



United States  
General Accounting Office  
Washington, D.C. 20548

---

Office of the General Counsel

B-272531.1

July 29, 1996

The Honorable Richard G. Lugar  
Chairman  
The Honorable Patrick J. Leahy  
Ranking Minority Member  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Pat Roberts  
Chairman  
The Honorable E (Kika) de la Garza  
Ranking Minority Member  
Committee on Agriculture  
House of Representatives

Subject: Pathogen Reduction: Hazard Analysis and Critical Control Point  
(HACCP) Systems

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by Department of Agriculture, Food Safety and Inspection Service, entitled "Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems" (RIN: 0583-AB69). We received the rule on July 10, 1996. It was published in the Federal Register as a final rule on July 25, 1996. 61 Fed. Reg. 38805.

The rule establishes requirements applicable to meat and poultry establishments designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, reduce the incidence of foodborne illness associated with the consumption of those products and provide a new framework for modernization of the current system of meat and poultry inspection.

Enclosed is our assessment of the Food Safety and Inspection Service's compliance with the procedural steps required by sections 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the Food Safety and Inspection Service complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Senior Attorney, at (202) 512-8210. The official responsible for GAO evaluation work relating to the Department of Agriculture, Food Safety and Inspection Service is Robert A. Robinson, Director of Food and Agriculture Issues. Our Office has issued Food Safety and Quality-Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152) and Food Safety-Risk-based Inspections and Microbial Monitoring Needed for Meat and Poultry (GAO/RCED-94-110) concerning the subject of this rule. Mr. Robinson can be reached at (202) 512-5138.

Robert P. Murphy  
General Counsel

Enclosure

cc: Michael R. Taylor  
Administrator  
Food Safety and Inspection Service

ENCLOSURE

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE  
ISSUED BY  
THE DEPARTMENT OF AGRICULTURE, FOOD SAFETY AND INSPECTION  
SERVICE  
ENTITLED  
"PATHOGEN REDUCTION: HAZARD ANALYSIS AND CRITICAL CONTROL POINT  
(HACCP) SYSTEMS"  
(RIN: 0583-AB69)

(i) Cost-benefit analysis

The Food Safety and Inspection Service (FSIS) prepared a cost-benefit analysis which concludes that the costs associated with the rule are far outweighed by the public health benefits to be derived.

The analysis concludes that the 20-year industry costs are estimated to be \$969 to \$1,156 million and the 20-year cost to the government to be \$56.5 million. The analysis considers data for average wages, the cost of specific processing equipment and the cost of conducting specific laboratory analyses.

The potential health benefits resulting from the elimination of the four pathogens is estimated to be \$7.13 to \$26.59 billion over 20 years. The range of benefits occurs because of the current uncertainty in the estimates of the number of cases of foodborne illness and death attributable to the pathogens that enter the meat and poultry supply at the manufacturing stage.

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

The Administrator of FSIS has concluded that the rule will have a significant economic impact on a substantial number of small entities and an initial regulatory flexibility analysis and final regulatory flexibility analysis has been prepared and included in the notice of proposed rulemaking and the final rule notice, respectively, as required by sections 603 and 604. The analyses comply with the informational requirements of the sections including the classes of small entities subject to the requirement and alternatives considered to reduce to the burden on the small entities.

The final regulatory flexibility analysis discusses the comments received from both the industry and the Office of Advocacy, Small Business Administration and the changes made to the proposed rule to grant regulatory relief to the small entities including the sequencing of implementation by establishment size.

The analyses use both quantifiable and general descriptions of the effects of the rule on small entities as required by section 607 and small entities, in addition to the actions required by 5 U.S.C. § 553, participated in the numerous meetings, forums and conferences held in connection with the preparation of the final rule as required by section 609.

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

Based on the cost-benefit analysis performed by FSIS, the rule will impose an unfunded mandate on the private sector of \$99.6 to \$119.8 million annually and therefore the rule is subject to the requirements of the Act.

As required by section 205, FSIS considered several regulatory alternatives to the imposition of the mandatory HACCP but determined that the requirements expressed in the final rule constituted the most cost-effective and least burdensome alternative that would meet the objective of the rule.

To fulfill the requirements of section 204 regarding providing an opportunity for input from State, local and tribal governments, a "Federal-State-Relations Conference" was held and the numerous comments received from these entities were considered and are discussed in the preamble and the final Regulatory Impact Analysis.

Finally, FSIS considered the comments of several state government officials that the rule imposed an unfunded mandate on State inspection programs because of the need for these programs to remain "at least equal to" the Federal inspection program. FSIS concluded that because of the necessary restructuring and reprogramming of the State inspection programs, FSIS assistance and the flexibility provided under the "equal to" provisions, most states should be able to complete the modifications to their programs with minimal additional cost. Moreover, any additional costs would be eligible to receive up to 50 percent Federal matching funds.

(iv) Other relevant information or requirements under Acts and Executive orders

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

The rule was promulgated using the notice and comment procedures of 5 U.S.C. § 553. A notice of proposed rulemaking was published on February 3, 1995. 60 Fed. Reg. 6774. The initial comment period of 120 days was extended for an additional 30 days and later reopened for an additional 95 days. Also, FSIS held seven informational briefings, three scientific and technical conferences, a 2-day

public hearing, a scoping session, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum. In addition to the information gained through these meetings and conferences, 6,800 comments were received in response to the Federal Register notice.

The preamble to the final rule contains an extensive discussion of the comments received and the changes to the proposed rule which were made as a result.

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

The rule requires establishments to document their compliance with the Hazard Analysis and Critical Control Points (HACCP) Systems, first in the development of a plan and thereafter in a continuous record of process performance. The information collection requirements were discussed in the preamble to the proposed rule making published on February 3, 1995. (60 Fed. Reg. 6832). At the same time, public comments to both FSIS and the Office of Management and Budget were requested.

In the preamble to the final rule, FSIS notes that the Office of Management and Budget has approved its information collection requirements system under OMB No. 0583-0103 with an annual burden of 14,371,901 hours. However, in view of comments received and a reevaluation of the requirements by agency subject matter experts and private consultants, FSIS has reduced the annual burden to 8,053,319 hours, a 6,318,582-hour reduction. This reduction was obtained through more accurate burden estimates and the elimination of certain requirements including time and temperature reports and personnel resumes of establishment employees.

FSIS has submitted these changes in the information collection requirements to OMB for its approval and certified to OMB that the information collection complied with each of the objectives identified in 44 U.S.C. § 3506(c)(3).

#### Statutory authorization for the rule

This rule is promulgated under the authorities of 21 U.S.C. §§ 451-470 (Poultry Products Inspection Act), 21 U.S.C. §§ 601-695 (Federal Meat Inspection Act) and 7 U.S.C. §§ 1901-1906 (Humane Methods of Slaughter Act of 1978).

#### Executive Order No. 12866

The rule has been determined to be economically significant under Executive Order No. 12866 requiring review by the Office of Information and Regulatory Affairs, OMB. Both the proposed rule and the final rule were reviewed and approved as complying with the requirements of the Order based on the information supplied by FSIS, including the initial and final Regulatory Impact Analyses.

Executive Order No. 12988

According to the preamble, the final rule was reviewed pursuant to Executive Order No. 12778, Civil Justice Reform. However, that Executive Order has been replaced by Executive Order 12988, Civil Justice Reform, effective May 5, 1996. The prior Executive Order contained a similar requirement now found at Section 3(b)(2)(A) of the newly effective Order requiring that the preemptive effect of the rule be specified. FSIS states that under the Poultry Products Inspection Act (PPIA) and the Federal Meat Inspection Act (FMIA), cited above, state and local jurisdictions are preempted from imposing any requirements with respect to federally inspected premises and facilities that are in addition to, or different from, those imposed under PPIA or FMIA.

FSIS did not identify any other statute or executive order imposing procedural requirements relevant to the rule.