



441 G St. N.W.
Washington, DC 20548

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December 16, 2015

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: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals*

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 “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (RIN: 0910-AG64). We received the rule on December 1, 2015. It was published in the *Federal Register* a final rule on November 27, 2015. 80 Fed. Reg. 74,226.

The final rule requires importers of food for humans and animals to verify that food they import into the United States is produced in compliance with the hazard analysis and risk-based preventive controls and standards for produce safety provisions of the Federal Food, Drug, and Cosmetic Act, is not adulterated, and is not misbranded with respect to food allergen labeling.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The final rule has a stated effective date of January 26, 2016. It was published in the *Federal Register* as a final rule on November 27, 2015. 80 Fed. Reg. 74,226. We received the rule on December 1, 2015. Therefore, this rule does not have a 60-day delay in effective date.

Enclosed is our assessment of FDA’s compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that, with the exception of the required 60-day delay in effective date, 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

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
“FOREIGN SUPPLIER VERIFICATION PROGRAMS
FOR IMPORTERS OF FOOD FOR HUMANS AND ANIMALS”
(RIN: 0910-AG64)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) prepared a cost-benefit analysis in conjunction with the final rule. FDA estimated that the total annualized costs of the final rule will be approximately \$435 million per year over 10 years. FDA stated that the final rule benefits the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations. FDA believes the final rule will be an important mechanism for improving and helping to ensure compliance with food safety regulations as they apply to imported food and that the greater the compliance with those regulations, the greater the expected reduction in illnesses and death as well as the costs associated with them. FDA accounts for the public health benefits of the final rule in the preventive controls, produce safety, and other applicable food safety regulations instead of in the final rule, because it does not have sufficient data to determine the extent to which particular regulations might be responsible for the expected reduction in foodborne illnesses.

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

FDA determined that the final rule will have a significant economic impact on a substantial number of small entities, because many small businesses will need to adopt foreign supplier verification programs or conduct additional verification activities.

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

FDA determined that the final rule will result in a 1-year expenditure that would meet or exceed the Unfunded Mandates Reform Act threshold, as adjusted for inflation, of \$144 million. Accordingly, FDA prepared a statement that included an assessment of anticipated costs and benefits as described above.

(iv) Other relevant information or requirements under acts and executive orders

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

FDA published a notice of proposed rulemaking in the *Federal Register* on July 29, 2013. 78 Fed. Reg. 45,730. FDA also published a supplemental notice of proposed rulemaking on September 29, 2014, which reopened the comment period on the proposed rule with respect to specific proposed provisions. 79 Fed. Reg. 58,574. FDA received more than 300 comments on

the proposed rule and more than 100 comments on the supplemental notice. FDA responded to the comments in the final rule.

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

The final rule contains information collection requirements under the Paperwork Reduction Act. FDA included in the final rule estimates of annual reporting burden and the annual recordkeeping burden. FDA has submitted the requirements to the Office of Management and Budget (OMB) for review, and the final rule states that FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information collection requirements before January 26, 2016, which is the stated effective date of the final rule.

Statutory authorization for the rule

FDA states that the final rule is authorized by section 301 of the FDA Food Safety Modernization Act (FSMA), which added sections 301(zz) and 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, FDA states that it derives authority for this final rule from sections 421(b) and 701(a) of the FD&C Act (21 U.S.C. §§ 350j(b), 371(a)), as well as sections 311, 361, and 368 of the Public Health Service Act (42 U.S.C. §§ 243, 264, 271).

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

FDA determined the final rule is a significant regulatory action under the Executive Order.

Executive Order No. 13,132 (Federalism)

FDA determined that the final rule does not contain policies that have substantial direct effects on the states, on the relationship between the federal government and the states, or on the distribution of power and responsibilities among the various levels of government.