Small Entity Compliance Guide: What You Need to Know About Establishment and Maintenance of Records and the Code of Federal Regulations (CFR) Title 21 Part 1 Subpart O.

Potential Problem Areas

The FDA has identified several problem areas where contamination during food transport is likely to occur. Examples include:

- Improper refrigeration or temperature control
- Improper packing of transportation units
- Improper loading and unloading practices, conditions, or equipment
- Lack of training

An extensive list of problem areas can be found in the FDA's Guidance for the Industry: Sanitary Transportation of Food. Reviewing this list along with rule requirements can help you identify problem areas in your transportation operation to concentrate your food safety efforts.

How to Meet the Rule's Requirements?

Before proceeding, review the exclusions, exemptions, and waivers to confirm you are covered by this rule. In addition, identify your role(s) in the transportation chain (e.g., shippers, receivers, loaders) and the corresponding requirements in more detail using the resources provided. There are several FDA-recommended resources available to the industry to ensure compliance with the regulations, such as:

- Contact FSMA Technical Assistance Network (TAN)
- Review FDA Guidance for Industry: Sanitary Transportation of Food
- Take the FDA Online Food Safety for Carriers Training

The Virginia Department of Agriculture and Consumer Services (VDACS) has multiple programs that can assist as well.

- Dairy Services: dairyservices@vdacs.virginia.gov
- Food Safety Program: foodsafety@vdacs.virginia.gov
- Produce Safety: produce.safety@vdacs.virginia.gov

References and Resources

Food and Drug Administration. (2018). FSMA Final Rule on Sanitary Transportation of Human Food and Animal Food. Available at:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-sanitary-transportation-human-and-animal-food>

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Food and Drug Administration. (2017). Training for Carriers Covered by the Sanitary Transportation of Human and Animal Food Rule. Available at:

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2025

FST-477NP(FST-505NP)