November 13, 2017

Scott Gottlieb, MD
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:

The Center for Science in the Public Interest and the Center for Food Safety write to oppose the FDA's proposed rule[1] extending the compliance dates for Subpart E of the final rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption ("the produce safety rule"). The proposed extension would prevent consumers from realizing the benefits of core protections within the Food Safety Modernization Act (FSMA) until 11 to 13 years after this important act was signed into law on January 4, 2011.[2]

The proposed delay is contrary to Congress's intent and the plain language of FSMA, which lays out specific statutory deadlines for both the rulemaking and implementation of the produce safety rule. The delay is also unnecessary, overly broad, and will contribute to needless illness and loss of life, potentially leading to more than 730,000 additional cases of foodborne illness and countless deaths. The inappropriateness of the delay is reflected in the agency's own economic analysis, which estimates that increased costs to consumers associated with increased disease burden as a result of the delay will outweigh any economic cost savings to industry by between $96 million and $822 million.

We urge the FDA to withdraw its proposed rule, and instead to focus agency resources on providing additional training and support to producers and federal, state, and local public health officials, to ensure that the rule's requirements be successfully implemented on the current timeline.

[1] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E. 82 *Fed. Reg.* 42963 (September 13, 2017). ["Proposed Delay Rule"].
[2] Pub. L. 111-353, January 4, 2011.

I. Factual and Regulatory Background.

The Centers for Disease Control and Prevention estimates that, every year, 47.8 million people (roughly one in six Americans) are sickened by foodborne illness.[3] Tragically, 3,000 die annually and nearly 128,000 are hospitalized.[4] Many suffer serious long-term effects such as kidney failure, autoimmune disease, and nerve and brain damage.[5] The annual cost to the U.S. economy in medical bills and productivity losses alone is over $77 billion.[6]

Food safety—the systematic effort to prevent this illness and loss of life—is a broadly supported American value. That is why FSMA, the first major overhaul of food safety laws since 1938, passed through Congress with strong bipartisan support, as well as support from industry and consumer groups. FSMA came on the heels of a number of deadly outbreaks linked to produce, including a 2006 outbreak of *E. coli* O157:H7 infections linked to Dole baby spinach, which led to over 100 hospitalizations, 31 cases of kidney failure, and 5 deaths.[7,8] That outbreak was eventually traced back to water contaminated with cattle and wild pig feces, which had made its way into spinach fields in California.[9]

FSMA and its implementing regulations offer improved safeguards for food production in numerous areas, including produce safety. Subpart E of FSMA's produce safety rule addresses the quality of water used in growing or processing produce, excluding sprouts.[10] The water safety requirements were a key component of the produce safety rule: in its cost-benefits analysis of the rule, the FDA stated that agricultural water is "the most important pathway of contamination" of produce.[11] At the core of Subpart E's water quality requirements were microbiological testing standards designed to ensure that water used in agriculture not carry high levels of *E. coli*, an indicator of fecal contamination. In essence, the standard ensures that people will not get sick from eating produce contaminated with feces.

To ensure that the produce safety rule and other FSMA rules be implemented swiftly, Congress included a specific timeline requiring the FDA to issue a proposed rule on produce water safety by January 4, 2012, and a final rule no later than one year after the close of the comment period on the

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[3] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg. Infect. Dis.* [serial on the Internet]. 2011 Jan. https://wwwnc.cdc.gov/eid/article/17/1/P1-1101_article.

[4] *Ibid.*

[5] Lindsay JA. Chronic sequelae of foodborne disease. *Emerg. Infect. Dis.* 1997 Oct-Dec;3(4):443-52.

[6] Scharff RL. Economic burden from health losses due to foodborne illness in the United States. *J. Food. Prot.* 2012 Jan;75(1):123-31.

[7] Centers for Disease Control and Prevention. Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Fresh Spinach (FINAL UPDATE). October 6, 2006. https://www.cdc.gov/ecoli/2006/spinach-10-2006.html. Only three of the five deaths met the CDC's definition of a "confirmed case."

[8] Weise E, Schmit J. Spinach recall: 5 faces. 5 agonizing deaths. 1 year later. *USA Today*. January 8, 2009. http://abcnews.go.com/Business/story?id=3633374.

[9] Gelting R. CDC Addendum Report, Irrigation Water Issues Potentially Related to 2006 *E. coli* 0157:H7 in Spinach Outbreak. Attachment 11. July 2011. www.cdc.gov/nceh/ehs/docs/investigation_of_an_e_coli_outbreak_associated_with_dole_pre-packaged_spinach.pdf.

[10] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 80 *Fed. Reg.* 74354 (November 27, 2015). ["Final Produce Safety Rule"].

[11] Food and Drug Administration. Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption. www.fda.gov/downloads/food/guidanceregulation/fsma/ucm334116.pdf.

proposed rule.[12] The FDA failed to meet these and other FSMA rulemaking deadlines, leading the Center for Food Safety to file suit against the agency in 2012.[13] As a result of this litigation, the FDA agreed to a timeline for completing the FSMA rules, and the final produce safety rule was finally issued on November 27, 2015.[14] That rule became effective on January 26, 2016.[15]

The final produce safety rule outlined generous time periods for industry to come into compliance. With respect to the water safety requirements of Subpart E, industry was generally given two to four years for compliance, depending on the size of the farm.[16] The FDA also provided a further two-year period for industry to come into compliance with specific requirements related to microbiological testing of water quality.[17] This meant that the general water safety requirements of Subpart E would be phased in between January 26, 2018, and January 26, 2020, and that the microbiological water quality testing requirements of Subpart E would be phased in between January 26, 2020, and January 26, 2022.

II. The Proposed Delay is Excessive, Unnecessary, and Overly broad, and Will Contribute to Unnecessary Illness and Loss of Life.

The FDA's new proposed rule pushes out the compliance dates for Subpart E's general requirements by four years, and its microbiological water quality testing requirements by two years. Under the new timeline, farms would not be required to phase in compliance on any of the Subpart E water safety requirements until January 26, 2022, to January 26, 2024.[18]

The FDA argues that such delay is justified by stakeholder concerns, particularly issues related to the burdens of microbiological testing requirements under the rule. The agency suggested that this "[a]dditional time would allow us to consider approaches to address these issues, as well as opportunities there may be to reduce the cost and enhance the flexibility of these requirements beyond those reflected in the final rule."[19] The FDA also cites Executive Orders 13777, 13771, and 13563, which relate to the current executive regulatory reform agenda and efforts to reduce the "regulatory burden" on industry.[20]

These concerns are insufficient to justify the proposed delay. First, further delay is excessive, as the FDA has already allowed industry ample time to comply with the microbiological testing requirements of the rule, which will not begin to be phased in until 2018 to 2022, a date range that is already two to six years after the effective date of the final rule and seven to 11 years after the FSMA was signed into law on January 4, 2011. The proposed delay would extend this timeline even further, meaning Americans would not see the full benefits of this part of FSMA until 2022 to 2024, six to eight years after the effective date of the final rule and 11 to 13 years after FSMA became law. This prolonged delay is contrary to Congress's intent and the plain language of FSMA, which laid out specific statutory deadlines for both the rulemaking and implementation of the produce safety rule.[21]

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[12] 21 U.S.C. § 350h.
[13] *See Ctr. for Food Safety v. Hamburg*, C 12-4529 PJH, 2013 WL 5718339, at *1 (N.D. Cal. Oct. 21, 2013).
[14] Final Produce Safety Rule, 80 *Fed. Reg.* at 74354.
[15] *Ibid.*
[16] *Ibid.* at 74357.
[17] *Ibid.*
[18] Proposed Delay Rule. 82 *Fed. Reg.* at 42965. Separate requirements of Subpart M, related to water used in the production of sprouts, have already been implemented.
[19] *Ibid.*
[20] *Ibid.*
[21] *See* Pub. L. 111-353, Sec. 105.

Second, further delay is unnecessary because the FDA already addressed stakeholder concerns appropriately in the final rule, which carefully balanced industry concerns related to regulatory burden with the need for scientifically appropriate standards protective of public health. Prior to promulgating that rule, the FDA took public comments on the rule for 11 months in total, extending the comment period on three separate occasions and issuing a supplemental proposed rule[22] in response to the comments on the initial proposed rule. The agency also held four public meetings to solicit oral comments. The preamble to the final rule devoted 167 pages to addressing approximately 36,000 submissions covering about 15,000 unique comments.[23]

The final rule also specifically addressed stakeholder concerns regarding the regulatory burden imposed by microbiological testing requirements. Specifically, the FDA's initial proposed produce safety rule included a strict requirement that growers immediately discontinue use of a water source for certain high-risk uses if a single sample of water from that source contained generic *E. coli* above a threshold level.[24] In response to comments that this standard was too demanding, the agency abandoned the single-sample threshold in favor of a more comprehensive water quality profile based on the collection of multiple samples to assess water quality over time.[25] This change already weakened the rule in order to addressed stakeholder concerns for regulatory flexibility. Additional delay to further reconsider stakeholder concerns is therefore unnecessary.

Third, the proposal is overly broad, pushing back all provisions of Subpart E rather than focusing specifically on the microbiological testing requirements that stakeholders claim pose the greatest concern. In addition to the microbiological testing requirements, Subpart E includes a requirement that producers train personnel and implement proper hygiene and food safety practices,[26] inspect and repair water distribution infrastructure,[27] monitor for the buildup of organic material in wash tanks and coolers,[28] maintain and monitor the temperature of water,[29] and keep records of the scientific support showing that effective methods are being used to treat contaminated water.[30] These important safeguards would have begun phasing in on January 26, 2018, but under the proposal they would be pushed back to January 26, 2022. Such a long delay is unjustified given that these requirements are not highly complex and there is little evidence that industry would have difficulty complying with these aspects of the rule on the current timeline.

Finally, the delay will contribute to unnecessary illness and loss of life. The FDA has estimated that contaminated water, both pre- and post-harvest, accounts for 30 percent of outbreaks linked to produce.[31] The final water safety rule would reduce pre- and post-harvest contamination by 55 and 73 percent, respectively.[32] The agency conservatively estimated that these pre- and post-harvest

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[22] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption 79 *Fed. Reg.* 58433 (Sept. 29, 2014) ["Supplemental Proposed Rule"].
[23] Final Produce Safety Rule. 80 *Fed. Reg.* at 74362-74529.
[24] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 78 *Fed. Reg.* 3504, 3568 (Jan. 16, 2013). ["Initial Proposed Rule"].
[25] Supplemental Proposed Rule. 79 *Fed. Reg.* at 58444.
[26] 21 C.F.R. § 112.22, § 112.31-33.
[27] 21 C.F.R. § 112.42.
[28] 21 C.F.R. § 112.48(b).
[29] 21 C.F.R. § 112.48(c).
[30] 21 C.F.R. § 112.50.
[31] Food and Drug Administration. Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.
www.fda.gov/downloads/food/guidanceregulation/fsma/ucm334116.pdf, Page 73, Table 23.
[32] *Ibid.* at Page 76-7, Table 24.

improvements would prevent over 365,000 cases of foodborne illness annually.[33] The proposed delay would mean that Americans would not appreciate these benefits for two to four additional years, potentially contributing to more than 730,000 additional cases of foodborne illness.

The delay will also lead to unnecessary deaths. While the FDA did not separately report on deaths in its economic estimates, it is clear that since the passage of FSMA, Americans have continued to die from contaminated produce at unacceptable rates. Deadly outbreaks traced to produce since FSMA's passage include:

- In 2011, an outbreak caused by *Listeria* in cantaloupes swept across 28 states, and was eventually linked to 147 illnesses, 143 hospitalizations, and at least 33 deaths.[34]
- In 2012, an outbreak caused by *Salmonella* in cantaloupes led to 261 illnesses, 94 hospitalizations, and 3 deaths.[35] FDA inspectors observed poor sanitary practices and other problems throughout the facilities where the cantaloupes were processed.[36]
- In 2014, *Listeria* in caramel apples caused an outbreak linked to 35 illnesses, 34 hospitalizations, and 7 deaths.[37] The outbreak was traced back to the apples, which had been contaminated in a packing facility.
- Also in 2014, an outbreak caused by cucumbers contaminated with *Salmonella* was linked to 275 illnesses, 48 hospitalizations, and 1 death.[38]
- The following year, 2015, another outbreak caused by *Salmonella* in cucumbers led to 907 illnesses, 204 hospitalizations, and 6 deaths.[39]
- In 2016, an outbreak caused by *Listeria* in frozen vegetables was linked to 9 illnesses, all of which required hospitalization, and 3 deaths.[40]
- In 2017, the FDA and the CDC traced a series of four outbreaks back to papayas contaminated with *Salmonella.* The largest of the four outbreaks was linked to 220 illnesses, 68 hospitalizations, and 1 death.[41]

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[33] *Ibid.* at Page 97, Table 33.

[34] Centers for Disease Control and Prevention. Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado (FINAL UPDATE). August 27, 2012. Ten patients sickened in the outbreak who also died were not counted in the total because the cause of death listed on each of their death certificates was not *listeriosis*. www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html.

[35] Centers for Disease Control and Prevention. Multistate Outbreak of *Salmonella* Typhimurium and *Salmonella* Newport Infections Linked to Cantaloupe (Final Update). October 5, 2012. www.cdc.gov/salmonella/typhimurium-cantaloupe-08-12/index.html.

[36] Food and Drug Administration. Form FDA 483. Chamberlain Farms, Inc. August 31, 2012. www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM322103.pdf.

[37] Centers for Disease Control and Prevention. Multistate Outbreak of Listeriosis Linked to Commercially Produced, Prepackaged Caramel Apples Made from Bidart Bros. Apples (Final Update). February 12, 2015. www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/index.html.

[38] Angelo K, Chu A, Anand M, et al. Outbreak of *Salmonella* Newport Infections Linked to Cucumbers — United States, 2014. *MMWR* 64(06);144-147 February 20, 2015. www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a3.htm?s_cid=mm6406a3_e.

[39] Centers for Disease Control and Prevention. Multistate Outbreak of *Salmonella* Poona Infections Linked to Imported Cucumbers (Final Update). March 18, 2016. www.cdc.gov/salmonella/poona-09-15/index.html.

[40] Centers for Disease Control and Prevention. Multistate Outbreak of Listeriosis Linked to Frozen Vegetables (Final Update). July 15, 2016. www.cdc.gov/listeria/outbreaks/frozen-vegetables-05-16/index.html.

[41] Centers for Disease Control and Prevention. Multistate Outbreak of *Salmonella* Infections Linked to Imported Maradol Papayas (Final Update). November 3, 2017. www.cdc.gov/salmonella/kiambu-07-17/index.html.

The water produce safety rule could have reduced this burden of illness and death by preventing a substantial number of these and other produce-related outbreaks. The additional delay in implementing key provisions of the rule undoubtedly undermines efforts to prevent deadly outbreaks, delaying lifesaving benefits for American consumers.

As further illustration of the inappropriateness of the proposed delay, the FDA's own cost-benefit analysis, published in the proposed rule, reveals that the economic costs of the proposed delay would outweigh its benefits. The FDA's summary of the changes in benefits and costs of the delay, published in the proposed rule, shows that the rule will reduced costs to industry by $12 million to $103 million, depending on the economic analysis used. However, the rule will increase foodborne illness and suffering, a cost to consumers that the FDA has valued at between $108 million to $925 million. Overall, the harms to consumers would outweigh any cost savings to industry by between $96 and $822 million.[42]

For the foregoing reasons, we oppose the proposed delay and urge the FDA to move forward with implementation of the water produce safety requirements under the previously established timeline.

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[42] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E. 82 *Fed. Reg.* 42963, 42967, Table 4 (Sept. 13, 2017).