U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

B-328136

June 10, 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: Mitigation Strategies To Protect Food Against Intentional Adulteration*

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 "Mitigation Strategies To Protect Food Against Intentional Adulteration" (RIN: 0910-AG63). We received the rule on May 27, 2016. It was published in the *Federal Register* as a final rule on May 27, 2016. 81 Fed. Reg. 34,166.

The final rule requires domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to address hazards that may be introduced with the intention to cause wide-scale public health harm. These food facilities are required to conduct a vulnerability assessment to identify significant vulnerabilities and actionable process steps and implement mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA is issuing these requirements as part of their implementation of the FDA Food Safety Modernization Act.

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 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
Department of Health and Human Services

ENCLOSURE

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
"MITIGATION STRATEGIES TO PROTECT FOOD
AGAINST INTENTIONAL ADULTERATION"
(RIN: 0910-AG63)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) analyzed the costs and benefits for the final rule. The total cost of the rule, annualized over 10 years at a 7 percent discount rate, is between $280 and $490 million. With a 3 percent discount rate, the annualized cost is between $270 and $480 million. The first-year cost is between $680 and $930 million. Counting only domestic firms, the total annualized costs are between $90 and $150 million, with initial costs of between $220 and $300 million. The average annualized cost per covered facility is between $9,000 and $16,000, and the average annualized cost per covered firm is between $27,000 and $47,000.

According to FDA, the benefits of the actions required by the rule are a reduction in the possibility of illness and death resulting from intentional adulteration of food. FDA monetized the damage that various intentional adulteration scenarios might cause and presented a breakeven analysis showing the number of prevented attacks at which the benefits are larger than the costs. For attacks that are similar in impact to acts of intentional adulteration that have happened in the United States in the past, the breakeven threshold, counting only producer costs, is 28 to 48 attacks prevented every year. For attacks causing similar casualties as major historical outbreaks of food-related illness, the breakeven threshold is one or two attacks every year. For catastrophic terrorist attacks causing thousands of fatalities, the breakeven threshold is one attack prevented every 270 to 460 years. In the rule, FDA included a table which showed the approximate, rounded, mean values for various cost components of the rule and that the benefits were unquantifiable.

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

The RFA requires FDA to analyze regulatory options that would minimize any significant impact of a rule on small entities. According to FDA, their analysis shows that the annualized costs per entity due to this rule are about $13,000 for a one-facility firm with 100 employees, and there are about 4,100 small businesses that would be affected by the rule. Consequently, FDA tentatively concluded that the final rule could 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, 2 U.S.C. §§ 1532-1535

FDA notes that the Unfunded Mandates Reform Act of 1995 (section 202(a)) requires it to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “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. According to FDA, this final rule may 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.

On December 24, 2013, FDA published a proposed rule in the *Federal Register*. 78 Fed. Reg. 78,014. On March 25, 2014, FDA extended the comment period for the notice of proposed rulemaking. 79 Fed. Reg. 16,251. FDA states that it received more than 200 public submissions on the proposed rule, each containing one or more comments. Comments were received from diverse members of the public, including food facilities (including facilities co-located on a farm); farms; cooperatives; coalitions; trade organizations; consulting firms; law firms; academia; public health organizations; public advocacy groups; consumers; consumer groups; Congress, federal, state, local, and tribal governments; and other organizations. According to FDA, some submissions included signatures and statements from multiple individuals. Comments addressed virtually every provision of the proposed rule, including requests for comment on including additional provisions that were not included in the proposed regulatory text. FDA described the comments, responded to them, and explained any revisions made to the proposed rule in response. FDA noted that some comments addressed issues that were outside the scope of this rule.

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

FDA states that the rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under PRA. FDA is requiring domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to address hazards that may be introduced with the intention to cause wide scale public health harm. These food facilities are required to identify and implement mitigation strategies that significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation. FDA estimates that respondents to the collection are food production facilities with more than $10 million in annual sales. FDA estimated there are 9,759 such facilities owned by 3,247 firms. FDA estimated there are 18,080 facilities with less than $10 million in annual sales that will need to show documentation of their exemption status under the rule, upon request. These 18,080 facilities must show documentation upon request to verify their exempt status under the regulations and FDA estimated that preparing and updating relevant files will require an average of 30 minutes per respondent for a total annual burden of 9,040 hours (30 minutes × 18,080).

Under the rule, the owner, operator, or agent in charge of a facility must prepare, or have prepared, and implement a written food defense plan, including a written vulnerability assessment; written mitigation strategies; written procedures for defense monitoring; written procedures for food defense corrective actions; and written procedures for food defense verification. The estimated recordkeeping burden associated with these activities, totals 2,515,258 annual burden hours and 409,486 annual responses. FDA included a table in the final rule that broke down the estimated hours and responses for recordkeeping burdens.

Statutory authorization for the rule

The rule was promulgated under sections 103 and 106 of the FDA Food Safety Modernization Act (FSMA). FSMA, Hazard Analysis and Risk-Based Preventive Controls, amends the FD&C Act to create a new section 418, which mandates rulemaking. Section 418(n)(1)(A) of the FD&C Act, 21 U.S.C. § 350g. Section 106 of FSMA, Protection Against Intentional Adulteration, amends the FD&C Act to create a new section 420, which mandates rulemaking. Section 420 of the FD&C Act requires FDA to issue regulations to protect against the intentional adulteration of food. 21 U.S.C. § 350i. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

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

FDA believes that the final rule is a significant regulatory action under Executive Order 12,866.

Executive Order No. 13,132 (Federalism)

FDA states that it has analyzed this final rule in accordance with the principles set forth in Executive Order 13,132. FDA has determined that the rule does not contain policies that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement was not required.