U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Washington, DC 20548

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December 16, 2015

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

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
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*

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 "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (RIN: 0910-AG35). We received the rule on December 1, 2015. It was published in the *Federal Register* a final rule on November 27, 2015. 80 Fed. Reg. 74,354.

The final rule, according to FDA, is intended to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce, and FDA established science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables grown for human consumption. FDA established these standards as part of the implementation of the FDA Food Safety and Modernization Act. These standards do not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity. In addition, according to the rule, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for exemption from the requirements of this rule. The rule sets forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. FDA expects the rule to reduce foodborne illness associated with the consumption of contaminated produce.

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 final rule has a stated effective date of January 26, 2016. It was published in the *Federal Register* as a final rule on November 27, 2015. 80 Fed. Reg. 74,354. We received the rule on December 1, 2015. Therefore, this rule does not have a 60-day delay in 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. Our review of the procedural steps taken indicates that, with the exception of the required 60-day delay in effective date, FDA complied with the applicable requirements.

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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Kenneth Cohen
Director, Regulations Policy and Management 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
"STANDARDS FOR THE GROWING, HARVESTING, PACKING,
AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION"
(RIN: 0910-AG35)

(i) Cost-benefit analysis

The Food and Drug Administration (FDA) prepared a cost-benefit analysis of the final rule. According to FDA, the primary benefits of the provisions in this final rule are an expected decrease in the incidence of illnesses related to microbial contamination of produce. Annualizing benefits over the first 10 years after the effective date of the rule at 7 percent, benefits are expected to derive from averting approximately 331,964 illnesses per year (362,059 at 3 percent), valued at $925 million annually ($976 million at 3 percent). Similarly, annualized costs, estimated at 7 percent, are expected to be approximately $366 million annually ($387 million at 3 percent). Additionally, annualized costs for foreign farms are estimated to be approximately $138 million annualized at 7 percent ($146 million at 3 percent).

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

FDA concluded that because small farms will bear a large portion of the costs, the final rule will 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 stated that the Unfunded Mandates Reform Act requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects this final rule to result in a 1-year expenditure that will exceed this amount.

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

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

On January 16, 2013, FDA issued the produce safety proposed rule (the 2013 proposed safety rule). 78 Fed. Reg. 3,504. FDA extended the comment period for the 2013 proposed produce safety rule in response to requests that it do so (78 Fed. Reg. 11,611, February 19, 2013; and 78 Fed. Reg. 24,692, April 26, 2013). FDA later extended the comment period to allow interested persons an opportunity to consider the interrelationships between the 2013 proposed

produce safety rule and the 2013 proposed foreign supplier verification programs (FSVP) and third-party certification rules (78 Fed. Reg. 48,637, August 9, 2013). FDA also issued a notice correcting several typographical, stylistic, and reference numbering errors (78 Fed. Reg. 17,155, March 20, 2013). At the time of that correction notice, FDA also made publicly available, in its entirety, the proposed produce safety rule with all errors corrected. The comment period for the 2013 proposed rule closed on November 22, 2013. (78 Fed. Reg. 69,605, Nov. 20, 2013). FDA held a number of public hearings and, according to FDA, based on the information heard at public meetings and based on a preliminary review of written comments submitted to the docket, then-currently available information, and FDA's subsequent analysis of the proposed provisions in light of this information, on September 29, 2014, FDA proposed certain new provisions and certain amendments to the provisions proposed in the 2013 proposed rule (79 Fed. Reg. 58,434). FDA received about 36,000 submissions representing approximately 15,000 unique comments from diverse members of the public including produce farms, facilities co-located on a farm, cooperatives, coalitions, trade organizations, consulting firms, law firms, academia, public health organizations, public advocacy groups, consumers, consumer groups, Congress, federal, state, local and tribal government agencies, and other organizations. FDA responded to comments in the final rule.

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

FDA states that the rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under PRA. FDA provided a description of these provisions along with an estimate of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. The provisions relate to: Agricultural Water—Documentation of Scientific Data, Sprouts—Establishment of Environmental Monitoring Plan, Sprouts—Establishment of Sampling Plan, Sprouts—Documentation of Scientific Data, Variances, Documenting Eligibility for Exemption by Qualified Exempt Farms, Training, Testing Requirement for Agricultural Water, Recordkeeping Related to Agricultural Water, Testing Requirements for Sprouts, Recordkeeping Related to Sprouts, Commercial Processing Exemption Recordkeeping, Records of Disclosures to Customers and Annual Written Assurances Obtained from Customers, and Third Party Disclosure Burdens, including Documentation, Posting Signage, and others. FDA provided tables summarizing the estimated annual recordkeeping burden (the one-time hourly burden and the annual hourly burden), and the estimated third party disclosure burdens (both the one-time third-party disclosure burden and the annual third-party disclosure burden).

Statutory authorization for the rule

FDA promulgated the 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). Specifically, the authorities in section 105 of FMSA (Pub. L. 111–353), section 419, 701(a), and 709 of the FD&C Act (21 U.S.C. 350h, 371(a), and 379a, respectively), and sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271).

Executive Order Nos. 12,866 and 13563 (Regulatory Planning and Review)

FDA concluded that the rule is a significant regulatory action under the Order. FDA stated that the final analysis conducted in accordance with Executive Orders and statutes is available in the docket for this rulemaking (Ref. 142) and at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.

Executive Order No. 13,132 (Federalism)

FDA analyzed this final rule in accordance with the principles set forth in the federalism order. FDA determined that the 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 and responsibilities among the various levels of government. Accordingly, FDA concluded that the final rule does not contain policies that have federalism implications as defined in the Order and stated that a federalism summary impact statement is not required.