



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

B-327370

October 1, 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: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for 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 "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (RIN 0910-AG10). We received the rule on September 17, 2015. It was published in the *Federal Register* as a final rule on September 17, 2015. 80 Fed. Reg. 56,170.

The final rule adds regulations to the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals. According to FDA, these regulations will, for the first time, establish requirements for the current good manufacturing practice for food for animals. In addition, the rule adds requirements for certain domestic and foreign animal food facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. FDA says it is taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to humans and animals and to implement new statutory provisions in the FDA Food Safety Modernization Act. Further, the rule is intended to build an animal food safety system for the future that makes modern science-based and risk-based preventive controls the norm across all sectors of the animal food system.

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
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
“CURRENT GOOD MANUFACTURING PRACTICE,
HAZARD ANALYSIS, AND RISK-BASED
PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS”
(RIN: 0910-AG10)

(i) Cost-benefit analysis

The final rule requires domestic and foreign facilities to adopt a food safety plan, perform a hazard analysis, and to institute preventive controls for the mitigation of those hazards identified as requiring a preventive control. It also includes requirements for facilities to institute risk-based environmental monitoring, product testing, and a supply-chain program as appropriate to the animal food, the facility, and the nature of the preventive controls, as well as a requirement to institute controls to help prevent hazards associated with economically motivated adulteration. The total annualized costs are estimated at \$139.0 to \$170.7 million per year (over 10 years at a 7 percent discount rate), and \$135.6 to \$166.7 million per year (over 10 years at a 3 percent discount rate). The total annualized benefits to pets are estimated at \$10.1–\$138.0 million. FDA included a table in the final rule that summarized the analysis.

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

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. According to FDA, because the final rule would impose annualized costs that range from \$25,000 to \$34,000 on many small entities, FDA determined 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, 2 U.S.C. §§ 1532-1535

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before finalizing “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 stated that it expects this final rule will likely result in a 1-year expenditure that will 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 October 29, 2013, FDA published a proposed animal food preventive controls rule. 78 Fed. Reg. 64,736. On September 29, 2014, FDA published new and re-proposed provisions in a supplemental notice. 79 Fed. Reg. 58,476. FDA states that it requested comment on all aspects of the proposed requirements, including an opportunity for public comment on potential requirements for product testing, environmental monitoring, a supplier program, and hazards that may be intentionally introduced for purposes of economic gain.

FDA received more than 2,400 public submissions on the 2013 proposed preventive controls rule for animal food, and more than 140 public submissions on the 2014 preventive controls supplement notice, each containing one or more comments. FDA received submissions from diverse members of the public, including animal 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; pet owners; consumer groups; Congress; federal, state, local, and foreign government agencies; and other organizations. Some submissions included signatures and statements from multiple individuals. Comments addressed virtually every provision of the proposed animal preventive controls rule. FDA described the comments, responded to them, and explained any revisions made to the proposed preventive controls rule for animal food in the final rule.

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

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under PRA. According to FDA, included in its estimate of the annual reporting, recordkeeping, and third-party disclosure burden is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

The final rule for preventive controls requires animal food facilities to have a written food safety plan that includes a hazard analysis; a description of preventive controls (including recall procedures); a supply-chain program; a description of procedures for monitoring the preventive controls; corrective action if preventive controls are not properly implemented; and a description of procedures for verifying implementation and effectiveness of the preventive controls. The final rule further requires facilities to establish and implement verification procedures for product testing and environmental monitoring, and requires that the hazard analysis and risk-based preventive controls for animal food take into account the possibility of economically motivated adulteration of animal food. Facilities that manufacture, process, pack, or hold food for animals and foods for human consumption and are subject to part 117 may choose to comply with part 117 with respect to the animal food, provided the food safety plan addresses the hazards specific to animal food where applicable. The final rule also establishes certain exemptions, under applicable regulations. The final rule imposes specific reporting requirements on facilities claiming the very small business qualified facility exemption. FDA states that respondents will be facilities that manufacture, process, pack, or hold food for animals. Generally, according to FDA, a facility is required to register if it manufactures, processes, packs, or holds animal food for consumption in the United States. At the time of FDA's analysis, the number of animal food facilities registered with the FDA was 7,469.

FDA included several summary tables in the final rule and explained that out of 7,469 animal food facilities registered with FDA, it estimated approximately 15 percent (1,120) could be “qualified” facilities under the very small business definition as discussed in the Final Regulatory Impact Analysis, and thus eligible for certain limited exemptions under the applicable regulations. There are exemptions of qualified facilities from certain sections of the regulations, which includes all of the hazard analysis and preventive controls requirements, including supply-chain program requirements. The average hourly time burden per response is based on FDA’s assumption that a facility will report its status electronically through a Web portal maintained by FDA, and that this will take approximately 0.5 hours (30 minutes).

Under the final rule, FDA estimated a total of 7,469 respondents (the number of registered animal food facilities) that are subject to recordkeeping requirements found in the applicable regulations. Although FDA believes that, in some cases, all respondents will incur new recordkeeping activities as a result of the final rule (e.g., documentation of training in the principles of animal food hygiene and safety), it believes other provisions may apply only to certain respondents (e.g., documentation of a supply-chain program), depending upon the applicable regulation.

Under the final rule, FDA estimated that all (7,469) respondents are subject to third-party disclosure requirements found in the applicable regulations. FDA estimated 0.25 hours per disclosure to prepare labeling, and affix to the containers, for a total of 20,399 burden hours.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA states that it will publish a notice in the *Federal Register* announcing OMB’s decision to approve, modify, or disapprove the information collection provisions in this final rule.

Statutory authorization for the rule

FDA states that the proposed rule contained an explanation of its legal basis under authorities in Food Safety Modernization Act (Pub. L. No. 111-353), which amended the Food, Drug, and Cosmetic Act (21 U.S.C. §§ 342, 371(a)), and the Public Health Service Act (42 U.S.C. § 243, 264, and 271). According to FDA, the legal authorities relied on for the final rule are generally the same as in the proposed rule unless otherwise described within the final rule.

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

FDA states that OMB has determined that this final rule is an economically significant regulatory action as defined by Executive Order 12,866.

Executive Order No. 13,132 (Federalism)

FDA 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 final 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.