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April 1, 2019

The Honorable Lamar Alexander  
Chairman  
The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Frank Pallone, Jr.  
Chairman  
The Honorable Greg Walden  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by Department of Health and Human Services, Food and Drug Administration (FDA) entitled “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E” (RIN: 0910-AH93). We received the rule on March 13, 2019. It was published in the *Federal Register* as a final rule on March 18, 2019. 84 Fed. Reg. 9706.

The final rule extends for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule published in November 2015 (November 2015 Rule). FDA is extending the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how it might further reduce the regulatory burden or increase flexibility while continuing to protect public health.

The Congressional Review Act (CRA) 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). The November 2015 rule had a stated effective date of January 26, 2016. 80 Fed. Reg. 74,354, 74,527 (Nov. 27, 2015). In our major rule report for the November 2015 rule, we reported that it did not have the required 60-day delay in effective date because it was not received until December 1, 2015. GAO, *Department of Health and Human Services, Food and Drug Administration: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption*, GAO-16-299R (Washington, D.C.: Dec. 16, 2015). The November 2015 Rule had staggered compliance dates ranging from 1 to 6 years from the effective date, depending on the size of the farm and the specific requirement.

The notice of proposed rulemaking for this rule was published in the *Federal Register* on September 13, 2017, and this final rule was published on March 18, 2019. 82 Fed. Reg. 42,963; 84 Fed. Reg. 9706. The rule was received by the House of Representatives on March 19, 2019, and the Senate received the rule March 18, 2019. 165 Cong. Rec. H2793 (Mar. 25, 2019); 165 Cong. Rec. S2039 (Mar. 27, 2019). The rule states that as of March 18, 2019, the compliance dates for certain provisions of the November 2015 Rule are delayed to January 26, 2024. Therefore 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 Janet Temko-Blinder at (202) 512-7104.

signed

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

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

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  
“STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND  
HOLDING OF PRODUCE FOR HUMAN CONSUMPTION;  
EXTENSION OF COMPLIANCE DATES FOR SUBPART E”  
(RIN: 0910-AH93)

(i) Cost-benefit analysis

Food and Drug Administration (FDA) included in this final rule an economic analysis of its impacts. FDA found that all initial startup costs and recurring costs remain the same as estimated in the final regulatory impact analysis for the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (November 2015 Rule). However, FDA found the annualized total costs decrease from \$291 million to \$280 million, resulting in a savings of \$12 million, when calculated with a 3 percent discount rate over 10 years or decrease from \$265 million to \$254 million resulting in a savings of \$10 million, when calculated with a 7 percent discount rate over 10 years. FDA found that the present value of total costs, discounted at 3 percent over 10 years, decreases from about \$2.5 billion to about \$2.4 billion, resulting in a savings of about \$99 million or, discounted at 7 percent over 10 years, decreases from about \$1.9 billion to about \$1.8 billion, resulting in a savings of about \$74 million.

FDA also found that there is a reduction in benefits associated with extending the compliance dates. Consumers eating non-sprout covered produce will not enjoy the potential health benefits (*i.e.*, reduced risk of illness) provided by the provisions of the November 2015 Rule until 2 to 4 years later than originally established in the produce safety regulation. Thus, FDA estimated the annualized total benefits to consumers, discounted at 3 percent over 10 years, decrease by \$104 million from \$800 million to \$696 million or discounted at 7 percent over 10 years, decrease by \$96 million from \$740 million to \$644 million. According to FDA, the present value of total benefits, discounted at 3 percent over 10 years, decreases from about \$6.8 billion to about \$5.9 billion or, discounted at 7 percent over 10 years, decreases from about \$5.2 billion to about \$4.5 billion.

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

FDA certified that this final rule will not have a significant economic impact on a substantial number of 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 determined that this final rule will not result in expenditure by state, local, and tribal governments, in the aggregate, in any year that meets or exceeds \$150 million (\$100 million adjusted for inflation).

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

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

On September 13, 2017, FDA published a proposed rule. 82 Fed. Reg. 42,963. FDA received comments from covered farms, consumer protection groups, groups representing these stakeholders, and state governments. FDA responded to comments within the scope of the proposed rule in the final rule.

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

FDA determined that this final rule contains no collection of information.

Statutory authorization for the rule

FDA promulgated the November 2015 Rule under the authorities of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food Safety Modernization Act (FSMA), and the Public Health Service Act (PHS Act). FDA specifically cited the authorities in section 105 of FSMA, sections 419, 701(a), and 709 of the FD&C Act and sections 311, 361, and 368 of the PHS Act. 21 U.S.C. §§ 350h, 371(a), 379a; 42 U.S.C. §§ 243, 264, 271. FDA did not identify statutory authority to delay the November 2015 Rule in this final rule.

Executive Order No. 12866 (Regulatory Planning and Review)

FDA determined that this final rule is 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 federalism implications as defined by the Order.