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United States Government Accountability Office
Washington, DC 20548

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August 15, 2007

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 Robert Goodlatte
Ranking Minority Member
Committee on Agriculture
House of Representatives

Subject: *Department of Agriculture, Food Safety and Inspection Service: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter*

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 Agriculture, Food Safety and Inspection Service (FSIS), entitled “Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter” (RIN: 0583-AC88). We received the rule on August 1, 2007. It was published in the *Federal Register* as an “affirmation of interim final rules with amendments” on July 13, 2007. 72 Fed. Reg. 38,700.

The final rule affirms two interim final rules published on January 12, 2004. 69 Fed. Reg. 1862, 1885. The interim rules and this final rule are measures taken to minimize human exposure to cattle materials that could potentially contain the bovine spongiform encephalopathy (BSE) agent. This final rule designates certain materials from cattle as specified risk materials (SRMs), including the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia from cattle 30 months or older and the distal ileum and tonsils from all cattle, and declares these SRMs are inedible, prohibiting their use for human food. Further, the final rule

prohibits the slaughter for human food of any non-ambulatory disabled cattle. The final rule also prohibits the use of “air-injection” stunning.

Enclosed is our assessment of FSIS’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 indicates that FSIS complied with the applicable requirements.

If you have any questions about this report, please contact Michael R. Volpe, Assistant General Counsel, at (202) 512-8236. The official responsible for GAO evaluation work relating to the subject matter of the rule is Robert Robinson, Managing Director, Natural Resources and Environment. Mr. Robinson can be reached at (202) 512-3841.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Alfred V. Almanza
Administrator, Food Safety and
Inspection Service
Department of Agriculture

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF AGRICULTURE,
FOOD SAFETY AND INSPECTION SERVICE
ENTITLED
"PROHIBITION OF THE USE OF SPECIFIED RISK MATERIALS FOR HUMAN
FOOD AND REQUIREMENTS FOR THE DISPOSITION OF NON-AMBULATORY
DISABLED CATTLE; PROHIBITION OF THE USE OF CERTAIN STUNNING
DEVICES USED TO IMMOBILIZE CATTLE DURING SLAUGHTER"
(RIN: 0583-AC88)

(i) Cost-benefit analysis

FSIS analyzed costs and benefits of this rule in its regulatory impact analysis. The benefits of the final rule primarily result from the relative reduction in human exposure to BSE infectivity and the restoration of beef exports. FSIS estimates that the total average annual cost of this final rule to be \$171.2 million annualized over 5 years. There are no costs associated with the prohibition of air-injection stunning because that method is no longer used in the United States.

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

FSIS conducted a Regulatory Flexibility Analysis and concluded that this final rule will not have a significant 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

FSIS conducted an analysis under this Act. The analysis included an assessment of this rule's effect on future costs; particular regions, communities, and industrial sectors; national productivity and economic growth; full employment and job creation; and exports.

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

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

This final rule makes permanent several interim final rules. The interim final rules were published on January 12, 2004, with good cause to forgo notice and comment procedures. 69 Fed. Reg. 1862. However, FSIS accepted comments on the interim rules and responded to them in this final rule and made amendments to the rule accordingly.

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

The new information collection requirements in this final rule have been submitted for approval to the Office of Management and Budget (OMB). FSIS has estimated the total annual burden for the new requirement to be 700 hours. FSIS has invited comments on this information collection.

Government Paperwork Elimination Act (GPEA), 44 U.S.C. § 3504 note

This final rule permits documentation of the implementation and monitoring of an establishment's procedures for the removal, segregation, and disposition of SRMs to be maintained on computers.

Statutory authorization for the rule

This final rule was promulgated under the authority found in section 450 and sections 1901 to 1906 of title 7 and sections 601 to 695 of title 21, United State Code.

Executive Order No. 12,866

This final rule was reviewed by OMB and was determined to be "economically significant" under the order. FSIS estimates that the total average annual cost of this final rule to be \$171.2 million annualized over 5 years. There are no costs associated with the prohibition of air-injection stunning because that method is no longer used in the United States.

Executive Order No. 12,988 (Civil Justice Reform)

This final rule was reviewed under this order. All state and local laws and regulations that are inconsistent with this rule will be pre-empted. This rule has no retroactive effect. Administrative proceedings will not be required before parties can file suit challenging this rule.