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February 13, 2001

The Honorable Richard G. Lugar
Chairman
The Honorable Tom Harkin
Ranking Member
Committee on Agriculture, Nutrition, and Forestry
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: Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice

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 "Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice" (RIN: 0910-AA43). We received the rule on February 1, 2001. It was published in the Federal Register as a final rule on January 19, 2001. 66 Fed. Reg. 6138.

The final rule mandates the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of fruit and vegetable juices.

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 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 Bob 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: Mr. Edwin V. Dutra, Jr.
Director, Regulations Policy and
Management Staff
Food and Drug Administration
Department 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
"HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HAACP);
PROCEDURES FOR THE SAFE AND SANITARY PROCESSING
AND IMPORTING OF JUICE"
(RIN: 0910-AA43)

(i) Cost-benefit analysis

FDA prepared a cost-benefit analysis of the final rule. The analysis finds that the costs in the first year are approximately $44 million to $58 million and $23 million in subsequent years. The quantified benefits of the final rule resulting from reduced illness and death from controlling pathogens is estimated at $151 million annually.

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

FDA has prepared a Final Regulatory Flexibility Analysis in connection with the final rule. The analysis contains the information required by the Act, including the reason and need for the rule; a description of the impact on small entities, including the number and size of the entities; and the steps taken to minimize the impact.

To minimize the burden, an extended compliance period of 2 and 3 years for small and very small entities, respectively, is included in the final rule.

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

The final rule does not contain an intergovernmental or private sector mandate, as defined in title II, of more than $100 million in any one year.

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

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

The final rule was issued using the notice and comment procedures contained at 5 U.S.C. 553. On April 24, 1998, FDA published in the Federal Register a Notice of Proposed Rulemaking. 63 Fed. Reg. 20450. In addition to workshops and public meetings, FDA received approximately 800 comments, which are discussed in the preamble to the final rule.

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

The final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The preamble to the final rule contains the information required by the Act, including the annual burden hours. FDA estimates that the collections will require 476,365.5 hours in the first year and 358,465.5 hours in subsequent years.

The approval request has been sent to OMB and when approved, FDA will publish a notice in the Federal Register.

Statutory authorization for the rule

The final rule is promulgated under the authority contained at 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, and 393 and 42 U.S.C. 241, 242l, and 264.

Executive Order No. 12866

The final rule was reviewed by OMB and found to be a "significant" regulatory action under the order.

Executive Order No. 13132 (Federalism)

FDA has determined that the final rule does not have federalism implications sufficient to warrant the preparation of a federalism assessment statement under the order.