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United States Government Accountability Office  
Washington, DC 20548

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B-310366

September 27, 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, Animal and Plant Health Inspection Service:  
Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of  
Live Bovines and Products Derived From Bovines*

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, Animal and Plant Health Inspection Service (APHIS), entitled “Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines” (RIN: 0579-AC01). We received the rule on September 19, 2007. It was published in the *Federal Register* as a final rule on September 18, 2007. 72 Fed. Reg. 53,314. The final rule is effective on November 19, 2007.

The final rule establishes conditions for the importation of certain commodities from regions that present a minimal risk of introducing bovine spongiform encephalopathy into the United States (currently only Canada): live bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of the export; blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines. The final rule also removes the delay of applicability of certain provisions of a final rule APHIS published in January 2005. The final rule amends Parts 93 through 96 of Title 9 of the Code of Federal Regulations and was published as a proposed rule in the *Federal Register* on January 9, 2007. 72 Fed. Reg. 1102.

Enclosed is our assessment of APHIS'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 APHIS 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: Chief, Regulatory Analysis and Development  
Animal and Plant Health 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,  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
ENTITLED  
"BOVINE SPONGIFORM ENCEPHALOPATHY;  
MINIMAL-RISK REGIONS; IMPORTATION OF LIVE BOVINES  
AND PRODUCTS DERIVED FROM BOVINES"  
(RIN: 0579-AC01)

(i) Cost-benefit analysis

APHIS performed a cost-benefit analysis of the final rule and concluded that the benefits of the rule will exceed costs overall. APHIS also conducted a risk assessment and evaluation of the issues and concluded that bovines and bovine products could be safely imported under the conditions described in the final rule. More specifically, APHIS determined that the previous restrictions are not warranted by scientific research and evidence and that they are unnecessary for maintaining a negligible risk (*i.e.*, the likelihood of establishment and the potential impacts of cases that may occur even without establishment) to the United States via imports of live bovines and bovine products from such regions.

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

A Final Regulatory Flexibility Analysis was prepared for the final rule. The analysis complies with the requirements of the Act, including the steps taken to reduce the economic impact on small entities. APHIS noted that many of the beneficiaries of the final rule are likely to be small entities, given their predominance among beef and dairy operations and feedlot establishments; affected businesses will be able to take advantage of a broader range of transactional opportunities than previously.

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

APHIS made no statements regarding the Unfunded Mandates Reform Act.

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

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

APHIS promulgated this final rule using the notice and comment procedures found in the Administrative Procedure Act. 5 U.S.C. § 553. On January 9, 2007, it published

a Notice of Proposed Rulemaking in the *Federal Register*. 72 Fed. Reg. 1102. APHIS received close to 400 comments and responded to the issues raised in the comments in the final rule.

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

APHIS states that the final rule does not contain any information collections that are subject to review under the Paperwork Reduction Act.

Statutory authorization for the rule

The final rule was promulgated under the authority in 7 U.S.C. §§ 1622 and 8301-8317, 21 U.S.C. §§ 136 and 136a, and 31 U.S.C. § 9701.

Executive Order No. 12,866

The final rule was reviewed by the Office of Management and Budget and found to be an “economically significant” regulatory action under the order.