April 22, 2016

The Honorable Lamar Alexander  
Chairman  
The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: Department of Health and Human Services, Food and Drug Administration: Sanitary Transportation of Human and Animal Food

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA) entitled “Sanitary Transportation of Human and Animal Food” (RIN: 0910-AG98). We received the rule on April 7, 2016. It was published in the Federal Register as a final rule on April 6, 2016. 81 Fed. Reg. 20,092.

The final rule establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport. This action is part of the larger effort to focus on prevention of food safety problems throughout the food chain and is part of the implementation of the Sanitary Food Transportation Act of 2005 (2005 SFTA) and the Food Safety Modernization Act of 2011 (FSMA).

Enclosed is our assessment of FDA’s compliance with the procedural steps required by section 801(a)(1)(B)(ii) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that FDA complied with the applicable requirements.
If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen
    Director, Regulations Policy and Management Staff
    Food and Drug Administration
    Department of Health and Human Services
(i) Cost-benefit analysis

The Food and Drug Administration (FDA) included a cost-benefit analysis in the final rule. FDA states that the final rule implements requirements addressing the sanitary transportation of human and animal food. It establishes requirements for sanitary transportation practices applicable to shippers, carriers by motor vehicle and rail vehicle, loaders, and receivers. Specifically, the finalized requirements address design and maintenance of vehicles and transportation equipment; sanitary practices during transportation operations that apply to shippers, receivers, loaders, and carriers; training of carrier employees; and records related to, for example, training, and written procedures. FDA included a table in the rule summarizing the costs which showed that the total annualized costs are estimated to be approximately $113 million per year, estimated with a 3 percent discount rate, and $117 million per year, estimated at 7 percent when discounted over 10 years. FDA concluded that it did not have sufficient data to fully quantify the benefits of this regulation.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

FDA stated that the final rule defines a small business subject to the rule as one that employs fewer than 500 full-time equivalent employees. For carriers by motor vehicle that are not also shippers and/or receivers, this term would mean a business subject to this rule having less than $27,500,000 in annual receipts. FDA concluded that the final rule will have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. §§ 1532-1535

FDA stated that UMRA requires the preparation of a written statement, which includes an assessment of anticipated costs and benefits, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that would meet or exceed this amount.
(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

FDA published an advance notice of proposed rulemaking in the Federal Register (75 Fed. Reg. 22,713, April 30, 2010) to request data and information on the food transportation industry and its practices to prevent the contamination of transported foods and any associated outbreaks. FDA subsequently published a proposed rule in the Federal Register (79 Fed. Reg. 7,006, Feb. 5, 2014), to establish sanitary transportation requirements for shippers, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of both human and animal food to ensure the safety of the food they transport. FDA states that it received about 240 submissions in response to the proposed rule. FDA received comments from individuals, industry and trade associations, consumer and advocacy groups, academia, law firms, professional organizations, federal and state, tribal and foreign government agencies, and other organizations. In the final rule, FDA responded to the comments and explained any revisions it made to the proposed rule in response to those comments. In addition, FDA states that it held three public meetings to discuss the proposed rule. The meetings took place on February 27, 2014, in Chicago, IL; March 13, 2014, in Anaheim, CA; and March 20, 2014, in Washington, DC.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

FDA stated that the final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under PRA. FDA stated that the new collection of information will be performed by shippers, receivers, loaders, and carriers of human and animal food. The records requirements of this final rule include records pertaining to: sanitary specifications, temperature during transportation operations, cleaning of bulk vehicles, training, and written procedures. In addition, the final rule includes submission requirements pertaining to waiver petitions, when appropriate. According to FDA, the total one-time estimated burden imposed by this collection of information is 254,923 hours (228,832 recordkeeping hours + 144 submission hours + 25,947 third-party disclosure hours). The total annual estimated burden imposed by this collection of information is 120,342 hours (120,163 recordkeeping hours + 48 submission hours + 113 third-party disclosure hours). FDA states that there are no capital costs or operating and maintenance costs associated with this collection of information. FDA estimates that firms will be able to fulfill recordkeeping requirements with existing record systems; that is, FDA estimates that it will not be necessary for firms involved in food transportation to invest in new recordkeeping systems. FDA included several summary tables in the final rule in its analysis.

Statutory authorization for the rule

FDA promulgated the rule under authority of the 2005 Sanitary Food Transportation Act of 2005 (SFTA) and as directed by section 111(a) of the FDA Food Safety Modernization Act (FSMA). More specifically the rule was promulgated under the authority under 21 U.S.C. 350e, 21 U.S.C. 342(i), 21 U.S.C. 331(hh), 21 U.S.C. 373, and 21 U.S.C. 371(a).

Executive Order No. 12,866 (Regulatory Planning and Review)

FDA stated that it believes that the final rule is a significant regulatory action as defined by Executive Order 12,866.
Executive Order No. 13,132 (Federalism)

FDA concluded that federal preemption of state or local rules that establish requirements for the sanitary transportation of human and animal food such that: (1) complying with the requirements of the state or political subdivision and with a requirement of section 416 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), or with this rule, is not possible; or (2) the requirements of the state or political subdivision, as applied or enforced, is an obstacle to accomplishing and carrying out section 416 of the FD&C Act or this rule, is consistent with this federalism order. FDA did not incorporate text in the rule to reflect this preemptive effect because section 416(e) of the FD&C Act expressly provides for this preemption.