



Consumer Federation of America

November 1, 2017

Scott Gottlieb, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

VIA ONLINE SUBMISSION

RE: Docket No. FDA-2011-N-0921, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E

Dear Dr. Gottlieb:

Consumer Federation of America writes to oppose further delay in implementation of the Food Safety Modernization Act (FSMA) and its standards for protecting Americans from contaminated produce. The agency's own analysis demonstrates that this delay would hurt consumers far more than it would help industry. At a minimum, the FDA should shorten the proposed delay from the current proposal, which would postpone compliance deadlines for some requirements by four years.

Consumers have already waited long enough for these protections. In 2010, FSMA passed through Congress with strong bipartisan support, and it was signed into law on January 4, 2011. The law directs FDA to issue, by January 4, 2012, a "proposed rulemaking" that includes "science-based minimum standards related to . . . water," and it provides that FDA "shall adopt a final regulation . . . [n]ot later than 1 year after the close of the comment period for the proposed rulemaking."¹ FDA missed the deadlines set by Congress, but a federal court eventually imposed its own timeline for the agency to implement FSMA, including promulgation of "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," aka "the Produce Safety Rule."²

FDA issued a proposed Produce Safety Rule on January 4, 2013.³ That rule included a requirement that growers must test agricultural water for generic *E. coli*, and "immediately discontinue use of that source of agricultural water and/or its distribution system" in the case

¹ 21 U.S.C. § 350h.

² See *Ctr. for Food Safety v. Hamburg*, C 12-4529 PJH, 2013 WL 5718339, at *1 (N.D. Cal. Oct. 21, 2013).

³ <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

that a “single sample” of 100mL contained more than 235 colony forming units (CFU).⁴ In response to comments, however, on September 29, 2014, the agency issued a “Proposed Supplemental Rule for Produce Safety” that abandoned a “maximum threshold of *E. coli* in a single sample.”⁵ Instead, FDA required growers to create a “Microbial Water Quality Profile,” on the basis of a collection of samples, to be taken over a period of two to four years.⁶ In order to demonstrate compliance with the numerical standards for a water quality profile, a grower would need time to take samples. Therefore, in the final Produce Safety Rule that the agency issued on November 27, 2015, FDA set the compliance dates for the provisions that established and referenced the numerical microbiological standards—21 C.F.R. § 112.44 and parts of §§ 112.45 and 112.46—to fall two years after the other agricultural water provisions in Subpart E.⁷

The other agricultural water provisions in Subpart E include more general requirements. In addition to an undefined mandate to only use agricultural water that is “safe and of adequate sanitary quality for its intended use,”⁸ they require growers to inspect and repair water distribution infrastructure,⁹ to monitor for the buildup of organic material in wash tanks and coolers,¹⁰ to maintain and monitor the temperature of water to minimize microbiological risks,¹¹ and to keep records of the scientific support for food safety interventions.¹² Complying with these provisions does not hinge on an analysis of a multi-year water profile, and many growers are already required to comply with similar standards under third-party audit schemes.¹³ Yet the compliance date for these provisions would be delayed for *four* years under FDA’s proposed rulemaking.

FDA has not adequately explained its rationale for the proposed delay, or for its length. For large growers, the proposed rule would delay by two years compliance dates previously set in 2020, and by four years compliance dates previously set in 2018. The proposed rule cites “feedback from numerous stakeholders raising issues regarding the practicality of some of the agricultural water requirements,” and particularly regarding “testing requirements.” However, it does not specify what those issues are, or why the agency needs so much “additional time . . . to consider approaches to address these issues.”¹⁴ The proposed rule likewise explains the four-year delay of provisions set to go into effect in just a few months as an effort to “simplify the subpart E compliance period structure,” which it claims would help to “alleviate confusion.” But the agency fails to explain the nature of this confusion, or why the proposed simplification and resulting four-year delay is necessary to address it.

⁴ 78 *Fed. Reg.* 3568 (Jan. 16, 2013).

⁵ FDA, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption 79 *Fed. Reg.* 58433 (Sept. 29, 2014) [“Supplemental Proposed Rule”].

⁶ 79 *Fed. Reg.* 58444.

⁷ FDA, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” 80 *Fed. Reg.* 74354 (Nov. 27, 2015) available at: <https://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>

⁸ 21 C.F.R. § 112.41.

⁹ 21 C.F.R. § 112.44.

¹⁰ 21 C.F.R. § 112.48(b).

¹¹ 21 C.F.R. § 112.48(c).

¹² 21 C.F.R. § 112.50.

¹³ See, e.g., <http://www.lgma.ca.gov/wp-content/uploads/2016/11/08.01.16-LGMA-and-Produce-Rule-FINAL.pdf>.

¹⁴ At 42965.

Unfortunately, FDA’s own cost-benefit analysis indicates that this delay would impose a burden on consumers that greatly outweighs any gains that may accrue to producers. Depending on the discount rate, the discrepancy runs between just under \$100 million and nearly \$1 billion, according to this proposed rule.¹⁵ According to FDA’s earlier economic analysis of the final Produce Rule, “Agricultural Water for growing and harvest activities is estimated to be the most important pathway of contamination [of produce], at about 16 percent.”¹⁶ This risk should not persist unchecked without good reason.

American consumers across the political spectrum want better government controls to ensure food safety. A 2014 poll of 2,236 adults found that 73% agreed with the statement that “there should be more government oversight in regards to food safety,” and a majority agreed that “food safety issues are an inevitable side effect of low food costs.”¹⁷ Prior to passage of FSMA, a poll by the Leafy Greens Marketing Association found that 89% of respondents favored “mandatory farm inspections by the government to verify compliance with the food safety practices.”¹⁸ Even where third-party audits are common, food safety regulations and government inspection serve an important check on private auditing companies, who are paid by the companies they are tasked with scrutinizing.¹⁹

For the foregoing reasons, we opposed the proposed delay.

Sincerely,



Thomas Gremillion
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Consumer Federation of America

¹⁵ Proposed Rule at 42967, Table 4.

¹⁶ FDA. Final Regulatory Impact Analysis. Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM472330.pdf>

¹⁷ The Harris Poll. “Nearly Three-Quarters of Americans Looking to Government for More Food Safety Oversight” Feb. 5, 2014 *available at*: http://www.theharrispoll.com/politics/Nearly_Three-Quarters_of_Americans_Looking_to_Government_for_More_Food_Safety_Oversight.html

¹⁸ See Scott Horsfall. “Survey Says: The People Want Government Food Safety Oversight.” *available at*: <http://www.lgma.ca.gov/2014/02/survey-says-people-want-government-food-safety-oversight/>

¹⁹ See, e.g. D.A. Powell, et al. “Audits and inspection are never enough: A critique to enhance food safety.” *Food Control* (2013).