

FDA ISSUES NEW REGULATIONS FOR FOOD SHIPPING AND TRANSPORT

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On April 5, 2016, the U.S. Food and Drug Administration (FDA)¹ announced final promulgation and issuance of a new food safety rule under the FDA Food Safety Modernization Act (FSMA)² that governs transportation of food. The new rule on **Sanitary Transportation of Human and Animal Food**, which goes into effect either one or two years following official publication depending on the size of the regulated business,³ will require those involved in transporting human and animal food by motor or rail vehicle to follow recognized best practices for sanitary transportation, such as properly refrigerating food, adequately cleaning vehicles between loads and properly protecting food during transportation.⁴

¹ The FDA, an agency within the U.S. Department of Health and Human Services, is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, tobacco products and products that give off electronic radiation.

² The FDA Food Safety Modernization Act, Pub. Law 111-353, amended the Federal Food, Drug and Cosmetic Act (FD&C Act) and created new statutory authority, codified as 21 U.S.C. §§301 *et seq.* Signed into law by President Obama on January 4, 2011, FSMA's purpose is to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. FDA's promulgation of the new Sanitary Transportation of Human and Animal Food rule is part of a larger effort to focus on prevention of food safety problems throughout the food chain. The new transportation rule implements the Sanitary Food Transportation Act of 2005 (SFTA) as well as the requirement in section 111 of FSMA that instructed FDA to issue SFTA regulations.

³ Technically, the new rule's effective date is June 6, 2016. However, recognizing that businesses, especially smaller businesses, may need more time to comply with the requirements, the FDA has established a two-tier timeline for compliance with the new Sanitary Transportation of Human and Animal Food rule. **Small Businesses**, defined as businesses other than motor carriers that are not also shippers and/or receivers that employ fewer than 500 persons, as well as motor carriers having less than \$27.5 million in annual receipts, would have to comply two years after the publication of the final rule. **All other businesses**, *i.e.*, any 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.

⁴ FDA originally included the definition of the term "food" in the proposed rule just as the term is defined in section 201(f) of the FD&C Act; that definition is codified as 21 U.S.C. 321(f). The agency ultimately deleted this definition from its final version of the new rule because § 1.904 of the rule states that "[t]he definitions and interpretations of terms in section 201 of the [FD&C Act] are applicable to such terms when used" in this rule." See ¶7 ("Food"), "Notice of Final Rule, Sanitary Transportation of Human and Animal Food," *Federal Register Notice*, 81 F.R. 20091 (April 6, 2016); this notice is accessible online via the Office of the Federal Register's Website at: <https://www.federalregister.gov/articles/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food#h-56> (last visited on April 7, 2016).

The new regulation generally applies to food transported within the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce. Shippers, loaders, carriers and receivers engaged in transportation operations of food imported by motor or rail vehicle and consumed or distributed in the United States also are subject to the final rule, unless exempted.

Core Requirements of the New Food Transport Rule

The 283-page Sanitary Transportation of Human and Animal Food rule has fashioned a broad array of regulatory requirements based on food industry members' best practices. The new requirements range from formalizing quality assurance operations and complying with detailed guidelines for refrigerating and transporting food, to record-keeping and reporting obligations intended to assure both compliance and traceability. FDA has enumerated four key requirements of the new rule:

1. **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 unsafe. For example, they must be suitable and adequately cleanable for their intended use and capable of maintaining temperatures necessary for the safe transport of food.
2. **Transportation operations:** The measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready to eat food from touching raw food, protection of food from contamination by non-food items in the same load or previous load, and protection of food from cross-contact, *i.e.*, the unintentional incorporation of a food allergen.
3. **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training. This training is required when the carrier and shipper agree that the carrier is responsible for sanitary conditions during transport.
4. **Records:** Maintenance of records of written procedures, agreements and training (required of carriers). The required retention time for these records depends upon the type of record and when the covered activity occurred, but does not exceed 12 months.⁵

The FDA's new rule is part of a larger effort to focus on prevention of food safety problems throughout the food chain, and implements the Sanitary Food Transportation Act of 2005 (SFTA) as well as the requirement in section 111 of FSMA that instructed FDA to issue SFTA regulations.

⁵ FDA Fact Sheet, "*FSMA Final Rule on Sanitary Transportation of Human and Animal Food*;" this guidance is accessible online via the FDA's Website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm383763.htm> (last visited on April 7, 2016).

Who Is, and Is Not, Covered By the New Rule

The Sanitary Transportation of Human and Animal Food rule applies broadly⁶ to shippers, receivers, loaders 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 also applies to shippers in other countries who transport food to the United States directly by motor or rail vehicle (from Canada or Mexico), or by ship or air, and arrange for the transfer of the intact container onto a motor or rail vehicle for transportation within the United States, if that food will be consumed or distributed in the United States.⁷ Also, companies involved in the transportation of food intended for export are covered by the rule until the shipment reaches a port or U.S. border. The rule does not apply to exporters who ship food through the United States (for example, from Canada to Mexico) by motor or rail vehicle if the food does not enter U.S. distribution.

While the new rule has broad application, there are key exemptions. The following businesses and activities are exempt from compliance:

- Shippers, receivers, or carriers engaged in food transportation operations that have less than \$500,000 in average annual revenue;
- Transportation activities performed by a farm;
- Transportation of food that is transshipped through the United States to another country;
- Transportation of food that is imported for future export and that is neither consumed or distributed in the United States;
- Transportation of compressed food gases, *e.g.*, carbon dioxide, nitrogen or oxygen authorized for use in food and beverage products, as well as food contact substances;
- Transportation of human food byproducts transported for use as animal food without further processing;
- Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety; and
- Transportation of live food animals, except molluscan shellfish.⁸

⁶ For example, the new rule clarifies that freight brokers who arrange for the transportation of food in the United States by a carrier or multiple carriers are included within the FDA's definition of "shippers" and must comply with the rule's requirements. See ¶17 ("Shipper"), "Notice of Final Rule, Sanitary Transportation of Human and Animal Food," *Federal Register Notice*, 81 F.R. 20091 (April 6, 2016); this notice is accessible online via the Office of the Federal Register's Website at: <https://www.federalregister.gov/articles/2016/04/06/2016-07330/sanitary-transportation-of-human-and-animal-food#h-56> (last visited on April 7, 2016).

⁷ The new rule does not apply to exporters who ship food through the United States, *e.g.*, from Canada to Mexico, by motor or rail vehicle if the food does not enter U.S. distribution.

⁸ During the notice and comment period for the new rule, FDA also acknowledged that it lacks jurisdiction for meat, poultry, and egg product activities that occur within meat, poultry, and egg product processing facilities regulated exclusively by U.S. Department of Agriculture (USDA). FDA consulted with USDA and modified § 1.900(b) of the new rule by adding a third category of persons exempt from the requirements. In the final rule, § 1.900(b)(3) excludes shippers, loaders, receivers, or carriers when they are engaged in transportation operations of food while the food is located in food facilities that are regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture. However, there are dual jurisdiction establishments that prepare, pack, hold, or otherwise handle both foods regulated by USDA and foods regulated by FDA. In the case of dual jurisdiction establishments, FDA would inspect in accordance with its existing Memorandum of Understanding (MOU) with USDA. See Memorandum of understanding between The Food Safety and inspection Service of the United States Department of Agriculture and the Food And Drug Administration United States Department of Health and Human Services, MOU #225-00-2000; this MOU is accessible online via the USDA's Website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Ingredients-Guidance/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbwMDIHQ08842MTDy8_YwMhYvyD

Moving to Completion of the Major 7

With the final issuance of its Sanitary Transportation of Human and Animal Food rule, the FDA has now promulgated six of the seven major rules that implement the core of FSMA. This latest regulation builds on the **Preventive Controls for Human Food** rule,⁹ the **Preventive Controls for Animal Food** rule,¹⁰ the **Produce Safety** rule (which includes standards for the growing, harvesting, packing and holding of produce for human consumption),¹¹ the **Foreign Supplier Verification Programs** rule,¹² and the **Accreditation of Third-Party Certification** rule,¹³ all of which FDA finalized in 2015. The seventh rule, which focuses on mitigation strategies to protect food against intentional adulteration, is expected to be finalized later in 2016.¹⁴

The FDA will be hosting a one-hour Webinar to explain the new Rule on Sanitary Transportation of Human and Animal Food. Open to the public, the Webinar will be held on April 25, 2016, beginning at 11:00 am Eastern time. Access information is as follows:

Dial: 888-946-8408, passcode: FSMA
International: 1-773-756-4630

To view the slide presentation during the webinar, go
to <https://www.mymeetings.com/nc/join.php?i=PW7654409&p=FSMA&t=c>.

If you have questions regarding the new final rule on Sanitary Transportation of Human and Animal Food, or would like assistance in complying with federal regulations governing the food and beverage industries, please contact [GrayRobinson's Food Law Group](#):

866-382-5132
<http://www.gray-robinson.com/food-law-practice>

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⁹ See FSMA Final Rule for Preventive Controls for Human Food, accessible online via the FDA's Website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm> (last visited on April 7, 2016).

¹⁰ See FSMA Final Rule for Preventive Controls for Animal Food, accessible online via the FDA's Website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm> (last visited on April 7, 2016).

¹¹ See FSMA Final Rule on Produce Safety, accessible online via the FDA's Website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm> (last visited on April 7, 2016).

¹² See FSMA Final Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, accessible online via the FDA's Website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm> (last visited on April 7, 2016).

¹³ See FSMA Final Rule on Accredited Third-Party Certification, accessible online via the FDA's Website at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361903.htm> (last visited on April 7, 2016).

¹⁴ See FSMA Proposed Rule for Focused Mitigation Strategies to Protect Food Against Intentional Adulteration, accessible online via the FDA's Website at: <http://www.fda.gov/food/guidanceregulation/fsma/ucm378628.htm> (last visited on April 7, 2016).