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

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule has been designated a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that annualized costs will not be larger than 3 percent of revenue for any covered farms, we anticipate that the proposed rule will not have a significant economic impact on a substantial number of small entities. If the proposed rule is finalized, we may, if appropriate, certify that the final rule does not have a significant impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current

(2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

We estimate costs of the proposed 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 is represented by the costs and benefits of the subpart E pre-harvest agricultural water provisions in the 2015 Produce Safety Final Rule, which would take effect absent the proposed 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 the proposed rule relative to an alternative baseline represented by a state of the world in which there are no pre-harvest agricultural water provisions. In both of these 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 2015 Produce Safety Final Rule absent the proposed rule, and we use the term "baseline costs" to represent the estimated costs of the 2015 Produce Safety Final Rule absent the proposed rule. Our primary estimates of annualized costs are approximately $11.3 million at a 3 percent discount rate and approximately $11.2 million at a 7 percent discount rate over 10 years.

[1] Because sprouts present a unique safety risk, the produce safety regulation establishes sprout-specific requirements on multiple topics, including agricultural water. Sprouts are not subject to the Subpart E compliance date extension that applies to other covered produce.

We estimate benefits of the proposed rule resulting from the dollar burden of foodborne illnesses averted, and we estimate forgone benefits of the proposed rule resulting from foodborne illnesses not averted due to the current pre-harvest agricultural water testing provisions. Our primary estimates of annualized benefits are approximately $9.9 million at a 3 percent discount rate and approximately $9.6 million at a 7 percent discount rate over 10 years. We discuss qualitative benefits of the proposed rule stemming from increased flexibility for covered farms to comprehensively evaluate their agricultural water systems. These changes to pre-harvest agricultural water provisions are being proposed, in part, to address practical implementation challenges of the current pre-harvest agricultural water testing requirements.

Table 1: Summary of Benefits, Costs and Distributional Effects of Proposed Rule (in millions)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$9.6	-$28.0	$48.9	2019	7%	10 years	Benefits are illnesses averted
		$9.9	-$28.8	$50.2	2019	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Increased flexibility in comprehensively evaluating potential hazards associated with pre-harvest agricultural water					10 years	
Costs	Annualized Monetized $millions/year	$11.2	$4.5	$17.4	2019	7%	10 years	
		$11.3	$4.8	$17.4	2019	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	From/ To	From:			To:			
	Other Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

II. Preliminary 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 (produce safety 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 §§112.41-112.50) 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
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 proposed 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 proposed 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 74353**) 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. Current agricultural water provisions (Subpart E of the 2015 Produce Safety Final Rule; §§112.41-112.50), although delayed, require, 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 must conduct an initial survey consisting of 20 tests (collected over 2-4 years) and update the microbial water quality profile with 5 new tests per year thereafter; for each untreated ground water source, a farm must conduct an initial survey consisting of 4 tests (taken during the growing season or over a period of 1 year) and update the water quality profile with 1 new test per year thereafter (§112.46(b)).

Pre-harvest agricultural water directly applied to covered produce must meet microbial quality criteria described in existing §112.44(b):

- 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
- 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).

The 2015 Produce Safety Final Rule initially established compliance dates for certain 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)) relative to the primary compliance date in the 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 Extension") 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. Existing compliance dates (Ref. 1) are:

- January 26, 2024 for very small farms.
- January 26, 2023 for small farms;
- January 26, 2022 for all other (large) farms;

As a result, the compliance dates for subpart E for covered produce other than sprouts have not yet passed.

B. Need for Federal Regulatory Action

The need for this proposed rule stems from stakeholder feedback on the pre-harvest agricultural water requirements in the 2015 produce safety regulation. 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. We are proposing to replace the microbial criteria and 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 be more feasible to implement across the wide variety of agricultural water systems, uses, and practices,

while also being adaptable to future advancements in agricultural water quality science, and achieving improved public health protections.

C. Purpose of the Proposed Rule

The proposed rule, if finalized, will replace the current water testing provisions for pre-harvest agricultural water used in direct application on non-sprout covered produce with provisions for an annual pre-harvest agricultural water assessment 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 would be required to implement mitigation measures no later than in the same growing season in which the assessment was conducted.

D. Baseline Conditions and Assumptions

Due to imperfect information about current and future pre-harvest agricultural water assessment behavior, we must make some assumptions about the baseline conditions and the behavior of entities conducting pre-harvest agricultural water

assessments to estimate the effects of the proposed rule. We request comment on these assumptions.

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 proposed regulatory text, covered farms must conduct pre-harvest agricultural water assessments 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. We request comment on this assumption.

(f) For the purposes of this analysis, we assume 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.

(g) We estimate costs and cost savings in 2019 dollars.

2. Baseline Conditions

Our preliminary estimates reflect an assumption that, without this proposed rule, farms covered by agricultural water provisions in the 2015 Produce Safety Final Rule, applicable to non-sprout covered produce, will comply with the current pre-harvest agricultural water testing provisions by the date specified in the 2019 compliance extension (84 FR 9706). For very small farms, this compliance date is January 26, 2024; for small farms, this compliance date is January 26, 2023; for all other farms, this compliance date is January 26, 2022 (Ref. 1). For the purposes of this analysis, the primary baseline is represented by the costs and benefits of the pre-harvest agricultural water provisions in the 2015 Produce Safety Final Rule, which would take effect absent the proposed rule. However, throughout the analysis, we conduct intermediate calculations of costs and benefits of both the 2015 Produce Safety Final Rule and the proposed rule relative to an alternative baseline represented by a state of the world in which there are no pre-harvest agricultural water provisions. In this document, we use the term "baseline benefits" to represent the estimated benefits of the 2015 Produce Safety Final Rule absent the proposed rule, and we use the term "baseline costs" to represent the estimated costs of the 2015 Produce Safety Final Rule absent the proposed rule.

As noted previously, stakeholders have expressed concern about the complexity and practical implementation challenges of pre-harvest agricultural water testing requirements (for covered produce other than sprouts) included in the 2015 Produce Safety Final Rule. While this analysis assumes that farms will comply with the 2015

Produce Safety Final Rule, we note that if some farms were unable to comply with current testing provisions, the benefits and costs of the proposed rule in this analysis would be underestimated. We request comment that would facilitate estimation of potential future non-compliance with the pre-harvest agricultural water testing provisions for non-sprout covered produce in the 2015 Produce Safety Final Rule if those provisions were to take effect.

a. Number of Affected Farms

To determine the number of farms that must read the proposed rule, we use estimates of the number of farms covered by the 2015 Produce Safety Final Rule from the 2015 FRIA (Ref. 2), which accounts for farms not covered by the rule and farms or produce eligible for exemption. This results in approximately 35,019 farms that must read the rule, including 22,781 very small farms, 3,956 small farms, and 8,292 large farms. While not all covered farms would need to conduct pre-harvest agricultural water assessments under the proposed provisions, we assume covered farms will read the rule to determine whether they need to conduct the assessments.

In a survey of produce growers conducted by researchers at ERS before the implementation of FSMA rules, USDA estimated that 45 percent of small growers covered by the 2015 Produce Safety Final Rule use non-public pre-harvest agricultural water that contacts produce (Ref. 3), where USDA defines "small" as growers with $25,000 to $500,000 in annual revenue. For the purposes of 2015 Produce Safety Final Rule requirements, 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 2015 Produce Safety Final Rule 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 proposed 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 8,218 very small farms, 1,613 small farms, and 4,283 large farms would be required to conduct pre-harvest agricultural water assessments under the proposed rule; as a result, a total of 14,114 farms would conduct pre-harvest agricultural water risk assessments. Table 2 presents the number of affected farms.

Table 2: Number of Affected Farms

	Very small	**Small**	**Large**	**Total**
Number of covered farms	22,781	3,956	8,292	35,029
Number of covered irrigated farms	18,262	3,585	7,916	29,763

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 risk assessments under proposed rule	8,218	1,613	4,283	14,114

*Percentage of farms using non-public pre-harvest water from Ref. 3
**Number of covered farms and covered irrigated farms from Ref. 2

b. Benefits and Costs

i. Baseline Benefits

As described in the 2019 agricultural water compliance date extension FRIA, the current pre-harvest agricultural water testing provisions in Subpart E of the 2015 Produce Safety Final Rule for covered produce other than sprouts would take effect in the absence of the compliance date extension. Therefore, baseline benefits for the current analysis would be represented by the dollar burden of foodborne illnesses averted under the current testing provisions. First, we estimate the dollar burden of foodborne illnesses attributable to non-sprout covered produce; using updated outbreak data from 2009-2018, we estimate that the annual dollar burden of foodborne illnesses attributable to non-sprout covered produce is $1,856.5 million (see Appendix A for a more detailed discussion of these calculations). The estimated burden of foodborne illnesses is drawn from Minor et al. (Ref. 14) 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. 5). Minor et al. (Ref. 14) calculate QALYs (quality-adjusted life-years) of functional disabilities and symptoms in prior studies and match these conditions to pathogens.

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. 2); 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 $569.8 million. However, both the provisions in the 2015 Produce Safety Final Rule that we are proposing to replace, and the provisions being proposed, 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. 6), 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 2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$172.8	$232.7	$296.1
1	$172.7	$232.7	$296.0

2	$172.8	$232.7	$296.2
3	$172.8	$232.7	$296.2
4	$172.7	$232.7	$296.1
5	$172.8	$232.7	$296.0
6	$172.9	$232.7	$296.1
7	$172.8	$232.7	$296.1
8	$172.8	$232.7	$296.1
9	$172.7	$232.7	$296.2
Annualized, 3%	$172.9	$232.7	$296.2
Annualized, 7%	$172.9	$232.7	$296.2

The baseline, absent the proposed rule, would be the current pre-harvest agricultural water testing provisions taking effect. 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. 6), we provided the current pre-harvest agricultural water testing provisions 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 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 current pre-harvest agricultural water

[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).

testing 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. 2). We estimate that annualized baseline benefits are approximately $72.6 million in 2019 dollars at a 3 percent discount rate. At a 7 percent discount rate, estimated annual baseline benefits are approximately $70.6 million. We use these estimated benefits of the current pre-harvest agricultural water testing provisions as the baseline for the proposed 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 Current Pre-harvest Agricultural Water Testing Provisions, Relative to No Provisions, (millions 2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$41.9	$68.2	$101.1
2	$45.9	$74.5	$110.2
3	$52.4	$85.3	$126.4
4	$52.8	$85.3	$125.6
5	$52.9	$85.3	$125.4
6	$52.5	$85.3	$126.5
7	$52.7	$85.3	$125.3
8	$52.8	$85.3	$126.5
9	$52.5	$85.3	$126.0
Annualized, 3%	$44.8	$72.6	$107.2
Annualized, 7%	$43.5	$70.6	$104.3

ii. Baseline Costs

As described in the 2019 agricultural water compliance date extension FRIA, the current pre-harvest agricultural water testing provisions in Subpart E of the 2015 Produce

Safety Final Rule for covered produce other than sprouts would take effect in the absence of the compliance date extension. Therefore, baseline costs for the current analysis would be represented by the costs associated with the current pre-harvest agricultural water testing provisions. 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

Current agricultural water provisions (Subpart E of the 2015 Produce Safety Final Rule; §§112.41-112.50) require, 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 must conduct an initial survey consisting of 20 tests (collected over 2-4 years) and update the microbial water quality profile with 5 new tests per year thereafter; for each untreated ground water source, a farm must conduct an initial survey consisting of 4 tests (taken during the growing season or over a period of 1 year) and update the water quality profile with 1 new test per year thereafter (§112.46(b)).

Table 5 presents estimates of the number of farms that would have to conduct testing of untreated surface water sources under the current pre-harvest agricultural water testing requirements. As discussed in the baseline number of affected farms section, we estimate that there are 18,262 covered irrigated very small farms, 3,585 covered irrigated small farms, and 7,916 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. 3). 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 2,622 very small farms, 515 small farms, and 1,366 large farms must perform the required baseline survey for untreated surface water sources. The 2015 FRIA estimates that the cost of a water sample, including supplies and shipping, is $110 (Ref. 2). We update this number to 2019 dollars and estimate that the cost of a water sample is $121. We request comment on the cost of conducting a water test as described in the current pre-harvest agricultural water testing provisions.

Table 5: Surface Water Testing Costs of Current Requirements (2019$)

Cost of testing untreated surface water				
	Very small	**Small**	**Large**	**Total**
Number of covered irrigated farms	18,262	3,585	7,916	29,763
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	2,622	515	1,366	4,502
Cost of collecting sample	$121	$121	$121	
Baseline testing frequency	5	5	5	
Annual testing frequency	5	5	5	
Baseline testing cost per source	$605	$605	$605	
Annual testing cost per source	$605	$605	$605	

Many farms may have more than one source of surface water that they need to test under the pre-harvest agricultural water requirements of the 2015 Produce Safety Final Rule. In our survey of subject matter experts (Ref. 6), we asked how many sources of surface water farms of the specified sizes would need to test under the current pre-

harvest agricultural water 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 current pre-harvest agricultural water testing provisions; 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 the current 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 $6.6 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $6.4 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 to Test Under the Current Pre-harvest Agricultural Water Testing Provisions

	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, Current Pre-harvest Agricultural Water Testing Provisions (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$2,046,746	$4,821,319	$8,304,798
2	$2,833,574	$5,651,584	$9,146,145
3	$5,135,008	$8,132,272	$11,750,810
4	$5,135,008	$8,132,272	$11,750,810
5	$5,135,008	$8,132,272	$11,750,810

6	$5,135,008	$8,132,272	$11,750,810
7	$5,135,008	$8,132,272	$11,750,810
8	$5,135,008	$8,132,272	$11,750,810
9	$5,135,008	$8,132,272	$11,750,810
Annualized, 3%	$3,962,402	$6,574,691	$9,753,157
Annualized, 7%	$3,800,200	$6,350,111	$9,455,951

Table 8 presents estimates of the number of farms that would have to conduct testing of untreated ground water sources under the current pre-harvest agricultural water testing requirements. Of farms that use untreated surface or ground water that contacts produce, USDA estimates that 68.1% use ground water (Ref. 3). We multiply the number of covered irrigated farms by these percentages to estimate that 5,596 very small farms, 1,099 small farms, and 2,916 large farms must perform the required baseline survey for untreated ground water sources. The 2015 FRIA estimates that the cost of a water sample, including supplies and shipping, is $110 (Ref. 2). We update this number to 2019 dollars and estimate that the cost of a water sample is $121. We request comment on the cost of conducting a water test as described in the current pre-harvest agricultural water testing provisions of the 2015 Produce Safety Final Rule.

Table 8: Ground Water Testing Costs of Current Requirements (2019$)

Cost of testing untreated ground water				
	Very Small	**Small**	**Large**	**Total**
Number of covered irrigated farms	18,262	3,585	7,916	29,763
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	5,596	1,099	2,916	9,611
Cost of collecting sample	$121	$121	$121	
Baseline testing frequency	4	4	4	
Annual testing frequency	1	1	1	
Baseline testing cost per source	$484	$484	$484	

Annual testing cost per source	$121	$121	$121	

Many farms may have more than one source of ground water that they need 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 the current pre-harvest agricultural water 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 current pre-harvest agricultural water testing provisions; 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 the current 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 $4.1 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $4.1 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 to Test Under the Current Pre-harvest Agricultural Water Testing Provisions

	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, Current Pre-harvest Agricultural Water Testing Provisions (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$3,495,508	$8,234,028	$14,183,241
2	$2,182,551	$3,742,330	$5,512,651
3	$4,844,889	$6,889,705	$9,422,439
4	$2,275,428	$3,582,023	$5,140,242
5	$2,275,428	$3,582,023	$5,140,242
6	$2,275,428	$3,582,023	$5,140,242
7	$2,275,428	$3,582,023	$5,140,242
8	$2,275,428	$3,582,023	$5,140,242
9	$2,275,428	$3,582,023	$5,140,242
Annualized, 3%	$2,408,933	$4,050,102	$6,040,438
Annualized, 7%	$2,392,678	$4,061,811	$6,089,246

ii. Corrective Measures

Current pre-harvest agricultural water provisions require, in relevant part, that water meet the requirements of §112.44, which state:

(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).

If water does not meet these criteria, §112.45(b) of the 2015 Produce Safety Final Rule requires that as soon as practicable and no later than the following year, farms must discontinue that use of agricultural water, unless they implement certain specified corrective measures. We are uncertain about the percentage of farms that, having conducted the prescribed water testing, would need to implement corrective measures as a result of failing to meet the pre-harvest microbial water quality criteria. The 2015 FRIA (Ref. 2) 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. 13) – 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 conduct water treatment. We request comment on the fraction of farms that, having conducted water testing as described in the current pre-harvest agricultural water testing provisions, would conduct treatment, including both farms that do and do not meet the water quality criteria as defined by the 2015 Produce Safety Final Rule.

USDA estimates that "small" covered farms ($25,000-$500,000 revenue) that conducted water treatment spent $1,189 annually. 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), "large" (annual treatment cost of $1,596), and "very large" (annual treatment cost of $22,864) 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 $5,796. Table 11 presents our estimates of the costs of treating surface water under the current provisions by year; Table 12 presents our estimates of the costs of treating ground water under the current 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 is $0.3 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $0.3 million annualized. Our primary estimate of the cost of treating ground water is $0.7 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $0.6 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, Current Pre-Harvest Agricultural Water Provisions (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$57,623	$258,662	$514,949
2	$77,429	$278,650	$535,263
3	$155,034	$380,471	$646,533
4	$156,341	$380,471	$649,062
5	$158,893	$380,471	$651,569
6	$157,980	$380,471	$655,442
7	$153,291	$380,471	$654,898

8	$154,048	$380,471	$657,716
9	$155,853	$380,471	$653,824
Annualized, 3%	$118,912	$312,784	$550,484
Annualized, 7%	$113,870	$302,863	$534,819

Table 12: Total Cost of Treating Ground Water, Current Pre-harvest Agricultural Water Provisions (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$122,989	$552,190	$1,099,258
2	$162,898	$594,861	$1,142,076
3	$332,906	$812,229	$1,394,455
4	$325,729	$812,229	$1,387,619
5	$336,528	$812,229	$1,395,648
6	$338,175	$812,229	$1,387,041
7	$332,797	$812,229	$1,388,230
8	$334,060	$812,229	$1,392,763
9	$333,648	$812,229	$1,392,712
Annualized, 3%	$253,871	$667,730	$1,173,887
Annualized, 7%	$242,961	$646,550	$1,140,851

iii. Recordkeeping

Current recordkeeping provisions (§112.50) that apply for pre-harvest water require 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. For very small and small farms, we use the fully-loaded BLS hourly cost of labor of $77.26 for "Farmers, Ranchers, and Other Agricultural Managers" (Ref. 4). For large farms, we use the fully-loaded BLS hourly cost of labor of $50.50 for "First-Line Supervisors of Farming, Fishing, and Forestry Workers" (Ref. 7). Following HHS guidelines, we double this to yield the fully-loaded cost of labor of $50.50. Table 13 presents estimated costs of recordkeeping under the current provisions

by year. Our primary estimate of the cost of recordkeeping is $1.9 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is also $1.9 million annualized.

Table 13: Total Cost of Recordkeeping, Current Pre-harvest Testing Provisions (2019$)

Years after publication	Cost
0	$0
1	$934,066
2	$1,030,547
3	$3,518,106
4	$2,220,975
5	$2,220,975
6	$2,220,975
7	$2,220,975
8	$2,220,975
9	$2,220,975
Annualized, 3%	$1,888,383
Annualized, 7%	$1,891,703

iv. Total Costs of the Current Pre-Harvest Requirements

Table 14 presents our low, primary, and high estimates of the total cost of the current pre-harvest agricultural water provisions by year. Our primary estimate of the total cost of current pre-harvest agricultural water provisions is $13.8 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $14.0 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 Current Pre-harvest Agricultural Water Provisions (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$7,260,322	$14,800,265	$24,207,361
2	$7,104,088	$11,297,972	$16,440,193
3	$15,097,155	$19,732,783	$25,187,941
4	$10,853,283	$15,127,970	$20,322,748
5	$10,882,646	$15,127,970	$20,307,736

6	$10,868,164	$15,127,970	$20,252,142
7	$10,865,136	$15,127,970	$20,261,609
8	$10,860,639	$15,127,970	$20,284,154
9	$10,894,830	$15,127,970	$20,322,003
Annualized, 3%	$9,270,472	$13,841,849	$19,067,123
Annualized, 7%	$8,996,187	$14,048,331	$19,434,455

E. Benefits of the Proposed Rule

In the baseline section, we present our estimates of the simulated stream of benefits of the current pre-harvest agricultural water testing provisions, which we treat as the baseline for the proposed rule.

The gained or forgone benefits of the proposed rule would stem only from the pre-harvest agricultural water provisions for non-sprout covered produce. The provisions for agricultural water assessments in the proposed 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 current pre-harvest requirements 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 proposed provisions would require farms to holistically consider potential hazards and time-varying conditions that may not be reflected when testing pre-harvest water under the current provisions. 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 proposed provisions may be less effective at preventing outbreaks if farmers fail to identify hazards during the water risk assessment or fail to properly mitigate identified hazards.

Because we acknowledge uncertainty about the effectiveness of pre-harvest agricultural water testing 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. 6), we provided the proposed pre-harvest agricultural water assessment provisions and asked them to estimate the percentage of illnesses that would occur under the proposed 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 proposed pre-harvest water assessment provisions; this method incorporates the uncertainty about the effectiveness of the proposed provisions. Table 15 presents our low, primary, and high estimates of the benefits (dollar burden of illnesses avoided) of the proposed pre-harvest agricultural water testing provisions relative to no pre-harvest agricultural water provisions, and Table 16 presents our low, primary, and high estimates of the benefits (dollar burden of illnesses avoided) of the proposed pre-harvest agricultural water assessment provisions relative to the baseline of the current pre-harvest agricultural water testing 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. 2). 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 current pre-harvest agricultural water testing provisions are approximately $9.9 million in 2019 dollars at a 3 percent discount rate. At a 7 percent discount rate, estimated annual baseline benefits are approximately $9.6 million.

Table 15: Estimated Benefits of Proposed Pre-harvest Agricultural Water Assessment Provisions, Relative to No Provisions (millions 2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$45.8	$77.6	$116.4
2	$50.1	$84.7	$127.3
3	$57.3	$96.9	$145.7
4	$57.1	$96.9	$146.3
5	$57.2	$96.9	$145.7
6	$57.1	$96.9	$146.6
7	$57.5	$96.9	$145.4
8	$57.8	$96.9	$145.5
9	$57.5	$96.9	$145.9
Annualized, 3%	$48.8	$82.4	$124.0
Annualized, 7%	$47.4	$80.2	$120.6

Table 16: Estimated Benefits of Proposed Pre-harvest Agricultural Water Assessment Provisions, Relative to Current Pre-harvest Testing Provisions (millions 2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	-$27.2	$9.3	$47.2
2	-$30.0	$10.2	$52.0
3	-$34.2	$11.6	$59.5
4	-$32.9	$11.6	$58.9
5	-$33.6	$11.6	$58.7
6	-$34.6	$11.6	$59.7
7	-$34.1	$11.6	$58.7
8	-$34.4	$11.6	$59.4
9	-$33.7	$11.6	$58.8
Annualized, 3%	-$28.9	$9.9	$50.3
Annualized, 7%	-$28.1	$9.6	$48.9

F. Costs of the Proposed Rule

1. Costs of the Proposed Rule

a. One-time Costs

In this section, we detail the one-time costs to industry associated with the proposed 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

All farms covered by the 2015 Produce Safety Final Rule will spend time reading the rule, if finalized, to become familiar with the new requirements regarding water risk 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) 2019 wage data[3] for "Farmers, Ranchers, and Other Agricultural Managers" (11-9013) from the National Industry-Specific Occupational Employment and Wage Estimates (Ref. 4) to yield a mean hourly wage rate of approximately $38.63. Following guidelines from the Department of Health and Human Services (HHS) (Ref. 5), we double the wage rate to account for overhead and benefits, yielding a fully-loaded hourly cost of labor of $77.26. Table 17 presents estimates of the cost of reading the rule by reading speed.

Table 17: Cost of Reading and Understanding the Rule (2019$)

	Low	Primary	High

[3] Costs in this document are estimated in 2019 dollars unless noted otherwise

Average reading speed (words per minute)	250	225	200
Total words in rule	29,458	29,458	29,458
Hours to read rule	1.96	2.18	2.45
Hourly cost of labor of farm managers	$77.26	$77.26	$77.26
Cost per farm	$152	$169	$190
Number of farms that read the rule	35,029	35,029	35,029
Total cost of reading and understanding rule	**$5,314,892**	**$5,905,436**	**$6,643,615**

b. Recurring Costs

i. Pre-Harvest Agricultural Water Assessments

The proposed rule would require farms that use pre-harvest agricultural water in direct application 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 include an evaluation of any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce, 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 in the proposed regulation (Ref. 6). 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 annual assessments 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 cost of labor of $77.26 for "Farmers, Ranchers, and Other Agricultural Managers" (Ref. 4). For large farms, we use the BLS hourly mean wage rate for "First-Line Supervisors of Farming, Fishing, and Forestry Workers" (45-1011) to yield an hourly cost of labor of approximately $25.25 (Ref. 8). Following HHS guidelines, we double this to yield the fully-loaded cost of labor of $50.50. 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 Proposed Pre-Harvest Agricultural Water Assessments for Very Small Farms (2019$)

	Low	Most Likely	High
Number of farms conducting assessments	8,218	8,218	8,218
Number of pre-harvest agricultural water assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$77.26	$77.26	$77.26
Time in hours to conduct each water risk assessment	6.0	10.0	18.0
Annual cost of assessment for very small farms	**$5,107,308**	**$7,449,669**	**$10,167,293**

Table 20: Cost of Conducting Proposed Pre-Harvest Agricultural Water Assessments for Small Farms (2019$)

	Low	Most Likely	High
Number of farms conducting assessments	1,613	1,613	1,613
Number of pre-harvest agricultural water assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$77.26	$77.26	$77.26
Time in hours to conduct each water risk assessment	6.0	12.0	18.0
Annual cost of assessment for small farms	**$1,133,953**	**$1,645,244**	**$2,156,384**

Table 21: Cost of Conducting Proposed Pre-Harvest Agricultural Water Assessments for Large Farms (2019$)

	Low	Most Likely	High
Number of farms conducting assessments	4,283	4,283	4,283
Number of pre-harvest agricultural water assessments conducted annually	1.1	1.1	1.1

Hourly cost of labor of farm supervisors	$50.50	$50.50	$50.50
Time in hours to conduct each water risk assessment	10.0	16.0	20.0
Annual cost of assessment for large farms	**$2,962,881**	**$3,727,037**	**$4,426,575**

Table 22: Total Cost of Conducting Proposed Pre-Harvest Agricultural Water Assessments, All Farms (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$2,962,881	$3,727,037	$4,426,575
2	$4,454,484	$5,372,281	$6,247,525
3	$10,291,740	$12,821,950	$15,669,709
4	$10,338,763	$12,821,950	$15,693,291
5	$10,297,687	$12,821,950	$15,678,480
6	$10,323,017	$12,821,950	$15,672,303
7	$10,290,637	$12,821,950	$15,667,341
8	$10,299,537	$12,821,950	$15,676,322
9	$10,307,175	$12,821,950	$15,671,974
Annualized, 3%	$7,694,558	$9,558,390	$11,637,097
Annualized, 7%	$7,342,207	$9,118,977	$11,095,342

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 proposed rule would require 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 die-off time between water application and harvest, increasing the time interval for die-off between harvest and end-of storage and/or conducting other activities (such as commercial washing), changing the method of water

application, treating the water, or an alternative mitigation measure (proposed §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 risk assessment as specified in the proposed rule, would subsequently conduct a mitigation measure (Ref. 6). We request comment on the percentage of farms that, having conducted an assessment, would need to conduct mitigation.

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. 6). We request comment on the percentage of farms that would conduct each type of mitigation action.

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 (Ref. 3) estimates that "small" covered farms ($25,000-$500,000 revenue) that conducted water treatment spent $1,189 annually. 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), "large" (annual treatment cost of $1,596), and "very large" (annual treatment cost of $22,864)

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 $5,796. We use these estimates of water treatment cost to remain consistent across the current preharvest agricultural water testing provisions and the proposed 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; 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; 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 (Ref. 6). We request comment on the cost of each type of mitigation action.

Table 27: Cost of Each Type of Mitigation, Very Small Farms (2019$)

Mitigation Action	Low	Primary	High
Necessary Changes	$100	$500	$1,000
Pre-harvest Die-off	$0	$0	$0
Postharvest Die-off	$550	$1,075	$1,350
Changing Water Application	$1,300	$2,575	$3,850
Alternative Options	$50	$600	$750

Table 28: Cost of Each Type of Mitigation, Small Farms (2019$)

Mitigation Action	Low	Primary	High
Necessary Changes	$500	$1,000	$2,000
Pre-harvest Die-off	$0	$0	$0
Postharvest Die-off	$2,600	$4,150	$5,250
Changing Water Application	$200	$2,000	$2,000
Alternative Options	$250	$1,250	$2,250

Table 29: Cost of Each Type of Mitigation, Large Farms (2019$)

Mitigation Action	Low	Primary	High
Necessary Changes	$100	$2,000	$3,000
Pre-harvest Die-off	$0	$0	$0
Postharvest Die-off	$3,550	$5,075	$6,600
Changing Water Application	$3,000	$4,000	$5,000

Alternative Options	$1,550	$2,350	$3,250

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 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 30: Total Cost of Mitigation, All Farms (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$5,024,309	$7,907,016	$11,246,027
2	$5,975,920	$8,959,208	$12,343,398
3	$8,261,510	$11,502,581	$15,152,863
4	$8,242,957	$11,502,581	$15,169,935
5	$8,249,668	$11,502,581	$15,110,961
6	$8,235,668	$11,502,581	$15,128,807
7	$8,237,829	$11,502,581	$15,110,722
8	$8,242,492	$11,502,581	$15,081,448
9	$8,268,849	$11,502,581	$15,086,895
Annualized, 3%	$6,709,538	$9,523,230	$12,674,357
Annualized, 7%	$6,485,797	$9,229,278	$12,306,034

iii. Recordkeeping

If finalized, the proposed rule would require 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 request comment on the time it takes to conduct recordkeeping.

We use the previously described fully-loaded hourly cost of labor "Farm Operators" ($77.26) for very small and small farms and cost of labor for "Farm Supervisors" for large farms ($50.50). 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.

Table 31: Cost of Recordkeeping, Very Small Farms (2019$)

	Low	**Most Likely**	**High**
Number of farms conducting assessments	8,218	8,218	8,218
Number of water risk assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$77.26	$77.26	$77.26
Time in hours to conduct recordkeeping	2.0	4.0	9.0
Annual cost of recordkeeping for very small farms	**$1,836,843**	**$3,142,829**	**$4,730,554**

Table 32: Cost of Recordkeeping, Small Farms (2019$)

	Low	**Most Likely**	**High**
Number of farms conducting assessments	1,613	1,613	1,613
Number of water risk assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm operators	$77.26	$77.26	$77.26
Time in hours to conduct recordkeeping	2.0	8.0	10.0

Annual cost of recordkeeping for small farms	**$649,943**	**$1,005,427**	**$1,287,130**

Table 33: Cost of Recordkeeping, Large Farms (2019$)

	Low	Most Likely	High
Number of farms conducting assessments	4,283	4,283	4,283
Number of water risk assessments conducted annually	1.1	1.1	1.1
Hourly cost of labor of farm supervisors	$50.50	$50.50	$50.50
Time in hours to conduct recordkeeping	3.0	9.0	11.0
Annual cost of recordkeeping for large farms	**$1,365,478**	**$1,982,467**	**$2,471,306**

Table 34: Total Cost of Recordkeeping, All Farms (2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0	$0	$0
1	$1,365,478	$1,982,467	$2,471,297
2	$2,299,684	$2,987,893	$3,577,066
3	$4,651,060	$6,130,722	$7,813,807
4	$4,654,899	$6,130,722	$7,824,015
5	$4,658,451	$6,130,722	$7,818,701
6	$4,649,878	$6,130,722	$7,835,208
7	$4,630,601	$6,130,722	$7,823,048
8	$4,652,755	$6,130,722	$7,824,266
9	$4,659,848	$6,130,722	$7,825,286
Annualized, 3%	$3,506,400	$4,637,391	$5,885,939
Annualized, 7%	$3,350,362	$4,433,813	$5,623,094

iv. Total Costs of the Proposed Rule by Year

Table 35 presents the estimated costs of the rule by year, relative to a state of the world with no pre-harvest agricultural water provisions. This includes the estimated costs of reading the rule, pre-harvest agricultural water assessments, 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 the proposed rule, relative to no pre-harvest agricultural water provisions, is $24.4 million

annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $23.6 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 the Proposed Rule Versus Current Provisions by Year Relative to no Pre-harvest Agricultural Water Provisions, All Farms (2019$)

Years after publication	Primary Estimate of Total Costs of Current Provisions	Primary Estimate of Total Costs of Proposed Rule
0	$0	$5,905,436
1	$14,800,265	$13,616,520
2	$11,297,972	$17,319,382
3	$19,732,783	$30,455,254
4	$15,127,970	$30,455,254
5	$15,127,970	$30,455,254
6	$15,127,970	$30,455,254
7	$15,127,970	$30,455,254
8	$15,127,970	$30,455,254
9	$15,127,970	$30,455,254
Annualized, 3%	$13,841,849	$24,391,145
Annualized, 7%	$14,048,331	$23,567,864

Table 36 presents the estimated costs of the rule by year, relative to a state of the world in which the current pre-harvest agricultural water testing provisions take effect. Our primary estimate of the total cost of the proposed rule, relative to the current pre-harvest agricultural water provisions, is $11.3 million annualized at a 3% discount rate; at a 7% discount rate, this primary estimate is $11.2 million annualized. We include 5th ("Low Estimate") and 95th ("High Estimate") percentile outcomes of the simulated burden as measures of uncertainty.

Table 36: Total Cost of the Proposed Rule by Year Relative to Current Pre-harvest Agricultural Water Testing Provisions, All Farms (2019$)

Years after publication	Low	Primary	High
0	$5,905,436	$5,905,436	$5,905,436
1	-$11,064,537	-$1,183,745	$7,194,475

2	-$30,662	$6,021,410	$11,625,130
3	$3,662,019	$10,722,471	$17,433,075
4	$8,529,493	$15,327,284	$21,814,281
5	$8,558,226	$15,327,284	$21,940,814
6	$8,579,652	$15,327,284	$21,753,419
7	$8,469,100	$15,327,284	$21,860,193
8	$8,583,823	$15,327,284	$21,834,423
9	$8,497,048	$15,327,284	$21,733,535
Annualized, 3%	$4,783,729	$11,281,030	$17,349,607
Annualized, 7%	$4,519,785	$11,169,283	$17,361,122

G. Distributional Effects

We do not anticipate any significant distributional effects or changes in consumer behavior resulting from the proposed rule. If farms conducting water risk assessments experience costs of the proposed rule, however, farms not covered by the proposed rule may benefit relative to farms that bear these costs. We request comment on any potential distributional effects of the proposed rule.

H. 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. We request comment on any potential international effects of the proposed rule.

I. Uncertainty and Sensitivity Analysis

We have identified sources of uncertainty about the expected costs and benefits of the proposed 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 addition, we ask for public comment on estimates used in the analysis where appropriate.

In our analysis of the baseline costs of the current pre-harvest agricultural water testing provisions, 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 need to test under the current pre-harvest agricultural water testing provisions. We are also uncertain about the percentage of farms that, having tested their water, would need to conduct corrective measures under the current requirements. 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 proposed pre-harvest water provisions, 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 proposed 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 proposed 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 proposed rule as measures of uncertainty.

In our analysis of benefits, we acknowledge uncertainty about the fraction of water-related produce outbreaks caused by pre-harvest agricultural water and the relative effectiveness at preventing outbreaks under the proposed pre-harvest agricultural water provisions compared to the current pre-harvest agricultural water requirements. We use subject matter expert estimates as parameters of distributions to simulate baseline benefits of the current pre-harvest agricultural water testing provisions and the benefits of the proposed 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 proposed rule as measures of uncertainty.

J. Analysis of Regulatory Alternatives to the Proposed Rule

Option 1: Remove all pre-harvest agricultural water provisions

Instead of replacing the current pre-harvest agricultural water testing provisions with the proposed pre-harvest agricultural water assessment provisions, one regulatory alternative would be to remove the Subpart E 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 current provisions. The only cost borne by

farms would be reading a rule that repeals the current provisions. For the purposes of this analysis, we assume a proposed rule repealing the current provisions would be the same length as this proposed rule. Table 37 presents costs by year (where negative costs represent cost savings) associated with this regulatory alternative. Annualized net costs of removing pre-harvest agricultural water provisions are approximately -$12.8 million annualized at a 3 percent discount rate and approximately -$12.3 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 38 presents the estimated forgone benefits of the alternative in which all pre-harvest agricultural water provisions are repealed. Annualized forgone benefits of removing pre-harvest agricultural water provisions are approximately $72.6 million annualized at a 3 percent discount rate and approximately $70.6 million annualized at a 7 percent discount rate.

Table 37: Costs of Removing Current Pre-harvest Agricultural Water Provisions (millions 2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$5.9	$5.9	$5.9
1	-$24.2	-$14.8	-$7.3
2	-$16.4	-$11.3	-$7.1
3	-$25.2	-$19.7	-$15.1
4	-$20.3	-$15.1	-$10.9
5	-$20.3	-$15.1	-$10.9
6	-$20.3	-$15.1	-$10.9
7	-$20.3	-$15.1	-$10.9
8	-$20.3	-$15.1	-$10.9
9	-$20.3	-$15.1	-$10.9
Annualized, 3%	-$17.9	-$12.8	-$8.6
Annualized, 7%	-$17.4	-$12.3	-$8.2

*Negative costs in the table represent cost savings

Table 38: Forgone Benefits of Removing Current Pre-harvest Agricultural Water Provisions (millions 2019$)

Years after publication	Low Estimate	Primary Estimate	High Estimate
0	$0.0	$0.0	$0.0
1	$42.2	$68.2	$100.8
2	$46.1	$74.5	$110.3
3	$52.8	$85.3	$125.1
4	$52.8	$85.3	$125.2
5	$52.6	$85.3	$125.5
6	$52.9	$85.3	$125.4
7	$53.0	$85.3	$125.7
8	$53.0	$85.3	$125.3
9	$52.6	$85.3	$125.7
Annualized, 3%	$44.9	$72.6	$106.8
Annualized, 7%	$43.7	$70.6	$103.9

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

Option 2: Require water risk assessments twice annually

The proposed rule would require 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 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 39 presents estimated costs by year of this regulatory alternative relative to current pre-harvest agricultural water testing provisions, assuming the same costs of reading the rule as in the current proposed rule. This regulatory alternative would be more costly for farms than the proposed 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. Annualized costs under no additional mitigation measures are approximately $25.1 million at a 3 percent discount rate and approximately $24.0 million at a 7 percent discount rate; annualized costs under 50 percent additional mitigation measures are approximately $29.9 million at a 3 percent discount rate and approximately $28.6 million at a 7 percent discount rate; annualized costs under 100 percent additional mitigation measures are approximately $34.7 million at a 3 percent discount rate and approximately $33.2 million at a 7 percent discount rate.

Table 39: Costs of Requiring Two Annual Assessments, Relative to Current Pre-harvest Agricultural Water Testing Provisions (Millions 2019$)

Years after publication	0% More Mitigation Measures	50% More Mitigation Measures	100% More Mitigation Measures
0	$5.9	$5.9	$5.9
1	$4.5	$8.5	$12.4
2	$14.4	$18.9	$23.3
3	$29.7	$35.4	$41.2
4	$34.3	$40.0	$45.8
5	$34.3	$40.0	$45.8
6	$34.3	$40.0	$45.8
7	$34.3	$40.0	$45.8
8	$34.3	$40.0	$45.8
9	$34.3	$40.0	$45.8
Annualized, 3%	$25.1	$29.9	$34.7
Annualized, 7%	$24.0	$28.6	$33.2

III. Initial 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 we estimate that annualized costs will not be larger than 3 percent of revenue for any covered

farms, we anticipate that the proposed rule will not have a significant economic impact on a substantial number of small entities. If the proposed rule is finalized, we may, if appropriate, certify that the final rule does 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 proposed rule qualify as small businesses as defined by the U.S. Small Business Administration. Current standards from the U.S. SBA (Ref. 8) define farms engaged in crop production as small businesses if annual revenues are below $1,000,000. 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 the requirements of the Produce Safety Rule. 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 proposed 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 8,218 affected very small farms and 1,613 small farms will qualify as small businesses; as a result, at least 9,831 of the 14,114 (70%) farms that would conduct pre-harvest agricultural water risk assessments qualify as small businesses.

We use the survey conducted by ERS (Ref. 3) 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 4,283 large covered farms are small businesses, 1,640 of these large farms qualify as small businesses. In this case, 11,471 of the 14,114 (81%) farms that will conduct pre-harvest agricultural water risk 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 proposed rule would experience annualized costs relative to current pre-harvest agricultural water testing provisions of $647 at a 3 percent discount rate and $637 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 current pre-harvest agricultural water testing provisions of $987 at a 3 percent discount rate and $979 at a 3 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 the requirements of the Produce Safety Rule. The estimated cost to very small farms of this rule would represent 2.6% of revenue for a farm with $25,000 in revenue; therefore, the costs of this rule would be, at maximum, 2.6% of revenue. Because the estimated costs are less than 3% of revenue for all covered

farms, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Alternatives to Minimize the Burden on Small Entities

While we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities, we note that we expect the proposed rule will implement staggered compliance dates, allowing affected small entities additional time to comply with the proposed rule.

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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 Rule FRIA (Ref. 2). 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 2018 (Ref. 9);
- CDC National Outbreak Reporting System (NORS) data on all foods from the 10-year span of 2009 to 2018 (Ref. 10); and
- expected dollar loss per case for foodborne illness agents from the Food Tracing PRIA (Ref. 11).

Table A1 presents updated counts of reported outbreaks, illnesses, hospitalizations, and deaths from covered non-sprout produce raw agricultural commodities (RACs) from 2009 to 2018. 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, 2009-2018.

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*	4	874	4	0
Mixed	*Cyclospora cayatenensis*	1	616	39	0
Nut*	*E. coli O157:H7*	1*	8*	3*	0*
Cucumber	*E. coli O157:H7*	1	8	1	0
Green cabbage	*E. coli O111*	1	18	4	0
Cantaloupe	*Listeria monocytogenes*	1	147	143	33
Stone fruit	*Listeria monocytogenes*	1	1	0	1
Berries	*Salmonella*	2	20	1	0
Cucumber	*Salmonella*	7	1,216	248	6
Melon	*Salmonella*	1	53	4	1

Tomato	*Salmonella*	7	487	81	0
Produce	*Salmonella*	3	533	61	0
Cantaloupe	*Salmonella*	4	329	105	3
Papaya	*Salmonella*	8	502	139	2
Mango	*Salmonella*	2	177	48	0
Leafy greens	*Salmonella*	1	15	1	0
Nut	*Salmonella*	3	49	7	0
Grapes	*Salmonella*	1	27	10	0
Mixed	*Salmonella*	1	209	47	0
Hot pepper	*Salmonella*	1	32	8	0
Yellow onion	*Salmonella*	2	178	43	0
RAC Total		**54**	**5,507**	**997**	**46**

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. 12). 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. 12). As noted in the 2015 FRIA (Ref. 2), 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 2018. This table is analogous to Table 6 in the 2015 FRIA for non-sprout produce.

Table A2: Estimated Number of Illnesses, 2009-2018.

Estimated Number of Illnesses Attributable to Produce RACs Other Than Sprouts

Agent	FDA RAC (2009-2018)	Identified Cases (2009-2018)	Percentage Attributable to RACs	Estimated Annual Foodborne Illnesses (Scallan)	Estimated Annual Illnesses Attributable to RACs
Salmonella	4,679	36,198	12.93%	1,072,450	138,626
Cyclospora cayatenensis	1,498	1,926	77.78%	13,906	10,816
Listeria monocytogenes	148	731	20.25%	1,680	340
E. coli O157:H7	16	2,945	0.54%	69,972	380
E. coli O111	18	88	20.45%	124,966	25,561
Total Identified RAC	6,359	41,888	15.18%	1,282,974	194,768

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 Food Tracing PRIA (Ref. 11). 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 $1,856.5 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, 2009-2018.

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	138,626	94.20%	130,586	$6,563	**$857**
Cyclospora cayatenensis	10,816	94.20%	10,188	$4,022	**$41**
Listeria monocytogenes	340	94.20%	320	$1,797,753	**$576**
E. coli, STECO157	380	94.20%	358	$9,376	**$3**
E. coli, non O157	25,561	94.20%	24,079	$2,266	**$55**
Total RAC Identified	194,768	94.20%	183,471		**$1,532**
Total RAC Unidentified			733,885	$442	**$325**
Total RAC			917,356		**$1,857**