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March 4, 2004

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

The Honorable Bob Goodlatte
Chairman
The Honorable Charles W. Stenholm
Ranking Minority Member
Committee on Agriculture
House of Representatives

Subject: *Department of Agriculture, Food Safety and Inspection Service: Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems*

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 "Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems" (RIN 0583-AC51). We received the rule on February 19, 2004. It was published in the Federal Register as an "interim final rule and request for comment" on January 12, 2004. 69 Fed. Reg. 1874.

The interim final rule covers meat produced by advanced meat recovery (AMR) systems. The rule is designed, in part, to prevent human exposure to the Bovine Spongiform Encephalopathy (BSE) agent by ensuring that AMR systems are not a means of introducing central nervous system tissue into products labeled as "meat."

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

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. 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

Kathleen E. Wannisky
Managing Associate General Counsel

cc: Garry L. McKee, Ph.D., M.P.H.
Administrator, Food Safety and
Inspection Service
Department of Agriculture

Enclosure

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
"MEAT PRODUCED BY ADVANCED MEAT/BONE SEPARATION
MACHINERY AND MEAT RECOVERY (AMR) SYSTEMS"
(RIN 0583-AC51)

(i) Cost-benefit analysis

FSIS states that in view of the emergency issuance of the interim final rule, the preparation of a cost-benefit analysis was not possible. However, the economic effects of the interim final rule are currently being assessed and when the assessment is completed, a notice of availability will be published in the Federal Register.

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

As noted above, the emergency nature of the rule issuance did not permit the preparation of an analysis of the impact of the rule on small entities prior to the interim final rule's publication.

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

At this time, FSIS has not indicated whether the final rule contains either an intergovernmental or private sector mandate, as defined in title II, of more than \$100 million in any one year pending the outcome of the above-noted economic assessment.

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

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

Following a cow testing positive for BSE in Washington State on December 23, 2003, FSIS has found "good cause" to forgo the notice and comment procedures and the 30-day delay in the effective date requirement found at 5 U.S.C. 553 and issue the interim final rule on an emergency basis. Previously, FSIS had published a Notice of Proposed Rulemaking on April 13, 1998, in the Federal Register. 63 Fed. Reg. 17959. While the NPRM discussed AMR systems and FSIS received comments in response,

the NPRM did not deal with the issue of BSE. FSIS, in the interim final rule, requests comments regarding the rule.

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

The interim final rule contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. FSIS has submitted the required information to OMB for emergency approval. FSIS estimates that the annual burden associated with the collection to be 18,088 hours.

Statutory authorization for the rule

The interim final rule was promulgated under the authority found in 7 U.S.C. 138f, 450, and 1901-1906 and 21 U.S.C. 601-695.

Executive Order No. 12866

The interim final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.