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### FSMA Sanitary Transportation Rule: A Guide for Industry

Authored by Alyssa Rosenbaum, Graduate Student, Department of Food Science and Technology, Virginia Tech; Christy Brennan, Virginia Rapid Response Team Coordinator, Virginia Department of Agriculture and Consumer Services; Alexis Hamilton, Assistant Professor and Extension Specialist, Food Science and Technology; and Laura K. Strawn, Associate Professor and Extension Specialist, Food Science and Technology, Virginia Tech

#### 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 implemented to mitigate 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 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 such food safety events are highlighted in Figure 1 to the right.

#### 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. 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 is covered?

As stated in the rule title 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 is covered. 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**

The rule focuses on requirements in 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. For example, the vehicle design must be adequately cleanable, temperaturecontrolled 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-contact between readyto-eat and raw foods, foods and their environment, 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. 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 time never exceeds 12 months. Shippers, receivers, loaders, and carriers have different record requirements.

#### **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 and ways to address these problems can be found in the <u>FDA's</u> <u>Guidance for the Industry: Sanitary Transportation</u> <u>of Food.</u>

# How to meet the rule's requirements?

There are several recommended resources available to the industry to ensure compliance with the regulations, such as:

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

#### **References and Resources**

- Food and Drug Administration. (2022). FSMA Technical Assistance Network (TAN). Available at: <u>https://www.fda.gov/food/food-safety-</u><u>modernization-act-fsma/fsma-technical-</u><u>assistance-network-tan</u>
- Food and Drug Administration. (2018). FSMA Final Rule on Sanitary Transportation of Human Food. Available at: <u>https://www.fda.gov/food/food-</u> <u>safety-modernization-act-fsma/fsma-final-rule-</u> <u>sanitary-transportation-human-and-animal-food</u>
- Food and Drug Administration. (2017). Small Entity Compliance Guide: Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation. Available at: <u>https://www.fda.gov/regulatory-</u> <u>information/search-fda-guidance-</u> <u>documents/small-entity-compliance-guide-</u> <u>sanitary-transportation-human-and-animal-food-</u> <u>what-you-need-know-about</u>
- Food and Drug Administration. (2017). Training for Carriers Covered by the Sanitary Transportation of Human and Animal Food Rule. Available at: <u>https://www.fda.gov/food/food-safety-</u> <u>modernization-act-fsma/training-carriers-</u> <u>covered-sanitary-transportation-human-and-</u> <u>animal-food-rule</u>
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