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.

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.

IV. References

Reference List

(1) Food Safety Modernization Act Sec. 419 (f) Exemption for Direct Farm Marketing. 1-4-2011.
Ref Type: Unenacted Bill/Resolution

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