

FDA'S NEW REGULATIONS FOR FOOD TRANSPORT EXCLUDE ALCOHOL BEVERAGES

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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, 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.³

Most noteworthy to the alcohol beverage industry, the new rule does NOT apply to the transportation of food fully enclosed by a container that does not require temperature control to prevent it from becoming unsafe. According to the FDA, this provision essentially excludes packaged alcohol beverage products from coverage under the new food transportation rule.

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 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).

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.⁴

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. The new rule becomes effective in June of 2016, although its implementation is staggered in terms of compliance requirements depending on the status of the food industry member.⁵

⁴ 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).

⁵ 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.

Packaged Alcohol Beverages Are NOT Covered By the New Rule

The Sanitary Transportation of Human and Animal Food rule applies broadly 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. However, during the public notice and comment period associated with the drafting of the rule, several public comments questioned whether such a rule should, or even could, apply to alcohol beverages, which the federal government regulates primarily through the U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB).

Several public comments asked FDA to amend its draft rule to clarify that under section 116(a) of the FSMA, a facility engaged in the manufacturing, processing, packing, or holding of alcohol beverage products is exempt from such rulemaking.⁶ The comments also argued that FDA should exempt the transport of all bulk or packaged beverage alcohol products from its proposed food transportation rule, including the transport of ingredients and the co-products or by-products used to manufacture alcohol beverages.⁷

The language of section 116 of FSMA specifies which sections of the statute apply to a facility engaged in the manufacturing, processing, packing, or holding of one or more alcohol beverage products:

SEC. 116. ALCOHOL-RELATED FACILITIES.

- (a) In General.--Except as provided by sections 102, 206, 207, 302, 304, 402, 403, and 404 of this Act, and the amendments made by such sections, nothing in this Act, or the amendments made by this Act, shall be construed to apply to a facility that--
 - (1) under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.) is required to obtain a permit or to register with the Secretary of the Treasury as a condition of doing business in the United States; and
 - (2) under section 415 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d) is required to register as a facility because such facility is engaged in manufacturing, processing, packing, or holding 1 or more alcoholic beverages, with respect to the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages.
- (b) Limited Receipt and Distribution of Non-alcohol Food. --Subsection (a) shall not apply to a facility

⁶ See, e.g., Joint Letter From National Beer Wholesalers Association (NBWA) and Wine and Spirits Wholesalers of America (WSWA) dated July 30, 2014 and submitted as public comment to Docket No. FDA-2013-N-0013/RIN 0910-AG98: Proposed Rule Regarding Sanitary Transportation of Human and Animal Food (NBWA-WSWA Joint Letter).

⁷ *Id.* at n. 2 and accompanying text. The commentators argued that “Congress intended to exempt certain alcohol-related facilities from section 418 of the [Food, Drug & Cosmetic] Act because it found that, in light of the relatively low public health risk presented by the manufacturing, processing, packing, and holding of alcoholic beverages and their joint regulation by both FDA and TTB, the current regulatory scheme was sufficient to control the hazards associated with the manufacturing, processing, packing, and holding of alcoholic beverages.” Referenced content is accessible online at <https://www.federalregister.gov/articles/2013/01/16/2013-00125/current-good-manufacturing-practice-and-hazardanalysis-and-risk-based-preventive-controls-for-human>.

engaged in the receipt and distribution of any non-alcohol food, except that such paragraph shall apply to a facility described in such paragraph [[Page 124 STAT. 3923]] that receives and distributes non-alcohol food, provided such food is received and distributed--

- (1) in a prepackaged form that prevents any direct human contact with such food; and
- (2) in amounts that constitute not more than 5 percent of the overall sales of such facility, as determined by the Secretary of the Treasury.

(c) Rule of Construction.--Except as provided in subsections (a) and (b), this section shall not be construed to exempt any food, other than alcoholic beverages, as defined in section 214 of the Federal Alcohol Administration Act (27 U.S.C. 214), from the requirements of this Act (including the amendments made by this Act).⁸

Commentators noted that unless a rule falls under Sections 102, 206, 207, 302, 304, 402, 403 or 404 of FSMA, Congress does not intend for it to apply to a facility engaged in manufacturing, processing, packing, or holding beverage alcohol products.⁹

Additional public comments further asserted that because section 111(a) of the FSMA (which directs FDA to issue food safety rules) is not one of the listed sections.¹⁰ The commentators reasoned that a facility exempt under section 116 also should be exempt from the sanitary food transportation rule.¹¹

Finally, a number of public comments noted that FDA should exempt the transport of alcohol beverage products, as well as any oversight of their production facilities, from the proposed food transportation rule to avoid intrusion into TTB's jurisdiction.¹² Commentators argued that extending the new food transportation rule's reach to alcohol beverages would produce a prohibited intrusion, and result in duplicative regulatory schemes implemented by both FDA and TTB.¹³ Overlap arises from existing TTB regulations relating to transportation of alcohol beverages.¹⁴

⁸ 21 U.S.C. 2206.

⁹ NBWA-WSWA Joint Letter at p. 2.

¹⁰ See, e.g., Letter From Beer institute (BI) dated July 30, 2014 and submitted as public comment to Docket No. FDA-2013-N-0013/RIN 0910-AG98: Proposed Rule Regarding Sanitary Transportation of Human and Animal Food (BI Letter).

¹¹ *Id.* at p. 2.

¹² 21 U.S.C. §2251(2) provides that nothing in the FSMA should be construed to "alter the jurisdiction between the Alcohol Tax and Trade bureau and the Secretary of Health and Human Services, under applicable statutes and regulations."

¹³ See, e.g., BI Letter at pp. 2-3.

¹⁴ See, e.g., 27 U.S.C. §203 (requiring any manufacturer, importer or distributor of alcohol beverages to obtain a permit under the Federal Alcohol Administration Act as a prerequisite to transporting alcohol beverages in interstate commerce). Also, commentators referenced the in-bond restrictions imposed by relevant tax regulations on transporting alcohol beverages as further evidence of existing regulations. See, e.g., Joint Letter From Beverage Alcohol Coalition dated July 30, 2014 and submitted as public comment to Docket No. FDA-2013-N-0013/RIN 0910-AG98: Proposed Rule Regarding Sanitary Transportation of Human and Animal Food at p. 3. The Beverage Alcohol Coalition members included: The Distilled Spirits Council of the United States; the National Association of

FDA responded to these public comments by noting that FSMA contains no language indicating that transportation operations for alcohol beverages should be exempt from the requirements of its proposed food transportation rule.¹⁵ Section 111(a) of the FSMA creates a deadline for the implementation of the 2005 SFTA final rule, and nothing in the FSMA otherwise addresses the 2005 SFTA. Consequently, FDA concluded that transportation operations for alcohol beverage products can be covered by a food safety rule focused on transportation.¹⁶ In responding to public comments, FDA also took the position that it was not aware of TTB regulatory requirements that would duplicate the requirements of this rule.¹⁷

Nevertheless, the FDA's final version of the new Sanitary Transportation of Human and Animal Food rule, as provided under the revised definition of "transportation operations" in § 1.904, does not apply to the transportation of food fully enclosed by a container that does not require temperature control to prevent it from becoming unsafe.¹⁸ According to the FDA, "[t]his provision essentially excludes packaged alcohol beverage products from coverage under this rule."¹⁹

Alcohol Beverage Manufacturing Byproducts MAY Be Covered By the New Rule

While packaged alcohol beverage products are exempt from compliance with the new Sanitary Transportation of Human and Animal Food rule, the field is not so clear for byproducts of the manufacturing processes used to create alcohol beverages. During the new rule's drafting process, FDA received public comments requesting that shippers and carriers who transport byproducts from an alcohol beverage processing facility, e.g., spent grain from brewery, be excluded from the rule.²⁰ Many industries have developed sustainable and cost-effective ways to use these byproducts as animal feed, and industry members were concerned that the new

Beverage Importers; The Presidents' Forum of the Distilled Spirits Industry; Wine America; The Wine Institute; and The Brewers Association.

¹⁵ See Section IV, Comment §14, "Notice of Final Rule, Sanitary Transportation of Human and Animal Food," *Federal Register Notice*, 81 F.R. 20100 (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).

¹⁶ See Section IV, Response §14, "Notice of Final Rule, Sanitary Transportation of Human and Animal Food," *Federal Register Notice*, 81 F.R. 20100 (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).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ See Section IV, Comment §75, "Notice of Final Rule, Sanitary Transportation of Human and Animal Food," *Federal Register Notice*, 81 F.R. 20124 (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).

recordkeeping and inspection requirements proposed by FDA's food transportation rule would hinder a beneficial practice that has worked successfully for many years.²¹

FDA partially accommodated this request in its final rule by excluding from the definition of transportation operations "human food byproducts transported for use as animal food without further processing."²² FDA has gone on record stating that the language of the final rule is intended to exclude from the definition of "human food" those byproducts that are not further processed into a manufactured animal feed.²³ According to the agency:

Most commonly, we expect that these byproducts move directly from the human food manufacturer to the farm, where they are fed directly to livestock, often by spreading on the ground. We do not intend to exclude from the definition of transportation operations human food byproducts that are transported to a business to be used as an ingredient in a manufactured animal food, or to be further processed in some way (e.g., rendered) in the production of animal feed. We believe the scale of the public health risk posed by the former activity to be minimal, with the byproducts being transported to only one or several farms, while the scale of the public health risk posed by the latter would be substantially greater, with the byproducts being manufactured into large quantities of animal feed, possibly with a wide distribution. Our concern here is primarily with the potential for chemical contamination, as we are aware that many of the byproducts will be heat treated (e.g., rendered) in a way that will minimize the risk of microbiological contamination.²⁴

Thus, brewers who supply spent grains to local farmers for soil enhancement are not covered by the new food transportation rule.

However, if the same brewer furnishes spent grains to local farmers in order to supplement animal feed, then the transportation of those grains would be covered by the new rule. With respect to transportation of human food byproducts for further processing into animal feed, the FDA declined to exclude such operations.²⁵ According to the agency, the final rule's

²¹ See, e.g., Comment from Jennifer Smith, Brewers Association, posted April 23, 2014, FDA-2013-N-0013-0008 (RIN 0910-AG98) ("[M]y family us spent grain from The Lumbearyard Brewery in Flagstaff, Arizona to supplement to feed purchased for the animals raised on our farm . . . If the proposed FDA regulations governing animal food under provisions of the FSMA are applied to alcohol beverage producers, the spent grain that I currently feed my livestock may no longer be available because the cost of compliance with the proposed regulations is greater than the cost of simply disposing of spent grains."); Comment from Kushal Hall, Speakeasy Ales & Lagers of San Francisco, CA, posted April 23, 2014, FDA-2013-N-0013-0006 (RIN 0910-AG98) ("The use of spent grain by farmers is a low-risk activity that has been mutually beneficial to brewers and farmers for decades. The alternative is to send the spent grain to landfills, wasting a reliable food source for farm animals and triggering a significant economic and environmental cost.").

²² See Section IV, Response §75, "Notice of Final Rule, Sanitary Transportation of Human and Animal Food," *Federal Register Notice*, 81 F.R. 20124 (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).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

recordkeeping and inspection requirements as applied to the transportation of such products “are not burdensome and are appropriate for these types of transportation operations.”²⁶ In comments accompanying publication of the final rule, FDA observed:

The requirements we are establishing in this rule require that transportation operations be conducted so as to prevent food from becoming adulterated during transportation. We do not envision, for example, that carriers who transport spent grain materials to animal feed manufacturing facilities would have to clean or inspect their vehicles any more frequently under this final rule than what is already typically being done to facilitate safe transportation. However, if carriers haul intervening loads of fertilizer, for example, they would need to clean their vehicles before transporting spent grain intended for use as animal feed. In addition, as we explained in our response to Comment 149 and Comment 160, in § 1.908(e)(4) and (e)(5) of this final rule, we have revised the proposed previous load and cleaning reporting requirements for bulk carriers in a manner that will reduce, and in some cases eliminate, recordkeeping requirements for these carriers.²⁷

Conclusion

The FDA’s new rule on Sanitary Transportation of Human and Animal Food generally requires 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. FDA has confirmed that the new rule does NOT apply to the transportation of packaged alcohol beverage products or “transportation of food fully enclosed by a container that does not require temperature control to prevent it from becoming unsafe.”

However, alcohol industry members who also repurpose spent grains for agricultural purposes should take heed. If those grains are used for animal feed purposes, then their transportation IS covered by the new food transportation regulation.

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 alcohol beverage industry, please contact [GrayRobinson's Nationwide Alcohol Beverage Team](#):

866-382-5132
<http://www.gray-robinson.com/alcohol-beverage-practice>

²⁶ *Id.*

²⁷ *Id.*