



GAO

Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

B-293043

October 23, 2003

The Honorable Judd Gregg
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable W.J. "Billy" Tauzin
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration:
Prior Notice of Imported Food Under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002*

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 "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (RIN: 0910-AC41). We received the rule on October 10, 2003. It was published in the Federal Register as an "interim final rule; request for comments" on October 10, 2003. 68 Fed. Reg. 58974.

The interim final rule requires submission to the FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Enclosed is our assessment of the 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 the FDA 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

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

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
"PRIOR NOTICE OF IMPORTED FOOD UNDER THE
PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS
AND RESPONSE ACT OF 2002"
(RIN: 0910-AC41)

(i) Cost-benefit analysis

FDA estimates that the cost of the interim final rule in the first year will be \$367 million, annual costs of \$261 million, and the present value of costs to be \$3 billion at the 7-percent discount rate and \$4 billion at the 3-percent discount rate for 20 years.

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

FDA prepared a Final Regulatory Flexibility Analysis and has determined that the interim final rule will have a significant economic impact on a substantial number of small entities. The analysis contains the required information—including the number of small entities affected (77,427 importers), a discussion of the impacts, and the options considered to reduce the burden on small entities. Since the Bioterrorism Act establishes an effective date for prior notice of imported foods, FDA could not exempt or delay the application of the interim final rule on small entities.

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

FDA states that the interim final rule will impose a mandate of over \$100 million in any one year on the private sector and in conjunction with its cost-benefit analysis has prepared the act's required statement.

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

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

The interim final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On February 3, 2003, FDA and the U.S. Customs Service issued a joint notice of proposed rulemaking. In response, approximately 470 comments were received and are discussed in the preamble to the final rule. Also, comments on the interim final rule will be accepted until December 24, 2003.

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

The interim final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. FDA has submitted the information required under the act to OMB for review, including the reasons for the collection, the number of establishments affected, and the estimated burden hours. FDA estimates that the one-time burden will be 3,406,795 hours and the recurring burden will be 2,836,781 hours.

Statutory authorization for the rule

The interim final rule is promulgated under the authority contained in section 307 of Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188, June 12, 2002).

Executive Order No. 12866

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

Executive Order No. 13132 (Federalism)

The interim final rule, according to the FDA, does not have sufficient federalism implications to warrant the preparation of federalism assessment.