



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2011-N-0921]

RIN 0910-AH93

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending, 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. We are extending the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to protect public health.

DATES: As of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] the compliance dates for the agricultural water provisions (subpart E) in the Standards for the “Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (November 27, 2015, 80 FR 74354), for covered produce other than sprouts, are delayed to January 26, 2024, for very small businesses, January 26, 2023, for small businesses, and January 26, 2022, for all other businesses.

FOR FURTHER INFORMATION CONTACT: Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1636.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
- II. Background
- III. Analysis and Response to Public Comments
- IV. Economic Analysis of Impacts
- V. Analysis of Environmental Impact
- VI. Paperwork Reduction Act of 1995
- VII. Federalism
- VIII. Consultation and Coordination with Indian Tribal Governments
- IX. References

I. Executive Summary

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. The agricultural water provisions are contained in subpart E of that rule. We are also simplifying the compliance date structure under subpart E as applied to non-sprout covered produce, while retaining date-staggering based on size. The new compliance dates for the agricultural water requirements in subpart E for non-sprout covered produce are January 26, 2024, for very small businesses; January 26, 2023, for small businesses; and January 26, 2022, for all other businesses.

The final rule does not alter the requirements in subpart E and therefore the estimated costs and benefits accrued in any given year of compliance with the produce safety regulation, relative to the first year of compliance, do not change. However, because the compliance dates for the agricultural water provisions are extended, the discounted value of both total costs and total benefits decrease.

The impact of this final rule is summarized in the following table.

Table 1.--Summary of Changes to Benefits and Costs as a Result of the Final Rule

Category		Primary Estimate	Units		
			Year Dollars	Discount Rate	Period Covered
Forgone Benefits	Annualized	\$96	2017	7%	2016-2025
	Monetized \$millions/year	\$104	2017	3%	2016-2025
Forgone Costs	Annualized	\$10	2017	7%	2016-2025
	Monetized \$millions/year	\$12	2017	3%	2016-2025

## II. Background

This extension of compliance dates concerns one of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR), Part 112 as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353):

“Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (the produce safety regulation, published in the *Federal Register* of November 27, 2015, 80 FR 74354) (<https://www.fda.gov/fsma>). We proposed this extension in a proposed rule published on September 13, 2017 (82 FR 42963). We have reviewed the comments submitted in response to the proposed rule, and we respond to those comments in section II. In this final rule we are extending the compliance dates as proposed.

In the preamble of the final rule establishing the produce safety regulation, we stated that the produce safety regulation would be effective on January 26, 2016, and provided for

compliance dates of 1 to 6 years from the effective date depending on farm size, commodity, and provision(s) (see table entitled “compliance dates” in the preamble of the final rule establishing the produce safety regulation, 80 FR 74354 at 74357, as corrected in a technical amendment at 81 FR 26466, May 3, 2016). (Some of the compliance dates identified in the technical amendment fall on weekends (i.e., January 26, 2019, is a Saturday and January 26, 2020, is a Sunday) and should therefore be read as referring to the next business day (i.e., January 28, 2019, and January 27, 2020, respectively). We use the latter dates throughout this document.)

For the majority of agricultural water provisions at subpart E (and for most of the other provisions in the rule), with respect to covered produce other than sprouts, we provided compliance periods of 4 years from the effective date of the rule for very small businesses, 3 years for small businesses, and 2 years for all other businesses.<sup>1</sup> We provided an additional 2 years beyond those compliance periods for certain water quality requirements in § 112.44 and related provisions in §§ 112.45 and 112.46. See table 2.

In a final rule, “The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules” (81 FR 57784, August 24, 2016) we also extended the compliance date for certain “customer provisions” in four of the seven foundational rules that we have established as part of our implementation of FSMA, including the produce safety regulation (§ 112.2(b)(3)). In that final rule, we also clarified how we interpret the compliance dates for certain agricultural water testing provisions established in the produce safety regulation.

---

<sup>1</sup> Under the produce safety regulation, a farm is a very small business if, on a rolling basis, the average annual monetary value of produce it sold during the previous 3-year period is no more than \$250,000. A farm is a small business if, on a rolling basis, the average annual monetary value of produce it sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business. See 21 CFR 112.3.

Table 2.--As Stated in Produce Safety Regulation, Compliance Dates for Requirements in Subpart E (Agricultural Water) for Covered Activities Involving Covered Produce (Except Sprouts Subject to Subpart M)

Compliance Dates of 2-4 Years Applicable to the Farm Based on its Size	Extended Compliance Date of Additional 2 years Beyond the Compliance Date Based on Size of Farm
§ 112.41 § 112.42 § 112.43 § 112.45(a) with respect to safe and adequate standard § 112.46(a) § 112.46(b)(1) with respect to untreated surface water § 112.47 § 112.48 § 112.49 § 112.50	§ 112.44 § 112.45(a) with respect to § 112.44(a) criterion § 112.45(b) § 112.46(b)(1) with respect to untreated ground water § 112.46(b)(2) and (b)(3) § 112.46(c)

FDA has received feedback from numerous stakeholders raising issues regarding the practicality of some of the agricultural water requirements in the produce safety regulation as applied to covered produce other than sprouts. Many of these concerns relate to the testing requirements for pre-harvest agricultural water, which are different for sprouts than they are for other types of covered produce. We are extending these compliance dates in light of the feedback we have received. Additional time allows us to consider how to approach these issues.

As part of this extension, we are simplifying the subpart E compliance period structure such that all the compliance dates for subpart E provisions as applied to non-sprout covered produce will occur at the same time, retaining date-staggering based on farm size. Accordingly, covered farms will have 2 years beyond the previously published compliance dates for the water quality requirements in § 112.44 and related provisions in §§ 112.45 and 112.46, to comply with all of subpart E. Put another way, we are extending the compliance dates for provisions in the first column of table 2 by 4 years and extending the compliance dates for provisions in the second column of table 2 by 2 years, so that the compliance dates for non-sprout covered produce for all provisions of subpart E are those listed in table 3.

Table 3.--Compliance Dates for Requirements in Subpart E for Covered Activities Involving Covered Produce (Except Sprouts Subject to Subpart M)

Size of Covered Farm	Time Periods Starting from the Effective Date of the November 27, 2015, Produce Safety Final Rule (January 26, 2016)	
	Compliance Period	Compliance Date
Very Small Business	8 years	January 26, 2024
Small Business	7 years	January 26, 2023
All Other Businesses	6 years	January 26, 2022

This rule is limited in scope to extending the compliance dates for covered produce other than sprouts. The rule does not address the underlying requirements in subpart E, but only the compliance dates for those requirements (for covered produce other than sprouts).

We conducted a qualitative assessment of risk of hazards associated with produce production during the produce safety rulemaking, which indicates that agricultural water is a potential route of contamination of produce during growing, harvesting, and on-farm postharvest activities and that use of poor agricultural practices could lead to contamination and illness even where the potential for contamination is relatively low. We remain firmly committed to science-based minimum standards directed to agricultural water to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342). To that end, we have been pursuing and will continue to pursue a rigorous stakeholder engagement plan in the coming months as we consider the practical implementation of the agricultural water requirements and how to best achieve these important public health objectives. Along with farmers and others in the produce industry, in February 2018 we participated in a summit at which participants proposed and discussed potential approaches to addressing concerns with the

existing agricultural water requirements. We are also continuing visits to farms throughout the country to further refine our understanding of the myriad variations in agricultural water sources and uses. We will continue to consult with experts in produce safety, water systems, and water microbiology, from both the public and private sectors, to take advantage of the very latest scientific developments and conclusions, particularly around water quality criteria, sampling, and testing.

This rule does not change the compliance dates for sprouts. In the final produce safety regulation, we provided staggered compliance periods based on farm size for covered activities involving sprouts. The compliance date for activities involving sprouts for very small businesses is January 28, 2019. The compliance date for activities involving sprouts for small businesses is January 26, 2018. The compliance date for activities involving sprouts for all other businesses is January 26, 2017. The final produce safety regulation established sprout-specific requirements on multiple topics, including agricultural water. The agricultural water requirements for sprouts are different from the agricultural water requirements for other produce commodities (compare §§ 112.44(a)(1) and 112.44(b)). We have not received any significant feedback from sprout farms that subpart E has posed particular challenges. Accordingly, as proposed, we are not taking action with regard to compliance dates for activities involving sprouts.

Table 4 summarizes the compliance dates for the produce safety regulation based on this final rule. Time periods start from the effective date of the produce safety rule (January 26, 2016) except as otherwise specified.

Table 4.--Compliance Dates for the Produce Safety Regulation Under this Final Rule (21 CFR Part 112)

Size of Farm	Compliance Dates Relating to Covered Activities on Covered Farms			Compliance Dates Relating to Certain Exemptions							
	Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of Part 112)	Covered activities involving all other covered produce (i.e., subject to part 112, except subpart M)		Farms eligible for a qualified exemption (if applicable)				Farms relying on the exemption in § 112.2(b) for produce that receives commercial processing that adequately reduces microorganisms of public health concern			
		Agricultural water requirements in subpart E	All other requirements	Retention of records supporting eligibility in §112.7(b)	Modified requirement in § 112.6(b)(1)	All other requirements in §§ 112.6 and 112.7 for farms producing sprouts	All other requirements in §§ 112.6 and 112.7 for farms not producing sprouts	Requirement to obtain customer written assurances in § 112.2(b)(3) for sprouts that would otherwise be subject to	All other requirements in § 112.2(b) for sprouts that would otherwise be subject to subpart M	Requirement to obtain customer written assurances in § 112.2(b)(3) for all other produce that would otherwise be covered	All other requirements in § 112.2(b) for all other produce that would otherwise be covered
Very Small Businesses	3 years (Jan. 28, 2019)	8 years (Jan. 26, 2024)	4 years (Jan. 27, 2020)	Effective date of rule (Jan. 26, 2016)	Jan. 1, 2020	3 years (Jan. 28, 2019)	4 years (Jan. 27, 2020)	5 years (Jan. 26, 2021)	3 years (Jan. 28, 2019)	6 years (Jan. 26, 2022)	4 years (Jan. 27, 2020)
Small Businesses	2 years (Jan. 26, 2018)	7 years (Jan. 26, 2023)	3 years (Jan. 28, 2019)			2 years (Jan. 26, 2018)	3 years (Jan. 28, 2019)	4 years (Jan. 27, 2020)	2 years (Jan. 26, 2018)	5 years (Jan. 26, 2021)	3 years (Jan. 28, 2019)
All Other Businesses	1 year (Jan. 26, 2017)	6 years (Jan. 26, 2022)	2 years (Jan. 26, 2018)	N/A				3 years (Jan.28, 2019)	1 year (Jan. 26, 2017)	4 years (Jan. 27, 2020)	2 years (Jan. 26, 2018)

### III. Analysis and Response to Public Comments

In response to the proposed rule, we received comments from covered farms, consumer protection groups, groups representing these stakeholders, and state governments. Many of the comments were supportive of the proposed extension and simplification of compliance dates. In

this final rule, we respond to comments related to whether FDA should extend the compliance dates and simplify the compliance date structure for the agricultural water requirements for covered produce other than sprouts. We did not consider and do not address comments that raised issues beyond the narrow scope of the proposed rule, including comments related to withdrawal or modifications to subpart E or comments related to broader policy issues. FDA will take these additional comments into consideration as we consider approaches to address agricultural water requirements. In this final rule we also do not address specific questions on the produce safety regulation, but the Technical Assistance Network remains an available resource for such questions (<https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm>). We have summarized the relevant comments received and provided our responses below.

(Comment 1) Many comments supported the proposed extension of compliance dates for the agricultural water provisions for covered produce other than sprouts. One comment stated that the extension would allow covered farms an opportunity to continue a dialogue with FDA around the best approaches to implementing the agricultural water provisions. An association said it “strongly supported” the proposed extension, that the agricultural water provisions are very complex, and explained it had been working to educate its members about the requirements but found that developing practical advice was a challenge given the complexity. Another organization expressed its support for the proposed extension and stated that the agricultural water provisions are complicated and difficult to understand. Another individual wrote in support of the extension, contending that covered farms and other stakeholders have been confused by the requirements, and opined that an extension would be particularly helpful to

smaller covered farms that could use the additional time to understand and implement these provisions.

(Response 1) These comments are consistent with the feedback we have been receiving on the complexity of the agricultural water provisions from stakeholders since the produce safety final rule published in 2015. We have repeatedly heard the message relayed in these comments-- that the requirements of subpart E, particularly the sampling and testing provisions, are complicated to understand, and questions remain about how to implement them in a practical manner. Accordingly, we have decided to finalize the extension as proposed.

(Comment 2) Some comments opposed FDA's proposal to extend the compliance dates because they did not believe we had sufficiently justified the proposed delay, or its length. These comments noted that the compliance dates for certain agricultural water testing requirements were already later than the compliance dates for the rest of the produce safety regulation. These comments also stated that FDA had already sufficiently addressed stakeholder concerns through the rulemaking process, noting that we revised the agricultural water requirements as a result of comments on the proposed and supplemental rules. Some comments also encouraged the Agency to withdraw the proposed rule and focus on implementing the produce safety regulation on time; these comments also noted the public health benefits of the produce safety regulation.

(Response 2) While we share the goal of public health expressed in these comments, we believe that a delay is necessary and justified for reasons different than those set out in the final rule for the changes to the agricultural water requirements. The feedback we have received since the final rule was published about the complexity and the attendant challenges with the produce safety regulation's agricultural water requirements has been frequent and consistent and has come from growers of many commodities in many regions. This feedback is new and is in

addition to the comments on the proposed rule. Since the final rule was published, many covered farms, both individually and in groups via associations, have strenuously expressed concerns, particularly around the complexity of the sampling and testing provisions. On numerous farm visits and industry gatherings across the country, stakeholders have frequently communicated to us that they view the agricultural water regulatory scheme as too complex and too burdensome, and have objected that it does not sufficiently allow for a variety of water uses and availabilities. In the face of these widespread and steady concerns, including new concerns that were not expressed in response to the proposed rule, we proposed this compliance date extension, for the purpose of further engaging stakeholders and determining what can be done to consider and address the concerns we have heard. Many comments to this docket repeat and reinforce what we have been hearing. We therefore conclude it is in the public's interest for us to institute this delay so that we may further collaborate with an array of stakeholders and pursue solutions that will allow us to achieve the shared goal of improved produce safety in a way that is more workable for covered farms.

The length of this delay in compliance dates was chosen to allow us sufficient time to explore these challenges with stakeholders and experts, and pursue solutions that improve the workability of these provisions. Covered farms also need a significant amount of time to prepare for compliance after the solutions are determined. A shorter time period would not have been sufficient for both robust stakeholder engagement and for covered farms to transition to implementation.

(Comment 3) Some comments opposed FDA's proposal to extend the agricultural water compliance dates, in general because they concluded the extension would harm consumers more than it would help covered farms. Some of these comments noted that FDA's cost-benefit

analysis indicates that this delay would impose a burden on consumers that outweighs any gains that may accrue to producers. Some comments contended that the extension has the potential to increase the risk of illness and death by potentially more than 730,000 additional cases of foodborne illness. Some comments noted that the proposed compliance date extension would mean covered farms would not be required to comply with these provisions until 11-13 years after FSMA was enacted, thereby delaying benefits to the public.

(Response 3) FDA remains committed to ensuring that the produce safety rule addresses the risks associated with agricultural water. We note that produce remains subject to the adulteration provisions of the FD&C Act during this extension of the compliance dates, and the agency encourages farms to focus their attention on good agricultural practices to maintain and protect the quality of their water sources. (See, e.g., FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm064574.htm>). We have, however, determined that it will serve the public health best to take time now to engage stakeholders and discern how best to achieve public health protections in the covered produce agricultural water arena. FDA believes that ignoring the widespread concerns raised about complexity and serious questions about how the requirements can be implemented in practical ways on farms is also likely to reduce the estimated public health benefits of the agricultural water provision of the rule. Farms that cannot understand the requirements and determine how to implement the requirements are not likely to be realizing full food safety measures. We thus believe it is critical to address the issues we have heard about the complexity of the final rule and the diversity of use and source of agricultural water, and the variety of factors that impact agricultural water. The agency also believes that further collaboration with

stakeholders to understand the source of the complexity and develop practical solutions is necessary to best allow us to achieve the shared goal of improved produce safety in a way that is more workable for covered farms.

The economic analysis we conducted for the produce safety final rule, in keeping with our standard practice, evaluated the costs and benefits of the rule in its first 10 years, or 2016-2025. We analyzed the costs and benefits of this extension over the same time horizon (2016-2025). We estimated that this extension would translate to a savings of \$12 (10) million for covered farms (annualized at 3 (7) percent over those 10 years), because we estimated covered farms would delay making additional investments to initially comply with the agricultural water provisions until the arrival of the extended compliance dates. Because our economic analysis spans ten years starting with the produce safety rule effective date, the delay in those initial investments shows as a savings over those 10 years, but over the longer term may be viewed as costs deferred rather than saved. Using the same time horizon (2016-2025), we also estimated that this extension would reduce expected benefits from the rule as a whole during those 10 years from \$800 (\$740) million to \$696 (\$644) million, annualized at 3 percent (7 percent) over those 10 years.

We do not know how the commenter arrived at the estimate that this extension could contribute to more than 730,000 additional cases of foodborne illness. We estimate that approximately 31,300 illnesses would not be prevented during the specified 10-year time horizon as a result of this extension.<sup>2</sup> Because we have not yet decided how to address the concerns that

---

<sup>2</sup> We arrive at this estimate by taking the decrease in the annualized benefits between the original produce safety rule and the rule with this extension (about \$104 million and \$96 million at 3 percent and 7 percent, respectively, over 10 years) and dividing it by the average cost per foodborne illness associated with covered produce other than sprouts. We estimate that approximately 30,103 and 32,554 illnesses annualized at 3 percent and 7 percent, respectively, that we estimate would not be prevented during the specified 10-year time horizon.

have been raised about the practicality of the requirements, we cannot estimate the economic impact or the effect on foodborne illness rates of any solutions that we might implement in the future.

With the delay of the compliance dates, we intend to lay the groundwork for a successful implementation, which will benefit all stakeholders. We will use this time to engage with all stakeholders and consult with experts to determine how to implement, explain, and/or revise the agricultural water provisions in ways that reduce complexity and improve their workability for covered farms while still attaining for the public the benefits of science-based agricultural water standards for covered produce. We will also use the time to continue our outreach and educational efforts, so that the myriad types of covered farms will have the opportunity to prepare for successful implementation.

(Comment 4) Some comments opposed FDA's proposal to extend compliance dates because they felt that the proposed rule was too broad in that it extends the compliance date for other agricultural water provisions in subpart E that are not dependent on an analysis of multiyear water profile (e.g. requirement for growers to inspect and repair water distribution infrastructure, monitor for the buildup of organic material in wash tanks and coolers, maintain and monitor the temperature of water to minimize microbiological risk, and keeping records of the scientific support for food safety interventions). Comments argued that some subpart E requirements are not complex, and it would not be difficult for covered farms to comply with such requirements by the original compliance dates. Comments also noted some third-party audits require compliance with standards that are similar to parts of subpart E, implying that some covered farms are already complying with similar provisions for that purpose.

(Response 4) FDA considered proposing to extend just the provisions in subpart E that, under the produce safety final rule, had a compliance date 2 years later than the rest of subpart E (see table 2), but we determined that there were other provisions in subpart E that were equally complex and challenging for stakeholders, particularly other sampling and testing provisions (see, e.g., § 112.46(b)(1) (testing requirement originally subject to the “earlier” compliance date in the context of untreated surface water)). Accordingly, retaining the original bifurcated structure was not an option. We have heard repeatedly from stakeholders that the compliance date structure under subpart E is confusing, so extending compliance dates for both a subset of the originally-not-extended provisions of subpart E, together with the originally-extended provisions of subpart E, would mean adding another layer of confusion to the subpart E compliance date situation, and that did not seem wise or workable.

Some third-party audits include agricultural water requirements with which farms must comply to obtain a passing audit or certification, and some of those requirements may be similar to provisions in subpart E. Although some segments of the industry do undergo third-party audits, that fact did not dissuade us from the conclusion that there is a need to extend the compliance date for all of subpart E (for covered produce other than sprouts), which is based on significant feedback received from stakeholders since publication of subpart E in the produce safety final rule as well as comments on the extension proposed rule.

(Comment 5) Some comments argued that FDA failed to explain the nature of the confusion over the rule’s compliance date structure that caused us to propose a simplification to that structure.

(Response 5) As evidenced by other comments, there was confusion over the compliance dates in subpart E and some stakeholders found it challenging to discern exactly which

regulatory requirements were subject to the longer compliance period. One comment noted that simply determining the relevant compliance date is a challenge and said simplifying the compliance date structure would help. Other comments noted being confused by the existing compliance date structure. We conclude there is sufficient justification for us to simplify the subpart E compliance date structure.

(Comment 6) Even with the compliance date extension and simplification we proposed in September 2017 and are finalizing here, some comments expressed confusion about the meaning of the compliance date with respect to initiating sampling versus completing the microbial water quality profile (MWQP). One comment specifically requested that the new compliance dates mean the dates on which farms must start to conduct the initial survey to develop the MWQP.

(Response 6) Farms are not required to have completed a MWQP by their compliance date. A farm's compliance date means the date on which the farm must begin sampling a water source for its initial survey, which will eventually result in a MWQP.

We note that this issue was addressed in the 2016 final rule that extended and clarified compliance dates for certain FSMA provisions (81 FR 57784 at 57793-94). However, we recognize that there is still confusion about when the MWQP must be completed under the simplified compliance date structure we are finalizing here. We are therefore clarifying that farms are not required to have already developed a completed MWQP as of their new compliance date. Rather, farms must begin sampling and testing their untreated water sources in accordance with § 112.46(b)(1), as applicable, by their compliance date. If the compliance date is not an appropriate time to engage in the relevant sampling and testing activities--for example, because of the requirement in § 112.46(b)(1)(ii) that samples be representative of your use of the

water--then compliance must begin by the first relevant time period that occurs after the compliance date.

To elaborate on what this would mean in practical terms, for a farm that is not small or very small, compliance must begin by the first relevant time period that occurs on or after January 26, 2022. For example, if a farm that is not small or very small only uses an untreated water source for agricultural water in May, a compliance date of January 26, 2022, would indicate that sample collection under § 112.46(b)(1) must take place in May 2022, as that is the time in which water samples collected would be representative of their use of the water. Farms that wish to develop or begin developing their MWQP prior to their compliance date are welcome to do so; but in the above example, FDA would not expect sample collection to have begun prior to May 2022.

To provide a few examples related to the number and timing of samples, all of the following possible approaches are acceptable for farms that are not small or very small:

- Beginning in 2022, conducting an initial survey of an untreated surface water source by taking 10 samples per year over 2 years (10 in 2022 and 10 in 2023) for a total of 20 samples in accordance with § 112.46(b)(1)(i)(A); calculating the MWQP for the first time upon completing the 20-sample data set in 2023; and applying any necessary corrective actions under § 112.45(b) as soon as practicable and no later than the following year (e.g., during the 2024 growing season).
- Beginning in 2022, conducting an initial survey of an untreated surface water source by taking 5 samples per year over 4 years (5 in 2022, 5 in 2023, 5 in 2024, and 5 in 2025) for a total of 20 samples, in accordance with § 112.46(b)(1)(i)(A); calculating the MWQP for the first time upon completing the 20-sample data set in 2025; and applying any

necessary corrective actions under § 112.45(b) as soon as practicable and no later than the following year (e.g., during the 2026 growing season).

- Beginning in 2022, conducting an initial survey of an untreated ground water source by taking 4 samples during the 2022 growing season in accordance with § 112.46(b)(1)(i)(B); calculating the MWQP for the first time upon completing the 4-sample data set at the end of the 2022 growing season; and applying any necessary corrective actions under § 112.45(b) as soon as practicable and no later than the following year (e.g., during the 2023 growing season).

(Comment 7) Some comments requested additional outreach and education as FDA explores modifications to the agricultural water testing provisions.

(Response 7) FDA intends to continue to work with an array of stakeholders to explore and address the concerns around subpart E. As described above, we will be implementing a rigorous stakeholder engagement plan over the course of several months. If we determine that changes to subpart E are necessary, that would require notice and comment rulemaking and thus the public would have an opportunity to comment on any proposed changes. If we determine that we can address concerns through guidance, such a guidance would be considered “Level 1” and would be subject to the notice and comment procedures outlined in § 10.115(g), which is part of FDA’s Good Guidance Practices regulations. We also remain committed to working with covered farms to prepare for compliance, through outreach, training and education, and other collaboration.

(Comment 8) Some comments stated the proposed extension is contrary to Congress’ intent and the plain language of FSMA, noting that the statute included a deadline for the produce safety final rule.

(Response 8) We do not agree that delaying the compliance date for subpart E is contrary to Congress's intent or the plain language of the statute. FSMA required FDA to establish science- and risk-based minimum standards for the safe production and harvesting of produce for human consumption (see section 419(a)(1)(A) of the FD&C Act (21 U.S.C. 350h(a)(1)(A))), which we have done by promulgating the produce safety regulation. Extending the compliance dates for subpart E (for covered produce other than sprouts) will allow us to evaluate how we can either improve the requirements or implement them in a way that is less confusing and more workable for covered farms, in light of the feedback we have received about subpart E, while still protecting the public health.

Although FSMA includes deadlines for issuing the proposed and final rules, there is nothing in the language or spirit of the statute that is contrary to FDA doing its due diligence to examine how we can achieve the public health regulatory objectives contained in the rule in a way that is more practical for covered farms. We reiterate that we are not changing the compliance dates for the entire produce safety regulation, just subpart E for covered produce other than sprouts.

(Comment 9) Comments stated that FDA should clearly communicate its expectations of agricultural water users during the extension.

(Response 9) With this final rule, we are extending the compliance dates for subpart E of the produce safety regulation for covered produce other than sprouts. FDA will therefore not expect growers of covered produce (other than sprouts) to implement subpart E until the new compliance dates. In the meantime, farms should focus their attention on good agricultural practices to maintain and protect the quality of their water sources. (See, e.g., FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," at

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm064574.htm>). Farms currently testing their water may choose to continue with their current water testing programs, and farms that are not currently testing their water may choose to begin doing so.

#### IV. Economic Analysis of Impacts

We have examined the impacts of this rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this final rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that will minimize any significant impact of a rule on small entities. Because this final rule only extends the compliance dates for certain provisions of the produce safety regulation, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to 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 \$150 million, using the most current (2017) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

This rule extends, for non-sprout covered produce, the compliance date for all of the provisions of subpart E to 4 years after the relevant farm’s compliance date for all other provisions of the produce safety regulation (which varies based on establishment size). The estimated costs and benefits accrued in any given year of compliance with the produce safety regulation, relative to the first year of compliance, do not change. However, because the compliance dates for certain provisions are extended, the discounted value of both total costs and total benefits decrease.

In the final regulatory impact analysis of subpart E of the produce safety regulation, we only considered §§ 112.42, 112.44, 112.45(a)(2), 112.45(b)(3), 112.46(b), and 112.46(c) to result in a cost. Therefore, while subpart E has other provisions, only the aforementioned provisions are relevant to and addressed in this cost and benefit analysis.

There is a reduction in costs (i.e., cost savings) associated with extending, for non-sprout covered produce, the compliance date for all of the provisions of subpart E to 4 years after the relevant farm’s compliance date for the rest of the produce safety regulation. With respect to their non-sprout covered produce, covered farms have 4 years from the compliance date for the other provisions of produce safety regulation to comply with the provisions in subpart E. Thus, while all initial startup costs and recurring costs remain the same as estimated in the final regulatory impact analysis for the produce safety regulation (Ref. 1), the annualized total costs, discounted at 3 (7) percent over 10 years, decrease from \$291 (\$265) million to \$280 (\$254)

million, resulting in a savings of \$12 (\$10) million.<sup>3</sup> The present value of total costs, discounted at 3 (7) percent over 10 years, decreases from about \$2.5 (\$1.9) billion to about \$2.4 (\$1.8) billion, resulting in a savings of about \$99 (\$74) million. No additional costs would be incurred by state, local, and tribal governments or the private sector as a result of this rule.

There is a reduction in benefits associated with extending the compliance dates as described previously. Consumers eating non-sprout covered produce will not enjoy the potential health benefits (i.e., reduced risk of illness) provided by the provisions of subpart E until 2 to 4 years (depending on the specific provision) later than originally established in the produce safety regulation. Thus, the annualized total benefits to consumers, discounted at 3 (7) percent over 10 years, decrease by \$104 (\$96) million from \$800 (\$740) million to \$696 (\$644) million. The present value of total benefits, discounted at 3 (7) percent over 10 years, decreases from about \$6.8 (\$5.2) billion to about \$5.9 (\$4.5) billion. Estimated changes in benefits and costs as a result of this extension are summarized in the following table.

Table 5.--Summary of Changes to Benefits and Costs as a Result of the Final Rule

Category		Primary Estimate	Units		
			Year Dollars	Discount Rate	Period Covered
Forgone Benefits	Annualized Monetized \$millions/year	\$96	2017	7%	2016-2025
		\$104	2017	3%	2016-2025
Forgone Costs	Annualized Monetized \$millions/year	\$10	2017	7%	2016-2025
		\$12	2017	3%	2016-2025

In line with Executive Order 13771, in table 6 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost-savings, this final rule will be considered a deregulatory action under Executive Order 13771.

<sup>3</sup> The \$12 million and \$10 million figures are rounded. The costs decrease from \$291.5 (\$264.8) million to \$279.8 (\$254.3) million, resulting in a savings of \$11.6 (\$10.5) million.

Table 6.--Executive Order 13771 Summary Table (in \$ Millions 2016 Dollars, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)	Primary Estimate (3%)
Present Value of Cost Savings	\$72	\$97
Annualized Cost Savings	\$5	\$3

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this rule (Ref. 2) at <https://www.regulations.gov>, and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

#### V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VI. Paperwork Reduction Act of 1995

This rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VII. Federalism

We have analyzed this rule in accordance with the principles set forth in Executive Order 13132. FDA has 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, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## VIII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

## IX. References

The following references are on display in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA, “Final Regulatory Impact Analysis, Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption.” November 2015. Available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm472310.htm>.

2. FDA, “Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for

Subpart E; Final Rule,” 2019. Available at:

<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/>.

Dated: March 6, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

[FR Doc. 2019-04652 Filed: 3/15/2019 8:45 am; Publication Date: 3/18/2019]