DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water

Docket No. FDA-2021-N-0471

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
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Executive Summary

The final rule replaces the microbial water quality criteria and uniform testing provisions for pre-harvest agricultural water used in direct application on non-sprout covered produce in the 2015 produce safety final rule with provisions for annual pre-harvest agricultural water assessments in which farms using pre-harvest agricultural water for non-sprout covered produce will holistically evaluate potential hazards that may impact their water systems and implement risk-reduction measures to reduce the potential for contamination of covered produce or food contact surfaces. We analyze the rule relative to a primary baseline of pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule and relative to an alternate baseline of no pre-harvest agricultural water provisions. We quantify benefits to the public from a reduction in foodborne illnesses. Additional (non-quantified) benefits include those related to recalls averted increased flexibility in comprehensively evaluating potential hazards associated with pre-harvest agricultural water. We quantify costs to farms from reading the rule, conducting pre-harvest agricultural water assessments, mitigation, and recordkeeping. We estimate that the annualized benefits over 10 years will range from $-29.4 million to $51.0 million at a 7 percent discount rate, with a primary estimate of $10.1 million, and from $-30.3 million to $52.4 million at a 3 percent discount rate, with a primary estimate of $10.3 million. The annualized costs will range from $6.7 million to $26.0 million at a 7 percent discount rate, with a primary estimate of $17.7 million, and from $6.8 million to $25.6 million at a 3 percent discount rate, with a primary estimate of $17.5 million.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some small entities may

incur costs larger than 3% of annual revenues, we cannot certify that the 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 estimates of anticipated impacts, before issuing "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 $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Benefits, Costs, and Transfers

We estimate costs of the rule resulting from reading the rule, conducting pre-harvest agricultural water assessments, conducting mitigation measures when reasonably necessary based on the outcomes of the pre-harvest agricultural water assessments, and recordkeeping as a result of the pre-harvest agricultural water assessments. For the purposes of this analysis, the primary baseline against which the costs and benefits of this rule are measured are the microbial quality criteria and testing provisions for pre-harvest agricultural water for non-sprout covered produce in the 2015 produce safety final rule.[1] However, throughout the analysis, we conduct intermediate calculations of costs and benefits of both the 2015 produce safety final rule subpart E pre-harvest agricultural water provisions and this rule relative to an alternate baseline

[1] Because sprouts present a unique safety risk, the 2015 Produce Safety Final Rule 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 (for example, sprout irrigation water is subject to the microbial criterion and testing requirements in § 112.44(a) and (b)).

represented by a state of the world in which there are no pre-harvest agricultural water provisions. Given FDA's announcement of an intent to exercise enforcement discretion for the pre-harvest agricultural water requirements in the 2015 produce safety final rule for covered produce (other than sprouts) while undergoing this rulemaking, and as this rule revises the 2015 produce safety final rule to remove the pre-harvest microbial quality criteria and uniform testing requirements, a baseline of no pre-harvest agricultural water provisions may better represent the state of the world absent this rule. As such, we include this as an alternate baseline in this analysis. In both scenarios, we consider only the effects of subpart E pre-harvest agricultural water provisions. Throughout this document, we use the term "baseline benefits" to represent the estimated benefits of the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule absent this rule, and we use the term "baseline costs" to represent the estimated costs of those provisions in the 2015 produce safety final rule absent the rule. Our primary estimates of annualized costs relative to the primary baseline of the 2015 pre-harvest agricultural water microbial quality criteria and testing provisions are approximately $17.5 million at a 3 percent discount rate and approximately $17.7 million at a 7 percent discount rate over 10 years.

We estimate benefits of this rule resulting from the dollar burden of foodborne illnesses averted, and we estimate forgone benefits of this rule resulting from foodborne illnesses not averted due to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule. Our primary estimates of annualized benefits are approximately $10.3 million at a 3 percent discount rate and approximately $10.1 million at a 7 percent discount rate over 10 years. We discuss non-quantified benefits of the rule stemming from avoiding overly broad recalls of products that would have occurred absent the rule. We also

discuss non-quantified benefits related to increased flexibility for covered farms to comprehensively evaluate their agricultural water systems, in light of the requirements for pre-harvest agricultural water assessments being designed to accommodate a wide range of agricultural water sources, uses, and practices. These changes to the pre-harvest agricultural water provisions are being finalized to improve public health protections with a regulatory approach that incorporates recent science, data, and other information available to FDA, and to address feedback on practical implementation challenges of the 2015 microbial water quality criteria and testing requirements.

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Final Rule (millions of 2022 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$10.1	-$29.4	$51.0	2022	7%	10 years	Benefits are illnesses averted
		$10.3	-$30.3	$52.4	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Increased flexibility in comprehensively evaluating potential hazards associated with pre-harvest agricultural water						
Costs	Annualized Monetized ($m/year)	$17.7	$6.7	$26.0	2022	7%	10 years	
		$17.5	$6.8	$25.6	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
	Other Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
Effects	State, Local, or Tribal Government: None Small Business: Small farms will incur costs of complying with the rule. Wages: None Growth: None							

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

FDA's proposed rule, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," (86 FR 69120) (2021 agricultural water proposed rule) was published on December 6, 2021. The comment period for the 2021 agricultural water proposed rule closed on April 5, 2022. On July 19, 2022, we published a supplemental notice to the proposed rule (87 FR 42973) in which we proposed dates for compliance with the pre-harvest agricultural water requirements for covered produce other than sprouts in the 2021 agricultural water proposed rule. The comment period for the supplemental notice closed on September 19, 2022.

In the paragraphs that follow, we describe and respond to the comments we received on the Preliminary Regulatory Impact Analysis (PRIA) for the 2021 agricultural water proposed rule (Ref. 1) that are within the scope of the rulemaking. We did not receive any comments on the PRIA for the supplemental proposed rule relevant to our economic analysis.

We have numbered each comment to help distinguish between different comment themes. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

Comment 1: General support for the rule

Several comments express general support for the rule, suggesting that it will protect public health by preventing foodborne illnesses. Some of these comments suggest that while the proposed requirements for pre-harvest agricultural water assessments may be more costly than the previous microbial quality and testing requirements, they consider the benefits of the rule to

be worth the costs. One comment suggests that while the costs of the proposed rule exceed the benefits in the PRIA, the "unseen" benefits are much greater.

Response: We appreciate the comments voicing support for the proposed rule. We developed this approach to pre-harvest agricultural water by considering the public health objectives we aim to achieve through pre-harvest agricultural water measures for covered produce other than sprouts while recognizing that each farm has a unique combination of agricultural water source(s), growing practices, current and previous uses of the farmland, and adjacent and nearby land uses, among other factors, that may influence the safety of its agricultural water.

In this FRIA, we estimate benefits of the rule resulting from the avoidance of foodborne illnesses and their attendant costs (quantified as dollar burden of foodborne illnesses averted) relative to a primary baseline of the 2015 provisions. Our primary estimates of annualized benefits of this rule are approximately $10.3 million at a 3 percent discount rate and approximately $10.1 million at a 7 percent discount rate over 10 years.

To the extent that the comment regarding "unseen" benefits is referring to non-quantified benefits of the rule, we agree that there are non-quantified benefits of the rule, in particular, those that stem from recalls averted and increased flexibility for covered farms to comprehensively evaluate their agricultural water systems. For discussion of general comments related to costs of the final rule, refer to comment 2.

Comment 2: General concern for costs borne by farms

Several comments express general concerns that the rule, if finalized, would result in increased costs to covered farms. A few of these express concern that the costs of the rule will

force some farms, especially small farms, out of business. Some comments suggest that making tools or templates available for farms would help to minimize the costs associated with complying with the rule.

Response: We acknowledge that there are costs associated with this rulemaking, as detailed in this FRIA. In our analysis, we estimate that the average cost of the requirements for pre-harvest agricultural water assessments relative to the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule, annualized at a 3% discount rate over 10 years, is $679 for very small farms; $1,036 for small farms; and $1,312 for all other farms. We recognize the importance of providing covered farms with education, outreach, and technical assistance, which may include, for example, guidance, templates or other tools. We remain committed to ensuring that educational outreach and training is made available across industry.

With respect to comments suggesting that farms may go out of business as a result of this rule, we have incorporated flexibility into the pre-harvest agricultural water requirements for farms to make decisions around the use of their water as appropriate given their agricultural water systems, operations, and conditions. See, e.g., § 112.45(b), which provides covered farms with various options for mitigation measures. See also comment 11. While we cannot guarantee that farms will not go out of business, we do not anticipate significant market exit to result from this rule. With respect to comments about small farms specifically, see comment 5.

Comment 3: Compare costs of the rule to costs of testing

Several comments request that we compare the costs of the proposed requirements for pre-harvest agricultural water assessments to the costs of the pre-harvest agricultural water testing provisions in the 2015 produce safety final rule. One comment suggests that replacing the

microbial quality criteria and testing requirements in the 2015 produce safety final rule with provisions for pre-harvest agricultural water assessments will reduce the burden on farms and potentially result in fewer costs than under the previous testing requirements.

Response: Consistent with our approach in the PRIA (Ref. 1), in this FRIA, we estimate and compare the costs of the pre-harvest microbial water quality and testing requirements in the 2015 produce safety final rule with the requirements for pre-harvest agricultural water assessments specified in this final rule as part of the benefit-cost analysis. We estimate benefits and costs of the rule relative to a primary baseline of pre-harvest microbial water quality and testing requirements in the 2015 produce safety final rule and relative to an alternate baseline of no pre-harvest microbial water quality and testing requirements. See section I.B. Our primary estimates of annualized costs relative to the primary baseline are approximately $17.5 million at a 3 percent discount rate and approximately $17.7 million at a 7 percent discount rate over 10 years. Our primary estimates of annualized benefits relative to the primary baseline are approximately $10.3 million at a 3 percent discount rate and approximately $10.1 million at a 7 percent discount rate over 10 years. Our primary estimates of annualized costs relative to the alternate baseline are approximately $36.1 million at a 3 percent discount rate and approximately $35.3 at a 7 percent discount rate. Our primary estimates of annualized benefits relative to the alternate baseline are approximately $86.1 million at a 3 percent discount rate and approximately $83.8 at a 7 percent discount rate. We also discuss non-quantified benefits of the rule stemming from recalls averted and increased flexibility for covered farms to comprehensively evaluate their agricultural water systems.

Comment 4: Account for staggered compliance dates

In response to the PRIA that accompanied the 2021 agricultural water proposed rule, which explained that for the purposes of that analysis, we assumed compliance dates of 3 years following publication of the rule for very small farms, 2 years following publication of the rule for small farms, and 1 year following publication of the rule for all other (large) farms, a few comments suggest that if FDA does not provide staggered compliance dates based on farm size with those intervals, then the cost estimates of the rule should be recalculated.

Response: We agree that cost estimates should be reflective of relevant compliance dates for covered farms. In the 2022 supplemental notice of proposed rulemaking, we proposed dates for compliance with the pre-harvest agricultural water provisions for covered produce (other than sprouts) of 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. With this rule, we are finalizing the dates for compliance with the pre-harvest agricultural water provisions for covered produce (other than sprouts) as proposed. For the purposes of this FRIA, we assume that a final rule will publish in April, 2024. See section II.D. For the purposes of this analysis, this results in assumed compliance dates for the pre-harvest agricultural water provisions for non-sprout covered produce of:

- January, 2027 for very small businesses;
- January, 2026 for small businesses;
- January, 2025 for all other (large) businesses.

Comment 5: Concern about cost to small businesses

Several comments voice concern about the costs imposed by the rule on small businesses. Some of these suggest that compliance costs for smaller farms will represent a larger proportion of their revenue compared to larger farms. One comment claims that the total burden of the rule will fall on small farms. A few comments suggest that smaller farms may need additional time to prepare for the economic burden that comes with complying with the proposed requirements for pre-harvest agricultural water assessments.

Response: We acknowledge that the rule imposes costs on businesses. Our primary estimate of the average per-farm cost of the rule for farms that conduct assessments relative to pre-harvest agricultural water testing provisions, annualized at a 3% discount rate over 10 years, is $679 for very small farms. For small farms, this per-farm estimate is $1,036. For farms that conduct at least one mitigation over the 10-year period, our primary estimate of the average per-farm cost of the rule relative to pre-harvest agricultural water testing provisions, annualized at a 3% discount rate over 10 years, is $1,090 for very small farms and $2,054 for small farms. See also section III, where we discuss impacts of the rule on small entities.

As the requirements being finalized here apply to farms of all sizes provided the farms are covered by the 2015 produce safety final rule and subject to the requirements in § 112.43 for pre-harvest agricultural water assessments for non-sprout covered produce, we disagree with the comment suggesting that the total burden of the rule will fall on small farms.

Additionally, we recognize that staggered compliance dates based on farm size allows businesses of various sizes time to come into compliance with the rule technically, financially, and operationally. In light of practical considerations for small and very small businesses, we consider that additional time for small and very small farms to come into compliance is

warranted. As such, we are finalizing compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce based on farm size as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses, and consider those compliance dates for the purposes of this analysis. See the final rule for additional discussion on staggered compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce.

Comment 6: Costs underestimated

Several comments express general concerns that the PRIA underestimates costs to farms. For example, a few comments suggest that it would cost more than the PRIA estimated if they were to convert to a different method of water application, such as drip irrigation. Other comments suggest that the PRIA underestimated the costs of water treatment, with a few of these suggesting that costs associated with treatment and other mitigation measures should be accounted for "at scale."

Response: We have updated our cost estimates in this FRIA in various ways, including updating values to 2022 dollars and updating wage rates and covered farm counts, to provide a more accurate estimate of costs.

With respect to costs associated with treatment of pre-harvest agricultural water, in the PRIA, we used findings from a USDA ERS survey (Ref. 2) to provide a single point estimate for each farm size for the cost of water treatment. We are not aware of, and comments did not provide, data or information as to estimates that would be more appropriate across the diversity of operations, agricultural water systems, and agricultural water uses of covered farms. However, we recognize that farms may incur a range of possible costs if treating their pre-harvest

agricultural water. For example, two covered farms may incur different treatment costs depending on various factors—such as the nature of their agricultural water systems and the methods used to treat their agricultural water—even if they are both considered "small farms." Therefore, we have replaced the point estimates used in the PRIA with a PERT distribution and use those estimates of water treatment costs to remain consistent across the pre-harvest microbial quality criteria and testing provisions in the 2015 produce safety final rule and the requirements for pre-harvest agricultural water assessments and measures that we are finalizing with this rule. See also sections II.D. and II.F.

With respect to costs associated with other mitigation measures (including changing the water application method) under the approach for pre-harvest agricultural water we are finalizing here, our estimates in the PRIA for those measures were based on results from a survey of subject matter experts (Ref. 3). In the PRIA, we provided these results as a range, with low, most likely, and high estimates each for very small, small, and large farms. We expect that these values account for a range of possible costs that may be incurred by farms in implementing those mitigation measures under the requirements we are finalizing with this rule. While some comments suggest that the costs associated with changing the water application method were underestimated, we are not aware of, and comments did not provide, data or information suggesting estimates that would be more applicable across the diversity that exists in industry. Therefore, we decline to adjust the cost estimates for changing the method of water application as a mitigation measure.

Comment 7: Burden on farms with multiple water sources

A few comments suggest that pre-harvest agricultural water assessments will be more costly and take more time for farms with multiple water sources.

Response: We recognize that the costs associated with the provisions for pre-harvest agricultural water assessments are likely to range for a variety of reasons, not limited to the number of agricultural water sources a covered farm uses for pre-harvest agricultural water for non-sprout covered produce. As such, in the PRIA we estimated costs associated with the requirements for pre-harvest agricultural water assessments on a per-farm basis, for which we also provided low, most likely, and high estimates. We expect that these values account for a range of possible costs that may be incurred by farms in implementing the provisions for pre-harvest agricultural water assessments that we are finalizing with this rule. We are not aware of, and comments did not provide, data or information suggesting estimates that would be more applicable across the diversity that exists in industry in agricultural water systems, operations, and conditions. As such, we use the same estimates for the time to conduct pre-harvest agricultural water assessments in this FRIA as used in the PRIA. See Table 18. To the extent that a farm may have multiple water sources, we expect that several of the factors evaluated in the assessment (for example, agricultural water use practices, commodity characteristics, and environmental conditions) might be similar regardless of the agricultural water system, thus limiting any increase in the time a farm may need to collect and consider information for agricultural water assessment purposes.

Comment 8: Cost of hiring a third party

Some comments claim that the rule appears to require farms to hire consultants, trained personnel, or other third parties to understand and implement the requirements, which would generate significant compliance costs for farms.

Response: In accordance with section 419(c)(1)(E) of the Food, Drug, and Cosmetic Act, we are not requiring a farm to hire a consultant or third party to identify, implement, certify, or

comply with the requirements being finalized with this rule. These standards are intended to be capable of implementation by those who engage in routine activities on the farm. See also 78 FR 3504 at 3519. As such, we disagree with the suggestion in the comments that the cost of hiring a consultant or other third party to ensure compliance should be included in the FRIA.

Comment 9: Other costs

One comment suggests that the economic analysis should consider costs beyond those associated with compliance. For example, the comment suggests that FDA consider cost savings in the form of averted outbreaks and recalls of food products that would result from the rule.

Response: We acknowledge that there may be cost savings to industry as a result of averted recalls due to the requirements we are finalizing for pre-harvest agricultural water assessments for non-sprout covered produce. We are not aware of, and comments did not provide, quantitative data or information related to recalls that can be directly attributed to pre-harvest agricultural water for non-sprout covered produce that would allow us to estimate those cost savings quantitatively. However, we have included a brief qualitative discussion about the potential cost savings of averted recalls in the FRIA.

Comment 10: Increased prices

One comment suggests that the rule will cause an increase in prices.

Response: It is unclear to us which prices the commenter expects to increase. To the extent the commenter is suggesting that consumer prices would increase, we are not aware of, and the comment did not provide, data or information that would allow for quantitative estimates of such potential effects. However, we note that the total cost of this rule ($17.5 million, as shown in Table 1) when fully implemented represent approximately 0.02% of the total value of

produce sold in the US ($ 75.1 billion) (Ref. 4). As the costs of this rule represent a small portion of the total value of the US produce market, we do not expect that there will be a significant price effect to consumers as a result of this rule.

Comment 11: Abandoning crops and food scarcity

A few comments suggest that under the proposed requirements, farms will be required to either change their water application method (such as from overhead to drip irrigation) or treat their water. These comments note limitations with these activities, including that some crops need to be irrigated with overhead irrigation, and that some farms (such as organic farms) may not have any treatments options available to use. These comments suggest that these limitations would result in some farms needing to abandon growing certain crops, which, the comments note, was not considered in the PRIA. Another comment suggests that food scarcity may result from farms complying with the rule and recommends that the economic analysis account for that occurring.

Response: We are not requiring that covered farms change their water application methods or treat their pre-harvest agricultural water as mitigation measures under § 112.45(b). Rather, we have incorporated flexibility to provide covered farms a range of options in § 112.45(b), which include:

- making necessary changes (for example, repairs);
- increasing the time interval between last direct water application and harvest to allow for microbial die-off;
- increasing the time interval between harvest and end or storage and/or conducting other activities during or after harvest to allow for microbial die-off or removal;

- changing the method of water application to reduce the potential for contamination of covered produce;
- treating the water in accordance with § 112.46; and
- taking an alternative mitigation measure provided the requirements in § 112.12 are met.

Given this flexibility, we do not expect that if mitigation measures are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water, covered farms will abandon growing certain crops instead of implementing mitigation measures in accordance with § 112.45(b). For this reason, we also do not believe that food scarcity will result from compliance with this rule. As such, we decline the suggestions to address food scarcity and farms that may abandon crops in the FRIA.

D. Summary of Changes

We have updated our estimates of the costs and benefits of the rule from the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water Preliminary Regulatory Impact Analysis" (Ref. 1) in the following ways:

- Updated calculations of benefits and costs from 2019 dollars to 2022 dollars
- Updated wage rates for labor categories used in the analysis from 2019 wage rates to 2022 wage rates
- Updated covered farm counts from 2015 Produce Safety Rule Final Regulatory Impact Analysis data (based on 2012 NASS Census of Agriculture data) to 2017 NASS Census of Agriculture data (most recent available)

- Replaced point estimates for treatment costs based on farm size with a range of estimated costs in response to comments
- Updated illness outbreak data used to calculate foodborne illness dollar burden baseline from 2009-2018 data to 2009-2020 data
- Incorporated estimates from the Requirements for Additional Traceability Records for Certain Foods Final Regulatory Impact Analysis (Ref. 5) of illnesses prevented by the traceability rule to adjust the baseline foodborne illness dollar burden for non-sprout covered produce that also could be affected by this rule
- Included a qualitative discussion of potential cost savings due to recalls averted as a result of this rule
- Adjusted the Small Entity Analysis in section III
    - In the PRIA, we proposed to certify that the rule would not have a significant impact on a substantial number of small entities. However, as some very small farms that conduct mitigation may have costs larger than 3% of revenue, we no longer certify that the rule would not have a significant impact on a substantial number of small entities.

II. Final Economic Analysis of Impacts

Acronyms, Initialisms, and Definitions in This Document

Term	What It Means
2015 FRIA	FDA's analysis of economic impacts of the 2015 produce safety final rule; "Analysis of Economic Impacts - Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (FRIA)," published in 2015

2015 produce safety final rule	Food Safety Modernization Act Produce Safety Regulation; "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," published in 2015
FSMA	FDA Food Safety Modernization Act
Subpart E	Subpart E (21 CFR §§112.40-112.50) of "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption"; agricultural water provisions
2019 compliance date extension	"Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E," published in 2019
2021 agricultural water proposed rule	2021 FDA rulemaking entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," published in December, 2021
2021 agricultural water PRIA	FDA's analysis of the impacts of the 2021 agricultural water proposed rule; "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water (Preliminary Regulatory Impact Analysis)," published in December, 2021
2022 supplemental notice of proposed rulemaking (compliance dates)	2022 supplemental notice of proposed rulemaking that specifies compliance dates for provisions in "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," published in July, 2022
Large farm	For the purposes of 2015 produce safety final rule requirements discussed in this document, "large farm" refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $500,000.
Small farm	For the purposes of 2015 produce safety final rule requirements discussed in this document, "small farm" refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $250,000 but no more than $500,000.
Very small farm	For the purposes of 2015 produce safety final rule requirements discussed in this document, "very small farm" refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $25,000 but no more than $250,000.

Agricultural water assessment	An assessment of potential pre-harvest agricultural water hazards as described in § 112.43 of the final rule
Mitigation measure	An action that is reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. Options for mitigation measures are described in § 112.45 of the final rule.

A. Background

In 2015, FDA issued the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (hereafter referred to in this document as the 2015 produce safety final rule), codified at 21 CFR 112; 80 FR 74354) pursuant to the FDA Food Safety Modernization Act (FSMA). The 2015 produce safety final rule encompasses science-based minimum standards for the safe growing, harvesting, packing, and holding of produce.

The 2015 produce safety final rule provisions focus on major routes of potential contamination of produce, including worker health and hygiene; agricultural water; biological soil amendments; domesticated and wild animals; and equipment, buildings, and tools. This rule replaces the microbial water quality criteria and uniform testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) that were established in subpart E of the 2015 produce safety final rule. Subpart E required, in relevant part, that farms test certain water sources used during pre-harvest activities for covered produce (other than sprouts) to ensure the water meets established microbial water quality criteria. For each untreated surface water source used for pre-harvest activities for covered produce (other than sprouts), a covered farm would have conducted an initial survey consisting of 20 tests (collected over 2-4 years) and updated the microbial water quality profile with 5 new tests per year thereafter; for each untreated ground water source, a farm would have conducted an initial survey consisting of 4

tests (taken during the growing season or over a period of 1 year) and updated the water quality profile with 1 new test per year thereafter. (See § 112.46(b) as established in the 2015 produce safety final rule.)

For pre-harvest agricultural water directly applied to non-sprout covered produce, the following microbial water quality criteria would have applied (see § 112.44(b) as established in the 2015 produce safety final rule):

- A geometric mean (GM) of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and
- A statistical threshold value (STV) of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

The 2015 produce safety final rule initially established compliance dates for most provisions of that rule, ranging from 2 to 4 years based on the size of the covered farm, with an additional 2 years to comply with some of the agricultural water provisions for non-sprout covered produce (see §§ 112.44, 112.45(a) (with respect to the § 112.44(a) criterion), 112.45(b), 112.46(b)(1) (with respect to untreated ground water), 112.46(b)(2) and (b)(3), and 112.46(c) as established in the 2015 produce safety final rule). In 2019, FDA issued an additional rule ("Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E," hereafter referred to as "2019 compliance date extension" (84 FR 9706)) that extended compliance dates for all subpart E

provisions for covered produce other than sprouts until 2 to 4 years after the original compliance dates specified in the 2015 produce safety final rule.

The 2021 agricultural water proposed rule ("Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water" (86 FR 69120)) preamble reminded stakeholders that at that time, covered farms were required to comply with the subpart E pre-harvest, harvest, and post-harvest agricultural water requirements for covered produce (other than sprouts) beginning on January 26, 2024, for very small farms; January 26, 2023, for small farms; and January 26, 2022, for all other covered farms (84 FR 9706). Further, it explained that FDA intended to exercise enforcement discretion for those requirements while working to address compliance dates in a targeted manner through the rulemaking process, with the goal of completing the rulemaking as quickly as possible (86 FR 69147).

In 2022, FDA issued a supplemental notice of proposed rulemaking ("Supplemental Notice of Proposed Rulemaking: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water" (87 FR 42973)) that proposed compliance dates for the pre-harvest agricultural water provisions in the 2021 agricultural water proposed rule for covered produce other than sprouts of:

- 2 years and 9 months after the effective date of a final rule for very small farms;
- 1 year and 9 months after the effective date of a final rule for small farms;
- 9 months after the effective date of a final rule for all other (large) farms.

We also explained that our goal was to complete that rulemaking as quickly as possible, and that in the meantime, we intended to exercise enforcement discretion for the pre-harvest agricultural water requirements in the 2015 produce safety final rule for covered produce other than sprouts.

B. Potential Need for Federal Regulatory Action

This rule stems from the need to amend the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule to be adequately protective based on recent science, data, and other information available to FDA. It also stems, in part, from frequent and consistent feedback on practical implementation challenges associated with the uniform 2015 pre-harvest agricultural water testing requirements that has come from farms of many commodities in many regions, both individually and in groups via associations. FDA has considered concerns raised about the complexity and practical implementation challenges of pre-harvest agricultural water testing requirements for covered produce other than sprouts. After evaluating relevant information gathered since publication of the 2015 produce safety final rule, considering feedback from an array of stakeholders, we have concluded that the most appropriate regulatory approach to address these concerns is to undertake rulemaking. This final rule replaces the microbial criteria and uniform testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) with provisions for systems-based agricultural water assessments that are designed to achieve improved public health protections and more comprehensively address a known route of contamination that can lead to preventable foodborne illness that is a significant public health problem. Moreover, these requirements are designed to be more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future advancements in agricultural water quality science.

C. Purpose of the Rule

This final rule replaces the pre-harvest agricultural water microbial quality criteria and uniform testing provisions for non-sprout covered produce with provisions for at least annual pre-harvest agricultural water assessments in which farms using pre-harvest agricultural water for non-sprout covered produce will holistically evaluate potential hazards that may impact their water sources. If covered farms determine there are known or reasonably foreseeable hazards associated with their pre-harvest agricultural water, they must conduct any mitigation measures that are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces as soon as practicable and no later than 1 year after the date of the agricultural water assessment, except for in certain circumstances, such as known or reasonably foreseeable hazards related to animal activity, biological soil amendments of animal origin, or untreated or improperly treated human waste associated with adjacent and nearby lands, in which covered farms are required to implement mitigation measures promptly, and no later than in the same growing season in which the assessment was conducted.

D. Baseline Conditions

Due to imperfect information about the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule and the requirements we are finalizing with this rule for pre-harvest agricultural water assessments, we make some assumptions about the baseline conditions and the behavior of entities conducting pre-harvest agricultural water assessments to estimate the effects of the final rule.

1. Assumptions

(a) All farms covered by the 2015 produce safety final rule will spend the necessary time to read and understand the rule.

(b) Farms not covered by the 2015 produce safety final rule will not read the rule.

(c) Reading and understanding the rule will be a one-time cost incurred in the year following the publication of the final rule.

(d) Industry costs associated with conducting pre-harvest agricultural water assessments occur in the year assessment occurs; industry costs associated with conducting mitigation of identified hazards occur in the year mitigation occurs.

(e) As specified in the regulatory text, covered farms must conduct pre-harvest agricultural water assessments at least once annually, as well as "whenever a significant change occurs in your agricultural water system." We assume that farms covered by these provisions will conduct 1.1 pre-harvest agricultural water assessments per year.

(f) For the purposes of this analysis, we assume that a final rule will publish in April, 2024. The final rule provides compliance dates for the pre-harvest agricultural water provisions for covered produce (other than sprouts) of 2 years and 9 months after the effective date of the final rule for very small farms, 1 year and 9 months for small farms, and 9 months for all other (large) farms. For the purposes of this analysis, this results in the following assumed compliance dates: January, 2027 for very small farms; January, 2026 for small farms; January, 2025 for all other (large) farms.

(g) We estimate costs and cost savings in 2022 dollars.

2. Baseline Conditions

As discussed throughout this section, this analysis conducts various calculations to estimate costs and benefits of the final rule. This analysis:

- Compares this rule to the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule;
- Compares this rule to a state of the world in which there are no pre-harvest agricultural water provisions; and
- Compares the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule to a state of the world in which there are no pre-harvest agricultural water provisions.

More specifically, for the purposes of this analysis, we treat the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule as the primary baseline, and we compare estimated benefits and costs of this rule to estimated benefits and costs of those pre-harvest agricultural water testing provisions.

Given FDA's announcement of an intent to exercise enforcement discretion for the pre-harvest agricultural water requirements in the 2015 produce safety final rule for covered produce (other than sprouts) while undergoing this rulemaking, and as this rule revises the 2015 produce safety final rule to remove the pre-harvest microbial quality criteria and testing requirements, the 2015 pre-harvest agricultural water testing requirements may not adequately reflect the state of the world absent this final rule. As a result, we also present estimates of the benefits and costs of the rule relative to an alternate baseline in which there are no pre-harvest agricultural water provisions, which may adequately reflect the state of the world absent this final rule.

Throughout the analysis, we conduct intermediate calculations of costs and benefits of both the 2015 produce safety final rule and this rule relative to an alternate baseline represented by a state of the world in which there are no pre-harvest agricultural water provisions. When

discussing the primary baseline, we use the term "baseline benefits" to represent the estimated benefits of the 2015 produce safety final rule absent this rule, and we use the term "baseline costs" to represent the estimated costs of the 2015 produce safety final rule absent this rule. When discussing the alternate baseline, we use the terms "alternate baseline benefits" and "alternate baseline costs" to represent the benefits and costs of this rule in a state of the world with no pre-harvest agricultural water provisions.

As noted previously, stakeholders have expressed concern about the complexity and practical implementation challenges of the uniform pre-harvest agricultural water testing requirements (for covered produce other than sprouts) included in the 2015 produce safety final rule. While the primary baseline in this analysis assumes that farms would comply with the 2015 produce safety final rule, we note that if some farms were unable to comply with those testing provisions, the portion of this analysis comparing against the primary baseline would underestimate the benefits and costs of the rule.

a. Number of Affected Farms

To determine the number of farms that must read the final rule, we use estimates of the number of farms covered by the 2015 produce safety final rule based on data from the National Agricultural Statistics Service 2017 Census of Agriculture, which accounts for farms not covered by the rule and farms or produce eligible for exemption. This results in approximately 43,510 farms that must read the rule, including 27,732 very small farms, 5,139 small farms, and 10,639 large farms. While not all covered farms would need to conduct pre-harvest agricultural water assessments under the provisions, we assume covered farms will read the rule to determine whether they need to conduct the assessments.

In a survey of produce farms conducted by researchers at ERS before the implementation of FSMA rules, USDA estimated that 45 percent of small farms covered by the 2015 produce safety final rule use non-public pre-harvest agricultural water that contacts produce (Ref. 2), where USDA defines "small" as farms with $25,000 to $500,000 in annual revenue. For the purposes of the requirements discussed in this analysis, we consider a farm within this category to be a "very small farm" if they are a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $25,000 but no more than $250,000; and a "small farm" if they are a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $250,000 but no more than $500,000. For the purposes of these requirements, a "large farm" refers to a covered farm for which, on a rolling basis, the average annual monetary value of produce the farm sold during the previous 3-year period is more than $500,000. USDA estimates that 54.7 percent of mid-size farms ($500,000 to $1,000,000), 53.8 percent of large farms ($1,000,000 to $5,000,000), and 54.7 percent of very large farms (above $5,000,000) use non-public pre-harvest agricultural water that contacts produce. We construct a weighted average of the percentages to determine that approximately 54.1 percent of covered large farms use non-public pre-harvest agricultural water that contacts produce.

We estimate the number of farms that would conduct the pre-harvest agricultural water assessments described in the rule by multiplying the number of covered irrigated farms by the estimated percentage of farms using non-public pre-harvest water that contacts produce for each farm size category and summing across categories. Using this method, we estimate that 9,911 very small farms, 2,057 small farms, and 5,392 large farms would be required to conduct pre-harvest agricultural water assessments under the rule; as a result, we estimate a total of 17,360

farms would conduct pre-harvest agricultural water assessments. Table 2 presents the number of affected farms.

Table 2: Number of Affected Farms

	Very small	Small	Large	Total
Number of covered farms	27,732	5,139	10,639	43,510
Number of covered irrigated farms	22,025	4,572	9,966	36,563
Percent of farms using non-public pre-harvest agricultural water that contacts produce	45.0%	45.0%	54.1%	
Number of farms that would conduct pre-harvest agricultural water assessments under rule	9,911	2,057	5,392	17,360

*Percentage of farms using non-public pre-harvest water from Ref. 2

**Number of covered farms and covered irrigated farms from National Agricultural Statistics Survey 2017 Census of Agriculture

b. Benefits and Costs

i. Baseline Benefits

For the purposes of this analysis, we treat the pre-harvest agricultural water microbial water quality criteria and testing provisions in the 2015 produce safety final rule as the primary baseline, and we compare estimated benefits and costs of this rule to estimated benefits and costs of those pre-harvest agricultural water testing provisions. However, because FDA announced an intent to exercise enforcement discretion for the pre-harvest agricultural water requirements in the 2015 produce safety final rule for covered produce (other than sprouts) while undergoing this rulemaking, and as we are finalizing compliance dates for the pre-harvest agricultural water provisions for covered produce other than sprouts in the 2021 agricultural water proposed rule

that have yet to occur, we also present estimates of the benefits and costs of the rule relative to an alternate baseline in which there are no pre-harvest agricultural water provisions.

We estimate the dollar burden of foodborne illnesses attributable to non-sprout covered produce; using updated outbreak data from 2009-2020, we estimate that the annual dollar burden of foodborne illnesses attributable to non-sprout covered produce is $2,667 million in 2022 dollars (see Appendix A for a more detailed discussion of these calculations). The estimated burden of foodborne illnesses is drawn from Minor et al. (Ref. 6) and comprised of direct and indirect costs. Direct costs include the costs of doctor visits, emergency room visits, and hospitalizations. Indirect costs include decreased quality of life (of which loss of productivity is a subset). Indirect costs are monetized using the value of a statistical life (VSL), following HHS guidelines (Ref. 7). Minor et al. (Ref. 6) calculate QALYs (quality-adjusted life-years) of functional disabilities and symptoms in prior studies and match these conditions to pathogens.

In 2022, FDA published the final rule "Requirement for Additional Traceability Records for Certain Foods" (hereafter "traceability rule", 87 FR 70910), which establishes additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods for which the FDA has determined those additional requirements are appropriate and necessary to protect the public health in accordance with FSMA.

Many foodborne illnesses are caused by produce covered by both the traceability final rule and this rule that relates to pre-harvest agricultural water for covered produce (other than sprouts). An illness prevented by the traceability final rule could not subsequently be prevented by this rule. To account for this, we remove illnesses estimated to be prevented by the traceability rule from the baseline dollar burden of foodborne illnesses attributable to non-sprout

covered produce. We use the estimated preventable illness percentage by illness type from the traceability rule Final Regulatory Impact Analysis (Ref. 6) to adjust the baseline dollar burden to account for illness assumed to be prevented by the traceability rule; after this adjustment, we estimate that the annual dollar burden of foodborne illnesses attributable to non-sprout covered produce and not assumed to be prevented by the traceability rule to be $1,938.9 million in 2022 dollars (see Appendix A for a more detailed discussion of these calculations).

There are various potential routes of contamination that may cause these illnesses, of which agricultural water is only one. The 2015 FRIA estimates that agricultural water (including for pre-harvest, harvest, and post-harvest uses) has a 30.69% likelihood of being the route of contamination in outbreaks (Ref. 8); we multiply this percentage by the annual burden to estimate that the annual dollar burden of foodborne illnesses attributable to agricultural water (pre-harvest, harvest, or post-harvest) is $595.1 million. However, both the provisions in the 2015 produce safety final rule that we are replacing and the provisions in this rule apply only to pre-harvest agricultural water for non-sprout covered produce.

We are unable to identify with certainty the fraction of outbreaks that can be attributed to contaminated pre-harvest, harvest, or post-harvest water. During outbreak investigations, investigation teams may be unable to investigate growing, harvesting, packing, and holding activities that are not taking place at the time of the investigation. Similarly, as some investigations may be conducted after the growing and harvesting season has concluded, fields may be fallow, therefore limiting the information that can be collected around growing activities, harvesting activities, or personnel. As it is often difficult to determine how and when contamination may have occurred, the precise route of contamination may remain uncertain. Investigators may also be unable to rule out sources or means of contamination that were not

identified during an investigation. We note that outbreaks of unknown origin may also have been caused by contaminated pre-harvest agricultural water, but we are unable to identify these. Because we are unable to identify with certainty the fraction of outbreaks that can be attributed to contaminated pre-harvest, harvest, or post-harvest water, we use survey responses from subject matter experts about the percentage of illnesses attributable to pre-harvest agricultural water.

In our survey of subject matter experts (Ref. 3), we asked them to estimate the percentage of illnesses attributable to agricultural water generally (including pre-harvest, harvest, or post-harvest) that would be attributable to pre-harvest agricultural water specifically. The median responses from subject matter experts for the low, most likely, and high estimates were 25%, 40%, and 60% of illnesses attributable to pre-harvest agricultural water specifically. We use these percentages as the parameters of a PERT distribution to simulate the dollar burden of foodborne illnesses attributable to pre-harvest agricultural water; this method incorporates the uncertainty about the fraction of illnesses attributable to pre-harvest agricultural water. We note that using a PERT distribution maps the "low" and "high" survey estimates to parameters corresponding to the minimum and maximum value of the distribution, respectively. Table 3 presents our low, primary, and high estimates of the dollar burden of illnesses attributable to pre-harvest agricultural water in the absence of any pre-harvest agricultural water provisions. We note that throughout the analysis, where we incorporate PERT distributions to account for uncertainty, primary estimates map to the mean of the PERT distribution, not the "most likely" parameter of the PERT distribution. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 3: Dollar Burden of Foodborne Illnesses Attributable to Pre-harvest Agricultural Water, No Pre-harvest Provisions in Effect (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$180.6	$243.0	$309.4
1	$180.6	$243.0	$309.4
2	$180.6	$243.0	$309.3
3	$180.6	$243.0	$309.4
4	$180.6	$243.0	$309.4
5	$180.6	$243.0	$309.4
6	$180.6	$243.0	$309.4
7	$180.6	$243.0	$309.3
8	$180.6	$243.0	$309.4
9	$180.6	$243.0	$309.4
Annualized, 3%	$180.6	$243.0	$309.4
Annualized, 7%	$180.6	$243.0	$309.4

Our primary baseline is the pre-harvest agricultural water microbial water quality criteria and testing provisions in the 2015 produce safety final rule. We acknowledge uncertainty about the effectiveness of pre-harvest agricultural water testing provisions at preventing illnesses.[2] For purposes of this analysis, we use survey responses from subject matter experts about the effectiveness of those pre-harvest agricultural water testing provisions. In our survey of subject matter experts (Ref. 3), we provided the pre-harvest agricultural water microbial water quality criteria and testing provisions in the 2015 produce safety final rule and asked how effective the provisions would be at preventing illnesses. The median estimates from subject matter experts of the low, most likely, and high estimates of the percentage of illnesses that would occur under the testing regime relative to no provisions were 40%, 65%, and 80%. We use these percentages as

[2] See, e.g., the 2019 agricultural water compliance date extension final rule, which states: "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" (84 FR 9706 at 9710; Mar. 18, 2019).

parameters of a PERT distribution to simulate the benefits of pre-harvest water testing provisions; this method incorporates the uncertainty about the effectiveness of pre-harvest water testing provisions. Table 4 presents our low, primary, and high estimates of the benefits (dollar burden of illnesses avoided) of the pre-harvest agricultural water microbial water quality criteria and testing provisions in the 2015 produce safety final rule. In year 0, there are no estimated benefits as provisions have not taken effect; in year 1, provisions have taken effect only for large farms, which constitute 80% of covered produce acreage; in year 2, provisions have taken effect for large farms and small farms, which constitute 87% of covered acreage; in years 3 and onward, provisions have taken effect for all farm sizes (Ref. 8). We estimate that annualized baseline benefits are approximately $75.8 million in 2022 dollars at a 3 percent discount rate. At a 7 percent discount rate, estimated annual baseline benefits are approximately $73.7 million. We use these estimated benefits of the pre-harvest agricultural water microbial water quality criteria and testing provisions in the 2015 produce safety final rule as the baseline for this rule. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated benefits as measures of uncertainty.

Table 4: Estimated Benefits of Pre-harvest Agricultural Water Microbial Quality Criteria and Testing Provisions in the 2015 Produce Safety Final Rule, Relative to No Provisions, (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$43.8	$71.3	$105.1
2	$48.1	$77.8	$114.6
3	$55.2	$89.1	$131.3
4	$55.4	$89.1	$131.3
5	$55.3	$89.1	$131.3
6	$55.1	$89.1	$131.4
7	$55.2	$89.1	$131.9
8	$54.4	$89.1	$131.1
9	$54.9	$89.1	$131.5

Annualized, 3%	$46.8	$75.8	$111.7
Annualized, 7%	$45.5	$73.7	$108.7

ii. Baseline Costs

For the purpose of this analysis, we use the pre-harvest agricultural water microbial water quality criteria and testing provisions in subpart E of the 2015 produce safety final rule for covered produce other than sprouts as the primary baseline. Therefore, baseline costs for the current analysis would be represented by the costs associated with the pre-harvest agricultural water testing provisions in the 2015 produce safety final rule. In this section, we estimate costs of testing untreated surface and ground water used during pre-harvest activities for non-sprout covered produce, treating surface and ground water used during pre-harvest activities for non-sprout covered produce, and recordkeeping.

i. Water Testing

The agricultural water provisions in the 2015 produce safety final rule required, in relevant part, that farms test certain water sources used during pre-harvest activities for covered produce (other than sprouts) to ensure the water meets established microbial water quality criteria. For each untreated surface water source used for pre-harvest activities for covered produce (other than sprouts), a covered farm would have conducted an initial survey consisting of 20 tests (collected over 2-4 years) and updated the microbial water quality profile with 5 new tests per year thereafter; for each untreated ground water source, a farm would have conducted an initial survey consisting of 4 tests (taken during the growing season or over a period of 1 year) and updated the water quality profile with 1 new test per year thereafter. (See § 112.46(b) as established in the 2015 produce safety final rule.)

Table 5 presents estimates of the number of farms that would have had to conduct testing of untreated surface water sources under the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule. As discussed in the baseline number of affected farms section, we estimate that there are 22,025 covered irrigated very small farms, 4,572 covered irrigated small farms, and 9,966 covered irrigated large farms. Of these, 45.0% of very small and small farms use untreated surface or ground water that contact produce, and 54.1% of large farms use untreated surface or ground water that contacts produce (Ref. 2). Of farms that use untreated surface or ground water that contacts produce, USDA estimates that 31.9% use surface water. We multiply the number of covered irrigated farms by these percentages to estimate that 3,162 very small farms, 656 small farms, and 1,720 large farms would have been required to perform the baseline survey for untreated surface water sources established in the 2015 produce safety final rule. The 2015 FRIA estimates that the cost of a water sample, including supplies and shipping, is $110 (Ref. 8). We update this number to 2022 dollars and estimate that the cost of a water sample is $137.

Table 5: Surface Water Testing Costs of Requirements in the 2015 Produce Safety Final Rule (2022$)

Cost of testing untreated surface water				
	Very small	**Small**	**Large**	**Total**
Number of covered irrigated farms	22,025	4,572	9,966	36,563
Percentage of covered farms that use untreated surface or ground water that contacts produce	45.00%	45.00%	54.10%	
Percentage of covered farms that use untreated surface or ground water that contacts produce that use surface water	31.90%	31.90%	31.90%	
Number of farms that must perform baseline survey	3,162	656	1,720	5,538
Cost of collecting sample	$137	$137	$137	
Baseline testing frequency	5	5	5	
Annual testing frequency	5	5	5	
Baseline testing cost per source	$685	$685	$685	

Annual testing cost per source	$685	$685	$685	

*Numbers may not add due to rounding

Many farms may have more than one source of surface water that they would have needed to test under the pre-harvest agricultural water requirements of the 2015 produce safety final rule. In our survey of subject matter experts (Ref. 3), we asked how many sources of surface water farms of the specified sizes would need to test under those requirements. Table 6 presents the median estimates of the subject matter experts. We use these low, most likely, and high estimates as parameters of a PERT distribution to estimate the costs of testing all necessary sources of surface water under the pre-harvest agricultural water testing provisions in the 2015 produce safety final rule; this method incorporates the uncertainty about the number of surface water sources farms would need to test. Table 7 presents our estimates of the costs of testing surface water under those provisions by year. In year 0, provisions have not taken effect; in year 1, provisions have taken effect only for large farms; in year 2, provisions have taken effect for large farms and small farms; in years 3 and onward, provisions have taken effect for all farm sizes. Our primary estimate is $9.3 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $9.0 million annualized. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 6: Number of Untreated Surface Water Sources that Would Need to Be Tested Under the Pre-harvest Agricultural Water Testing Provisions of the 2015 Produce Safety Final Rule

	Low	Most Likely	High
Very Small	1	1	3
Small	1	2	4
Large	1	3	6

Table 7: Total Cost of Testing Untreated Surface Water Sources, Under the Pre-harvest Agricultural Water Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$2.7	$6.9	$11.1
2	$3.8	$8.1	$12.3
3	$6.7	$11.5	$15.6
4	$6.7	$11.5	$15.6
5	$6.7	$11.5	$15.6
6	$6.7	$11.5	$15.6
7	$6.7	$11.5	$15.6
8	$6.7	$11.5	$15.6
9	$6.7	$11.5	$15.6
Annualized, 3%	$5.2	$9.3	$13.0
Annualized, 7%	$5.0	$9.0	$12.6

Table 8 presents estimates of the number of farms that would have had to conduct testing of untreated ground water sources under the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule. Of farms that use untreated surface or ground water that contacts produce, USDA estimates that 68.1% use ground water (Ref. 2). We multiply the number of covered irrigated farms by these percentages to estimate that 6,750 very small farms, 1,401 small farms, and 3,672 large farms would have been required to perform the baseline survey for untreated ground water sources established in the 2015 produce safety final rule. The 2015 FRIA estimates that the cost of a water sample, including supplies and shipping, is $110 (Ref. 8). We update this number to 2022 dollars to estimate the cost of a water sample is $137.

Table 8: Ground Water Testing Costs of Requirements in the 2015 Produce Safety Final Rule (2022$)

Cost of testing untreated ground water				
	Very Small	**Small**	**Large**	**Total**
Number of covered irrigated farms	22,025	4,572	9,966	36,563

Percentage of covered farms that use untreated surface or ground water that contacts produce	45.00%	45.00%	54.10%	
Percentage of covered farms that use untreated surface or ground water that contacts produce that use ground water	68.10%	68.10%	68.10%	
Number of farms that must perform baseline survey	6,750	1,401	3,672	11,823
Cost of collecting sample	$137	$137	$137	
Baseline testing frequency	4	4	4	
Annual testing frequency	1	1	1	
Baseline testing cost per source	$548	$548	$548	
Annual testing cost per source	$137	$137	$137	

*Numbers may not add due to rounding

Many farms may have more than one source of ground water that they would have needed to test under the pre-harvest agricultural water provisions of the 2015 produce safety final rule. In our survey of subject matter experts, we asked how many sources of ground water they thought farms of the specified sizes would need to test under those requirements. Table 9 presents the median estimates of the subject matter experts. We use these low, most likely, and high estimates as parameters of a PERT distribution to estimate the costs of testing all necessary sources of ground water under the pre-harvest agricultural water testing provisions in the 2015 produce safety final rule; this method incorporates the uncertainty about the number of ground water sources farms would need to test. Table 10 presents our estimates of the costs of testing ground water under those provisions by year. In year 0, provisions have not taken effect; in year 1, provisions have taken effect only for large farms; in year 2, provisions have taken effect for large farms and small farms; in years 3 and onward, provisions have taken effect for all farm sizes. Our primary estimate is $5.7 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $5.7 million annualized. We include 5th (“Low Estimate”) and 95th (“High Estimate”) percentile outcomes of the simulated burden as measures of uncertainty.

Table 9: Number of Untreated Ground Water Sources that Would Need to Be Tested Under the Pre-harvest Agricultural Water Testing Provisions of the 2015 Produce Safety Final Rule

	Low	Most Likely	High
Very Small	1	1	3
Small	1	2	4
Large	1	4	10

Table 10: Total Cost of Testing Untreated Ground Water Sources, Under the Pre-harvest Agricultural Water Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$4.7	$11.7	$18.9
2	$2.9	$5.4	$7.4
3	$6.3	$9.6	$12.2
4	$3.0	$5.1	$6.8
5	$3.0	$5.1	$6.8
6	$3.0	$5.1	$6.8
7	$3.0	$5.1	$6.8
8	$3.0	$5.1	$6.8
9	$3.0	$5.1	$6.8
Annualized, 3%	$3.2	$5.7	$8.0
Annualized, 7%	$3.1	$5.7	$8.1

ii. Corrective Measures

The pre-harvest agricultural water provisions in the 2015 produce safety final rule required, in relevant part, that water meet the requirements of § 112.44(b), which stated:

(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with §112.49):

(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and

(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

Section 112.45(b) of the 2015 produce safety final rule would have required that if water did not meet those criteria, then as soon as practicable and no later than the following year, farms would be required to discontinue that use of agricultural water, unless they implemented certain specified corrective measures. We are uncertain about the percentage of farms that, having conducted the prescribed water testing in the 2015 produce safety final rule, would have needed to implement corrective measures as a result of failing to meet the pre-harvest microbial water quality criteria. The 2015 FRIA (Ref. 8) estimates that 2.4% of water would not meet the pre-harvest microbial water quality criteria under the 2015 produce safety final rule. The EPA's fact sheet on the 2012 recreational water quality criteria (Ref. 9) – which we used in the 2015 produce safety final rule as a starting point for quantitative microbial criteria that are generally applicable to minimize the risk of hazards associated with the use of pre-harvest agricultural water – states that no more than 10% of water samples should exceed the microbial water quality criteria. We use a PERT distribution with parameters 0%, 2.4%, and 10% to estimate the percentage of farms that, having conducted the prescribed testing, would have conducted water treatment.

USDA estimates that "small" covered farms ($25,000-$500,000 revenue) that conducted water treatment spent $1,189 annually (Ref. 2). We update this number to $1,445 in 2022 dollars. These farms encompass farms in the "very small" and "small" categories for the purposes of this analysis. The "large" category of this analysis is composed of farms in USDA's "midsize" (annual treatment cost of $1,568, updated to $1,906 in 2022 dollars), "large" (annual treatment cost of $1,596, updated to $1,940 in 2022 dollars), and "very large" (annual treatment cost of $22,864, updated to $27,793 in 2022 dollars) categories. We construct a weighted average of these treatment costs by number of farms surveyed to estimate that the annual treatment cost for a "large" farm in our analysis is $7,046 in 2022 dollars. Several public comments suggested that we underestimated water treatment cost but did not provide specific information as to estimates that would be more appropriate across the diversity of operations, agricultural water systems, and agricultural water uses of covered farms. To incorporate uncertainty about water treatment cost, we replace the use of a single estimate for each farm size with a PERT distribution with parameters corresponding to 50% of the above calculated treatment cost, 100% of the above calculated treatment cost, and 200% of the above calculated treatment cost for each farm size category. We use these estimates of water treatment cost to remain consistent across the pre-harvest microbial quality criteria and testing provisions in the 2015 produce safety final rule and the requirements for pre-harvest agricultural water assessments and measures that we are finalizing with this rule.

Table 11 presents our estimates of the costs of treating surface water under the pre-harvest agricultural water provisions in the 2015 produce safety final rule by year; Table 12 presents our estimates of the costs of treating ground water under those provisions by year. In year 0, provisions have not taken effect; in year 1, provisions have taken effect only for large

farms; in year 2, provisions have taken effect for large farms and small farms; in years 3 and onward, provisions have taken effect for all farm sizes. Our primary estimate of the cost of treating surface water under the 2015 produce safety final rule is $0.5 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $0.5 million annualized. Our primary estimate of the cost of treating ground water under the 2015 produce safety final rule is $1.1 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $1.1 million annualized. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 11: Total Cost of Treating Surface Water, Pre-Harvest Agricultural Water Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$0.1	$0.4	$0.9
2	$0.1	$0.5	$0.9
3	$0.2	$0.6	$1.1
4	$0.2	$0.6	$1.1
5	$0.2	$0.6	$1.1
6	$0.2	$0.6	$1.1
7	$0.2	$0.6	$1.1
8	$0.2	$0.6	$1.1
9	$0.2	$0.6	$1.1
Annualized, 3%	$0.2	$0.5	$0.9
Annualized, 7%	$0.2	$0.5	$0.9

Table 12: Total Cost of Treating Ground Water, Pre-harvest Agricultural Water Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$0.2	$0.9	$1.9
2	$0.2	$1.0	$1.9
3	$0.5	$1.3	$2.3
4	$0.5	$1.3	$2.3

5	$0.5	$1.3	$2.3
6	$0.5	$1.3	$2.3
7	$0.5	$1.3	$2.3
8	$0.5	$1.3	$2.3
9	$0.5	$1.3	$2.3
Annualized, 3%	$0.4	$1.1	$2.0
Annualized, 7%	$0.3	$1.1	$1.9

iii. Recordkeeping

The agricultural water recordkeeping provisions in the 2015 produce safety final rule that apply for pre-harvest agricultural water would have required that farms keep written records of all analytical water tests conducted. We assume that recordkeeping has a time burden of one hour for each test conducted. We use wage data for "Farm Operators" for very small and small farms and wage data for "Farm Supervisors" for large farms, and double the rates to yield fully-loaded labor costs, as per HHS guidelines. For very small and small farms, we use the fully-loaded BLS hourly cost of labor of $80.58 for "Farmers, Ranchers, and Other Agricultural Managers" (Ref. 10). For large farms, we use the fully-loaded BLS hourly cost of labor of $56.56 for "First-Line Supervisors of Farming, Fishing, and Forestry Workers" (Ref. 11). Table 13 presents estimated costs of recordkeeping related to the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule by year. Our primary estimate of the cost of recordkeeping is $2.5 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is also $2.5 million annualized.

Table 13: Total Cost of Recordkeeping, Pre-harvest Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Cost
0	$0
1	$1.3
2	$1.4
3	$4.5

4	$2.9
5	$2.9
6	$2.9
7	$2.9
8	$2.9
9	$2.9
Annualized, 3%	$2.5
Annualized, 7%	$2.5

iv. Total Costs of the Pre-Harvest Agricultural Water Microbial Quality Criteria and Testing Requirements in the 2015 Produce Safety Final Rule

Table 14 presents our low, primary, and high estimates of the total cost of the pre-harvest agricultural water microbial quality criteria and testing provisions by year. Our primary estimate of the total cost of these provisions is $19.8 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $20.1 million annualized. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 14: Total Cost of the Pre-harvest Agricultural Water Microbial Quality Criteria and Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$10.0	$21.4	$32.7
2	$10.0	$16.5	$22.3
3	$20.1	$27.7	$33.6
4	$14.7	$21.6	$27.3
5	$14.7	$21.6	$27.4
6	$14.7	$21.6	$27.3
7	$14.7	$21.6	$27.3
8	$14.7	$21.6	$27.3
9	$14.7	$21.6	$27.3
Annualized, 3%	$12.6	$19.8	$25.7
Annualized, 7%	$12.2	$20.1	$26.1

E. Benefits of the Rule

In the baseline conditions section, we present our estimates of the simulated stream of benefits of the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule, which we treat as the primary baseline for the rule.

The gained or forgone benefits of this rule would stem only from the pre-harvest agricultural water provisions for non-sprout covered produce. The provisions for agricultural water assessments in the rule are designed to be flexible to accommodate a wide range of agricultural water sources, uses, and practices; stakeholders have provided feedback that they find the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule to be inflexible due to imposing a "one-size-fits-all" approach that is difficult to implement across the wide variety of sources, uses, and practices covered by the rule. The provisions require farms to holistically consider potential hazards and time-varying conditions that may not be reflected when testing pre-harvest water under the agricultural water provisions in the 2015 produce safety final rule. Requiring farms to conduct an assessment of their pre-harvest agricultural water systems for conditions that may introduce hazards may better assist them in identifying potential sources of human pathogens in pre-harvest water that contacts produce. However, the provisions may be less effective at preventing outbreaks if farms fail to identify hazards during the agricultural water assessment or fail to properly mitigate identified hazards.

The rule may also help avoid overly broad recalls of products for outbreaks that would have occurred absent the rule, which would lead to cost savings for industry. We are not aware of—and comments did not provide—quantitative data or information related to recalls that can be directly attributed to pre-harvest agricultural water for non-sprout covered produce that would allow us to estimate these cost savings quantitatively or compare these cost savings to recalls

potentially averted due to pre-harvest agricultural water testing provisions, but we note that the rule may provide cost savings to industry in the form of potential recalls averted.

We acknowledge uncertainty about the effectiveness of the pre-harvest agricultural water assessment provisions at preventing illnesses; we use survey responses from subject matter experts to estimate the expected effectiveness of these provisions. In our survey of subject matter experts (Ref. 3), we provided the pre-harvest agricultural water assessment provisions and asked them to estimate the percentage of illnesses that would occur under the pre-harvest agricultural water assessment provisions relative to no pre-harvest agricultural water provisions. The median estimates from subject matter experts of the low, most likely, and high estimates of the percentage of illnesses that would occur under the assessment approach relative to no provisions were 30%, 60%, and 80%. We use these percentages as parameters of a PERT distribution to simulate the benefits of the pre-harvest water assessment provisions; this method incorporates the uncertainty about the effectiveness of the provisions. Table 15 presents our low, primary, and high estimates of the benefits (dollar burden of illnesses avoided) of the pre-harvest agricultural water assessment provisions relative to the baseline of the pre-harvest agricultural water microbial quality criteria and testing provisions, and Table 16 presents our low, primary, and high estimates of the benefits (dollar burden of illnesses avoided) of the pre-harvest agricultural water testing provisions relative to no pre-harvest agricultural water provisions. In year 0, there are no estimated benefits as provisions have not taken effect; in year 1, provisions have taken effect only for large farms, which constitute 80% of covered produce acreage; in year 2, provisions have taken effect for large farms and small farms, which constitute 87% of covered acreage; in years 3 and onward, provisions have taken effect for all farm sizes (Ref. 8). We include 5th (“Low Estimate”) and 95th (“High Estimate”) percentile outcomes of the simulated

benefits as measures of uncertainty. We estimate that annualized benefits relative to the baseline of pre-harvest agricultural water microbial quality criteria and testing provisions are approximately $10.3 million in 2022 dollars at a 3 percent discount rate. At a 7 percent discount rate, estimated annual baseline benefits are approximately $10.1 million.

Table 15: Estimated Benefits of Pre-harvest Agricultural Water Assessment Provisions, Relative to Primary Baseline of Pre-harvest Agricultural Water Microbial Quality Criteria and Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	-$28.8	$9.7	$48.6
2	-$31.6	$10.6	$54.4
3	-$35.8	$12.1	$62.2
4	-$34.5	$12.1	$62.2
5	-$34.9	$12.1	$61.3
6	-$35.4	$12.1	$61.9
7	-$36.0	$12.1	$61.3
8	-$35.8	$12.1	$61.6
9	-$35.9	$12.1	$61.4
Annualized, 3%	-$30.3	$10.3	$52.4
Annualized, 7%	-$29.4	$10.1	$51.0

Table 16: Estimated Benefits of Pre-harvest Agricultural Water Assessment Provisions, Relative to Alternate Baseline of No Provisions (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$47.9	$81.0	$121.4
2	$52.1	$88.5	$132.5
3	$59.9	$101.2	$152.5
4	$59.7	$101.2	$152.5
5	$59.9	$101.2	$151.6
6	$59.9	$101.2	$152.7
7	$60.1	$101.2	$152.4
8	$59.5	$101.2	$152.7
9	$59.6	$101.2	$151.6
Annualized, 3%	$50.9	$86.1	$129.4
Annualized, 7%	$49.5	$83.8	$125.9

F. Costs of the Rule

a. One-time Costs

In this section, we detail the one-time costs to industry associated with the rule. We estimate that one-time costs occur in the year following the publication of the final rule and do not recur.

i. Reading and Becoming Familiar with the Rule

We assume all farms covered by the 2015 produce safety final rule will spend time reading this rule to become familiar with the requirements regarding pre-harvest agricultural water assessments. We assume farms will incur these one-time costs in the year following the publication of the final rule. To calculate costs of reading the rule, we draw on Bureau of Labor Statistics (BLS) 2022 wage data for "Farmers, Ranchers, and Other Agricultural Managers" (11-9013) from the National Industry-Specific Occupational Employment and Wage Estimates (Ref. 10) to yield a mean hourly wage rate of $40.29. Following guidelines from the Department of Health and Human Services (HHS) (Ref. 7), we double the wage rate to account for overhead and benefits, yielding a fully-loaded hourly cost of labor of $80.58. Table 17 presents estimates of the cost of reading the rule by reading speed.

Table 17: Cost of Reading and Understanding the Rule (2022$)

	Low	**Primary**	**High**
Average reading speed (words per minute)	250	225	200
Total words in rule	82,979	82,979	82,979
Hours to read rule	5.5	6.1	6.9
Hourly cost of labor of farm managers	$80.58	$80.58	$80.58

Cost per farm	$446	$495	$557
Number of farms that read the rule	43,510	43,510	43,510
Total cost of reading and understanding rule (millions)	**$19.4**	**$21.6**	**$24.2**

b. Recurring Costs

i. Pre-Harvest Agricultural Water Assessments

This rule requires farms that use pre-harvest agricultural water in direct application for non-sprout covered produce to prepare a written pre-harvest agricultural water assessment annually and "whenever a significant change occurs in your agricultural water system." A pre-harvest agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, which includes an evaluation of each agricultural water system, agricultural water practices associated with application methods for those systems, crop characteristics, environmental conditions, and other relevant factors (§ 112.43).

We conducted a survey of subject matter experts in which we asked them to estimate the amount of time it would take farms of varying sizes to conduct pre-harvest agricultural water assessments as specified (Ref. 3). Table 18 presents the median estimates from subject matter experts of the low, most likely, and high labor hours it would take farms to conduct an assessment. We use these estimates as parameters of a PERT distribution to calculate the cost of conducting assessments; this method incorporates the uncertainty about the amount of time it takes to conduct assessments. These estimates do not include the estimated recordkeeping burden, which we address in a later section.

Table 18: Estimated Time to Conduct a Pre-harvest Agricultural Water Assessment (hours)

Farm Size	Low	Most Likely	High
Very small	6.0	10.0	18.0
Small	6.0	12.0	18.0
Large	10.0	16.0	20.0

We use these estimated time burdens to calculate the estimated annual costs of conducting assessments. We assume affected farms will conduct approximately 1.1 assessments annually, in accordance with the requirement to conduct assessments at least once annually and "whenever a significant change occurs in your agricultural water system." We use wage data for "Farm Operators" for very small and small farms and wage data for "Farm Supervisors" for large farms. For very small and small farms, we use the fully-loaded BLS hourly mean wage rate for "Farmers, Ranchers, and Other Agricultural Managers" to yield an hourly cost of labor of $80.58 (Ref. 10). For large farms, we use the fully-loaded BLS hourly mean wage rate for "First-Line Supervisors of Farming, Fishing, and Forestry Workers" to yield an hourly cost of labor of $56.56 (Ref. 11). Table 19 presents the estimated annual cost of conducting pre-harvest agricultural water assessments for very small farms; Table 20 presents the estimated annual cost of conducting pre-harvest agricultural water assessments for small farms; and Table 21 presents the estimated annual cost of conducting pre-harvest agricultural water assessments for large farms. Table 22 presents estimated costs of conducting pre-harvest agricultural water assessments for all farms by year. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 19: Cost of Conducting Pre-Harvest Agricultural Water Assessments for Very Small Farms (2022$)

	Low	Most Likely	High
Number of farms conducting assessments	9,911	9,911	9,911
Number of pre-harvest agricultural water assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$80.58	$80.58	$80.58
Time in hours to conduct each agricultural water assessment	6.0	10.0	18.0
Annual cost of assessment for very small farms (millions)	**$6.0**	**$9.7**	**$14.1**

Table 20: Cost of Conducting Pre-Harvest Agricultural Water Assessments for Small Farms (2022$)

	Low	Most Likely	High
Number of farms conducting assessments	2,057	2,057	2,057
Number of pre-harvest agricultural water assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$80.58	$80.58	$80.58
Time in hours to conduct each agricultural water assessment	6.0	12.0	18.0
Annual cost of assessment for small farms (millions)	**$1.4**	**$2.3**	**$3.2**

Table 21: Cost of Conducting Pre-Harvest Agricultural Water Assessments for Large Farms (2022$)

	Low	Most Likely	High
Number of farms conducting assessments	5,392	5,392	5,392
Number of pre-harvest agricultural water assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm supervisors	$56.56	$56.56	$56.56

Time in hours to conduct each agricultural water assessment	10.0	16.0	20.0
Annual cost of assessment for large farms (millions)	**$3.9**	**$6.0**	**$8.6**

Table 22: Total Cost of Conducting Pre-Harvest Agricultural Water Assessments, All Farms (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$3.9	$6.0	$8.6
2	$5.9	$8.3	$11.0
3	$13.4	$18.0	$23.1
4	$13.4	$18.0	$23.0
5	$13.4	$18.0	$23.1
6	$13.5	$18.0	$23.0
7	$13.5	$18.0	$23.0
8	$13.4	$18.0	$23.0
9	$13.4	$18.0	$23.0
Annualized, 3%	$10.0	$13.6	$17.5
Annualized, 7%	$9.6	$13.0	$16.8

ii. Mitigating Known or Reasonably Foreseeable Hazards

When a covered farm conducts a pre-harvest agricultural water assessment and determines that there are conditions reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, the rule requires them to implement any mitigation measures that are that are reasonably necessary to reduce the potential for contamination with such known or reasonably foreseeable hazards. Mitigation measures may include making necessary changes (such as repairs), increasing the time between last water application and harvest to allow for microbial die-off, increasing the time interval between harvest and end-of storage and/or conducting other harvest or post-harvest activities to allow for microbial die-off or removal, changing the method of water application, treating the water, or an alternative mitigation measure (§112.45(b)).

We are uncertain about the fraction of farms that conduct pre-harvest agricultural water assessments that would subsequently need to conduct a mitigation step each year. Table 23 presents the median estimates from subject matter experts of the low, most likely, and high percentage of farms that, having conducted a pre-harvest agricultural water assessment as specified, would subsequently conduct a mitigation measure (Ref. 3).

Table 23: Percentage of Farms That Conduct an Assessment That Mitigate

Farm Size	Low	Most Likely	High
Very small	10	25	50
Small	10	20	50
Large	15	30	50

We are uncertain about the fraction of farms that, having determined a mitigation action is necessary, would conduct each type of mitigation action. Table 24 presents the median estimates from subject matter experts of the low, most likely, and high fraction of very small farms that, having determined they would need to conduct a mitigation action, would conduct each type of mitigation action; Table 25 presents the median estimates from subject matter experts of the low, most likely, and high fraction of small farms that, having determined they would need to conduct a mitigation action, would conduct each type of mitigation action; Table 26 presents the median estimates from subject matter experts of the low, most likely, and high fraction of large farms that, having determined they would need to conduct a mitigation action, would conduct each type of mitigation action (Ref. 3).

Table 24: Fraction of Very Small Farms That Mitigate That Conduct Each Action

Mitigation Action	Low	Most Likely	High
Necessary Changes	0.25	0.40	0.60
Pre-harvest Die-off	0.23	0.30	0.50
Postharvest Die-off	0.15	0.30	0.50

Changing Water Application	0.05	0.10	0.10
Water Treatment	0.10	0.15	0.20
Alternative Options	0.10	0.20	0.35

Table 25: Fraction of Small Farms That Mitigate That Conduct Each Action

Mitigation Action	Low	Most Likely	High
Necessary Changes	0.25	0.30	0.70
Pre-harvest Die-off	0.20	0.30	0.50
Postharvest Die-off	0.15	0.30	0.50
Changing Water Application	0.10	0.20	0.25
Water Treatment	0.10	0.20	0.35
Alternative Options	0.10	0.25	0.45

Table 26: Fraction of Large Farms That Mitigate That Conduct Each Action

Mitigation Action	Low	Most Likely	High
Necessary Changes	0.23	0.40	0.80
Pre-harvest Die-off	0.23	0.30	0.50
Postharvest Die-off	0.15	0.35	0.50
Changing Water Application	0.10	0.15	0.23
Water Treatment	0.15	0.30	0.40
Alternative Options	0.10	0.25	0.40

We are uncertain about the cost of each type of mitigation action. USDA estimates that "small" covered farms ($25,000-$500,000 revenue) that conducted water treatment spent $1,189 annually (Ref. 2). We update this number to $1,445 in 2022 dollars. These farms encompass farms in the "very small" and "small" categories for the purposes of this analysis. The "large" category of this analysis is composed of farms in USDA's "midsize" (annual treatment cost of $1,568, updated to $1,906 in 2022 dollars), "large" (annual treatment cost of $1,596, updated to $1,940 in 2022 dollars), and "very large" (annual treatment cost of $22,864, updated to $27,793 in 2022 dollars) categories. We construct a weighted average of these treatment costs by number of farms surveyed to estimate that the annual treatment cost for a "large" farm in our analysis is

$7,046 in 2022 dollars. Several public comments suggested that we underestimated water treatment cost but did not provide specific data or information as to estimates that would be more appropriate across the diversity of operations, agricultural water systems, and agricultural water uses. To incorporate uncertainty about water treatment cost, we replace the use of a single estimate with a PERT distribution with parameters corresponding to 50% of the above calculated treatment cost, 100% of the above calculated treatment cost, and 200% of the above calculated treatment cost for each farm size category. We use these estimates of water treatment cost to remain consistent across the pre-harvest microbial quality criteria and testing provisions in the 2015 produce safety final rule and the requirements for pre-harvest agricultural water assessments and measures that we are finalizing with this rule.

Table 27 presents the median estimates from subject matter experts of the low, most likely, and high cost to very small farms of each type of non-treatment mitigation action, updated to 2022 dollars; Table 28 presents the median estimates from subject matter experts of the low, most likely, and high cost to small farms of each type of non-treatment mitigation action, updated to 2022 dollars; Table 29 presents the median estimates from subject matter experts of the low, most likely, and high cost to large farms of each type of non-treatment mitigation action, updated to 2022 dollars (Ref. 3).

Table 27: Cost of Each Type of Mitigation, Very Small Farms (2022$)

Mitigation Action	Low	Primary	High
Necessary Changes	$112	$559	$1,118
Pre-harvest Die-off	$0	$0	$0
Postharvest Die-off	$615	$1,202	$1,509
Changing Water Application	$1,453	$2,878	$4,304
Alternative Options	$56	$671	$838

Table 28: Cost of Each Type of Mitigation, Small Farms (2022$)

Mitigation Action	Low	Primary	High
Necessary Changes	$559	$1,118	$2,236
Pre-harvest Die-off	$0	$0	$0
Postharvest Die-off	$2,906	$4,639	$5,869
Changing Water Application	$224	$2,236	$2,236
Alternative Options	$279	$1,397	$2,515

Table 29: Cost of Each Type of Mitigation, Large Farms (2022$)

Mitigation Action	Low	Primary	High
Necessary Changes	$112	$2,236	$3,353
Pre-harvest Die-off	$0	$0	$0
Postharvest Die-off	$3,968	$5,673	$7,378
Changing Water Application	$3,353	$4,471	$5,589
Alternative Options	$1,733	$2,627	$3,633

We estimate mitigation costs using the low, most likely, and high estimates presented in the tables above as parameters of PERT distributions to account for the uncertainty in the estimates of the fraction of farms that, having conducted an assessment, would conduct a mitigation action; the uncertainty in the estimates of the fraction of farms that would conduct each mitigation action; and the uncertainty in the estimates of the costs of each type of mitigation action. Table 30 presents estimated costs of conducting mitigation for all farms by year. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 30: Total Cost of Mitigation, All Farms (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$6.8	$11.7	$16.0
2	$8.0	$13.3	$17.4
3	$10.9	$16.8	$20.9

4	$10.9	$16.8	$20.9
5	$11.0	$16.8	$20.9
6	$10.9	$16.8	$20.9
7	$10.9	$16.8	$21.0
8	$10.9	$16.8	$20.9
9	$11.0	$16.8	$20.9
Annualized, 3%	$8.9	$14.0	$17.6
Annualized, 7%	$8.6	$13.5	$17.1

iii. Recordkeeping

The final rule requires farms to establish and maintain written records of the pre-harvest agricultural water assessments conducted, including descriptions of factors evaluated and written determinations (§ 112.50(b)). We use median subject matter expert estimates of the low, most likely, and high time burden of recordkeeping as parameters of a PERT distribution to model the cost to farms of various sizes to establish and maintain the required records once the assessment has been completed; this method incorporates the uncertainty about the time it takes to conduct recordkeeping.

We use the previously described fully-loaded hourly cost of labor "Farm Operators" ($80.58) for very small and small farms and cost of labor for "Farm Supervisors" for large farms ($56.56). Table 31 presents the estimated annual cost of recordkeeping for very small farms; Table 32 presents the estimated annual cost of recordkeeping for small farms; and Table 33 presents the estimated annual cost of recordkeeping for large farms. Table 34 presents estimated costs of recordkeeping for all farms by year. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty. We provide summary tables of the total estimated costs of this rule relative to the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule and relative to no pre-harvest agricultural water provisions in section H.

Table 31: Cost of Recordkeeping, Very Small Farms (2022$)

	Low	Most Likely	High
Number of farms conducting assessments	9,911	9,911	9,911
Number of assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$80.58	$80.58	$80.58
Time in hours to conduct recordkeeping	2.0	4.0	9.0
Annual cost of recordkeeping for very small farms (millions)	**$2.3**	**$4.0**	**$6.0**

Table 32: Cost of Recordkeeping, Small Farms (2022$)

	Low	Most Likely	High
Number of farms conducting assessments	2,057	2,057	2,057
Number of assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$80.58	$80.58	$80.58
Time in hours to conduct recordkeeping	2.0	8.0	10.0
Annual cost of recordkeeping for small farms (millions)	**$0.9**	**$1.3**	**$1.7**

Table 33: Cost of Recordkeeping, Large Farms (2022$)

	Low	Most Likely	High
Number of farms conducting assessments	5,392	5,392	5,392
Number of assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm supervisors	$56.56	$56.56	$56.56
Time in hours to conduct recordkeeping	3.0	9.0	11.0
Annual cost of recordkeeping for large farms (millions)	**$1.9**	**$2.8**	**$3.5**

Table 34: Total Cost of Recordkeeping, All Farms (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0

1	$1.9	$2.8	$3.5
2	$3.2	$4.1	$5.0
3	$6.2	$8.1	$10.2
4	$6.2	$8.1	$10.3
5	$6.2	$8.1	$10.2
6	$6.2	$8.1	$10.3
7	$6.2	$8.1	$10.3
8	$6.2	$8.1	$10.2
9	$6.2	$8.1	$10.2
Annualized, 3%	$4.7	$6.2	$7.8
Annualized, 7%	$4.5	$5.9	$7.4

G. Transfers Caused by the Rule

We do not anticipate that this rule will cause any transfers.

H. Summary of Benefits, Costs, and Transfers

Table 35 presents the estimated costs of both this rule and the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule by year, relative to a state of the world with no pre-harvest agricultural water provisions. This includes the estimated costs of reading this rule, conducting pre-harvest agricultural water assessments, implementing mitigation measures that may result from pre-harvest agricultural water assessments, and recordkeeping of the pre-harvest agricultural water assessments. Our primary estimate of the total cost of this rule, relative to no pre-harvest agricultural water provisions, is $36.1 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $35.3 million annualized. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 35: Total Cost of this Final Rule Versus the Pre-harvest Agricultural Water Provisions in the 2015 Produce Safety Final Rule by Year Relative to no Pre-harvest Agricultural Water Provisions, All Farms (millions 2022$)

Years after publication	Primary Estimate of Total Costs of Pre-harvest Agricultural Water Provisions in the 2015 Produce Safety Final Rule	Primary Estimate of Total Costs of this Final Rule
0	$0	$21.6
1	$21.4	$20.6
2	$16.5	$25.7
3	$27.7	$42.9
4	$21.6	$42.9
5	$21.6	$42.9
6	$21.6	$42.9
7	$21.6	$42.9
8	$21.6	$42.9
9	$21.6	$42.9
Annualized, 3%	$19.8	$36.1
Annualized, 7%	$20.1	$35.3

Table 36 presents a comparison of the primary estimates of costs by category in this analysis for this rule and the 2015 produce safety final rule pre-harvest water quality and testing requirements. The increase in costs associated with this rule compared to the uniform 2015 pre-harvest agricultural water testing requirements is largely a result of more mitigation occurring in response to findings from pre-harvest agricultural water assessments than as a result of the previous testing requirements.

Table 36: Breakdown by Category of the Primary Estimate of Annualized Cost of this Final Rule Versus the Pre-harvest Agricultural Water Provisions in the 2015 Produce Safety Final Rule, Relative to no Pre-harvest Agricultural Water Provisions, All Farms (millions 2022$)

	Estimated Cost by Category of the Pre-Harvest Agricultural Water Provisions in the 2015 Produce Safety Final Rule	Estimated Cost by Category of this Final Rule
Reading the Rule	$0	$2.5
Conducting Testing or Assessment	$15.0	$13.6
Conducting Mitigation or Corrective Measures	$1.6	$14.0
Recordkeeping	$2.5	$6.2

*Numbers may not sum exactly to total costs presented in other tables due to rounding

Table 37 presents the estimated costs of this rule by year, relative to a state of the world in which the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule take effect. Our primary estimate of the total cost of the rule, relative to the 2015 pre-harvest agricultural water testing provisions, is $17.5 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $17.7 million annualized. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 38 presents the estimated costs of this rule by year, relative to a state of the world in which there are no pre-harvest agricultural water provisions. Our primary estimate of the total cost of the rule is $36.1 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $35.3 million annualized. We include 5^{th} ("Low Estimate") and 95^{th} ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 37: Total Cost of the Rule by Year Relative to Pre-harvest Agricultural Water Testing Provisions in the 2015 Produce Safety Final Rule, All Farms (millions 2022$)

Years after publication	Low	Primary	High
0	$20.6	$21.6	$22.7
1	-$16.0	-$0.9	$10.3
2	-$0.6	$9.2	$16.7
3	$3.6	$15.1	$23.9
4	$10.0	$21.3	$29.9
5	$10.0	$21.3	$29.9
6	$10.1	$21.3	$29.8
7	$10.1	$21.3	$30.0
8	$10.1	$21.3	$29.6
9	$10.1	$21.3	$29.8
Annualized, 3%	$6.8	$17.5	$25.6
Annualized, 7%	$6.7	$17.7	$26.0

Table 38: Total Cost of the Rule by Year Relative to No Pre-harvest Agricultural Water Testing Provisions, All Farms (millions 2022$)

Years after publication	Low	Primary	High
0	$20.6	$21.6	$22.6
1	$15.3	$20.6	$26.3
2	$20.6	$25.7	$31.6
3	$36.0	$42.9	$50.7
4	$35.7	$42.9	$50.7
5	$35.9	$42.9	$50.9
6	$35.7	$42.9	$50.7
7	$36.1	$42.9	$50.3
8	$35.8	$42.9	$50.9
9	$35.8	$42.9	$50.0
Annualized, 3%	$30.2	$36.1	$42.7
Annualized, 7%	$29.5	$35.3	$41.7

Table 39: Primary Estimate of Benefits and Costs of the Rule by Baseline, All Farms (millions 2022$)

	Relative to Primary Baseline of Pre-harvest Agricultural Water Testing Provisions in the 2015 Produce Safety Final Rule	Relative to no Pre-harvest Agricultural Water Provisions
Primary Estimate of Total Benefit of the Rule, Annualized, 3%	$10.3	$86.1
Primary Estimate of Total Cost of the Rule, Annualized, 3%	$17.5	$36.1

I. Analysis of Regulatory Alternatives to the Rule

Option 1: Remove Pre-harvest Agricultural Water Microbial Quality Criteria and Water Testing Provisions in the 2015 Produce Safety Final Rule

Instead of replacing the uniform pre-harvest agricultural water microbial quality criteria and testing provisions with the pre-harvest agricultural water assessment provisions, one regulatory alternative would be to remove the pre-harvest agricultural water microbial quality criteria and testing provisions for pre-harvest agricultural water for non-sprout covered produce. In this alternative, farms would experience cost savings resulting from the removal of the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule. The only cost borne by farms would be reading a rule that repeals those provisions. For the purposes of this analysis, we assume a rule repealing those provisions would be the same length as this rule. Table 40 presents costs by year (where negative costs represent cost savings) associated with this regulatory alternative. Our primary estimate of annualized net costs of removing the pre-harvest agricultural water microbial quality criteria and testing

provisions are approximately -$16.7 million annualized at a 3 percent discount rate and approximately -$15.9 million annualized at a 7 percent discount rate.

This regulatory alternative would also result in forgone benefits in the form of lost public health protections from potential contaminants. Table 41 presents the estimated forgone benefits of the alternative in which the pre-harvest agricultural water microbial quality criteria and testing provisions are repealed. Annualized forgone benefits of removing those provisions are approximately $75.8 million annualized at a 3 percent discount rate and approximately $73.7 million annualized at a 7 percent discount rate.

Table 40: Costs of Removing Pre-harvest Agricultural Water Microbial Quality Criteria and Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$20.6	$21.6	$22.7
1	-$34.9	-$21.4	-$10.7
2	-$23.8	-$16.5	-$10.5
3	-$35.4	-$27.7	-$21.1
4	-$28.9	-$21.6	-$15.5
5	-$29.0	-$21.6	-$15.5
6	-$28.9	-$21.6	-$15.5
7	-$29.0	-$21.6	-$15.4
8	-$29.0	-$21.6	-$15.5
9	-$29.0	-$21.6	-$15.6
Annualized, 3%	-$24.1	-$16.7	-$10.7
Annualized, 7%	-$23.2	-$15.9	-$9.8

*Negative costs in the table represent cost savings

Table 41: Forgone Benefits of Removing Pre-harvest Agricultural Water Microbial Quality Criteria and Testing Provisions in the 2015 Produce Safety Final Rule (millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$44.2	$71.3	$105.1
2	$48.3	$77.8	$115.0
3	$54.9	$89.1	$131.0

4	$55.4	$89.1	$130.1
5	$55.2	$89.1	$131.0
6	$55.1	$89.1	$132.5
7	$55.0	$89.1	$130.9
8	$54.8	$89.1	$130.5
9	$55.2	$89.1	$132.4
Annualized, 3%	$46.9	$75.8	$111.6
Annualized, 7%	$45.6	$73.7	$108.6

*Positive benefits values in the table represent forgone benefits (not realized).

Option 2: Require Pre-harvest Agricultural Water Assessments Twice Annually

The rule requires affected farms to conduct one pre-harvest agricultural water assessment annually and as necessary due to changes that could affect the quality of their pre-harvest agricultural water. A more stringent alternative would be to require farms to conduct pre-harvest agricultural water assessments twice annually and as necessary due to changes. Additional assessments may lead to additional mitigation measures if farms identify additional hazards in their additional assessments. We are uncertain about whether additional mitigation measures would occur under an alternative in which farms conduct assessments twice annually, because under the approach we are finalizing with this rule, farms are required to conduct reassessments and implement necessary measures in response to significant changes. As a result, we present estimated costs for no increase in mitigation measures, a 50-percent increase in mitigation measures, and a 100-percent increase in mitigation measures. Table 42 presents estimated costs by year of this regulatory alternative relative to pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule, assuming the same costs of reading the rule as in the current rule. This regulatory alternative would be more costly for farms than the rule requiring one assessment annually. This alternative may have larger public health benefits than those estimated in the main analysis if additional pre-harvest agricultural water assessments result in farms identifying and mitigating more potential hazards associated with

their pre-harvest agricultural water and if those additional hazards, without mitigation, would have caused illnesses not prevented by initial mitigation. We are not aware of, and comments did not provide, quantitative data or information that would allow us to estimate potential benefits of conducting an additional assessment each year. Annualized costs under no additional mitigation measures are approximately $36.7 million at a 3 percent discount rate and approximately $35.4 million at a 7 percent discount rate; annualized costs under 50 percent additional mitigation measures are approximately $43.7 million at a 3 percent discount rate and approximately $42.1 million at a 7 percent discount rate; annualized costs under 100 percent additional mitigation measures are approximately $50.6 million at a 3 percent discount rate and approximately $48.9 million at a 7 percent discount rate.

Table 42: Costs of Requiring Two Annual Assessments, Relative to Pre-harvest Agricultural Water Microbial Quality Criteria and Testing Provisions in the 2015 Produce Safety Final Rule (Millions 2022$)

Years after publication	0% More Mitigation Measures	50% More Mitigation Measures	100% More Mitigation Measures
0	$21.6	$21.6	$21.6
1	$8.0	$13.8	$19.7
2	$21.7	$28.3	$34.9
3	$41.2	$49.6	$58.0
4	$47.4	$55.8	$64.2
5	$47.4	$55.8	$64.2
6	$47.4	$55.8	$64.2
7	$47.4	$55.8	$64.2
8	$47.4	$55.8	$64.2
9	$47.4	$55.8	$64.2
Annualized, 3%	$36.7	$43.7	$50.6
Annualized, 7%	$35.4	$42.1	$48.9

Option 3: Require All Farms to Test Pre-harvest Agricultural Water as Part of An Assessment

This rule requires affected farms to conduct one pre-harvest agricultural water assessment annually and as necessary due to changes that could affect the quality of their pre-harvest agricultural water. The rule also includes a requirement to test pre-harvest agricultural water in certain circumstances; that is, when doing so would not delay action where most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary. A different alternative would be to require all farms to conduct water testing as one part of an assessment using the flexible approach in § 112.43(d) of this rule. For the purpose of this analysis, we assume that when testing pre-harvest agricultural water as part of an assessment, farms would use the sampling frequencies as described in the 2015 produce safety final rule.

We provide estimated costs assuming that farms would conduct mitigations resulting from the 2015 testing provisions and mitigations resulting from assessments. Table 43 presents estimated costs by year of this regulatory alternative relative to the primary baseline of 2015 water testing provisions, assuming the same costs of reading the rule as in the current rule. Our primary estimate of annualized costs of requiring that all farms test as part of an assessment is $36.1 million at a 3% discount rate and $35.3 million at a 7% discount rate. Our primary estimate of annualized costs of requiring that all farms test as part of an assessment relative to the alternate baseline of a state of the world with no pre-harvest agricultural water provisions is $55.3 million at a 3% discount rate and $54.0 million at a 7% discount rate. This regulatory alternative would be more costly for farms than the current rule in which testing as part of an assessment is not required for all farms. We are uncertain about the interaction between testing

and assessments for the purposes of quantifying benefits. We are not aware of, and comments did not provide, quantitative data or information that would allow us to estimate potential benefits of requiring that all farms test as part of an assessment.

Table 43: Costs of Requiring Pre-Harvest Agricultural Water Testing as Part of An Assessment, Relative to a Baseline of 2015 Pre-Harvest Agricultural Water Testing Provisions (Millions 2022$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$20.6	$21.6	$22.6
1	$15.3	$20.6	$26.3
2	$20.6	$25.7	$31.6
3	$36.0	$42.9	$50.7
4	$35.7	$42.9	$50.7
5	$35.9	$42.9	$50.9
6	$35.7	$42.9	$50.7
7	$36.1	$42.9	$50.3
8	$35.8	$42.9	$50.9
9	$35.8	$42.9	$50.0
Annualized, 3%	$30.2	$36.1	$42.7
Annualized, 7%	$29.5	$35.3	$41.7

J. Distributional Effects

We do not anticipate any significant changes in consumer behavior resulting from the rule. If farms conducting pre-harvest agricultural water assessments experience costs of the rule, however, farms not covered by the rule may benefit relative to farms that bear these costs.

There may be distributional effects of the rule if foodborne illnesses prevented by the rule do not impact all population groups uniformly. For example, adults age 65 and older, children younger than 5 years, pregnant women, and people whose immune systems are weakened may experience higher risks associated with foodborne illness (Ref. 12). Academic research suggests that there are relationships between foodborne illnesses (including their incidence and severity) and demographic and socioeconomic variables. Strassle et al. (2018) find that age and sex are

associated with specific food categories in outbreaks (Ref. 13). McCrickard et al. (2018) find that Black men have the highest incidence of severe shigellosis (Ref. 14). A report by the Consumer Federation of America explains that poverty puts consumers, particularly those under five years of age, at higher risk of infection from foodborne pathogens such as *Campylobacter*, *Salmonella*, and *Shigella* (Ref. 15). Similarly, Quinlan (2013) finds that those with lower socioeconomic status have persistently higher levels of foodborne infections caused by *Salmonella*, *Shigella* and *Campylobacter* (Ref. 16) and Hadler et al. (2020) find that children and older adults living in higher-poverty neighborhoods are at higher risk of acquiring *Salmonella* infection overall and with each of the 10 most common serotypes (Ref. 17). Individuals in population groups more affected by foodborne illness may experience larger benefits of the rule that those in less-affected groups.

K. International Effects

The rule does not impose different requirements on domestic and foreign firms, and we do not anticipate any significant effects on international trade.

L. Uncertainty and Sensitivity Analysis

We have identified sources of uncertainty about the expected costs and benefits of the rule. Throughout the main analysis, we have incorporated much of this uncertainty into our estimates through simulation of costs and benefits, where low, most likely, and high estimates of various factors are used as the parameters of distributions.

In our analysis of the baseline costs of the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule, we use estimates from subject matter experts of the number of untreated surface water sources and untreated ground water sources farms of various sizes would have needed to test under those provisions. We are

also uncertain about the percentage of farms that, having tested their water, would have needed to conduct corrective measures. When possible, we include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated baseline costs as measures of uncertainty.

In our analysis of costs of the pre-harvest agricultural water provisions specified in the rule, we use estimates from subject matter experts regarding the number of hours it would take a farm to conduct a pre-harvest agricultural water assessment as specified in the rule; we also use subject matter expert estimates of the percentage of farms that, having conducted a pre-harvest agricultural water assessment as described in the rule, would conduct a mitigation action. Subject matter experts have provided estimates of the percentage of farms that, having determined they need to conduct a mitigation, would conduct each type of mitigation. Additionally, subject matter experts have also provided estimated costs of each individual type of mitigation action, as well as estimates of the time burden of recordkeeping associated with the assessments. We incorporate the uncertainty surrounding these subject matter expert estimates in our estimation of costs through simulation by providing lower and upper bounds of the estimated costs of conducting pre-harvest agricultural water assessment and mitigation measures. When possible, we include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated costs of the rule as measures of uncertainty.

In our analysis of benefits, we acknowledge uncertainty about the fraction of agricultural water-related produce outbreaks caused by pre-harvest agricultural water specifically and the relative effectiveness at preventing outbreaks of the pre-harvest agricultural water assessment provisions and the pre-harvest agricultural water microbial quality criteria and testing requirements in the 2015 produce safety final rule. We use subject matter expert estimates as

parameters of distributions to simulate baseline benefits of this rule and of the pre-harvest agricultural water microbial quality criteria testing provisions in the 2015 produce safety final rule. In our estimation of benefits, we use simulation to estimate marginal benefits using distributions of these parameters and present 5th-percentile, mean, and 95th-percentile estimates. When possible, we include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated benefits of the rule as measures of uncertainty.

In our analysis, we incorporate estimates of illnesses prevented by the traceability rule to adjust the baseline foodborne illness dollar burden for non-sprout covered produce that also could be affected by this rule (see Appendix Table A5 for details). Our primary estimates in this document use the primary estimates of illness reduction by foodborne pathogen from the traceability RIA (Ref. 5); however, we also provide benefits below using the low and high estimates of illness reduction by foodborne pathogen from the traceability RIA. Appendix Tables A6 and A7 provide the adjusted baseline dollar burdens for the low and high estimated illness reduction of the traceability rule. In the main analysis, our primary estimate of the benefits of this rule relative to the primary baseline of 2015 pre-harvest water quality and microbial testing criteria is $10.3 million, annualized at 3% over 10 years. Our estimate of benefits of this rule using the low illness prevention estimate from the traceability RIA is $11.2 million, annualized at 3% over 10 years; our estimate of the benefits of this rule using the high illness prevention estimate from the traceability RIA is $9.0 million, annualized at 3% over 10 years.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some farms may incur costs that would exceed 3% of annual revenues, we cannot certify that the rule will not

have a significant impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

Most farms affected by this rule qualify as small businesses as defined by the U.S. Small Business Administration. Current standards from the U.S. SBA (Ref. 18) define farms engaged in crop production as small businesses if annual revenues are below $2,500,000. If a farm's average annual value of produce sold during the previous 3-year period is $25,000 or less, adjusted for inflation with a baseline year of 2011, then the farm is not subject to these requirements. However, certain farms with an average annual monetary value of produce sold during the previous 3-year period of more than $25,000 may be affected by this rule and qualify as small businesses as defined by the U.S. SBA.

Using this threshold, all small farms and very small farms as defined in this analysis are considered small businesses. Additionally, some fraction of large farms (revenue greater than $500,000) will also qualify as small businesses. This means that 9,911 affected very small farms and 2,057 small farms will qualify as small businesses; as a result, at least 11,969 of the 17,360 (69%) farms that would conduct pre-harvest agricultural water assessments qualify as small businesses.

We use the survey conducted by ERS (Ref. 2) to calculate that approximately 38.3% of covered farms with revenue greater than $500,000 have revenue less than $1,000,000. If 38.3% of the 5,392 large covered farms are small businesses, 2,065 of these large farms qualify as small businesses as defined by U.S. SBA. In this case, 14,034 of the 17,360 (81%) farms that will conduct pre-harvest agricultural water assessments will qualify as small businesses.

B. Description of the Potential Impacts of the Rule on Small Entities

Based on our analysis, our primary estimate is that the average very small farm required to conduct the pre-harvest agricultural water assessments described in the rule would experience annualized costs relative to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule of $679 at a 3 percent discount rate and $668 at a 7 percent discount rate; our primary estimate is that the average small farm required to conduct pre-harvest agricultural water assessments would experience annualized costs relative to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule of $1,036 at a 3 percent discount rate and $1,028 at a 3 percent discount rate.

Relative to an alternate baseline of no pre-harvest agricultural water provisions, our primary estimate is that the average very small farm required to conduct the pre-harvest agricultural water assessments described in the rule would experience annualized costs of $1,251 at a 3 percent discount rate and $1,231 at a 7 percent discount rate; our primary estimate is that the average small farm required to conduct pre-harvest agricultural water assessments would experience annualized costs of $2,052 at a 3 percent discount rate and $2,053 at a 7 percent discount rate.

However, these averages are taken across all farms that would conduct assessments under the rule. Our primary estimate for the annualized cost of the rule relative to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule for the subset of very small farms that conduct at least one mitigation over a 10-year period under the rule is $1,090 at a 3 percent discount rate and $1,071 at a 7 percent discount

rate; our primary estimate for the annualized cost of the rule relative to a state of the world with no pre-harvest provisions for the subset of very small farms that conduct any type of mitigation under the rule is $1,417 at a 3 percent discount rate and $1,396 at a 7 percent discount rate.

The smallest average annual revenue a farm in the "very small farm" category could have is $25,000; if a farm's average annual value of produce sold during the previous 3-year period is $25,000 or less, adjusted for inflation with a baseline year of 2011, then the farm is not subject to these requirements. For a farm at the lower revenue boundary for coverage that conducts at least one mitigation action over the 10-year period, the annualized cost of the rule relative to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule could represent at least 4.4% of annual revenue; for this farm, the annualized cost of the rule relative to a state of the world with no pre-harvest agricultural water provisions could represent at least 5.7% of annual revenue.

Because it is possible that some percentage of very small farms would experience impacts of at least 3% of annual revenue, we cannot certify that the rule will not have a significant impact on a substantial number of small entities.

C. Alternatives to Minimize the Burden on Small Entities

We note the rule provides staggered compliance dates based on farm size, allowing affected small entities additional time to comply with the rule. The regulatory alternative in which all pre-harvest agricultural water provisions are repealed (Option 1) would remove the costs to very small and small farms, which would lessen the burden on these small entities. This alternative would also result in forgone benefits of averted foodborne illnesses.

IV. References

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Appendix A

To establish a quantitative baseline, we draw on the dollar burden of foodborne illnesses estimated in the 2015 produce safety final rule FRIA (Ref. 8). For non-sprout covered produce, the estimated annual dollar burden of illnesses in the 2015 FRIA is approximately $2,045 million in 2015 dollars. The 2015 produce safety final rule estimate primarily draws on data from the 10-year span of 2003 to 2012; we update this estimate with more recent data from several sources, including:

- FDA outbreak data on covered produce from the 10-year span of 2009 to 2020 (Ref. 19);
- CDC National Outbreak Reporting System (NORS) data on all foods from the 10-year span of 2009 to 2020 (Ref. 20); and
- expected dollar loss per case for foodborne illness agents from the traceability rule FRIA (Ref. 5).

Table A1 presents updated counts of reported outbreaks, illnesses, hospitalizations, and deaths from covered non-sprout produce raw agricultural commodities (RACs) from 2009 to 2020. This table is analogous to Table 5 in the 2015 FRIA for non-sprout produce; we omit outbreak data for sprouts.

Table A1: FDA Outbreak Data, 2009-2020.

Outbreak Data Attributed to Produce RACs Other Than Sprouts					
Commodity	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Berries	*Cyclospora cayatenensis*	1	8	0	0
Herb	*Cyclospora cayatenensis*	8	1,183	13	0
Mixed	*Cyclospora cayatenensis*	2	631	39	0
Leafy greens	*Cyclospora cayatenensis*	2	737	38	0

Nut*	*E. coli O157:H7*	1*	8*	3*	0*
Cucumber	*E. coli O157:H7*	1	8	1	0
Leafy greens	*E. coli O157:H7*	9	350	165	0
Green cabbage	*E. coli O111*	1	18	4	0
Leafy greens	*E. coli O111*	1	10	3	0
Cantaloupe	*Listeria monocytogenes*	1	147	143	33
Stone fruit	*Listeria monocytogenes*	1	1	1	0
Avocado	*Listeria monocytogenes*	1	10	9	0
Leafy greens	*Listeria monocytogenes*	1	9	9	1
Mushrooms	*Listeria monocytogenes*	1	36	31	4
Berries	*Salmonella*	3	116	21	0
Cucumber	*Salmonella*	8	1,224	250	6
Melon	*Salmonella*	2	201	49	1
Tomato	*Salmonella*	9	511	90	0
Produce	*Salmonella*	3	533	61	0
Cantaloupe	*Salmonella*	6	574	189	3
Papaya	*Salmonella*	9	583	166	2
Mango	*Salmonella*	3	214	62	0
Leafy greens	*Salmonella*	1	15	1	0
Nut	*Salmonella*	3	49	7	0
Grapes	*Salmonella*	1	27	10	0
Mixed	*Salmonella*	2	214	47	0
Hot pepper	*Salmonella*	1	32	8	0
Yellow onion	*Salmonella*	3	1,310	210	0
Mushrooms	*Salmonella*	1	55	6	0
Peach	*Salmonella*	1	101	28	0
Berries	*Hepatitis A virus*	2	51	29	0

RAC Total		**89**	**8,966**	**1,693**	**50**

Note: The *E. coli* O157:H7 nut outbreak is associated with hazelnuts, which are not covered by the final 2015 produce safety final rule. We exclude this outbreak from further calculations.

To estimate the annual number of illnesses attributable to covered produce RACs, we apply FDA and CDC outbreak data to the estimated number of illnesses estimated by Scallan et al. (Ref. 21). For each observed foodborne illness agent, we divide the number of FDA-regulated covered produce illnesses by the total number of outbreaks for all foods (i.e., CDC outbreak data) to yield the estimated foodborne illnesses attributable to covered produce RACs. The resulting percentage is multiplied by the estimated incidence of each foodborne illness agent estimated in Scallan et al. to yield the estimate annual illnesses attributable to covered produce RACs (Ref. 15). As noted in the 2015 FRIA (Ref. 8), this corrects for potential under-reporting and under-identification of foodborne illnesses in CDC data.

Table A2 presents the updated estimated number of illnesses from covered non-sprout produce RACs from 2009 to 2020. This table is analogous to Table 6 in the 2015 FRIA for non-sprout produce.

Table A2: Estimated Number of Illnesses, 2009-2020.

Estimated Number of Illnesses Attributable to Produce RACs Other Than Sprouts					
Agent	**FDA RAC (2009-2020)**	**Identified Cases (2009-2020)**	**Percentage Attributable to RACs**	**Estimated Annual Foodborne Illnesses (Scallan)**	**Estimated Annual Illnesses Attributable to RACs**
Salmonella	6,455	41,227	15.66%	1,072,450	167,916
Cyclospora cayatenensis	2,559	3,871	66.11%	13,906	9,193

Listeria monocytogenes	203	818	24.82%	1,680	417
E. coli O157:H7	366	3,229	11.33%	69,972	7,931
E. coli O111	28	83	33.73%	124,966	42,157
Hepatitis A virus	51	909	5.61%	1,665	93
Total Identified RAC	**9,611**	**50,137**	**19.17%**	**1,284,639**	**246,259**

To estimate the total dollar burden of illnesses from covered produce RACs, we first multiply the estimated number of annual illnesses attributable to covered produce by the estimated percent of produce acres associated with preventable illness (here and in the 2015 FRIA, approximately 94.2 percent). This yields an estimate of the number of preventable illnesses attributable to covered produce. We multiply this number by the expected dollar loss per case for each foodborne illness agent; each estimated cost per case is drawn from the central cost estimates used in the traceability rule FRIA (Ref. 5). This yields the estimated dollar burden of all preventable foodborne illnesses associated with each agent.

Table A3 presents the estimated dollar burden attributable to covered produce RACs in 2019 dollars. This table is analogous to Table 7 in the 2015 FRIA. We estimate that the annual total covered dollar burden is approximately $2,354.1 million in 2019 dollars and use this estimate as a baseline monetized annual burden of the preventable illnesses linked to produce other than sprouts.

Table A3: Estimated Dollar Burden of Illnesses, 2009-2020.

Estimated Dollar Burden Attributable to Produce RACs Other Than Sprouts					
Agent	**Est. Annual Illnesses Attributable to RACs**	**% Produce Acres Associated with Preventable Illness**	**Est. Preventable Attributable Illnesses**	**Expected Dollar Loss per Case FTR (2019$)**	**Covered Dollar Burden (millions)**
Salmonella	167,916	94.20%	158,177	$6,563	**$1,038**
Cyclospora cayatenensis	9,193	94.20%	8,660	$4,022	**$35**
Listeria monocytogenes	417	94.20%	393	$1,797,753	**$706**
E. coli, STECO157	7,931	94.20%	7,471	$9,376	**$70**
E. coli, non O157	42,157	94.20%	39,712	$2,266	**$90**
Hepatitis A virus	93	94.20%	88	$52,854	**$5**
Total RAC Identified	194,768	94.20%	231,976		**$1,944**
Total RAC Unidentified			927,902	$442	**$410**
Total RAC			1,159,878		**$2,354.1**

This estimated baseline may include some illnesses that will be prevented by the Agency's *Requirements for Additional Traceability Records for Certain Foods* final rule (Ref. 5). The estimated dollar burden of illnesses presented in Table A3 may therefore overstate the dollar burden of illness in this analysis. We adjust the number of illnesses by subtracting the estimated number of illnesses that are used in this analysis and the analysis for the traceability rule. Table A4 presents the number of illnesses that we subtract from the estimated number of FDA RAC illnesses reported in Table A2.

Table A4: Illnesses Used in Both the Agricultural Water Rule and the Traceability Rule Analyses

Agent	FDA RAC (2009-2020)	Illnesses Used in Both Analyses	Adjusted Number of Illnesses
Salmonella	6,455	3,484	2,971
Cyclospora cayatenensis	2,559	1,490	1,069
Listeria monocytogenes	203	147	56
E. coli O157:H7	366	8	358
E. coli O111	28	-	28
Hepatitis A virus	51	-	51
Total Identified RAC	**9,611**	**5,129**	**4,533**

We use the adjusted number of illnesses to estimate an adjusted covered dollar burden of illness, representing the burden of illness that would be prevented by this rule. The difference between the initial estimate of the covered dollar burden and the adjusted dollar burden represents the number of illnesses covered by the traceability rule. We estimate that a proportion of illnesses covered by the traceability rule will be prevented by that rule and that the remainder will not be prevented. For each pathogen, we estimate the dollar burden of the proportion of illnesses not prevented by the traceability rule and add these illnesses to the adjusted covered dollar burden of this rule. We estimate that the total covered dollar burden of illnesses is approximately $1,711.5 million in 2019 dollars. We update these dollar burdens to 2022 dollars in the main body of the document. Table A5 presents the adjusted estimated dollar burden of illnesses used in the baseline of this analysis.

Table A5: Adjusted Estimated Dollar Burden of Illnesses, 2009-2020.

Estimated Dollar Burden Attributable to Produce RACs Other Than Sprouts						
Agent	**Covered Dollar Burden (millions)**	**Adjusted Covered Dollar Burden (millions)**	**Dollar Burden Covered by Traceability**	**Percent of Illnesses Prevented by Traceability**	**Dollar Burden Not Prevented by Traceability**	**Adjusted Dollar Burden of Illness Covered by This Rule**
Salmonella	$1,038	$478	$560	24%	$426	$904
Cyclospora cayatenensis	$35	$15	$20	13%	$18	$32
Listeria monocytogenes	$706	$195	$511	56%	$225	$420
E. coli, STEC O157	$70	$69	$2	11%	$1	$70
E. coli, non O157	$90	$90	-	-	-	$90
Hepatitis A virus	$5	$5	-	16%	-	$5
Total RAC Identified	$1,944	$850	$1,093		$670	$1,520
Total RAC Unidentified	$410	$191	$219			$191
Total RAC	**$2,354**	$1,042	$1,312			**$1,711**

Table A6: Adjusted Estimated Dollar Burden of Illnesses, Low Traceability Effectiveness, 2009-2020.

Estimated Dollar Burden Attributable to Produce RACs Other Than Sprouts						
Agent	**Covered Dollar Burden (millions)**	**Adjusted Covered Dollar Burden (millions)**	**Dollar Burden Covered by Traceability**	**Percent of Illnesses Prevented by Traceability (Low)**	**Dollar Burden Not Prevented by Traceability (Low)**	**Adjusted Dollar Burden of Illness Covered by This Rule (Low)**
Salmonella	$1,038	$478	$560	2%	$549	$1,027
Cyclospora cayatenensis	$35	$15	$20	4%	$19	$34
Listeria monocytogenes	$706	$195	$511	50%	$256	$450
E. coli, STECO157	$70	$69	$2	3%	$1	$70
E. coli, non O157	$90	$90	-	-	-	$90
Hepatitis A virus	$5	$5	-	0%	-	$5
Total RAC Identified	$1,944	$850	$1,093		$826	$1,671
Total RAC Unidentified	$410	$191	$219			$191
Total RAC	**$2,354**	$1,042	$1,312			**$1,863**

Table A7: Adjusted Estimated Dollar Burden of Illnesses, High Traceability Effectiveness, 2009-2020.

Estimated Dollar Burden Attributable to Produce RACs Other Than Sprouts						
Agent	**Covered Dollar Burden (millions)**	**Adjusted Covered Dollar Burden (millions)**	**Dollar Burden Covered by Traceability**	**Percent of Illnesses Prevented by Traceability (High)**	**Dollar Burden Not Prevented by Traceability (High)**	**Adjusted Dollar Burden of Illness Covered by This Rule (High)**
Salmonella	$1,038	$478	$560	55%	$252	$730
Cyclospora cayatenensis	$35	$15	$20	23%	$16	$30
Listeria monocytogenes	$706	$195	$511	63%	$189	$384
E. coli, STECO157	$70	$69	$2	17%	$1	$70
E. coli, non O157	$90	$90	-	34%	-	$90
Hepatitis A virus	$5	$5	-	-	-	$5
Total RAC Identified	$1,944	$850	$1,093		$458	$1,304
Total RAC Unidentified	$410	$191	$219			$191
Total RAC	**$2,354**	$1,042	$1,312			**$1,495**