



GAO

Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

B-286970

December 20, 2000

The Honorable Richard G. Lugar
Chairman

The Honorable Tom Harkin
Ranking Minority Member
Committee on Agriculture, Nutrition, and Forestry
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:
Food Labeling, Safe Handling Statements, Labeling of Shell Eggs;
Refrigeration of Shell Eggs Held for Retail Distribution

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 "Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution" (RIN: 0910-AB30). We received the rule on December 13, 2000. It was published in the Federal Register as a final rule on December 5, 2000. 65 Fed. Reg. 76092.

The final rule revises FDA's food labeling regulations to require a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms. The rule also requires that, when held at retail establishments, shell eggs be stored and displayed under refrigeration at a temperature of 7.2°C (45°F) or less.

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 Bob Robinson, Managing Director, Natural Resources and Environment. Mr. Robinson can be reached at (202) 512-3841.

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
"FOOD LABELING, SAFE HANDLING STATEMENTS,
LABELING OF SHELL EGGS; REFRIGERATION OF
SHELL EGGS HELD FOR RETAIL DISTRIBUTION"
(RIN: 0910-AB30)

(i) Cost-benefit analysis

The Food and Drug Administration performed a Regulatory Impact Analysis that includes a discussion of the costs and benefits of the final rule. FDA estimates that the median annual benefit for the first year will be \$260 million and will be \$260 million in all other years. The median estimated costs are \$56 million in the first year and \$10 million per year thereafter.

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

The FDA performed a Final Regulatory Flexibility Analysis that is contained in the preamble to the final rule. FDA concludes that the final rule will have a significant economic impact on a substantial number of small entities. The analysis discusses the size and number of small entities affected by the rule and discusses the steps taken to minimize the impact. An extension of the effective date of the rule was made in the final rule so that producers could use more of their inventory of egg cartons before the warning notice was required.

(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 May 19, 1998, FDA and the Department of Agriculture, Food Safety and Inspection Service, jointly published an Advanced Notice of Proposed Rulemaking in the Federal Register, 63 Fed. Reg. 27502, seeking information on decreasing food safety risks associated with shelled eggs.

On July 6, 1999, FDA published a Notice of Proposed Rulemaking in the Federal Register. 64 Fed. Reg. 36492. FDA received 790 comments in response and discusses the comments in the preamble to the final rule.

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

The final rule does not contain any information collections that are subject to review and approval by the Office of Management and Budget under the Paperwork Reduction Act.

Statutory authorization for the rule

The final rule was promulgated under the authority contained in 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; and 42 U.S.C. 201-262, 263b, and 364.

Executive Order No. 12866

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

Executive Order No. 13132 (Federalism)

While the proposed rule was issued before the order became effective, FDA believes it satisfied the requirements of the order. While the final rule will have a preemptive effect, the effect is very narrow and is necessary to ensure that national standards will be followed to achieve the food safety goals of the rule. The preemptive effect is limited to state or local requirements that are not as stringent and states and localities were advised of the preemption in the proposed rule.