



FDA FINAL RULEMAKING ON THE SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD

I. Introduction

As part of the Food Safety Modernization Act (FSMA), signed into law January 2011, the Food and Drug Administration (FDA) has published a final rule on section 111 - the sanitary transportation of human and animal food. According to FDA, “the goal of the rule is to ensure that transportation practices do not create safety risks”. FDA hopes to address three areas: 1) ensuring food is properly refrigerated, 2) vehicles and equipment are properly cleaned and sanitized, and 3) ensuring food is properly protected during transportation. The rule is based on the Sanitary Transportation of Food Act of 2005 and current best industry practices. Significant changes were made from the proposed rule offering more flexibility to carriers and shippers to set industry specific guidelines, minimizing burdensome requirements. The rule goes into effect on June 5, 2016 with compliance beginning one year later. Small businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and having less than \$27.5 million in annual receipts would have to comply within two years after the final rule goes into effect.

II. Background

The FSMA was enacted into law after several food borne related outbreaks, including salmonella and E. coli, were reported across the U.S. Many of these outbreaks have been traced back to the handling, processing and manufacturing of the food. Due to this recent history, the majority of the FSMA was directed at those sections of the food supply chain, and the sanitary transport of food section simply closes loopholes within that supply chain.

III. Cost/Benefit

The new rule estimates it will cover 83,609 firms, including carriers engaged in transporting food and food facilities that ship food. Total first year cost is estimated to be \$162.7 million, and total annual cost is estimated at \$93.5 million. Unfortunately, FDA “lacks the sufficient data to quantify the potential benefits of the proposed rule”. They further explain that there is not sufficient data to quantify the likelihood of food becoming adulterated during its transport.

IV. Established Requirements

The rule defines transportation as “any movement of food in commerce by motor vehicle or rail vehicle”. The rule will establish requirements for sanitary transportation for shippers, loaders, carriers, and receivers engaged in food transport operations. Specifically the rule establishes requirements for:

- Vehicles and transportation equipment - The design and maintenance of vehicles and transportation equipment to ensure that they do not cause the food that they transport to become contaminated.
- Transportation operations - The measures taken during transportation to ensure food is not contaminated, such as adequate temperature controls and separation of food from non-food items in the same load. Packaging may constitute separation.
- Information exchange - Procedures for exchange of information about prior cargos, cleaning of transportation equipment and temperature control between the shipper, carrier, and receiver, as appropriate to the situation. For example, a carrier transporting bulk liquid non-dairy foods would want to ensure that vehicles that have previously hauled milk will not introduce allergens into non-dairy foods through cross contact.
- Training - Training of carrier personnel in sanitary transportation practices and documentation of the training.
- Records - Maintenance of written procedures and records by carriers, loaders, and shippers related to transportation equipment cleaning, prior cargos, and temperature control, when contractually required.
- Waivers - Procedures by which the FDA will waive any of these requirements if it determines that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and that it is in the public interest.

V. Exemptions

- Transportation of food that is completely enclosed by a container, except food that requires temperature control for safety;
- Shippers, loaders, receivers, or carriers with less than \$500,000 in total annual revenue;
- Transportation activities performed by a farm;
- Food transshipped through the United States to another country; food imported for future export that is not consumed or distributed in the United States;
- Transportation of compressed food gases; and
- Transportation of live food animals.

AFTC, in collaboration with its food safety subcommittee, filed comprehensive comments on July 30, 2014. This white paper is to provide an overview of the STF rule. For further information please read the [STF overview document](#) or feel free to contact AFTC Executive Director Jon Samson: jsamson@trucking.org.