GAO

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June 24, 1997

The Honorable James M. Jeffords
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

Subject: Department of Health and Human Services, Food and Drug Administration: Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

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 "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" (RIN: 0910-AA91). We received the rule on June 10, 1997. It was published in the Federal Register as a final rule on June 5, 1997. 62 Fed. Reg. 30936.

FDA is issuing this rule to reduce the risk of an outbreak of transmissible spongiform encephalopathy (TSE) in the United States. In the United Kingdom, one form of TSE, bovine spongiform encephalopathy (BSE), is believed to be linked to cattle feed containing rendered protein by-products from sheep and goats infected with scrapie, a disease related to BSE. FDA suggests there may be an association between BSE and a form of human TSE known as new variant Creutzfeldt-Jakob disease. BSE has not been diagnosed in the United States. This rule is intended to prevent the establishment and amplification of BSE in the United States through feed and, thereby, to minimize the risk to animals and humans.

This rule amends FDA regulations to provide that animal protein derived from mammalian tissues for use in ruminant feed is a food additive subject to certain provisions in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.). FDA is taking this action because ruminants are being fed protein derived from animals in which TSE has been found and such proteins may cause TSE in ruminants.

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

If you have any questions about this report, please contact Kathleen Wannisky, Associate General Counsel for Operations, at (202) 512-5207. The official responsible for GAO evaluation work relating to the Department of Health and Human Services, Food and Drug Administration is Robert Robinson, Director, Food and Agriculture Issues. Mr. Robinson can be reached at (202) 512-5138.

Robert P. Murphy
General Counsel

Enclosure

cc: The Honorable Donna E. Shalala
Secretary of Health and Human Services

ENCLOSURE

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED;
ANIMAL PROTEINS PROHIBITED IN RUMINANT FEED"
(RIN: 0910-AA91)

(i) Cost-benefit analysis

In the preamble to the rule, FDA presents a summary of its economic analyses, discussing the potential benefits of the proposed rule and the economic impact that could occur as a result of its implementation. Full texts of both the cost analysis and an addendum were provided to GAO at the time the agency filed the rule with us. In accordance with Executive Order 12866, the analyses describe the regulatory options available to reduce the risk of an outbreak of BSE in the United States and the costs and benefits associated with each option.

FDA estimates the direct compliance costs of the rule will be about $44.3 million per year and that the initial value of the affected meat and bone meal will be reduced by $171 million annually. In contrast, nonruminant animal producers may gain up to $162 million in lower feed costs. FDA estimates that the aggregated net annualized costs of the rule, accounting for both losses and gains, will total $52.9 million.

The primary benefit of this rule, as described in the economic analyses, is the costs that would be averted by reducing the risk of BSE becoming established and proliferating in the United States through feed. FDA stated that it could not quantify the costs of all the benefits associated with this rule, such as the value of human lives saved or the medical costs that would be avoided by preventing an outbreak of BSE. However, it did provide estimates of some of the costs that might be incurred if the rule were not implemented and an outbreak of BSE were to occur in the United States. FDA estimates that costs of $93 million would be incurred in direct livestock losses due to BSE infection, that costs of $4.7 billion would be incurred slaughtering at-risk cattle culled to prevent BSE spread, and that costs of $593 million would be incurred imposing feed regulations at the time BSE was detected.

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

On January 3, 1997, FDA published a summary of its Initial Regulatory Impact Analysis in the preamble to the proposed rule (62 Fed. Reg. 552 at 572). FDA concluded that the rule will have a significant impact on a substantial number of small entities. The vast majority of entities involved in ruminant production and meat preparation are considered small businesses according to size standards set by the Small Business Administration. The analysis also discusses the regulatory alternatives FDA considered in drafting the proposed rule.

FDA published a summary of its Final Regulatory Flexibility Analysis in the preamble to the final rule published on June 5, 1997 (62 Fed. Reg. 30936 at 30966). In that analysis FDA discusses the need for the rule, the benefits anticipated from the implementation of the rule, and a summary of the impacts of the final rule. The preamble summarizes the issues raised by the public comments to the proposed rule, describes the numbers of small entities affected by the rule, and describes the recordkeeping burden of the rule. The preamble also describes the seven alternatives considered by FDA in promulgating this rule and why it believes that the alternative selected (the mammalian-to-ruminant prohibition--with exceptions) is the most cost-effective regulatory alternative that meets the objective of the agency. FDA also points out that it revised the rule in several respects to decrease the burden on small entities in response to comments received from small businesses.

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

FDA determined that, because this rule imposes no mandates on government entities and will result in expenditures of less that $100,000,000 in any one year, that no further analysis is needed under 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.

This rule was published as a notice of proposed rulemaking on January 3, 1997 (62 Fed. Reg. 552) under the notice and comment procedures of 5 U.S.C. § 553. Based on the numerous comments it received, FDA published the codified provisions of the draft final rule on April 17, 1997 (62 Fed. Reg. 18728) and provided an opportunity for the public to comment. FDA made some changes to the draft language based on those comments and published the final rule on June 5, 1997 (62 Fed. Reg. 30936). The preamble to the final rule discusses the comments received and the actions taken upon them.

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

This final rule contains information collection requirements which are subject to the Paperwork Reduction Act. FDA submitted the information collection request to OMB for approval at the time the proposed rule was published (January 3, 1997). OMB did not approve the information collection as submitted, but required FDA to invite comments on the information collection when the final rule was published. After FDA evaluates the comments received, makes any revisions, and receives final OMB approval for the information collection, FDA will announce in the Federal Register that approval and the effective date of the part of the regulations that relate to the information collection.

Executive Order 12866

This final rule is considered to be an "economically significant regulatory action" under Executive Order 12866. In accordance with the provisions of the executive order, FDA assessed the costs and benefits of regulatory alternatives and appears to have selected the approach that maximizes net benefits while still meeting agency objectives.

Executive Order 12612

FDA states that it has analyzed this rule in accordance with the principles set forth in Executive Order 12612, Federalism, and has determined that the rule does not warrant the preparation of a Federalism Assessment.

Statutory authorization for the rule

FDA cites sections 201, 402, 403, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 321, 342, 343, 348, and 721) as statutory authority for this rule.