U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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December 28, 2022

The Honorable Patty Murray
Chairwoman
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Requirements for Additional Traceability Records for Certain Foods*

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 "Requirements for Additional Traceability Records for Certain Foods" (RIN: 0910-AI44). We received the rule on December 14, 2022. It was published in the *Federal Register* as a final rule on November 21, 2022. 87 Fed. Reg. 70910. The effective date is January 20, 2023.

The final rule, according to FDA, establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods designated for inclusion on the Food Traceability List. Also, according to FDA, the rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. According to FDA, the rule will help FDA rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded.

The Congressional Review Act requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This final rule was published in the *Federal Register* on November 21, 2022. 87 Fed. Reg. 70910. The final rule was received by the House of Representatives and the Senate on December 12, 2022, and December 13, 2022, respectively. 168 Cong. Rec. H9908 (daily ed. Dec. 20, 2022); 168 Cong. Rec. S7198 (daily ed. Dec. 14, 2022). The rule has a stated effective date of January 20, 2023. Therefore, based on the dates of congressional receipt, the final rule does not have the required 60-day delay in its effective date.

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. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen
Director, Regulations Policy & Mgmt. Staff
Food and Drug Administration
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS
FOR CERTAIN FOODS"
(RIN: 0910-AI44)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration (FDA) summarized the benefits, costs, and distributional effects of this final rule. The benefits of the rule, according to FDA, are increased food supply system efficiencies, more expedient initiation and completion of recalls, avoidance of costs due to unnecessary preventive actions, reduction of food waste, and other efficiencies from a standardized approach to traceability. FDA also identified monetized health benefits from an estimated 83 percent improvement in traceback time for four pathogens, and non-health benefits of avoiding overly broad recalls. Specifically, FDA estimated annualized benefits of between $59 million and $2,238 million per year, in 2020 dollars, at the seven percent discount rate, and between $61 million and $2,322 million per year, in 2020 dollars, at the three percent discount rate.

The costs of the rule, according to FDA, include farming, manufacturing, or cooking-related actions that, as a result of new information flows, address risks of foodborne illness. FDA identified monetized costs due to a portion of foreign costs that could be passed on to domestic consumers. Specifically, FDA estimated annualized costs of between $63 million and $2,323 million per year, in 2020 dollars, at the seven percent discount rate, and between $53 million and $2,267 million per year, in 2020 dollars, at the three percent discount rate. Lastly, FDA estimated that the rule will not result in transfers.

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

FDA stated that this final rule will have a significant economic impact on a substantial number of small entities. FDA further stated that it developed a comprehensive economic analysis document that assesses the impacts of the rule and includes the Final Regulatory Flexibility Analysis, among other things, which is available in the docket for the rule.

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

FDA stated that this final rule would result in an expenditure in at least one year that meets or exceeds the current threshold after adjustment for inflation of $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product.

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

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

On September 23, 2020, FDA published a proposed rule. 85 Fed. Reg. 59984. FDA stated that it received approximately 1,100 comments from consumers, consumer groups, trade organizations, farmers, industry, public health organizations, state and local governments, foreign governments and organizations, and others. FDA responded to the comments in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

FDA determined that this final rule contains information collection requirements (ICRs) under the PRA. FDA stated the ICR, titled *Establishment, Maintenance, and Availability of Records; Traceability Records for Certain Foods* (Office of Management and Budget (OMB) Control Number 0910-0560), has an estimated one-time recordkeeping burden of 8,289,635 hours; an estimated annual reporting burden of 201 hours; and an estimated annual recordkeeping burden of 10,555,000 hours.

Statutory authorization for the rule

FDA promulgated this final rule pursuant to sections 1333, 1453, 1454, 1455, and 4402 of title 15; sections 1490 and 1491 of title 19; sections 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223 of title 21; and sections 216, 241, 243, 262, 264, and 271 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA stated that the Office of Information and Regulatory Affairs, within OMB, has designated this final rule as an economically significant regulatory action as defined by the Order.

Executive Order No. 13132 (Federalism)

FDA determined that this final rule does not contain policies that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power among the various levels of government. Accordingly, FDA determined the rule does not contain policies that have federalism implications.