DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

Docket No. FDA-2011-N-0921

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

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Executive Summary

The rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The rule addresses microbiological risks from certain routes of contamination, including workers, agricultural water, biological soil amendments of animal origin, buildings, tools and equipment and sanitation, and wild and domesticated animals. The rule also includes specific requirements for sprouts. Using a science-based framework, we characterized the public health risks associated with the consumption of produce and are establishing specific provisions that address the risks of microbial contamination from these routes of contamination. The primary benefits of the provisions in this rule are an expected decrease in the incidence of illnesses related to microbial contamination of produce. Annualizing benefits over the first ten years after the effective date of this final rule at seven percent, benefits are expected to derive from averting approximately 331,964 illnesses per year (362,059 at three percent), valued at $925 million annually ($976 million at three percent). Similarly, annualized costs, estimated at seven percent, are expected to be approximately $366 million annually ($387 million at three percent).Additionally, annualized costs for foreign farms are estimated to be approximately $138 million annualized at seven percent ($146 million at three percent).

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final 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 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies 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). The Agency believes that this final rule *will* be an economically significant regulatory action as defined by Executive Order 12866.

If a rule has a significant economic impact on a substantial number of small businesses, the Regulatory Flexibility Act requires Agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. FDA has determined that this final rule *will* have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $141 million, using the most

current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA *does* expect this final rule to result in any 1-year expenditure that will meet or exceed this amount.

B. Summary of Costs and Benefits

The requirements of the final Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation (Produce Safety rule, the final rule, or the rule) will lead to higher costs for both the industry and consumers than the current state of no new regulatory action. As described in the preamble, the final rule includes requirements for covered domestic and foreign farms engaged in the growing, harvesting, packing, and/or holding of one or more raw agricultural commodities (RACs)[1] that are covered produce. The final rule also requires covered domestic and foreign farms to train their employees; take certain measures related to employees' health and hygiene; monitor, understand, and take certain measures related to their agricultural water; assess for domesticated and wild animals activity in areas used for covered activities; take certain measures during growing, harvesting, packing, and holding activities; and take certain measures relating to sanitation, including cleaning and sanitizing equipment and tools, and appropriately maintaining buildings. In addition, the rule establishes certain requirements for the growing, harvesting, packing, and holding of sprouts. Farms will be required, to take appropriate corrective actions, and maintain certain records, including records that document these corrective actions. The affected farms will incur costs to comply with this final regulation. Depending on how the farms

[1] When discussing Raw Agricultural Commodities (RAC), we refer to RACs covered by the rule unless otherwise noted.

in the affected markets respond to these requirements, some of the costs may ultimately be borne by consumers as prices rise. The higher prices, however, will likely not be sufficient to fully offset the costs borne by farms.

Table 1 summarizes the costs and benefits of the Produce Rule. More detail on these estimates is provided in the relevant sections of this document, specifically benefits come from Table 6 and costs come from Table 37.

Table 1: Summary of Benefits and Costs of Final Rule (in millions)

	Discount Rate	Primary Estimate	Low Estimate	High Estimate
Annualized Benefits over 10 years	3%	$976	$748	$1,195
	7%	$925	$710	$1,132
NPV of Benefits over 10 years	3%	$8,322	$6,381	$10,190
	7%	$6,498	$4,988	$7,950
Annualized Costs over 10 years	3%	$387	$319	$425
	7%	$366	$301	$401
NPV of Costs over 10 years	3%	$3,304	$2,717	$3,624
	7%	$2,571	$2,113	$2,817

In addition to the costs presented in Table 1, we estimate there will also be costs incurred by foreign farms shipping RACs to the U.S. We estimate a total annualized cost to foreign farms shipping produce RACs to the US of $136 million annually, using a 7 percent discount rate ($146 million using a 3 percent discount rate).

C. Comments on the Preliminary Regulatory Impact Analysis and Our Responses

FDA's proposed rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (78 FR 3504; the 2013 proposed rule) was

published on January 16, 2013 and its comment period ended November 22, 2013. In addition, we published a supplemental notice to the proposed rule on September 29, 2014 (79 FR 58434) and its comment period ended December 15, 2014. (We refer to both of these documents collectively as "the proposed produce safety rule.") We prepared a full "Preliminary Regulatory Impact Analysis" in connection with the proposed and supplemental rule. We also included sections titled "Costs and Benefits" and "Initial Regulatory Flexibility Analysis" in the preamble to the proposed rule (76 FR 19192 at 19220-19225). In the following paragraphs, we describe and respond to the comments we received on our analyses of the impacts presented in those sections. We have numbered each comment to help distinguish between different comments. 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) Several commenters express concern about the magnitude of the cost of the rule. Specifically, they state that the rule would: cost farmers over half of their profits; put an unfair financial burden on small and medium farms; cause many farms to go out of business; deny farmers access to local food markets by making it harder to diversify (e.g., a small strawberry operation that is part of a large non-produce farm may be subject to the rule even if the specific sales of strawberries are below the exemption cutoff); and prevent new farmers from starting to farm.

Response 1) FDA recognizes that the cost of this rulemaking is not inconsequential. However, we believe the need for a safer food supply warrants such expenditures. In our analyses, we find that the average cost of the rule for very small farms is $2,885 per farm, while the average value of produce sales is $85,616. Similarly,

we find the average cost for small farms is $15,265 per farm, while the average value of produce sales is $358,814 per farm. We do not believe that this rule will in any way hinder farmers' access to local markets. In fact, exemptions are set up in such a way as to encourage sales of produce locally (Ref. 1). We have revised our provisions related to coverage of the rule (see 112.4, which establishes the monetary threshold based on sales of produce (rather than sales of food)), and the rule, as finalized, will not hinder the diversity or force those farms that have a relatively small amount of produce grown on their farm to exit the industry. Finally, we recognize that these costs will affect farmers entering into the industry, but we believe that all new farmers should be practicing safe food practices, especially in the cases where the produce is likely to be consumed raw. See also section III of the rule.

Comment 2) Several commenters state that the proposed produce safety rule will have additional health costs because, by being disadvantageous to small and local farms, they will reduce access to fresh, local, and healthy food. Commenters also suggest that FDA needs to consider large scale crop losses, harm to soil and the municipal water supply, and ecological impacts brought on by the water testing requirements, in its cost analyses.

Response 2) FDA does not believe that this rule will reduce access to produce. In fact, exemptions are set up in such a way as to encourage sales of produce locally (Ref. 1). Additionally, FDA has conducted an assessment of impacts of the rule on the human environment of the United States, and prepared an environmental impact statement (Ref. 2). According to the EIS, "providing that any pesticide that is EPA-registered and is handled and applied in accordance with labeling requirements should not result in significant environmental impacts to vegetation, wildlife, and wetland resources. However, such

applications may result in short-term minimal to moderate impacts on these resources particularly if applied preceding substantial periods of precipitation which may increase run-off. Such impacts would be intermittent and acute." It further states that "if approved products are used in accordance with labeling requirements, chemical contamination is not expected to pose a human health risk." In terms of soil, the EIS states, "…chloride is not adsorbed by soils and moves readily with the soil-water; is taken up by the crop; moves in the transpiration stream; and accumulates in the leaves. The chemical reactions that occur when chlorine and organic matter are exposed to each other also produce toxic and carcinogenic by-products. The use of antimicrobials, however, would not be expected to exceed the threshold that would be toxic to crops, as long as labeling requirements are followed for application purposes, and adverse effects to crops from overexposure to chemical treatments should not occur."

Comment 3) Several commenters state that the water testing requirements will be overly costly to farms using water from creeks, streams and rivers,.

Response 3) We acknowledge that there is a cost to testing water; however, we believe that the testing is important given the significant risk of foodborne illnesses presented by agricultural water as a potential route of contamination. Numerous changes have been made to make the requirements for agricultural water more flexible (see section XIII of the rule) and we have attempted to account for those flexibilities within this analysis. In total we estimate that agricultural water provisions, as written in the final rule, will cost approximately $37 million dollars annually, which represents an average cost to a single farm of approximately $1,058 per year.

Comment 4) One comment states that FDA did not compare less costly alternatives, such as establishing labeling requirements to instruct consumers to wash produce.

Response 4) We believe that such an approach would be ineffective at reducing the human health burden associated with contaminated produce, and therefore we did not analyze the cost of such an approach. There are already a number of education campaigns currently in progress, or that have been completed, which try to stress safe food handling practices to the consumer. However, these are not completely effective in reducing foodborne illness. We also note that establishing new labeling requirements does have the potential to involve significant costs, especially where no label is currently required, such as for many produce RACs.

Comment 5) Several commenters state that the costs of water testing are particularly burdensome for operations with multiple water sources.

Response 5) The water testing provisions have been revised. The most burdensome testing regimen is associated with the use of untreated surface water that is used during growing of covered produce (other than sprouts) using a direct water application method. If farms use untreated surface water source(s) for this purpose, they will generally need to perform, for each source, an initial survey of 20 samples and recurring annual samples of five per year, which is estimated to cost approximately $692 annualized over 10 years. The rule includes a provision allowing sharing of water testing data under certain circumstances (§ 112.47(a)(2)). This will allow some farms to reduce testing costs by sharing testing data.

Comment 6) Several commenters state that customers may require partial or full compliance with the produce rule standards even for operations that may be otherwise exempt, therefore causing these operations to incur the costs of the produce rule.

Response 6) FDA recognizes that some costs may potentially be incurred by farms not covered by this rule that are not required by FDA. To our knowledge, however, there is no data on which to base a reasonable estimate of these costs not directly attributable to the rule. Uncovered farms that incur these costs likely do so in order to maintain market share and thus maximize revenues. We include the costs for farms not covered or otherwise exempt for maintaining paperwork related to certain produce exempt from the Produce Safety rule, and costs of complying with modified requirements for those farms eligible for a qualified exemption with modified requirements. Anything done by a farm to comply with aspects of the rule from which they are officially exempt would likely be performed to preserve market share and/or profitability.

Comment 7) Several commenters state that the FDA should not assume small and very small farms only operate three months out of the year, and that large farms operate only 6 months per year and harvest, pack or hold produce only 90 days. Some suggest increasing season estimates for all farms depending on the region.

Response 7) We agree that the original time estimates for very small, small, and large farms may have been underestimated for some farms. Therefore, we have increased our estimates of operating days for very small farms to 100, small farms to 150, and large farms to 200. This is not to say that these farms do not carry on operations year round, but, for our costs analysis, we are primarily concerned with those times when the harvested or harvestable portions of the produce are exposed on the farm. Additionally,

because we do not explicitly examine farms by region, but are tasked with the average costs to all farms operating within the US, applying regional differences to operations is not possible for this analysis.

Comment 8) Several commenters state that FDA should include costs for farm mixed-type facilities in their cost-benefit analyses.

Response 8) We currently estimate the cost to all farms that meet the current farm definition. The analysis of the costs and benefits of the produce rule is not affected by whether or not a covered farm is also a facility subject to the Preventive Controls for Human Food (PCHF) Rule. If a farm is covered under the produce rule, then it must adhere to the rule. If that farm is also a facility subject to the PCHF rule, then the costs it incurs by adhering to the PCHF rule will be accounted for in the cost and benefit analysis of the PCHF rule (Ref. 3).

Comment 9) Several commenters state that FDA should analyze how the costs of the rules will be passed on to consumers (e.g., via increased prices).

Response 9) FDA estimates the costs to industry and society as a whole but does not estimate who will actually incur those costs (e.g., farms, intermediaries, retail establishments, or end consumers). This is largely due to the lack of quantifiable data on the issue. However, the total costs of this rule ($560 million, as shown in Table 34) when fully implemented represent approximately 1.5 percent of the total value of produce sold in the US ($38 billion). Additionally, the total cost to foreign farms that ship to the US is $211 million (as estimated in Section H, International Effects), once the rule is fully in effect, meaning that the total cost of this rule, foreign and domestic, represents approximately 2 percent of the total value of the US produce market. This means that

even if the total costs of compliance were passed on to consumers, which are highly unlikely, it would represent a price increase of only 2 percent.

Comment 10) Several commenters state that "FDA disguises the first-year costs of the regulations by annualizing them over 7 years for depreciation," which "ignores the issue of whether the farmer has the money to comply in the first year to begin with, as well as the fact that many small farmers do not have sufficient income to make depreciation cycles relevant."

Response 10) FDA annualizes cost in accordance with Circular A-4 and Executive Order 12866 (Ref. 4;5). This is not to 'disguise' the costs, but rather to illustrate the likely costs of financing larger purchases over the long term. However, to illustrate the complete first year costs, not annualized over any time horizon, we also present these costs in Table 34. Summary of Costs for the Produce Safety Rule (in millions)

Comment 11) One commenter states that FDA's estimated rental value of $359 per acre for a full year is too small.

Response 11) This estimate was based on the best data that we could find on crop land values for the proposed rule. However, because certain requirements related to biological soil amendments of animal origin have been removed from the final rule, related costs estimates have also been removed from this analysis and the rental value of land no longer enters any of our calculations of costs to a farm.

Comment 12) One commenter states that there are not any EPA approved water treatments, and that farmers would either have to stop irrigating (which will lead to crop damage) or turn to public water sources, which can be more expensive. Another

comment adds that the "cost required to invest in a groundwater pump can be significant and initial costs can be substantial. In 2013, in many parts of the West, drilling and developing a new groundwater irrigation well costs between $100,000 and $500,000 to supply water to 120 acres of productive farm land"

Response 12) As discussed in section XIII of the final rule, in § 112.45, we are providing for different options that a covered farm can consider when agricultural water is found to be not safe or of adequate sanitary quality for its intended use and/or does not meet the relevant microbial quality criteria in § 112.44(a) or (b), and treatment is only one of those options. We anticipate that covered farms will consider and implement the flexible options provided in §§ 112.45(a) and (b) and 112.49, as appropriate, prior to or in conjunction with considering whether to treat water to ensure that it meets the applicable requirements for its intended use. Indeed, we believe some of these options are likely to be more feasible than the option to treat water. Moreover, covered farms will have two additional years (beyond the date of compliance for the remainder of the rule) to comply with many of the water provisions of this rule for covered activities involving covered produce (except sprouts), which is intended to help farms to consider and implement measures that are most appropriate for their operations.

Comment 13) Several commenters state that the Clean Water Act statistics do not provide a good estimate of how much irrigation water would fail to meet the EPA recreational water standard. They state that there is no information in the report about which of the water sources that don't meet the standards are used for irrigation, how much irrigation water is drawn from impaired sources, and groundwater usage.

Response 13) We agree that EPA's Clean Water Act statistics do not provide precisely the measurements we would prefer to estimate the amount of water that is likely to fail to meet the microbial water quality criteria in § 112.44(b); however, in the absence of another source, we believe this to be the most comprehensive and nationally representative source of data available. Because commenters did not provide any additional data or sources of data on this topic, and because we were unable to find any new or additional sources, we retain this as our source for estimates of water quality in the final analysis.

Comment 14) Several commenters state that there is no analysis of the cost of imposing microbial water quality criteria.

Response 14) The costs of imposing microbial water quality criteria are realized through treatment of water used in growing or post-harvest activities (an estimate affected by the number of farms we estimate that will be able to use other methods to meet the microbial water quality criteria, such as reinspection/correction and reliance on die-off or removal rates). These costs are presented in Table 18 and Table 19 of the analysis.

Comment 15) Several commenters argue with FDA's cost analysis by providing counterexamples, which primarily referred to one farm, one specific region, or one specific crop.

Response 15) For a national analysis of the costs and benefits of this rule we are not able to comprehensively account for farms by commodities or agricultural region. We are aware that there are differences in needs and resources across different farms, and as such we attempt to provide a national average estimate that reflects this variety.

Commodities and regions of production are taken into account when constructing our costs estimates whenever there are data which allow us to do so.

Comment 16) Several commenters state that FDA needs to account for travel and staff/lab time in the costs of water testing.

Response 16) We explicitly account for these costs in the original analysis. Table 43 estimates the 0.5 hours of farm labor and 1 hour of laboratory travel time labor per sample (Ref. 6) This represented a total cost of a single water test of $87.30; for the final analysis we have increased this estimate to $110 per sample. The hourly estimate is retained in the final analysis; however, wage rates have changed from those presented in the PRIA.

Comment 17) One commenter states that FDA underestimates the costs associated with subpart E (Agricultural Water), and offers their own estimation, which states that the minimum cost for compliance with the rule, including testing and the associated, time, labor and other incurred costs, would be $7,912 for a single surface water supply source (regardless of farm size). They state that FDA's initial economic estimate for a very small farm was $4,697, which was less than 60 percent of the cost they estimated.

Response 17) We have re-evaluated the costs associated with Subpart E, Agricultural Water. Our final estimate indicates that water testing will cost an average of $1,058 per year. While this is somewhat below the commenter's average costs, we believe it represents the most accurate estimate utilizing the most recent and applicable data sources.

Comment 18) Several commenters express concern that the costs of water testing requirements will fall disproportionately on small farmers and farms in remote areas. For

example, it may be more costly for a single-operator farm to spend time on testing. Farms in remote areas may have trouble accessing a lab, and may need to pay extra expenses to ship samples to far away labs.

Response 18) We include the cost of shipping samples to labs when one is not nearby. We then average the costs of a local laboratory sample and shipped sample together to produce one average cost of laboratory testing across farms. The original estimate was provided in Table 43 of the PRIA (Ref. 6;7) and is retained here in the final analysis. See also section IV.G. of the final rule where we address comments about reducing burden on small farms.

Comment 19) One commenter states that this rule "will impose substantial economic burdens upon American citizens which will not be imposed upon foreign producers. Consequently, foreign produce will be less expensive than produce grown in the United States."

Response 19) This rule applies equally to domestically-produced and imported produce. Covered entities in the United States and abroad must adhere to the same standards. As such, we do not agree that it will disadvantage United States farms as compared to foreign farms.

With respect to enforcement, FDA intends to use the resources at its disposal to ensure that both domestic and foreign producers are following the requirements of the rule. As discussed in Subpart Q of the rule, our strategy to ensure the safety of produce, both domestically produced and originating from foreign farms, will focus on education, training, and guidance to achieve compliance. This will include outreach to foreign governments. We will also work to provide education and assistance in local languages to

reach farmers exporting covered produce into the United States, including by working with organizations and other sources of information that are familiar and accessible to the produce farming community (such as alliances, international organizations, universities, trade associations, foreign partners, Joint Institute of Food Safety And Nutrition, and federal agencies (such as United States Agency for International Development and United States Department of Agriculture), among others).

Inspections will also play a key role. Under the FD&C Act, FDA has authority to inspect produce farms and can take enforcement action when needed, such as to prevent significant hazards from entering the food supply or in response to produce safety problems. While FDA is not in a position to inspect every foreign farm that produces food for consumption in the United States, the inspections FDA is able to conduct will be bolstered by other efforts, such as the final Foreign Supplier Verification Program rule establishing subpart L of 21 CFR part 1. The FSVP regulation establishes requirements for importers to verify that imported food (including produce) is produced in compliance with the produce safety regulation or is produced in accordance with processes and procedures that ensure the same level of public health protection as is required in the United States.

Comment 20) One commenter references data from the USDA, which estimated that the average net farm income for farmers nationally was 10 percent of sales in 2011, and argues that the estimation implies that for a farm with less than $250,000 in annual sales, complying with the Produce Safety rule requirements may consume more than half of their profits.

Response 20) We have found sources from the USDA that confirm the fact that, for many farms, farming is not the primary source of income (Ref. 8), and that, in general, roughly 90 percent of farm income comes from off farm sources (Ref. 9). However, these statistics refer to total farm income, while our cost estimates are based on sales of produce. We do not include any other farm income sources in our estimations of farms that are covered by this rulemaking; produce sales alone are what determines coverage throughout the analysis.

Comment 21) One comment suggests that FDA has not considered the fact that FSMA regulations are different from USDA GAP (or other third party) audits. Some suggest that FDA allow the use of GAP.

Response 21) See section IV.F. of the final rule where we address comments about existing industry guidelines and certification programs. Where requirements are different for farms already performing GAPs we have estimated the cost for a change in practice. However, if farms are already conducting the required activities through GAPs or some other agreement, we have attempted to remove previously incurred costs out of our analysis.

Comment 22) One comment states that FDA's cost analysis does not differentiate between costs across crops or across production regions.

Response 22) This is true. For a national analysis of the costs and benefits of this rule we are not able to differentiate farms by commodities or agricultural regions. We are aware that there are differences in needs and resources across different farms, and as such we attempt to provide a national average estimate that reflects this variety. Although, the costs are not differentiable by these factors both commodities and regions of production

are taken into account when constructing our costs estimates whenever there are data which allow us to do so.

Comment 23) One commenter states that FDA's estimates do not match with current average costs for the produce sector, and cite things such as "outdated wage rates and inconsistent application of wage rates throughout, and "a lack of cost estimates for replacing tools and equipment that were not able to be brought into compliance with FDA's proposed rule." Another commenter offers an alternative estimation based on more recent BLS data.

Response 23) In an attempt to more accurately reflect the true costs to farms, FDA has updated its wage rates to 2013 levels according to the BLS. Additionally, we now apply a one hundred percent overhead to all wages to more accurately account for the indirect costs of labor which may be incurred. The rule requires that certain tools/equipment must be of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained, and requires keeping tools/equipment clean and in sanitary condition. We expect the replacement of tools/equipment as a result of this rule to be rare, however, as such requirements are sufficiently flexible to accommodate many types of equipment and tools.

Comment 24) A few commenters offer their own estimates of the costs of the produce rule. They state that these estimates are based in "more accurate and current data," and on their own independent research (e.g., interviews). Specifically, they assume that: 1) labor costs are higher, based on updating wage rates from 2000 to 2012; 2) average cost of water sampling is higher, based on a higher expected cost of analysis; 3) covered farms would test their water more frequently (weekly), based on a higher

expected frequency of irrigation; 4) large farms have two irrigation water distribution systems to inspect, based on the assumption that larger farms may have more irrigation facilities than smaller ones; 5) farm owners or managers are responsible for recordkeeping, due to potential liability issues; 6) record keeping hours are much longer, based on interviews with industry associations; and 7) the time per acre it takes to comply with the rule is higher, based on the fact that FDA's costs are calculated using an expected minimum that does not apply to all farms. Overall, these commenters state that FDA needs to perform a more detailed, crop-specific analysis, and not make generalizations for all products and regions. They also suggest that a sensitivity analysis could be beneficial.

Response 24) These analyses provide a number of suggestions for improving the analysis and we have incorporated changes where the data were nationally applicable and relevant. Additionally, we do provide a sensitivity analysis both in this document and in the original PRIA. In response to the individual suggestions: 1) we have updated wage rates to 2013, which more accurately reflects the costs that may be incurred by farmers today; 2) similar to the 25 percent increase in wage rates (from 50 percent overhead to 100 percent), we have increased the estimated cost of a single water test by approximately 25 percent; 3) the weekly testing frequency originally proposed for certain water sources and uses in the 2013 proposed rule have been removed from the final water testing requirements in favor of a tiered testing frequency that results in less frequent testing; therefore we do not estimate that any weekly water testing will occur; 4) we have doubled the time estimated for large farms to inspect their agricultural water systems; 5) while it is true that the owner, operator, or agent in charge of the farm will be responsible

for keeping records, we believe that the actual people creating the records will typically be the farm's workers; 6) while some records may take longer to produce from scratch, we believe, based on a study of industry recordkeeping practices from Economics Research Group (Ref. 7) that our estimated recordkeeping burden is close to accurate; and 7) we believe the time costs estimated throughout the document represent a reasonable average by estimated farm size. Finally, it should be noted that a crop by crop analysis was not feasible given the large number of individual crops covered and the nature of farms that grow multiple crops on the same acres; therefore, we believe our approach, estimating costs to the average covered farm based on inputs, is the most logical way to estimate compliance costs with this rule.

Comment 25) One commenter states that on page 6 of the report, the Farm Supervisor Mean Wage Rate is calculated as $30.26 per hour, while in the section on agricultural water testing, a wage rate of $30.83 per hour is used instead.

Response 25) We have simplified our analysis to incorporate only those wage rates discussed in section 2. Additionally we have updated wage rates to 2013, which more accurately reflects the costs that may be incurred by farmers today.

Comment 26) One commenter states that the probability of other significant events that could impact produce farms and create a need to prevent contamination from sewage is ignored. For example, the commenter notes hurricanes and tornadoes could both generate problems with sewage and septic systems, but the cost of monitoring after these events is not included.

Response 26) We agree that these events can have a significant impact on the actions a farm may take to prevent contamination of their produce. Our analysis of the

cost of the rule, however, takes into account average current farming practices. We are not able to estimate the probability of a natural disaster followed by the expected cost of contamination reduction.

Comment 27) According to one commenter, FDA assumes that it takes one minute to clean and sanitize one tool, and there is one tool per farm job, but sometimes more than one tool is used or it takes longer than 1 minute to clean the tool.

Response 27) For a national analysis of the costs and benefits of this rule, we are not able to differentiate our estimates based on individual cases (i.e., individual jobs). We are aware that there are differences in needs and resources across different jobs, and as such we attempt to provide a national average estimate that reflects this variety. While some tools may take longer to clean, others will take a much shorter time, and certain jobs may not even require a tool at all (e.g., harvesting by hand).

Comment 28) One commenter stated that feedback from several produce industry groups suggests that their crops would require additional irrigation beyond 0.77 acre feet per growing season, and that the amount of water needed from planting to harvest varies significantly by crop.

Response 28) In Table 49 of the original PRIA, we estimate that it takes approximately 2.16 acre/ft. of water to irrigate a single acre using direct water application techniques. Because this estimate comes directly from the 2008 Farm and Ranch Irrigation Survey (FRIS), we retain it in the final analysis (Ref. 10). Additionally, because we do not explicitly examine farms by crop, but are instead tasked with providing the average costs to all farms operating within the US, applying crop-based differences to operations is not possible for this analysis. Finally, our estimate is very

similar to that found by the U.S. Geological Survey, which states the national average application rate for irrigated water in 2005 was 2.35 acre-feet per acre (Ref. 11). This estimate is not preferred because it is not as current, but it provides further support for our retained estimate.

Comment 29) One commenter states that FDA's estimates of the number of not covered and exempt farms by sales class is difficult to verify and analyze because the data does not come from a publicly available source.

Response 29) We get our data to estimate the number of not covered and exempt farms from the National Agricultural Statistics Service's Census of Agriculture, which is publicly available. Summary tables are available at the Census of Agriculture's website (Ref. 12), which allow the public to see the data in summary format. Anyone can apply for access to the micro-data (Ref. 13), which will allow for a full, independent analysis. Due to data restrictions and disclosure concerns, we are not able to provide the full data set ourselves.

Comment 30) One commenter suggests that FDA should consider using a value of eight hours of additional training in food safety, which greatly increases the cost.

Response 30) Table 112 from the PRIA estimates that farm operators are involved in food safety training for a total of eight hours, seven in training and one additional for travel time. These time estimates are retained in the final analysis; however, wage rates have been updated to more accurately reflect the current state of the industry. We do not believe that it will be necessary to further train each worker for eight hours in food safety, once the manager/operator has received the more comprehensive training.

Comment 31) One commenter asks how FDA will determine if a farm is exempt.

Response 31) We are adding a new provision § 112.7 to establish certain recordkeeping requirements in relation to a qualified exemption. Records required under this provision will assist farms in determining whether they are eligible for a qualified exemption and will assist FDA in verifying eligibility.

Comment 32) Several commenters state that a specific type of produce (e.g., apples) has never been associated with food borne illness outbreaks, which means that, in the case of this type of produce, in the commenters' view, there are no benefits from the rule. Some suggest that FDA should look at comparative benefits by type of produce. Others say that grouping high and low risk commodities together in our analysis distorts the risk, and therefore the benefits estimation. In addition, several commenters state that a specific part of the rule (e.g., agricultural water testing) will provide no benefit.

Response 32) Although certain commodities have never been implicated in an outbreak during the time period analyzed, there are numerous outbreaks which occurred in association with produce commodities that had previously not been implicated in an outbreak. These cases are of great public health concern and failing to take into account the sporadic nature of foodborne illness may miss a large potential threat to public health. Table 8 provides a pathway specific breakdown of the implicated causes of outbreak illnesses. Additionally, the rule focuses on the potential routes of contamination of produce, and covers specific practices, procedures, and processes on a farm, all of which may present significant risk, regardless of the commodity grown, harvested, packed, or held at the farm. See discussion in section IV of the rule.

Comment 33) Several commenters state that FDA has not provided "real" evidence of a public benefit to this rule.

Response 33) The estimation of benefits are based on the most accurate and up-to-date data on produce related foodborne illness. Additionally, the estimates of effectiveness are based on a number of studies, citing experts in produce related foodborne illness, which all point to these safety measures having a measureable effect on the number of produce related foodborne illness.

Comment 34) Many sources state that FDA hasn't done a cost-benefit analysis for the supplier program. Comments suggest that FDA doesn't present any information as to how that program will affect farms, especially those already affected by the produce rule.

Response 34) We interpret these comments to be referring to requirements of the PCHF and FSVP rules, not this produce safety rule. There are only a few specific requirements in this rule that relate to entities in a farm's supply chain other than the farm itself, and we do not consider any of these requirements to constitute a "supplier program." The relevant provisions are: § 112.2(b)(2) for produce eligible for exemption because it receives commercial processing to adequately reduce pathogens (requiring certain disclosures to, and written assurances from, a farm's customers related to such processing); § 112.60(b)(1) for treated biological soil amendments of animal origin received from third parties (requiring covered farms to keep certain documentation related to the third party's treatment and handling of such materials); § 112.142(b)(2) relating to seeds or beans used for sprouting that may be contaminated with a pathogen (requiring sprouting operations to report that information to seed/bean suppliers under certain circumstances); and §§ 112.142(e) and 112.150(b)(1) allowing sprouting operations to rely on prior treatment of seeds or beans for sprouting conducted by a grower, distributor, or supplier with appropriate documentation. The costs and benefits of

these provisions have been included in our analysis for this rule. The costs and benefits associated with the supplier programs in FDA's PCHF and FSVP regulations are discussed in the FRIAs related to those rules.

Comment 35) Many cite the benefits of diversification, and say FSMA should incentivize diversification, not discourage it. Similar comments are made about the benefits of organic food, rich top soil, etc.

Response 35) While FDA believes there may be benefits to the farmer and farmland of diversification of crops and organic farming, to our knowledge, there are no quantifiable impacts on the human health burden associated with produce from these two activities. Additionally, the primary goal of our integrated approach to this rule was to not single out any specific crop or to limit diversification of crops in any way. See section IV.I. of the rule.

Comment 36) One comment states that no real cost-benefit analysis has been done because we perform a qualitative risk analysis. This comment further suggests that we have not complied with Executive Order 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives.

Response 36) The Qualitative Assessment of Risk (QAR) is only one piece of information that helped to inform both the rule and the quantified estimation of benefits. FDA believes that we have fulfilled all the requirements for a complete regulatory impact analysis required under the pertinent Executive Orders.

Comment 37) Several commenters suggest that FDA significantly overestimated the benefits of the proposed rule, and made "unjustified leaps of logic". Specifically, they state that applying Scallan's multiplier to estimate foodborne illness leads to an

overestimation of foodborne illnesses attributed to produce, and that our estimates were significantly higher than Scallan's (Ref. 31). They suggest that FDA's use of this multiplier is unjustified, and that we should look at more than one study. They also criticize FDA's use of a "shaky survey" to estimate the effectiveness of the rule, as well as the fact that FDA extrapolates to all produce some results based on the leafy greens and tomato industries, which are associated with the highest number of outbreaks.

Response 37) FDA does not believe that it has overestimated the benefits of this rule. We acknowledge that some assumptions were made when data were less than robust, specifically when estimating the 'unidentified' burden of illnesses. To alleviate this concern we provide a more conservative estimate, which reduces our estimated number of unidentified illnesses. To get this number, we multiply the total number of estimated preventable illnesses attributable to FDA regulated produce by 4 to obtain a number of unidentified illnesses which is consistent with Scallan, et al., who estimate that unidentified illnesses make up about 80% of all foodborne illnesses. Additionally, we only implicitly, not directly, apply Scallan et al.'s multiplier in the estimation of quantified benefits. We use only the annual incidence of foodborne illness by pathogen to compute the number of annual illnesses associated with produce, although this does implicitly have a pathogen multiplier that is estimated by Scallan using active and passive surveillance.

Comment 38) One commenter suggests that FDA has overestimated the benefits of the rule, and proposes omitting Fresh Cut produce from the benefits, as well as unidentified illnesses, which may be "too speculative." They offer their own estimates, which suggest that the costs will overtake the benefits with the omission of Fresh Cut and

unidentified illnesses. Other commenters recommend removing Fresh Cut produce from the estimation of illnesses due to RACs, and state that Fresh Cut produce most likely is contaminated outside of the farm and in the processing facility.

Response 38) FDA agrees that Fresh Cut should be omitted from the benefits analysis of the produce rule. We have, therefore, moved Fresh Cut from this FRIA related to the produce safety rule to the cost-benefit analysis related to PCHF rule. In terms of the unidentified illnesses, we have refined our estimation to be more conservative in terms of the number of unidentified illnesses. However, we have included an alternative calculation of benefits without unidentified illness in Table 11, which shows that omitting unidentified illnesses does not drastically change the benefits, and does not cause the costs to overtake the benefits.

Comment 39) One commenter states that many covered farms in North Carolina have made significant capital outlays in equipment appropriate to the scale of their operations, and will incur significant expenses in order to retrofit existing infrastructure. The commenter requests that FDA grandfather capital equipment for an additional seven years.

Response 39) We realize that replacing capital equipment, which typically has a long lifetime, would pose a significant burden to farmers; however, the rule has been written in a way that we expect to minimize such needs. The rule is not prescriptive as to the nature of tools or equipment used in covered activities by covered farms and, therefore, as long as relevant tools and equipment are of adequate design, construction, and workmanship to enable them to be adequately clean and properly maintained, it will not be necessary to replace a farm's tools or equipment to comply with this rule. To that

end we have estimated the cost of cleaning current capital equipment, rather than the replacement value. Additionally, to provide increased flexibility to all farms, we stagger compliance dates (see section XXIV of the rule).

Comment 40) One commenter states that the PRIA should reflect net profit instead of sales.

Response 40) We prefer sales rather than net profit because sales data serve as a proxy for total produce volume on a farm. Although we realize this is an imperfect measure, net profits could significantly understate the volume of food leaving any particular farm. Additionally, data on sales is easily observable and shared by many farmers, where information on profits is not.

II. Final Regulatory Impact Analysis

A. Background

Table 2 presents a side-by-side comparison of the estimated costs of the proposed rule and updated estimated costs of the final rule. To present a valid comparison, we have updated the (previously published) estimated costs of the proposed rule using the latest data and techniques. Estimated total steady state costs to domestic operations, using a 7 percent discount rate over 10 years, are $530 million for the proposed rule, and $560 million for the final rule.

Table 2. Comparison of Costs of the Rulemaking across Data Sources (in millions)

Cost Sections	Original Analysis With Updated Data	Final Analysis
Personnel Qualifications and training	$124.12	$187.38
Health and Hygiene	$141.87	$135.61
Agricultural water	$58.94	$37.07

Biological soil amendments of animal origin	$9.19	$2.47
Domesticated and wild animals	$37.78	$15.86
Growing, harvesting, packing, and holding activities	$0.52	$2.25
Equipment, tools, buildings, and sanitation	$72.99	$118.69
Sprouting operations	$7.51	$6.77
Recordkeeping	$40.18	$27.49
Administrative cost to learn the rule	$34.31	$23.25
Corrective steps	$2.01	$3.25
Variances	$0.10	$0.11
Total Costs (annual in millions)	$529.51	$560.19
Net present value (7 percent)	$2,929	$15,992
Annualized costs (7 percent)	$417	$366

Note: This table utilizes two different timing scenarios when calculating NPV. For the original analysis with updated data large farms are given an extra year for compliance, small farms are given two years, and very small farms are given three. The timing for the current analysis is more complex, and fully laid out in Table 4 of this analysis. Additionally the new timing allows farms more time to implement requirements, thus lessening the burden when discounted.

Using the steady-state comparison illustrated in Table 2, the final rule has estimated costs ($560.16 million annually) that are 21.9 percent higher than the estimated costs of the proposed rule ($459.56 million annually). This 21.9 percent increase in estimated costs is attributable to the changes in the provisions of the rule from the proposal to the final stage. Between the publication of the proposed rule and the final rule, however, we updated some of the data and techniques used to estimate costs. We have updated wage data, updated the way we account for overhead costs in relation to wages, updated data on the number of operations affected by the rule, and we adopted new techniques for modeling some of the provisions, based on comments and other information gathered since the publication of the proposed rule. The published estimate of the annualized costs of the proposed rule was $459.56 million using a 7 percent discount rate (Ref. 6) The adjusted estimate of $529.51 million in annual costs of the proposed rule in Table 2 above reflects a 15.2 percent increase compared to the previous

estimate, and this 15.2 percent increase is attributable to changes in the data and techniques used in our cost estimation, not changes in the provisions of the rule.

One significant cause for the increase in our estimated steady state cost is the change in our estimate of costs of labor hours. Following DHHS guidelines, we corrected our estimate for computing overhead costs to include a 100 percent adjustment relative to the money wage, rather than the 50 percent adjustment used in the original estimates. New DHHS guidelines, for computing labor costs recommend (based on general industry data) benefits plus other overhead costs equal 100 percent of pre-tax wages (Ref. 14). This correction results in a roughly 13.3 percent ($66 million) increase in estimated costs. We also updated the base year for computing wage rates from 2010 to 2013, the most recent year for which the Bureau of Labor Statistics has complete wage rate data. This update alone results in a 2.9 percent ($15.8 million) increase in costs. The sum effect of the two updates to the wage estimates results in a roughly 16 percent ($81.8 million) change in estimated annualized costs.

We obtained more recent data for the farm count from the USDA, National Agriculture Statistical Service's (NASS) 2012 Census of Agriculture (Ref. 15) Our estimate of the total farms covered decreases from the 40,496 estimated in 2007 to 35,029 using the latest census numbers. The new farm count results in a 9 percent (roughly $55.2 million) net decrease in costs.

Based on data and information gathered from and in response to public comments, as well as other new sources, we changed the way we modeled the cost estimates of a number of provisions. For example, we have increased the estimate for the number of operational days where the harvested or harvestable portion of produce is exposed,

increased the time estimated to inspect agricultural water sources and systems, decreased the time estimated for farms not covered or eligible for a qualified exemption to read and learn about the rule, and increased the average estimated cost of environmental testing for sprout operations and water testing for all covered farms. In addition, some of the proposed provisions in the 2013 proposed rule and the supplemental notice have changed for this final rulemaking. For example, the inclusion of an allowance for microbial die-off in relation to use of agricultural water during growing of covered produce (other than sprouts) using a direct water application method, has allowed us to reduce some of the burden to farmers. These adjustments led to changes in total estimated costs. The net effect of all of these changes from the proposed rule is a roughly 16.1 percent increase (almost $73.4 million) in total estimated costs.

The combined effect of updating and correcting our method for estimating overhead costs, using the most recent baseline for calculating wage rates, the most recent farm count, and other adjustments to estimates based on public comment and changes to the regulatory requirements, change the steady state estimate of total domestic costs of the proposed rule from approximately $459.56 million (the originally published estimate with no update to wages or data) to $560.16 million, a 21.9 percent increase.

We use the revised wage rates, most recent base year, the revised farm count, and other adjustments throughout our analysis of the final rule.

The estimated benefits of the proposed rule and the updated estimated benefits of the final rule also differ. In all, the estimated number of prevented illnesses decreases by about two-thirds from the proposed rule to the final rule, while the total estimated benefits increase by about one-third. This somewhat counterintuitive change is due to an

increase in the dollar costs of illnesses, combined with new data and estimation methods for the number of illnesses.

The final rule uses a higher VSL and QALD than the proposed rule. The new VSL values are taken from Robinson and Hammitt (2015) (Ref. 16). They present a VSL of $9 million and a QALD value of $1,260, whereas the proposed rule uses a VSL of $7.9 million and a QALD value of $586. The updated values of both QALD and VSL lead to increases in the quantified burden of illnesses. The increase in QALD implies particularly large increases for illnesses that last for long periods of time, while the increase in VSL leads to greater increases when the percentage fatality rate associated with a particular illness is high.

An increase in data range, combined with a more conservative estimate of unidentified goods, leads to an increase in more burdensome illnesses, but a decrease in less burdensome illnesses (i.e., unidentified illnesses). The data used in the final rule covers 2003 through 2012, while the data in the proposed rule only covers 2003 through 2008. Because 2008 through 2012 saw the relative incidence of outbreaks associated with produce RACs rise, our estimated number of illnesses, which is based on the ratio of reported FDA-regulated produce RAC outbreaks to total CDC identified illnesses in the same time period, increased. This increase, however, was somewhat offset by the large decrease in unidentified illnesses. In the final rule, we employ the more conservative estimate, of the two published in the original analysis, of unidentified illnesses, which have a very low estimated cost per illness. This change strictly drives the number of unidentified illnesses down. We also omit outbreak illnesses associated with Fresh Cut

products, as they are now addressed in the Preventive Controls rule, which further reduces the estimated number of illnesses.

B. Need for Regulation

The need for this rule stems from a market failure caused by the asymmetric information associated with the safe production and consumption of raw agricultural commodities that are covered produce. If covered farms do not apply the socially optimal level of food safety practices, they create a potentially harmful situation for consumers, which is largely unobservable to consumers. There is not a sufficiently significant direct link between poor produce safety practices and food-related illnesses, which suggests that food safety is not an experience good (product for which characteristics, such as quality or price, are difficult to observe in advance, but can be ascertained upon consumption); with rare exceptions, the link between consumption of raw agricultural products and experiencing a food-related illness cannot be determined by consumers.

This final rule aims to reduce the effects of the information asymmetry by requiring certain science-based minimum standards for the safe growing, harvesting, packing, and holding of covered produce across all covered farms, thereby reducing foodborne illnesses from this source.

Using a science-based framework we characterize the magnitude of the public health risks associated with the consumption of produce, and establish specific standards that address the risks of microbial contamination from significant agricultural inputs (labor, water, biological soil amendments of animal origin, and tools and equipment), unsanitary conditions in buildings, and wild and domesticated animals, as well as the risks of microbial contamination in the production of sprouts. We provide a framework to

evaluate the effectiveness of the rule for addressing the public health risks associated with biological hazards in produce.

We define thresholds for different farm size categories that will be covered, with each farm size category linked to a quantitatively defined level of public exposure to risk. We estimate the costs of each provision by farm size.

The rule also responds to lower-than-socially-optimal private incentives to provide safe practices. These are a result of uncertainties in the individual farm's understanding of the magnitude of the public health risk from the consumption of produce grown on their farm, as well as the effectiveness of measures and controls at addressing that risk. At this point in time, public health surveillance is often unable to determine whether an illness resulted from a foodborne pathogen or which particular food or food category may have served as the vehicle for the pathogen that caused the illness. It is also frequently unable to identify the specific farm or practice implicated in a produce-associated outbreak. This may result in the underestimation by producers of the costs to society from consuming produce and may cause them to discount the value of food safety practices and to provide less-than-the-socially optimal amount.

In addition, this rule responds to a statutory mandate in Section 419 of the Federal Food, Drug, and Cosmetic Act requiring that the Secretary of HHS adopt a regulation setting forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including those determined to be reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into fruits and vegetables, and to provide reasonable

assurances that the produce is not adulterated under Section 402 of the Federal Food, Drug, and Cosmetic Act.

C. Purpose of the Rule

The rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The rule addresses microbiological risks from certain routes of contamination, including workers, agricultural water, biological soil amendments of animal origin, and tools and equipment, unsanitary conditions in buildings, and wild and domesticated animals during growing, harvesting, packing, and holding activities of covered produce, including sprouts.

D. Inputs and Assumptions

The following section outlines some of the standard information utilized throughout the remainder of the analysis. First, we present all standard cost estimates and assumptions that allow us to calculate the costs of implementation at the farm level. This section includes things like standard labor costs and data sets used to inform estimates and assumptions. Next, we provide information on the coverage of the analysis and how it relates to the US produce industry as a whole. Finally, we provide some information on the timing of both costs and benefits of this regulation. Detailed discussion of how these estimates and data are used to estimate industry costs are included in the detailed analysis of costs section.

Measuring Costs

We measure costs based on the best available information from government, industry, and academic sources. We list some common conventions used throughout the cost analysis here.

All wage rates used come from the Bureau of Labor Statistics (BLS), Occupational Employment Statistics, May 2013, National Industry-Specific Occupational Employment and Wage Estimates, under NAICS 11 – Agriculture, Forestry, Fishing, and Hunting (Ref.17). Wages are increased by 100 percent to account for overhead.

- Farm Operator or Manager Mean Wage Rate: Our estimate for the mean hourly wage rate for a farm operator or manager is $72.12 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for Farmers, Ranchers, and Other Agricultural Managers working in the agriculture industry as shown in (Ref.17) of $36.06 and we add 100 percent for fringe benefits and other overhead costs ($36.06) for a total estimate of $72.12.
- Farm Supervisor Mean Wage Rate: Our estimate for the mean hourly wage rate for farm supervisors is $42.74 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for First-Line Supervisors of Farming, Fishing, and Forestry Workers as shown in (Ref.17) of $21.37 and we add 100 percent for fringe benefits and other overhead costs ($21.37) for a total estimate of $42.74
- Farm Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for farm workers (nonsupervisory) is $18.56 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for Farmworkers and Laborers, Crop, Nursery, and Greenhouse as

shown in (Ref.17) of $9.28 and we add 100 percent for fringe benefits and other overhead costs ($9.28) for a total estimate of $18.56.

We use the 2012 Census of Agriculture farm-level database to derive the total number of domestic farms (including greenhouses) that grow produce, the number of produce acres operated, the amount of labor employed, and their food sales; to estimate the number of farms that are eligible for the qualified exemption created by section 419(f) of the FD&C Act; and to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices). (Ref.18)

We use FDA's Operational and Administrative System for Import Support (OASIS) database to estimate the number of foreign farms that will be covered by the rule. (Ref.19)

We use the following surveys and literature where possible to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices):

- 1999 Fruit and Vegetable Agricultural Practices Survey (FVAP) (Ref.20)
- Farm Food Safety Practices: A Survey of New England Growers (Ref.21)
- Growers' Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs (Ref.22)
- USDA Agricultural Marketing Service (AMS) Fresh Produce Audit Verification Program, including commodity-specific audits for the tomato and mushroom industries (Ref.23).
- Food safety regulations and marketing agreements: Florida Tomato Regulation (Florida Rule 5G-6.011) (Ref.24), and the Leafy Greens Marketing Agreements in

California (Ref.25) and Arizona (Ref.26) (together, sometimes referred to as "LGMA").

- National Agricultural Workers Survey (NAWS), U.S. Department of Labor, Public Access Database, 1989 to 2006, for years 2005 to 2006 to estimate the number of workers that are employed on multiple farms, and the number of workers employed by farm task; it is also used to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices) (Ref.27)

We annualize any one time costs over 10 years at discount rates of 7 percent and 3 percent. For ease of reading, in the main document, we report only results derived from the 7 percent discount rate. In the sensitivity analysis and summary sections, we also report results derived from the 3 percent discount rate

To classify farms that are covered by the rule by size, we identified farms as very small when they generate over $25K but no more than $250K annually in produce sales, small when they generate over $250K but no more than $500K annually in produce sales, and large when they generate more than $500K annually in produce sales.

We estimate that very small farms operate 100 days out of the year where the edible portion of produce may be exposed, small farms operate 150 days, and large farms operate 200 days (non-consecutive).[2]

We estimate that the farm operator or manager is the person responsible for training on all farms.

[2] This estimate is based on annual planting data from USDA (Ref.18). This estimate is based on annual planting data from USDA (Ref.18).

For the purposes of this analysis, we use the term post-harvest activities to refer to all covered activities that occur after produce is removed from the growing area. We note that for the purposes of the rule, the term "harvesting" is broad enough to encompass some of these activities. We do not use the term "harvesting" in the same sense here but rather use it to refer only to removing produce from the growing area.

We use FDA's Evaluation of Recordkeeping Costs for Food Manufacturers, February 13, 2007, for our estimates for the hours necessary to perform the various recordkeeping functions, for our estimate of the frequency of recordkeeping by record type; and the average minutes spent keeping records by record type. Recordkeeping estimates in this report are based on expert opinion and an extensive literature review (Ref.7).

Coverage of the Analysis

1. All Farms

The rule applies to covered farms that grow covered produce including fruits and vegetables such as berries, leafy greens, herbs, and sprouts. It applies equally to farms located domestically and farms in foreign countries exporting covered produce to the US. There are approximately 121,116 farms in the U.S. that grow produce for sale excluding sprouting operations, which we analyze separately (Ref.18). This number was derived using the 2012 Census of Agriculture and includes farms with on-farm packing, greenhouses, farms eligible for qualified exemption (§ 112.5), farms that grow covered produce for commercial processing (§ 112.2(b)), and farms that are not covered by the rule (§ 112.4). We estimate that there are approximately 475 sprouting operations, which include farms eligible for qualified exemptions, and sprouting operations that are not

covered by the final rule. Sprouting operations will be considered in the sprouts section. We estimate that there are 70,395 foreign farms that will offer covered produce for import into the U.S., which includes farms eligible for qualified exemptions, and farms that are not covered by the final rule (Ref.19). This number was estimated using the number of foreign produce manufacturers in the OASIS database from fiscal year 2008, and multiplying it by the ratio of domestic farms to domestic manufacturers in the U.S.

2. Eligibility for Exemption and Corresponding Modified Requirements

The rule identifies certain farms and certain produce that are eligible for exemptions provided certain requirements are met. The eligibility for an exemption is established under two criteria: (1) the monetary value of all food sold on the farm and direct marketing of a portion of the food, and (2) produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g. a microbial kill-step). Farms, or produce, that qualify for either exemption are subject to a subset of the administrative provisions of the regulation, which are discussed in detail in the summary of records section of this analysis.

a. Monetary value of all food sold and direct farm marketing ("Qualified Exemption")

Farms are eligible for a qualified exemption if the average value of their food sales over the last 3 years was less than $500,000 and if more than 50 percent of their food sales were direct sales to qualified end-users as that term is defined in the rule (see §§ 112.3(c), 112.5, 112.6, and 112.7). "Food" is defined in § 112.3(c) and Section 201(f) of the Federal Food, Drug, and Cosmetic Act. In order to estimate the number of farms that meet this qualification, we use data from the 2012 Census of Agriculture. We

estimate that there are approximately 3,134 total farms, including 171 sprouting operations, eligible for the qualified exemption after accounting for farms that are not covered, which is explained in part c. of this section, "Coverage of the Analysis".

b. Commercially processed produce

Produce that is commercially processed in a manner so as to adequately reduce pathogens is eligible for exemption from the rule provided that certain required steps are taken (see § 112.2(b)). Processing of low acid or acidified foods (in compliance with applicable FDA regulations in Parts 113 and 114) and processing of juice (in compliance with applicable FDA regulations in Part 120) are examples of eligible processing methods. Produce that is destined for the frozen or fresh-cut markets is typically not eligible since there is generally no adequate reduction of pathogens in the processing method.

We estimate the number of farms whose covered produce would qualify for this exemption using production information, specifically the amount sold to fresh versus processed markets, available in published reports for citrus, non-citrus, berries, vegetables, and tree nuts from the 2012 Census of Agriculture (Ref. 15). There are approximately 3,199 farms whose produce would qualify for this exemption, after accounting for farms that are not covered, and farms that do not also grow other covered produce. Farms that grow covered produce that is eligible for the commercial processing exemption and that also grow other covered produce will be subject to the regulation only with respect to their other covered produce.

3. Farms and produce not covered

Farms not covered by the regulation are those with an average annual monetary value of produce sold during the previous three-year period of $25,000 or less (see § 112.4). Produce that is rarely consumed raw, such as beets, potatoes, sweet corn, and sweet potatoes, is also not covered by the rule (the rule includes an exhaustive list of such produce, from which we have provided only a few examples here) (see § 112.2(a)(1)). A farm that only grows these commodities, and does not also grow covered produce, will not be subject to the regulation. Farms that grow these commodities and covered produce will be subject to the regulation only with respect to their covered produce. Produce for personal or on-farm consumption is also not covered by the regulation (see § 112.2(a)(2)). A farm that only grows produce for personal or on-farm consumption, and does not also grow covered produce, will not be subject to the regulation. Farms that grow produce for personal or on-farm consumption and covered produce will be subject to the regulation only with respect to their covered produce.

The USDA National Commission on Small Farms defines a small farm as a family farm with less than $250,000 total monetary value of food a year (Ref.28). The Commission's recommendation was based on the reasoning that these farms are the likeliest to exit the industry, and have the greatest need to improve net farm incomes since they receive only 41 percent of all gross sales revenue, but make up 94 percent of all U.S. farms (Ref.28). We use the $250,000 monetary value of produce threshold for the upper end of our very small farm category. Covered produce farms below this threshold make up 17 percent of produce acres, and 87 percent of all produce farms. We use the monetary value cutoff of $500,000 from the qualified exemption for direct farm marketing in § 419(f) of the FD&C Act as the upper end of our small farm category.

Farms below this $500,000 threshold make up 24 percent of produce acres and 92 percent of all produce farms. Farms that are not covered because they have no more than $25,000 in average annual monetary value of produce make up about 5 percent of produce acres, but 62 percent of all produce farms.

d. Summary of Farms Eligible for Exemption, Farms Not Covered, and Produce Not Covered

Table 3 shows the total number of domestic farms, the number of covered and exempt/not covered farms, and a breakdown of the number of farms that are eligible for a qualified exemption and that are not covered by the rule. All farm numbers are calculated from the NASS 2012 Census of Agriculture (Ref.18). Not accounting for sprouts, we estimate that there are a total of 21,666 farms that would be eligible for the qualified exemption, and 18,381 of those farms generate $25,000 or less in produce sales and therefore are not covered. Similarly, we estimate that there are a total of 4,153 farms all of whose covered produce would be eligible for the commercially processed produce exemption, and 954 of these farms generate $25,000 or less in produce sales and therefore are not covered. We estimate there are 16,190 farms not covered because they grow produce that is rarely consumed raw, and 11,518 of those farms generate $25,000 or less in produce sales and therefore are not covered. Lastly, there are 44,078 farms not covered under this rule because they generate $25,000 or less in produce sales and therefore are not covered. After accounting for those farms that are eligible for a qualified exemption and also generate $25,000 or less in produce sales and therefore are not covered, we estimate that a total of 86,087 farms (21,666 + 4,153 + 16,190 + 44,078) are

not covered under the rule. The numbers for sprouting operations are covered in the sprouts section.

Table 3. Breakdown of Covered and Exempt Farms

	$25K or less monetary value of produce produced	**very small**	**small**	**large**	**Total**
Total Produce Farms	**74,931**	**30,952**	**5,128**	**10,105**	**121,116**
Total Produce Acres	**410,319**	**1,050,000**	**580,969**	**6,380,000**	**8,422,103**
Qualified exemption farms	18,381	3,015	270	-	21,666
% total produce acres	1%	1%	1%	-	3%
Exempt produce – commercially processed	954	1,991	448	760	4,153
% total produce acres	1%	2%	1%	8%	12%
Not covered produce - rarely consumed raw	11,518	3,165	454	1053	16,190
% total produce acres	1%	2%	1%	9%	14%
Not covered farms –$25,000 or less monetary value of produce	44,078	-	-	-	40,078
% total produce acres	2%	-	-	-	2%
Total Covered Farms	**-**	**22,781**	**3,956**	**8,292**	**35,029**
% total produce acres	**-**	**7%**	**4%**	**58%**	**70%**

The 21,666 ‘qualified exemption’ farms, who have less than $500K in average annual monetary value of food sales over a rolling 3-year period and sell over half of their food directly to qualified end-users, account for about 3 percent of all US produce acreage. The 74,931 farms that generate $25,000 or less in produce sales, account for only 5 percent of all domestic produce acreage, but for 62 percent of all farms that grow produce. They have average produce sales of $6,539 per farm and grow an average of 5.5 produce acres. After accounting for farms that would not be covered because they grow produce that is rarely consumed raw or that receives commercial processing, qualified exemption farms still account for about 2 percent of all covered domestic

produce acreage. After accounting for the farms that are eligible for a qualified exemption or that grow produce that is rarely consumed raw or commercially processed, then the leftover 44,078 not covered farms only account for about 2 percent of all domestic produce acreage. In total, the rule covers about 29 percent of all domestic produce farms, and about 94 percent of all domestic produce acres that are not dedicated to growing commodities rarely consumed raw or that will receive commercial processing.

Timing of Costs and Benefits

Because the timing of the rule's compliance dates varies across provisions, by farm size, and for sprouts, it is necessary to discount these costs and benefits accordingly, as neither will be realized immediately. Table 4 presents the timing of all costs and benefits as they accrue across farm sizes for the first ten years after publication of this final rule. Zero costs and benefits are estimated to be incurred by covered farms in the first two years following publication, because all farms are given two years to implement the provisions of the rule (except with regard to sprouts, discussed separately below). In addition to this, all small farms are given an additional year and very small farms are given two additional years to implement the required provisions. Finally, all farms, regardless of size are given an additional two years from their specific compliance date to implement certain required water provisions (except with regard to sprouts).

In addition, the timing for sprout operations is different from other farms. Large sprouting operations have one year to comply with the rule, small sprouting operations have two years, and very small sprouting operations have three years, with no additional time for any particular provisions.

Finally, qualified exempt farms will have to begin complying with the record retention requirement for records supporting eligibility in § 112.7(b) upon the effective date of the rule, and with the modified requirement in § 112.6(b)(1) on January 1, 2020. Otherwise, qualified exempt small farms will have three years to comply with the remaining modified requirements in §§ 112.6 and 112.7, and very small qualified exempt farms will have four years. We do not explicitly estimate a cost to keeping the records required by 112.7(b), as we expect that such records would be kept under normal business practices.

Table 4. Timing of Produce Costs and Benefits

Farms	Year1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Covered Farms										
Very Small	--	--	--	--	Costs/ Benefits Less Water[1] (CBLW)	CBLW	Full Costs/ Benefits (FCB)	FCB	FCB	FCB
Small	--	--	--	Costs/ Benefits Less Water[1] (CBLW)	CBLW	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB
Large	--	--	Costs/ Benefits Less Water(CBLW)	CBLW	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB
Covered Sprout Operations										
Very Small Sprouts	--	--	--	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB	FCB
Small Sprouts	--	--	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB	FCB	FCB
Large Sprouts	--	Full Costs/ Benefits (FCB)	FCB	FCB	FCB	FCB	FCB	FCB	FCB	FCB

Exempt Farms										
Very Small Exempt	--	--	--	--	Full Costs (FC)	FC	FC	FC	FC	FC
Small Exempt	--	--	--	Full Costs (FC)	FC	FC	FC	FC	FC	FC
Large Exempt	--	--	Full Costs (FC)	FC	FC	FC	FC	FC	FC	FC

Note: Certain water testing-related provisions are delayed by two years from initial compliance dates.

Throughout the remainder of this document, we estimate the annual costs of compliance across farm sizes and provisions, as well as the benefits that are likely to occur; these are the primary estimates presented in the benefits or specific costs calculations. Following this, to reflect the nature of the way these costs and benefits will be realized, we take a net present value (NPV) over these 10 years for both costs and benefits, and we annualize them according to the table above, using both a 3 and 7 percent discount rate. Both costs and benefits are discounted in the same manner to provide easily comparable annualized estimates.

E. Benefits of the Rule

The primary benefits of the provisions in this rule are an expected decrease in the incidence of illnesses relating to produce from microbial contamination. For the purpose of this analysis, we develop a conceptual framework that describes how implementing this rule is likely to reduce the level of foodborne illness.

1. Baseline Risk of Foodborne Illness[3]

[3] The estimated burden of illness and subsequent estimations of rule benefits include illnesses occurring in the U.S. tied to imported produce. We do not attempt to estimate the benefits that would accrue due to the mitigation of produce related illness in other countries due to improvements in the safety of U.S. exports or produce grown and consumed in other countries on farms covered by the rule. A rough estimate of costs

To estimate the number of baseline illnesses attributable to produce from microbial contamination only, we begin with only those outbreaks we can directly attribute to FDA-regulated produce that has suffered microbial contamination. Table 5 presents all outbreaks, organized by produce commodity and pathogen, which can be linked to microbial contamination of produce raw agricultural commodities (RAC) other than sprouts, and sprouts (treated separately), based on illnesses recorded in FDA's outbreak database (Ref. 29). This does not include Fresh Cut (FC), which are not RACs. In total, there are 69 outbreaks, 7,050 illnesses, and 46 deaths in the FDA database attributable to FDA-related produce. This averages out to about 7 outbreaks, 705 illnesses, and 4.6 deaths per year observed in the outbreak database.

The data span of 2003-2012 is utilized for this analysis because it represents the most current, and comprehensive data available. We are unable to look at years beyond 2012, because the full outbreak data, from CDC, has not been completely collected, sorted, cleaned, and made available for public use. Additionally, collection methods by both FDA and CDC have improved vastly in recent years, and data further back may be more subject to underreporting biases. It is important to note that our data span differs from that of the PRIA (Ref. 6), which uses the years, 2003-2008. This drives up the raw numbers of outbreaks, cases, hospitalizations, and deaths in this final RIA, but does not necessarily impact our annual estimates. The fact that the years 2008 through 2012 saw a higher relative incidence of FDA covered RAC attributable illnesses than the previous years does drive up the ratio of reported FDA RAC outbreaks to total CDC identified

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can be found in the Unfunded Mandates section.

illnesses. The implications of extending the outbreak data to 2012 are further discussed in the Uncertainty and Sensitivity Analysis section.

Table 5. FDA Outbreak Data, 2003-2012

Outbreak Data Attributed to Produce RACs Other Than Sprouts 2003-2012					
Commodity	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
berries	*Cyclospora*	2	67	2	0
berries	*Salmonella*	2	20	1	0
green onion	*Hepatitis A*	1	919	128	3
herb	*Cyclospora*	2	622	1	0
herb	*E. coliO157:H7*	1	108	8	0
leafy greens	*Cyclospora*	1	38	0	0
leafy greens	*E. coliO157:H7*	3	60	15	0
leafy greens	*Salmonella*	1	15	1	0
melon	*Listeria monocytogenes*	1	147	143	33
melon	*Salmonella*	8	514	140	6
melon	*Shigella sonnei*	1	56	3	0
nut*	*E. coliO157:H7*	1*	8*	3*	0*
nut	*Salmonella*	2	95	12	1
other	*Cyclospora*	2	172	0	0
other	*Salmonella*	6	1925	370	2
tomato	*Salmonella*	8	661	80	0
unknown	*Salmonella*	6	860	132	0
RAC Total		**48**	**6287**	**1039**	**45**
Outbreak Data Attributed to Sprouts, 2003-2012					
sprout	*E. coliO157: NM (H-)*	3	36	3	0
sprout	*E. coliO157:H7*	2	27	5	0
sprout	*E. coliO26*	1	29	7	0
sprout	*Listeria monocytogenes*	1	20	16	0
sprout	*Salmonella*	14	651	56	1
Sprout Total		**21**	**763**	**87**	**1**
Total		**69**	**7050**	**1126**	**46**

Note: The E. Coli nut outbreak is associated with hazelnuts, which are not covered by the final rule (they are exempt as rarely consumed raw under § 112.2(a)(1)). Therefore we do not include this outbreak in calculating the estimated benefit of the rule.

Table 6 presents the estimation of the total number of illnesses attributable to produce RACs other than sprouts based on FDA outbreak data combined with CDC outbreak data (Ref. 30) and applied to Scallan, et al.'s estimate of the total number of foodborne illnesses (Ref.31). To estimate the number of total illnesses associated with

FDA regulated produce, we employ a two-step calculation, fully explained in the Preliminary Regulatory Impact Analysis (Ref. 6): First, to determine the percent of illness attributable to produce we examine FDA specific outbreak data and the whole universe of identified pathogen illnesses, accounting for all outbreaks associated with an identified food vehicle. Dividing the number of observed FDA-regulated produce-associated illnesses by the total outbreak illnesses, gives us the percentage attributable to FDA-regulated produce. This number is then multiplied by Scallan, et al.'s estimate of the total annual incidence of each specific foodborne pathogen (Ref.31). This step corrects for numerous downward biases in the CDC database of illnesses such as under-reporting and under-identification of a foodborne illness. Multiplying the percentage attributable to FDA-regulated produce by the annual incidence yields the annual estimated illnesses attributable to FDA-regulated produce.

Dividing the number of produce acres associated with covered farms by the number of produce acres more susceptible to contamination resulting in preventable illness (i.e., produce that is not commercially processed or rarely consumed raw), we find that approximately 94.2 percent of produce acres associated with preventable illness are covered by the produce rule. This means that 5.8 percent of produce associated with illnesses potentially preventable by the rule is exempt or not covered. If the marginal risk of illnesses associated with a unit of output were distributed uniformly across farms within a given commodity,[4] then we could see a total reduction in preventable illnesses of

[4] There has been no evidence to suggest that the marginal risk of illness from a unit of output on large farm is smaller or larger than the marginal risk of illness from a unit of output on a small farm.

about 5.8 percent, or to 130,398 (138,424 x [1-.058]) for produce RACs other than sprouts and 52,888 (56,145 x [1-.058]) for sprouts.[5]

We multiply the total number of estimated preventable illnesses attributable to FDA regulated produce (130,398+52,888 = 183,826) by 4 to obtain 733,146 unidentified illnesses. This creates a ratio of identified to unidentified illnesses that is consistent with Scallan, et al., who estimate that unidentified illnesses make up about 80% of all foodborne illnesses (Ref.31). Using this calculation methodology, the total number of preventable foodborne illnesses caused by microbial contamination of FDA-regulated produce is estimated to be 916,432 (183,826+733,146, rounded). This is the more conservative of the two estimation methods presented in the PRIA (Ref. 6), which reduces our estimate of total unidentified illnesses.

Table 6. Estimated Number of Illnesses

Estimated Number of Illnesses Attributable to Produce RACs other than sprouts					
Agent	**FDA RAC (2003-2012)**	**Identified Cases (2003-2012)**	**Percentage Attributable to RACs**	**Estimated Annual Foodborne Illnesses (Scallan)**	**Estimated Annual Illnesses Attributable to RACs**
Salmonella	4,090	36,790	11.12%	1,072,450	119,226
Shigella sonnei	56	3,044	1.84%	154,053	2,834
Listeria monocytogenes	147	361	40.72%	1,680	684
Hepatitis A	919	1,250	73.52%	1,665	1,224
Cyclospora cayatenensis	899	1,109	81.06%	13,906	11,273
E.coli, STEC0157	168	3694	4.55%	69,972	3,182
Total Identified RAC	6,279	46,349	13.56%	1,438,692	138,424
Estimated Number of Illnesses Attributable to sprouts					
Agent	**FDA Sprouts (2003-2012)**	**Identified Cases (2003-2012)**	**Percentage Attributable to Sprouts**	**Estimated Annual Foodborne Illnesses (Scallan)**	**Estimated Annual Illnesses Attributable to Sprouts**

[5] We do not consider there to be a significant drop in benefits due to the exclusion of produce rarely consumed raw or produce headed for commercial kill step processing, as such produce can be expected to receive treatment to reduce risk from biological hazards and is therefore considered to present lower risk than other types of produce.

Salmonella	651	36,790	1.77%	1,072,450	18,977
Listeria monocytogenes	20	361	5.54%	1,680	93
E.coli, STEC0157	63	3,694	1.71%	69,972	1,193
E.coli, STEC non 0157	29	101	28.71%	124,966	35,881
Total Identified sprouts	763	46,349	1.65%	1,438,692	56,145

We estimate the monetized value of reducing foodborne illnesses from produce by multiplying the annual number of illnesses per pathogen by the estimated cost (including willingness-to-pay for longevity and avoided pain and suffering) per case. The estimated cost per case is a pathogen specific estimate of dollar burden a typical case of this particular foodborne illness places on an individual, which comes from Minor et al (2014) (Ref. 32). Our estimated costs per illness are higher than those in the PRIA because we utilize a higher Value of Statistical Life (VSL), $9 million, and a higher QALD estimate, $1,260, for all pathogens (Ref. 16). Table 7 presents the burden of illness attributable to microbial contamination of FDA-regulated produce RACs other than sprouts and sprouts. Column two contains the total number of preventable illnesses attributable to FDA-regulated produce, previously calculated. This number is multiplied by the expected dollar loss per case, to give the annual cost of each pathogen in the US population. Taken together, we estimate that the total cost of the illnesses linked to all items of produce is approximately $2.5 billion. As discussed below, these figures are not the expected benefits associated with the provisions in this rule. We expect that the rule would eliminate only some portion of illnesses linked to produce and so would have lower real-world benefits.

Table 7. Estimated Dollar Burden of Illnesses

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	Covered Dollar Burden (millions)
Salmonella	119,226	94.2%	112,311	$6,015	**$676**
Shigella sonnei	2,834	94.2%	2,670	$3,323	**$9**
Listeria monocytogenes	684	94.2%	645	$1,574,670	**$1,015**
Hepatitis A	1,224	94.2%%	1,154	$46,704	**$54**
Cyclospora cayatenensis	11,273	94.2%	10,620	$4,056	**$43**
E.coli, STEC0157	3,182	94.2%	2,998	$11,631	**$35**
Total RAC Identified	138,575	94.2%	130,398		**$1,831**
Total RAC Unidentified	-		521,592	$409	**$214**
Total RAC	-		651,990		**$2,045**
Estimated Dollar Burden Attributable to sprouts					
Agent	**Est. Annual Illnesses Attributable to RACs**	**% produce acres associated with preventable illness**	**Est. Preventable Attributable Illnesses**	**Expected Dollar Loss per Case**	**Covered Dollar Burden (millions)**
Salmonella	18,977	94.2%	18,977	$6,015	**$108**
Listeria monocytogenes	93	94.2%	93	$1,574,670	**$138**
E.coli, STEC0157	1,193	94.2%	1,193	$11.631	**$13**
E.coli, STEC non 0157	35,881	94.2%	35,881	$2,253	**$76**
Total Sprouts Identified	56,145	94.2%	52,888		**$335**
Total Sprouts Unidentified	-		211,554	$409	**$87**
Total Sprouts	-		264,442		**$421**
TOTAL					**$2,466**

2. Produce Rule Model of Risk Reduction

We examine the overall effectiveness of the regulation in reducing human foodborne illnesses. To do this, we estimate the public health benefits of the produce regulation provisions in two distinct ways: as a whole and by pathways of contamination. We specify eight pathways of contamination: Agricultural Water for growing and harvest activities; Agricultural Water for postharvest activities; Biological Soil Amendments;

Worker Health and Hygiene in growing and harvest activities; Worker Health and Hygiene in postharvest activities; Domesticated and Wild Animals; Equipment, Tools, Buildings, and Sanitation in growing and harvest activities; and Equipment, Tools, Buildings, and Sanitation in postharvest activities. These pathways come from the Qualitative Assessment of Risk (QAR), which defines five routes of contamination: Water, Soil Amendments, Animals, Worker Health and Hygiene, and Equipment and Buildings (Ref. 33). We split Water, Worker Health and Hygiene, and Equipment and Buildings into two separate pathways each, based on timing (growing and harvest versus postharvest activities), for a total of eight pathways. These eight pathways are addressed by an Expert Elicitation, the results of which are used to assign risk reduction values to each pathway (Ref. 34).

We estimate the change in the probability of produce contamination as a function of the relative likelihood of contamination from each specific pathway and the effectiveness of the rule in reducing the risk of produce contamination within a specific pathway of contamination. This change in the probability of contamination is then applied to the current baseline of preventable foodborne illnesses attributable to FDA-regulated produce. Based on current scientific literature, expert elicitation, census data, research, and outbreak investigations, we can estimate the range of measureable effectiveness of the produce safety regulation on the current burden of illness as a whole (Ref.34;35;36;37). Additionally, these data are stratified to examine the effect amongst specific commodities, or contamination pathways.

Table 8 presents the associated illnesses and mean relative weights and effectiveness used in the model, as well as the calculation of the percentage reduction in

contamination, by pathway and for the rule as a whole. For more detailed information on how the weights and effectiveness values are assigned, see the PRIA and relevant sources (Ref. 6;34;36;37). Because the weights and the effectiveness values are based on the average values of distributions, we acknowledge the uncertainty they introduce. We account for this in our uncertainty analysis of benefits in Section II, subsection I, (formerly addressed in section IV, subsection H, subsection 3 in the PRIA). In the uncertainty analysis, we run Monte Carlo simulations in which the values of the weights and effectiveness, among others, vary based on our calculated parameters of their distributions (mean, 5^{th} percentile, 95^{th} percentile). This allows us to calculate low and high estimates of the benefits, taking into account the possible uncertainty of the weights and effectiveness values.

To translate this percentage reduction in farm contamination to human health outcomes, we estimate that a reduced probability of contamination will result in a corresponding reduction in the expected number of illnesses. This means that roughly a 56 percent reduction in contamination will similarly reduce costs of illnesses. We apply this percentage reduction to the average cost of illness, specific to produce-associated illnesses, to estimate the overall benefits of the rule through illness prevention. We can also use these assumptions to examine potential benefits of this rule by contamination pathway. These calculations are also presented in Table 8.

Table 8. Mean Reduction in Risk of Contamination/ Benefits by Pathway

Mean Reduction in Risk of Contamination/ Benefits by Pathway attributable to Produce RACs other than sprouts					
Contamination Pathway	**Covered Dollar Burden (millions)**	**Likelihood of Being the Path of Contamination**	**Effectiveness of Controls**	**Reduction in Risk**	**Benefits (millions)**
Agricultural Water (growing/harvest)	$2,045	16.32%	54.49%	8.89%	$182

Agricultural Water (postharvest)	$2,045	14.37%	72.55%	10.42%	$213
Biological Soil Amendments	$2,045	13.81%	65.62%	0.7%*	$15
Worker Health and Hygiene (growing/harvest)	$2,045	15.62%	66.04%	10.32%	$211
Worker Health and Hygiene (postharvest)	$2,045	15.20%	73.50%	11.17%	$228
Domesticated and Wild Animals	$2,045	14.09%	58.04%	8.18%	$167
Equipment, Tools, Building and Sanitation (growing/harvest)	$2,045	4.18%	56.71%	2.37%	$49
Equipment, Tools, Buildings and Sanitation (postharvest)	$2,045	6.42%	67.97%	4.36%	$89
Total				**56.43%**	**$1,154**
Mean Reduction in Risk of Contamination/ Benefits by Pathway attributable to sprouts					
Contamination Pathway**	**Covered Dollar Burden (millions)**	**Likelihood of Contamination**	**Effectiveness of Controls**	**Reduction in Risk**	**Benefits (millions)**
Agricultural Water (growing/harvest)	$421	16.32%	54.49%	8.89%	$38
Agricultural Water (postharvest)	$421	14.37%	72.55%	10.42%	$44
Biological Soil Amendments	$421	13.81%	65.62%		-
Worker Health and Hygiene (growing/harvest)	$421	15.62%	66.04%	10.32%	$44
Worker Health and Hygiene (postharvest)	$421	15.20%	73.50%	11.17%	$47
Domesticated and Wild Animals	$421	14.09%	58.04%	8.18%	$35
Equipment, Tools, Building and Sanitation (growing/harvest)	$421	4.18%	56.71%	2.37%	$10
Equipment, Tools, Buildings and Sanitation (postharvest)	$421	6.42%	67.97%	4.36%	$18
Total				**55.71%**	**$234**

*The estimated effectiveness of Biological Soil Amendments has changed from the PRIA, because certain proposed requirements for this section have been removed in the rule (see § 112.56(a)(1)(i)). See below for a full explanation of the calculations. ** We do not have data to estimate risk reduction due to sprout specific contamination pathways and therefore analyze the same pathways for sprouts as we do for other produce..

From the table, we see that Agricultural Water for growing and harvest activities is estimated to be the most important pathway of contamination, at about 16 percent. This

is followed by Worker Health and Hygiene in postharvest activities (16 percent), Worker Health and Hygiene in growing and harvest activities (15 percent), and Domestic and Wild Animals (14 percent). Equipment, Tools, Buildings, and Sanitation in growing and harvest activities represents the lowest contamination pathway, accounting for only about 4 percent overall.[6]

We also see that the rule is estimated to do the best job of controlling risk of contamination for Worker Health and Hygiene in postharvest (ph) activities, about a 74 percent reduction. This is followed closely by controls on Agricultural Water used in postharvest activities (ph), estimated to have around 73 percent effectiveness in reducing the associated risks of contamination. Controlling Agricultural Water used for growing and harvest (g/h) activities is estimated to have the lowest effectiveness, at about 55 percent.

Provisions covering worker health and hygiene in postharvest (g/h) activities are estimated to have the most impact on overall contamination, reducing it by an estimated 11 percent. Provisions covering Equipment, Tools, Buildings, and Sanitation in growing and harvest (g/h) activities are estimated to contribute the least, at only about a 2 percent reduction in contamination.

Taken together, this adds up to about a 56.43 percent reduction in risk of contamination for produce RACs other than sprouts, and 55.71 percent reduction risk of

[6] The number of outbreaks attributed to Equipment, Tools, Buildings, and Sanitation may be biased for a few reasons. When it is implicated in the data, outbreaks are typically associated with multiple contamination pathways, forcing the illnesses to be split amongst them, lowering the overall share of illnesses attributable to this specific pathway. Additionally, problems with things like sanitation or tools may be incorrectly attributed to another category, like worker health and hygiene. It could be that a worker improperly washes their hands or cleans their tools because sufficient hand-washing facilities or cleaning materials were not provided; however, when a resulting outbreak is recorded, only worker contact may be cited as a contamination pathway. With the current data available, these are only speculations, and we assign illnesses based only on the observable data.

contamination for sprouts. Note, in Table 8, we only account for a very small reduction in risk associated with our requirements related to Biological Soil Amendments because certain proposed requirements that we accounted for in the PRIA have now been eliminated from the rule (see § 112.56(a)(1)(i)). The originally estimated benefits attributable to Biological Soil Amendments would have contributed an approximate $226 million in additional benefits (or 9.06 % of all foodborne illnesses attributable to FDA RACs). We estimate that the remaining provisions will produce smaller costs and benefits than previously estimated. Since the use of most Biological Soil Amendments of Animal Origin in growing covered root crops is prohibited by the rule (because it is not possible to minimize the potential for contact between soil amendments and root crops, only amendments that meet the requirements of 112. 55(a) may be used in growing covered root crops), we turn our focus to root crop farms. The proportion of covered non-sprout farms that grow root vegetables is 8% (Ref. 15). Therefore, we estimate that the benefits associated with the remaining requirements of BSA are 0.7% (9.06% x 8%) of all foodborne illnesses attributable to FDA regulated produce RACs other than sprouts, or approximately $15 million.

We are unable to account for the provisions specific to sprouts, namely batch testing, seed treatment, and environmental monitoring because we are unable to parse out their individual effects beyond what has already been done for all covered produce. However, Ding and Fu (2013) (Ref. 38) and Montville and Schaffner (2004) (Ref. 39), suggest that these sprout-specific provisions are effective in reducing or preventing contamination. Therefore, our estimates likely represent a low estimate of the reduction in risk of foodborne illnesses attributable to sprouts.

Table 9 shows the estimated reduction in illnesses that may be attributable to the regulation, shown both in illnesses averted and total dollar costs attributable to those avoided illnesses. The overall benefits are higher than those in the PRIA, yet the number of illnesses prevented is lower than that of the PRIA. This is mainly attributable to the higher annual incidence of identified outbreaks associated with produce RACs other than sprouts and sprouts. Combined with a more conservative estimate of unidentified goods, which have a very low estimated cost per illness, we estimate a lower number of total illnesses, which have a higher average costs per illness.

Table 9. Summary of Annual Benefits of Produce Regulation

	Reduction in Risk	Illnesses Attributable to Produce Covered by this Rule	Illnesses Prevented	Cost Per Illness	Total Benefits (in millions)
Produce RACs other than sprouts	56.43%	651,990	367,949	$3,136	$1,1154
Sprouts	55.71%	264,442	147,321	$1,593	$235
Total		916,432	515,269		$1,389

We estimate that this rule may prevent, when fully implemented, about 515,269 illnesses, with an associated benefit of approximately $1.4 billion, annually. Furthermore, the effectiveness of the rule may increase over time as farms learn by doing. However, these benefits of this rule will not be immediately realized, nor will they be uniformly implemented, due to the staggered nature of compliance times. Table 10 presents the annual values of benefits as they are estimated to occur.

Table 10. Timing of Produce Benefits (in millions)

Farms	Year1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Covered Farms										

Very Small	0	0	0	0	$90	$90	$137	$137	$137	$137
Small	0	0	0	$50	$50	$76	$76	$76	$76	$76
Large	0	0	$620	$620	$942	$942	$942	$942	$942	$942
Covered Sprout Operations										
Very Small Sprouts	0	0	0	$28	$28	$28	$28	$28	$28	$28
Small Sprouts	0	0	$15	$15	$15	$15	$15	$15	$15	$15
Large Sprouts	0	$191	$191	$191	$191	$191	$191	$191	$191	$191
Exempt and Not Covered Farms										
Very Small Exempt	0	0	0	0	0	0	0	0	0	0
Small Exempt	0	0	0	0	0	0	0	0	0	0
Large Exempt	0	0	0	0	0	0	0	0	0	0

The annualized benefits in Table 10 are calculated based on timing of produce costs and benefits schedule shown in Table 4. For example, in year 2, full benefits are realized from large sprout operations (roughly $191 million, which is calculated as the total benefits attributable to sprouts operations multiplied by the percentage of covered farms that fall into the large category). Because no other farms are affected, no other benefits are being realized in year 2. This means that the total benefits realized in year 2 are roughly $191 million. In year 3, full benefits are realized from large sprout operations ($191 million). Also in year 3, full benefits are realized from small sprout operations ($15 million, which is calculated as the total benefits attributable to sprouts operations multiplied by the percentage of covered farms that fall into the small category), and benefits minus those related to certain water provisions, are realized from large covered, non-sprout operations (roughly $620 million, which is calculated as the total benefits attributable to non-sprout operations, less the benefits attributable to certain

water provisions, multiplied by the percentage of covered farms that fall into the large category). This means that the total benefits in year 3 are roughly $826 million. This continues, and in year 7, all benefits are realized, continuing on through our examined timeline. Adding over the different operation types and sizes for year 7 yields our full benefit estimation of roughly $1.4 billion. This is also the case for year 8, year 9, and onward.

Next, we annualize estimates of the benefits below in Table 11. In this estimate, we take into account the time that different sized farms have to comply with the rule, as well as the different compliance times (notably, for agricultural water provisions, the initial survey testing requirement for untreated surface water used for direct water application during growing for produce other than sprouts, and certain related provisions, are subject to the earlier compliance dates). Estimates are annualized over 10 years.

Table 11. Net Present Value and Annualized Benefits of Produce Regulation

	Annualized Quantified Illnesses	**Annualized Monetized Benefits (millions)**
Net present value at 3 percent	3,181,093	$8,322
Net present value at 7 percent	2,494,785	$6,498
Annualized Values		
Annualized @ 3 percent over 10 years	362,059	$976
Annualized @ 7 percent over 10 years	331,964	$925
Excluding Unidentified Illnesses		
Annualized @ 3 percent over 10 years	72,411	$854
Annualized @ 7 percent over 10 years	66,392	$809

Annualizing benefits over the first ten years after publication of the rule, benefits are expected to be approximately 362,059 illnesses averted per year, valued at $976 million annually.

F. Costs of the Rule

With the data available we have attempted to accurately estimate the baseline safety practices of the produce industry, and the costs related to the changes in those practices as required by the rule. We utilize the most current and representative data available.

We estimated most of the costs of the rule in the PRIA (which accompanied the 2013 proposed rule) and supplemental analysis (which accompanied the supplemental notice), which contain detailed explanations of all calculations (Ref. 6) Where costs have not changed substantially from those presented in either the proposed or supplemental analysis, we do not present those detailed estimates here. Instead, we provide the summary tables of the relevant Subpart, noting that only wages and farm counts have changed, while underlying methodology and requirements remain constant.

1. Personnel and Training (Subpart C)

We did not receive substantial comments on the cost estimates for Personnel and Training requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart C do not affect our cost estimates. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 12 provides the total cost for Personnel and Training; for full information on how these costs are estimated please refer to Tables 112-115 of the original PRIA (Ref. 6). The underlying estimates of this section have not changed; however, these requirements are almost exclusively reliant on labor hours so the increase

in wage rates has increased the costs. Also, based on public comments we increased the wage rate of the training official from a supervisor to operator level, which accounts for the majority of the increase in costs from those presented in the PRIA.

Table 12. Total costs for personnel qualifications and training (in thousands)

	Very Small	Small	Large	Total
Outside Training	$2,975	$517	$714	**$4,205**
Management Personnel Food Safety	$880	$465	$940	**$1,986**
Personnel Food Safety Training	$4,118	$2,637	$7,576	**$14,330**
Ensuring Personnel Compliance with	$33,171	$50,760	$82,932	**$166,863**
Total Costs Accrued to Farms	**$41,143**	**$54,078**	**$92,162**	**$187,383**

2. Health and Hygiene (Subpart D)

We did not receive substantial comments on the cost estimates for Health and Hygiene requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart D do not affect our cost estimates.[7] Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 13 provides the total cost for Personnel and Training; for full information on how these costs are estimated please refer to Tables 35 – 39 of the original PRIA (Ref. 6)

Table 13. Total Cost for Health and Hygiene (in thousands)

	Very Small	Small	Large	Total
Costs to exclude ill workers	$1,808	$723	$5,845	$8,377
Costs to wash and dry hands thoroughly	$12,653	$10,176	$82,090	$104,919
Costs to avoid contact with animals	$121	$98	$676	$896

[7] There is new language that requires jewelry to be removed or covered and prohibits eating, chewing gum, or consuming tobacco in certain areas. We estimate that farms are largely already in compliance with this language and therefore do not present new estimates.

Costs to wash hands before glove use and maintain/replace gloves	$380	$306	$2,467	$3,153
Costs to inform, ensure compliance by, and have toilets for visitors	$13,144	$2,282	$2,835	$18,261
Total Costs (annual)	**$28,107**	**$13,585**	**$93,914**	**$135,606**

3. Agricultural Water (Subpart E)

Agricultural water has undergone the most changes due to changes in requirements from those proposed, public comments, and updated data. Therefore, we lay out all estimates related to Agricultural water below. The most significant impacts on the estimated costs from those presented in the proposed analysis are: increased our assumption about the time it takes for farms to conduct a water system inspection based on public comments; reduced the number of annual tests a farm must conduct due to changes in the rule's requirements; increased the number of farms that are required to conduct water testing, as this requirement does not apply to only farms with post-harvest activities; and allowed for die-off as a means to avoid water treatment, due to changes in the rule's requirements. Although some of these changes served to increase the costs of the Agricultural Water requirements, such as broader application of water testing and increased time to inspect water systems, the overall impact of these changes serves to reduce the costs of the Agricultural Water requirements, where changes in the rule's requirements have led to the largest reductions in costs.

We estimate the cost of inspecting water systems, in accordance with § 112.42, for the proportion of covered farms that are not currently conducting inspections; we find that 22,781 very small, 3,956 small, and 8,292 large farms will need to implement inspections. We estimate that very small and small farms will take four hours annually to inspect agricultural water systems and that large farms will take eight hours annually, this

estimate is based on data cited in the PRIA (Ref. 6) and public comments received on the same document. We multiply these time burdens by the average farm operator wage rate and estimate an annual per farm inspection cost of $288 for very small and small farms, and $342 for large farms. Table 14 presents the total cost of inspecting water systems.

These estimates are largely taken from the PRIA (Ref. 6) with the exception of hours to inspect which has been increased in response to comments.

Table 14. Cost of inspecting water systems

	Very Small	Small	Large	Total
Number of covered farms	22,781	3,956	8,292	35,029
Rate of current practice	1.30%	0.60%	3.78%	
Number of farms that need to inspect	22,485	3,932	7,979	34,396
Hours to inspect	4.00	4.00	8.00	
Farm operator wage rate	$72.12	$72.12	$42.74	
Annual cost of inspection per farm	$288.48	$288.48	$341.92	
Total annual cost of inspection	**$6,486,429**	**$1,134,380**	**$2,728,030**	**$10,348,838**

We estimate the cost of sampling and testing untreated surface water for covered farms when the water is used in a direct application method during growing of covered produce (other than sprouts), in accordance with § 112.46(b). We estimate that 42 percent of irrigated farms use untreated surface water for the relevant purpose (direct water application during growing produce other than sprouts) (Ref. 40). This results in 7,703 very small farms, 1,512 small farms, and 3,339 large farms that must conduct untreated surface water testing. We estimate that the cost of collecting a water sample, including collection, shipping costs, analysis, and travel is $110. In the initial two years of sampling, we estimate that farms will collect 10 samples annually to develop a microbial water quality profile, and then collect five samples annually to update their microbial water quality profile using a 20-sample rolling dataset (see § 112.46(b)(1)(i)(A) and

(b)(2)(i)(A)) at a per farm cost of $550 (five samples at $110 each). Additionally, it may be necessary for farms to take a total of 20 new samples starting in any given year to develop a new water quality profile, if the farm has determined or has reason to believe that its microbial water quality profile no longer represents the quality of its water, in accordance with § 112.46(b)(3)(i)(A). We estimate that 7.5 percent of farms using untreated surface water will need to take 20 new samples starting in any given year to develop a new water quality profile.

Table 15 presents the total costs of testing untreated surface water used for the relevant purpose. We estimate that the total costs of testing surface water are $7.9 million for very small farms, $1.6 million for small farms, and $3.4 million for large firms, totaling to $12.9 million. These estimates are from the PRIA (Ref. 6) with the exception of the testing frequency which we have updated in finalizing the rule.

Table 15. Costs of Sampling and Testing Untreated Surface Water used in Direct Application During Growing Produce (Other than Sprouts)

	Very small	Small	Large	Total
Number of irrigated farms	18,262	3,585	7,916	29,763
Percent of farms that use surface water	42.18%	42.18%	42.18%	
Number of farms that must perform initial survey	7,703	1,512	3,339	12,554
Cost of collecting sample	$110.00	$110.00	$110.00	
*Baseline survey testing frequency**	5	5	5	
Annually recurring cost of 5 tests	$550.00	$550.00	$550.00	
Percent of farms that will need to develop new water quality profile	7.5%	7.5%	7.5%	
Testing frequency (20 samples – 5 already estimated for all farms)	15	15	15	
Cost of 20 annual sample testing for 7.5% of farms	$3,013,230	$591,525	$1,306,140	$4,910,895
Cost of 5 annual sample testing for all farms	$4,927,653	$967,344	$2,135,982	$8,030,978
Total cost of sampling and testing untreated surface water	**$7,940,883**	**$1,558,869**	**$3,442,122**	**$12,941,873**

Note: The initial survey of 20 samples must be in place before farms can comply with some of the other annual requirements for agricultural water that relate to the microbial water quality profile developed from the initial survey. For untreated surface water, testing for this will begin in year 3 for large farms, year 4 for small farms, and year 5 for very small farms.

We estimate the cost of sampling and testing untreated groundwater for covered farms when the water is used in a direct application method during growing of covered produce (other than sprouts), in accordance with § 112.46(b). Assuming that 32 percent of covered farms use groundwater for the relevant purpose (direct water application during growing produce other than sprouts) (Ref. 40), 5,811 very small farms, 1,141 small farms, and 2,519 large farms must test their untreated groundwater. We estimate that the cost of collecting a water sample is $110 and in the first year, all farms will collect four samples (see § 112.46(b)(1)(i)(B)), at a cost of $440 per farm. In subsequent years, most farms will collect one sample annually (see § 112.46(b)(2)(i)(B)), at a cost of $110 per farm per year. Additionally, it may be necessary for farms to take a total of 4 new samples in any given year to develop a new water quality profile, if the farm has determined or has reason to believe that its microbial water quality profile no longer represents the quality of its water, in accordance with § 112.46(b)(3)(i)(B). We estimate that 5 percent of farms using untreated ground water will need to collect four new samples in any given year to develop a new water quality profile. Table 15 presents the costs of testing untreated groundwater used for the relevant purpose. We estimate that the total costs of testing groundwater are $1.3 million for very small farms, $246 thousand for small farms, and $542 thousand for large farms, totaling to $2.0 million.

Table 16. Costs of sampling and testing untreated groundwater used in Direct Application During Growing Produce (Other than Sprouts)

	Very small	Small	Large	Total
Number of irrigated farms	18,262	3,585	7,916	29,763
Percent of farms that use ground water	31.82%	31.82%	31.82%	31.82%
Number of farms that must test	5,811	1,141	2,519	9,471
Initial testing frequency	4	4	4	

Initial testing cost (year 1)	$440.00	$440.00	$440.00	
Annual testing frequency	1	1	1	
Annual testing cost	$110.00	$110.00	$110.00	
Percent of farms that will need to develop new water quality profile	5%	5%	5%	
Testing frequency (4 samples – 1 already estimated for all farms)	3	3	3	
NPV (at 3%)	$1,259	$1,259	$1,259	
NPV (at 7%)	$1,081	$1,081	$1,081	
Annualized costs (at 3%)	$148	$148	$148	
Annualized costs (at 7%)	$154	$154	$154	
Cost of testing for farms testing 4 times per growing season or year	$401,764	$78,870	$174,152	$654,786
Cost of testing for farms testing once annually	$849,652	$166,795	$368,297	$1,384,744
Total cost of testing ground water	**$1,251,416**	**$245,665**	**$542,449**	**$2,039,530**

We estimate the cost of sampling and testing untreated ground water when used for certain uses specified in § 112.44(a) (including, for example, water used as sprout irrigation water, and water applied in a manner that directly contacts covered produce or food-contact surfaces during or after harvest), in accordance with § 112.46(c). All covered farms and sprouting operations that use untreated ground water for such purposes (i.e., farms that do not use water exempt from testing under § 112.46(a) such as public (e.g., municipal) water sources meeting the established criteria in that section or water treated in accordance with the requirements of § 112.43) must conduct water sampling and testing. We estimate that 41 percent of sprouting operations use untreated ground water for sprout irrigation, and that 30 very small, 25 small, and 62 large sprouting operations must therefore test their untreated groundwater in accordance with § 112.46(c). We estimate that 32 percent of farms use ground water for other purposes identified in § 112.44(a) (other than sprout irrigation water) and 26 percent of these farms use water exempt from testing under § 112.46(a), and 1.3 percent of very small farms, 0.6 percent of small farms, and 3.8 percent of large farms are already conducting water sampling and

testing (20;Ref. 40). The remaining proportion of non-sprout farms and sprouting operations includes 5,292 very small farms, 942 small farms, and 1,896 large farms. We estimate that the cost of collecting and testing a water sample is $110 and that all farms required to conduct these tests will test an average of 1.5 times per year (the midpoint between 1 and 2 samples). This estimated average is derived from the required testing frequency in § 112.46(c), which requires at least 4 tests in the first year, allowing one test per year thereafter if the results meet the quality criterion, with required resumption of 4 tests per year if any annual test fails to meet the quality criterion. Table 17 presents the total costs of water sampling and testing for farms that use water for § 112.44(a)activities. We estimate that the total costs of water sampling and testing are $873 thousand for very small farms, $155 thousand for small farms, and $313 thousand for large farms, totaling to $1.3 million.

Table 17. Cost of sampling and testing untreated ground water for § 112.44(a) purposes

	Very small	**Small**	**Large**	**Total**
Total number of farms	22,781	3,956	8,292	35,029
Number of sprout operations that use untreated ground water	30	25	62	117
Total number of farms	22,811	3,981	8,354	35,146
Percent of non-sprout farms that use ground water	31.82%	31.82%	31.82%	
Number of non-sprout farms that use ground water	7,279	1,283	2,700	
Rate of practice for water treatment	1.30%	0.60%	3.78%	
Percent of farms using public water	26.0%	26.0%	26.0%	
Number of farms that must test under the rule	5,292	942	1,896	
Testing frequency	1.5	1.5	1.5	
Testing cost	$110.00	$110.00	$110.00	
Total costs of water sampling and testing	**$873,183**	**$155,432**	**$312,879**	**$1,341,495**

All covered irrigated farms that do not use public water sources exempt from testing and that use water for purposes in § 112.44(b) may choose to conduct water treatment to meet the microbial quality criteria (see § 112.45(b)(3)). Treatment of water is one of multiple options provided in § 112.45(b) to meet the microbial quality criteria in § 112.44(b). Farms may use the option to treat water, for example, if the farm is not able to take advantage of the provisions for microbial die-off and/or microbial removal, provided in § 112.45(b)(1), or the provision for re-inspection and corrections in § 112.45(b)(2). We estimate 22,025 farms (or 74 percent of covered irrigated farms) will conduct testing. We also estimate that 48 percent of irrigated farms use application methods where the water is intended to contact covered produce and 33 percent use application methods where the water is likely to contact covered produce; these include farms growing commodities such as cantaloupe, honeydew, other melons (including Canary, Crenshaw and Persian), pineapple, strawberries, summer squash (such as patty pan, yellow and zucchini), and watermelon (10;Ref. 15;40). We calculate the number of farms that use direct water application methods by adding the proportions and multiplying by the number of farms that must conduct testing, and estimate that this includes 10,946 very small farms, 2,149 small farms, and 4,745 large farms, or 17,840 farms in total. We divide the number of operating days per year across farm size by 360 and multiply this proportion by the average number of irrigated acres for very small, small, and large farms and estimate that there are 122,817 irrigated acres for very small, 131,080 irrigated acres for small, and 2,746,960 irrigated acres for large farms. We estimate that 2.4 percent of irrigated acres do not meet the microbial quality criteria (Ref. 6) and that approximately 80 percent of all farms can use the die-off provisions in §

112.45(b)(1) or the re-inspection and correction provisions in § 112.45(b)(2), leaving 590 acres on very small farms, 629 acres on small farms, and 13,185 acres on large farms that may treat their water to meet the microbial quality criteria. We estimate there to be 2.16 acre-feet of water per acre and multiply (Ref. 40) this by the number of acres to be treated, resulting in 1,273 acre-feet for very small farms, 1,359 acre-feet for small farms, and 28,480 acre-feet for large farms. We estimate that the current rate of practice for water treatment is 1.3 percent for very small farms, 0.6 percent for small farms, and 3.8 percent for large farms, resulting in 1,257 acres on very small farms, 1,351 acres on small farms, and 27,404, acres on large farms to be treated (Ref. 20) We multiply acres by our estimated treatment costs per acre-foot ($543 for very small farms, $289 for small farms, and $32 for large firms) to find total costs. Table 18 presents total costs of water treatment to meet the microbial quality criteria. We estimate that the total costs of treatment are $682,449 for very small farms, $390,405 for small farms, and $876,925 for large farms, totaling to $1,949,779.

Table 18. Water treatment to meet microbial quality criteria of GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL

	Very small	Small	Large	Total
Number of covered irrigated farms	18,262	3,585	77,916	29,763
Percent of farms that use public water	26%	26%	26%	
Number of farms that test water	13,514	2,653	5,858	22,025
Percent of farms using agricultural water intended to contact covered produce	48%	48%	48%	
Percent of farms using agricultural water likely to contact covered produce	33%	33%	33%	
Number of farms using direct water application	10,946	2,149	4,745	17,840
Percent of season when produce is present	33%	50%	83%	
Farms with irrigated acreage using direct water application methods, weighted by percentage of season when produce is present	3,612	1,074	3,952	8,639
Average irrigated acres	34	122	695	
Irrigated acres using direct water application	122,817			

methods		131,080	2,746,960	
Percent of farms that do not meet quality criteria	2.4%	2.4%	2.4%	
Acres to be treated	2,948	3,146	65,927	
Percent where die-off until harvest or storage is an option	80%	80%	80%	
Acres that must be treated	590	629	13,185	
Acre-ft of water per acre	2.16	2.16	2.16	
Acre-ft of water to be treated	1,273	1,359	28,480	
Rate of current practice	1.3%	0.6%	3.8%	
Acres that will treat	1,257	1,351	27,404	
Treatment costs per acre-ft	$543	$289	$32	
Total cost	**$682,449**	**$390,405**	**$876,925**	**$1,949,779**

All covered farms that use water for purposes in § 112.44(a) that is not public water exempt from testing may choose to conduct water treatment to meet the microbial quality criterion. Treatment of water is one of multiple options provided in § 112.45(a) to meet the microbial quality criterion in § 112.44(a) (see § 112.45(a)(1)(ii)). Farms may use the option to treat water, for example, if the farm is not able to take advantage of the provisions for re-inspection and corrections in § 112.45(a)(1)(i). We estimate that 15.2 percent of water does not meet quality criteria of no detectable E. coli (6;10;20;40;Ref. 41) The number of farms requiring treatment is calculated by multiplying the number of farms using water for § 112.44(a) purposes by the percent of farms that do not meet quality criteria and by the portion of farms that do not use public water exempt from testing. This yields 2,534 very small farms, 446 small farms, and 906 large farms that may treat. We estimate that one-time capital costs will be $2,441.34 for very small farms, $3,678.13 for small farms, and $3,567.78 for large farms and that annual operating costs will be $117 for very small farms, $1,099 for small farms, and $6,714 for large farms(Ref. 6;41;42;43) We add annualized one-time capital costs and annual operating costs and multiply by the number of farms that initially test and then treat water to estimate total

costs of $1.2 million for very small farms, $724 thousand for small farms, and $6.5 million for large farms, totaling to $8.4 million. Table 19 presents the total costs of water treatment to meet the microbial quality requirement in § 112.44(a).

Table 19. Water treatment to meet quality criterion of no detectable E. coli for purposes in § 112.44(a)

	Very small	Small	Large	Total
Number of covered farms	22,781	3,956	8,292	35,029
Percent of farms using public water	26.0%	26.0%	26.0%	
Number of sprout operations that use untreated ground water	30	25	62	117
Number of farms subject to microbial testing requirements in § 112.46(c) (to meet § 112.44(a) criterion)	16,888	2,952	6,198	26,038
Percent contaminated	15.2%	15.2%	15.2%	
Number of farms that require treatment	2,567	449	942	3,958
Current rate of practice	1.3%	0.6%	3.8%	
Number of farms that test	2,534	446	906	3,886
One-time capital costs	$2,441.34	$3,678.13	$3,567.78	
Annualized costs (3%)	$286.20	$431.19	$418.25	
Annualized costs (7%)	$347.59	$523.68	$507.97	
Operating cost per year	$117.26	$1,099.32	$6,713.74	
Total costs for water treatment	**$1,177,771**	**$723,886**	**$6,546,385**	**$8,448,015**

Table 20 presents a summary of the costs of the agricultural water provisions. Excluding recordkeeping, the total cost of the water provisions is $18 million for very small farms, $4 million for small farms, and $14 million for large farms, totaling to $37 million.

Table 20. Summary of the costs of the agricultural water provisions (in thousands)

Description	Very small	Small	Large	Total
Inspection and maintenance of agricultural water systems	$6,486	$1,134	$2,728	**$10,349**
Cost of testing untreated surface water used in direct application during growing for produce other than sprouts	$7,941	$1,559	$3,442	**$12,942**
Cost of testing untreated ground water used in direct application during growing for produce other than sprouts	$1,251	$246	$542	**$2,040**
Cost of testing untreated ground water used for 112.44(a) purposes (including sprout irrigation water)	$873	$155	$313	**$1,341**

Water treatment to meet criteria of GM of 126 CFU / 100 mL or STV of 410 CFU / 100 mL for direct application during growing of produce other than sprouts	$682	$390	$877	**$1,950**
Treatment to meet criteria of no detectable E. coli for 112.44(a) purposes, including sprout irrigation water	$1,178	$724	$6,546	**$8,448**
Total cost by size category	**$18,412**	**$4,209**	**$14,449**	**$37,070**
Cost per farm	$808	$1,064	$1,742	$1,058

4. Biological Soil Amendments (Subpart F)

The minimum application intervals for biological soil amendments of animal origin, which we proposed in the 2013 proposed rule, have been removed from the rule. We estimate that removing these application intervals will remove an overwhelming majority of all costs originally estimated. Therefore, we have eliminated the original costs estimates attributed to Biological Soil Amendments of animal origin attributable to this rulemaking. There are still recordkeeping requirements related to Biological Soil Amendments, and those costs are presented in the Recordkeeping (Subpart O) section of this analysis.

In addition, the use of Biological Soil Amendment of Animal Origin in growing covered root crops is prohibited unless the amendment meets the requirements of 112.55(a). Therefore, the costs of root crop farms that use BSA of animal origin switching to permissible soil amendments are presented in Table 21. Using data from the NASS Agricultural Census, we estimate that approximately eight percent of covered farms grow root crops (Ref. 15), and 15 percent of total farms apply any type of BSA (Ref. 6;20). Therefore, we estimate that 273 very small farms (22,781 farms x 8 percent x 15 percent), 47 small farms (3,956 farms x 8 percent x 15 percent), and 100 large farms

(8,292 farms x 8 percent x 15 percent) will incur a cost of switching amendment types.[8] From the PRIA, we estimate that the average cost of switching to commercial chemically treated compost is $1,600 for very small farms, $6,600 for small farms, and $17,300 for large farms, and we expect that a switch to permissible amendments for covered root crops (such as amendments not containing materials of animal origin, or BSAs treated to meet the § 112.55(a) microbial standard) will represent a comparable cost.[9] In total, we estimated that the cost of switching away from most BSAs for root crops is approximately $2.5 million, annually.

Table 21. Cost to root crop farms of switching from compost or raw manure of animal origin

	Very small	**Small**	**Large**	**Total**
Number of farms	22,781	3,956	8,292	35,029
Percent of farms that grow root crops	8%	8%	8%	
Number of root crop farms	1,822	316	663	2,802
Percent of farms using biological soil amendments of any type	15%	15%	15%	
Number of root crop farms using biological soil amendments	273	47	100	420
Average cost of switching to treated BSAs that meet the microbial standard in § 112.55(a) or other permissible amendments	$1,600	$6,600	$17,300	
Total cost by category	**$437,395**	**$313,315**	**$1,721,419**	**$2,472,130**

5. Domesticated and Wild Animals (Subpart I)

We did not receive substantial comments on cost estimates for Domesticated and Wild Animals; therefore, we have not altered the underlying methodology from those

[8] We recognize that there may be more efficient means of meeting the requirements for an individual farm, such as chemical treatment or switching to a vegetative manure source; however, either of these activities would likely be utilized as a cost savings measure if they are employed instead of purchasing commercial compost. Therefore, our average costs estimates may be viewed as somewhat higher than those that are likely to be realized by individual farms.

[9] Costs are calculated without taking into account opportunity or time costs of searching for new suppliers or rewriting contracts.

originally proposed and estimated in the PRIA. The rule's requirements have been altered in two key ways that reduce the cost estimated for Domesticated and Wild Animals. First, assessment requirements have been limited to only operational days where the harvestable portion of the product is present. This is a reduction from year round monitoring estimated in the PRIA. Additionally the waiting period requirement related to grazing animals has been removed completely from the rule and thus all of the associated costs have been removed. Table 22 provides the total cost for Domesticated and Wild Animals; for full information on how these costs are estimated please refer to Tables 82 – 83 of the original PRIA (Ref. 6).

Table 22. Cost for Domesticated and Wild Animals

	Very small	**Small**	**Large**	**Total**
Number of produce farms	22,781	3,956	8,292	35,029
Per-acre monitoring cost increase	3.36	3.36	3.36	
Increase in cost per affected farm	$378	$1,260	$2,520	
Percent of year in operation	27%	41%	55%	
Total cost per category	**$2,359,238**	**$2,048,449**	**$11,449,775**	**$15,857,462**

6. Growing, Harvesting, Packing, and Holding Activities (Subpart K)

We did not receive substantial comments on the cost estimates for Growing, Harvesting, Packing, and Holding Activities; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart K do not affect our cost estimates. Thus, we present the estimates utilizing more current wage information and farm counts. Table 23 provides the total cost for Growing, Harvesting, Packing, and Holding Activities. These requirements are reliant on labor hours so the increase in wage rates has increased the costs. Additionally, based on public comments we have revised the number of operational days upwards to 100 for very small farms, 150

for small farms, and 200 for large farms (up from 45, 45, and 90), which increases the estimated costs. Finally, in the PRIA we estimated that only farms with post-harvest activities would incur costs of Growing, Harvesting, Packing, and Holding Activities; however, we now estimate that all farms with reusable food contact surfaces will need to clean and sanitize. All of these changes have substantially increased the cost estimates of Growing, Harvesting, Packing, and Holding Activities.

Table 23. Cost of Cleaning and Sanitizing Food Contact Surfaces

	Very small	Small	Large	Total
Number of Farms	22,781	3,956	8,292	35,029
Percentage of farms with reusable food contact surfaces	18%	18%	18%	
Number of farms with reusable food contact surfaces	4,101	712	1,493	
Percentage of farms that do not clean/sanitize food contact surface	30%	30%	30%	
Number of farms that need to clean/sanitize food contact surface	2,870	498	1,045	
Time to clean/sanitize (hours)	0.17	0.25	0.25	
Non-supervisor wages	$18.56	$18.56	$18.56	
Labor cost to clean/sanitize a food contact surface	$3.16	$4.64	$4.64	
Cost of sanitizer per farm job	$0.05	$0.05	$0.05	
Daily per farm cost to clean/sanitize	$3.21	$4.69	$4.69	
Operational harvest days	100	150	200	
Annual per farm cost to clean/sanitize food contact surfaces	$321	$704	$938	
Total cost to clean/sanitize food contact surfaces	**$920,023**	**$350,664**	**$980,015**	**$2,250,701**

7. Equipment, Tools, Buildings, and Sanitation (Subpart L)

We did not receive substantial comments on cost estimates for Equipment, Tools, Buildings, and Sanitation requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart L do not affect our cost estimates. Thus, we present only summary statistics of estimates utilizing more current

wage information, farm counts, and operational days where the harvested or harvestable portion of produce is exposed. Table 24 provides the total cost for Equipment, Tools, Buildings, and Sanitation; for full information on how these costs are estimated please refer to Tables 88 – 94 of the original PRIA (Ref. 6). These requirements are almost exclusively reliant on labor hours so the increase in wage rates has increased the costs. Additionally, based on public comments we have revised the number of operational days upwards to 100 for very small farms, 150 for small farms, and 200 for large farms (up from 45, 45, and 90), which greatly increases the costs of these sections.

Table 24. Summary of Equipment, Tools, Buildings, and Sanitation Costs (in Millions)

	Very small	Small	Large	Total
Total cost to clean and sanitize tools	$5.44	$6.27	$22.86	**$34.57**
Total cost to clean machinery	$7.15	$3.39	$24.22	**$34.76**
Total cost of pest control	$0.75	$0.51	$1.07	**$2.33**
Total cost to provide toilets and hand washing	$3.05	$1.05	$12.25	**$16.34**
Total cost to prevent sewage contamination	$0.01	$0.00	$0.02	**$0.03**
Total cost to dispose litter and land drainage	$3.09	$2.69	$24.88	**$30.66**
Total cost of trash removal	$0.06	$0.02	$0.04	**$0.11**
Total costs of equipment, tools, buildings, and sanitation	**$19.49**	**$13.91**	**$85.29**	**$118.69**

8. Sprouts (Subpart M)

We did not receive substantial comments on cost estimates for Sprouts requirements; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart M do not affect our cost estimates related to subpart M, other than those captured in other parts of this document. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 26

provides the total cost for Sprouts; for full information on how these costs are estimated please refer to Tables 102 – 107 of the original PRIA (Ref. 6).

Table 25 presents updated costs to conduct batch tests related to sprouts. The initial estimate has not changed substantially from those presented in the PRIA. We estimate that it costs approximately $147 to test each batch of sprouts for E. Coli O157:H7 and Salmonella, and there are approximately 3,710 batches from the 74 very small sprouting operations, 2,976 batches from the 60 small sprouting operations, and 33,623 batches from the 151 large sprouting operations. We estimate that batch testing for E. Coli O157:H7 and Salmonella will cost approximately $5 million, annually. New language has been added to the rule which requires sprouting operations to hold their batches while awaiting the test results. We estimate holding costs as a function of the total value of sprouts produced by the operation. We estimated that very small sprouting operations generate total revenue of $70 thousand annually, small sprouting operations generate revenue of $300 thousand annually, and large sprouting operations generate annual revenue of approximately $600 thousand annually (Ref. 44). We estimate that very small operations will need to hold 25 percent of their product while awaiting test results, small operations will hold 10 percent of their product, and large operations will only need to hold 5 percent of their product. Additionally, commonly cited holding costs in the manufacturing literature are 25% of the total value. This yields an annual holding cost for very small sprouting operations of $43,750 ($70 thousand x .25 x .25), small operations of $7,500 ($300 thousand x .10 x .25), and large operations of $30,000 ($600 thousand x .05 x .1), and a total estimate of approximately $81 thousand. There is also a requirement that sprout operations take appropriate action to prevent any food that is

adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (Ref. 44) from entering commerce; however, we do not estimate any additional costs to this language as any such product is already illegal to sell. Finally, we add 10 percent on to the bottom line to account for language which requires batch testing for additional pathogens if and when certain criteria are met. In total we estimate that batch testing of sprouts will cost approximately $5 million dollars annually.

Table 25. Total costs to test each batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and additional pathogens as applicable

	Very small	Small	Large	Total
Number of sprouting operations	74	60	151	285
Number of batches	3,710	2,976	33,623	
Testing costs	$545,444	$437,532	$4,943,253	
Rate of industry practice	55%	55%	55%	
Total cost by size category	$245,450	$196,889	$2,224,464	$2,666,803
Average Sales Volume	$70,000	$300,000	$600,000	
Inventory Holding Cost	25%	25%	25%	
Additional Holding Time	14%	14%	14%	
Per Facility Cost of Holding Product Awaiting Test Results	$2,500	$10,714	$21,429	
Rate of industry practice	55%	55%	55%	
Total Cost of Holding Product Awaiting Test Results	$83,250	$289,286	$1,456,071	$1,828,607
Percent needing to be held	25%	10%	5%	
Inventory Holding Cost	25%	25%	25%	
Inventory Holding Cost	$323,750	$450,000	$1,132,500	$1,906,250
Addition for additional pathogen testing costs	10%	10%	10%	
Additional pathogen testing costs	$56,920	$64,689	$335,696	$457,305
Total cost of E. coli O157:H7 and Salmonella batch testing, holding, prevention, and additional pathogen tests	**$626,120**	**$711,578**	**$3,692,660**	**$5,030,358**

There are new requirements for sprout producers to establish a written corrective action plans as part of their environmental monitoring plan and written sampling plans; however, these costs are presented in the recordkeeping section of this analysis rather than the sprout requirements.

Table 26. Summary of the Total Costs of the Sprouts Provisions

	Very small	Small	Large	Total
Costs to disinfect seeds	$79,190	$63,523	$717,683	**$860,396**
Costs to implement an environmental monitoring plan	$117,957	$164,759	$588,495	**$871,212**
Costs for a specified protocol for collecting environmental samples and testing for L. sp., or L. monocytogenes	$795	$644	$1,622	**$3,061**
Cost of E. coli O157:H7 and Salmonella batch testing, holding, prevention, and additional pathogen tests	$626,120	$711,578	$3,692,660	**$5,030,358**
Total costs of the sprouts provisions	**$824,062**	**$940,504**	**$5,000,461**	**$6,765,027**

9. Recordkeeping (Subpart O)

Farms will incur recordkeeping costs related to demonstrating qualified exemption status; the commercial processing exemption; the agricultural water provisions; the biological soil amendments of animal origin provisions; cleaning equipment, tools, buildings, and sanitation; sprouting operations; and food safety training. We present detailed costs for the recordkeeping activities required for agricultural water and new provisions for sprouting operations; however, the other records have not changed substantially from the PRIA (though there have been some changes to recordkeeping, discussed in greater detail in the Paperwork Reduction Act analysis), and we therefore present in this section only summary statistics of the remainder of recordkeeping activities. For more on the full methodology please refer to the PRIA (Ref. 6).

We estimate that farms will incur recordkeeping costs pertaining to the water provisions (under Subpart O and § 112.50), including keeping records of inspection of water systems (§ 112.50(b)(1)), test results of untreated surface water (§ 112.50(b)(2)), test results of untreated ground water (§ 112.50(b)(2)), scientific information supporting adequacy of water treatment methods (§ 112.50(b)(3)), water treatment monitoring results (§ 112.50(b)(4)), documentation of corrective actions including use of microbial

die-off or removal rates (§ 112.50(b)(6)) and scientific data relied on for such rates between harvest and end of storage (§ 112.50(b)(5)), use of public water sources (§ 112.50(b)(7)), data to support any alternatives (including alternative microbial quality criteria, alternative microbial die-off rates and maximum time intervals, or alternative minimum numbers of samples for initial and annual surveys in testing untreated water used for direct water application in growing produce other than sprouts) (§ 112.50(b)(8)), and analytical methods used in lieu of those incorporated in the rule (§ 112.50(b)(9)).

We estimate that all covered farms not currently keeping such records will maintain records of inspection of water systems (§ 112.50(b)(1)) and that the time burden is one hour annually. We multiply the farm operator wage rate by the time burden and annual frequency and estimate the costs of water inspection records are $1.6 million for very small farms, $284 thousand for small farms, and $341 thousand for large farms.

From earlier estimates of water testing, we estimate that there are a total of 26,038 farms that use untreated ground water will incur the costs maintaining records of their results from testing the water for 0 detectable generic E. coli (§ 112.50(b)(2)). We estimate that the time burden of recordkeeping is 0.33 hours and that the annual frequency of recordkeeping is estimated to be 2 times. We multiply the farm operator wage rate by the time burden and the annual frequency and estimate the costs of surface water testing records are $804 thousand for very small farms, $141 thousand for small farms, and $175 thousand for large farms.

From earlier estimates of water testing, we estimate that 12,544 farms (those that use untreated surface water less the percentage estimated to use public water sources) will incur costs maintaining records of their results from testing the water for GM of 126

CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli (§ 112.50(b)(2)). We estimate that the time burden of recordkeeping is 0.33 hours and that the annual frequency of recordkeeping is estimated to be 10 times in the first two years and 5 times in subsequent years. We multiply the farm operator wage rate by the time burden and the net present value of the annual frequency over ten years and estimate the costs of surface water testing records are $1.2 million for very small farms, $226 thousand for small farms, and $296 thousand for large farms.

From earlier estimates of water testing, we estimate that 9,471 farms (those that use untreated ground water less the percentage estimated to use public water sources) will incur costs maintaining records of results from testing the water for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli (§ 112.50(b)(2)). We estimate that the time burden of recordkeeping is 0.33 hours and that the annual frequency of recordkeeping is 4 times in the first year and once in subsequent years. We multiply that farm operator wage rate by the time burden and the net present value of the annual frequency over ten years and estimate the costs of ground water testing records $194 thousand for very small farms, $38 thousand for small farms, and $50 thousand for large farms.

We estimate that 20 percent of farms that treat water to meet quality criteria of GM of 126 CFU / 100ml or STV of 410 CFU /100ml and 50 percent of farms that treat water to meet quality criterion of no detectable E. coli (a total of 5,547 farms) will maintain records of the adequacy of their water treatment methods (§ 112.50(b)(3)). We estimate that 5,547 will maintain records, with a one-time burden of 0.5 hours. We multiply the farm operator wage rate by the number of farms, the hourly time burden, and

estimate that the costs of maintaining records of data to support method adequacy are $194 thousand for very small farms, $38 thousand for small farms, and $50 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

From earlier estimates of water testing, we estimate that all farms that treat their water (an estimated total of 5,547 farms) will maintain records of the results of water treatment monitoring (§ 112.50(b)(4)), with an annual time burden of one hour. We multiply the farm operator wage rate by the number of farms, the hourly time burden, and the annual frequency and estimate that the costs of maintaining records of water treatment monitoring are $250 thousand for very small farms, $47 thousand for small farms, and $61 thousand for large farms.

Farms that rely on a microbial die-off or removal rate to determine a time interval between harvest and end of storage, including other activities such as commercial washing, to achieve a calculated log reduction of generic E. coli in accordance with § 112.45(b)(1)(ii), must have documentation of the scientific data or information they rely on to support that rate (§ 112.50(b)(5)). We estimate that 25 percent of all farms that rely on die-off, 3,661 (17,840 farms from table 18 of the FRIA x 80 percent that rely on die off + 371 irrigated farms subject to a corrective action x 25 percent) would generate these records for postharvest die-off intervals. It is estimated that two recordkeepers for each of 3,661 farms will spend .5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data and information. We multiply the farm operator wage rate by the number of farms, the hourly time burden, and estimate that the costs of maintaining records of data to support microbial die-off are

$162 thousand for very small farms, $32 thousand for small farms, and $41 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

When covered farms take corrective actions in accordance with § 112.45, they must maintain certain required records (§ 112.50(b)(6)), including keeping certain records about specific time intervals or log reductions applied. We calculate that 14,643 farms will incur the costs of documentation of any corrective actions taken in accordance with § 112.45, including any time intervals or calculated log reductions applied. Therefore, it is estimated that 1 recordkeeper on each of the 14,643 farms will spend an average of 0.5 hours per year on recordkeeping related to corrective actions applied. The total costs of corrective action recordkeeping, including microbial die-off or removal records, is $325 thousand for very small farms, $63 thousand for small farms, and $83 thousand for large farms.

All covered farms that use public water sources exempt from testing, such as municipal water, will maintain certain required records related to those public water systems (§ 112.50(b)(7)). We estimate that 9,108 farms (the number of farms using public water systems such as municipal water sources) will need to keep these records and that the time burden is 0.33 hours annually (Ref. 6;10;40) We multiply the farm operator wage by the proportion of farms that use municipal water and estimate that public water system recordkeeping costs are $141 thousand for very small farms, $24 thousand for small farms, and $30 thousand for large farms.

Section 112.50(b)(8) requires all farms that choose to rely on an alternative under § 112.49 to have documentation of the scientific data or information they rely on to

support that alternative. There are four types of alternatives that may be employed according to 112.49(a)-(d).

Section 112.49(a) provides for an alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b). Farms must maintain records supporting any such alternative microbial criteria they use (§ 112.50(b)(8)). We estimate that approximately 8,757 farms that irrigate (35,029 total farms x 25 percent) will generate these alternative records. We estimate each farm will spend half an hour one time on this documentation. We multiply the farm operator wage by the number of farms and estimate that this alternative microbial quality criterion recordkeeping costs are $205 thousand for very small farms, $36 thousand for small farms, and $44 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

Section 112.49(b) provides for an alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i). Farms must maintain records supporting any such alternative die off rate and maximum time interval they use (§ 112.50(b)(8)). We estimate that approximately 3,661 farms that irrigate (14,643 total farms x 25 percent) will generate these alternative records. We estimate each farm will spend half an hour one time on this documentation. We multiply the farm operator wage by the number of farms and estimate that this alternative microbial die-off rate recordkeeping costs are $81 thousand for very small farms, $16 thousand for small farms, and $21 thousand for large farms. Because this is a onetime cost, we then annualize over 10 years.

Section 112.49(c) provides for an alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A). Farms must maintain records supporting any such alternative sampling rate they use (§ 112.50(b)(8)). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources x 20 percent) will generate these alternative records. We estimate that 1,541 very small farms, 302 small farms, and 668 large farms will develop one record that will take 0.5 hours to complete. In total, we estimate that this recordkeeping will cost very small farms $56 thousand, small farms $11 thousand, and large farms $14 thousand. Because this is a onetime cost, we then annualize over 10 years.

Section 112.49(d) provides for an alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A). Farms must maintain records supporting any such alternative sampling rate they use (§ 112.50(b)(8)). We estimate that approximately 2,551 farms that utilize surface water (12,554 irrigated farms that use surface water less the percentage estimated on public water sources x 20 percent) will generate these alternative records. We estimate that 1,541 very small farms, 302 small farms, and 668 large farms will develop one record that will take 0.5 hours to complete. In total, we estimate that this recordkeeping will cost very small farms $56 thousand, small farms $11 thousand, and large farms $14 thousand. Because this is a onetime cost, we then annualize over 10 years.

All farms that are required to test their agricultural water in compliance with § 112.46 must have documentation of any analytical methods that they choose to use for such testing in lieu of the methods that are incorporated by reference in § 112.151 (§ 112.50(b)(9)). It is not known how many farms will use other analytical methods; however, to the extent that they do this it will likely be as a cost savings measure. Therefore, we do not include any cost of recordkeeping for 112.50(b)(9) here. This is acknowledged in the PRA analysis.

Table 27 presents the recordkeeping costs of the water provisions. We estimate that the total costs of recordkeeping are $4.5 million for very small farms, $0.83 million for small farms, and $1.0 million for large farms, totaling to $6.4 million.

Table 27. Recordkeeping Costs of the Water Provisions

	Very small	Small	Large	Total
Farm operator wages	$72.12	$72.12	$42.74	
Inspection of water systems (§ 112.50(b)(1))				
Number of farms	22,485	3,932	7,979	34,396
Time burden	1	1	1	
Frequency	1	1	1	
Total inspection recordkeeping costs	$1,621,607	$283,595	$341,004	$2,246,206
Initial and annual tests for 0 detectable Generic E. coli (§ 112.50(b)(2))				
Number of farms	16,888	2,952	6,198	26,038
Time burden	2	2	2	
Frequency	0.33	0.33	0.33	
Baseline recordkeeping costs of testing ground water for 0 detectible generic E. coli	$803,869	$140,515	$174,835	$1,119,219
Initial and annual tests of surface water for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli (§ 112.50(b)(2))				
Number of farms	7,703	1,512	3,339	12,554
Time burden	0.33	0.33	0.33	
Frequency	6.29	6.29	6.29	
Baseline recordkeeping costs of testing surface water for GM 126 CFU/STV 410 CFU/100 mL generic E. coli	$1,153,122	$226,369	$296,218	$1,675,708

Initial and annual tests of ground water for GM of 126 CFU / 100 mL and STV of 410 CFU / 100 mL Generic E. coli (§ 112.50(b)(2))				
Number of farms	5,811	1,141	2,519	9,471
Time burden	0.33	0.33	0.33	
Frequency	1.4	1.4	1.4	
Baseline recordkeeping costs of testing ground water for GM 126 CFU/STV 410 CFU/100 mL generic E. coli	$193,618	$38,009	$49,737	$281,365
Cost of records of data to support adequacy of a treatment method used to satisfy § 112.43(a)(1) and (a)(2) (§ 112.50(b)(3))				
Number of farms	3,473	654	1,420	5,547
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping costs of data to support method adequacy	$125,228	$23,588	$30,346	179,161
NPV (@7%)	$17,830	$3,358	$4,321	$25,509
Cost of records of results of water treatment monitoring records (§ 112.50(b)(4))				
Number of farms	3,473	654	1,420	5,547
Time burden	1	1	1	
Frequency	1	1	1	
Recordkeeping costs of water treatment	$250,455	$47,175	$60,692	358,322
NPV (@7%)	$35,659	$6,717	$8,641	$51,017
Cost of records of data to support microbial die-off/max time interval between harvest and end of storage or removal during activities such as commercial washing (§ 112.50(b)(5))				
Number of farms	2,251	440	970	3,661
Time burden	0.5	0.5	0.5	
Frequency	2	2	2	
Recordkeeping costs of data to support die-off or maximum time interval	$162,339	$31,727	$41,454	$235,520
Costs of records for corrective actions under § 112.45, including die-off or removal use (§ 112.50(b)(6))				
Number of farms	9,004	1,760	3,880	14,643
Time burden	1	1	1	
Frequency	0.5	0.5	0.5	
Recordkeeping costs for corrective actions, including die-off or removal use	$324,677	$63,454	$82,909	$471,039
Costs of records related to public water systems (§ 112.50(b)(7))				
Number of covered irrigated farms	5,923	1,029	2,156	9,108
Time burden	0.33	0.33	0.33	
Frequency	1	1	1	

Recordkeeping cost of public water systems	$140,966	$24,479	$30,408	$195,853
Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49(a) (§ 112.50(b)(8))				
Number of farms	5,695	989	2,073	8,757
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping cost of data to support alternatives	$205,371	$35,663	$44,300	$285,334
NPV (@7%)	$29,240	$5,078	$6,307	$40,625
Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49(b) (§ 112.50(b)(8))				
Number of farms	2,251	440	970	3,661
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping cost of data to support alternatives	$81,169	$15,863	$20,727	$117,760
NPV (@7%)	$11,557	$2,259	$2,951	$16,766
Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49(c) (§ 112.50(b)(8))				
Number of farms	1,541	302	668	2,511
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping cost of data to support alternatives	$55,553	$10,906	$14,271	$80,730
NPV (@7%)	$7,910	$1,553	$2,032	$11,494
Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49(d)(§ 112.50(b)(8))				
Number of farms	1,541	302	668	2,511
Time burden	0.5	0.5	0.5	
Frequency	1	1	1	
Recordkeeping cost of data to support alternatives	$55,553	$10,906	$14,271	$80,730
NPV (@7%)	$7,910	$1,553	$2,032	$11,494
Total recordkeeping costs of the water provisions	**$4,510,303**	**$828,664**	**$1,042,849**	**$6,381,815**

Sprouting operations will incur one-time and recurring recordkeeping costs (Subpart O and § 112.150).

One-time recordkeeping costs include an environmental monitoring plan (§ 112.150(b)(2)) with a one-time burden of 7 hours for very small farms, 12 hours for small firms, and 17 hours for large firms (Ref. 3) not already estimated to be performing these actions. These time burdens are multiplied by the number of sprouting operations and the wage rate for farm operators ($72.12 for very small and small farms, $42.74 for large farms) to estimate a total one-time cost of $123,379.

One-time recordkeeping costs also include an irrigation water sampling plan (§ 112.150(b)(3)) with a one-time burden of 8 hours per sprouting operation not already performing these actions. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate a one-time irrigation water sampling plan recordkeeping cost of $79,944.

Sprout operations are required to have documentation of any analytical methods used in lieu of the methods for both environmental testing and batch testing that are incorporated by reference in §§ 112.152 and 112.153 (§ 112.150(b)(5)). It is not known how many sprout operations will use other analytical methods; however, to the extent that they do this it will likely be as a cost savings measure. Therefore, we do not include any cost of recordkeeping for 112.50(b)(5) here. This is acknowledged in the PRA analysis. In addition, § 112.144(c) requires sprout operations to conduct testing for additional pathogens when certain conditions are met, and § 112.150(b)(5) requires sprouting operations to have documentation of any analytical methods used for such testing because there is no specific method for such testing incorporated by reference in § 112.152 or 112.153. It is not known if or when there will be a pathogen(s) meeting the relevant criteria; however, it is estimated that one 2 hour record will fulfill this requirement,

estimated as the time needed to establish a new testing routine. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate a one-time record of analytical testing method recordkeeping cost of $19,986.

One-time environmental monitoring plan, irrigation water sampling plan, and additional pathogen analytical test method recordkeeping costs total to $56,251 for very small operations, $59,023 for small operations, and $108,036 for large operations. Table 28 presents these totals annualized at 7 percent for 10 years, estimated at $8,009 for very small operations, $8,404 for small operations, and $15,382 for large operations, totaling to $31,794.

Table 28. One-time Recordkeeping Costs for Sprouts

One-time recordkeeping costs	Very small operations	Small Operations	Large Operations	Total
Environmental monitoring plan (§ 112.150(b)(2))				
Number of sprout operations	46	37	94	177
Time burden	7	12	17	
Frequency	1	1	1	
Recordkeeping cost of environmental monitoring	$23,162	$32,194	$68,022	$123,379
NPV (@7%)	$3,298	$4,584	$9,685	17,566
Irrigation water sampling plan(§ 112.150(b)(3))				
Number of sprout operations	46	37	94	177
Time burden	8	8	8	
Frequency	1	1	1	
Recordkeeping cost of water sampling plan	$26,471	$21,463	$32,011	$79,944
NPV (@7%)	$3,769	$3,056	$4,558	11,382
Record of analytical method for additional pathogen testing(§§ 112.150(b)(5), 112.44(c))				
Number of sprout operations	46	37	94	177
Time burden	2	2	2	
Frequency	1	1	1	
Recordkeeping cost of analytical method	$6,618	$5,366	$8,003	$19,986
NPV (@7%)	$942	$764	$1,139	2,846
Total one-time recordkeeping costs by size category	$56,251	$59,023	$108,036	$223,309
Annualized one-time recordkeeping	**$8,009**	**$8,404**	**$15,382**	**$31,794**

costs by size category (7 percent for 10 years)				

We estimate that sprouting operations not already performing certain recordkeeping activities will incur recurring recordkeeping costs, including documentation of seed treatment (§ 112.150(b)(1)), environmental monitoring plan - annual maintenance (§ 112.150(b)(2)), environmental monitoring test results (§ 112.150(b)(4)), spent irrigation water sampling plan – annual maintenance (§ 112.150(b)(3)), spent irrigation water test results (§ 112.150(b)(4)), and documentation of corrective actions taken under §§ 112.142(b) and (c), 112.146, and 112.148 (§ 112.150(b)(6)).

We estimate that records of documentation of seed or bean treatment (including documentation of previous treatment by a third party) ((§ 112.150(b)(1)), will need to be documented by 128 sprouting operations not already performing these activities. This record will need to be made 50 times for small and very small operations, and 223 times for large operations, based on the number of batches. We estimate that this record will take approximately 12 minutes to make (20 percent of one hour). These time burdens multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual record of seed treatment recordkeeping cost of $173,015.

Environmental monitoring plan- annual maintenance recordkeeping (§ 112.150(b)(2)) will need to be documented by 177 sprouting operations not already performing these activities. This record will need to be made once annually by each operation. We estimate that this record will take approximately 9 minutes to make (15 percent of one hour). These time burdens are multiplied by the number of sprouting

operations and by the farm operator wage rate to estimate an annual environmental monitoring plan- annual maintenance recordkeeping cost of $1,499.

Environmental monitoring test result records (§ 112.150(b)(4)) will need to be documented by 128 sprouting operations not already performing these activities. This record will need to be made 60 times for very small operations, 120 times for small operations, and 180 times for large operations, based on the number of tests conducted. We estimate that this record will take approximately 10 minutes to make (17 percent of one hour). These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual environmental monitoring test result recordkeeping cost of $153,088.

Spent irrigation water sampling plan – annual maintenance recordkeeping (§ 112.150(b)(3)) will need to be documented by 177 sprouting operations not already performing these activities. This record will need to be made once for each operation. We estimate that this record will take approximately one hour to make. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual spent irrigation water sampling plan – annual maintenance recordkeeping cost of $9,993.

Spent irrigation water test results records (§ 112.150(b)(4)) will need to be documented by 128 sprouting operations not already performing these activities. This record will need to be made 125 times for very small and small operations, and 558 times for large operations, based on batches. We estimate that this record will take approximately 9 minutes (15 percent of one hour) to make. These time burdens are

multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual spent irrigation water test results recordkeeping cost of $324,403.

Documentation of corrective actions taken under §§ 112.142(b) and (c), 112.146, and 112.148 (§ 112.150(b)(6)) will need to be documented by 285 sprouting operations. This record will need to be made once for each corrective action. We estimate that this record will take approximately 30 minutes (50 percent of one hour) to make. These time burdens are multiplied by the number of sprouting operations and by the farm operator wage rate to estimate an annual corrective action recordkeeping cost of $8,059.

Each of these time burdens is multiplied by the hourly wage rate for farm operators at very small, small, and large operations. Table 29 presents the recurring recordkeeping costs for the sprouts provisions. We estimate the total recurring recordkeeping costs for sprouts are $100,016 for very small operations, $100,956 for small operations, and $469,085 for large operations.

Table 29. Recurring Recordkeeping Costs for Sprouts

Recurring recordkeeping costs	Very small operations	Small Operations	Large Operations	Total
Documentation of seed treatment (§ 112.150(b)(1))				
Number of sprout operations	33	27	68	128
Time burden	50	50	223	
Frequency	0.20	0.20	0.20	
Recordkeeping cost of seed treatment	$24,016	$19,472	$129,527	$173,015
Environmental monitoring plan – annual maintenance(§ 112.150(b)(2))				
Number of sprout operations	46	37	94	177
Time burden	1	1	1	
Frequency	0.15	0.15	0.15	
Recordkeeping cost of environmental monitoring - annual maintenance	$496	$402	$600	$1,499
Environmental monitoring test results(§ 112.150(b)(4))				
Number of sprout operations	33	27	68	128
Time burden	60	120	180	
Frequency	0.17	0.17	0.17	

Recordkeeping cost of environmental monitoring test results	$24,496	$39,724	$88,868	$153,088
Spent Irrigation water sampling plan –annual maintenance(§ 112.150(b)(3))				
Number of sprout operations	46	37	94	177
Time burden	1	1	1	
Frequency	1	1	1	
Recordkeeping cost of water sampling plan - annual maintenance	$3,309	$2,683	$4,001	$9,993
Spent irrigation water test results(§ 112.150(b)(4))				
Number of sprout operations	33	27	68	128
Time burden	125	125	558	
Frequency	0.15	0.15	0.15	
Recordkeeping cost of spent irrigation water test results	$45,030	$36,511	$242,862	$324,403
Recordkeeping costs of corrective actions taken under §§ 112.142(b) and (c), 112.146, and 112.148 (§ 112.150(b)(6))				
Number of sprout operations	74	60	151	285
Time burden	1	1	1	
Frequency	0.50	0.50	0.50	
Recordkeeping cost of spent irrigation water test results	$2,668	$2,164	$3,227	$8,059
Total recurring recordkeeping costs by size category	**$100,016**	**$100,956**	**$469,085**	**$670,057**

Table 30 presents a summary of recordkeeping costs. The total costs of recordkeeping are $16 million for very small farms, $4.2 million for small farms, and $7.3 million for large farms, totaling to $27.5 million for all farms.

Table 30. Summary of Recordkeeping Costs (annually, in thousands)

Recording activity	Very Small	Small	Large	Total
Qualified exempt farms labeling and documentation (§ 112.7)	$5,239	$469	$0	$5,709
Agricultural water (§ 112.50)	$4,510	$829	$1,043	$6,382
Biological soil amendments of animal origin (§ 112.60)	$184	$32	$40	$256
Equipment, tools, buildings, and sanitation (§ 112.140)	$4,829	$2,620	$5,492	$12,941
Sprouting operations (§ 112.150)	$108	$109	$484	$702
Training (§ 112.30)	$1,069	$186	$227	$1,482
Documentation relating to commercial processing exemption	$13	$3	$3	$18

(§ 112.2(b)(4))				
Total cost (annual in thousands)	**$15,951**	**$4,249**	**$7,290**	**$27,490**

10. Administrative Provisions

We did not receive substantial comments on the cost estimates for Administrative Provisions; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing those provisions do not affect our cost estimates. Thus, we present the estimates utilizing more current wage information and farm counts. Table 31 provides the total cost for Administrative Provisions.

In total we estimate that learning about the rule will cost all farms approximately $23 million, annualized at 7 percent over ten years. These costs are comprised of all qualified exempt and non-covered farms spending 4 hours with the rule, which was lowered from 10 hours estimated in the PRIA based on public comment and feedback from public meetings. Very small covered farms are estimated to spend 40 hours with the rule, and small and large covered farms spend 40 hours with the rule as well as 40 hours of legal review (for a total of 80 hours); these estimates have not been altered from those originally proposed.

Table 31. Total Costs of Reading and Learning about the Rule Requirements

	Exempt	**Very Small**	**Small**	**Large**	**Total**
Number of qualified exempt and non-covered farms	74,931	30,952	5,128	10,105	121,116
Farm operator wage	$42.74	$72.12	$72.12	$42.74	
Time reading and learning rule	4	4	4	4	
Per farm learning cost	$171	$288	$288	$171	
Cost to learn about the rule	$12,810,204	$8,929,032.96	$1,479,325	$1,727,551	
Number of covered farms	0	22,781	3,956	8,292	35,029
Farm Operator Wage		$72.12	$72.12	$42.74	

Time reading and learning rule		40	40	40	
Legal analyst wage			$96.00	$96.00	
Time reading and learning rule			40	40	
Per farm learning cost		$2,885	$6,725	$5,550	
Cost to learn about the rule		$65,718,629	$26,603,309	$46,017,283	
Total One Time Cost	**$12,810,204**	**$74,647,662**	**$28,082,634**	**$47,744,834**	**$163,285,334**
Costs annualized over 10 years	**$1,823,885**	**$10,628,148**	**$3,998,335**	**$6,797,790**	**$23,248,158**

11. Corrective Steps

Although the requirements have not changed dramatically from those proposed in the original rule, our estimates of Corrective Steps have increased from those originally provided. Primarily in response to comments received on the economic analysis, we have doubled the frequency at which we estimate that corrective actions may occur. Otherwise, we generally retain our costs methodology from those in the PRIA. The analysis include all steps taken under 112.45, for example, when agricultural water is not safe/adequate or fails to meet a microbial standard, and all the steps required in subpart M for sprouters when they get an environmental positive or a batch pathogen positive (required under 112.146 and 148). Our changes to the proposed requirements for corrective actions were in relation to the requirements for agricultural water and sprouts. Thus, we present only summary statistics of estimates utilizing more current wage information and farm counts. Table 32 provides the total cost for Corrective Steps related to agricultural water and sprouts; for full information on how these costs are estimated please refer to Tables 119 – 120 of the original PRIA(Ref. 6).

Table 32. Summary of Costs of Corrective Steps (in thousands)

	Very Small	**Small**	**Large**	**Total**
Failed standards Directed to Agricultural Water	$412	$97	$260	$770
Failed standards Directed to Sprouts	$322	$336	$1,818	$2,476

Total Costs of Corrective Steps (annual)	**$735**	**$433**	**$2,078**	**$3,246**

12. Variances

We did not receive substantial comments on the cost estimates for Variances; therefore, we have not altered the underlying methodology from those originally proposed and estimated in the PRIA. In addition, our changes to the proposed requirements in finalizing subpart P do not substantively affect our cost estimates. Thus, we present the estimates utilizing more current wage information and a slightly increased number of applicants, to account for the allowance for tribal applications. Table 33 provides the total cost for Administrative Provisions.

Table 33. Total Costs of Preparing and Reviewing Initial Petition

	Cost Components
Hours to complete petition	80
Wage (GS 14.1)	$75.62
Cost to complete petition	$6,049.60
Hours to internally review	40
Wage (GS 15.3)	$94.88
Cost to internally review petition	$3,795.20
Cost to complete & review	$9,844.80
Hours for FDA review	80
Wage (GS 13.7)	$76.79
Cost for FDA review	$6,143.20
Total individual cost of petition	$15,988
Potential number of applicants	7
Total Cost of Preparing and Reviewing Final Petition	**$111,916**

13. Summary of Costs

The total costs by standard in the rule and other sections are summarized in Table 34 by farm size. The “not covered” category only includes the 74,931 farms that generate an average annual monetary value of produce sold of $25,000 or less. All farms

either covered or not by the rule would incur the costs to learn the rule. In addition to learning the rule, the 30,952 covered by the rule would incur the costs of implementing the standards directed to personnel health and hygiene; agricultural water; domesticated and wild animals; growing, harvesting, packing, and holding activities; equipment, tools, buildings, and sanitation; personnel qualifications and training; sprouts (only for sprout farms); and recordkeeping.

Farms that are eligible for a qualified exemption would incur costs to not only learn the rule and retain documentation demonstrating their eligibility for the qualified exemption, but also costs to change labels if necessary or otherwise disclose their name and complete business address at the point of sale. For farms that grow, harvest, pack, or hold produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, costs will be incurred in making required disclosures and receiving and maintaining records of written assurances from customers. The costs to these farms of these requirements are included in the total recordkeeping costs of the rule.

The estimates in Table 34 are reported in millions for ease of readability with the exception of the average cost per farm estimates, which are reported with no abbreviation.

Table 34. Summary of Costs for the Produce Safety Rule (in millions)

Cost Sections	**Not Covered**	**Very Small**	**Small**	**Large**	**Total**
Personnel Qualifications and training	$0.00	$41.14	$54.08	$92.16	**$187.38**
Health and Hygiene	$0.00	$28.11	$13.59	$93.91	**$135.61**
Agricultural water	$0.00	$18.41	$4.21	$14.45	**$37.07**
Biological soil amendments of animal origin	$0.00	$0.44	$0.31	$1.72	**$2.47**
Domesticated and wild animals	$0.00	$2.36	$2.05	$11.45	**$15.86**
Growing, harvesting, packing, and holding activities	$0.00	$0.92	$0.35	$0.98	**$2.25**
Equipment, tools, buildings, and	$0.00	$19.49	$13.91	$85.29	**$118.69**

sanitation					
Sprouting operations	$0.00	$0.82	$0.94	$5.00	**$6.77**
Recordkeeping	$5.71	$10.71	$3.78	$7.29	**$27.49**
Administrative cost to learn the rule	$1.82	$10.63	$4.00	$6.80	**$23.25**
Corrective steps	$0.00	$0.73	$0.43	$2.08	**$3.25**
Variances	$0.00	$0.00	$0.00	$0.11	**$0.11**
Total Costs (annual in millions)	**$7.53**	**$133.76**	**$97.65**	**$321.24**	**$560.19**
Average Cost per farm	$101	$5,872	$24,683	$38,741	**$15,992**

The costs of the rule may decrease over time as farms learn by doing. However, these costs of this rule will not be immediately realized, nor will they be uniformly implemented, due to the staggered nature of compliance times. Table 35 presents the annual estimates of costs as they are estimated to occur.

Table 35. Timing of Produce Costs (in millions)

Farms	Year1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Covered Farms										
Very Small	$0	$0	$0	$0	$115	$115	$133	$133	$133	$133
Small	$0	$0	$0	$92	$92	$97	$97	$97	$97	$97
Large	$0	$0	$302	$302	$316	$316	$316	$316	$316	$316
Covered Sprout operations										
Very Small Sprouts	$0	$0	$0	$1	$1	$1	$1	$1	$1	$1
Small Sprouts	$0	$0	$1	$1	$1	$1	$1	$1	$1	$1
Large Sprouts	$0	$5	$5	$5	$5	$5	$5	$5	$5	$5
Exempt Farms										
Very Small Exempt	$0	$0	$0	$0	$7	$7	$7	$7	$7	$7
Small Exempt	$0	$0	$0	$1	$1	$1	$1	$1	$1	$1
Large Exempt	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0

Note: Summing across a single year gives a single year cost of full may not match the actually estimated cost of this rulemaking due to rounding errors in this table, which is meant for illustrative purposes.

Next, we annualize estimates of the costs below in Table 36. In this estimate, we take into account the time that different sized farms have to comply with the rule, as well as the different compliance times for agricultural water provisions and for activities relating to sprouts. Estimates are annualized over 10 years. We estimate that the annualized costs of the final rule would be approximately $368 million per year using a discount rate of 7 percent over 10 years. The average cost per covered farm is $10,351. We note that within size categories costs borne by individual farms will diverge widely from the averages reported here, depending upon whether or not the farm is already in compliance with most of the provisions of the rule.

Table 36. Summary of Costs for the Produce Safety Rule Considering Time to Comply with the Rule (in millions)

Cost Sections	Not Covered	Very Small	Small	Large	Total
Personnel Qualifications and training	$0.00	$21.30	$33.87	$68.44	**$123.61**
Health and Hygiene	$0.00	$14.55	$8.51	$69.74	**$92.80**
Agricultural water	$0.00	$6.48	$1.87	$7.76	**$16.11**
Biological soil amendments of animal origin	$0.00	$0.23	$0.16	$0.89	**$1.28**
Domesticated and wild animals	$0.00	$1.22	$1.28	$8.50	**$11.01**
Growing, harvesting, packing, and holding activities	$0.00	$0.48	$0.22	$0.73	**$1.42**
Equipment, tools, buildings, and sanitation	$0.00	$10.09	$8.71	$63.33	**$82.14**
Sprouting operations	$0.00	$0.52	$0.70	$4.34	**$5.55**
Recordkeeping	$4.24	$5.55	$2.37	$5.41	**$17.57**
Administrative cost to learn the rule	$1.35	$5.50	$2.50	$5.05	**$14.41**
Corrective steps	$0.00	$0.38	$0.27	$1.54	**$2.19**
Variances	$0.00	$0.00	$0.00	$0.08	**$0.08**
Total Costs (annual in millions)	**$5.59**	**$66.29**	**$60.47**	**$235.82**	**$368.17**
Average Cost per farm*	$74.65	$2,910.02	$15,285.87	$28,438.88	**$10,350.83**

Note: Average costs values not reported in millions.

Annualizing costs over the first ten years after publication of this final rule, costs are expected to be approximately at $368 million annually at 7 percent and $389 million at 3 percent.

Table 37. Net Present Value and Annualized Costs of the Produce Safety Rule (in millions)

	Exempt	Very Small	Small	Large	Total
Net present value at 3 percent	$37	$613	$550	$2,104	**$3,304**
Net present value at 7 percent	$28	$462	$424	$1,657	**$2,571**
Annualized at 3 percent over 10 years	$4	$72	$65	$247	**$387**
Annualized at 7 percent over 10 years	$4	$66	$60	$236	**$366**
Average Cost Per Farm at 3 percent	$58	$3,155	$16,304	$29,749	**$11,059**
Average Cost Per Farm at 7 percent	$53	$2,885	$15,265	$28,452	**$10,449**

Note: Average costs values not reported in millions.

G. Distributional Effects

We do not expect that the rule will have any adverse distributional effects on any one specific party. That is, depending on how the farms in the affected markets respond to these requirements, some of the costs may ultimately be borne by consumers as price increases. The higher prices, however, will likely not be sufficient to fully offset the costs borne by food establishments. As an overly simple example, if 100 percent of the costs of this rule were passed along directly to consumers this would increase the market price for fresh produce by only 2.1 percent ($231+ foreign costs + $560 domestic costs million divided by $38 billion). Additionally, it is highly unlikely that any one party, either consumers or industry, will bear the entire burden of costs from compliance with this rule. Rather, the costs will likely be shared amongst all parties based on numerous factors such

as the relative price elasticity of the produce market and producers' ability to set prices in the marketplace.

H. International Effects

For the FRIA, we retained the methodology for the number of foreign farms that will be covered by our rule based on the latest number of foreign farms shipping produce to the US. As with domestic farms, we adjust these numbers based on new data sources. Our estimate for the total number of foreign farms exporting produce to the US is approximately 45,000. Of those farms exporting RACs to the US, we estimate that approximately 13,000 might incur compliance costs to continue exporting to the US.[10] Because we lack survey data about baseline foreign farms' food safety practices and the likely costs to incorporate all the changes to comply with the rule, we estimate the costs by assuming that the average costs will be the same for foreign and domestic farms; they will have the same proportion of baseline practices and the same proportion of farms not covered or eligible for an exemption. Applying the average annualized cost of the rule for domestic farms of roughly $10,000 per farm using a 7 percent discount rate ($11,000 at a 3 percent discount rate) yields an estimated total annualized cost to foreign operations of $136 million ($146 million using a 3 percent discount rate). Additionally, those farms that are exempt from or not covered by the rule are estimated to incur the same average costs of domestic exempt or non-covered farms. Applying the average annualized cost of the rule for domestic farms of roughly $53 per farm using either a 7

[10] This estimate is derived from the total number of entities importing RACs from OASIS data (45,000) multiplied by the percent of domestic farms that are covered by this rulemaking, 29 percent (35,029 covered farms divided by 121,116 total farms). The methodology has not changed from the proposed analysis but both sources of data are now updated.

percent discount rate ($58 using a 3 percent discount rate) yields an estimated total annualized cost to exempt or non-covered foreign operations of $1.7 million using a 7 percent discount rate ($1.8 million using a 3 percent discount rate). Together, we estimate an annual cost to foreign farms shipping produce RACs to the US of $138 million annualized, using a 7 percent discount rate ($146 million using 3 percent).

This analysis may overstate or understate the true cost to foreign farms. From our OASIS data, we know that foreign operations will often only send a small fraction of their total production to the US and therefore our estimate is likely the upper bound estimate. If average foreign wage rates are significantly lower than average US wage rates, if total production costs are lower, or if some foreign farms simply cease to ship their products to the US because of the regulatory compliance costs, the total costs to foreign farms might be significantly less. Conversely, if fewer foreign farms are already preforming some of the required activities, or if average foreign wage costs are higher, then the total costs to foreign farms could be higher.

I. Uncertainty and Sensitivity Analysis

1. Costs

A source of uncertainty is our FVAP survey (Ref. 20) The survey is older data, from 1999, and it is highly likely that the produce industry has made significant improvements in safety measures since it was originally conducted. There has been a growing industry wide understanding of the benefits of safe food handling practices and more and more establishments are adopting some food safety controls. If the survey overstates the number of operations that lack our controls today by 25 percent, to account

for trends in industry practices, the total costs of the rule would decline to $301 million as shown in Table 38.

In addition, it could be that farm food safety practices have actually decreased since this survey was conducted. Therefore we additionally lower the percentage compliance rates by 10% to more fully capture the variability inherent in this analysis. We adjust compliance percentages downwards somewhat less than we adjusted upwards, because we believe that it is much less likely that farms have regressed in their safety activities since the survey was conducted. If the survey understates the number of operations that lack practices compliant with part 112 today by 10 percent, the total costs for the final rule would rise to $401 million as shown in Table 38.

The costs of the water provisions are another source of uncertainty we address in our sensitivity analysis. We raise water provision compliance rates by 25 percent in our low estimate and decrease them to zero percent in our high estimate. In addition, because the costs to treat water are somewhat more uncertain than some other cost estimates, we also lower water treatment costs to $32 in our low estimate and raise water treatment costs to $543 in our high estimate, to capture the full potential range of marginal water treatment costs. Because water costs represent about 6.6 percent of the total costs of the rule, substantial changes such as doubling or halving them would only result in a 6.6 percent increase or a 3.3 percent decrease in the total costs of the rule.

Table 38. Sensitivity Analysis of Costs (in millions)

	Low	**High**
Annualized at 3 percent	$319	$425
Annualized at 7 percent	$301	$401

2. Benefits

Previously presented benefits are mean values derived from multiple data ranges and distributions. In order to more fully characterize the expected benefits of this rule and highlight the uncertainty built into this estimation, we present ranges for estimates. Our primary outcomes of interest are presented below in Table 39. For simplicity of interpretation, we only examine the total outcomes, but all estimates previously presented were derived from multiple distributions, including the annual incidence, full costs per pathogen, and efficacy estimates. In our sensitivity analysis below, we run Monte Carlo simulations in which these values vary based on our calculated parameters of their distributions (mean, 5^{th} percentile, 95^{th} percentile). This allows us to calculate low (5^{th} percentile) and high (95^{th} percentile) estimates of the benefits.

Table 39. Sensitivity Analysis of Benefits (in millions)

	Illnesses		**Benefits (millions)**	
	Low	**High**	**Low**	**High**
Annualized at 3 percent	273,227	449,626	$748	$1,195
Annualized at 7 percent	250,212	412,504	$710	$1,132

Another source of uncertainty in the estimation of benefits is the data on reported outbreaks associated with FDA-regulated produce RACs. The incidence of reported outbreaks varies by year, with some periods of time experiencing more of these outbreaks than others. Because our estimated number of total outbreaks related to FDA regulated produce RACs is calculated as the ratio of reported FDA regulated produce RAC outbreak illnesses to total CDC identified illnesses, the variability in the reported FDA regulated produce RAC outbreak illnesses may lead to an overestimation or underestimation of the total outbreaks related to FDA regulated produce RACs. If the data span used encompasses a time period with a relatively low incidence of reported

FDA regulated produce RAC outbreak illnesses, it may lead to an underestimation of the total outbreaks related to FDA regulated produce RACs, while if it encompasses a time period with a relatively high incidence of reported FDA regulated produce RAC outbreak illnesses, it may lead to an overestimation of the total outbreaks related to FDA regulated produce RACs.

For example, if we examine only the time frame available for the PRIA, 2003-2008, our total estimated benefits would be slightly below $900 million, as opposed to the $1.4 billion in steady state benefits we currently estimate; a reduction of approximately 35 percent. Additionally, if we were to exclude the year with the most total reported illnesses attributable to FDA RACs, 2011, our total estimate of benefits would fall by approximately 42 percent, to approximately $810 million, annually. Conversely, if we were to exclude the year with the least total reported illnesses, 2007, our total estimate of benefits would rise by approximately 8 percent, to approximately $1.5 billion, annually.

3. Net Benefits

Finally, we compare the range of estimate benefits to the range of estimate costs. This information is presented in Table .

Table 40. Sensitivity Analysis of Net Benefits (in millions)

	Low	Mean	High
Benefits	$1,059	$1,389	$1,719
Costs	$301	$366	$390
Net Benefits	$758	$1,023	$1,329

J. Analysis of Regulatory Alternatives to the Rule

FDA identified and assessed several regulatory alternatives including: (1) relying

on non-regulatory solutions, (2) a lower or higher monetary value threshold for farms not covered under the rule, (3) longer or shorter compliance periods, and (4) reduced requirements.

1. Non-regulatory Solutions

In the absence of FSMA, under this alternative, FDA could rely on some or all of the following:

- voluntary recommendation of some or all provisions of the regulation,
- current or enhanced State and local enforcement of existing state or local laws to bring about a reduction of potential harm from contaminated produce, or
- the tort system, with litigation or the threat of litigation serving to bring about the goals of the rule.

The advantage of this alternative is that it is already in place and the produce industry generally understands the requirements in the rule. The disadvantage of this alternative is that the regime lacks several of the most important provisions of the rule that have the potential to prevent avoidable foodborne illnesses that we estimate are worth approximately $976 million per year.

By voluntarily introducing procedures, establishments that do so demonstrate that their expected private economic benefits will exceed their private costs. Voluntary adoption of any practices will occur when it is profitable to do so. Although many establishments have adopted some food safety practices in order to meet the public demand for safer produce, numerous surveys show that many farms have not adopted the practices that provide socially optimal levels of food safety.

Public and private health agencies, consumer groups, competitors, trade

organizations or other independent parties could publicize the risks from produce not grown, harvested, packed or held using appropriate practices and allow consumers to decide for themselves about the risks of adulteration. The weakness of this approach is that independent organizations cannot discover food safety hazards until after consumers are sickened. In the absence of the produce safety standards, the burden of monitoring safety practices fall more heavily on consumers.

Finally, FSMA requires that we issue a Produce Safety regulation. Therefore, this is not a legally viable alternative.

2. Lower or Higher Monetary Value Threshold for Farms not Covered

The rule does not cover farms with $25,000 or less in annual produce sales. As this monetary value threshold falls, the number of farms not covered will fall. Table 41 shows the costs and benefits for a monetary value threshold of $10,000 in annual produce sales.

Table 41. Lower Monetary Value Threshold for Farms not Covered

	7%	3%
Annualized Costs	$460	$489
Annualized Benefits	$940	$991

Conversely, as this monetary value threshold rises, the number of farms not covered rises. Table 42 shows the costs and benefits for a monetary value threshold of $100,000 in annual produce sales.

Table 42. Higher Monetary Value Threshold for Farms Not Covered

	7%	3%
Annualized Costs	$345	$364
Annualized Benefits	$899	$938

3. Shorter or Longer Compliance Periods

The rule could have established shorter compliance periods, such as one year for farms of all sizes. With a one year compliance period, the affected farms would need to begin the process of compliance immediately. With a one-year compliance period, the costs increase to $438 million, and smaller farms with fewer resources must adopt the requirements in a time period that does not allow them to adopt the requirements correctly or fully, which might add to their costs and not add to public health. Moreover, FSMA establishes certain minimum compliance periods, so this is not a legally viable option. Table 43 shows the benefits and costs under this option.

Table 43: One-year Compliance Period

	7%	3%
Annualized Costs	$435	$450
Annualized Benefits	$1,089	$1,125

The rule could have established a longer compliance period for all affected farms, such as three years for large farms and a corresponding extra year for all other farms. With a three -year compliance period, the affected farms would have more time to implement the produce safety standards required by the rule. With a three-year compliance period, the costs decrease to $308 million as smaller operations with fewer resources are able to implement the requirements in a time period that would allow them to adopt them correctly or fully.

Table 44. One Extra Year Compliance Period (3 years for Large Farms)

	7%	3%
Annualized Costs	$307	$331
Annualized Benefits	$771	$830

4. Fewer Requirements

Under this Option, the rule could establish less extensive requirements. Several provisions could be combined to provide a less extensive set of standards than those in

the rule. Certain prevention measures could be separated and put forth as stand-alone regulations; for example, requirements regarding agricultural water could be issued as a separate rule. As an alternative, certain provisions could be eliminated altogether; for example, as shown in Table 45, eliminating provisions related to domesticated and wild animals and growing, harvesting, packing, and holding activities would reduce the cost of the rule by nearly $12 million; however, potential benefits would also be reduced by about $154 million. Another alternative shown in Table 45 is eliminating provisions related to agricultural water for growing or harvest pathway activities, which would reduce the cost of the rule by nearly $16 million; however, potential benefits would also be reduced by about $127 million (annualized at 3 percent).

It is not possible to present each combination of provisions as separate options; however, the individual effects of the various on-farm prevention measures can be seen in the summary of costs and benefits. Dropping measures would, individually, generate lower costs than the integrated program outlined in the rule. However, we also expect that dropping measures would, individually, lead to the number of illnesses prevented being lower than in the integrated program outlined in the text.

Table 45. Fewer Requirements

Eliminating provisions related to domesticated and wild animals and growing, harvesting, packing, and holding activities		
	7%	**3%**
Annualized Costs	$354	$374
Annualized Benefits	$778	$822
Eliminating provisions related to agricultural water for growing or harvest pathway activities		
	7%	**3%**
Annualized Costs	$351	$371
Annualized Benefits	$808	$849

5. Summary of Alternatives

Table 46 summarizes the costs and benefits of the rule and under several regulatory alternatives.

Table 46. Summary of Regulatory Alternatives (Present Values, $ million)

Alternative		Costs at 3%	Benefits at 3%	Costs at 7%	Benefits at 7%
Lower monetary value threshold for farms not covered	Incremental	$102	$15	$94	$15
	Total	$489	$991	$460	$940
Higher monetary value threshold for farms not covered	Incremental	-$23	-$38	-$21	-$26
	Total	$364	$938	$345	$899
One-year compliance period for all farms	Incremental	$63	$149	$69	$164
	Total	$450	$1,125	$435	$1,089
Three-year compliance period for all farms	Incremental	-$56	-$146	-$59	-$154
	Total	$331	$830	$307	$771
Fewer requirements: domesticated and wild animals	Incremental	-$13	-$154	-$12	-$147
	Total	$374	$822	$354	$778
Fewer requirements: agricultural water	Incremental	-$16	-$127	-$15	-$117
	Total	$371	$849	$351	$808
The Rule, as finalized	Incremental	--	--	--	--
	Total	$387	$976	$366	$925

Note: incremental costs and benefits are relative to previously-listed alternative.

III. Final Small Entity Analysis

The Small Business Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Small entities have fewer resources to devote to regulatory compliance and, therefore, may be more affected by regulatory compliance costs. The agency finds that the rule will have a significant economic impact on a substantial number of small entities.

A. Description and Number of Affected Small Entities

The Small Business Administration defines farms involved in crop production as "small" if their total revenue is less than $750,000 (Ref. 45). Approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition, and

these farms account for 62 percent of covered produce production. Exempting all of these small entities would substantially reduce the expected health benefit of the rule.

As described in the preamble, section 419(a)(3)(F) of the FD&C Act requires FDA to define the terms "small business" and "very small business." For purposes of this rule, FDA has defined a small business as a farm that is covered by the rule whose average annual monetary value of produce, on a rolling basis, sold during the previous three-year period is no more than $500,000, and that is not a very small business. FDA has defined a very small business in part 112, as a farm that is covered by the rule and whose average annual monetary value of produce, on a rolling basis, sold during the previous three-year period is no more than $250,000. See § 112.3(b). The definitions for small business and very small business exclude farms that are not subject to the rule per § 112.4(a), that is, farms with $25,000 or less in average annual monetary value of produce sold. Approximately 3,956 farms that are covered by the rule are considered small businesses under the rule, and these farms account for 5 percent of covered produce. Approximately 22,781 farms that are covered by the rule are considered very small businesses under the rule, and these farms account for 9 percent of covered produce.

The rule reduces the burden on small entities in part through the use of exemptions: certain small entities are eligible for a qualified exemption based on average monetary value of food sold and direct sales to qualified end users (§ 112.5). The rule additionally reduces the burden on small entities by not covering farms with $25,000 or less of average annual monetary value of produce sold (§ 112.4(a)). The rule additionally provides all farms flexibility for alternative practices to be used for certain specified requirements related to agricultural water, provided the farm has adequate scientific

support (see §§ 112.12 and 112.49). The rule also provides for States, Tribes, and foreign countries to submit a request for a variance for one or more requirements of the rule. To be granted, the procedures, processes, and practices to be followed under the variance must be reasonably likely to ensure that the produce is not adulterated under Section 402 of the Act and to provide the same level of public health protection as the requirements of the rule.

Farms (except sprout operations) defined as small businesses have 3 years to comply with most provisions of the rule after the effective date of the rule, and farms (except sprout operations) defined as very small businesses have 4 years. There is also an additional 2-year compliance period beyond the respective compliance date for certain requirements related to agricultural water. See section XXIV of the rule.

Table 47 summarizes the total number of domestic farms covered by the rule, the percentage of covered farms and produce they account for, and their average annual monetary value of food sold by size. For purposes of the small business analysis, Columns 2 and 3 of the table identify the farms that meet our definition of a very small and small business, respectively.

Table 47. Covered Farms in the Rule

	Very Small	Small	Large	Total
Number of covered farms	22,781	3,956	8,292	35,029
Percentage of covered farms	66%	11%	23%	100%
Percentage of produce acres	9%	5%	60%	74%
Average annual monetary value of food	$86,000	$360,000	$3,450,000	$882,000

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

The costs to implement the rule will vary across farms as their current practices vary, and farms whose practices, processes, or procedures are not already in compliance

with the requirements will bear the costs for compliance. If a farm's profit margin is significantly reduced after the regulatory costs are subtracted from its pre-regulatory revenues, then the farm will be at risk of halting production of the crops that it deems too costly to grow, pack, harvest, and hold. Regulatory cost burdens tend to vary across different-sized farms. Farm size is an important determinant of regulatory impacts and for determining business risk. Small entities with above average costs of doing business will be at a competitive disadvantage. Some small entities might determine that their new expected costs are likely to exceed their revenues.

This may be especially true for small sprouting operations, whose average costs of compliance may be higher due to the additional requirements on their production. We estimate that average revenues for very small sprouting operations are approximately $49,000 and small sprouting operations are $67,000. Average costs to very small and small sprouting operations estimated to be approximately $17,000, or approximately 36 and 26 percent of revenues for very small and small sprouting operations, respectively. These costs are in addition to the other applicable costs of the rule for sprouting operations.

Table 48 shows the average costs and average upfront costs of implementing the requirements of the rule (annualized at 7 percent over 10 years) as a percentage of the average annual monetary value of food sales per very small and small farm. For comparison, we include the results for large farms. Average costs make up 3 percent of the average food sales for very small farms and 4 percent for small farms. Small and very small farms whose practices, processes, or procedures are not already in compliance

with a significant portion of the requirements will incur a larger cost than the average shown.

Table 48. Average Costs of Implementing Proposed Rule as Percentage of Food Sales by Farm Size

	Very Small	Small	Large	All Farms
Average costs of implementing provisions in the proposed rule	$2,885	$15,265	$28,452	$10,449
Average upfront costs of implementing provisions in the proposed rule	$5,027	$23,382	$36,396	$14,525.69
Average annual monetary value of food sold	$86,000	$360,000	$3,450,000	$882,000
Average costs percentage of average annual monetary value of food sold	3%	4%	1%	1%

Note: Because of the timing of the rule, farms will incur upfront costs in different years. Average upfront costs to firms are estimated here by calculating the average cost for farms of different sizes based on the first year in which they incur costs. Additionally, this estimate does not include the costs of the water provisions as these costs are further delayed for farms of all sizes.

C. Alternatives to Minimize the Burden on Small Entities

In the final rule, we have introduced several provisions for regulatory relief for small entities. The most important are the modified requirements for businesses that qualify for a "qualified exemption." In addition, small and very small businesses have additional time to comply with the requirements: small businesses (except sprout operations) have three years and very small businesses (except sprout operations) have four years to come into compliance after the effective date of the final rule. This is an additional 12 months or 24 months, respectively, beyond the time given to larger operations to comply with this rule. We have also provided for extended compliance dates for certain agricultural water requirements for all covered farms with respect to covered produce other than sprouts. See section XXIV of the rule.

The final rule provides substantial cost relief to small businesses. We identified two other options for regulatory relief that were not adopted.

a. Longer compliance period for small businesses

Small entities may find it more difficult to learn about and implement the requirements than it will be for large entities. Lengthening the compliance period for small businesses beyond the additional time we currently allow would provide some additional regulatory relief by allowing small businesses to take advantage of increases in industry knowledge and experience in implementing these regulations. A longer compliance period will allow additional time to learn about the requirements of the rule, to hire or train workers, to take samples for their initial water quality survey, to purchase new or replacement equipment, to arrange financing and for any other initial expenditure of time, effort and money. It will also delay the impact of the annual costs of compliance. The annualized costs savings from the delay are estimated to be approximately $70 million.

b. Fewer Requirements

The alternative to only require certain provisions and not require others (for example, not require small businesses to comply with the standards related to personnel qualifications and training or those related to agricultural water) would reduce average costs for small businesses. Under this alternative, the costs for all small businesses would be reduced from $175 million to $94 million, annualized.

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