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United States Government Accountability Office  
Washington, DC 20548

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B-318435

July 24, 2009

The Honorable Tom Harkin  
Chairman  
The Honorable Saxby Chambliss  
Ranking Minority Member  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Collin C. Peterson  
Chairman  
The Honorable Frank D. Lucas  
Ranking Minority Member  
Committee on Agriculture  
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:  
Prevention of Salmonella Enteritidis in Shell Eggs During Production,  
Storage, and Transportation*

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 "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation" (RIN: 0910-AC14). We received the rule on July 10, 2009. It was published in the *Federal Register* as a final rule on July 9, 2009, with a stated effective date of September 8, 2009. 74 Fed. Reg. 33,030.

The final rule requires shell egg producers to implement measures to prevent *Salmonella* Enteritidis (salmonella) from contaminating eggs on the farm and from further growth during storage and transportation. Further, this rule requires producers to register with the FDA and to maintain records concerning their compliance with the rule. According to FDA, it is establishing this rule because salmonella is one of the leading bacterial causes of food-borne illness in the United States and shell eggs are a primary source of human salmonella infections. FDA expects this rule to reduce salmonella-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with salmonella.

Enclosed is our assessment of the 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: Edwin V. Dutra, Jr.  
Director, Regulations Policy and  
Management Staff, FDA  
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  
"PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS DURING  
PRODUCTION, STORAGE, AND TRANSPORTATION"  
(RIN: 0910-AC14)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) analyzed the costs and benefits of this final rule. After the on-farm adjustment phase (up to 4 years), FDA expects the final rule will prevent approximately 79,170 cases of *Salmonella* Enteritidis (salmonella) per year at a cost of \$1,000 per illness averted. FDA estimates that the mean dollar values of the benefits of this rule range from \$228 million to over \$9.5 billion, depending on certain assumptions. FDA believes that the eventual annual cost of this rule will be between \$57.5 million and \$116.5 million. The lowest estimate of \$228 million in annual benefits is well above the highest estimate of \$116.5 million in annual costs. Net benefits of the final rule could be as low as \$111 million annually and as high as \$9.4 billion annually. FDA's central estimates result in net benefits in excess of \$1.4 billion.

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

FDA certified that this major rule will have a significant economic impact on a substantial number of small entities. FDA estimates that more than 99 percent of the farms covered by this rule are considered small. More than 1,000 small farms, as defined by Small Business Administration standards, will be affected by the rule. For the industry as a whole, FDA estimates that the average annual cost of this final rule will be about \$24,100 per farm site covered by the rule. This translates to an average cost of \$0.30 per layer. Since almost all farms are small, these overall industry costs are representative of the average costs to small farms.

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

FDA has determined that this final rule is significant under the Act because it expects the rule to result in 1-year expenditures of \$100 million (\$130 million adjusted for inflation) or more by state, local, and tribal governments, or by the private sector.

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

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

FDA issued a proposed rule on September 22, 2004, to prevent salmonella contamination in shell eggs during production, which had a 90-day comment period. 69 Fed. Reg. 56,824. During this period, FDA received approximately 2,000 timely submissions. FDA held three public meetings in 2004 on this proposed rule. On May 10, 2005, FDA reopened the comment period until July 25, 2005. 70 Fed. Reg. 24,490. FDA received approximately 20 timely submissions in response to the reopened comment period. FDA grouped the relevant comments by 60 major issues and responded to the comments in the final rule. 74 Fed. Reg. 33,034–33,049.

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

This final rule contains information collection provisions subject to review by the Office of Management and Budget (OMB) under the Act. FDA has submitted the information collection provisions of the rule to OMB for review. In the final rule, FDA invites comments on these information collection requirements. FDA estimates that the total annual recordkeeping burden for this rule for the first year will be 387,962 hours and for following years will be 331,354 hours.

Statutory authorization for the rule

FDA promulgated this final rule under the authority of sections 1451–1461 of title 15; sections 141–149, 321–394, 467f, 679, 821, and 1034 of title 21; section 2112 of title 28; and sections 201-262, 263b, and 364 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA determined that this final rule is an economically significant rule under the Order. FDA submitted this rule to OMB for review.

Executive Order No. 13132 (Federalism)

FDA determined that this final rule preempts state or local rules regarding the prevention of salmonella in egg shells during production, storage, and transportation that are less stringent than this rule. This rule does not preempt state and local laws, regulations, and ordinances that establish more stringent requirements. According to FDA, state and local regulations that would impose less stringent requirements for prevention of salmonella would undermine FDA's goal of ensuring that shell eggs are produced, stored, and transported using measures that will prevent salmonella contamination. FDA believes that the requirements of this final rule are the minimal national measures necessary to ensure safety. FDA noted that it provided state and local governments with an opportunity for appropriate participation in this rulemaking when it invited comments on the proposed rule and when it composed a working group of state officials. Also, state and local officials participated in the three public meetings on the proposed rule.