

FSMA Facts

Proposed Rule on Sanitary Transportation of Human and Animal Food

Summary

The FDA's proposed rule would require those who transport food to use sanitary transportation practices to ensure the safety of food.

The proposed rule, which is required by the FDA Food Safety Modernization Act (FSMA), would help maintain the safety of both human and animal food during transportation by establishing criteria, e.g., conditions and practices, training and record keeping, for the sanitary transportation of food.

The FDA is proposing that the requirements be effective 60 days after the final rule is published in the Federal Register. Recognizing that small businesses may need more time to comply with the requirements, the FDA is proposing tiered compliance dates based on business size. The proposed rule displayed on Jan. 31, 2014, and comments are due by May 31, 2014.

Background

FSMA was signed into law on Jan. 4, 2011, to better protect human and animal health by helping to ensure the safety and security of the food and feed supply. FSMA embraces preventing food safety problems as the foundation of a modern food safety system and recognizes the need for a global approach to food and feed safety. The FDA has proposed six additional rules that are foundational to this preventive approach encompassed by FSMA. In addition to the rule on sanitary transportation, the FDA has proposed: (1) preventive controls requirements for human food, (2) preventive controls requirements for animal food, (3) standards for produce safety, (4) a Foreign Supplier Verification Program for importers, which requires importers to take steps to help ensure that imported human and animal food is as safe as that which is produced domestically, (5) a program for the accreditation of third-party auditors, also known as certification bodies, to conduct food safety audits and issue

certifications of foreign facilities and the foods they produce for humans and animals, and (6) and focused mitigation strategies to prevent intentional adulteration aimed at causing large-scale public health harm.

The goal of the proposed rule on the sanitary transportation of human and animal food is to prevent practices that create food safety risks, such as failure to properly refrigerate food, inadequate cleaning of vehicles between loads, and failure to properly protect food during transportation. The proposed rule addresses the sanitary transportation of both human and animal food traveling via motor or rail vehicle by establishing criteria for the safe transportation of food. Specifically, the proposed rule would establish requirements for: vehicles and transportation equipment, transportation operations, information exchange, training, records, and waivers.

Who is Covered?

With some exceptions, this proposed rule would apply to shippers, receivers, and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. It would also apply to a person outside of the United States, such as an exporter, who ships food to the United States in an international freight container by oceangoing vessel or in an air freight container, and arranges for the transfer of the intact container in the United States onto a motor vehicle or rail vehicle for transportation in U.S. commerce, if that food will be consumed or distributed in the United States. The FDA would consider this person to be a shipper under this proposed rule because the person would be initiating a shipment of food by motor vehicle or rail vehicle, even if doing so from abroad, that would be entering U.S. commerce.

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Highlights of the Proposed Rule

Specifically, the proposed rule would establish requirements for:

- **Vehicles and transportation equipment:** The design and maintenance of vehicles and transportation equipment to ensure that it does not cause the food that it transports 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.
- **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 and shippers related to transportation equipment cleaning, prior cargos, and temperature control.
- **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.

Effective and Compliance Dates and Definitions for Small Businesses

The FDA is proposing the effective date for businesses subject to the new requirements to be 60 days after the final rule is published. Recognizing that small

businesses may need more time to comply with the requirements, the compliance dates are adjusted accordingly.

Compliance Dates:

- **Small Businesses**—businesses other than motor carriers who are not also shippers and/or receivers employing fewer than 500 persons and motor carriers having less than \$25.5 million in annual receipts would have to comply two years after the publication of the final rule.
- **Other Businesses**—a business that is not small and is not otherwise excluded from coverage would have to comply one year after the publication of the final rule.

Economic Impact of the Proposed Rule

Improving food transportation systems could reduce the likelihood of conditions during transportation that can lead to human or animal illness or injury or product recalls and reduce the losses of contaminated human and animal food and feed ingredients and products. This proposed rule is estimated to cover 83,609 businesses. This number includes carriers engaged in food transportation and facilities that ship food subject to this proposed rule. The total first-year cost is estimated to be \$149.1 million (with an average of \$1,784 per business), and the total annual cost is estimated to be \$30.08 million (with an average of \$360 per business).

Rulemaking Process and How to Submit Comments

The proposed rule, “Sanitary Transportation of Human and Animal Food,” is published in the Federal Register so that the public can review it and submit comments. The FDA considers comments received during the comment period on the proposed rule and then considers revising the rule, based on its review of the comments, before issuing a final rule. The proposed rule and supporting documents are filed in the

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FDA's official docket on <http://www.regulations.gov> and also can be accessed at www.fda.gov/fsma.

The FDA will hold public meetings on this proposed rule and will conduct additional outreach during the comment period.

For Additional Information

- [FDA Food Safety Modernization Act website](#)
- The Food Safety Law and the Rulemaking Process: [Putting FSMA to Work](#)
- Video: [The Rulemaking Process: A Primer by FDA](#)
- Video: [FDA Food Safety Modernization Act: A Primer by FDA](#)

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Exemptions and Modified Requirements for Sanitary Transportation of Human and Animal Food*

Excluded or exempted from coverage
Shippers, receivers, or carriers engaged in food transportation operations that have less than \$500,000 in total annual sales
Transportation activities for raw agricultural commodities performed by a farm
Food that is transshipped through the United States to another country
Food that is imported for future export and that is neither consumed or distributed in the United States
Transportation of shelf stable food that is completely enclosed by a container
Transportation of compressed food gases
Transportation of live food animals

*This chart does not contain all of the information necessary to determine the proposed requirements for compliance in a particular circumstance. Consult the proposed rule for specific requirements.