Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption

IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 13563 and12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. FDA has developed a comprehensive preliminary regulatory impact analysis (PRIA); the PRIA is available at http://www.regulations.gov Docket No. XXXX, and is also available on FDA's website at (insert appropriate web address). This proposed rule has been designated an "economically" significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Small Business Administration defines farms involved in crop production as "small" if their total revenue is less than $750,000 (Ref.1). Approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition. Accounting for the proposed exemptions for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, farms that are eligible for a qualified exemption based on average annual value of food sold and direct farm marketing, and produce and farms that are otherwise not covered by the rule, 80 percent of covered farms would fit within the SBA definition of small. Because nearly all farms that grow produce are considered small by SBA's definition and farms with less than $750,000 in food sales will bear a large portion of the costs, the agency tentatively concludes that the proposed rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA expects this proposed rule may result in a 1-year expenditure that would meet or exceed this amount.

B. Need for Regulation

Section 105(a) of the FDA Food Safety and Modernization Act requires that " not later than 1 year after enactment, the Secretary … shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death." Using a science-based framework we characterize the magnitude of the public health risks associated with the consumption of fresh produce, and define specific standards that would address the risks of microbial contamination from all agricultural inputs (labor, water, biological soil amendments, and tools and equipment), unsanitary conditions in buildings, and contact with wild and domesticated animals, as well as the risks of microbial contamination in the production of sprouts intended for human consumption. We provide a framework to evaluate the efficacy of the proposed rule for addressing the public health risks in general, and emphasize the importance of some salient provisions as well.

We define thresholds for different farm size and income categories that would be covered, with each farm size and income category linked to a quantitatively defined level of public exposure to risk. We estimate the costs of each proposed provision by farm size. Among the regulatory alternatives to the proposed option that we analyze, we allow the definitions of the farm size to vary, and estimate the effect on the costs, coverage and public exposure to risk from each, relative to the proposed option. We request comment on whether there are other options for addressing the risk of an outbreak and cost of preventing an outbreak.

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

C. Overview of Data and Estimates Used Throughout the Analysis

The following section outlines some of the standard information utilized throughout the remainder of the analysis. First, we present all standard cost estimates and assumptions that allow us to calculate the costs of implementation at the farm level. This section includes things like standard labor costs and data sets used to inform estimates and assumptions. Next, we provide information on the coverage of the analysis and how it relates to the US produce industry as a whole. Finally, we present estimations on the current baseline practices of farms already in place in the affected industry. This includes information on current regulations, marketing agreements in place, and a description of the data sources used to estimate how the industry is currently operating. Detailed discussion of how these estimates and data are used to estimate practice specific current industry practice and costs are included in the detailed analysis of costs section.

1. Measuring Costs

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

- All wage rates used come from the Bureau of Labor Statistics (BLS), Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates, under NAICS 11 – Agriculture, Forestry, Fishing, and Hunting (Ref.2). Wages are increased by 50 percent to account for overhead.

    a. Farm Operator or Manager Mean Wage Rate: Our estimate for the mean hourly wage rate for a farm operator or manager is $47.40 including fringe benefits and other overhead. Farm operators are the persons who have completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA. We derive our estimate from the BLS mean hourly wage rate for Farmers, Ranchers, and Other Agricultural Managers working in the agriculture industry as shown in (Ref.2) of $31.60 and we add 50 percent for fringe benefits and other overhead costs ($15.80) for a total estimate of $47.40.

    b. Farm Supervisor Mean Wage Rate: Our estimate for the mean hourly wage rate for farm supervisors is $30.26 including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for First-Line Supervisors/Managers as shown in (Ref.2) of $20.17 and we add 50 percent for fringe benefits and other overhead costs ($10.09) for a total estimate of $30.26.

    c. Farm Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for farm workers (nonsupervisory) is $14.00

including fringe benefits and other overhead. We derive our estimate from the BLS mean hourly wage rate for Farmworkers and Laborers, Crop, Nursery, and Greenhouse as shown in (Ref.2) of $9.33 and we add 50 percent for fringe benefits and other overhead costs ($4.67) for a total estimate of $14.00.

- We use the 2007 Census of Agriculture farm-level database to derive the total number of domestic farms and greenhouses that grow produce, the number of produce acres operated, the amount of labor employed, and their food sales; to estimate the number of farms that are eligible for the qualified exemption created by section 419(f) of the FD&C Act; and to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices). (Ref.3)

- We use FDA's Operational and Administrative System for Import Support (OASIS) database to estimate the number of foreign farms that will be covered by the proposed rule. (Ref.4)

- We use the 2008 Organic Production Survey to estimate the number of farms that are eligible for the qualified exemption created by section 419(f) of the FD&C Act; it is also used to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices). (Ref.5)

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

a. 1999 Fruit and Vegetable Agricultural Practices Survey (Ref.6)

b. Farm Food Safety Practices: A Survey of New England Growers (Ref.7)

c. Growers' Compliance Costs for the Leafy Greens Marketing Agreement and Other Food Safety Programs (Ref.8)

d. USDA Agricultural Marketing Service (AMS) Fresh Produce Audit Verification Program, including commodity-specific audits for the tomato and mushroom industries (Ref.9).

e. Food safety regulations and marketing agreements: Florida Tomato Regulation (Florida Rule 5G-6.011) (Ref.10), and the Leafy Greens Marketing Agreements in California (Ref.11) and Arizona (Ref.12) (together, sometimes referred to as "LGMA").

- We use the National Agricultural Workers Survey (NAWS), U.S. Department of Labor, Public Access Database, 1989 to 2006, website at http:/www.doleta.gov/agworker/naws.cfm NAWS database for years 2005 to 2006 to estimate the number of workers that are employed on multiple farms, and the number of workers employed by farm task; it is also used to create estimates of the rates of specific food safety practices currently being undertaken by farms (current industry practices) (Ref.13)

- We annualize any one time costs over 7 years at discount rates of 7 percent and 3 percent. For ease of reading, in the main document, we report only results derived from the 7 percent discount rate. In the sensitivity analysis and summary sections, we also report results derived from the 3 percent discount rate. This is consistent with OMB's basic guidance on the discount rate provided in OMB Circular A-94 (Ref.14). OMB selected the 7 percent rate as an estimate of the average before-tax rate of return to private capital in the U.S. economy. OMB selected as an alternative, an estimate for the "social rate of time preference," which means the rate at which a society discounts future consumption flows to their present value. OMB selected the rate that the average saver uses to discount future consumption as the measure of the social rate of time preference, which they determined can be approximated by the real rate of return on long-term government debt after adjusting for inflation, to provide an approximation. Over the last thirty years, this rate has averaged around three percent in real terms on a pre-tax basis. OMB Circular A-94 further suggests that when discounting, estimates for costs and benefits should be based on credible changes in technology over time. We used seven years for our horizon for discounting, based on the IRS allowable recovery periods for agriculture as shown in IRS publication (Ref.15). The use of the IRS equipment recovery period is a good approximation for the average useful life, as well as for the written procedures and training and other costs that must be discounted that are strongly complementary to the depreciable equipment in the produce industry. We ask for comment on the use of 7 years as our horizon for evaluating the effects of this rule.

- To classify farms that are covered by the rule by size, we identified farms as very small when they generate $250K or less in food sales, small when they generate

$500K or less in food sales (and are not considered very small), and large when they generate more than $500K in food sales[1].

- We estimate that very small and small farms operate 3 months per year where the harvest period is 45 days, and that large farms operate for 6 months per year where the harvest period is 90 days (non-consecutive).[2]

- We estimate that the farm operator or manager is the person responsible on farms with less than 20 employees, but that farm supervisors are responsible on farms with at least 20 employees.

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

- We use Tables 2-4 through 2-10 from FDA’s Evaluation of Recordkeeping Costs for Food Manufacturers, February 13, 2007, for our estimates for the hours necessary to perform the various recordkeeping functions, for our estimate of the frequency of recordkeeping by record type; the average minutes spent keeping records by record type. Estimates in these tables are based on expert opinion and an extensive literature review (Ref.16).

[1] We use the $500,000 monetary cutoff from the qualified exemption for direct farm marketing in § 419(f) of the FD&C Act.
[2] This estimate is based on annual planting data from USDA (Ref.3). We request comment on this estimation.

2. Coverage of the Analysis

a. All Farms

The proposed regulation applies to covered farms that grow covered produce including fruits and vegetables such as berries, tree nuts, herbs, and sprouts. It applies equally to farms offering food for sale in the United States, whether located domestically or in foreign countries exporting to the US. There are approximately 189,636 farms in the U.S., the District of Columbia, and the Commonwealth of Puerto Rico that grow produce for sale excluding sprouting operations (Ref.3). This number was derived using the 2007 Census of Agriculture and includes farms with on-farm packing, greenhouses, farms eligible for qualified exemptions, and farms that are not covered by the proposed rule. We estimate that there are approximately 475 sprouting operations, which include farms eligible for qualified exemptions, and sprouting operations that are not covered by the proposed rule. Sprouting operations will be considered in the sprouts section. We estimate that there are 70,395 foreign farms that will offer covered produce for import into the U.S., which includes farms eligible for qualified exemptions, and farms that are not covered by the proposed rule (Ref.4). This number was estimated using the number of foreign produce manufacturers in the OASIS database from fiscal year 2008, and multiplying it by the ratio of domestic farms to domestic manufacturers in the U.S. We seek comment on this methodology for estimating the number of foreign farms which will offer covered produce.

b. Qualified Exemptions

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

i. Monetary value of all food sold and direct farm marketing

Farms are eligible for a qualified exemption if the average value of their food sales over the last 3 years was less than $500,000 and if more than 50 percent of their food sales were sold directly to qualified end-users. Qualified end-users are defined as the consumers of the food regardless of location, or a restaurant or retail food establishment in the same state or not more than 275 miles from the farm. Food sales include all products grown or raised for human or animal consumption or to be used as ingredients in any such item (i.e. produce that is a RAC, processed produce (non-RACs such as fresh-cut produce), animal-derived products such as milk and meat, aquaculture).

In order to estimate the number of farms that meet this qualification, we use data from the 2007 Census of Agriculture and the 2008 Organic Survey. The Census provides the number of farms that grow covered produce while the Organic Survey provides information for examining farm sales to qualified end-users. The survey defines local and regional food sales as being less than 500 miles from the farm site. Although the qualified exemption in the proposed rule has a different regional cut-off from the information collected in the survey, we estimate that the 500 mileage cut-off accounts for not only the 275 mile regional constraint, but is also a good measure of the within-state locality constraint.

Since the organic survey focuses on farms that grow organic products, we adjust the percentage of qualifying organic farms to account for size and market channel differences between organic and non-organic producers. Organic farms tend to be slightly smaller than non-organic farms. Organic farms with food sales of less than $25K account for 66 percent of all organic farms compared to 62 percent of non-organic farms, which is a 4 percentage point difference. To adjust for this difference, we multiply the percentage of organic farms exempt by the ratio of the percentage of non-organic farms to organic farms by size. Organic farms are also more likely to derive at least 50 percent of their food sales from direct to consumer sales. Approximately 29 percent of all organic farms generate at least 50 percent of their food sales from this market channel compared to only 18 percent of non-organic farms. We adjust the percentage of organic farms exempt to acknowledge this difference by multiplying it by the ratio of the percentage of non-organic farms that have at least 50 percent of food sales derived from direct sales to organic farms with the same criteria by size. After correcting the percentage of qualified organic farms to apply to non-organic farms, we estimate that there are approximately 13,541 total farms, including 171 sprouting operations eligible for the qualified exemption after accounting for farms that are not covered, which are explained in part c. of this section, “Coverage of the Analysis”.

ii. <u>Commercially processed produce</u>

Produce that is commercially processed in a manner so as to adequately reduce pathogens is eligible for exemption from the rule provided that certain documentation is kept. Canning (in compliance with applicable FDA regulations) and processing of juice (in compliance with applicable FDA regulations) are examples of processing methods that satisfy this condition. Farms that grow produce that is destined for the frozen or fresh-cut markets are not eligible since there is generally no adequate microbial kill-step in the processing method. Farms whose produce is destined for kill step processing will often have a contract in place that says so. This is because produce for processing and produce for fresh consumption are often grown separately. However, it is possible that some fresh produce could be purchased for kill step processing without the knowledge of the farmer. We request comment on whether and to what extent farmers will be able to take advantage of this exemption from the proposed provisions.

We estimate the number of farms whose only covered produce would qualify for this exemption using production information, specifically the amount sold to fresh versus processed markets, available in published reports for citrus, non-citrus, berries, vegetables, and tree nuts along with information from industry experts (Ref.6;Ref.17). Specific information on the type of processing method, such as whether the product is sold for juice, canned, or frozen markets, was available for citrus, non-citrus, and vegetables. Type of processing method was not available for berries or tree nuts. We estimate that the same proportion of berries is sent to commercial processing with a kill-step as is for non-citrus commodities. For tree nuts, we estimated that all California almonds go through a kill-step process as required by law (Ref.18), approximately 10 percent of pecan and walnut production is consumed raw (Ref.19), and that approximately 8 percent of pistachios are consumed raw (Ref.20). Tree nuts are usually used in confections, blanched, and roasted (Ref.17;Ref.19). There are approximately

16,435 farms whose only covered produce would qualify for this exemption, after accounting for farms that are not covered, and that do not also grow other covered produce. Farms that grow covered produce that is eligible for the commercial processing exemption and that also grow other covered produce will be subject to the complete proposed regulation only with respect to their other covered produce.

c. Farms and produce not covered

Farms not covered by the regulation are those with an average annual monetary value of food sold during the previous three-year period of $25,000 or less.[3] Produce that is rarely consumed raw, such as beets, brussel sprouts, potatoes, sweet corn, and sweet potatoes, is also not covered by the proposed rule (the proposed rule includes an exhaustive list of such produce, from which we have provided only a few examples here). A farm that only grows these commodities, and does not also grow covered produce, will not be subject to the proposed regulation. Farms that grow these commodities and other covered produce will be subject to the proposed regulation only with respect to their other covered produce. Produce for personal or on-farm consumption, and not for sale to consumers, is also not covered by the proposed regulation. A farm that only grows produce for personal or on-farm consumption, and does not also grow covered produce, will not be subject to the proposed regulation. Farms that grow produce for personal or on-farm consumption and other covered produce will be subject to the proposed regulation only with respect to their other covered produce.

In order to determine the cutoff for a farm that is not covered, and also to define the size of a farm, FDA utilizes a measure of the monetary value of all food sold on the

[3] We present multiple dollar values for a farm qualification cutoff in the summary of costs and benefits section, Table 12.

farm. This measure should serve as a valid proxy for both the volume and value of production within size category and commodities.

The USDA National Commission on Small Farms defines a small farm as a family farm with less than $250,000 total monetary value of food a year (Ref.21). The Commission's recommendation was based on the reasoning that these farms are the likeliest to exit the industry, and have the greatest need to improve net farm incomes since they receive only 41 percent of all gross sales revenue, but make up 94 percent of all U.S. farms (Ref.21). We use the $250,000 monetary value of food threshold for our cutoff of a very small farm since covered produce farms below this threshold receive only 12 percent of industry gross sales and make up 83 percent of all produce farms. We use the monetary value of food cutoff of $500,000 from the qualified exemption for direct farm marketing in § 419(f) of the FD&C Act as the threshold for a small farm. Farms below the $500,000 monetary value of food cutoff make up 89 percent of covered farms, and receive 18 percent of all gross sales. We use the $25,000 monetary value of food threshold for a farm that is not covered since they receive less than 2 percent of all food gross sales, and make up 60 percent of all produce farms.

We use the value of production to determine if a farm is covered. We define a farm that is not covered as one with $25,000 or less monetary value of food. A very small farm is defined as one that generates $250,000 or less in food sales on a rolling basis for the previous 3 years, and is also covered by the proposed regulation. A small farm is defined as one that generates $500,000 or less in food sales on a rolling basis for the previous 3 years, is not defined as very small, and is covered by the proposed rule.

d. Summary of Qualified Exempt Farms and Farms Not Covered

Table 1 shows the total number of domestic farms, those farms that are eligible for a qualified exemption and that are not covered by the proposed rule, and the number of farms covered by the proposed rule. All farm numbers are calculated from the National Agricultural Static Service (NASS) 2007 Census of Agriculture (Ref.3). Table 2 shows the number of farms that are eligible for a qualified exemption and that are not covered by the proposed rule broken down in further detail. Not accounting for sprouts, we estimate that there are a total of 75,716 farms that would be eligible for the monetary value of food sales and direct farm marketing qualified exemption, and 62,194 of those farms generate $25,000 or less in food sales and therefore are not covered. Similarly, we estimate that there are a total of 29,972 farms all of whose covered produce would be eligible for the commercially processed food exemption, and 13,537 of these farms are not covered. We estimate there are 9,304 farms not covered because they grow food that is rarely consumed raw, and 3,705 of those farms are small enough to be additionally not covered. Lastly, there are 34,333 farms not covered under this rule because they are smaller than our definition of very small farms. After accounting for those farms that are eligible for a qualified exemption and also generate $25,000 or less in food sales, we estimate that a total of 149,425 farms (75,716 + 29,972 + 9,304 + 34,433) are not covered under the proposed rule. The numbers for sprouting operations are covered in the sprouts section. Although farms that are not covered or eligible for exemptions will not be subject to the requirements in the proposed rule, it is expected that many will be subject to buyer requirements. As will be discussed in the current produce safety practices section, commodity buyers, such as fresh-cut processors, foodservice, or retail, will often set food safety requirements of their own. Farms are required to implement the specific food safety practices in order to sell their product to the buyer.

Table 1. - Covered Domestic Farms and Farms Eligible for Qualified Exemptions and Farms Not Covered[1]					
	$25K or less monetary value of food produced	very small	small	large	Total
Total Number of Farms	**113,870**	**53,429**	**9,147**	**13,191**	**189,637**
Total Covered Farms	--	26,947	4,693	8,571	40,211
Total Farms Exempt/Not Covered	**113,870**	**26,482**	**4,454**	**4,620**	**149,426**

[1] The calculated number of farms within each size definition is actually subject to two criteria, total value of food produced and an acreage cutoff. Because of this additional criterion, the number of very small, small, and large farms may be slightly overestimated.

Table 2. - Detailed Break Down of Farms Eligible for Qualified Exemptions and Farms Not Covered					
	$25K or less monetary value of food produced	very small	small	large	Total
Qualified exemption[1]	62,194	11,719	1,690	113	75,716
Exempt – Only grow commercially processed produce	13,537	11,685	1,953	2,797	29,972
Not covered - Only grow produce that is rarely consumed raw	3,705	3,078	811	1,710	9,304
Additional Farms Not covered – $25,000 or less monetary value of food	34,433	-	-	-	34,433
Total Farms Exempt/Not Covered	**113,870**	**26,482**	**4,454**	**4,620**	**149,426**

[1] Farms qualify for this exemption if they meet two requirements: (1) the farm must have food sales averaging less than $500,000 per year during the last three years; and (2) the farm's sales to qualified end-users must exceed sales to others. A qualified end-user is either (1) the consumer of the food or (2) a restaurant or retail food establishment that is located in the same State as the farm or not more than 275 miles away.

The 75,716 farms, considered 'qualified' farms, who have a low monetary value of food sales and sell over half of their produce through a direct marketing channel, account for about account for about 7.5 percent of all US produce acreage. The 113,870 farms, that generate $25,000 or less in food sales, account for only 4 percent of all domestic produce acreage, but for 60 percent of all farms that grow produce. They have average food sales of $6,663 per farm and grow an average of 3.5 produce acres. After accounting for farms that would not be covered because they grow produce that is rarely consumed raw, qualified farms account for 13.4 percent of all covered domestic produce acreage. After accounting for the farms that would qualify for an exemption or that grow produce that is rarely consumed raw, then the leftover 34,433 farms only account for .7 percent of all domestic produce acreage. In total, the rule covers about 50 percent of all domestic produce acres, and about 86 percent of all domestic produce acres that are not dedicated to growing commodities rarely consumed raw or destined for kill step processing. We estimate that the acreage harvested is a reasonable approximation of the food produced by these farms, but we seek comment on whether this is reasonable.

e. Costs to Farms that are exempt from some provisions

Labeling and Disclosure Requirements for Farms Eligible for a Qualified Exemption Based on Monetary Value of Food Sales and Direct Farm Marketing

Farms eligible for a qualified exemption based on monetary value of food sales and direct farm marketing must comply with certain food labeling or disclosure requirements, as applicable. If a food packaging label is required on the food that would otherwise be covered produce, as dictated by the FD&C Act or its implementing regulations, then farms eligible for a qualified exemption are required to include the name and complete business address of the farm where the food that would otherwise be covered produce was grown on the food packaging label. If a food packaging label is not required, then the name and complete business address of the farm must be displayed on a label, poster, or sign at the point of purchase. Documents delivered with the covered produce, such as a receipt or invoice, can be used to satisfy this requirement. The information required on the label or documentation includes the business name, street address or post office box, city, state, and zip code.

Recordkeeping Requirements for Farms Eligible for a Qualified Exemption Because of Commercial Processing

Farms eligible for a qualified exemption because all of their covered produce receives commercial processing that adequately reduces microorganisms of public health significance are required to establish and keep documentation that identifies the recipient of the covered produce that performs the commercial processing. The documentation must be accessible at the business within 24 hours of request for official inspection and copying, and can be stored off-site after 6 months after the record was made. The documentation must be kept for two years past the date that it was created.

We note that the eligibility status of some qualified exempt farms may change over time due to increased or decreased revenues, marketing channel changes, or a withdrawal of exemption due to inspection results, for example. We do not have enough information to estimate how often these situations will occur or to estimate the burden associated with these changes.

Costs of Labeling and Disclosure Requirements for Farms Eligible for a Qualified Exemption Based on Monetary Value of Food Sales

Where the proposed rule would require the name and complete business address of the farm where the covered produce was grown to appear on labels (where labels are required under the FD&C Act or implementing regulations), this would be in addition to what is currently required on labels under other provisions of the FD&C Act. A food packaging label is required on produce retail packages, such as bags or clamshells, and currently must be labeled with the name and place of business of the manufacturer, packer, or distributor, along with other information (Ref.22). Commodities that are more commonly packed in retail packages are berries, some citrus and non-citrus fruit, mushrooms, and some herbs. Although there are exempt farms that grow these specific commodities, we expect that these farms do not package their products in retail packages and instead use baskets or boxes since these farms are mostly small. This is possibly an underestimate of the number of farms that must comply with the increased food labeling requirements, and we seek comment on the number of exempt farms that must label their packages. For this analysis, we estimate that farms will primarily use a display at the point of purchase, or provide documentation with their covered produce, to satisfy the labeling/disclosure requirement.

Farms exempt by monetary value and direct farm marketing will often have multiple marketing channels. Although they sell more than 50 percent of their produce direct to consumers, restaurants, or retailers, the rest may be sold to wholesalers, fresh-cut or commercial processors, distributors, or other buyers. We estimate that all farms that sell direct to consumers will choose to display the name and complete business address of the farm at the point of purchase, and that farms that sell to other markets will include the name and complete business address on their invoice or receipt. For farms that sell both directly to consumers and to other markets, we estimate that they will do both activities.

There are 11,816 very small farms, 1,763 small farms, and 134 large farms that are required to comply with the food labeling/disclosure requirements. These numbers include the farms estimated in the previous section, and the number of sprouting operations estimated in the sprouts section. We estimate that 26 percent of very small, 16 percent of small, and 9 percent of large farms sell some of their covered produce direct to consumers (i.e. roadside stands, farmers markets, and pick your own operations) (Ref.3). This is approximately 3,082 very small farms (.26 x 11,816), 275 small farms (.16 x 1,763), and 12 large farms (.09 x 134) that will display the name and complete business address of their farm at the point of purchase. We expect that farms will choose to comply with this provision in a variety of methods ranging from using a poster board to buying a permanent banner. We do not expect them to provide their name and complete business address in documents accompanying the covered produce since many of these farms do not currently provide paper receipts with business information, and it would be costlier to change practices in order to do so. Since the poster board option is the lowest cost, we estimate that all farms will choose this.[4]

We estimate that it will take the farm operator approximately 1 hour, at a cost of $47 per hour, to buy and prepare one poster board. We expect that the operator will buy posters bi-weekly since the poster can get tattered and worn-out. This estimate considers that some farms sell their produce at farmers markets or roadside stands everyday, which would require a poster change more frequently, while others only do so on weekends, which would require a poster change less frequently. The total annual time required to buy and prepare a poster board is 24 hours [(60 minutes x 24)/60]. The annual cost for

[4] It is unlikely a farm will choose a more costly option simply to display their contact information. It is possible that a farm may purchase a permanent banner for marketing purposes, and add their contact info at relatively little additional cost.

the farm operator's time is $1,128 ($47 x 24 hours). The annual cost of materials to comply with this provision is approximately $6 for 24 poster boards (Ref.23). We do not estimate a cost for the use of a marker to write on the poster since it is expected that this cost is minimal since the farmer will likely use something he has on hand. The total per farm annual cost is $1,134 ($1,128 + $6).

Table 3 summarizes the total costs to exempt farms of having to display their name and complete business address at the point of purchase. Multiplying the per farm cost by the number of farms that need to comply per size, we estimate that it will cost $3,494,988 for very small farms (3,082 x $1,134), $311,850 for small farms (275 x $1,134), and $13,608 for large farms (12 x $1,134) to comply. The total cost is $3,820,446($3,494,988 + $311,850 + $13,608).

Table 3 - Cost to exempt farms required to display name and complete business address at point of purchase

	Very Small	Small	Large	Total
Number of farms - point of purchase display	3,082	275	12	3,333
Farm operator wage rate (hourly)	$47	$47	$47	
Time to prepare and buy display (annual hours)	24	24	24	
Annual farm operator time cost	$1,128	$1,128	$1,128	
Cost of materials	$6	$6	$6	
Annual cost per farm	$1.134	$1,134	$1,134	
Total cost	$3,494,988	$311,850	$13,608	$3,820,446

Costs of Labeling and Disclosure Requirements for Farms Eligible for a Qualified Exemption Based on Direct Farm Marketing

We estimate that farms with other marketing channels will provide their name and complete business address on an invoice or receipt that accompanies their product. We estimate that 95 percent of very small, 98 percent of small, and 99 percent of large farms will have to provide an invoice or receipt. These percentages were obtained by subtracting the percentage of farms that sell 100 percent of their produce directly to consumers from all exempt farms by size (Ref.3). Multiplying the percentages by the number of farms required to label, we obtain 11,216 very small farms (.95 x 11,816), 1,727 small farms (.98 x 1,763), and 133 large farms (.99 x 134). This is perhaps an overestimate of the number of farms since it doesn't exclude farms that currently include their name and address on their invoice or receipt.

We expect that these farms already provide an invoice that accompanies their product, but that it does not include the full information required by the proposed rule. We estimate that it will take a farm operator, at $47 per hour, 5 minutes to change this on the computer for new invoices. We also estimate that this cost will be incurred one-time only. Therefore, the one-time cost per farm is $4 [(5/60) x $47.4]. Multiplying this by the number of farms by size, we obtain $44K for very small farms (11,216 x $4), $6.8K for small farms (1,727 x $4), and $525 for large farms (133 x $4). The total one-time cost is $51.6K ($44K + $6.8K + $525). Annualizing these costs over 7 years at 7 percent, we obtain $8.2K for very small farms, $1.3K for small farms, and $97 for large farms, and a total annual cost of $9.6K. Table 4 summarizes this cost information.

Table 4 - Cost to farms required to provide name and complete business address in documents

	Very Small	Small	Large	Total
Number of farms subject to food labeling	11,816	1,763	134	13,542
Percent of farms sell in other markets	95%	98%	99%	
Number of farms - invoice name and address	11,216	1,727	133	12,911
Farm operator wage rate (hourly)	$47.40	$47.40	$47.40	
Time to change invoice (one-time)	0.1	0.1	0.1	
One-time cost per farm	$3.95	$3.95	$3.95	
Total costs (one-time in thousands)	$44.3	$6.82	$.53	$51.6
Annualized costs (in thousands)	$8.2	$1.3	$.097	$9.6
Cost per affected farm	$0.73	$0.73	$0.73	$0.73

Costs of Labeling and Disclosure Requirements for Farms Eligible for a Qualified Exemption Based on Commercial Processing

Farms that are exempt because all of their covered produce receives commercial processing with a kill step must establish and keep documentation that identifies the recipient of the covered produce that performs the commercial processing, such as a contract between the grower and processor.[5] It is assumed that these farms have practices that are already aligned with this proposed requirement. We request comment on this assumption. Therefore, no recordkeeping costs are estimated for farms that sell produce to processors. Farms with sales to processors are likely to keep receipts for tax purposes. Farms that process their own product under existing regulations (parts 113, 114, or 120) are already required by those regulations to keep records that would satisfy this requirement. We seek comment on whether these expectations are reasonable, and on whether these farms will incur additional costs not considered. We are uncertain whether all farms keep this documentation for two years. We seek comment on the current industry practices for the length of recordkeeping, and the cost of having to keep a record for two years.

Table 5 summarizes the total costs to exempt farms. Annualizing the one-time costs, we estimate that the total cost is $3.8 million. The cost per farm is $283 ($3,830,043/13,542).

[5] For example, a tomato grower must have documentation available, such as a contract, to verify that the produce is sold to a processor, such as a cannery. However, the tomato grower would not be required to keep information about the thermal process the canner uses to, for example, make tomato paste.

Table 5 – Total Costs to Exempt Farms[6]				
	Very Small	Small	Large	Total
Cost to exempt farms that must display name and business address at point of purchase (annualized in thousands)	$3,494,988	$311,850	$13,608	$3,820,446
Cost to exempt farms that must provide name and business address in documents (annualized at 7% and in thousands)	$8,200	$1,300	$.97	$9,597
Total costs (annualized in thousands)	**$3,503,188**	**$313,150**	**$13,705**	**$3,830,043**
Cost per estimated exempt farm	$295	$183	$140	$283

f. Covered Farms

We estimate that there are 40,211 covered farms (other than covered farms that are sprouting operations) under the proposed rule (from Table 1: 189,636 total farms – 149,425 farms not covered or exempt). We estimate that there are 285 covered farms that are sprouting operations, and the derivation of this number is described in the sprouts section (Ref.24). Table 6 describes the number of covered farms, the total number of produce acres operated, the average produce acres operated per farm, and the average food sales per farm by farm size. There are approximately 26,947 very small farms, 4,693 small farms, and 8,571 large farms covered in the proposed rule not including sprouting operations. Very small farms account for 67 percent of these covered farms and operate 10 percent of covered acres. Large farms account for 21 percent of these covered farms and operate 81 percent of covered acres. The average produce acres operated per farm is 111, and the average food sales per farm is approximately $650K.

[6] It is noted that, while this proposed rule does not require exempt farms to register with FDA, the Agency does request comment on a registration requirement.

Table 6 - Covered farms other than sprouting operations[1]				
	Very Small	Small	Large	Total
Number of Farms	26,947	4,693	8,571	40,211
% by Size	67%	12%	21%	100%
Produce Acres	447,342	389,610	3,636,623	4,473,575
% by Size	10%	9%	81%	100%
Average Produce Acres per farm	16.6	83.0	424.3	111.3
Average Food Sales per farm	$75,279	$320,696	$2,638,384	$650,233

[1] The calculated number of farms within each size definition is actually subject to two criteria, total value of food produced and an acreage cutoff. Because of this additional criterion, the number of very small, small, and large farms may be slightly overestimated. Additionally, the number of exempt farms may be slightly underestimated. This means our estimates may somewhat overstate the costs of regulation. In total we estimate that no more than 1,000 additional farms would be exempt under a strictly monetary cutoff.

Table 7 characterizes these covered farms by the commodity category they grow specifically berries, citrus fruit, greenhouses, non -citrus and non-berry fruit, tree nuts, and other vegetables. Farms are often diverse, and do not specialize in growing only one commodity. Approximately 20 percent of covered farms grow something outside of their commodity category shown in the table, and even more grow multiple commodities within their commodity category. The number of these covered farms in each commodity category is estimated by calculating the percentage of farms by commodity group for all produce farms, and applying the same percentages to these covered farms. We recognize that this is a simplification since each commodity category has a different size distribution and it is possible that there are more exempt farms within one commodity versus another. These estimates will be refined for the final rule. The commodity category with the largest number of farms is other vegetables with approximately 12,541 of these covered farms. This is followed by non-citrus fruit with 12,097 covered farms. There are only 1,128 covered greenhouses, and this accounts for the smallest number of these covered farms.

Table 7 - Covered Farms by Commodity Category other than sprouts				
	Very Small	Small	Large	Total
Berries	2,842	412	718	3,972
Citrus Fruit	2,516	417	655	3,588
Greenhouses	857	99	171	1,128
Non Citrus & Non Berry Fruit	8,418	1,381	2,297	12,097
Tree Nuts	4,709	779	1,396	6,885
Other Vegetables	7,604	1,604	3,333	12,541
Total	26,947	4,693	8,571	40,211

We estimate that there are approximately 68,635 (40,211 x 1.7) farm operators on these covered farms, or an average of 1.7 operators per farm. We estimate that there are approximately 667,892 farmworkers employed on these covered farms. We estimated this number using the average number of workers employed per produce farm available from the 2007 Census of Agriculture, along with worker information obtained in available literature (Ref.25). Table 8 summarizes the number of farm operators, the number of workers, and the number of farm jobs occupied on these covered farms by farm size. The number of workers differs from the number of farm jobs occupied since workers usually work for more than one farm in one year and would be counted more than once in the Census of Agriculture. We estimate that approximately 38 percent of workers work for more than one farm (Ref.3;Ref.25).[7] The total number of farm jobs occupied on covered farms that grow produce is approximately 898,130. The distinction between a farm job and a farm worker is made to account for costs that are borne by the worker and the costs that are borne by the employer.

Table 8 also distinguishes between workers by farm task. Farm tasks were estimated using the occupations reported by farm workers in fruits and vegetable

[7] Kandel (Ref.25) reports that there are approximately 752,000 hired workers. The Census shows that farms reported they hired approximately 1.04 million workers. This gives us that 38 percent of workers work for more than one farm.

production in the NAWS survey (Ref.13). Approximately 26 percent of workers are employed in pre-harvest occupations, 58 percent are employed in harvest occupations, and 16 percent are employed in post-harvest occupations (Ref.13). Farms on average have 22 positions available for either direct or contract hired labor. Very small farms have 8 farm jobs available, small farms have 18 farm jobs, and large farms have 70 farm jobs available on average. These numbers are also used to calculate the costs throughout the analysis.

Table 8 - Labor on Covered Farms

	Very small	Small	Large	Total
Number of Farm Operators	42,760	8,027	17,848	68,635
Average Farm Operators per farm	1.6	1.7	2.1	1.7
Total Number of Farm jobs occupied	212,710	85,180	600,241	898,130
By Task				
Pre-harvest	56,121	22,474	158,367	236,961
Harvest & Semi-skilled	123,446	49,434	348,350	521,230
Post-harvest	33,143	13,272	93,525	139,939
Average Farm jobs per farm	7.9	18.1	70.0	22.3
By Task				
Pre-harvest	2.1	4.8	18.5	5.9
Harvest & Semi-skilled	4.6	10.5	40.6	13.0
Post-harvest	1.2	2.8	10.9	3.5
Total Number of Farmworkers	158,181	63,343	446,368	667,892
By Task				
Pre-harvest	41,734	16,712	117,769	176,215
Harvest & Semi-skilled	91,800	36,761	259,049	387,611
Post-harvest	24,646	9,870	69,549	104,065
Average Farmworkers per farm	5.9	13.5	52.1	16.6
By Task				
Pre-harvest	1.5	3.6	13.7	4.4
Harvest & Semi-skilled	3.4	7.8	30.2	9.6
Post-harvest	0.9	2.1	8.1	2.6

3. Current Baseline Industry Practices

Current produce safety practices, or baseline practices, are those safety practices currently implemented in the growing, harvesting, and post-harvesting of produce to comply with current Federal, state and local regulations, international and industry-wide standards and the grower's own private standards. It is necessary to know about the industry's current practices because the cost of the proposed rule will be the result of the difference between current practices and the provisions of the proposed rule.

The data on current produce industry practices is sparse and some of it is dated. We have attempted to piece together information where available, and to correct for biases, to best estimate baseline industry practices. However, because some of the data predates modern safety initiatives, and some of it is not necessarily nationally representative, the estimates are imperfect, and may be biased. We seek comment on our methods, and specifically request data that would allow us to make better estimates of baseline practices.

To learn about the domestic produce industry's baseline food safety practices and to help us estimate the number of farms that are likely to change practices to comply with the proposed rule, we use information from a number of sources. Specifically, we use information from the following food safety regulations and programs:

- Florida tomato safety regulation
- California and Arizona Leafy Greens Marketing Agreements (LGMA)
- USDA Agricultural Marketing Service (AMS) GAPs audits
- California Tomato Farmers' Cooperative GAPs audits
- Mushroom industry's GAPs audits.

We also use the following surveys:

- 1999 Fruit and Vegetable Agricultural Practices Survey (Ref.6)
- 2001 New England farm food safety survey (Ref.7)
- 2007 Census of Agriculture (Ref.3)

- 2008 Farm and Ranch Irrigation Survey (Ref.17)
- National Agricultural Workers Survey (Ref.13); and
- 2008 Organic Production Survey (Ref.17).

Growers of fresh produce are currently not subject to specific food safety regulatory requirements (other than the FD&C Act) with the exception of tomato growers in Florida. In cases where there is an industry marketing agreement with a focus on food safety such as in California and Arizona, requirements are mandatory for only the signatory members who are the handlers of the commodity. In some commodity-specific industries and/or regions, such as the fresh tomato industry in the U.S. or the strawberry industry in California, guidance on good agricultural practices is followed by some growers, but is not mandatory. Requirements for farms to follow food safety practices can also be set by the buyers of the commodity such as fresh-cut processors, foodservice, or retail customers. It is difficult to assess compliance with specific food safety requirements since farms are not required to follow a single set of standards. Whether a farm currently follows good agricultural practices usually varies with buyer requirements and personal choice. Therefore, we rely on farm surveys to assess compliance with general food safety practices, and infer that these surveys capture farms implementing food safety standards that are not currently required. This section estimates the number of fresh produce farms that are following current food safety regulations, marketing agreements, guidance, or other standards as described in surveys.

a. Current Regulations

Florida is the only State that currently has a produce safety regulation. The regulation mandates tomato growers, packers, and re-packers to comply with the Tomato

Best Practices Manual which is composed of both Tomato Good Agricultural Practices (T-GAPs) and Tomato Best Management Practices (T-BMPs) (Ref.26). Compliance is verified through inspections by the Florida Department of Agriculture and Consumer Services (DACS) as frequently as needed, but at least once a year in packinghouses. T-GAPs and T-BMPs require growers to implement similar practices as the provisions in the proposed regulation. Requirements for worker health and hygiene, irrigation water, equipment sanitation, domestic and wild animals, training workers, recordkeeping and others will be explained when appropriate throughout the analysis. An example of a requirement in the Florida tomato rule that is similar to one in the proposed rule is that growers must complete a GAPs course every year.

There were a total of 350 tomato growers (329 farms and 21 greenhouses) in Florida in 2007 (Ref.3). We estimate that there are approximately 149 farms that qualify for the average monetary value of all food sold and direct farm marketing qualified exemption in the proposed rule. This was estimated using the same percentage of tomato farms exempt in the U.S. by size for Florida tomato farms. We estimate that there are 103 Florida tomato farms that are not covered by the proposed rule based on their size. This was estimated using the same size distribution for tomato farms in the U.S. and applying it to tomato farms in Florida. Therefore, we estimate that there are 99 tomato farms (350 – 149 – 103) in Florida that are covered under the proposed rule and that follow the Florida regulation. The Florida regulation exempts growers from complying with T-GAPs and T-BMPs if the grower donates tomatoes to charities and if the grower sells tomatoes directly to the consumer on the premises in which they are grown or at the local farmers market as long as this quantity does not exceed two twenty-five pound boxes per customer (Ref.10). It is expected that these farms also qualify for one of the exemptions in the proposed rule.

b. Measurable Voluntary Food Safety Programs

There are multiple voluntary food safety programs implemented throughout the produce industry that are enforced through audits. We are able to estimate the number of farms that currently comply with the following programs based on information in audits and provided by the program: California and Arizona LGMAs, USDA AMS audits, the California Tomato Farmers' Cooperative GAPs audits, and the Mushroom industry's GAPs audits. We have little information regarding the number of farms that implement other voluntary food safety programs not addressed here. We estimate their current food safety practices with survey information discussed in the next section (c. Farm Food Safety Surveys).

i. California and Arizona LGMAs

The leafy greens industries in California and Arizona implemented marketing agreements in 2007 that impose food safety requirements on leafy greens growers. The signatories of these marketing agreements are handlers of lettuce, cabbage, spinach, and other very small production leafy greens. The food safety requirements in the LGMA are enforced through audits, and handlers are required to buy leafy greens only from growers that have passed an audit. Details on the specific food safety requirements in the LGMAs will be addressed when appropriate in the analysis.

The LGMAs do not apply to all leafy greens growers in California or Arizona. The California LGMA covers approximately 99 percent of the volume of California leafy greens (Ref.11). The Arizona LGMA covers hundreds of farmers and approximately 85 percent of the leafy greens products consumed in the U.S. and Canada from November to March (Ref.12). We estimate that all growers covered by the California and Arizona LGMA are also covered under the proposed rule.

In California, there are a total of 904 farms that grow leafy greens (Ref.3). We estimate that approximately 321 of these farms qualify for the average monetary value of all food sold and direct farm marketing qualified exemption in the proposed rule. This was estimated using the same percentage of leafy greens farms exempt in the U.S. by size for California leafy greens farms. We estimate that there are 203 farms that would not be covered by the proposed rule based on their size. This was estimated using the same size distribution for leafy greens farms in the U.S. and applying it to California leafy greens farms. Therefore, we estimate that there are 380 leafy greens farms (904 – 321 – 203) in California that are covered under the proposed rule and that follow the requirements outlined in the LGMA. We recognize the possibility that the 380 leafy greens farms is an overestimate of the number of farms following the LGMA requirements, and we seek comment on this estimate. However, since the California LGMA covers approximately 99 percent of the volume of California leafy greens, we conclude that all 380 farms are highly likely to be in the program and is a reasonable estimate.

In Arizona, there are a total of 97 farms that grow leafy greens (Ref.3). We estimate that approximately 34 of these farms qualify for the average monetary value of all food sold and direct farm marketing qualified exemption in the proposed rule. This was estimated using the same percentage of leafy greens farms exempt in the U.S. by size for Arizona leafy greens farms. We estimate that there are 22 farms that that would not be covered by the proposed rule based on their size. This was estimated using the same size distribution for leafy greens farms in the U.S. and applying it to Arizona leafy greens farms. Therefore, we estimate that there are 41 leafy greens farms (97 – 34 – 22) in Arizona that are covered under the proposed rule and that follow the requirements outlined in the LGMA. It is possible that the 41 farms is an overestimate of the number of farms following the LGMA requirements, and we seek comment on this estimate. However, since the Arizona LGMA covers hundreds of farmers and approximately 85 percent of the leafy greens products consumed in the U.S., we conclude that all 41 farms are highly likely to be in the program and is a reasonable estimate.

ii. USDA AMS GAPs Audits

In 1998, FDA and USDA issued the GAPs guide which establishes good agricultural practices for growing, harvesting, washing, sorting, packing, and transporting of fresh fruits and vegetables. Although the practices outlined are not mandated, there are farm operations in the U.S. that are following the guide. The AMS of the USDA (Ref.9) conducts farm audits to verify adherence to the GAPs guide. The audits are voluntary, but can be required from buyers of fresh produce that want to ensure fruits and vegetables are being grown in accordance with the GAPs guide. The GAP audit can be conducted for all fruits (including nuts) and vegetables, including specialty crops such as mushrooms and fresh herbs. AMS also conducts commodity-specific audits for the tomato and mushroom industries.

In 2010, there were approximately 1,073 farms in the U.S. that were GAPs certified for a fresh fruit or vegetable commodity covered in the proposed rule (Ref.9). This number is potentially a lower bound of the number of farms that are implementing the GAPs guide since farms could be adhering to the GAPs guidelines, but not have a

GAPs audit by AMS. This includes farms that have obtained an audit by a third party, have conducted a self-audit, or have not obtained an audit at all. Further, farms could have obtained an audit in another year but would not be counted in 2010 since GAPs certification is valid for one year only.

We expect that zero farms qualify for the average monetary value of all food sold and direct farm marketing qualified exemption in the proposed rule since GAPs audits are typically required by buyers who are not qualified end-users. However, it is possible that farms obtain audits voluntarily, and we seek comment on the number of farms that receive GAPs audits and that are also eligible for a qualified exemption. We estimate that there are 616 farms that are not covered by the proposed rule based on their size. This was estimated using the same size distribution for farms in the U.S. and applying it to the GAPs audited farms. Therefore, we estimate that there are 457 farms (1,073 – 616) that are covered under the proposed rule and that follow the requirements outlined in the GAPs audit.

iii. California Tomato Farmers

The California Tomato Farmers (CTF) is an organization of family farms that grow fresh tomatoes for approximately nine large multi-state distributors (Ref.27). CTF members follow the food safety standards in the Tomato Audit Protocol (TAP) which is an audit conducted by the USDA AMS (Ref.9). The TAP is based on the Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain issued by industry groups in 2008 (Ref.28).

CTF members account for more than 50 growers and approximately 90 percent of the fresh tomatoes produced in California (Ref.27). The CTF audit database indicates that there were 116 field audits conducted in 2010 for approximately 98 different farms (Ref.29). We estimate that none of these farms qualify for the average monetary value of all food sold and direct farm marketing qualified exemption in the proposed rule since they sell their tomatoes to distributors and not to qualified end-users. We estimate that there are zero farms that are not covered by the proposed rule based on their size since the CTF members account for approximately 90 percent of all tomatoes produced in California. Using tomato acres as a proxy for tomato production, we estimate that all 98 farms fall under the largest size category and therefore, all are covered under the proposed rule.

iv. Mushroom Good Agricultural Practices Program

The American Mushroom Institute (AMI) and Penn State University introduced mushroom specific good agricultural practices (M-GAPs) guidance in 2008 (Ref.30). Mushrooms require large capital investments since they are grown in climate-controlled rooms requiring large building and energy expenses. M-GAPs have general practices that are similar to the proposed regulation, but also have specific practices that only apply to the mushroom industry. For example, soil requirements are specific to the different phases of manure preparation and pasteurization treatment, and are unique to the industry.

In 2010, there were 43 mushroom operations that passed the M-GAPs audit conducted by AMS (Ref.9). This is potentially a lower bound since other audit companies can also conduct the audits. Approximately 80 percent of mushroom production in the U.S. is grown under the requirements in the M-GAPs (Ref.30). Using mushroom square feet as a proxy for production, all 43 farms are estimated to be considered large farms. We estimate that all farms that have been audited for M-GAPs are covered under the proposed rule, and that none qualify for an exemption.

v. <u>Other Voluntary Programs</u>

In addition to the produce safety programs mentioned, the FDA and industry trade associations have published commodity-specific guidance for melons, lettuce and leafy greens, tomatoes, green onions, citrus, strawberries, apples, peppers, almonds, and avocados (Ref.20;Ref.31). University extensions also provide general GAPs assistance and offer food safety courses for farmers and other produce suppliers (Ref.32;Ref.33). These guides and training courses are meant to assist the fresh produce supplier in implementing food safety programs in their operation. They are not enforced, and it is uncertain how many farms follow the guides.

To learn about all programs, including other voluntary programs, and to help us estimate the number of farms that are implementing food safety practices, we contracted with RTI International to conduct a review and provide a report of the number of farms that follow some type of food safety program, what the food safety programs require, and whether and how effectively these programs are enforced (Ref.34). In developing their study, RTI searched websites, contacted grower organizations, and consulted food safety program publications. RTI found over 50 organizations representing various commodities that promote food safety on the farm. These organizations provide food safety research, guidance, or voluntary training, but it is very difficult to assess the number of farms that take advantage of the services they offer. Therefore, we do not attempt to estimate the number of farms that are currently complying with any of these guides specifically. We also do not attempt to estimate the number of farms that comply with buyer food safety audits since there is no set standard that they must comply with, and there is no mechanism to count the number of farms. We do, however, attempt to account for these farms using information found in grower surveys. We seek comment to the extent in which farms follow other food safety programs.

c. Farm Food Safety Surveys

We rely on grower surveys to obtain additional information on food safety industry practices not captured by the Florida regulation and the five voluntary food safety programs mentioned in the previous section. Produce farm operators perhaps choose to follow a specific food safety program or might be required by the buyer of their crop to do so. It is necessary to obtain information on which practices are the most prevalent in order to accurately measure the costs to farms of the proposed rule. In order to do so, we use two primary surveys, the 1999 Fruit and Vegetable Agricultural Practices Survey (FVAPS) (Ref.6) and a 2001 New England farm food safety survey (NEFFSS) (Ref.7), and apply the information in these surveys to farms not in measurable programs.

The 1999 FVAPS was conducted in response to the issuance of the 1998 GAPs guide in order to establish the baseline of food safety agricultural practices (Ref.6). The survey represents growers of fresh fruits and vegetables in the top 14 producing states: Arizona, California, Florida, Georgia, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania, South Carolina, Texas, Washington, and Wisconsin. Although the survey was conducted over 10 years ago, it is the only survey that asks specific food safety questions to a large sample, close to 7,000, of fruit and vegetable growers. Since it is only representative of farms in the top 14 producing states, we use information available in the 2001 NEFFSS to obtain information on current practices for other states.

The 2001 NEFFSS was conducted by a group of researchers at the University of Massachusetts in order to identify and measure the prevalence of food safety practices advised in the GAPs guide in the New England region (Ref.7). The survey's sample population was 297, and results were extrapolated to the farms in the New England region using the 1997 Census of Agriculture. We estimate that the results from this survey are also representative of other farms outside of the top 14 producing states. We expect that farms outside of the top 14 producing states are similar with regards to awareness of food safety practices. For example, 83 percent of farms audited by AMS are located in the top 14 producing states, and there are likely more education and training opportunities for growers in top producing states than in other states (e.g. Arizona LGMA training course and GAPs training courses conducted by the California Strawberry Commission, Cornell University, and Pennsylvania State University (Ref.32;Ref.33;Ref.35).

The top 14 states may have different practices overall than other states. They are more likely to have regulations and organized voluntary programs in place. We have netted out the effect of the regulations and compliance with voluntary programs, so we only compare farms in the Top 14 producing states that are not complying with a regulation or voluntary program with similar farms in other states. This method may introduce bias either upwards or downwards in estimating baseline practices, because farms that in the top 14 states not covered by a regulation or program may be more or less likely to have practices in line with the proposed rule than farms in other states. Where possible, we use data specific to other states to avoid this potential bias. We request comment on our methods, and request data that would better allow us to estimate current industry practices.

Since both of these surveys predate a modern movement towards safer practices on produce farms, including GAPs, state and local regulations, and various voluntary programs and buyer agreements, we expect that the use of these surveys will underestimate, sometimes significantly, the current application of food safety practices. We attempt to obtain current farm information from nationally representative surveys available through USDA and the Department of Labor. We use the 2007 Census of Agriculture, the 2008 Farm and Ranch Irrigation Survey (FRIS), the 2008 Organic Production Survey, and the NAWS in specific sections of the analysis to obtain information on current industry practices for all covered farms whether or not they are in a measurable program. These surveys are nationally representative and current.

d. Summary of Current Industry Practices

Table 9 shows the number of farms implementing a measurable enforced food safety program as discussed in section 4.b. Throughout the analysis, we consider whether the farms in these programs are in full compliance with a specific provision in the proposed rule. If so, then we subtract these farms from our total estimate of covered farms, and we do not estimate a cost for them. After we subtract these farms from our total number, we then use the information found in the grower surveys for farms not in one of these programs.

Table 9: Number of Farms with Food Safety Programs in Place					
Food safety program	Year Started	Very small	Small	Large	Total
FL Tomato Regulation	2008	78	8	13	99
CA LGMA	2007	234	37	109	380
AZ LGMA	2008	25	4	12	41
CA Tomato Farmers Co-Op	2008	0	0	98	98
Mushroom GAPs	2008	0	0	43	43
USDA AMS GAPs audits	1998	318	55	83	457
TOTAL		655	104	358	1,117

D. Regulatory Options

FDA considered several regulatory options for the growing, harvesting, packing, and holding of produce for human consumption to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. The options that we considered include: (1) no new regulatory action, (2) exclude commodities not associated with outbreaks, from some or all of the provision of the rule ,(3) requiring less-extensive standards, (4) requiring more-extensive standards, and (5) a lower threshold to define a covered farm based on having an average annual monetary value of food sold during the previous three year period of more than $10,000, and, (6) the proposed rule.

<u>Option (1) No New Regulatory Action</u>

Under this option, FDA would rely on:

- current guidance such as the GAPs guidance and other commodity-specific guidance,
- voluntary adoption of some or all provisions of the proposed regulation,
- current or enhanced State and local enforcement activity to bring about a reduction of potential harm from adulterated foods, or
- the tort system, with litigation or the threat of litigation serving to bring about the goals of the proposed rule.

This option is not legally viable because Section 105(a) of FSMA requires us to conduct this rulemaking establishing produce safety standards. Moreover, we believe that these methods are unable to fully minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce. The advantage of this option is that there would be no costs to the produce industry, but the disadvantage is that there would also be no benefits.

Option (2) Exclude Commodities Not Associated with Outbreaks

FDA has incorporated considerations of risk into the proposed rule in a number of ways. For instance, we do not apply the provisions of the proposed rule to products that we believe to present very low risk of causing illness, such as items destined for further processing that contains a kill-step or items that are rarely consumed raw by the consumer. As another example, we have proposed additional standards for sprouts because they present unique considerations as compared to other covered produce. Nevertheless, we do not specifically exclude commodities or commodity groups based on different variables that could inform relative risk or on the basis that they have not been commonly associated with human illness from the proposed rule.

As discussed in section IV.C of the proposed rule, in addition to outbreak data, we could attempt to draw additional conclusions and exclude additional commodities or commodity groups based on relative risk as determined by data on pathogen surveillance data, commodity characteristics, or market channels. Each data source for relative risk consideration presents certain gaps that make it challenging to consider a commodity-specific approach that would adequately minimize risk of serious adverse health consequences or death.

Outbreak data provide the most direct representation of public health burden, even considering the confines associated with these data. One possible commodity-specific approach would be to cover those commodity groups that have been associated with outbreaks. Commodity groups "associated with outbreaks" could be identified as, for example, commodity groups associated with one or more outbreaks during a set period of time. The remaining commodity groups could then either not be subject to the proposed rule, or be subject to the proposed rule but with less stringent requirements. A commodity-specific approach that covers the commodity groups associated with outbreaks would target the commodity groups that present the greatest public health burden. In addition, as discussed above in section IV.C.1.a. of the proposed rule, there are various drawbacks with using outbreak data in this way. For example, because only a small percentage of outbreaks are both reported and assigned to a food vehicle, outbreak data may not provide a complete picture of the commodities upon which we need to focus to minimize current and future risk of illness. We could calculate cost reductions for specific additional exemptions. For example, exempting farms growing commodities either implicated in a single outbreak or closely related to a commodity implicated in an outbreak[8] would require roughly 18,000 fewer farms to implement the standards outlined in the proposed rule. We would have roughly12,000 fewer very small farms, 2,000 fewer small farms, and 4,000 fewer large farms included in the rule. Using an average cost per farm, this would represent an annual cost reduction of about $204.57 million (12,000 x $4,697 + 2,000 x $12,972 + 4,000 x $30,566) compared to the amount estimated in the proposed rule. However, without additional data, we cannot estimate a change in future

[8] For example, for the purpose of this analysis, we include all berries though only raspberries and blackberries have been implicated recently.

benefits of the rule. In simply removing a specific commodity that has never recorded an outbreak from any one of the aggregate commodity groups, the simple mechanics of the model used to estimate costs and benefits would produce a result that suggests costs would decrease without any loss in estimated benefits. However, we do not believe this is necessarily true, and the model is not intended to be used this way. Because, based on historic observation, the commodity outbreaks that have occurred only once appear to happen unpredictably and randomly, relative to commodities with a more observable pattern of outbreaks, it is likely that at least some commodities that currently have never been implicated in an outbreak have a positive probability of being implicated in a future outbreak. Therefore, while we cannot quantify what the effect of this option would have on the benefits of the rule, we can say the benefits would likely decrease, potentially significantly, unless commodities could be chosen that we are relatively certain have little probability of a being tied to a future outbreak..

Another possible commodity-specific approach that attempts to account for the drawbacks of the above approach would be to cover *all* of the commodities that have been identified as associated with an outbreak at any time. Produce commodities that have not been identified as associated with an outbreak could then either not be subject to the proposed rule, or be subject to the proposed rule but with less stringent requirements. This option would address more than the percent of known outbreaks addressed by the above approach in that it would address all known outbreaks. This approach would also significantly reduce the costs of the proposed rule by exempting produce categories that have never been associated with human illness. As discussed above, however, outbreaks have been associated with commodities without an illness history. Although we would expect to use additional data to update any list we might develop of commodities subject to the provisions of the rule, we would expect that this approach would lead to the occurrence of some number of additional outbreaks and illnesses.

Section IV.C of the proposed rule discusses the limitations with each of the above methods of creating a risk-based exemption from the rule. We could also combine two or more of the approaches used above to create a more holistic picture of risk. For example, we might combine a history of outbreak data with the growing characteristics of a commodity or class of commodity. Such an approach could potentially exempt additional commodities that pose minimal or no risk (i.e., in addition to those we already considered in the proposed approach: those specified as rarely consumed raw and those that are commercially processed). This could potentially reduce the cost of the rule without significantly reducing the calculated benefits of the rule. However, we have not been able to fully develop an approach that might combine a history of outbreak data with the growing characteristics of a commodity or class of commodities to create risk-based exemptions from the rule and, thus, minimize the risk of serious adverse health consequences or death.

We seek comment on this issue. Specifically, We request comment on the appropriateness of excluding produce commodities that have never been associated with an outbreak, commodities that have not commonly been associated with outbreaks, or some subset of those commodities otherwise deemed lower risk, from some or all of the provisions of the proposed rule. If commenters believe that it is appropriate, we request comment on the provisions to which those produce commodities should be subject, as well as supporting data or other information.

Option (3) Less-Extensive Standards

Under this Option, the proposed rule could require less extensive provisions then the proposed rule outlined in Option 6. Several provisions could be combined to provide a less extensive set of controls than in the rule. Certain prevention measures could be separated and put forth as stand-alone regulations; for example, provisions regarding agricultural water could be issued as a separate proposed rule. As an alternative, certain provisions included in Option 6 could be eliminated altogether; for example, eliminating provisions related to domesticated and wild animals and biological soil amendments would reduce the cost of the proposed rule (Option 6) by nearly $47 million; however, potential benefits would also be reduced by about $166 million.

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 of Option 6. The various individual measures would, by themselves, generate lower costs than the integrated program outlined in the proposed rule. However, the number of illnesses prevented would potentially be lower by each individual measure compared to the integrated program outlined in the proposed rule. Please refer to Table 120 to see how costs and benefits compare for less extensive combinations of requirements. We encourage commenters who may have relevant information on this topic to submit it, along with any analysis that would enable FDA to make assessments on costs and benefits of each of the provisions of the proposed rule.

FDA has not selected this alternative because we believe that all requirements are important in reducing the level of contamination and human health burden associated with produce. Additionally, the likely reduction in costs from cutting these requirements would probably not outweigh the forgone benefits.

Option (4) More-Extensive Standards

The proposed rule could be broader in scope and have more extensive provisions including: (1) covering all farms with an average annual monetary value of food sold during the previous three-year period of $25,000 or less (on a rolling basis), and (2) including more on-farm provisions than those in the proposed rule. Additional on-farm provisions include requiring a food safety plan and operational assessment.

Covering all farms with an average annual monetary value of food sold during the previous three-year period of $25,000 or less (on a rolling basis) would increase costs by $161.8 million per year (34,452 x $4,697), an approximately 38 percent increase, and would only cover an additional 1.5 percent of covered produce acres. Since these farms account for only 1.5 percent of production, requiring them to comply with all of the standards in the proposed rule would have a small effect on the volume of production that could become contaminated. In addition, covering these farms likely would result in the cessation of produce production at a large number of farms.

Requiring additional on-farm provisions such as a food safety plan and a yearly operational assessment would result in increased costs of $25 million. This is based on the per farm cost of conducting an assessment of all agricultural water sources on the farm of $723 per very small farm, and $470 per small and large farm, and accounting for the number of farms that are currently implementing a food safety program. We note that this cost is a lower bound since it is likely that conducting an operational assessment will take longer than the time it takes to conduct an assessment of agricultural water sources of 15.26 hours. Therefore, the additional costs would be a minimum of $25 million annually. FDA has not selected this alternative because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms.

Option (5) A Lower Threshold for the Definition of a Covered Farm

Under this option, we would require that farms or farm mixed-type facilities with an average annual monetary value of food sold during the previous three-year period of more than $10,000 would be considered covered farms subject to the proposed rule. This option would require 15,756 additional farms to implement the standards outlined in the proposed rule. Instead of having 27,201 very small covered farms, as is the case under the proposed covered farm threshold, we would have 42,776 very small farms for a total of 56,251 covered farms. Using the average cost per very small farm of $4,697, calculated in the summary of costs section of the RIA, we estimate that the total annual cost for very small farms under this option is $200.92 million (42,776 x $4,697), which is $73.16 million more per year, approximately a 16 percent increase over the proposed rule. The additional amount of produce covered in the proposed rule would be 1.1 percent, and .7 percent of produce that has been commonly associated with FDA outbreaks, or roughly $7.25 million in additional estimated annual benefits.

The number of farms not covered under option (5) would be 18,696 and would account for 25 percent of farms after taking out the qualified exemptions and the farms that exclusively grow commodities rarely consumed raw. They account for 0.4 percent of all covered produce and for 0.3 percent of acreage that is used for commodities that have been associated with outbreaks. Their average food sales are $3,266, and– assuming that the marginal rate of illness per unit of output is constant across farm size -

the costs of illness potentially linked to these farms would be $378.[9] Under this option, there would be 42,776 very small farms with average food sales of $50,939. It is important to note that the increased benefits in this option cannot be directly compared to the increased costs. In estimating the average costs, we have taken into account differences between size categories that would account for differences in the relative average costs per farm. The differences in current safety practices have not been accounted for in estimating the average benefit per farm, so in this way, the estimated benefits for covering the very smallest farms, which are likely, on average, to have less safety practices currently in place, is downward biased.

FDA has not selected this alternative because the anticipated costs outweigh the potential benefits from eliminating all illnesses associated with these farms.

Option (6) The Proposed Rule

The costs and benefits of the proposed rule are summarized at the beginning of this section, and are discussed at length in the preceding sections of this analysis. We seek comment on whether a select number of specific provisions would be more appropriate for the proposed rule.

E. Summary of Costs and Potential Benefits of the Proposed Rule

In this section, we summarize the costs and benefits of the proposed rule. In section IV.G of this document, we provide a more thorough summary of the costs and potential benefits of the proposed rule. Table 10 summarizes the costs of the proposed rule and Table 11 summarizes the potential benefits of the proposed rule. The estimated

[9] The average health burden is based on the assumption that risk of foodborne illness is distributed uniformly across the food supply .This means that a very small farm will have less risk associated with it simply because they distribute less than a larger farm.

illnesses attributable to produce RACs other than sprouts, fresh-cut, and sprouts are 3.1 million, and the baseline estimate for preventing all illnesses associated with microbial contamination of FDA-regulated produce is $1.88 billion. The proposed regulation covers produce responsible for about $1.61 billion of this estimate. We do not expect that this proposed rule will eliminate all foodborne illness linked to covered produce. Instead, we expect that the proposed produce safety regulation will prevent about 65% of this illness burden from recurring. The effectiveness of this regulation and the corresponding reduction in food contamination and foodborne illness is estimated to be $1.04 billion, annually.

We estimate that the total first year costs for domestic farms to implement the proposed rule (if the compliance period were to be the same for all farms, with no staggered compliance) would be approximately $699.7 million, and that the total recurring costs to farms would be $365.65 million per year as shown in Table 10. We estimate that the annualized costs of the proposed rule would be approximately $459.60 million per year using a discount rate of 7 percent for all future years. We obtain a total cost of approximately domestic $419.28 million per year using a discount rate of 3 percent for all future years. The annualized costs for foreign farms are estimated to be about $170.62 million per year using a 7% discount rate and $135.74 million per year using a 3% discount rate. We discuss our use of the 3 and 7 percent discount rates and our use of a 7 year time preference in accordance with OMB Circular A-4 in our section that describes cost conventions.

Table 10: Summary of Costs of the Proposed Rule (in millions)					
	Total First Year Costs (with uniform compliance periods)	Total Recurring Costs	Annualized Costs (with 7% discount rate and 7 year time preference)	Annualized Costs (with 3% discount rate and 7 year time preference)	Annualized Costs (with 7% discount rate and 7 year time preference) Relative to Food Revenue (%)
Domestic	$699.79	$365.65	$459.60	$419.28	1.71%
Foreign	$259.77	$135.74	$170.62	$106.28	--

Table 11: Summary Potential Benefits of the Proposed Rule (in millions)				
Estimated Illnesses Attributable to Produce	Total Dollar Burden of Illness Attributable to Produce	Estimated Effectiveness	Estimated Illnesses Averted	Total Estimated Benefits
3.12	$1,875	56.09%	1.75	$1,036.40

* We estimate the rule will actually prevent about 65 percent of on farm contamination; however, only about 85 percent of all produce associated with foodborne illness is covered under this proposed rule.

Although, the RIA calculates the cost of the proposed regulation with a small farm cutoff of $25,000 in annual revenue, we consider multiple cutoffs for this size threshold and present estimates for $50,000; $100,000; $250,000; and $500,000 in Table 12. Selecting $50,000 as the threshold for coverage would require 11,958 fewer farms to be covered by the proposed rule, resulting in a total of 28,253 farms covered. This change would cover 1.3 percent fewer produce acres. We estimate that the total annual cost for farms under this scenario is approximately $348 million. Assuming that the likelihood of a farm causing illness is proportional revenues and that smaller farms are not relatively riskier than larger farms, we estimate a total reduction in benefits of roughly 47,000 illnesses that would not be prevented, equivalent to reduction of $28 million in benefits annually as compared to the $25,000 limit.

FDA has not selected this alternative because, although the cost savings to industry are relatively substantial, we tentatively conclude that the potential additional 47,000 illnesses that would result from increasing the minimum threshold for coverage are too great to justify this option. The proposed limit of $25,000 accounts for only 1.3 percent of covered produce, representing an estimated 26,000 illnesses per year, increasing the threshold to $50,000 would represent substantial public health impact, nearly doubling the number of preventable illnesses that would not be avoided.

FDA requests comment on the appropriate threshold values to define the limits on farm size for coverage in the proposed rule, as well as supporting data and other information.

Table 12. Summary of Costs and Benefits for Different Small Farm Exclusions

	< $25K	< $50K	< $100K	< $250K	< $500K
Prevented Illnesses (in millions)	1.73	1.69	1.63	1.53	1.42
Additional Illnesses not covered	--	47,000	52,000	99,000	117,000
Covered Farms	40,211	28,253	20,140	12,615	8,500
Exempt or Non-covered Farms	149,426	161,384	169,497	177,022	181,137
Produce acres not covered	14.1%	16.4%	19.0%	23.9%	29.7%
Total Domestic Benefits (in millions)	$1,032	$1,004	$973	$914	$844
Total Domestic Costs (in millions)	$460	$348	$316	$282	$234
Net Domestic Benefits (in millions)	$582	$656	$657	$632	$610
Average Domestic Cost (per farm)	$11,430	$12,313	$15,699	$22,383	$27,566
Total Foreign Costs (in millions)	$171	$152	$131	$112	$91

F. Detailed Analysis of Benefits of the Proposed Rule

Provisions required in the proposed rule

The proposed rule would establish science-based minimum standards for the safe growing, harvesting, packing, and holding of produce on farms. The proposed rule would address microbiological risks from all agricultural inputs (people, agricultural water, biological soil amendments, and tools and equipment), from unsanitary conditions in buildings, and from contact with wild and domesticated animals during growing, harvesting, packing, and holding activities of covered produce, including sprouts intended for human consumption. Specifically, the rule would establish standards in the following areas:

- Worker Training, Heath, and Hygiene: Establish qualification and training requirements for all personnel who handle (contact) covered produce or food-contact surfaces and their supervisors; Require documentation of required training; and Establish hygienic practices and other measures needed to prevent persons, including visitors, from contaminating produce with microorganisms of public health significance.
- Agricultural Water: Require that all agricultural water must be of safe and sanitary quality for its intended use. Agricultural water is defined in part as water that is intended to, or likely to, contact the harvestable portion of covered produce or food-contact surfaces; Establish requirements for inspection, maintenance, and follow-up actions related to the use of agricultural water, water sources, and water distribution systems associated with growing, harvesting, packing, and holding of covered produce; Require treatment of agricultural water if it is known or there is reason to believe that the water is not safe and of adequate sanitary quality for its intended use, including requirements for treating such water and monitoring its treatment; Establish specific requirements for the quality of agricultural water that is used for certain specified purposes, including provisions requiring periodic analytical testing of such water (with exemptions provided for use of public water supplies under certain specified conditions or treated water), and requiring certain actions to be taken when such water does not meet the quality standards; and Require certain records, including documentation of inspection findings, scientific data or information relied on to support the adequacy of water treatment methods,

treatment monitoring results, water testing results, and scientific data or information relied on to support any permitted alternatives to requirements.

- Biological Soil Amendments: Establish requirements for determining the status of a biological soil amendment of animal origin as treated or untreated, and for their handling, conveying, and storing; Prohibit the use of human waste for growing covered produce except in compliance with EPA regulations for such uses or equivalent regulatory requirements; Establish requirements for treatment of biological soil amendments of animal origin with scientifically valid, controlled, physical and/or chemical processes or composting processes that satisfy certain specific microbial standards; Establish application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin; and Require certain records, including documentation of application and harvest dates relevant to application intervals; documentation from suppliers of treated biological soil amendments of animal origin, periodic test results, and scientific data or information relied on to support any permitted alternatives to requirements.
- Domesticated and Wild Animals: If animals are allowed to graze or are used as working animals in fields where covered produce is grown and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, require, at a minimum, an adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed, and measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce; and If under the circumstances

there is a reasonable probability that animal intrusion will contaminate covered produce, require monitoring of those areas that are used for a covered activity for evidence of animal intrusion immediately prior to harvest and, as needed, during the growing season.

- Equipment, Tools, and Buildings: Establish requirements related to equipment and tools that contact covered produce and instruments and controls (including equipment used in transport), buildings, domesticated animals in and around fully-enclosed buildings, pest control, hand-washing and toilet facilities, sewage, trash, plumbing, and animal excreta; and Require certain records related to the date and method of cleaning and sanitizing equipment used in growing operations for sprouts, and in covered harvesting, packing, or holding activities.

- Sprouts: Establish measures that must be taken related to seeds or beans for sprouting; Establish measures that must be taken for the growing, harvesting, packing, and holding of sprouts; Require testing the growing environment for Listeria spp. or L. monocytogenes and testing each production batch of spent irrigation water or sprouts for E. coli O157:H7 and Salmonella species and taking appropriate follow-up actions; and Require certain records, including documentation of treatment of seeds or beans for sprouting, a written environmental monitoring plan and sampling plan, test results, and certain methods used.

Quantifying the benefits of the proposed rule

We welcome comment on the potential benefits of the rule, and we particularly request any information that would permit FDA to more accurately quantify the likely benefits of the proposed provisions for individual commodities or for groups or classes of commodities.

The primary benefit of the provisions in this rule would be an expected decrease in the incidence of illnesses relating to produce from microbial contamination. For the purpose of this analysis, we develop a conceptual framework that describes how implementing this rule would likely reduce the level of foodborne illness. Estimating the rule's foodborne illness reduction benefits would require the following: (1) baseline risk of foodborne illness attributable to FDA-regulated produce under the scope of this rule; (2) a measure of lost health as measured by morbidity and mortality effects attributable to foodborne illness; (3) value of lost health due to foodborne illness; (4) the changes from baseline food production practices due to the rule; and (5) the effectiveness of the preventive controls.

1. Baseline Risk of Foodborne Illness[10]

a. Foodborne Illness Attributable to Produce from Microbial Contamination

We estimate that there are 2.68 million illnesses per year associated with produce that would be covered by this rule and that these illnesses cost $1.6 billion per year. We expect that the proposed rule would eliminate some portion of these illnesses and costs.

To estimate the number of baseline illnesses attributable to produce from microbial contamination only, we begin with only those outbreaks we can directly attribute to FDA-regulated produce from microbial contamination. Table 13 presents all outbreaks, organized by produce commodity and pathogen, which can be linked to

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

microbial contamination of produce raw agricultural commodities (RAC) and fresh cut produce, based on illnesses recorded in FDA's outbreak database. In total, there are 4,257 illnesses from 22 separate outbreaks that are linked to produce RACs other than sprouts for the years 2003-2008; this data represents only reported and laboratory confirmed illnesses from outbreaks. The data span of 2003-2008 is utilized for this analysis because it represents the most current, and comprehensive data available. We are unable to look at years beyond 2008, because the full outbreak data, from CDC, has not been completely collected, sorted, cleaned, and made available for public use. We do not go back further in the data, because there are regulations in the industry that took effect prior to these dates, and we want to look at a baseline estimate with all current regulations in place and functioning. Additionally, collection methods by both FDA and CDC have improved vastly in recent years, and data further back may be more subject to underreporting biases. This data is directly from an FDA database generated from outbreak investigations and reports (Ref.36). We note that, because of the infrequency of outbreaks, using a short time period may overstate the riskiness of a particular commodity if it happened to have an outbreak during the period evaluated. If additional data are available from the CDC at the final rule stage we will add it to the analysis. In addition, both 2003 and 2008 had unusually high numbers of illnesses caused by produce, relative to illnesses in adjacent years. We seek comment on whether and how use of our chosen time period may affect the results of our analysis and whether it would be more appropriate to use a different period of analysis.

Table 13. FDA Outbreak Data for Illnesses Attributed to RACs Other Than Sprouts, 2003-2008					
Commodity	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Berries	*Cyclospora*	1	59	2	0
Herbs	*Cyclospora*	3	678	1	0
Leafy Greens	*Cyclospora*	1	38	0	0
Peas	*Cyclospora*	1	116	0	0
Herbs	*E. Coli* O157:H7	1	108	8	0
Leafy Greens	*E. Coli* O157:H7	2	16	1	0
Onions	Hepatitis A	1	919	128	3
Nuts	*Salmonella*	1	42	10	1
Melons	*Salmonella*	4	156	30	2
Peppers	*Salmonella*	1	1535	308	2
Tomatoes	*Salmonella*	5	570	68	0
Melons	Shigella sonnei	1	56	3	0
TOTAL		**22**	**4,293**	**559**	**8**

Additionally, there are 1,445 illnesses from 17 separate outbreaks that are linked to Fresh Cut Produce for the years 2003-2008, and 151 illnesses from 9 outbreaks linked to Sprouts. Table 14 and Table 15 present all outbreaks, organized by pathogen, which can be linked to Fresh Cut Produce and Sprouts, respectively.

As shown in Table 16 taken together (RACs (other than sprouts), Fresh Cut, and Sprouts), there are 48 outbreaks, 5,889 illnesses, and 15 deaths in the FDA database attributable to FDA-related produce. This averages out to about 8 outbreaks, 981 illnesses, and 2.5 deaths per year observed in the outbreak database.

Table 14. FDA Outbreak Data for Illnesses Attributed to Fresh Cut, 2003-2008					
Commodity	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Leafy Greens	*E. Coli* O157:H7	10	599	223	6
Melons	*Salmonella*	2	99	22	0
Tomatoes	*Salmonella*	5	747	153	0
TOTAL		**17**	**1,445**	**398**	**6**

Table 15. FDA Outbreak Data for Illnesses Attributed to Sprouts, 2003-2008					
Commodity	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Sprouts	*Salmonella*	4	95	8	1
Sprouts	*E. Coli* O157:NM	2	15	1	0
Sprouts	*E. Coli* O157:H7	3	41	5	0
TOTAL		**9**	**151**	**14**	**1**

Table 16. FDA Outbreak Data for Illnesses Attributed to RACs (including sprouts) and Fresh Cut, 2003-2008					
Commodity	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Berries	*Cyclospora*	1	59	2	0
Herbs	*Cyclospora*	3	678	1	0
Leafy Greens	*Cyclospora*	1	38	0	0
Peas	*Cyclospora*	1	116	0	0
Herbs	*E. Coli* O157:H7	1	108	8	0
Leafy Greens	*E. Coli* O157:H7	2	16	1	0
FC-Leafy Greens*	*E. Coli* O157:H7	10	599	223	6
Sprouts	*E. Coli* O157:H7	3	41	5	0
Sprouts	*E. Coli* O157:NM	2	15	1	0
Onions	Hepatitis A	1	919	128	3
Nuts	*Salmonella*	1	42	10	1
Melons	*Salmonella*	4	156	30	2
Peppers	*Salmonella*	1	1535	308	2
Tomatoes	*Salmonella*	5	570	68	0
FC-Melons*	*Salmonella*	2	99	22	0
FC-Tomatoes*	*Salmonella*	5	747	153	0
Sprouts	*Salmonella*	4	95	8	1
Melons	Shigella sonnei	1	56	3	0
TOTAL		**48**	**5,889**	**971**	**15**

*Fresh Cut (FC)

Over the entire six year time horizon, we observe 15 outbreaks and 769 illnesses attributable to leafy greens. Additionally, there are 9 outbreaks and 1,194 illnesses associated with tomatoes. These two commodities represent the highest number of average annual outbreaks and illnesses in our available data. After these top two commodities, herbs, with 3 outbreaks and 730 illnesses; melons, with 7 outbreaks and 313 illnesses; and sprouts, with 9 outbreaks and 151 illnesses, represent the most prevalent commodities in our outbreak data. These commodities are also a likely source of a significant portion of the estimated average annual burden of illness that this proposed rule aims to mitigate.

There are also commodities that appear relatively infrequently in this outbreak data. These include: peppers, peas, green onions, nuts, and berries, each with only one associated outbreak over the six year time horizon. Although these commodities appear to be lower in risk than other types of produce (such as leafy greens), they are subject to the same types of hazards as other produce. The fact that an outbreak did occur during this time period confirms FDA's understanding that all produce is subject to sporadic and largely unpredictable outbreaks and illnesses without appropriate mitigation steps. These commodities and their associated outbreaks, show that a variety of produce, that is not typically cooked or receiving kill step processing, even if it is not typically associated with foodborne outbreak may be vulnerable to occasional contamination to a degree that produces a widespread or lethal outbreak.

It considerably more difficult to project the extent to which benefits will be derived from preventing these, since due to their nature, they are unpredictable in the commodity, when they will occur, and the root cause of the outbreak. Therefore, it is uncertain that a regular pattern of outbreaks associated with these products will emerge. We believe that the proposed rule will prevent some meaningful number of these sporadic outbreaks and lead to reductions in human illness.

Table 17 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 and applied to Scallan, et al.'s estimate of the total number of foodborne illnesses (Ref.37). To estimate the number of total illnesses associated with FDA regulated RACs other than sprouts, we employ a two-step calculation[11]: 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 illnesses by the total, gives us the percentage attributable to FDA. This number is then multiplied by Scallan, et al.'s estimate of the total annual incidence of each specific foodborne pathogen (Ref.37). 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 by the annual incidence yields the annual estimated illnesses attributable to FDA regulated RACs other than produce. Additionally we estimated the illnesses caused by unidentified pathogens attributable to FDA regulated RAC's other than sprouts. To do this, we assumed that the share of unidentified cases attributable to food covered by this rule is the same as the share of all cases attributable to food covered by this rule. We used the ratio of the number of FDA-reported cases attributable to regulated RACs other than sprouts to all CDC foodborne cases as a proxy for the percentage of unidentified pathogen illnesses attributable to FDA. We make this assumption because outbreak data on unidentified pathogens, specifically their associated food commodity, is extremely sparse. This estimation presumes that the percentage of identified illnesses, across all pathogens, attributable to FDA products is the same as the percentage of unidentified pathogens attributable to FDA products. FDA cases is the sum of all illnesses in the FDA database. Total identified cases, however, is larger than the sum of observed illnesses from the five produce implicated pathogens. This is because we estimate the percentage out of all

[11] This methodology is laid out completely in Appendix A.

identified pathogens (31), that are implicated in any foodborne illnesses, produce related or not.

Using this calculation methodology, the total number of foodborne illnesses caused by microbial contamination of FDA-regulated produce RACs other than sprouts is estimated to be 2,314,715.

We note that using this methodology our estimate of the share of illnesses attributable to unidentified pathogens is about 91.4%, which is larger than the overall share estimated by Scallan, et al. They estimated that illnesses attributable to unidentified pathogens represent roughly 80% of all illnesses. Therefore, we also present an alternative estimate of the number of illnesses attributable to unidentified pathogens that is based on this 80% estimate. Using this alternative methodology we estimate that there are 797,112 illnesses attributable to unidentified pathogens.

Using this calculation methodology, the total number of foodborne illnesses caused by microbial contamination of FDA-regulated produce RACs other than sprouts is estimated to be 996,390. This is considerably smaller than the number of illnesses estimated under our other methodology. We request comment on both methodologies and their underlying assumptions.

Table 17 Estimated Number of Illnesses Attributable to Produce RACs other than sprouts

Agent	**FDA RAC (2003-2008)**	**Identified Cases (2003-2008)**	**Percentage Attributable to RACs**	**Estimated Annual Foodborne Illnesses**	**Estimated Annual Illnesses Attributable to RACs**
Cyclospora	891	919	96.95%	13,906	13,482
E. Coli O157:H7	124	2,452	5.06%	69,972	3,539
Hepatitis A	919	1,086	84.62%	1,665	1,409
Salmonella	2303	14,709	15.66%	1,072,450	167,914
Shigella sonnei	56	667	8.40%	154,053	12,934
Total Identified	4,293	79,347	5.41%		
Unidentified			5.41%	39,099,360	2,115,437

TOTAL	8,514				2,314,715

Tables 18 and 19 present baseline estimates of illnesses associated with microbial contamination of Fresh Cut Produce and Sprouts. In total, we estimate there are 753,958 illnesses associated with fresh cut produce and 82,109 illnesses associated with sprouts. Some Fresh Cut illnesses are associated with contamination at the processing level rather than the farm level. For example, there was a celery outbreak in 2010, which caused 10 illnesses and 5 deaths, due to contract Listeria monocytogenes. The contamination in this instance was likely caused by poor sanitation and maintenance at the fresh-cut facility, and thus such illnesses would not be considered preventable by this rule. .However, we are unable observe source of contamination thereby separating out the Fresh Cut illnesses caused by contamination at the processing level from those caused by contamination at the farm level, so we have included all of these illnesses in the benefits estimate of this rule. Consequently, we have overestimated the benefits of the rule to a certain extent. To avoid double-counting, the illnesses from Fresh Cut have been omitted from the accompanying Preventive Controls rule. We examine the effect of relaxing this assumption in our analysis of uncertainty section, below and seek comment on additional data that could refine these estimates

Table 18 Estimated Number of Illnesses Attributable to Fresh Cut

Agent	FDA Fresh Cut (2003-2008)	Identified Cases (2003-2008)	Percentage Attributable to Fresh Cut	Scallan, et al. Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to Fresh Cut
E. Coli O157:H7	599	3,283	18.25%	69,972	11,978
Salmonella	846	18,836	4.49%	1,072,450	48,168
Total Identified	1,445	79,347	1.82%		
Unidentified			1.82%	39,099,360	693,812
TOTAL	**2,816**				**753,958**

Table 19 Estimated Number of Illnesses Attributable to Sprouts					
Agent	**FDA Sprouts (2003-2008)**	**Identified Cases (2003-2008)**	**Percentage Attributable to Sprouts**	**Scallan, et al. Estimated Annual Foodborne Illnesses**	**Estimated Illnesses Attributable to Sprouts**
E. coli O157:H7	63	2,452	2.57%	13,143	338
Salmonella	101	14,709	0.69%	1,072,450	7,364
Total Identified	151	79,347	0.19%		
Unidentified			0.19%	39,099,360	74,407
Total	**302**				**82,109**

In total this represents 3,150,782 illnesses attributable to produce. However, this proposed rule would not cover the entire produce industry; rather, there are some exemptions based on farm size, distribution channel, and eating habits that may need to be taken into account. Specifically, farms exempt by size and distribution channel, regardless of commodity produced, likely are responsible for a portion of these illnesses. We estimate that farms exempt solely due to having less than $25,000 monetary value of food account for about 0.7 percent of the total value of produce and 'qualified' farms, exempt because of low monetary value of food sales and direct marketing, account for about 13.4 percent of produce sales. If the marginal risk of illnesses associated with a unit of output were distributed uniformly across farms within a given commodity,[12] then we could see a total reduction in potential illnesses of about 14.1 percent, or 2,703,144 million (3.15 million x [1-.141]). However, our analysis indicates that smaller farms are less likely to be already in compliance with many of the provisions of the rule. Thus, these farms may account for a somewhat larger fraction of the affected acreage and

[12] 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.

produce sales from farms not already in compliance. We seek comment on whether we have accurately captured the number of illnesses likely to be attributable to farms exempt from the rule.

To preserve the ratio of illnesses and their associated costs, we carry through the estimation of all illnesses attributable to produce and then remove 14% from the total dollar estimate, rather than removing those illnesses here.

b. Economic burden of illnesses attributable to Produce

We estimate cost of eliminating foodborne illnesses from produce by multiplying the annual number of illnesses per pathogen by the estimated cost 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. It is made up of direct medical costs, days ill, hospitalization and death rates, QALYs, and the value of a statistical life (VSL).[13] QALYs and VSLs are used so that we capture not only the direct costs of a foodborne illness but also the substantial intangibles that go along with an illness, such as lost productivity, cost of pain and suffering, etc. Table 20 presents the burden of illness attributable to microbial contamination of FDA-regulated produce RACs other than sprouts. Column two contains the total number of attributable FDA illnesses, previously calculated. This number is multiplied by the expected dollar loss per case, in column three, to give the annual cost of each pathogen in the US population, presented in column four. Summing over all pathogens, we estimate an average cost per foodborne illness of $584 and a potential annual cost savings of approximately $1.3 billion dollars if all illnesses attributable to FDA-regulated produce RACs other than sprouts were to be

[13] A detailed description of how each cost of illness is determined is presented in Appendix A.

eliminated. (More information about the cost per illness can be found in Appendix A.)

Table 20- Estimated Dollar Burden Attributable to FDA-produce RACs other than sprouts			
Agent	**Estimated Attributable Illnesses**	**Expected Dollar Loss per Case**	**Dollar Burden**
Cyclospora	13,482	$1,889	$25,468,090
E. Coli O157:H7	3,539	$7,547	$26,705,447
Hepatitis A	1,409	$39,195	$55,224,347
Salmonella	167,914	$4,622	$776,100,181
Shigella sonnei	12,934	$2,066	$26,721,613
Unidentified	2,115,437	$214	$452,703,445
TOTAL	**2,314,715**	**$589**	**$1,362,923,123**

Tables 21 and 22 present the estimated total burden of illnesses associated with microbial contamination of FDA-regulated Fresh Cut Produce and Sprouts, respectively. In total, Fresh Cut Produce accounts for approximately $462 million and Sprouts represent about $53 million in potential annual cost savings.

Table 21- Estimated Dollar Burden Attributable to FDA-Fresh Cut			
Agent	**Estimated Attributable Illnesses**	**Expected Dollar Loss per Case**	**Dollar Burden**
E. Coli O157:H7	11,978	$7,547	$90,397,966
Salmonella	48,168	$4,622	$222,632,496
Unidentified	693,812	$214	$148,475,768
TOTAL	**753,958**	**$612**	**$461,506,230**

Table 22- Estimated Dollar Burden Attributable to FDA-Sprouts			
Agent	**Estimated Attributable Illnesses**	**Expected Dollar Loss per Case**	**Dollar Burden**
E. coli O157:H7	338	$7,547	$2,548,525
Salmonella	7,364	$4,622	$34,036,526
Unidentified	74,407	$214	$15,923,182

Total	**82,109**	**$639**	**$52,508,233**

Taken together, we estimate that the total cost of the illnesses linked to all items of produce is $1.88 billion per year. However, to obtain the total burden of illness with foods that would be affected by the proposed provisions, we must subtract out facilities that are exempt from the regulation and qualified facilities.

This proposed rule would not cover the entire produce industry; rather, there are some exemptions based on farm size, distribution channel, and eating habits that may need to be taken into account. Specifically, farms exempt by size and distribution channel, regardless of commodity produced, could be responsible for a portion of these illnesses. We estimate that farms exempt solely due to having less than $25,000 monetary value of food account for about 0.7 percent of the total value of produce and ‘qualified’ farms, exempt because of low monetary value of food sales and direct marketing, account for about 13.4 percent of produce sales. If the marginal risk of illnesses associated with a unit of output were distributed uniformly across farms within a given commodity,[14] then we could see a total reduction in potential benefits of about 14.1 percent, or $265 million ($1.88 billion x .141). We do not consider there to be a potential drop in benefits due to the exclusion of produce commonly consumed cooked or produce headed for kill step processing, as these commodities have never been implicated in an outbreak. Thus, the maximum total potential benefits that could be achieved by totally eliminating foodborne illness linked to produce would range from$1.61 billion. As discussed below, these figures are not the expected benefits associated with the provisions in this proposed rule.

[14] 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.

We expect that the rule would eliminate only some portion of illnesses linked to produce and so would have lower real-world benefits.

c. Confounding Factors in the Estimation of the Burden of Foodborne Illness

It is important to note that the estimates of the cost burden attributed to produce on an annual basis may not provide a full accounting of all costs of foodborne illness for several reasons. First, our starting point, the FDA outbreak database, represents only illnesses where the cause of the food contamination could be directly linked to produce. This creates a smaller than possible weighting factor when estimating FDA-regulated foods' share of total foodborne illnesses from the CDC outbreak database. In some instances foodborne illnesses that have been attributed to problems at retail or in the household may have actually had a root cause at the farm level. For example, consumer mishandling of a product that led to the sufficient growth of a bacteria in a food to cause illness could have been ultimately caused by food contamination (and the bacteria's survival) during harvest.

Second, the FDA outbreak database is limited to cases where the FDA was involved in the outbreak investigation, and this is not true of the entire CDC outbreak database. In fact some outbreaks are only reported to the CDC database at the end of the year from different state health departments. In these cases, there is no way that FDA could be involved even if the contaminated ingredient were interstate produce. This creates a smaller than probable weighting factor for estimating the total FDA-regulated foods' share of illnesses from the CDC outbreak database, because we have full information on reported foodborne outbreaks but limited access to all outbreaks which may have been caused by FDA regulated products or processes. FDA is called in to help with foodborne outbreaks and trace backs at the request of the state and local health authorities. While all the smaller outbreaks may be reported to CDC, if FDA did not get involved with a particular outbreak we will not have detailed information on that particular outbreak in our internal database.

2. Produce Rule Model Potential of Risk Reduction

a. Overview

We examine the potential overall effectiveness of the proposed regulation on reducing human foodborne illnesses. To do this, we estimate the potential public health benefits of the proposed produce regulation provisions in three distinct ways: as a whole, by pathways of contamination, and by produce commodity. 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 (Qualitative Risk Assessment).

We estimate the potential change in the probability of fresh produce contamination as a function of the relative likelihood of contamination from each specific pathway and the potential efficacy of the proposed preventive controls in reducing the risk of fresh produce contamination within a specific pathway of contamination. This change in the probability of contamination is then applied to the current baseline of foodborne illnesses attributable to FDA-regulated produce. Based on current scientific literature, expert elicitation, census data, research, and outbreak investigations, we think that we can estimate potential range of measureable effectiveness of the proposed produce regulation on the current burden of illness as a whole. Additionally, these data are stratified to examine the effect amongst specific commodities, or contamination pathways.

b. Theoretical Model

The model of the probability of a contamination event (P_c) can be written as follows:

$$\Delta P_c = \sum_{1}^{i} \left(X_i * B_i \right)$$

s.t.: P_c, X_i, and B_i, are all bound between 0 and 1; $\sum_{1}^{i} \left(B_i \right) = 1$

where P_c is the probability of fresh produce contamination; X_i is the efficacy of the proposed preventive controls in reducing the risk of fresh produce contamination within a specific pathway of contamination; B_i is the likelihood of contamination from each specific pathway. Further detail on each step is provided below.

c. Estimation of the Model

i. Assigning likelihood of contamination to each specific pathway

To assign relative likelihood of contamination to each specific pathway (B_i), we examine outbreak data between 1971 and 2009. In total, we look at 72 produce outbreaks, with 8,843 associated illnesses. Similar to the Quantative Risk Assessment, using information from Harris et al. (Ref.38) for all outbreaks prior to 2000 and then adding additional individual outbreak investigation reports for outbreaks occurring between 2000 and 2009, we are able to assign a particular probable contamination pathway to each outbreak.[15]

Data is from Harris et al. (Ref.38) for all outbreaks prior to 2000 and from individual outbreak investigation reports for outbreaks occurring between 2000 and 2009. This is the same methodology over the entire time span, but peer-reviewed, published results are not available for the most recent outbreaks. We examine this data range, 1971-2009, because it is the most comprehensive indication of what has historically gone wrong on the farm, which contributed to an outbreak. The time span must be larger in scope for this portion of the analysis, because not every outbreak can be traced back to the farm level, and even then, a formal investigation is not always performed. Outbreaks where no potential cause of contamination was determined, investigations were not performed, or data was inconclusive were omitted from our sample. Given the changes in growing practices in the last forty years, it would be appropriate to look only at more recent outbreak data. However, because there is so little available data on outbreaks, we have opted to include older data in our analysis. We seek comment on how this may affect our results.

Likelihood of contamination is calculated by comparing the relative number of outbreaks attributed to each pathway over the time period for which data are available for each pathway. Additionally, when multiple pathways are identified, we perform different analyses to examine a range of assumptions. Specifically, we initially assume that all cited pathways have an equal probability of causing the contamination, this is the measure most closely associated with our mean estimates. Then, to account for the

[15] Source of contamination is determined by on farm investigations performed after an outbreak has occurred and was traced back to the originating farm. These retrospective investigations then observe the farm and record the likely source of contamination that lead to the outbreak. This information may or may not accurately record the problem that led to the outbreak, but it remains the best source of data linking outbreaks to contamination pathway.

uncertainty within this data, we perform the analysis multiple times assuming the source of contamination is due solely to one of the cited pathways. These estimates provide us with a full range for all contamination pathways. Of course, if only one pathway is identified for an outbreak, it will receive the same weight in all estimations. Table 23 presents the associated illnesses and mean relative weights used in the model.

TABLE 23. RELATIVE LIKELIHOOD OF CONTAMINATION BY CONTAMINATION PATHWAY

Contamination Pathway	Associated Outbreaks	Likelihood of Contamination (B_i)		
		5th percentile	Mean	95th percentile
Agricultural Water (growing/harvest)	12	11%	16.32%	22%
Agricultural Water (postharvest)	11	11%	14.37%	18%
Biological Soil Amendments	10	9%	13.81%	19%
Worker Health and Hygiene (growing/harvest)	12	13%	15.62%	18%
Worker Health and Hygiene (postharvest)	11	13%	15.20%	18%
Domesticated and Wild Animals	10	7%	14.09%	21%
Equipment, Tools, Building and Sanitation (growing/harvest)	3	1%	4.18%	7%
Equipment, Tools, Building and Sanitation (postharvest)	5	3%	6.42%	10%

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 (15 percent), Worker Health and Hygiene in growing and harvest activities (15 percent), and Domestic and Wild Animals (14 percent).[16] Equipment, Tools, Building, and Sanitation in growing and harvest activities represents the lowest contamination pathway, accounting for only about 4 percent overall.[17]

[16] We are unable to separate domestic and wild animal intrusion. We request comment on this data limitation.

[17] The number of outbreaks attributed to Equipment, Tools, Buildings, and Sanitation may be biased for a

ii. Efficacy of the proposed preventive controls within a specific pathway

Direct estimates of the quantitative efficacy were not available, so to assign an estimated quantitative figure for the efficacy of the proposed preventive controls within a specific pathway (X_i), we rely on numerous discussions with experts on the subject, conducted in a variety of settings.

Eastern Research Group (ERG) conducted two comprehensive literature searches on the mechanisms for *E. coli* contamination during the growing, harvest, packing, storage, transportation, and distribution of leafy greens and tomatoes in order to systematically evaluate known and suspected contamination pathways and control options (Ref.39;Ref.40). The published literature was then supplemented by interviews with academic researchers and agricultural extension advisors to identify other potential contamination pathways and control options not found in the literature.[18] Taken together, the findings constitute one potential way to assess the efficacy of production practices on reducing the likelihood of contamination during each stage in the production of leafy greens and tomatoes.

Most preventive measures and production practices reviewed in the literature and supplemented by extension and academic project advisors have, to some extent, been incorporated in this proposed rule. Information on the effectiveness of preventive measures was scarce. Consequently, interviews with produce industry experts was used

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, things like sanitation or tools may be incorrectly attributed to something like worker health and hygiene. It could be that a worker improperly washes their hands or tools because reasonable accommodations were not provided; however, when this outbreaks is recorded, only worker contact is cited as a contamination pathway. With the current data available, these are only speculations, and we assign illnesses based only on the observable data.

[18] Both ERG 2009 studies (Ref.39;Ref.40) have a comprehensive list of the industry experts polled and their qualifications, as such.

to estimate the likely effectiveness of preventive measures applied to production practices during the growing, harvest, packing, storing, transportation, and distribution stages (Ref.39;Ref.40).

The agricultural industry experts and academics were asked to estimate effectiveness of preventive measures using a continuous scale, from 0 to 100 percent, to indicate the estimated reduction in contamination relative to a given reference production practice.[19] For many production practices there was were several control option scenarios that the experts ranked in terms of the relative likelihood of contamination posed under each option. For example, in assessing the relative likelihood of contamination associated with various options for irrigation water source used in leafy green production, experts indicated the relative contamination risk associated with using "treated flowing surface water", "untreated flowing surface water", "treated standing surface water", "untreated standing surface water", "deep well water", and "potable water". For each vector of contamination, we attempted to select those production activities (or conditions) and their control option scenarios that tracked somewhat closely to the preventive measures and standards required in the proposed regulation.[20]

Many of the questions asked in these expert interviews do not directly mirror the requirements of the proposed rule because these experts were asked to only respond with estimates concerning the leafy green or tomato industry, and the experts were polled on the state of the industry more than three years ago. Instead we interpret responses from the experts as proxies for the effects of the proposed rule on the industry as a whole. We

[19] The baseline in these expert interviews, as in the following elicitation, was to think of current industry practices and estimate a reduction in contamination that the implementation of certain controls would provide above current levels.
[20] For more explanation of exactly how expert elicitation responses were used in the estimation, see FDA (2012) Technical Appendix (Ref.41).

supplement these sources of information with a set of discussions with in-house experts. FDA experts were asked, based on the current state of the produce industry, to estimate how much of the likelihood of contamination associated with each pathway that the proposed rule might be able to mitigate (on a scale of 0 to 100 percent).[21] These individual responses were then compiled into an overall estimate of efficacy of the proposed preventive controls. The results derived from each set of experts are reassuringly corroborative. These estimates should be interpreted as averages, across commodities. We expect that the efficacy of the controls, given some level of probability of contamination, would be relatively stable across commodities. Ideally though, the relative likelihoods of contamination by pathway would be estimated as commodity (or even commodity group) specific (though they would still add to 100 percent). However, performing the commodity specific assessment is beyond the capacity of the data. We specifically note this as weakness of the current estimate and request comment.

In terms of the overall predicted percentage reduction in contamination events, with 90 percent confidence, the FDA experts estimated a 50-77 percent reduction, the leafy greens expert estimated a 54-76 percent reduction, and the tomato experts estimated a 50-71 percent reduction. Table 24 presents the mean estimates, considering all three sources, of the efficacy of the proposed preventive controls within a specific pathway.

TABLE 24. EFFICACY OF PROPOSED PREVENTIVE CONTROLS FOR ALL COVERED ITEMS

[21] For a complete write-up of the internal expert elicitation, see FDA (2012) Memo to file, "Expert elicitation exercise to assist with the characterization of likely reduction of contamination expected by implementation of the proposed Produce Rule" dated April 25, 2012.

Contamination Pathway	Efficacy of Proposed Controls (X)		
	5th percentile	mean	95th percentile
Agricultural Water (growing/harvest)	44%	54.49%	61%
Agricultural Water (postharvest)	66%	72.55%	79%
Biological Soil Amendments	53%	65.62%	74%
Worker Health and Hygiene (growing/harvest)	44%	66.04%	75%
Worker Health and Hygiene (postharvest)	62%	73.50%	81%
Domesticated and Wild Animals	48%	58.04%	66%
Equipment, Tools, Building and Sanitation (growing/harvest)	46%	56.71%	66%
Equipment, Tools, Building and Sanitation (postharvest)	56%	67.97%	76%

Here we see that the proposed 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 Agricultural Water used in postharvest activities (ph), estimated to have around 73 percent effectiveness in reducing the associated risks of contamination. Equipment Agricultural Water used for growing and harvest (g/h) activities is estimated to have the lowest effectiveness, at about 54 percent.

iii. Estimation of the Reduction in the Risk of Contamination

Multiplying the likelihood of contamination by the estimated efficacy of the proposed preventive controls and summing over all pathways yields the total reduction in the risk of contamination from the proposed rule. Preventive measures that are relatively effective and that are also applied to the highest likelihoods of contamination have the greatest probability of reducing the risk of contamination. Preventive measures that are relatively ineffective and also applied to lower likelihood production practices would be least likely to reduce the risk of contamination. Table 25 presents the calculation of the percentage reduction in contamination, by pathway and for the rule as a whole.

TABLE 25. PERCENTAGE REDUCTION IN THE RISK OF CONTAMINATION

Contamination Pathway	**Likelihood of Contamination**	**Efficacy of Proposed Controls**	**% Reduction in the Risk of Contamination**		
			5th percentile	**mean**	**95th percentile**
Agricultural Water (g/h)	16.32%	54.49%	6%	8.89%	12%
Agricultural Water (ph)	14.37%	72.55%	8%	10.42%	13%
Biological Soil Amendments	13.81%	65.62%	6%	9.06%	13%
Worker Health and Hygiene (g/h)	15.62%	66.04%	7%	10.32%	13%
Worker Health and Hygiene (ph)	15.20%	73.50%	9%	11.17%	14%
Domesticated and Wild Animals	14.09%	58.04%	4%	8.18%	13%
Equipment, Tools, Building and Sanitation (g/h)	4.18%	56.71%	1%	2.37%	4%
Equipment, Tools, Building and Sanitation (ph)	6.42%	67.97%	2%	4.36%	7%
Total			42%	64.77%	88%

Worker health and hygiene in postharvest (g/h) activities is estimated to have the most impact on overall contamination, reducing it by an estimated 11 percent. 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. In total, we estimate that this rule will reduce total on farm contamination by about 65 percent.

d. Aggregate Benefits Estimates

To translate this percentage reduction in on farm contamination to human health outcomes, we utilize a simplifying assumption. We assume that a reduced probability of contamination will result in a corresponding reduction in the expected number of illnesses. If this assumption is correct, it means that a 65 percent reduction in contamination will similarly reduce illnesses, attributable to on farm contamination, by 65 percent.

While this may be true on average, we know different pathogens have different dose response curves and, similarly, different outbreaks have differing lengths of exposure. So, if this assumption holds on average, it is unlikely to be true in very specific instances. Our relatively large span of data should mitigate some of this concern; however, we relax this assumption in the sensitivity analysis, to see what effect a lower or higher ratio of contamination to illnesses has on our estimates. Specifically, we assume a 40% variation in the relationship; varying 20% above or below the 1 to 1 relationship we assume here.

We then apply this percentage reduction to the estimated number of illnesses annually attributable to produce, to get the total number of annual illnesses this proposed rule may prevent. This number is previously calculated in the regulatory impact analysis (RIA) and is derived by examining produce specific outbreak data. The associated outbreak illnesses are then scaled up to account for underreporting, under identification, unidentified pathogen illnesses, and sporadic foodborne illnesses. Additionally, illnesses are scaled down based on total value of production (TVP) percentages exempt from the rulemaking. This is accomplished by estimating the percent of all produce exempt from size requirements of the proposed rule. In all, about 14.1 percent of all outbreak related produce is exempt from the proposed rule. Therefore, only 85.9 percent of all illnesses associated with produce outbreaks are considered as preventable in this model.

These prevented illnesses are then multiplied by an average cost of illness, specific to produce illnesses,[22] to estimate the overall benefits of the proposed rule through illness prevention. Table 26 shows the estimated reduction in illnesses that may

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[22] Pathogen specific costs are estimated and used in the RIA; however, since this data is not pathogen specific, it is necessary to use the illness weighted, average cost of a produce illness.

be attributable to the proposed regulation, shown both in illnesses averted and total dollar costs attributable.

TABLE 26. AGGREGATE BENEFITS OF THE PRODUCE REGULATION					
	% Reduction in the Risk of Illness	**Illnesses Attributable to Produce Covered by this Rule**	**Illnesses Prevented**	**Cost Per Illness**	**Total Benefits (in millions)**
All Produce	64.77%	2,703,144	1,750,913	$592	$1,036.40

* From the estimation of total costs in the regulatory impact analysis.

Based on the foregoing series of assumptions, we estimate that this rule may prevent, in total, about 1.7 million illnesses, with an associated benefit of approximately $1.0 billion.

Furthermore, the effectiveness of the rule is likely to increase over time as farms learn by doing. Also, FDA intends to perform retrospective reviews to identify changes that would make the rules more effective or less costly. We request comment on the total costs of foodborne illness from produce that would be covered by the provisions of this proposed rule.

e. Contamination Pathway Specific Analysis

We can also use these assumptions to examine potential benefits of this proposed rule by contamination pathway. These calculations are presented in Table 27.

TABLE 27. ESTIMATED (MEAN) POTENTIAL BENEFITS, BY CONTAMINATION PATHWAY					
Input	**% Reduction in the Risk of Illness**	**Illnesses Attributable to Produce**	**Illnesses Prevented**	**Cost Per Illness**	**Benefits (in millions)***
Agricultural Water (g/h)	8.89%	2,703,144	240,347	$592	$142.27
Agricultural Water (ph)	10.42%	2,703,144	281,736	$592	$166.77
Biological Soil Amendments	9.06%	2,703,144	244,917	$592	$144.97
Worker Health and Hygiene (g/h)	10.32%	2,703,144	278,848	$592	$165.06
Worker Health and Hygiene (ph)	11.17%	2,703,144	302,031	$592	$178.78
Domesticated and Wild Animals	8.18%	2,703,144	221,009	$592	$130.82
Equipment, Tools, Building and Sanitation (g/h)	2.37%	2,703,144	64,145	$592	$37.97
Equipment, Tools, Building and Sanitation (ph)	4.36%	2,703,144	117,880	$592	$69.78

f. Commodity Specific Analysis

Because the outbreak data associated with the number of illnesses attributable to produce is separable by commodity, we are also able to estimate this model on a commodity specific basis (for the specific subsets of commodities that regularly show up in outbreak data). This is an important limitation to the current study. Because FDA attribution data is based on outbreaks from 2003-2008, we are only able to portion data based on outbreaks that occur during this time period. It is likely that if we extended or collapsed that time period, we would see slightly different results. Data is limited to this time span for two reasons: 2008 is the latest complete year of CDC outbreak data, which is needed to calculate attributable illnesses; and we only go back to 2003 to capture the most current state of the produce industry.

The model is estimated just as before, but we are able to apply the percentage reduction in contamination to illnesses associated with specific produce commodities.[23]

[23] As before, we account for underreporting, under identification, unidentified pathogen illnesses, and sporadic foodborne illnesses in all instances. Illnesses are additionally scaled down based on TVP

Commodities are split into six categories: Herbs, Leafy Greens, Melons, Sprouts, Tomatoes, and Other.[24] The first five categories are separable because they all appear multiple times in the data set. 'Other' is comprised of all outbreaks, whose associated commodity only appears once in the data set; these outbreaks essentially show that a large portion of outbreaks are seemingly random.[25] We assume that the percentage reduction in contamination will be equal across different types of commodities. We seek comment on this assumption. Table 28 shows the reduction in illnesses, when we are looking at commodity specific illnesses. For ease of interpretation, only total illness reductions are considered (rather than contamination pathway specific reductions) at the commodity level.

TABLE 28. ESTIMATED (MEAN) REDUCTION IN PRODUCE ILLNESSES, BY COMMODITY

Commodity	% Reduction in Contamination*	Illnesses Attributable	Illnesses Prevented
Herbs	64.77%	132,998	86,147
Leafy Greens	64.77%	267,485	173,259
Melons	64.77%	337,967	218,912
Sprouts	64.77%	87,190	56,476
Tomatoes	64.77%	926,450	600,091
Other	64.77%	951,054	616,029

* These estimates are averages across all produce commodities. We note this weakness of the current estimate and request comment

Table 28 indicates that the 'Other' category accounts for the largest total number of preventable illnesses, at 616,029. This is largely based on a single outbreak in 2008 involving hot peppers. This outbreak caused 1,535 illnesses—more than one-third of the total for the 2003-2008 period. This single outbreak leads us to estimate that 'Other'

percentages exempt from the rulemaking. This is accomplished by estimating the percent of each individual produce commodity exempt by size requirements of the proposed rule.

[24] We believe that these groupings capture commodities with similar features and risks in the production process, such as romaine lettuce, iceberg lettuce, and spinach, all combined into leafy greens; while still allowing for ease of interpretation in the results.

[25] For our time period this includes green onions, peas, almonds, squash, peppers, and raspberries. If the time period examined was increased or decreased, we would expect to see a different set of commodity groups. For example, mangoes and grapes were implicated in 1990's.

accounts for the largest total number of illnesses. Expanding the time period of our analysis would reduce the impact of this outlier on our analysis and reduce our estimate of the share of illnesses attributable to ‘Other.’ We seek comment on this.

Tomatoes are estimated to account for the next highest number of annual illnesses--600,091annual illnesses. Sprouts are estimated to have the lowest contribution to overall prevented illnesses, at 56,476.

We also estimate the dollar burden associated with the average illness generated by each specific commodity. This is accomplished by taking a weighted average of the pathogen specific cost of all illnesses associated with each commodity. A commodity will have a higher average cost of illness if it has more severe illness outcomes associated with its individual outbreaks. Table 29 presents the total benefits of the proposed rule separable by produce commodity.

TABLE 29. ESTIMATED (MEAN) BENEFITS, BY COMMODITY

Commodity	Illnesses Prevented	Average Cost Per Illness	Benefits (in millions)*
Herbs	86,147	$492	$42.35
Leafy Greens	173,259	$762	$131.95
Melons	218,912	$498	$109.00
Sprouts	56,476	$294	$16.59
Tomatoes	600,091	$588	$353.02
Other	616,029	$615	$379.15

* Average cost of illness does not exactly match the estimates from Table 4, but they are comparable. This is because we are now using a weighed cost of illness by commodity and due to some rounding errors in this more complicated procedure. Also, all values in this table and all previous calculations are derived mean values from a set of distributions, which makes convergence more difficult.

From Table 29, we see that ‘Other’ commodities contribute the most overall to the benefits of the proposed rule, accounting for nearly $379 million in annual benefits from prevented illnesses. Tomatoes are estimated to be the second highest contributor to the benefits of this proposed rule, accounting for about $353 million, annually. Sprouts are estimated to be the lowest contributor to overall benefits, due to their relatively low number of illnesses and lower average cost per illness.

g. Summary of Assumptions for the Benefits Analysis

The assumptions in the benefits analysis have been discussed in detail throughout the analysis. This section collects and summarizes these assumptions and their likely effect on the estimates.

A number of assumptions about the data sources and how they fit together must be utilized in order for us to estimate the potential benefits attributable to this proposed rule. Although we have tried to lay these out in the text whenever they occur, we also collect all of the major assumptions here so that we can discuss their likely effects on our benefits estimation. Additionally, we relax many of these assumptions in the following section to estimate the effect under different circumstances.

- Extrapolate outbreak identified foodborne illnesses up to outbreaks and sporadic foodborne illness.

To determine the percent of outbreak and sporadic illness attributable to produce multiply the percentage of illnesses attributable to FDA regulated produce by the total annual incidence of each specific foodborne pathogen. The annual incidence of foodborne illness in the US is taken directly from the estimates set forth in Scallan et al. (Ref.37). This step accounts for numerous downward biases such as under-reporting and under-identification of a foodborne illness. They reach this estimate by using both active and passive illness surveillance data to estimate the annual occurrence of each of the 31 major foodborne pathogens. Laboratory and hospital confirmed and documented cases of each illness are compared with survey data of the national incidence of each pathogen. From this information, they are able to extrapolate the cases confirmed to a national total that accounts for under reporting and under diagnosis for all illnesses. In total, Scallan et al. estimate that 9.4 million episodes of foodborne illness occur in the US each year due to these 31 pathogens. By multiplying out percentage attributable by the totals from Scallan we should be accounting for numerous undercounting biases present in solely outbreak data.

Additionally, calculating total illnesses based solely on outbreak data may introduce its own biases. There are numerous pathogens that are not likely to be picked up by an outbreak investigation. This is because they are either rarely linked back to a specific food item or treatment of the illnesses is not sought, and thus a lab confirmed sample is never obtained, because the illness is so mild. One example of this would be foodborne illnesses attributable to norovirus. This is a relatively mild disease associated with food, but often is considered to be mild enough that no treatment is sought. Therefore, potential outbreaks of norovirus are likely to go undocumented. If this is the case, our numbers will not capture any illnesses, outbreak or sporadic, due to norovirus or other similarly under-represented pathogens, that are, in fact, attributable to FDA regulated produce. Scallan et al. are able to adjust their numbers based on survey data which accounts for total annual incidence. However, this will not mitigate the downward bias created by our starting point of only outbreak data, as national survey data does not collect associated food vehicle information, which outbreak investigations do.

- Assume the percentage of all identified illnesses due to produce is equal to the percentage of unidentified foodborne illnesses due to produce

We are able to calculate a percentage of illnesses due to all pathogens, but we are unable to observe any data on 'unidentified pathogen' illnesses. In this case, there is no data linking these illnesses to a specific food source or pathogen. This is because these illnesses are due to other, emerging pathogens other than the 31 well known and regularly tested for pathogens. Scallan further estimates that as many as 80% of foodborne illnesses are due to unidentified pathogens. This is estimated by examining nationally representative survey data on foodborne illnesses in the US. From this survey, the occurrence total foodborne illnesses episodes are estimated to be about 47.78 million, annually. Having previously estimated that 9.4 million of these are due to the 31 major pathogens, the authors are able to conclude that approximately 38.39 million foodborne illnesses each year are due to 'unidentified' pathogens. That is, pathogens that have not yet been fully identified by scientists, and are still very difficult to observe, test for, or link to any specific food or outbreak. We assume that the proportion of identified illnesses holds over the 'unidentified' illnesses. Lacking further information, we apply this percentage to the total estimated number of 'unidentified' pathogen illness to determine the total number of illnesses attributable to FDA regulated products. It is equally likely that this assumption may over or underestimate the actual number of 'unidentified' illnesses due to FDA regulated produce. In the absence of any data, we are unable to tell. We estimate a range of 50 percent (25 percent in either direction) in all estimations in the sensitivity analysis, to present a full range of 'unidentified' illness estimates.

- Estimation of contamination pathway weights

To assign relative likelihood of contamination to each specific pathway, we examine outbreak data between 1971 and 2009. Data is from Harris et al. (Ref.38) for all outbreaks prior to 2000 and from individual outbreak investigation reports for outbreaks occurring between 2000 and 2009. This is the same methodology over the entire time span, but peer-reviewed, published results are not available for the most recent outbreaks. We examine this data range, 1971-2009, because it is the most comprehensive indication of what has historically gone wrong on the farm, which contributed to an outbreak. The time span must be larger in scope for this portion of the analysis, because not every outbreak can be traced back to the farm level, and even then, a formal investigation is not always performed. Outbreaks where no potential cause of contamination was determined, investigations were not performed, or data was inconclusive were omitted from our sample. Source of contamination is determined by on farm investigations performed after an outbreak has occurred and was traced back to the originating farm. These retrospective investigations then observe the farm and record the likely source of contamination that lead to the outbreak. This information may or may not accurately record the problem that led to the outbreak, but it remains the best source of data linking outbreaks to contamination pathway.

There is some concern that the earlier outbreaks as far back as 1971 may not be accurately representing contemporary problems in the produce industry. We are not overly concerned with this, because changing the time span used will only dramatically change the relative weights of each contamination pathway but will not largely affect overall estimate of efficacy, since this is primarily estimated by the expert elicitations on efficacy. However, we perform an alternative run of the model, using only data from 1990 to 2009. The results are detailed in the sensitivity analysis.

- Estimation of proposed rule efficacy

To estimate the efficacy of the proposed preventive controls within a specific pathway, we rely on numerous discussions with experts on the subject, conducted in a variety of settings. Initially, interviews with produce industry experts was used to estimate the likely effectiveness of preventive measures applied to production practices during the growing, harvest, packing, storing, transportation, and distribution stages Many of the questions asked in these expert interviews do not directly mirror the requirements of the proposed rule because these experts were asked to only respond with estimates concerning the leafy green or tomato industry, and the experts were polled on the state of the industry more than three years ago. So, we supplement these sources of information with a set of discussions with in-house experts. FDA experts were asked, based on the current state of the produce industry, to estimate how much of the likelihood of contamination associated with each pathway that the proposed rule might be able to mitigate. The results from these three elicitations are combined to represent the industry on average, as a whole. Because the results are reported in percentage efficacy terms, and not in absolute efficacy terms, it is less of a problem to make this assumption. However, it is possible, even likely that what is effective on lettuce or tomato farm may be more or less effective, even in percentage terms, on a farm growing a different commodity. That being said, the results derived from each set of experts are reassuringly corroborative.

There is also uncertainty introduced by combining the elicitation results with data generated from outbreak investigations. We realize that expert elicitation is not preferred to hard data on outbreaks or illnesses, but in the absence of such data on efficacy we are forced to rely on expert opinions. We acknowledge this as a limitation of the study and request comment on potential sources data.

- Assume a percent reduction in on-farm contamination is comparable to a reduction in foodborne illness

We assume that a reduced probability of contamination will result in a corresponding reduction in the expected number of illnesses. Unless there is a systematic bias, within whatever commodity group we're examining (total, or sub categories), that causes the rule to be more or less effective in percentage reduction of contamination on farms whose contamination events are more or less likely to cause an outbreak, the assumption holds. We have no reason to believe this systematic bias exists. If this assumption does not hold, the ratio of percent reduction in contamination events to percent reduction in illnesses may be higher or lower. We run the model with alternate assumption in th sensitivity analysis. Specifically, we assume a 40% variation in the relationship; varying 20% above or below the 1 to 1 relationship we assume here.

Further we run the model in the sensitivity scaling down the percentage reduction in illness relative to the percent reduction in contamination from pathways covered by the rule, to account for the possibility there may be a set of outbreaks that could happen because of things we do not yet know how to control, or are not addressed by the rule.

h. Sensitivity Analysis

Previously presented results are mean values derived from multiple data ranges and distributions. In order to more fully characterize the expected benefits of this proposed rule and highlight the variability built into this estimation, we present ranges for estimates. Our primary outcomes of interest are presented below in Table 30. For simplicity of interpretation, we only examine the total outcomes, but all estimates previously presented were derived from multiple distributions.

The sensitivity analysis presented captures the structural uncertainty associated with the model and its resulting outputs. All estimates are based on the data available. If, however, the data itself is biased in any way, we are unable to capture that parameter uncertainty with this, or any, sensitivity analysis. For example, if the data used in this analysis does not capture the current state of produce related illnesses or is subject to measurement error, we will not be able to provide an accurate measure of this uncertainty. Similarly, if there are problems with the way this data was collected or reported, we will be unable to accurately quantity this uncertainty.

Table 30 presents the assumptions described in the analysis.

TABLE 30. SENSITIVITY ANALYSIS OF ESTIMATED METHODOLOGY	
	mean
% Reduction in the Risk of Illness	
All Produce	64.77%
Pathway	
Agricultural Water (g/h)	8.89%
Agricultural Water (ph)	10.42%
Biological Soil Amendments	9.06%
Worker Health and Hygiene (g/h)	10.32%
Worker Health and Hygiene (ph)	11.17%
Domesticated and Wild Animals	8.18%
Equipment, Tools, Building and Sanitation (g/h)	2.37%
Equipment, Tools, Building and Sanitation (ph)	4.36%
Illnesses Prevented*	
All Produce	1,750,913
Pathway	
Agricultural Water (g/h)	240,347
Agricultural Water (ph)	281,736
Biological Soil Amendments	244,917
Worker Health and Hygiene (g/h)	278,848
Worker Health and Hygiene (ph)	302,031
Domesticated and Wild Animals	221,009
Equipment, Tools, Building and Sanitation (g/h)	64,145
Equipment, Tools, Building and Sanitation (ph)	117,880
Commodity	
Herbs	86,147
Leafy Greens	173,259
Melons	218,912
Sprouts	56,476
Tomatoes	600,091
Other	616,029
Benefits (in millions)**	
All Produce	$1,036
Pathway	
Agricultural Water (g/h)	$142
Agricultural Water (ph)	$167
Biological Soil Amendments	$145
Worker Health and Hygiene (g/h)	$165
Worker Health and Hygiene (ph)	$179
Domesticated and Wild Animals	$131
Equipment, Tools, Building and Sanitation (g/h)	$38
Equipment, Tools, Building and Sanitation (ph)	$70

Commodity	
Herbs	$42
Leafy Greens	$132
Melons	$109
Sprouts	$17
Tomatoes	$353
Other	$379

* Uncertainty in the number of illnesses prevented stems primarily from the range of % reduction due to the rule, a 50% margin of error (25% in either direction) on the estimate of unidentified illnesses attributable to FDA regulated produce,
** Uncertainty in the dollar benefits estimate stems from the variability in the cost per illness, generated from different values of a statistical life, different number of days ill, different EQ-5D score (QALD loss), and different percentage of illness by severity.

From Table 30, we see that total illnesses prevented by the proposed rule are estimated with a mean estimate of 1.8 million illnesses prevented, annually.

In the previous methodology, we assume that an outbreak due to a specific contamination pathway is equivalent in severity to an outbreak caused by any other pathway. However, looking over the outbreaks associated with each pathway, there is some indication that certain pathways may have more illnesses and deaths associated with their particular outbreaks than others. For this reason, we present results assuming that severity of outbreak may be linked to contamination pathway. To estimate this, we utilize number of illnesses associated with each contamination pathway, rather than number of outbreaks, to determine the likelihood of contamination for each individual pathway. This method presumes that all outbreaks are not equal, and that those which result in more illnesses (and likely deaths, although that is not captured explicitly in our data) should be more heavily weighted. Table 31 presents the estimates for the illness weighted likelihood of contamination methodology.

TABLE 31. SENSITIVITY ANALYSIS OF SEVERITY WEIGHTED PATHWAYS	
	mean
% Reduction in the Risk of Illness	
All Produce	63.76%
Pathway	
Agricultural Water (g/h)	17.24%
Agricultural Water (ph)	5.20%
Biological Soil Amendments	4.81%
Worker Health and Hygiene (g/h)	13.78%
Worker Health and Hygiene (ph)	16.12%
Domesticated and Wild Animals	4.54%
Equipment, Tools, Building and Sanitation (g/h)	0.64%
Equipment, Tools, Building and Sanitation (ph)	1.42%
Illnesses Prevented	
All Produce	1,723,639
Pathway	
Agricultural Water (g/h)	466,138
Agricultural Water (ph)	140,537
Biological Soil Amendments	129,989
Worker Health and Hygiene (g/h)	372,541
Worker Health and Hygiene (ph)	435,831
Domesticated and Wild Animals	122,807
Equipment, Tools, Building and Sanitation (g/h)	17,411
Equipment, Tools, Building and Sanitation (ph)	38,384
Commodity	
Herbs	84,805
Leafy Greens	170,560
Melons	215,502
Sprouts	55,596
Tomatoes	590,743
Other	606,433
Benefits (in millions)*	
All Produce	$1,020
Pathway	
Agricultural Water (g/h)	$276
Agricultural Water (ph)	$83
Biological Soil Amendments	$77
Worker Health and Hygiene (g/h)	$221
Worker Health and Hygiene (ph)	$258
Domesticated and Wild Animals	$73
Equipment, Tools, Building and Sanitation (g/h)	$10
Equipment, Tools, Building and Sanitation (ph)	$23
Commodity	
Herbs	$42
Leafy Greens	$130
Melons	$107

Sprouts	$16
Tomatoes	$348
Other	$373

* Uncertainty in the number of illnesses prevented stems primarily from the range of % reduction due to the rule, a 50% margin of error (25% in either direction) on the estimate of unidentified illnesses attributable to FDA regulated produce,
** Uncertainty in the dollar benefits estimate stems from the variability in the cost per illness, generated from different values of a statistical life, different number of days ill, different EQ-5D score (QALD loss), and different percentage of illness by severity.

From Table 31, we see that plausible estimates of the overall percentage reduction in contamination events are slightly lower. Total illnesses prevented by the proposed rule, too, are estimated lower with a mean estimate of 1.7 million illnesses prevented, annually. Although the overall reduction has not changed drastically, the between contamination pathway weights have been altered substantially. Agricultural water for growing and harvest activities is now estimated to be the most important contamination pathway, accounting for about 17% of the total percent reduction in the risk of illness. Equipment, tools, buildings, and sanitation for growing and harvest activities is now estimated to be the lowest contributor, at less than one percent.

Next, we present results assuming that we are unable to account for all factors related to a produce outbreak. To estimate this, we assume that there is some portion of outbreaks, 10% for this exercise, which we are unable to affect with this rule. We have no data to estimate the actual percentage that is likely unaffected by this proposed rule, because all outbreaks that have been linked to a source of contamination are covered by one of the provisions. Therefore, we request comment on this assumption and the associated 10% estimate. Table 32 presents the estimates where some outbreaks are likely to be unaffected by the proposed rule.

TABLE 32. SENSITIVITY ANALYSIS OF UNAFFECTED OUTBREAKS	
	mean
% Reduction in the Risk of Illness	
All Produce	58.30%
Pathway	
Agricultural Water (g/h)	8.00%
Agricultural Water (ph)	9.38%
Biological Soil Amendments	8.15%
Worker Health and Hygiene (g/h)	9.28%
Worker Health and Hygiene (ph)	10.06%
Domesticated and Wild Animals	7.36%
Equipment, Tools, Building and Sanitation (g/h)	2.14%
Equipment, Tools, Building and Sanitation (ph)	3.92%
Illnesses Prevented	
All Produce	1,575,822
Pathway	
Agricultural Water (g/h)	216,313
Agricultural Water (ph)	253,562
Biological Soil Amendments	220,425
Worker Health and Hygiene (g/h)	250,964
Worker Health and Hygiene (ph)	271,828
Domesticated and Wild Animals	198,908
Equipment, Tools, Building and Sanitation (g/h)	57,730
Equipment, Tools, Building and Sanitation (ph)	106,092
Commodity	
Herbs	77,532
Leafy Greens	155,933
Melons	197,021
Sprouts	50,828
Tomatoes	540,082
Other	554,426
Benefits (in millions)*	
All Produce	$933
Pathway	
Agricultural Water (g/h)	$128
Agricultural Water (ph)	$150
Biological Soil Amendments	$130
Worker Health and Hygiene (g/h)	$149
Worker Health and Hygiene (ph)	$161
Domesticated and Wild Animals	$118
Equipment, Tools, Building and Sanitation (g/h)	$34
Equipment, Tools, Building and Sanitation (ph)	$63
Commodity	
Herbs	$38
Leafy Greens	$119
Melons	$98

Sprouts	$15
Tomatoes	$318
Other	$341

* Uncertainty in the number of illnesses prevented stems primarily from the range of % reduction due to the rule, a 50% margin of error (25% in either direction) on the estimate of unidentified illnesses attributable to FDA regulated produce,
** Uncertainty in the dollar benefits estimate stems from the variability in the cost per illness, generated from different values of a statistical life, different number of days ill, different EQ-5D score (QALD loss), and different percentage of illness by severity.

From Table 32, we see that plausible estimates of the overall percentage reduction in contamination events are even lower. Total illnesses prevented by the proposed rule, too, are estimated lower with a mean estimate of 1.6 million illnesses prevented, annually. Similarly, the total dollar benefits from the proposed rule is with a mean estimated benefit of $933 million, annually. In this scenario, the overall estimate is lowered, but the within commodity and pathway ratios remain unaffected.

Next, we present results using only contemporary data to calculate the initial weights for each contamination pathway. In the analysis we use information going back as far as possible because of the limited amount of data on this topic. We believe the time span must be larger in scope for this portion of the analysis, because not every outbreak can be traced back to the farm level, and even then, a formal investigation is not always performed. Outbreaks where no potential cause of contamination was determined, investigations were not performed, or data was inconclusive were omitted from our sample. This leads to a very small number of outbreaks which inform the relative importance of potential contamination pathways. However, there is some concern that the earlier outbreaks may not be accurately representing contemporary problems in the produce industry. Therefore, we omit any outbreaks which occurred before 1990 in our calculation of the pathway weights. Table 33 presents the estimates for this subset of the data.

TABLE 33. SENSITIVITY ANALYSIS OF EARLIER DATA FOR PATHWAY WEIGHTS	
	Mean
% Reduction in the Risk of Illness	
All Produce	63.04%
Pathway	
Agricultural Water (g/h)	9.94%
Agricultural Water (ph)	3.58%
Biological Soil Amendments	3.70%
Worker Health and Hygiene (g/h)	10.66%
Worker Health and Hygiene (ph)	11.60%
Domesticated and Wild Animals	8.07%
Equipment, Tools, Building and Sanitation (g/h)	8.79%
Equipment, Tools, Building and Sanitation (ph)	6.70%
Illnesses Prevented	
All Produce	1,704,046
Pathway	
Agricultural Water (g/h)	268,821
Agricultural Water (ph)	96,679
Biological Soil Amendments	99,932
Worker Health and Hygiene (g/h)	288,093
Worker Health and Hygiene (ph)	313,636
Domesticated and Wild Animals	218,216
Equipment, Tools, Building and Sanitation (g/h)	237,517
Equipment, Tools, Building and Sanitation (ph)	181,151
Commodity	
Herbs	83,841
Leafy Greens	168,621
Melons	213,052
Sprouts	54,964
Tomatoes	584,028
Other	599,539
Benefits (in millions)*	
All Produce	$1,009
Pathway	
Agricultural Water (g/h)	$159
Agricultural Water (ph)	$57
Biological Soil Amendments	$59
Worker Health and Hygiene (g/h)	$171
Worker Health and Hygiene (ph)	$186
Domesticated and Wild Animals	$129
Equipment, Tools, Building and Sanitation (g/h)	$141
Equipment, Tools, Building and Sanitation (ph)	$107
Commodity	
Herbs	$41
Leafy Greens	$128
Melons	$106
Sprouts	$16
Tomatoes	$344
Other	$369

* Uncertainty in the number of illnesses prevented stems primarily from the range of % reduction due to the rule, a 50% margin of error (25% in either direction) on the estimate of unidentified illnesses attributable to FDA regulated produce,
** Uncertainty in the dollar benefits estimate stems from the variability in the cost per illness, generated from different values of a statistical life, different number of days ill, different EQ-5D score (QALD loss), and different percentage of illness by severity.

From Table 33, we see that total illnesses prevented by the proposed rule are estimated with a mean estimate of 1.7 million illnesses prevented, annually. Similarly, the total dollar benefits from the proposed rule is with a mean estimated benefit of $1.0 billion, annually. In this scenario, the overall estimate is relatively unchanged, but the within pathway ratios are changed dramatically. Specifically, agricultural water used in postharvest activities is estimated to have much lower benefits, as is biological soil amendments. Equipment, tools, buildings, and sanitation in growing, harvest, and postharvest activities, however, is estimated to have a much higher associated benefit.

Finally, we present results assuming only a fraction of fresh cut illnesses are preventable by this proposed rule. In the analysis we assume all illnesses reported at a fresh cut facility are preventable by this rule; however, it is likely that some illnesses are due to processing problems that this rule would not address. We do not have any formal information on the frequency that this occurs, so we assume that anywhere between 0 and 100 percent of all illnesses at a fresh cut facility may be preventable under this proposed rule for this sensitivity analysis. Table 34 presents the estimates for this subset of the data.

Table 34. Sensitivity ANALYSIS OF Fresh Cut Illnesses	
	mean
% Reduction in the Risk of Illness	
All Produce	64.77%
Pathway	
Agricultural Water (g/h)	8.89%
Agricultural Water (ph)	10.42%
Biological Soil Amendments	9.06%
Worker Health and Hygiene (g/h)	10.32%
Worker Health and Hygiene (ph)	11.17%
Domesticated and Wild Animals	8.18%
Equipment, Tools, Building and Sanitation (g/h)	2.37%
Equipment, Tools, Building and Sanitation (ph)	4.36%
Illnesses Prevented	
All Produce	1,543,349
Pathway	
Agricultural Water (g/h)	211,855
Agricultural Water (ph)	248,337
Biological Soil Amendments	215,883
Worker Health and Hygiene (g/h)	245,792
Worker Health and Hygiene (ph)	266,226
Domesticated and Wild Animals	194,810
Equipment, Tools, Building and Sanitation (g/h)	56,541
Equipment, Tools, Building and Sanitation (ph)	103,906
Commodity	
Herbs	86,147
Leafy Greens	173,259
Melons	218,912
Sprouts	56,476
Tomatoes	600,091
Other	408,465
Benefits (in millions)*	
All Produce	$914
Pathway	
Agricultural Water (g/h)	$125
Agricultural Water (ph)	$147
Biological Soil Amendments	$128
Worker Health and Hygiene (g/h)	$145
Worker Health and Hygiene (ph)	$158
Domesticated and Wild Animals	$115
Equipment, Tools, Building and Sanitation (g/h)	$33
Equipment, Tools, Building and Sanitation (ph)	$62
Commodity	
Herbs	$42
Leafy Greens	$132
Melons	$109
Sprouts	$17
Tomatoes	$353
Other	$251

* Uncertainty in the number of illnesses prevented stems primarily from the range of % reduction due to the rule, a 50% margin of error (25% in either direction) on the estimate of unidentified illnesses attributable to FDA regulated produce,
** Uncertainty in the dollar benefits estimate stems from the variability in the cost per illness, generated from different values of a statistical life, different number of days ill, different EQ-5D score (QALD loss), and different percentage of illness by severity.

From Table 34, we see that plausible estimates of the overall percentage reduction in contamination events remain the same, with a mean of 64.77 percent. Total illnesses prevented by the proposed rule are estimated lower with a mean estimate of 1.5 million illnesses prevented, annually. Similarly, the total dollar benefits from the proposed rule is with a mean estimated benefit of $914 million, annually. In this scenario, the overall estimate of the number of preventable illnesses is lowered, thus lowering the overall estimate of attributable benefits.

G. Detailed Analysis of Costs of the Proposed Rule[26]

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. As discussed in detail Section IV.C, the data on current produce industry practices is relatively sparse, not always nationally representative, and some of it is out of date with regards to industry adoption of safety procedures and safety regulations. We expect that the use of these surveys will underestimate, sometimes significantly, the current application of food safety practices. We utilize more current

[26] The estimated costs detailed in this section only cover costs directly related to the requirements of the regulations. While not a direct cost of the regulation, we acknowledge that some buyers may change their requirements to more closely resemble the regulatory requirements, even for farms exempt from the regulation. We do not know of a way to estimate the effect of future structural changes in the private market requirements that may happen as a result of the proposed rule. We request comment and data that would help us to quantify this effect.

and representative data in specific sections, when available and applicable, but numerous cost estimates rely on data that may be outdated and not capturing the contemporary cost to the produce industry of this proposed rule. Even after attempting to correct for these biases, we believe these estimates are imperfect. We request comment on the estimation methods and data used, and specifically request additional data to improve the cost estimates.

Additionally, we believe that we may have overestimated costs in some places due to economies of scope and scale. In this analysis, we have not been able to estimate which activities may be more easily performed by a larger operation, or which may be folded into the regular course of everyday activates, already implemented on the farm. We specifically request comment on which estimates, if any, may be combined in order to lower the total costs to industry.

In all subsequent tables that contain cost estimates we additionally provide two average cost calculations by farm size. First, 'average cost per affected farm' is the cost to one farm that will incur costs. This calculation makes no inference on how many farms are already in compliance. Second, 'average cost per farm' is simply an average of total costs over all covered farms. This average distributes costs evenly amongst all farms, even those we estimate are already in compliance.[27]

1. Standards Directed to Health and Hygiene

The provisions in this subpart are intended to minimize the risk for produce contamination associated with people on the farm operation by requiring appropriate

[27] One exception to this is in the estimate of costs to sprouting farms. We do not spread costs to all other farms when calculating their average costs, rather these costs are distributed only amongst all sprout producers.

worker and visitor health and hygiene practices. The provisions require farms to prevent ill people from working in operations that may result in contamination of covered produce, require workers to follow and maintain adequate hygienic practices, and require farms to inform visitors of policies and take steps reasonably necessary to ensure that all visitors comply with such policies on the farm operation.

Farm operators are required to exclude any person with applicable health conditions from working in operations that may result in contamination of covered produce. Examples of such operations are those in which workers contact covered produce or food-contact surfaces directly. The applicable health conditions include communicable illnesses, or infectious diseases, infections, open lesions, vomiting, or diarrhea. The specific illnesses of concern that can result in contamination of covered produce or food-contact surfaces with microorganisms of public health significance are norovirus, hepatitis A virus, *Shigella* spp., Shiga toxin-producing *E.coli*, and *Salmonella* Typhi (Ref.42). Farm supervisors will have a difficult time assessing whether workers have these specific illnesses. Therefore, it is necessary for supervisors to exclude workers with symptoms, such as open lesions, vomiting, or diarrhea, which mimic the specific illnesses of concern. Once the worker shows no signs of illness, he can return to his usual task on the farm. The farm operator, or other responsible person on the farm, is also required to instruct their workers that they must notify their supervisor if they have any of the symptoms or illnesses described. This provision is considered as part of worker training and is discussed in the section for Personnel Qualifications and Training.

All farm workers who handle (contact) covered produce are required to follow hygienic practices in order to prevent contamination of covered produce or food-contact surfaces. These practices include maintaining adequate personal cleanliness, washing hands and drying hands thoroughly at certain times, keeping gloves (if used in handling covered produce or food-contact surfaces) in an intact and sanitary condition and replacing gloves when it is no longer possible to do so, and avoiding contact with animals other than working animals and minimizing contact with covered produce when in direct contact with working animals. Farm workers are required to wash their hands before work, before putting on gloves, after using the toilet, after a break or other absence from the work station, as soon as practical after touching an animal or animal waste, and at any other time when the hands could have become contaminated.

The provisions for visitors on the farm require farm operators to inform all visitors of policies and procedures to prevent contamination of fresh produce or food-contact surfaces. If a visitor is on the farm operation to buy produce (e.g. a pick your own farm) or otherwise, the visitor must know and comply with the policies and procedures enforced by the farm in order to prevent contamination of covered produce or food-contact surfaces. Therefore, the farm is required to inform the visitors, which may be done, for example, verbally or with signage. The farm is also required to take steps reasonably necessary to ensure that the visitor is complying, which may be done, for example, by monitoring visitors' behavior while on the farm. The farm must also allow visitors to use the toilet and hand-washing facilities on the farm.

Current Industry Practices

We use survey data, estimates in published articles, and the food safety program information estimated in the Current Produce Safety Practices (CPSP) section to estimate the current practices that pertain to the provisions in this section. Farms who currently implement food safety programs will already be in compliance with the following provisions: excluding ill workers from operations that may result in contamination of covered produce and food-contact surfaces, avoiding/minimizing contact with animals, maintaining gloves in an intact and sanitary condition, and requirements for visitors on the farm.

In New England, 78 percent of produce growers exclude ill workers from the entire operation or from handling the food directly (Ref.7). Since supervisors are required to exclude workers with applicable health conditions, we obtain prevalence data of these conditions in order to quantify the costs. We specifically obtain information on gastrointestinal illnesses, Hepatitis A, and respiratory illnesses. Gastrointestinal illnesses not only include the microorganisms of public health significance of norovirus, *Shigella* spp., Shiga toxin-producing *E.coli*, and *Salmonella* Typhi, but also illnesses whose symptoms are similar as these such as intestinal parasites and non-infectious conditions. Since the symptoms for Hepatitis A are not gastrointestinal, we obtain prevalence data for Hepatitis A separately. Since respiratory illnesses such as the flu can have symptoms that mimic all illnesses of concern, such as fever, fatigue, vomiting, and diarrhea, we also obtain prevalence data on respiratory illnesses. We differentiate between the three different types of illnesses since the severity of the illness will have different farm costs due to the number of days that an ill worker is away from work.

We use several data sources for the prevalence of gastrointestinal illnesses, and obtain an average based on the different data sources since it is uncertain whether any one estimate is representative of the illnesses infecting the farm worker population. In a national survey of farm workers, approximately 11 percent of farm workers in Georgia, and 9.5 percent in North Carolina reported having intestinal parasites (Ref.43;Ref.44). In a 2010 survey of U.S. farm workers, approximately 3 percent of farm workers reported having possibly infectious diarrhea defined as diarrhea that lasts greater than 3 days (Ref.45)[28]. In a bi-national farm worker survey in the U.S. and Mexico, 6.2 percent of farm workers reported suffering from infectious and non-infectious gastrointestinal diseases (Ref.46). Taking an average of the four sources, we estimate that approximately 7.4 percent [(11% + 9.5% + 3% + 6.2%)/4] of farm workers will have to be excluded because of a gastrointestinal illness that is possibly of concern. Approximately 1.5 out of 100,000 people in the U.S. have Hepatitis A (Ref.47), based on this national data, we estimate that on average .002 percent (1.5/100,000) of farm workers have Hepatitis A. The bi-national farm worker survey from the U.S. and Mexico also shows that 1 percent of farm workers suffered from respiratory illnesses which include a cold or the flu (Ref.46).

A 2008 study in Monterey County, California reported that 9 percent of workers, washed their hands before work, and 75 percent of workers washed their hands after using the toilet (Ref.48). Although current Occupational Safety and Health Administration (OSHA) regulations and food safety programs require supervisors to train farm workers in handwashing practices, compliance levels are uncertain. Therefore, we do not use those programs as a way to measure current practices regarding the outer garments or hand-washing provisions.

Farm workers must avoid contact with animals other than working animals and minimize contact with covered produce when in direct contact with working animals.

[28] [28] It is estimated that this represents 3% of workers at any given time.

Farm workers on farms with livestock or pets are required to avoid contact with them when working in areas used for a covered activity. Approximately 31.5 percent of very small farms, 27.3 percent of small farms, and 26.2 percent of large farms have livestock (Ref.3). Of these farms, 91 percent always exclude their animals from being in their produce fields (Ref.7). We estimate that the same percentage of American households that own pets, 70 percent, also applies to farms (Ref.49). In New England, 48 percent of pick-your-own farms with pets exclude them from being in their produce fields (Ref.7). We expect that these percentages apply to those farms that are not pick-your-own farms, as well as to farms in other States.

Gloves are not always necessary for farm workers. The Monterey County study reported that 43 percent of farm workers wore gloves of which 93 percent wore latex gloves and 7 percent wore reusable gloves (Ref.48). We expect that workers wear gloves due to the nature of their commodity harvest, company culture, or personal preference.

Farms are expected to inform visitors of their policies, take steps reasonably necessary to ensure visitors are following the policies, and make their toilets and hand-washing facilities available to all visitors on the farm. Agritourism farms in the U.S. have the largest number of visitors – for example, 2.4 million total visitors in California and 3.5 million total visitors in Tennessee annually (Ref.50;Ref.51). Agritourism farms offer festivals, corn-mazes, farmers markets, on-farm tours, on-farm retail markets, on-farm vacations, petting zoos, horseback-riding, wine tasting, or pick-your-own produce among other attractions (Ref.50). In Tennessee, agritourism farms have 22,944 visitors on average per year per farm (Ref.50), and in California, 51 percent of agritourism farms had less than 500 visitors per farm, but 12 percent had over 20,000 visitors in 2008 per farm (Ref.51).

After considering the qualified exempt farms, approximately 1.4 percent of very small and small covered farms, and 1 percent of large covered farms had positive sales from agritourism in 2007 (Ref.3). It is uncertain whether these covered farms offer agritourism activities that would require informing visitors of their food safety policies and taking reasonable steps to ensure that visitors comply with those policies to protect covered produce and food-contact surfaces, and it is possible that these farms are offering activities that are unrelated to covered produce on the farm. It is also uncertain whether these covered farms that offer agritourism also implement a food safety program. We seek comment on the number of covered farms that offer agritourism activities and the types of activities they offer. Produce farms without agritourism operations are likely to still have visitors on the farm. We seek comment on the number and frequency of visitors per year on non-agritourism produce farms.

Costs

Cost of Excluding Ill Workers

In order to calculate the total costs of the health and hygiene provisions, we must estimate the number of farms that are not currently implementing the requirements imposed by the proposed rule. First, we consider the number of farms that need to comply with excluding ill workers from operations that may result in contamination of covered produce or food contact surfaces. We estimate that 22 percent of farms need to exclude ill workers since 78 percent of farms already either exclude workers from the entire operation or from handling produce directly. All 22 percent of farms will have to monitor their workers for the symptoms and illnesses of concern, and will have to exclude an estimated 7.4 percent with gastrointestinal illnesses, 0.002 percent with Hepatitis A, and one percent with respiratory illnesses from certain operations. This is based on the reasoning that ill workers are distributed equally across farms that currently exclude workers and those that do not.

We also consider the 1,117 farms that are currently implementing a food safety program that covers this provision. We subtract the 1,117 farms in food safety programs by size to obtain 39,379 total farms where 26,366 are very small (27,021-655), 4,649 are small (4,753-104), and 8,364 are large (8,722-358). The estimated percentage of farms not in compliance, 22 percent, is then applied to each farm size category, as the data needed to refine this estimate is not available. We obtain a total of 8,663 farms, where 5,801 very small farms (.22 x 26,366), 1,023 small farms (.22 x 4,649), and 1,840 large farms (.22 x 8,364), that will need to comply with monitoring and excluding ill workers from operations that may result in contamination of covered produce or food contact surfaces.

In order for the operator to exclude the ill worker from the operation, the operator must monitor all employees for these symptoms (including responding to incidents in which workers report their health conditions to their supervisors) and take time to exclude the worker. The operator or supervisor monitoring time costs are included in the personnel qualifications and training section. Excluding an ill worker includes the time spent asking the worker questions, and perhaps finding something else for him to do. We estimate that it takes 5 minutes for the operator to do this and exclude the worker.

Whether the worker notifies their supervisor of the illness or not, the same time costs apply. The time cost of the supervisor to take time to exclude his employees is based on the operator's wage rate of $47.40 on very small and small farms, and on the supervisor's wage rate of $30.26 on large farms including 50 percent for overhead expenses per hour. Therefore, it will cost operators $4 on very small farms and small farms [5 minutes x ($47.4/60)], and $2.5 on large farms [5 minutes x ($30.26/60)] to exclude an ill worker.

The cost per farm of excluding the ill worker from operations that may result in contamination of covered produce or food-contact surfaces varies by the average number of ill workers per farm by size. We use the number of workers employed per farm, and not the number of farm jobs, since using the number of jobs would overestimate the number of workers with illnesses since ill workers can work for more than one farm. In order to estimate the number of ill workers that the operators or supervisors will have to exclude, we use the average number of workers per farm during harvest and post-harvest and multiply by the percentage of workers that have gastrointestinal illnesses (7.4 percent), Hepatitis A (.002 percent), and respiratory illnesses (1 percent). We expect that workers with open lesions will continue to work after covering up, and we do not estimate an additional exclusion cost for this condition. We seek comment on whether this is reasonable. We also estimate that workers with applicable health conditions will be sent home instead of working in non-produce task for a couple of reasons: the majority of farms send their workers home if they are ill (Ref.7), and it is likely that farms will already have designated people conducting the tasks that do not present a risk of contaminating covered produce or food-contact surfaces, and it will be difficult for the farm operator to substitute a new worker that has no skills in these tasks.

Multiplying 7.4 percent by the average number of workers per farm in growing, harvesting, packing, and holding activities by size, we estimate the annual number of workers with gastrointestinal illnesses is approximately 0.42 on very small farms (0.074 x 5.7 average workers), 0.98 on small farms (0.074 x 13.2 average workers), and 3.8 on large farms (0.074 x 50.8 average workers). Multiplying .002 percent by the average number of workers per farm by size, we estimate the annual number of workers with Hepatitis A is approximately 0.0001 on very small farms (0.00002 x 5.7 average workers), 0.0001 on small farms (0.00002 x 13.2 average workers), and 0.001 on large farms (0.00002 x 50.8 average workers) which is essentially zero for all workers. Multiplying one percent by the average number of workers per farm by size, we estimate the annual number of workers with respiratory illnesses is approximately 0.06 on very small farms (0.01 x 5.7 average workers), 0.1 on small farms (0.01 x 13.2 average workers), and 0.4 on large farms (0.01 x 50.8 average workers).

We estimate the time cost of a farm operator to exclude ill workers by multiplying the total number of ill workers by the cost per operator or supervisor to exclude a worker. Adding the number of workers with applicable health conditions per farm by size, we estimate that there are 0.48 ill workers per very small farm (0.42 + 0.0001 + 0.06), 1.11 ill workers on small farms (0.98 + 0.0001 + 0.1), and 4.28 ill workers on large farms (3.8 + 0.001 + 0.4). The time cost of a very small farm operator to exclude ill workers is $1.9 ($4 x 0.48 ill workers), of a small farm operator is $4.38 ($4 x 1.11 ill workers), and of a farm supervisor on a large farm is $10.8 ($2.5 x 4.28 ill workers). This cost is not incurred by each supervisor on a large farm since the number of ill workers is for the entire farm operation and not per supervisor crew.

We also consider the cost of the loss in productivity when workers are excluded from working. We estimate that the cost of one hour of productivity loss is equivalent to the wage rate of $14/hour. We use two sources to obtain the average number of days that workers with an illness are excluded from working with produce directly. The first source, Appendix A, describes the duration of a foodborne illness in days per year for the specific illnesses caused by microorganisms of public health significance. For each illness, we estimate an average of the number of days per year the condition lasts weighted by the percent of cases that are non-hospitalized and hospitalized. For example, 99.73 percent of norovirus cases last on average 1.5 days (1 to 2 days) for non-hospitalizations, while .27 percent of cases last on average 4 days (1 to 7 days) for hospitalizations. To obtain the average number of days a worker with norovirus will be away from work, we estimate the weighted average of 1.6 days (1.5 x .9973 + 4 x .0027). We do this for each gastrointestinal illness caused by microorganisms of public health significance and take the average of all illnesses to obtain 5.9 days [(7.6 days for *E.coli* O157:H7 + 7.5 days for *E.coli* non-O157 STEC + 5.6 days *Salmonella* spp. + 7 days *Shigella* spp. + 1.6 days for Norovirus)/5].

The second source that provides the number of days a worker will be out of work is the NAWS survey. The survey shows that workers with possibly infectious diarrhea, defined as diarrhea that lasts longer than 3 days, reported having the condition on average for 4 days (Ref.45). We estimate the average number of days a worker with a gastrointestinal illness will be off of the worksite as the average of the two estimates, 5.9 days and 4 days, and obtain approximately 5.4 days since we are uncertain which estimate accurately reflects the number of days workers will be out of work due to a gastrointestinal illness. For workers with Hepatitis A, we also use Appendix A, and estimate the average number of days as 16.2 days (14 days x .937 + 49.5 days x .063). For workers with respiratory illnesses, the CDC recommends people stay home for 24 hours after a fever has subsided, therefore, we estimate that the worker will be away from work for two days (Ref.47).

Multiplying the average number of days workers with applicable health conditions will be away from work by the number of workers with these health conditions, we estimate that for workers with gastrointestinal illnesses it will cost $257 per very small farm (5.4 days x 8 hours x $14 x 0.42), $591 per small farm (5.4 days x 8 hours x $14 x 0.98), and $2,279 per large farm (5.4 days x 8 hours x $14 x 3.8) in productivity losses. For workers with Hepatitis A, we estimate productivity losses are $0.16 per very small farm (16.2 days x 8 hours x $14 x 0.0001), $0.36 per small farm (16.2 days x 8 hours x $14 x 0.0001), and $1.38 per large farm (16.2 days x 8 hours x $14 x 0.001). For workers with respiratory illnesses, we estimate productivity losses are $12.8 per very small farm (2 days x 8 hours x $14 x 0.06), $29.5 per small farm (2 days x 8 hours x $14 x 0.13), and $113.7 for large farms (2 days x 8 hours x $14 x 0.51).

Table 35 summarizes the costs associated with excluding ill workers from the operation by farm size. The cost per farm for having to comply with excluding ill workers from contacting produce or food-contact surfaces directly is $272 for very small farms ($1.9 + $257 + $0.16 + $12.8), $625 for small farms ($4.38 + $591 + $0.36 + $29.5), and $2,405 for large farms ($10.8 + $2,279 + $1.38 + $113.7). Multiplying the number of farms needed for compliance by the cost to comply per farm by size gives us a total cost of $6.6 million where $1.6 million is incurred by very small farms (5,801 x

$272), $0.64 million is incurred by small farms (1,023 x $625), and $4.4 million is incurred by large farms (1,840 x $2,405).

Table 35: Costs to Exclude Ill Workers				
	Very Small	Small	Large	Total
Number of Farms	5,801	1,023	1,840	8,663
Average number of workers per farm (harvest & post)	5.7	13.2	50.8	
Proportion of workers that will need to be excluded				
Gastrointestinal illness (GI) (7.4%)	0.4	1.0	3.8	
Hepatitis A (.002%)	0.0	0.0	0.0	
Respiratory illness (1%)	0.1	0.1	0.5	
Total Ill workers	0.5	1.1	4.3	
Cost of excluding each worker per farm				
Operator/Supervisor's time to exclude worker (5 mins)	$2	$4	$11	
Worker loss of productivity if GI or other (5 days)	$257	$591	$2,279	
Worker loss of productivity if Hepatitis A (16 days)	$0	$0	$1	
Worker loss of productivity if Respiratory Illness (2 days)	$13	$29	$114	
Cost per farm to comply	$272	$625	$2,405	
Total Costs (annual)	$1,576,293	$639,022	$4,425,048	$6,640,364
Costs per affected farm	$272	$625	$2,405	$766
Costs per farm	$58	$134	$507	$164

Cost of Worker Hygienic Practices

We now estimate the cost of the worker hygienic practices which are based on the time it takes workers to wash their hands when indicated in the proposed rule, change their gloves when necessary (if using gloves in handling covered produce or food-contact surfaces), and avoid or minimize contact with animals as indicated in the proposed rule. We do not estimate a cost for personal cleanliness since we expect that all farm workers are currently complying. However, we seek comment on whether this is reasonable.

The proposed rule requires workers to wash and dry their hands approximately 4 times in one 8-hour work day: before work, after using the toilet (assume twice in one day), and after being away from the work station. Workers on farms with animals will have to wash their hands more often, and these costs will be estimated separately. The National Agricultural Workers Survey estimates that 91 percent of farm workers do not wash their hands before work, and 25 percent do not wash their hands after using the toilet (Ref.45). For the purpose of this analysis, we estimate that the same percentage that do not wash their hands before work also do not wash their hands after being away from the work station. We seek comment on these estimates.

We multiply the 91 percent and the 25 percent estimates by the average number of workers per farm by size to calculate the number of workers per farm that will need to wash their hands before work and after being away from the workstation, respectively. We estimate that on a very small farm, 5 additional workers (0.91 x 5.7 workers) on average will need to wash their hands before work and after a break, and 1.4 workers (0.25 x 5.7 workers) on average will need to wash their hands after using the toilet. We estimate that on a small sized farm, 12 workers (0.91 x 13.2 workers) on average will need to wash their hands before work and after a break, and 3.3 workers (0.25 x 13.2 workers) on average will need to wash their hands after using the toilet. We estimate that on a large farm, 46 workers (0.91 x 50.8 workers) on average will need to wash their hands before work and after being away from the work station, and 12.7 workers (0.25 x 50.8 workers) on average will need to wash their hands after using the toilet.

We estimate that the act of hand-washing takes approximately 1 to 3 minutes (with an average of 2 minutes) since the worker must wash his hands for at least 20 seconds in order for it to be an effective means of preventing contamination, and the worker must take time to walk to and from the work station. We ask for comment on the accuracy of this estimate. We estimate that it costs $0.47 ($14/30) of the worker’s time to wash his hands each time. Since these workers will need to wash their hands daily, we estimate that the average cost per very small farm is $218 ($0. 47 x 90 days x 5) to comply with hand-washing before work, $218 ($0. 47 x 90 days x 5) after being away from the work station, and $120 ($0.47 x 90 days x 1.4 x 2 times/day) after using the toilet. The average cost per small farm is $1,006 ($0.47 x 180 days x 12) to comply with hand-washing before work, $1,006 ($0.47 x 180 days x 12) after being away from the work station, and $552 ($0.47 x 180 days x 3.3 x 2 times/day) after using the toilet. The average cost per large farm is $3,880 ($0.47 x 180 days x 46) to comply with hand-washing before work, $3,880 ($0.47x 180 days x 46) after being away from the work station, and $2,132 ($0.47x 180 days x 12.7 x 2 times/day) after using the toilet. Additional material costs, such as soap, clean water, and paper towels, are calculated in the field sanitation section.

Table 36 describes the total costs to farms of the hand-washing provisions in the proposed rule. For very small farms, the cost of hand-washing before work is $5.89 million ($218 x 27,021 farms), after a break is the same at $5.89 million ($218 x 27,021 farms), and after the toilet is $3.24 million ($120 x 27,021 farms). The total cost for very small farms to comply with the hand-washing provisions is $15.02 million ($5.89 million + $5.89 million + $3.24 million). For small farms, the cost of hand-washing before work is $4.8 million ($1006 x 4,753 farms), after a break is $4.8 million ($1006 x 4,753 farms), and after the toilet is $2.6 million ($552 x 4,753 farms). The total cost for small farms to comply with the hand-washing provisions is $12 million ($4.8 million + $4.8 million + $2.6 million). For large farms, the cost of hand-washing before work is $33.8 million ($3880 x 8,722 farms), after a break is $33.8 million ($3880 x 8,722 farms), and after the toilet is $18.6 million ($2132 x 8,722 farms). The total cost for large farms to comply with the hand-washing provisions is $86.2 million ($33.8 million + $33.8 million + $18.6 million). The total time cost to all farms to comply with the hand-washing provisions is $113.6 million ($15.0 million + $12.2 million+ $86.2 million).

Table 36 – Time Costs of Hand-washing Requirements

	Very Small	Small	Large	Total
Number of Farms	27,021	4,753	8,722	40,496
Average number of workers per farm	5.7	13.2	50.8	
Hand-washing practices				
Before work (91%)	5.2	12.0	46.2	
After a break (91%)	5.2	12.0	46.2	
After toilet (25%)	1.4	3.3	12.7	
Cost of Hand-washing practices per farm				
Before work	$218	$1,006	$3,880	
After a break	$218	$1,006	$3,880	
After toilet - twice in one day	$120	$552	$2,132	
Total Cost of Hand-washing practices				
Before work	$5,890,578	$4,781,518	$33,841,360	$44,513,456
After a break	$5,890,578	$4,781,518	$33,841,360	$44,513,456
After toilet	$3,242,520	$2,623,656	$18,595,304	$24,461,480
Total Costs (annual)	$15,023,676	$12,186,692	$86,278,024	$113,488,392
Costs per affected farm	$556	$2,564	$9,892	$2,802
Costs per farm	$556	$2,564	$9,892	$2,802

Cost of Avoiding Contact with Animals

We assume that the cost of having workers avoid contact with animals other than working animals, and minimizing contact with covered produce when in direct contact with working animals will only be incurred by farms that have livestock or pets on the field because workers on all farms are unlikely to contact wild animals on a regular basis. Additionally, it is likely that farms that do contact wild animals are currently avoiding contact with them immediately prior to contacting produce or food contact surfaces. Farms that follow food safety programs will already be complying with this provision. We use the farm numbers after subtracting the food safety program farms of 26,366 very small farms, 4,649 small farms, and 8,364 large farms. Approximately 31.4 percent of very small farms, 27.3 percent of small farms, and 26.2 percent of large farms have livestock (Ref.3). Of these farms, 9 percent do not exclude their animals from being in their produce fields (Ref.7). This implies that approximately 746 very small farms (.314 x .09 x 26,366 farms), 113 small farms (.27 x .09 x 4,649 farms), and 194 large farms (.26 x .09 x 8,364 farms) will need to avoid contact with livestock animals in the field.

To estimate the number of farms that have pets, we use the same percentage of American households that own pets of 70 percent, and apply it to farms (Ref.49). Of the farms that have pets, 52 percent do not exclude them from being in their produce fields (Ref.7). This implies that workers on approximately 9,542 very small farms (.70 x .52 x 26,366 farms), 1,683 small farms (.70 x .52 x 4,649 farms), and 3,027 large farms (.70 x .52 x 8,364 farms) will need to avoid contact with pets in the field. We estimate costs for the 15,304 total farms (1,052 livestock farms + 14,252 pet farms) that need to avoid contact with animals during production.

We estimate that the only cost to avoiding contact with animals is the hand-washing that results from actually touching an animal. We expect that half of the workers on these farms will need to wash their hands an additional one time per week. Here, we use the average number of worker jobs on farms, and not the number of workers, since the baseline information regarding livestock and pet farms is based on farm numbers and not on worker numbers. Therefore, 3.9 workers on very small farms (7.9 average worker jobs x .5) will have to wash their hands one additional time per week, or 13 additional times (90 days/7) per year. For small farms, 9.1 workers (18.1 x .5) will have to wash their hands an additional 26 times (180/7) per year. For large farms, 35 workers (70 x .5) will have to wash their hands an additional 26 times (180/7) per year.

Table 37 summarizes the costs to farms of workers having to avoid contact with animals. Recall that the cost of hand-washing once is $0.23. The cost per very small farm of avoiding animals is then $12 (3.9 x 13 x $0.23), per small farm is $54 (9.1 x 26 x $0.23), and per large farm is $210 (35 x 26 x $0.23). Multiplying the cost per farm by the number of farms that have livestock or pets, we estimate that it costs very small farms $0.12 million [$12 x (746 + 9,542)], small farms $0.1 million [$54 x (113 + 1,683)], and large farms $0.68 million [$210 x (194 + 3,027)], for a total of $0.9 million.

Table 37: Costs of Avoiding Contact with Animals

	Very Small	Small	Large	Total
Produce farms with livestock (35.6%)	8,288	1,252	2,152	25,239
Livestock restricted from crops (9%)	746	113	194	
Produce farms with pets (70%)	18,351	3,236	5,821	
Pets restricted from crops (52%)	9,542	1,683	3,027	
Worker Jobs per Farm	3.9	9.1	35.0	
Days worker must avoid livestock or pets on farm (once a week)	13	26	26	
Cost per farm to avoid animals	$12	$54	$210	
Total Costs (annual)	$121,776	$97,709	$676,435	$895,920
Costs per affected farm	$15	$78	$314	$35
Costs per farm	$5	$21	$78	$22

Cost to Replace and Maintain Gloves

The cost of washing hands before glove use (if gloves are used in handling covered produce or food-contact surfaces) and replacing gloves when necessary require us to know how many workers currently do not follow these practices when they should. We are unaware of this frequency, but use the same data source on the estimated percentage of workers that do not wash their hands before work (91 percent) to estimate that 91 percent of workers that wear gloves will have to wash and replace their gloves one time every day during the year. It is possible that less than 91 percent of workers that wear gloves will have to wash their hands before glove use and replace their gloves when necessary, and it is also possible that they will have to do so more times during the year. We seek comment on whether either of these estimations is reasonable. Farms that follow food safety programs will already be complying with this provision except for farms following the Florida tomato rule and the GAPs audits. We use the farm numbers after accounting for the food safety program farms, but include the FL tomato rule and GAPs audits farms. We obtain 26,762 very small farms, 4,712 small farms, and 8,460 large farms.

Glove use costs are only incurred by workers that wear gloves. It is possible that the majority of workers that wear gloves work on farms that follow a food safety program. In order to account for this, we estimate a range for the costs of this provision: from zero costs if all workers are employed on farms with food safety programs to the full cost if no workers are employed on farms with food safety programs. We then take the midpoint of these costs as our estimate of the costs of washing and maintaining gloves.

Approximately 43 percent of farm workers wear gloves where 93 percent use disposable gloves and 7 percent use reusable gloves (Ref.48). Of these workers, 91 percent will have to incur the costs of replacing their gloves once every day. Multiplying these percentages together, we obtain that 36 percent (0.43 x 0.93 x 0.91) and 2.7 percent (0.43 x 0.07 x 0.91) of workers will replace their disposable and reusable gloves, respectively. This indicates that on very small farms, 2.1 workers (0.36 x 5.7 workers) will replace their disposable gloves and .2 workers (0.027 x 5.7 workers) will replace their reusable gloves. On small farms, 4.8 workers (0.36 x 13.2 workers) will replace their disposable gloves and .4 workers (0.027 x 13.2 workers) will replace their reusable gloves. On large farms, 18.5 workers (0.36 x 50.8 workers) will replace their disposable gloves and 1.4 workers (0.027 x 50.8 workers) will replace their reusable gloves.

The cost of one pair of disposable gloves is approximately $0.09, and the cost for one pair of reusable gloves is $1.21 (Ref.52). The cost per very small farm of replacing disposable gloves is $17 (2.1 workers x $0.09 x 90 days), on a small farm is $79 (9.1 workers x $0.09 x 180 days), and on a large farm is $304 (35 workers x $0.09 x 180 days). The total cost of replacing reusable gloves on a very small farm is $17 (0.2 workers x $1.21 x 90 days), on a small farm is $79 (0.4 workers x $1.21 x 180 days), and on a large farm is $303 (1.4 workers x $1.21 x 180 days). Multiplying these costs with the number of farms, we obtain a total cost of $0.92 million for very small farms [($17 + $17) x 26,762], $0.74 million for small farms [($79 +$79) x 4,712], and $5.1 million for large farms [($304 + $303) x 8,460] for a total of $6.8 million if no glove users work on food safety program farms.

Table 38 summarizes the cost to farms of washing hands before glove use (if gloves are used in handling covered produce or food-contact surfaces) and replacing gloves when necessary. Considering that all glove users are possibly working on food safety program farms and that the costs of this provision are perhaps zero, we estimate that the costs to maintain and replace gloves are $0.46 million for very small farms [($0.92 million + 0)/2), $0.37 million for small farms [($0.74 million + 0)/2), and $2.6 million [($5.1 million + 0)/2) for large farms for a total of $3.4 million ($0.46 million + $0.37 million + $2.6 million).

Table 38: Costs to Maintain and Replace Gloves				
	Very Small	Small	Large	Total
Number of farms	26,762	4,712	8,460	39,934
Average number of workers per farm	5.7	13.2	50.8	
Workers that must maintain disposable gloves (36%)	2.1	4.8	18.5	
Workers that must maintain reusable gloves (2.7%)	0.16	0.36	1.4	
Cost to maintain/replace disposable gloves per farm per year	$17	$79	$304	
Cost to maintain/replace reusable gloves per farm per year	$17	$78	$303	
Total Costs (annual)	$915,729	$741,438	$5,136,434	$6,793,601
Total Costs Accounting for Range (annual)	$457,864	$370,719	$2,568,217	$3,396,800
Costs per affected farm	$17	$79	$304	$85
Costs per farm	$17	$78	$294	$84

Cost to Inform Visitors of Policies and Procedures

The cost to inform visitors of policies and procedures, to take reasonable steps to ensure that visitors follow them, and to allow visitors access to the toilets and hand-washing facilities on the farm is based on the manager or supervisor's time. We expect that farms will allow visitors to use the toilets and hand-washing facilities that are available for their workers, and farms that do not currently have toilets or hand-washing facilities will rent them. This cost is estimated in the sanitation section. We expect that farms with food safety programs will be complying with this provision, and therefore we do not estimate costs for them. We use the farm numbers after subtracting the food safety program farms of 26,366 very small farms, 4,649 small farms, and 8,364 large farms. Since we do not know if the 1.4 percent of very small and small covered farms and 1 percent of large covered farms offer agritourism activities that would require informing and monitoring visitors to protect covered produce and food-contact surfaces, we do not estimate additional costs for these farms.

We estimate that all farms have visitors on the farm for one full day out of the year. Since the majority of people visit agritourism farms, and many of these farms are not covered under this proposed rule (e.g. corn-mazes, pumpkin pick-our-owns, wineries, etc.), then we expect that there are very few visitors on non-agritourism farms. We expect farm operators to inform and monitor visitors on very small and small farms at a cost of $47/hour, but for farm supervisors to do it on large farms at a cost of $30/hour. We estimate that it will take 8 hours total per year for the operator to inform visitors of the farm policies, including showing them where the restrooms are, and to take reasonable steps to ensure their compliance, such as monitoring visitors to ensure they are following the policies and procedures. We estimate that it will cost very small and small farms $379 ($47 x 8 hours), and supervisors on large farms $242 ($30 x 8 hours) to inform visitors and take steps to ensure compliance by visitors annually.

Table 39 summarizes the costs to farms of having visitors on the farm. Multiplying the per farm cost of complying with the provision by the total number of farms that must comply, we obtain a total cost of $10 million for very small farms ($379 x 26,366), $1.8 million on small farms ($379 x 4,649), and $2 million on large farms ($242 x 8,364). The total cost of complying with this provision in $13.8 million ($10 million + $1.8 million + $2 million).

Table 39: Costs of Visitors on the Farm

	Very Small	Small	Large	Total
Number of farms	26,366	4,649	8,364	39,379
Average number of days with visitors per year	1	1	1	
Average time spent informing and taking reasonable steps to ensure compliance by visitors (minutes)	8	8	8	
Cost to inform and ensure compliance by visitors per farm per year	$379	$379	$242	
Total Costs (annual)	$9,997,961	$1,762,876	$2,024,339	$13,785,177

Costs per affected farm	$379	$379	$242	$364
Costs per farm	$370	$371	$232	$340

Summary

Table 40 summarizes the total costs of the worker health and hygiene provisions. The total costs to farms to comply are $81.5 million ($6.6 million + $56.8 million + $0.9 million + $3.4 million + $13.8 million). The provision to wash and dry hands thoroughly make up the largest portion of that cost at $56.8 million, followed by the visitor practices provisions at $13.8 million.

Table 40: Summary of Costs of Health and Hygiene

	Very Small	Small	Large	Total
Costs to exclude ill workers	$1,576,293	$639,022	$4,425,048	$6,640,364
Costs to wash and dry hands thoroughly	$15,023,676	$12,186,692	$86,278,024	$113,488,392
Costs to avoid contact with animals	$121,776	$97,709	$676,435	$895,920
Costs to wash hands before glove use and maintain/replace gloves	$457,864	$370,719	$2,568,217	$3,396,800
Costs to inform, ensure compliance by, and have toilets for visitors	$9,997,961	$1,762,876	$2,024,339	$13,785,177
Total Costs (annual)	$27,177,570	$15,057,018	$95,972,063	$138,206,653
Costs per farm	$1,006	$3,168	$11,003	$3,413

2. Agricultural Water

The proposed rule requires a review of agricultural water sources, distribution systems, facilities and equipment under a farm's control at the beginning of the growing season, and the regular inspection and maintenance of agricultural water sources and distribution systems and equipment under the farm's control. The proposed rule defines certain specific quality criteria for agricultural water and also requires that it be safe and of adequate sanitary quality for its intended use. It requires the discontinued use of the water source or distribution system whenever the quality criteria are not met (both the specific criteria and that the water must be safe and of adequate sanitary quality for its intended use). When water quality criteria are not met, the farm may choose to attempt to make changes that would allow resuming use of the water system or water source, or may choose to treat the water using an effective method , with treatment monitoring.

The proposed quality criteria includes the assurance that there is no detectable *E*. coli per 100 ml sample of water that is intended for harvest, packing and holding uses that directly contact covered produce (including washing, cooling and preventing dehydration, and for the production of ice that will contact covered produce), as well as for water used as sprout irrigation water during growing, water used to make a treated agricultural tea, water and ice used to contact food-contact surfaces, and water used for washing hands during and after harvest activities. Agricultural water that is applied to covered produce other than sprouts during growing (irrigation water) using a direct water application method is required to have a microbiological quality criterion of less than 235 MPN / 100 ml generic *E*. coli and a rolling geometric mean (n=5) of 126 CFU (or MPN) per 100 ml. Samples of groundwater intended for any of these uses must be collected and analyzed at the beginning of the growing season and at least once every 3 months thereafter during the growing season. An untreated surface water source that is used for any of these uses must be sampled and tested more frequently: either every 7 days during the growing season if it is likely to receive a significant quantity of runoff drainage (such as a river or natural lake), or at least once each month during the growing season if it is underground aquifer water transferred to a surface containment constructed to minimize the potential for contamination via run-off (such as a man-made water reservoir). No testing is required for water received from public sources with certain documentation indicated in the proposed rule, or to water treated in compliance with the proposed rule's treatment requirements. Specific methods required to analyze water samples are proposed.

The proposed rule also requires the establishment and implementation of water management practices to prevent the build-up of organic matter in re-circulated water and for water used in dump tanks, flumes, for cooling and other harvest, packing, and holding operations, as well as to monitor water temperatures whenever appropriate. Required documentation includes the findings of the inspection of the agricultural water system, analytic test results, treatment monitoring results, and documentation received from public water sources if applicable. Documentation of any scientific findings that support an alternative to the proposed non-sprout direct application irrigation water microbial standard or that support the farm's treatment method is also required.

Data and literature on current agricultural water use

We use data from the 2008 FRIS and from the 2007 Census of Agriculture conducted by NASS to estimate the costs of the agricultural water provisions of the proposed rule (Ref.17). The 2008 FRIS is based on a supplemental survey of detailed questions asked to a subset of farmers from the 2007 NASS Census of Agriculture who reported using irrigation (Ref.17). The 2007 Census of Agriculture captures information on farms with more than $1,000 in sales of agricultural products, and we do not estimate the impacts of farms with fewer than $1,000 in sales. The 2008 FRIS estimates a total of 83,104 produce farms that irrigated 7,041,075 acres in 2007.

When the qualified exemptions and exclusions for commodities rarely consumed raw are taken into account, the number of irrigated produce farms and greenhouses covered by options considered in this analysis is 43,221 and the number of irrigated acres of produce covered by the proposed rule is 5,008,456. These numbers also include those farms that are out-of-scope in the proposed option because of their size. When these farms are subtracted from the subtotal we estimate a total of 27,248 irrigated farms and 4,950,539 irrigated acres would be covered by the proposed option.

For purposes of this analysis we estimate that there are 2 production cycles per year and that production occurs for 6 months out of the year based on estimates from the 2007 Census of Agriculture described earlier in the analysis. This may understate the length of production cycles in states such as Florida that grow year-round, and overstate the length of production cycles in northern states where the growing season is short.

Where data on rates of current practice are scarce, we use estimates of the numbers of adherents to California and Arizona LGMA, Florida Tomato Rule (FTR) and California Tomato Farm Coop (CTEC) (Ref.11;Ref.12;Ref.13), all of which have agricultural water provisions, in conjunction with descriptions of those standards to estimate baseline practices for the analysis. The CA LGMA and AZ LGMA require testing for generic E. coli for water used in foliar applications, pre-harvest non-foliar applications, and postharvest applications that directly contact the produce or food contact surfaces (Ref.11;Ref.12). Similar to the proposed requirements, the testing frequencies specified by the marketing agreements are based on whether the water is used for foliar application, non-foliar application, or for postharvest use.

The testing frequencies and locations within the water distribution required for sampling in the leafy greens marketing agreements and FTR are slightly different than the proposed requirements. For example, FTR requires monitoring surface water quarterly and groundwater annually when it is to be used for direct application while the CA and AZ LGMA require surface water and groundwater used for direct application to be monitored monthly – with municipal water exempt from the requirement and groundwater qualifying for an exemption if findings from 5 succeeding samples all report non-detectable levels of E. coli. This implies an increased frequency of testing for Florida Tomato farmers and a possibly an increase in testing requirements for members of the CA and AZ LGMA if this proposed rule were to become final.

The FTR, CA and AZ LGMA and CTFC all have requirements: foliar applications must meet potable standards at the time of harvest as must water used for postharvest applications (Ref.11;Ref.12;Ref.13),. Irrigation systems are required to be inspected seasonally by the CA and AZ LGMA, while FTR only requires an inspection to identify a contamination source and to document a previous land-use. Consequently, these imply a possible increase in the frequencies of system inspections relative to the FTR requirements if this proposed rule were to become final.

We do not have precise enough information to estimate the additional costs of the proposed rule relative to the FTR, CA and AZ LGMA requirements. To account for differences in testing frequencies required by the FTR, CA and AZ LGMA and CTFC relative to the proposed requirements, we estimate that adherents to FTR, CTFC and CA and AZ LGMA would incur 50 percent of the costs incurred by non-adherents from the proposed agricultural water provisions.

There may be growers that adhere to similar requirements specified in other food safety programs that are not considered in this analysis. This may result in an overestimate of the costs of the proposed requirements. We ask for comment on the magnitude of the effects of the requirements from other food safety programs on current industry practices. Other data from the literature used to estimate rates of current industry practice include the results from a 2001 survey of New England produce growers (Ref.7) and a 1999 survey of food safety practices by produce growers across the major producing states (Ref.6). In addition, we use the results of a 1998 survey of the California sprout industry to estimate baseline water use practices of that industry (Ref.53).

Cost to inspect agricultural water sources and distribution systems

The proposed rule requires a review of agricultural water sources, distribution systems, facilities and equipment under a farm's control at the beginning of the growing season, and the regular inspection and maintenance of agricultural water sources and distribution systems and equipment under a farm's control. We use 2008 FRIS data on the extent groundwater and surface water sources as well as information obtained from FDA inspectors to estimate the time required to inspect irrigated farms with groundwater and surface water sources. We use wage rates obtained from the BLS to value the time required for water source and distribution system inspection and maintenance by farm size.

We use 2008 FRIS data to estimate that 51.3 percent of all irrigated farms use groundwater for irrigation, and we estimate the average number of wells on irrigated farms that use groundwater from the distribution of the number of wells per farm reported in FRIS, and the percentage of farms that have the corresponding number of wells (Ref.17). We note that the number of wells per farm that uses groundwater sources reported in the 2008 FRIS includes the number of wells that are operational and the number of wells that may not be operational. Moreover, the data used in this analysis do not distinguish between the number of wells per farm that grows produce and the number of wells per farm that grows grain, livestock, or any other crop. To the extent that the data include wells that that are not operational, our estimates will overstate the number of wells per-farm. Moreover, if the average number of wells per farm that grows produce is different than the average number of wells per-farm that grows grain, livestock, and all other commodities our estimates that depend on this data will be biased.

The 2008 FRIS data report the high category of the number of wells per farm that use groundwater as “20 or more”, without reporting the average number of wells per farm that has “20 or more” wells. We use the number “22” as the mean number of wells for farms that have 20 or more wells for purposes of calculating the corresponding weight for the weighted average number of wells on farms that use groundwater sources (the calculation would multiply 22 by the fraction of farms that have 20 or more wells). We estimate a weighted average of 3.84 wells per irrigated farm that use groundwater. Approximately 4 percent of farms reported in 2008 FRIS to use groundwater have “20 or more” wells, and to the extent that the average number of wells for farms that have “20 or more” wells is different than “22”, the estimated weighted average number of wells for farms that use groundwater sources will be different than 3.84. We ask for comment on the distribution of the number of wells on farms that have more than 20 wells.

We estimate that the inspection of wells requires the inspection of each well and surrounding area to identify any potential hazards that might contaminate the water source as well as visual verification that each source and surrounding area is in good repair and properly maintained. We base our estimate of the time burden for inspecting a farm’s water sources on comments by FDA field personnel, who stated that it would take approximately 8 hours to inspect a hypothetical farm with "2 ponds and 2 wells,” Based on FDA field personnel comments, we estimate that it would take approximately 0.5 hour to inspect each well and surrounding area for potential hazards. From 2008 FRIS data we estimate that approximately 9 percent of irrigated farms use both surface and ground sources for irrigation (Ref.17). Because of the generally larger sizes of lakes, ponds, and reservoirs relative to groundwater installations, and to be consistent with comments by FDA field personnel, we estimate the inspection burden for a surface water source to be 3.5 hours (8 hours to inspect a farm with 2 wells and 2 surface water sources: 2 wells x ½ hour per well + 2 surface water sources x 3.5 hours per source = 8 hours).

We estimate that farms will regularly inspect their water sources and surrounding areas twice a production cycle; once close to the time of planting and once close to the time of harvest. Consistent with the discussion in the section entitled “Economic Analysis Costs: Overview of Cost Conventions and Farms Covered,” we estimate there are 2 production cycles per year. Consequently, we estimate the average burden for inspecting agricultural water sources and distribution systems is approximately 15.26 hours per farm (0.5 hours x 3.82 wells per farm that use groundwater x 43 percent of irrigated farms that use groundwater x 4 inspections per year + 3.5 hours to inspect a surface water source x 1 source per farm x 57 percent of irrigated farms that use surface water sources x 4 inspections per year + 1 hour to inspect the irrigation distribution system x 1 distribution system per farm x 100 percent of irrigated farms have distribution systems x 4 inspections per year). The estimated time burdens and inspection frequencies from the proposed requirement for inspecting agricultural water sources are reported in Table 41.

Table 41: Estimated annual burdens and the numbers of agricultural water sources and distribution systems to be inspected per farm				
	Share of irrigated farms	Number of units per farm that use groundwater sources	Time burden per unit	Frequency
Inspect and maintain groundwater wells	0.43	3.82	0.5	4
Inspect and maintain surface sources	0.57	1	3.5	4
Inspect and maintain distribution system and adjacent areas	1	1	1	4

We use the mean hourly wage for a farm operator reported in the BLS under the heading of Farmers, Ranchers, and Other Agricultural Managers working in the agriculture industry of $31.60 multiplied by 1.5 to account for overhead to estimate the cost of inspecting water sources for very small and small farms. We use the mean hourly wage for first-line supervisors/managers of farming, fishing and forestry workers of $20.55 multiplied by 1.5 to account for overhead to estimate the cost of inspecting water sources for large farms. Consequently, we estimate the cost for inspecting a large farm to be approximately $470.44 (15.26 hours x $30.83 per hour) and the cost for inspecting a very small and small farm to be approximately $723 (15.26 hours x $47.40). Per the discussion on current agricultural water use, the percentage of irrigated farms that are members of the CA and AZ LGMA, FTR, or CTFCF are assumed to incur 50 percent of the cost incurred by non-members from the proposed requirement to inspect and maintain agricultural water sources and distribution systems.

There may also be growers that adhere to similar requirements specified in other food safety programs not considered in this analysis. This may result in an overestimate of the costs of the proposed requirements. We ask for comment on the magnitude of the effects of the requirements included in the CA and AZ LGMA, CTFC and the FTR as well as from other food safety programs on current industry practices. The aggregate cost of the requirement to inspect and maintain agricultural water sources by farm size is reported in Table 42.

Table 42: The costs of inspecting agricultural water sources and irrigation distribution systems by farm size, including rates of current practice			
	Very small	**Small**	**Large**
Number of covered irrigated farms	16,623	3,377	7,248
Cost per affected farm	$723	$470	$470
Rate of current practice[5]	1.3%	0.06%	3.78%
Total cost per size category	$11,869,172	$2,441,242	$3,220,538
Total	$17,530,952		

Costs of the water sampling and testing requirements

The proposed quality criteria and standard includes the assurance that there is no detectable E. coli per 100 ml sample of water that is intended for direct contact with covered produce during or after harvest, including washing, cooling and preventing dehydration, for the production of ice that will contact covered produce, as well as for water used for treated agricultural teas, water and ice that will contact food-contact surfaces, to wash hands during and after harvest activities, and to grow sprouts (sprout irrigation water). Agricultural water that is directly applied to covered produce other than sprouts during the growing operation (direct application method irrigation water) is required to be less than the microbiological quality criterion of 235 MPN / 100 ml of generic *E.* coli and a rolling geometric mean (n=5) of 126 CFU (or MPN) per 100 ml.

Samples of groundwater intended for any of these uses must be collected and analyzed at the beginning of the growing season and at least once every 3 months thereafter. An untreated surface water source that receives significant runoff is used for any of these uses must be sampled and tested every 7 days during the growing season. An untreated surface water source that contains water transferred from an underground aquifer and is constructed to minimize the potential for contamination via run-off used for any of these uses is required to be tested monthly during the growing season. These testing frequencies do not apply to water received from public sources with certain documentation indicated in the proposed rule, or to water treated in compliance with the proposed rule's treatment requirements. No testing is required for water from such sources.

We first estimate the costs of collecting and analyzing a water sample for generic *E.* coli and then estimate the number of farms that use agricultural water in their growing operations that would be subject to the 3-month, monthly, and weekly testing regimes during the production season. We then multiply the number of farms estimated to be subject to each testing regime by the corresponding number of tests required annually and then again by the estimated cost to collect and analyze a water sample to estimate the costs of the proposed water sampling and testing requirement for agricultural water used during the growing operation. We use a similar framework for estimating the costs of the proposed water sampling and testing requirement for harvest and post-harvest water that directly contacts covered produce, water to make treated agricultural teas, water for hand-washing used during and after harvest, water and ice that will contact covered produce or food-contact surfaces, and water for growing sprouts.

Per-sample microbial water testing costs include the time required to obtain a sample from each farm water source, and the costs of the laboratory to analyze the sample to detect the particular microbes of interest. Farms may either hire a sample collector from the laboratory or collect water samples themselves. We do not have information on how many farms will choose to hire a sample collector and how many will collect the samples themselves. Farms will choose to collect the water sample themselves and ship it to a laboratory for analysis if the cost of doing so is less than the cost of having a sample collected and analyzed by the laboratory or another party. For purposes of this analysis, we have assigned an equal probability (50 percent probability) for making each choice. For hiring a sample collector we estimate the costs of the time to travel to the farm, collect the water sample, and travel back to the laboratory to have it analyzed. For in-house sample collection, we estimate the costs of the supplies necessary for sample collection, time to collect the sample themselves, and the costs to send it to the laboratory via an overnight shipping service. In the case where the farm is located close to the laboratory, we estimate the shipping cost would include the materials (fuel, wear and tear on the car, etc.) as well as the cost of the time spent transporting the sample to the laboratory, delivering the sample, and returning to the farm and would fall within the range of the cost for overnight shipping estimated for the more general case of in-house sample collection. We ask for comment on proportion of the farms that would choose in-house sample collection.

For sample collecting by a laboratory or other party, firms charge an hourly rate for travel and collection (Ref.54). We do not have information on average travel times for hired sample collectors. We estimate that the average round-trip travel time by a sample collector to and from the farm would be range from a low of 0.5 hours to a high of 1.5 hours. We further estimate that once on the farm, the time to collect the sample would be ½ hour. Based on e-mail quotes from a laboratory in the fresh produce industry (Ref.54), the hourly charge for travel for sample collection is $45 per hour and the quote for analyzing a water sample for *E.* coli is $12. Consequently, we estimate that a laboratory would charge $80.00 (a travel and sample collection time of between 1 hour and 2 hours with a midpoint of 1.5 hours @ $45 per hour, plus $12 for the analysis) for sample collection and analysis.

For the 50 percent of farms that collect the sample themselves, there would be no travel costs. The time for collecting a sample in-house would also be 0.5 hours. Using the mean hourly wage of $20.07 for a biological technician (Ref.2), and multiplying by 1.5 to account for overhead expenses, we estimate the labor cost for in-house sample collection to be $30.10 per hour, and approximately $15 for half an hour to collect the sample. We estimate the supplies (rubber gloves, alcohol wipes, and a bottle) needed to collect a sample would cost approximately $5 per sample (Ref.55). We estimate the costs of shipping supplies, including an insulated shipping carton and gel packs necessary to keep the samples at the appropriate refrigerated temperatures until analyzed by the laboratory to be $21.76 (Ref.55). The shipping costs for a 5lb package range between $22 (zone 2) and $60 (zone 9) per package (Ref.56). Consequently, in-house collection, shipping and the laboratory analysis would cost would be approximately $94.60 for sample collection and analysis ($15.05 for one half-hour for sample collection + $5 for sample collection supplies + $21.76 for shipping supplies + between $41 for overnight shipping, + $12 for the laboratory analysis for *E*. coli). The weighted average cost of laboratory water sample collection and analysis and in-house collection with subsequent shipment to a laboratory for analysis is estimated to be approximately $87.30 (50 percent in-house sample collection and analysis x $94.60 + 50 percent laboratory collection and analysis x $80.00). Table 43 below reports the costs of sample collection and analysis.

Table 43: Cost of collecting a water sample and analyzing for generic E. coli

Laboratory collection and analysis				In-house collection and analysis				
Laboratory analysis for *E.* coli	Laboratory travel	Laboratory sample collection		Laboratory analysis for *E.* coli	Collection supplies	Shipping supplies	Overnight shipping	Sample collection burden
$12	$45	$23		$12	$5	$21.76	$41.00	$14.84
Total costs for laboratory collection and analysis				Total costs for in-house collection and analysis				
$80.00				$94.60				
Weighted average cost for sample collection and analysis								
$87.30								

Costs of the water sampling and testing requirements for farms that directly apply surface water during growing to covered produce other than sprouts

We do not have information on the extent to which agricultural water is directly applied to the produce during growing. We assume that farms that apply irrigation water using overhead, furrow or flooding methods may incur costs from this proposed provision since the water may directly contact the harvestable portion of some produce if the produce were present. We assume that farms that apply water using drip irrigation or other subsurface or low-flow methods would not incur costs from this proposed provision since it would not directly contact the harvestable portion of produce commodities even if the produce were present.

The water applied using some gravity-based irrigation methods may be likely or intended to contact the harvestable portion of the produce on some crops and not on others even when the produce is present. Water applied using some gravity-based irrigation methods may be likely to contact melons, squashes, or other crops where the produce is grown at ground level while it may not be likely to contact other crops such as peppers and staked tomatoes where the produce is grown above ground level. Moreover, for crops such as fruits and nuts grown on trees, water applied using gravity-based methods would not be likely to or intended to contact the produce at any time during the production cycle. Farms that grow tree fruits and nuts that apply water using gravity-based methods would not incur costs from this provision.

We assume that all produce crops are equally likely to be irrigated using an overhead, gravity-based, or drip or other low-flow method. Without better information we estimate that 100 percent of produce farms that use overhead spray methods of irrigation and 50 percent of farms that use other gravity-based irrigation methods would incur costs from this proposed provision if the water were to be applied while the produce were present. The estimate that only 50 percent (rather than 100 percent) of farms that use gravity based irrigation methods would incur costs from this proposed provision accounts in part for farms that grow tree fruits and nuts where water applied using these methods would not be intended or likely to contact the harvestable portion of the produce. From 2008 FRIS data, 38 percent of irrigated farms use overhead spray irrigation methods and 16 percent of irrigated farms use gravity-based irrigation methods (Ref.17). Consequently, we estimate that 46 percent of irrigated farms (38 percent + 50 percent x 16 percent) use an irrigation method such that the water may be likely to come in contact with the harvestable portion of the produce if the produce were present and would incur costs from this provision (Ref.17). This estimate may result in overstating the costs incurred from this proposed provision if more than 50 percent of farms that use gravity based irrigation methods grow tree fruits and nuts.

On some crops, such as leafy greens where the harvestable portion emerges early in the production cycle, water used from overhead spray methods and some gravity-based methods may be likely to contact the produce during most of the production cycle. For other crops, such as tomatoes where the harvestable portion emerges later in the production cycle, water from overhead sprays and some gravity-based irrigation systems may be likely to contact the produce for a smaller fraction of the production cycle. For purposes of this analysis we estimate that the produce is present during 75 percent of the production cycle and may be in contact with irrigation water applied from overhead spray and some gravity-based methods. We seek comment on these estimates.

From the 2008 FRIS data, we estimate that approximately 53 percent of all irrigated farms use a surface water source for irrigation, with approximately 31 percent using a surface water source from an off-farm supplier (the Bureau of Reclamation, other Federal Agencies, or other water suppliers), and approximately 22 percent using an on-farm surface water source (one that is not controlled by a water supply organization, and includes water from a stream, drainage ditch, lake, pond, spring or reservoir on or adjacent to the farm).

Without additional information on the risk of contamination and construction characteristics of surface water sources, we estimate that 50 percent of farms that use surface water for irrigation get it from an untreated source such as a lake, pond, or reservoir constructed to minimize the potential for contamination via run-off and would be required to be tested for generic *E*. coli monthly during the growing season if directly applied to the produce during growing and that 50 percent of farms that use surface water for irrigation would be required to test for generic *E*. coli weekly during the growing season if directly applied during growing. This implies that 26.5 percent of all irrigated farms would be required to test their irrigation water source weekly (50 percent x 53 percent of irrigated farms that use surface water sources), and 26.5 percent of irrigated farms would be required to test their water source monthly. We ask for comment on the extent to which the method for estimating required surface water testing frequencies as described above is consistent with the definition of surface water used in this proposed rule.

Pending the outcome from laboratory test results of the 1st water sample taken during the production season, we estimate that some farms may choose to treat their water for the remainder of the season so that it would meet the criterion of 235 MPN generic *E*. coli per 100 ml of water and a rolling geometric mean (n=5) of 126 CFU (or MPN) per 100 ml. We estimate the number of farms that would have to treat their water in order for it to satisfy the criterion as well as the quantity of water that would need to be treated later in the analysis. The total sampling and testing costs for this requirement are reported in Table 44.

Table 44: Sampling and testing directly applied irrigation surface water

		Costs
Number of covered produce farms that apply surface water directly to their produce during growing	7,435	
Cost per sample		$87.30
Number of weeks per year when covered produce is present	19.5	
Produce farms that would test 1 time and opt to treat water that is directly applied[1]	289	$25,162
Produce farms that would test surface water that is directly applied with a weekly frequency	3,573	$6,072,813
Produce farms that would test surface water that is directly-applied with a monthly frequency	3,573	$1,868,558
Total Testing Costs Gross of Current Rates of Practice	$7,966,534	

[1] We estimate the number of farms that would have to treat based on the percent of acreage potentially irrigated with contaminated water derived from data contained in a 2005 EPA report to congress (Ref. 58) and estimated in the section below entitled “The quantity of agricultural water that would need to be treated from the proposed quality criterion.”

To estimate the number of irrigated farms in each size category that would incur water sampling and testing costs due to the proposed rule, we apply the same percent of all covered farms in each size category estimated from 2007 NASS Census of Agriculture data to the total number of irrigated farms that directly apply surface water. We estimate the per-farm costs in each category by dividing the total testing costs reported in Table 44 by the number of farms estimated in each category. Per the discussion on current agricultural water use, the percentage of irrigated farms that are members of the CA and AZ LGMA, FTR, or CTFCF are assumed to not incur 50 percent of the cost incurred by non-members from the proposed requirement to sample agricultural water.

There may also be growers that adhere to similar requirements specified in other food safety programs not considered in this analysis. This consideration may result in an overestimate of the costs of the proposed requirements. We ask for comment on the magnitude of the effects of the requirements included in the CA and AZ LGMA, CTFC and the FTR as well as from other food safety programs on current industry practices. The aggregate cost of the requirement to sample and test agricultural water by farm size is reported in Table 45.

Table 45: Costs of the water sampling and testing requirements during growing operations by farm size, and including rates of current practice

Farm sizes	Very small	Small	Large
Number of covered produce farms that apply surface water directly to their produce during growing	4,983	868	1,585
Cost per year	$5,338,669	$929,849	$1,698,016
Rate of current practice	1.30%	0.06%	3.78%
Total cost per farm size category	$5,269,349	$929,274	$1,633,809
Total cost of the requirement	$7,832,432		

Costs of the water sampling and testing requirements for farms that use water or ice in direct contact with covered produce for harvest, packing and holding operations, water for hand-washing during and after harvest, water or ice for direct contact

with food-contact surfaces, water for treated agricultural teas, and also for sprouting operations

Produce growers that directly apply water to covered produce for harvest-related and post-harvest activities, that use water to grow sprouts, that use water for hand washing during and after harvest, that use water or ice in direct contact with food-contact surfaces, and that use water to make treated agricultural teas would have to meet the microbiological criterion of no detectable *E*. coli per 100ml water sample for those uses, and would need to sample and test water used for those purposes once every three months during the production cycle (or more frequently, if using untreated surface water) unless the water comes from a public water supply with documentation indicated in the proposed rule or is treated as set forth in the proposed rule. We assume that the probability of meeting the proposed quality criterion of no detectable generic *E*. coli per 100ml sample is very low for untreated surface water, and that all surface water used for these purposes would not incur sample collection and testing costs and would be treated unless it comes from a municipal source. The costs for treating the surface water used by these farms are reported later in the analysis in the section entitled "Water treatment costs for uses subject to the proposed quality criterion of no detectable generic *E*. coli."

We assume that groundwater used for these purposes would be subject to the proposed sampling and testing requirements and that a fraction of farms that use groundwater for these operations would sample once and either opt to treat in order to satisfy the criterion of no detectable generic *E.* coli per 100ml sample, change ground water sources and sample the new source every 3 months during the production cycle, or take other preventive actions. Without information on the qualities of groundwater across the multitude of agricultural regions, we estimate that 50 percent of farms (the midpoint between 0 and 100 percent) that use groundwater for these operations would test once and opt to either treat their water in order to satisfy the water quality criterion of no detectable generic *E.* coli per 100ml sample, change their water source, or take other preventive actions. We estimate that 50 percent of this number (25 percent) would choose to treat and 50 of this number (25 percent) would change their water source or take other preventive actions. The costs for treatment for these farms are reported in the section entitled "Water treatment costs for uses subject to the proposed quality criterion of no detectable generic *E*. coli." We estimate that the remaining 50 percent of farms that use groundwater for these purposes would meet the quality criteria and incur sampling and testing costs every three months during the production cycle.

We assume that farms that use water for hand washing purposes during or after harvest are currently in compliance with OSHA requirements that it be of drinking water quality (Ref.57). However, OSHA does not require water used for hand-washing to be tested and we assume that all farms that harvest covered produce would be subject to the testing requirements for water used for hand-washing during and after harvest if it is not from a municipal source. We assume that the source of water used for hand-washing during and after harvest is currently independent of the source of water used for other production purposes. We ask for comment on this assumption. Moreover, we assume that no surface water source would be of drinking quality and that no farm that uses a surface water source for other production purposes would use it for hand-washing purposes since it would not meet the OSHA requirement that it be of drinking quality. These farms would obtain water for hand-washing from outside suppliers, including from municipal suppliers. We ask for comment on this assumption. Consequently, we assume that unless it is provided by a municipal source, only groundwater used for purposes of hand-washing during and after harvest would be subject to the proposed sampling and testing requirements,

The total number of farms and the distribution by farm size that would be subject to the sampling and testing requirement for purposes of hand washing during and after harvest are reported in the section entitled “Health and Hygiene” (40,496 farms). We multiply the number of these farms by the fraction of irrigated farms that use groundwater estimated from 2008 FRIS and reported earlier in the section entitled “Costs of the water sampling and testing requirements for farms that directly apply surface water” (53 percent of irrigated farms use surface water sources, 47 percent use groundwater sources) and subtract the number of farms found to use municipal water for post-harvest uses described below.

We do not have information on the number of farms that apply water directly to covered produce during or after harvest, that use water or ice that would contact food contact surfaces or that use agricultural teas. We use information from a 1999 survey on food safety practices to estimate that 46 percent of covered produce farms have post-harvest operations (Ref.6) and that 50 percent of farms with post-harvest operations (the midpoint between 0 and 100 percent) use water in their harvest, packing, or holding operations and would be required to comply with the proposed testing requirements.

We estimate the number of covered farms that use water or ice in direct contact with covered produce for harvest, packing and holding operations, water for hand-washing during and after harvest, water or ice for direct contact with food-contact surfaces, water for treated agricultural teas that would not be subject to the proposed testing requirements because it is obtained from a municipal source using findings from a 2001 survey of New England produce growers (Ref.7). In that survey 26 percent of respondents reported using municipal water as the source for the farm's drinking water. We use this information to estimate that 26 percent of covered farms apply municipal water during for the uses of water subject to the requirement of 0 detectable generic *E.* coli per 100 ml, and would not be subject to the testing requirement.

We estimate the testing requirements for irrigation in sprouting operations using a framework similar to that used for farms that use water for the other operations subject to the proposed 0 detectable E. coli standard. We estimate that 50 percent of covered sprouting operations that use groundwater would have to treat the water they use for sprouts production. We estimate the total number of covered sprouting operations to be 289 based on testimony at a public meeting given by a representative of the International Sprout Growers Association, and taking into account statutory exemptions and out-of scope producers (Ref.53). We multiply the percent of farms that use groundwater sources (47 percent) to obtain the number of sprouts producers that would test their water once or quarterly, pending the results of their test. We use information from a 1998 survey of California sprout growers that reports that 74 percent respondents use municipal water as the source for growing sprouts and would not have to treat their water to satisfy the water quality criterion of no detectable generic E. coli per 100ml water sample, and that the remaining sprout growers reported using groundwater sources (Ref.53). We describe the costs of maintaining the required documentation for farms that use water from a public source in the section entitled "Agricultural Water Recordkeeping

Costs." The testing and sampling costs for covered farms that use surface and groundwater sources for uses subject to the proposed 0 detectable E. coli standard are reported in Table 46.

Table 46: Costs of the water sampling and testing requirements for water subject to the proposed 0 detectable *E*. coli standard

	Number of farms	**Percent municipal water supply**	**Costs**
Cost per sample			$87.30
Produce farms that use surface water sources for post-harvest uses that would treat their water directly rather than incur any sampling and testing costs	21,463		0
Produce farms that use groundwater sources for hand-washing purposes during and after harvest and would test 2 times during the production season	19,033	26%	$2,455,106
25 percent of produce farms that use groundwater sources for post-harvest uses that would sample and test 1 time and then opt to treat	1,087	26%	$70,087
50 percent of produce farms that use groundwater sources during and after harvest that would sample and test 2 times	2,173	26%	$280,348
25 percent of produce farms that use groundwater sources during and after harvest that would sample and test 1 time and then switch wells and sample 2 more times (for a total of 3 times)	1,087	26%	$210,261
50 percent of sprouts producers who use groundwater that would sample and test 1 time	142	74%	$6,451
50 percent of sprouts producers who use groundwater that would sample and test quarterly	142	74%	$12,903
Total Testing Costs Gross of Current Rates of Practice	$3,035,155		
Cost per farm that would sample and test their water	$128		

To estimate the costs per size category for farms that use water in these operations and would be subject to the sampling and testing requirement we apply the same percent of all covered farms in each size category estimated from 2007 NASS Census of

Agriculture data to the total number of farms that would use groundwater for hand washing purposes. We then multiply the cost per farm reported in Table 46 by the number of farms estimated to incur sample collection and testing costs in each category. Per the discussion on current agricultural water use, the percentage of irrigated farms that are members of the CA and AZ LGMA, FTR, or CTFCF are assumed to incur 50 percent of the cost incurred by non-members from the proposed requirement to sample agricultural water. We assume the probability of double counting farms that use municipal water sources (accounted for in Table 46) and that also are members of one of the leafy greens marketing agreements the FTR or the CTFCF is low. The costs of the requirement to sample and test water for compliance with the 0 detectable E. coli standard by size category are reported in Table 47.

Table 47: Costs of the water sampling and testing requirements for compliance with the 0 detectable E. coli standard by farm size, including rates of current practice

	Very small	Small	Large
Number of covered produce farms that use water or ice in direct contact with covered produce for harvest, packing and holding operations, water for hand-washing during and after harvest, water or ice for direct contact with food-contact surfaces, water for treated agricultural teas and sprout producers that would test their water	15,589	2,762	5,044
Cost per year	$2,033,970	$354,262	$646,924
Rate of current practice	1.30%	0.06%	3.78%
Total Costs	$2,007,560	$354,042	$622,462
Total costs of the requirement	$2,984,064		

Water treatment costs to satisfy the proposed quality criteria of 235 MPN / 100 ml sample for agricultural water that is directly applied during the growing operation

The proposed rule requires that when water quality criteria are not met, the farm either use an effective method for treating the water and monitor the treatment at frequencies that ensure that the quality criteria are consistently satisfied, or must take certain corrective actions discussed in section VI.G.9 of this document. We estimate the number of acres and the quantity of agricultural water used in growing operations that would require farms to either treat or take other corrective actions by estimating the quantity of surface water that would fail to meet the proposed criteria using information from a survey of surface water qualities conducted by States and compiled by the EPA (Ref.58). We use 2007 NASS data on the average farm sizes of irrigated farms to estimate the number of farms that would choose to treat their agricultural water by farm size. We then estimate treatment costs per operation size for very small, small and large farms, multiply by the number of farms in the corresponding size category, and add them together to estimate the costs for meeting the proposed water quality criteria.

The estimated quantity of surface water used for agriculture that would not meet the proposed quality criteria

We use information from an EPA report to Congress on the qualities of national bodies of water (Ref.58) as well as data from FRIS on the fraction of on-farm sources of surface water used for irrigation to estimate the percentage of farms that use surface water that would fail either of the specific microbial quality criteria and therefore would require farms to treat their water unless an alternative water source were available. The EPA reports on findings from state regulatory bodies that 50.0 percent of stream-miles sampled were found to be impaired for their primary designated use, and that 6.6 percent of the stream-miles designated primarily for agriculture were found to be impaired The estimate of 6.6 percent impaired stream-miles may understate the extent of impairment of stream-miles used for agriculture if stream-miles designated primarily for uses other than agriculture are also used for agriculture as a secondary use. We estimate the percent of stream-miles designated primarily for uses other than agriculture that are also used secondarily for agriculture, and incorporate it into an upper estimate of the extent to which stream-miles for agriculture are impaired. Without additional information on the secondary uses of stream-miles that are primarily used for purposes other than agriculture, we use the midpoint of between 0 and 100 percent (50 percent) to estimate the percentage of stream-miles designated primarily for uses other than agriculture that are also used secondarily for agriculture. We ask for comment on the percent of stream-miles primarily designated for uses other than agriculture that are also secondarily used for agriculture.

High concentrations of pathogens were reported to be the primary cause of impairment in approximately 15.2 percent of the stream-miles sampled across all designated uses (Ref.58). The microbes assessed for this survey were based on EPA's recommended microbial standard for water used for purposes of recreation, hereafter referred to as EPA's microbial standard for water. 15.2 percent may understate the extent that stream-miles fail to meet EPA's microbial standard for water if that standard was not considered a cause of impairment for each designated use. Our low estimate is that 1.0 percent of stream-miles designated for use in agriculture may fail to meet EPA's microbial standard for water (6.6 percent of stream-miles for agriculture found to be impaired x 15.2 percent of all stream-miles found to fail EPA's microbial standard for water). We use the possibility that stream miles designated for primary uses other than agriculture are also used secondarily in agriculture as an upper bound, and that 3.8

percent of stream-miles used for agriculture may fail to meet EPA's microbial standard for water (15.2 percent of stream-miles for all designated uses found to fail EPA's microbial standard for water x 50 percent of all stream-miles sampled found to be impaired for their designated use x 50 percent of stream miles primarily designated for a use other than agriculture are also secondarily used in agriculture). In our estimates of the quantity of surface water that would need to be treated, we use the midpoint of the range between 1.0 percent and 3.8 percent (2.4 percent) of stream-miles destined for agriculture would fail to meet EPA's microbial standard for water.

We do not have information on the extent to which lakes, ponds, and reservoirs fed by underground aquifers fail to meet EPA's microbial standard for water. Unlike the EPA-reported findings for rivers and streams, the reported causes of impairment for the designated uses of lakes, ponds, and reservoirs do not include "pathogens" as an indicator. Consequently, we model the likelihood of lakes, ponds and reservoirs being impaired for the designated use because of high concentrations of pathogens based on the estimate that rivers and streams were found to be impaired because of high concentrations of pathogens. We ask for comment on the use of high concentrations of pathogens in rivers and streams to model the concentrations of pathogens in lakes, ponds, and reservoirs.

Lakes, ponds and reservoirs are fed by underground aquifers or by surface waters such as rivers and streams. We estimate that those lakes, ponds, and reservoirs fed by rivers and streams that failed to meet EPA's microbial standard for water would also fail that water standard. However, lakes, ponds, and reservoirs fed by underground aquifers or from rivers and streams that meet EPA's microbial standard for water may also fail

EPA's microbial standard for water due to contaminated run-off from adjacent lands onto those lakes, ponds, or reservoirs or from contact with wildlife. We assume that the likelihood of underground aquifers as a source of contamination of lakes, ponds, and reservoirs is small. Consequently, we assume that between 1.0 percent and 3.8 percent, with a mid-point of 2.4 percent of all surface water bodies used for agriculture would have high concentrations of pathogens.

We acknowledge that this estimate may understate the extent to which surface water bodies fail to meet EPA's microbial standard for water because it does not incorporate the possibility that those bodies that are fed by underground aquifers may also fail EPA's microbial standard for water due to run-off from adjacent lands or from contact with wildlife. We acknowledge uncertainty in this estimate and ask for comment on the methodology used for estimating the extent to which surface water used in the production fails to meet EPA's microbial standard for water. The statistics used to estimate the extent to which surface water used for agriculture fails to meet EPA's microbial standard for water are reported in Table 48.

Table 48: Statistics derived from EPA Report to Congress[1]	
Percent of all stream-miles found to be impaired for any reason	50.0%
Percent all stream miles that fail EPA's microbial standard for water	15.2%
Percent of stream miles designated for agriculture impaired for any reason	6.6%
Percent of all stream miles designated for agriculture estimated to fail EPA's microbial standard for water (low estimate)[2]	1.0%
Percent of all stream miles designated for a non-agricultural use estimated to be also used for agriculture[3]	50.0%
Percent of all stream miles designated for a non-agricultural use but also used for agriculture estimated to fail EPA's microbial standard for water (high estimate)[4]	3.8%
Midpoint between stream-miles designated for agriculture and stream-miles designated for a non-agricultural use but also used for agriculture estimated to fail EPA's microbial standard for water	2.4%

[1]Information is from an EPA report to congress on the qualities of national bodies of water (Ref.58)

The quantity of agricultural water that would be treated due to the proposed quality criterion of 235 MPN generic *E*. coli per 100ml sample

In order to estimate the amount of surface water that would need to be treated because of its use as direct application method of irrigation water for covered produce other than sprouts, we use 2008 FRIS data to determine the number of produce acres that are irrigated with water from on-farm and off-farm surface water sources and multiply by 2.4 percent (the percent of surface water used for agriculture that is impaired due to high concentrations of pathogens). This estimate may overstate the number of acres irrigated with surface water that would fail EPA's standard for water if the application of irrigation water is not uniformly distributed across irrigated acreage. To obtain the number of acres that are subject to a direct application method, we multiply by the fraction of all acreage irrigated using a direct application method (46 percent of irrigated acreage), and then multiply by the fraction of the growing season when the covered produce would be present (75 percent of the growing season). This calculation yields an estimate of the number of produce acres for which farms may choose to comply with the proposed rule by using treated irrigation water. Using 2008 FRIS data we estimate a weighted average per-acre quantity of water applied using overhead spray and gravity based methods (2.16 acre-ft), and multiply by the estimated number of produce acres for which farms may choose to comply with the proposed rule by using treated irrigation water to obtain the estimated volume of irrigation water that may be treated be treated. We do not have detailed information that would allow us to estimate the fraction of these farms that would have to treat their water and we estimate the midpoint of between 0 and 100 percent (50 percent) of these farms would opt to treat their water and 50 percent would choose an alternative water source and would not have to treat their water. The parameters used to estimate the amount of irrigation water that would be treated are reported in Table 49.

Table 49: Parameters used to estimate the amount of irrigation water that would be treated to satisfy the 235 MPN per 100 ml proposed criterion	
2.4% acres irrigated with contaminated surface water	56,974
Fraction of acres irrigated using a direct application method	0.48
Fraction of growing season when produce is present	0.75
Acre-ft of water applied per acre using direct application method	2.16
Total acre-ft of water that would need to be treated	44,391
Fraction of farms that use contaminated surface water that would opt to treat	0.50

While there are currently no EPA-approved pesticides for treating irrigation water for the purposes described in this proposed rule, there are numerous EPA-registered antimicrobial pesticide products that bear a claim to control pest microorganisms that pose a threat to human health in drinking water. For purposes of estimating the costs for water treatment under this proposed rule, we assume that the differences between the costs of meeting currently defined standards including for drinking water and the proposed standard for agricultural water is negligible. We discuss how the costs for treatment (for other purposes) currently vary by technology and volume of water treated so that we can estimate treatment costs that would result if this proposed rule were to become final. We ask for comment on how treatment costs will vary across different irrigation technologies.

As described in the preamble, there are currently no EPA-approved water treatments that are available to consumers. For this reason, we have delayed the effective date of these water provisions for an additional two-year period; it is our belief that this will be sufficient time for evaluation and approval of mitigation means to treat agricultural water to conform with proposed produce safety rule requirements. For the purposes of this analysis, we will discuss and analyze several potential mitigations. It is important to note, however, that in the absence of an US EPA approved mitigation, farms without an alternate source of water would be required to draw on clean, public water or to stop irrigating their crops. Clearly, either of these alternatives would greatly increase the costs of this provision. We request comment on this provision, FDA's assumptions, and these estimates of costs.

There are a variety of technologies that might be used to treat water to the proposed microbiological standard. Each has its advantages and disadvantages reflected in the capital, operating, and maintenance requirements. In addition to the labor and material costs for irrigation water treatment, there may be a loss in productivity from residual sodium or calcium accumulation in the soil over time (Ref.59). We do not have data to estimate the costs due to any loss in soil productivity from physical or chemical changes in the soil composition that may result from treating irrigation water. We request comment on the likelihood and extent of any loss in soil productivity due to changes in the physical and chemical properties that may accompany irrigation water treatment due to this proposed rule.

Information on systems for treating irrigation water comes from a newsletter that targets greenhouse produce growers published by the Water Education Alliance (WEA) with the University of Florida (Ref.31), a slide presentation by an agricultural water treatment firm (Ref.60), Pulse Instruments, AquaPulse Systems, and from a report prepared for the US Armed Forces (Ref.61). There are many treatment technologies that are currently available and used by some in the industry. Treatment technologies described in a WEA newsletter include sodium hypochlorite, calcium hypochlorite, hypochlorous acid, and chlorine dioxide. Currently water treatment is used to improve flow consistency, clear irrigation emitters, prevent algal growth in irrigation systems, and prevent mineral deposits from forming in irrigation lines (Ref.31). Water treatment is also commonly used to address the risk of exposure to plant pathogens – especially when recycled water is used for irrigation (Ref.31).

All treatment technologies involve one-time costs and recurring costs. One-time costs may include injection equipment, monitoring equipment, and a tank of appropriate size where injection may take place. Some technologies, such as that described for treatment using chlorine dioxide may require a generator to produce liquid chlorine dioxide which is then injected directly into a the irrigation distribution system while other technologies such as calcium hypochlorite and sodium hypochlorite may rely on the introduction of tablets into a stock tank where the treatment solution is made prior to injection (Ref.31). The choice of technology would depend on the purpose for treatment, the volume of water to be treated, as well as other characteristics of the farm and distribution system.

One-time and recurring costs will vary by technology and the volume of water treated. For example, a newsletter targeting greenhouse horticultural operators, reports recurring treatment costs to be $1 per 1,000 gallons of treated water using hypochlorous acid technology, $1.66 per 1,000 gallons treated water using chlorine dioxide technology that relies on tablets dissolved in a stock tank prior to introduction into the irrigation system, and $0.25 per 1,000 gallons treated water using liquid chlorine dioxide that is generated on-site and injected continuously into the irrigation system (Ref.31). Moreover, a manufacturer of the liquid chlorine dioxide treatment technology reports treatment costs using on-site generation of approximately $98 per million gallons of treated water, or $0.098 per 1,000 gallons of treated water (Ref.60). The latter treatment cost estimates are based on a technology that requires on-site liquid chlorine dioxide generation, and are a small fraction of those that would be incurred using the same disinfectant but without requiring the capital costs associated with on-site generation. The difference between the treatment costs per 1,000 gallons treated reflects the degree to which there are economies of scale in the volume of water treated.

We use the low estimate of $0.098 per 1,000 gallons treated water for large farms and the high estimate of $1.66 per 1,000 gallons reported previously for the hypochlorous acid technology for very small farms. We expect that farms would adopt various treatment technologies at rates we cannot predict, and we take the midpoint of the range between $0.098 and $1.66 ($0.88) for 1,000 gallons treated to estimate treatment costs for small farms. Using the conversion factor of 1 million gallons = 3.07 acre-ft, we convert these costs to units of acre-ft and estimate that treatment costs for very small farms would be $543 per acre-ft ($1,666 per million gallons treated / 3.07 million gallons per acre-ft), treatment costs for small farms would be $289 per acre-ft ($880 per million gallons treated / 3.07 acre ft per million gallons), and treatment costs for large farms would be $31.92 per acre-foot ($98 per million gallons treated / 3.07 acre ft per million gallons). These recurring treatment cost estimates do not fully account for the rental rates associated with the one-time capital costs for the corresponding treatment technologies. However, one-time capital costs for water treatment technologies are estimated and reported in the section entitled “Water treatment costs for uses subject to the proposed quality criterion of no detectable generic *E*. coli,” to avoid double counting the one-time capital costs of water treatment.

We estimate the number of acres for which treated irrigation water may be used by farm size category by multiplying the total acreage for which treated water may be used by the fraction of irrigated produce acres in each size category derived from data from the 2007 NASS Census of Agriculture. We estimate the total acre-ft that might be treated by farm size by multiplying the fraction of total acreage by farm size by then total amount of acre-ft that may be treated. We estimate the number of farms that would choose to treat their water by dividing the acreage for which treated irrigation water may be used in each size category by the average acres per irrigated farm in each size category using 2007 NASS data and multiplying by 50 percent to account for the possibility that an alternative water source exists. Per the previous discussion, related recommendations concerning water quality are made in the CA and AZ LGMA as well as the FTR and CTFC and we estimate that adherents to these requirements would incur 50 percent of the costs incurred by non-adherents associated with the proposed harvest water requirements. The treatment costs of the proposed water quality criteria by farm size are reported in Table 50.

Table 50: Surface water treatment costs by farm size, including rates of current practice

Farm Size	Very small	Small	Large
Acreage for which treated irrigation water may be used	5,174	4,641	47,826
Number of farms that have surface water that fails to meet EPA's microbial standard for water	176	36	77
50 percent of these farms that would choose to treat their surface water that fails to meet EPA's microbial standard for water	88	18	38
Total acre-ft of water that would be treated	1,992	1,787	18,416
Treatment costs per acre-ft	$543	$289	$32
Rate of current practice	1.30%	0.06%	3.78%
Total cost by farm size	$1,067,804	$516,098	$565,647
Total cost of treatment	$2,149,549		

Water treatment costs for uses subject to the proposed quality criterion of no detectable generic *E*. coli

The standard of no-detectable E. coli is consistent with microbial requirements in the current EPA drinking water standard. The costs of water treatment are estimated based on current technologies available to attain the microbial requirements in EPA's drinking water standard. We estimate that all farms that use surface water in harvest, packing, and holding operations, water that contacts food contact surfaces including as ice, for treated agricultural teas and for sprouts productions would opt to treat their water unless it comes from a municipal source. Farms that use surface water for hand washing purposes are assumed to be already using potable water for this purpose to comply with OSHA regulations. Per the discussion in the section entitled "Costs of the water sampling and testing requirements for farms that use water or ice in direct contact with covered produce for harvest, packing and holding operations, water for hand-washing during and after harvest, water or ice for direct contact with food-contact surfaces, water for treated agricultural teas, and also for sprouting operations" we estimate that 25 percent of farms that use groundwater for harvest, packing, and holding operations, including for ice and hand washing and for sprouts production would opt to treat their water pending the results of their testing. We assume that no farms would incur costs to treat the water they use for hand-washing during and after harvest since they would already be in compliance with OSHA regulations.

We do not have information on the number of farms that use water for agricultural teas and would opt to treat water used for that purpose or the number of farms that use water that contacts food contact surfaces for direct contact with produce or food-contact surfaces and would opt to treat the water used for those purpose. We assume that the number of farms that apply agricultural teas for direct contact with produce or food-contact surfaces and would opt to treat is included in the number of farms that would opt to treat their water for purposes of meeting the agricultural water criterion for direct application during growing operations estimated above in the section entitled “Costs of the water sampling and testing requirements for farms that directly apply surface water.” That estimate does not take into account the number of non-irrigated farms, and would not include non-irrigated farms that also apply agricultural teas for direct contact with produce or food-contact surfaces. We ask for comment on the number of non-irrigated farms that also apply agricultural teas for direct contact with produce or food-contact surfaces.

We estimate all covered sprouts producers that use surface water and 50 percent of covered sprouts producers that use groundwater would have to treat the water they use for sprouts production using the same percentages of groundwater and surface water users as those reported earlier for farms that have harvest, packing and holding operations. We reported the estimate of the number of covered farms that apply water during harvest, packing and holding operations that would have to treat their water for these purposes as well as those that would not have to treat the water because it is obtained from a municipal source in the section entitled “Costs of the water sampling and testing requirements for farms that use water or ice in direct contact with covered produce for harvest, packing and holding operations, water for hand-washing during or after harvest, water or ice for direct contact with food-contact surfaces, water for treated agricultural teas, and also for sprouting operations.” The numbers of covered farms that would have to treat their water to meet the criterion of 0 detectable *E*. coli are reported in Table 51.

Table 51: Number of covered farms and sprout producers that would treat their water to meet the criterion of 0 detectable generic *E*. coli			
	Number of covered farms	Municipal Water Source (%)	Number of farms that would treat their water to meet the specified criterion
Covered produce farms that also have post-harvest operations	9,248		
Produce farms that use surface water sources (53 percent)	4,902	26%	3,627
25 percent of produce farms that use groundwater sources for post-harvest operations	1,087	26%	804
Covered sprout farms	289		
50 percent of sprout farms that use groundwater sources	142	74%	37
Total number of farms that would incur treatment costs	4,468		

We use one-time capital costs and recurring costs for chlorine dioxide technology reported in the WAE newsletter for operations that use approximately 1,500 gallons per day and 27,000 gallons per day to estimate the one-time and recurring treatment costs for very small and small farms that would need to treat their water for harvest, packing and holding operations. We use information from a report on the costs for water treatment technologies prepared for the US Army to estimate the one-time capital and operating costs for large farms, and to adjust the one-time capital cost estimates for very small and small farms to account for differences in the technologies that may be used (Ref.61). The WEA newsletter reports that a farm consuming 100,000 liters per day (approximately 27,000 gallons per day) would incur capital costs of $25,000 and annual operating costs of $2,500, using the chlorine dioxide technology while the capital and annual operating costs would be approximately $15,000 and $400, respectively, for a nursery that consumes approximately 1,500 gallons per day (Ref.31). A report prepared for the US

Army in 1998 reports one-time capital costs for sodium and calcium hypochlorite technologies both as approximately $2,500 with the recurring costs of approximately $10,000 and $15,000 respectively (Ref.61). We use the CPI deflator to report these one-time and recurring costs in 2010 dollars as $3,253 in one-time capital costs and recurring costs of $13,012 and $19,519 respectively.

We use the midpoint of the one-time capital costs of $3,253 and $15,000 ($9,126.50) to estimate the one-time capital costs for water treatment for very small harvest, packing, and holding operations that would need to satisfy the criterion of no detectable *E.* coli per 100 ml sample. We use the midpoint between $2,500 and $25,000 ($13,750) to estimate to the one-time capital costs for water treatment for small harvest, packing and holding operations that would need to satisfy the criterion of no detectable *E.* coli per 100 ml sample. We use the estimates of the annual operating costs reported in the WEA newsletter and above for very small and small harvest, packing or holding operations that would need to treat their water ($400 and $2,500 respectively), divide by 365 days in a year, and multiply by the number of days estimated to be in operation (45 days for very small operations, and 90 days for small operations).

To estimate the one-time capital and operating costs for large operations that harvest, pack or hold and would need to treat their water we use the average cost estimates reported in the US Army report for capital and operating costs for the on-site generation of sodium hypochlorite technology and calcium hypochlorite technology, (approximately $18,000 and $3,000 expressed as $23,422 and $3,904 in 2010 dollars by applying the CPI respectively for the sodium hypochlorite technology, and $2,500 and $14,600, expressed as $3,253 and $18,998 in 2010 dollars by applying the CPI for calcium hypochlorite technology). We do not include any opportunity cost of space that may be used by large operations for treating agricultural water and request comment on this assumption. Consequently, we estimate that one-time costs for large harvest, packing, or holding operations that would need to treat their water would incur one-time costs of $13,337.50 ($23,422 + $3,253 added together and divided by 2), and operating costs of $11,451 ($3,904 + 18,998 added together and divided by 2). We divide the annual operating costs by 365 days in a year, and multiply by the number of days estimated to be in operation (90 days for large operations). We ask for comment on the estimates for the one-time capital and operating costs that would be incurred by large farms.

Per the discussion on current agricultural water use, the percentage of irrigated farms that are members of the CA and AZ LGMA, FTR, or CTFCF are assumed to incur 50 percent of the cost incurred by non-members from the proposed requirement to sample agricultural water. We assume the probability of double counting facilities that use municipal water sources (accounted for in Table 51) and that also are members of one of the leafy greens marketing agreements the FTR or the CTFCF is low.

Table 52: Costs of the proposed water quality criterion of no detectable generic E. coli per 100ml of water used in harvest, packing and holding operations, and including rates of current practice

Distributed across farm sizes	**very small**	**Small**	**Large**
Number of farms	2,726	554	1,189
One time capital costs	$9,127	$13,750	$13,337
Annualized capital costs (7 percent over 7 years)	$1,693	$2,551	$2,475
Reported operating costs	$400	$2,500	$11,451
Number of days in operation	45	90	90
Operating costs per year	$49	$616	$2,824
Rate of current practice	1.3%	0.1%	3.8%
Total costs by size category	$4,689,237	$1,753,115	$6,059,174
Total cost of the provision	$12,501,526		

Costs to establish and implement water management practices, conduct visual monitoring of water, and monitor water temperatures during harvest, packing and holding operations

The proposed rule also requires the establishment and implementation of water management practices to maintain adequate sanitary quality of water and minimize the potential for contamination of covered produce and food contact surfaces (including by establishing water change schedules), requires visual monitoring the quality of water used in these activities for build-up of organic matter (for example, in water used for dump tanks, flumes, cooling and other harvest, packing, and holding activities), and requires monitoring of water temperatures whenever appropriate to minimize the potential for infiltration of microorganisms. All three of these requirements are referred to collectively as establishing and implementing water management practices in this discussion and we assume that farms that use water for harvest, packing and holding operations would incur costs from this requirement. We ask for comment on the number of farms and growing operations that would incur costs from these requirements.

We use information from a 1999 survey on food safety practices to estimate that 46 percent of covered produce farms have post-harvest operations (Ref.6). From the previous discussion in the section entitled "Water treatment costs for uses subject to the proposed quality criterion of no detectable generic *E*. coli," we estimate that 50 percent of farms with post-harvest operations (the midpoint between 0 and 100 percent) use water in their harvest, packing, or holding operations and would be required to comply with these proposed requirements.

We estimate the amount of time required to establish and implement water management practices for harvest, packing, and holding operations using recordkeeping burdens for writing SOPs for environmental monitoring records by food manufacturers reported in the *Evaluation of Recordkeeping Costs for Food Manufacturers* (ERCFM) (Ref.16). The ERCFM reports these recordkeeping burdens as 7 hours, 12 hours, and 17 hours for small, medium, and large food manufacturing facilities, respectively. We apply these burdens to estimate the one-time burdens for establishing water management practices for very small, small, and large harvest, packing and holding operations.

We do not have information on the annual costs to implement the requirement to visually monitor the build-up of organic matter in water used for harvest, packing, and holding activities, as well as to monitor water temperatures whenever appropriate for operations that harvest, pack, or hold covered produce. We assume the great majority of the cost of implementing these practices would be in labor costs and estimate a recurring cost of 10 minutes per hour of operation. We ask for comment on this assumption and estimate. We estimate that very small farms would operate their harvest, packing, and holding operations 2 hours daily and small and large farms would operate their harvest, packing or holding operations 4 hours daily. Moreover, we estimate that very small farms would operate for 45 days per year during the harvest periods and small and large farms would operate 90 days per year during the harvest periods.

For large farms we use an hourly wage of $30.25, which is the mean hourly wage reported in 2010 BLS for first-line supervisors for farming of $20.55, multiplied by 1.5). For very small and small farms, we use an hourly wage of $41.40 which is the mean hourly wage for a farm operator reported in the BLS under the heading of Farmers, Ranchers, and Other Agricultural Managers working in the agriculture industry ($31.60) multiplied by 1.5 to account for overhead to estimate the hourly one-time cost of establishing water management practices.

Related recommendations concerning post-harvest water are made in the CA and AZ LGMA as well as the FTR and CTFC and we estimate that adherents to these requirements would incur 50 percent of the costs incurred by non-members associated with the proposed requirements to implement and establish water management practices. There may also be growers that adhere to similar requirements specified in other food safety programs not considered in this analysis. These latter considerations may result in an overestimate of the costs of the proposed requirements. We ask for comment on the magnitude of the effects of the requirements included in the CA and AZ LGMA, CTFC and the FTR as well as from other food safety programs on current industry practices. The cost of the requirement to establish and implement management practices for water used during harvest, packing and holding operations by farm size is reported in Table 53.

Table 53: **Establish and implement water management practices during harvest, packing, and holding operations, and including rates of current practice**

	Very small	small	large
Number of affected farms	6,198	1,079	1,971
One-time costs of establishing practices	$332	$569	$524
Annualized one-time costs (7% over 7 years)	$62	$106	$97
Daily cost of implementation	$8	$10	$10
Number of days of operation	45	90	90
Total costs per farm	$417	$1,030	$1,022
Rate of current practice	1.3%	0.1%	3.8%
Total cost per size category	$2,551,300	$1,093,199	$1,902,877
Total cost of the requirement	**$5,547,376**		

A summary of the total costs of the agricultural water provisions are reported in Table 54.

Table 54: Summary of the costs of the agricultural water provisions, excluding recordkeeping

Description	Very small	Small	Large
Inspection and maintenance of agricultural water sources	$11,869,172	$2,441,242	$3,220,538
Water sampling and testing surface water used for direct application irrigation water other than for sprouts	$5,269,349	$929,274	$1,633,809
Water sampling and testing for farms that use water or ice in direct contact with covered produce or food contact surfaces, for harvest, packing and holding operations, water for hand-washing during and after harvest, water for treated agricultural teas, and also for sprouting operations	$2,007,560	$354,042	$622,462
Water treatment to meet quality criteria of 235 MPN / 100ml	$1,067,804	$516,098	$565,647
Water treatment to meet quality criteria of no detectable E. coli	$4,689,237	$1,753,115	$6,059,174
Establish and implement water management practices for harvest, packing, and holding operations	$2,551,300	$1,093,199	$1,902,877
Total cost by size category	$27,454,421	$7,086,971	$14,004,506
Total cost of the agricultural water provisions	$48,545,899		

Agricultural water recordkeeping costs

The proposed documentation requirements include the water system inspection findings, analytic test results, the results of water treatment monitoring, and documentation from a public water supplier if applicable. In addition, if applicable, documentation is required for any scientific data that support an alternative to the proposed water quality requirement for direct application irrigation water for covered produce other than sprouts, or to support the adequacy of a farm's water treatment method.

We use the recordkeeping burdens reported in the ERCFM (Ref.16), as a framework for estimating the paperwork burden of the proposed agricultural water controls. For very small and small facilities, we value the recordkeeping burden by the farm operator or manager mean wage rate described in the section entitled “Economic Analysis Costs: Overview of Cost Conventions and Farms Covered” of $47.40 to estimate the hourly costs. For large facilities we use the mean Farm Supervisor Mean Wage Rate described in the section entitled “Economic Analysis Costs: Overview of Cost Conventions and Farms Covered” of $30.26 to estimate the hourly costs.

All farms would be subject to the recordkeeping burden associated with the requirement to inspect agricultural water sources and distribution systems under the farm’s control. We assume that the costs from this requirement would be incurred by irrigated farms. We estimate that the burden includes the time to record observations during an inspection as well as the burden for developing an inspection form to be filled out prior to the inspection. We estimate the recordkeeping burden for inspecting water sources and distribution and delivery systems to be approximately 7.5 minutes (the midpoint of the reported range of 3 and 12 minutes for environmental monitoring records). We estimate the burden for sampling and testing records to be approximately 9 minutes (the midpoint of the reported range of between 5 and 13 minutes for sampling and testing records). We estimate the burden for recording the analytic results of the water samples taken during an inspection to be approximately 10.5 minutes (the midpoint of the reported range of between 6 and 15 minutes for analytic testing records). Similarly, we estimate the burden for maintaining the required documentation for water from a public source to be approximately 10.5 minutes. We assume that the burden for developing an inspection form is approximately 30 minutes.

Farms that use untreated surface water for direct application during growing to covered produce other than sprouts would incur the burden for filling out labels for sample collection equipment and shipping materials of 9 minutes, and the burden for recording the analytic results of water samples taken during an inspection of 10.5 minutes. These include farms that would test their agricultural water weekly, farms that would test their water monthly, and farms that would test once and then opt to treat for the remainder of the production cycle. .

Farms that directly apply water or ice directly to covered produce at or after harvest, that use water to make treated agricultural teas, that use water or ice to contact food contact surfaces, that use water for hand-washing during and after harvest, and produce sprouts for human consumption would also incur a burden for filling out labels for sample collection equipment and shipping materials of 9 minutes, and the burden for recording the analytic results of water samples taken during an inspection of 10.5 minutes. The annual burden for this requirement is reported in Table 55.

Farms that opt to treat their agricultural water would need to document their monitoring of that treatment to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use. Farms that use untreated surface water for irrigation of covered produce other than sprouts using a direct application method whose untreated water fails to meet the relevant quality standard would choose to treat their water and therefore incur this burden. Farms that that use water or ice in direct contact with covered produce for harvest, packing and holding operations, water for hand-washing during and after harvest, water for treated agricultural teas, and also for sprouting operations whose untreated water fails to meet the relevant quality standard and in the absence of effective corrective actions would also choose to treat their water and therefore incur this burden.

The number of farms that would choose to treat and monitor their treatment is reported in Table 55. We estimate this annual burden to be approximately 29 minutes (the midpoint of the reported range of between 10 minutes and 48 minutes for process validation records), and that the burden for developing a form that is used for recording the monitoring information for each event is approximately 15 minutes.

Findings from the New England survey of produce growers report that 41 percent of respondents keep records of water testing results (Ref.7) and we apply that percentage to the recordkeeping burdens for water sampling and analysis. The parameters used to estimate the per-activity annual burdens are reported in Table 55.

Table 55: Recordkeeping burdens and current rates of industry practice						
Documentation Requirement	Per-activity hourly burden	Annual frequency per farm	Average annual hourly burden per farm	Number of farms	Rate of current practice[1]	Annual burden net of current practice
112.50 (b)(1) Findings of the ag water inspection	0.80	6	4.8	27,248	0.03	126,866
§112.50 (b)(5) Sampling and analytic test results for farms directly applying surface water and test 1 x and opt to treat	0.33	1	0.33	289	0.41	55
§112.50 (b)(5) Sampling and analytic test results for farms directly applying surface water and test weekly	0.33	26	8.45	3,573	0.41	17,814
§112.50 (b)(5) Sampling and analytic test results for farms directly applying surface water and test monthly	0.33	6	1.95	3,573	0.41	4,111
§112.50 (b)(5) Sampling and analytic test results for farms using groundwater for hand-washing used in harvest and post-harvest operations	0.33	2	0.65	14,085	26%	6,775
§112.50 (b)(5) 25 percent of produce farms that use groundwater sources for harvest and post-harvest that would sample and test 1 time and then opt to treat	0.33	1	0.33	804	26%	193
§112.50 (b)(5) 50 percent of produce farms that use groundwater sources for harvest and post-harvest uses that would sample and test 2 times	0.33	2	0.65	1,608	26%	774
§112.50 (b)(5) 25 percent of produce farms that use groundwater for harvest and post-harvest uses that would sample and test 1 time and then switch wells and sample 2 more times (for a total of 3 times)	0.33	3	0.98	804	26%	580
§112.50 (b)(5) 50 percent of sprout producers who use	0.33	1	0.33	142	74%	6

groundwater that would sample and test 1 time						
§112.50 (b)(5) 50 percent of sprout producers who use groundwater that would sample and test quarterly	0.33	4	1.30	142	74%	23
§112.50 (b)(5) farms required to document water from a public source	0.33	1	0.33	5,052	0%	1,642
§112.50 (b)(4) Monitoring water treatment, and scientific data to support adequacy of the method for farms that use surface water in a direct application and opt to treat	0.98	1	0.98	289	0%	284
§112.50 (b)(4) Monitoring water treatment, and scientific data to support adequacy of the method for farms that use water or ice in direct contact with covered produce or food contact surfaces, for harvest, packing and holding operations, water for hand-washing during and after harvest, water for treated agricultural teas, and also for sprouting operations and would opt to treat	0.98	1	0.98	4,468	0%	4,394
Total recordkeeping burden for the water provision				62,078		163,500

We distribute the recordkeeping costs for the agricultural water provisions across farm size categories by multiplying the annual burden net of current practice reported in Table 55 by the number of farms reported to incur that burden, and then by the wage that corresponds to each farm size described earlier in this section. The distribution of recordkeeping costs across farm sizes are reported in Table 56 below.

Table 56: The Recordkeeping Costs by Farm Size Categories			
	Cost for very small farms	Cost for small farms	Cost for large farms
112.50 (b)(1) Findings of the ag water inspection	$4,029,846	$701,888	$833,666
§112.50 (b)(5) Sampling and analytic test results for farms directly applying surface water and test 1 x and opt to treat	$1,758	$306	$364
§112.50 (b)(5) Sampling and analytic test results for farms directly applying surface water and test weekly	$565,858	$98,557	$117,061
§112.50 (b)(5) Sampling and analytic test results for farms directly applying surface water and test monthly	$130,583	$22,744	$27,014
§112.50 (b)(5) Sampling and analytic test results for farms using groundwater for hand-washing used in harvest and post-harvest operations	$215,193	$37,481	$44,518
§112.50 (b)(5) 25 percent of produce farms that use groundwater sources for harvest and post-harvest that would sample and test 1 time and then opt to treat	$6,143	$1,070	$1,271
§112.50 (b)(5) 50 percent of produce farms that use groundwater sources for harvest and post-harvest uses that would sample and test 2 times	$24,573	$4,280	$5,083
§112.50 (b)(5) 25 percent of produce farms that use groundwater for harvest and post-harvest uses that would sample and test 1 time and then switch wells and sample 2 more times (for a total of 3 times)	$18,430	$3,210	$3,813
§112.50 (b)(5) 50 percent of sprout producers who use groundwater that would sample and test 1 time	$382	$67	$79
§112.50 (b)(5) 50 percent of sprout producers who use groundwater that would sample and test quarterly	$1,528	$266	$316
§112.50 (b)(5) farms required to document water from a public source	$52,157	$9,084	$10,790
§112.50 (b)(4) Monitoring water treatment, and scientific data to support adequacy of the method for farms that use surface water in a direct application and opt to treat	$9,018	$1,571	$1,866
§112.50 (b)(4) Monitoring water treatment, and scientific data to support adequacy of the method for farms that use	$139,571	$24,309	$28,873

water or ice in direct contact with covered produce or food contact surfaces, for harvest, packing and holding operations, water for hand-washing during and after harvest, water for treated agricultural teas, and also for sprouting operations and would opt to treat			
Total recordkeeping cost for the water provision by size category	**$5,195,040**	**$904,833**	**$1,074,714**
Total recordkeeping cost	**$7,174,586**		

3. Biological Soil Amendments of Animal Origin and Human Waste

This proposed rule establishes certain processes that are acceptable for treating biological soil amendments of animal origin if they are validated to meet listed microbial validation standards. Such treatments include chemical processes, physical processes, combinations of chemical and physical processes, and composting. Each type of treatment process is linked to application requirements that would need to be followed in using the treated biological soil amendment of animal origin to grow covered produce (including manner of application requirements and application intervals, as applicable). In addition, the proposed rule prescribes application requirements for untreated biological soil amendments of animal origin (both a manner of application requirement and a 9 month, and for certain situations, 0 day application intervals). As an example, raw manure is an untreated biological soil amendment of animal origin. The proposed rule also requires biological soil amendments of animal origin to must be handled, conveyed, and stored in a manner and location such that they do not become a potential source of contamination and in a manner and location that minimizes the risk that treated biological soil amendments of animal origin will become contaminated by an untreated or in-process biological soil amendment of animal origin. Contaminated biological soil amendments of animal origin must be handled, conveyed and stored as though they were untreated.

This proposed rule also prohibits the use of human waste for growing covered produce except sewage sludge biosolids used in accordance with relevant EPA regulations or equivalent regulatory requirements. Lastly, the proposed rule establishes recordkeeping requirements with respect to the use of biological soil amendments of animal origin.

Current Practices

The provisions of the proposed rule will affect any farm that applies biological soil amendments of animal origin or human waste to covered produce acres. Therefore, any farm that uses biological soil amendments of animal origin or human waste will incur compliance costs if any of these standards are not currently being met.

Farms estimated to use raw manure as a soil amendment

In order to estimate the number of farms that will be likely to substitute away from using untreated raw manure as a soil amendment, as well as the resulting costs, it is necessary to first estimate the number of farms that use raw manure and estimate the number of produce acres to which manure is applied. Table 57 presents the total number of produce farms that use manure, total number of acres to which manure is applied and total number of produce acres, by size.

Table 57—Number of Produce Farms and Percentage of Produce Acres by Size (Produce Acres) and Total Value of Production (TVP), Excluding Farms Growing Vegetables for Processing and Potatoes			
Farm Size	**Number of Produce Farms That Use Manure**	**Total Number of Produce Acres**	**Total Number of Manure Acres**
Very Small	2,748	56,441	112,987
Small	562	52,114	67,622
Large	1,128	440,882	392,407
Total	**4,438**	**549,437**	**573,016**

Using this data from the USDA's National Agricultural Statistics Service (NASS), the number of produce farms that use biological soil amendments or animal origin (a figure that does not include pre-consumer vegetative waste and yard waste, which are not biological soil amendments of animal origin) on produce acres must be estimated. According to the NASS, nearly 4,438 produce farms in the United States covered by this proposed rule reported using biological soil amendments of animal origin (specifically manure)[29]. However, this data does not indicate if the manure was applied directly to produce acres and does not indicate if the manure was treated.

In order to estimate the number of produce farms that currently apply biological soil amendments of animal origin to produce acres (specifically raw animal manure), it is necessary to examine different farming operations that use soil amendments. That is, it is necessary to divide the number of farms in Table 57 into three categories: produce farms that run livestock or poultry operations, organic farms, and other remaining produce

[29] Proposed §112.56(a)(1)(b) states that produce farms using untreated biological soil amendments of animal origin in a manner that does not contact covered produce during or after application face a minimum application requirement of 0 days. Therefore, the data analyzed in this section with respect to proposed §112.56(a)(1) do not include covered non-citrus tree crop farms or citrus farms estimated to use untreated manure, as it is estimated that any of these farms would not incur costs in order to meet the proposed requirement in §112.56(a)(1). These farms will continue to be subject to the general requirements of this Subpart, such as § 112.52; however, there are no costs estimated for this section as it is estimated that produce farms have practices that are already aligned with these requirements.

farms. Dividing produce farms into these three categories will aid in modeling costs related to soil amendment provisions.

Livestock and Produce Farms

It is estimated that produce farms that also raise livestock or poultry use their own manure as a soil amendment on produce acres. Using data from the 2007 Census of Agriculture, it is estimated that there are 2,829 farms covered by this proposed rule currently producing both livestock or poultry and fresh produce. It is estimated that these farms also use biological soil amendments of animal origin (manure) on the acres used for growing produce, however the data do not differentiate between manure used as a soil amendment for growing produce covered by this proposed rule or manure used as a soil amendment for growing some other commodity. For example, the untreated raw manure could be used on land used to grow wheat, soybeans or corn. However, this is not disaggregated in the data. Therefore, it is estimated that, if the number of produce acres in each size category is less than the number of manure acres in each size category, then it is estimated that all produce acres are applied with manure. As seen in Table 58, all produce acres are estimated to be applied with manure for covered produce farms that also have livestock or poultry. The Agency acknowledges the uncertainty in this estimation and requests comment on the estimated number of acres used for growing covered produce that are applied with manure.

Table 58-Livestock and Produce Farms by Size and Total Value of Production, With Estimated Produce Acres To Which Manure is Applied				
Acres	**Number of Farms**	**Manure Acres**	**Produce Acres**	**Estimated Manured Produce Acres**
Very Small	1,819	72,090	29,036	29,036
Small	354	39,233	23,882	23,882
Large	656	210,418	118,556	118,556
Totals	**2,829**	**321,741**	**171,474**	**171,474**

The data in the NASS do not include information on the number of farms or that use untreated manure, or the number of untreated manure acres, therefore, given the number of estimated acres to which manure is applied (which may either be treated or untreated) in Table 58, it is necessary to estimate the number of acres covered with untreated biological soil amendments of animal origin, including raw manure. The 1999 USDA Fruit and Vegetable Agricultural Practices (Ref.6) estimates that 25% of all fruit acres are covered with an untreated biological soil amendment and 3% of all vegetables are covered with an untreated biological soil amendment. It is not possible to disaggregate produce acres used for growing covered fruits from produce acres used for growing covered vegetables in the data. Therefore, the midpoint of these two percentages (14%) is applied to the number of estimated number of produce acres to which manure is applied to arrive at an estimated number of acres covered in untreated manure[30]. Subtracting the estimated number of untreated manure acres from the estimated number of total produce acres covered in manure provides the estimated number of acres covered in treated manure.

[30] The data also do not indicate the application interval of raw manure to acres used to grow covered produce. It is, therefore, estimated that the percent of acres to which manure is applied includes acres that have not had manure applied in conformance with the application intervals outlined in this proposed rule. Throughout the analysis, this estimation is applied also to the percentage of farms using untreated biological soil amendments of animal origin, including raw manure, and to all types of farms analyzed (livestock and produce farms, organic farms, and other produce farms). The Agency acknowledges the uncertainty in this estimation, and requests comment.

Table 59--Estimated Number of Produce Acres to Which Biological Soil Amendments of Animal Origin, including Manure is Applied on Livestock and Produce Farms, Untreated and Treated				
Acres	**Number of Farms**	**Estimated Total Manured Produce Acres**	**Estimated Number of Untreated Manure Acres**	**Estimated Number of Treated Manure Acres**
Very Small	1,819	29,036	4,065	24,971
Small	354	23,882	3,344	20,539
Large	656	118,556	16,598	101,958
Totals	**2,829**	**171,474**	**24,006**	**147,468**

The number of produce and livestock farms using untreated manure is estimated in a similar way. According to the USDA's Fruit and Vegetable Agricultural Practices survey (Ref.6), 22% of all fruit farms do not use treated manure as a soil amendment and 15% of all vegetable farms do not use treated manure as a soil amendment. Again, it is not possible to disaggregate produce acres used for growing covered fruits from produce acres used for growing covered vegetables in the data so the midpoint of these two percentages (18.5%) is used to estimate the number of covered produce farms using untreated manure.

Table 60—Estimated Number of Livestock and Produce Farms Using Biological Soil Amendments of Animal Origin, Including Manure, Untreated and Treated			
Acres	**Number of Farms with Manured Produce Acres**	**Estimated Number of Farms Using Untreated Manure**	**Estimated Number of Farms Using Treated Manure**
Very Small	1,819	337	1,483
Small	354	66	289
Large	656	121	534
Totals	**2,829**	**524**	**2,306**

Therefore, as a result of the provisions in this proposed rule, 524 livestock and produce farms that are estimated to use raw manure as a soil amendment will incur costs to conform to the application requirements of this proposed rule, or switch to another soil amendment with lesser application restrictions, such as compost (referred to in the preamble as "humus"). To the extent that the other 2,306 farms may already conform to some, but not all, of the requirements of this subpart, they will also incur costs to comply with this proposed rule. The Agency requests comment on current practices related to the use of untreated biological soil amendments of animal origin, including raw manure.

Table 61 combines data from Tables 59 and 60 in order to present the average number of untreated manure acres per farm. Over all estimated covered produce farms using untreated manure, the average number of untreated manure acres is just over 45.

Table 61--Number of Livestock and Produce Farms Using Untreated Biological Soil Amendments of Animal Origin, including Manure, Including Untreated Acres to Which the Soil Amendment is Applied, and Average Acres Per Farm

Acres	Estimated Number of Farms Using Untreated Manure	Estimated Number of Untreated Manure Acres	Average Number of Untreated Manure Acres Per Farm
Very Small	337	4,065	12.08
Small	66	3,334	51.02
Large	121	16,598	136.87
Totals	**524**	**24,006**	**45.87**

Organic Farms

Organic farms typically use manure as part of regular farm soil fertilization programs. According to the USDA Organic Program (Ref.5) certified organic farmers are required to have a farm plan detailing the methods used in the application of manure or composted manure. Using information from the USDA Census of Agriculture (Ref.3), Table 62 presents the number of organic farms using green or animal waste.

Table 62—Organic Produce Farms Using Green or Biological Soil Amendments of Animal Origin, Including Manure By Farm Size				
Size		**Number of Manure Acres**	**Number of Produce Acres**	**Estimated Number of Manured Produce Acres**
Very Small	402	11,494	5,385	5,385
Small	55	5,336	4,489	4,489
Large	131	56,542	89,065	56,542
Totals	**588**	**73,371**	**98,940**	**66,416**

Source: USDA 2007 National Organic Survey

Employing the method applied to livestock and produce farms, it is estimated that 66,416 produce acres are those to which manure has been applied. The organic survey does not distinguish between farms that use green manure and those farms that use animal manure. Green manure is a crop that is grown then plowed into the soil or otherwise left to decompose for the purpose of soil improvement, such as clover, rye or soybeans. It is not the same as raw manure and is not affected by this proposed rule. Therefore, it is necessary to estimate the number of produce acres to which raw manure is applied, and where the application requirements of this rule are not being met, and the number of organic farms using raw manure and that are not already conforming to the application requirements of this proposed rule. Using the previous method, it is estimated that the farms using untreated manure are 18.5% of the total number of organic farms using manure and the number of produce acres to which untreated manure is applied is 14% of the total number of produce acres to which manure is applied. Table 63 presents the estimated number of organic produce farms applying untreated manure to produce acres, along with the estimated number of produce acres to which untreated manure is applied, derived from Table 61. It is estimated that 109 organic farms will incur costs in order to align soil amendment usage with the requirements of the proposed rule.

Table 63—Organic Produce Farms Estimated to Use Untreated Biological Soil Amendments of Animal Origin, including Manure, By Size and Number of Estimated Produce Acres to which Untreated Biological Soil Amendments of Animal Origin, including Manure is Applied			
Size	Estimated Number of Organic Farms Using Untreated Manure	Estimated Number of Organic Produce Acres Covered in Untreated Manure	Average Number of Untreated Manure Acres Per Farm
Very Small	74	754	10.13
Small	10	629	62.14
Large	24	7,916	326.76
Totals	**109**	**9,298**	**85.51**

Other Farming Operations

Other farms that are neither livestock producers nor organic farms but who also grow produce and use biological soil amendments of animal origin, including manure comprise the last category of farms estimated to use manure. These farms are estimated, for each size category, taking the difference between total produce farms (Table 57) that use manure and the estimated number of Livestock/Manure farms using manure (Table 58) and organic farms (Table 61).   Thus, there are a remaining 1,021 produce farms are currently using manure on 263,072 acres of manured produce land. To estimate the number of farms applied untreated manure to produce acres, 1,021 is multiplied by 18.5%. Therefore, 1,021 x .185 = 188 farms are estimated to use untreated manure on 36,830 produce acres (263,072 remaining manure acres x .14 = 36,830 untreated manure produce acres).

Table 64—Estimated Remaining Farms Using Biological Soil Amendments of Animal Origin, Including Manure					
Size	Number of Other Farms Using Manure	Estimated Number of Farms Using Untreated Manure	Estimated Number of Remaining Manured Acres	Estimated Number of Remaining Untreated Manure Acres	Average Number of Untreated Manure Acres Per Remaining Farms
Very Small	527	97	22,020	3,083	31.64
Small	153	28	23,742	3,324	117.38
Large	342	63	217,310	30,423	481.50
Totals	**1,021**	**188**	**263,072**	**36,830**	**195**

Therefore, it is estimated that there are 820 (523 livestock/manure farms + 109 organic farms+ 188 other farms = 820) produce farms that will have to change practices related to the use of soil amendments as a result of this proposed rule.

Costs Related to Soil Amendment Usage Requirements of this Subpart

For these farms estimated to currently use untreated raw manure, it is estimated that they will switch to the lowest cost alternative in order to meet the requirements of this proposed rule.[31] Costs are estimated for switching from raw manure to either purchased compost or fertilizer, or implementing a 9 month waiting period from application of raw manure to harvest.[32] These costs are then applied to each of the three

[31] The Agency acknowledges this may be an oversimplification. Regional soil differences, location of composters, and other variables may influence a grower's decision regarding choice of soil amendment. The Agency requests comment on these variables and how they may influence a grower's choice of soil amendment.

[32] It is estimated that there are no costs associated with the application period of 0 days for the untreated biological soil amendments of animal origin when applied in a manner that does not contact covered

types of farms evaluated in this analysis (livestock/produce farms, organic farms, and other produce farms) and farms that use other untreated biological soil amendments of animal origin, such as untreated non-fecal animal by-products, and farms that use untreated human waste [33]to determine total and average costs related to this subpart by farm size. In addition to the three different cost scenarios, the costs of producing compost is estimated for livestock/produce farms only and are discussed in the section on livestock/produce costs. It is estimated that farms in each category will opt for the lowest cost alternative. We seek comment on our assumptions related farms opting for alternatives.

Costs of purchasing and applying synthetic fertilizers instead of manure

The cost of switching from using manure on produce acres is estimated as the purchase and application costs of synthetic fertilizer on produce acres. The costs of fertilizer for produce farmers range between $0.51 and to $.92 per pound of Nitrogen, about $.94 per pound of Phosphorus, and about $.92 per pound of Potassium (Schupska 2008)[34]. Using target nutrient requirements of Nitrogen=110 lbs, Phosphorus= 50 lbs and Potassium= 150 lbs per acre and using the midpoint of $0.72 per pound of Nitrogen, the estimated material cost of using synthetic fertilizer instead of raw manure is about $264/acre ((110 x .72) + (50 x .94) + (150 x .92) = $264). The costs of application of

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produce during or after application. Furthermore, there are no costs to comply with the minimum application period of 45 days for compost when applied in a manner that minimizes contact with covered produce as it is estimated that current practices are aligned with this requirement. The Agency acknowledges the uncertainty in this estimation and requests comment on practices related to the application of compost.

[33] In this analysis, no U.S. farms are estimated to use untreated human waste, due to EPA's restrictions on this practice. However, to the extent that foreign farms may use untreated human waste as a soil amendment, they will incur costs to comply with the requirements of this rule. We have no information on the extent of this practice on foreign farms, and the costs have not been quantified.

[34] These costs are based on 2008 costs and adjusted for inflation.

synthetic fertilizer are $7.00 per acre and, depending on the number of affected acres to which manure is applied, the costs of hauling the raw manure away can range from ($4.39-$6.10) (Ref.62). The cost of switching from manure to synthetic fertilizer ranges from about $277 per acre for very small farms ($264 + $7 +$6.10) to about $276 per acre for small farms ($264 +$7 +$5.25) to about $275 per acre for large farms ($264 + $7 + $4.39), as shown in Table 65.[35]

Table 65-Costs per farm of switching from manure to synthetic fertilizer, by farm size		
Size	Cost of Fertilizer, per acre	Cost of Hauling Manure, Per Acre
Very Small	$271	$6.10
Small	$271	$5.25
Large	$271	$4.39

Costs of using commercially produced compost

To estimate the compost application rates needed to substitute for manure, we use a compost calculator from the Washington Organic Recycling Council (Ref.63). The compost cost model requires entering parameter estimates for soil organic matter (SOM%.= 3%) and other parameter estimates such as soil type, that would reasonably allow a target nutrient requirement of 110 lbs/acre for Nitrogen, 50 lbs/acre for Phosphorous and 150 lbs/acre of Potassium (Ref.64). Table 66 shows cost estimates for compost required varying by soil characteristics.

The costs of purchasing compost can vary according to the quality of the compost. Hughes and Dusault (Ref.65) estimate compost prices of $20 per ton. Depending on the distance travelled, delivery charges for compost can range between $3.78 and $4.48 per ton (Ref.65), therefore, the estimated average price for compost is about $25/ ton (including delivery costs). Thus, the total costs switching from manure to commercial compost is estimated at $25/ton and it is estimated that compost is applied to land using the same equipment used for spreading manure. Based on data available to the Agency, it is estimated that 5 tons of manure are used, per acre (Ref.66)[36].

Table 66-Costs per farm of switching from manure to purchased compost, by farm size.

Size	Cost of Compost Per Ton (5 tons/acre)	Cost of Hauling Manure, Per Acre
Very Small	$25	$6.10
Small	$25	$5.25
Large	$25	$4.39

Table 66 presents costs of switching from raw manure to compost for a given produce farm, by farm size. Calculations are presented in later tables.

Restricting raw manure application using a 9 month application interval

This subpart allows the use of untreated biological soil amendments of animal origin, including raw manure, in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application, with a minimum application interval of 9 months. Furthermore, for produce grown in which the manner of application does not contact covered produce during or after application (as with tree fruit, for example), the minimum application interval is 0 days. The proposed rule would allow farms to establish and use alternatives to the 9 month application interval under certain conditions, including that the farm has adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the 9 month application interval and would not increase the likelihood that the covered produce would be adulterated under section

[36] The Agency acknowledges that the amount of manure used can vary depending on environmental factors and crop grown. This estimate is intended to be an average and the Agency requests comments regarding the amount of manure used in the growing of covered produce.

402 of the FD&C Act. The costs of restricting the application of untreated biological soil amendments of animal origin, including raw manure, to 9 months or more before harvest are estimated as the opportunity costs of land, measured by the value of cash rents for agricultural land, minus a percentage of rent estimated to be recovered from rotating cover crops onto the land.

Data on of value of cash rents for all crops are available from USDA; however, these data do not separate out rents for fruits and vegetables. Data from the University of Georgia do separate vegetable rents from other crops. In Georgia, vegetable rents are, on average, 86% more than all other crops. This percentage will be used as a proxy for the value of rents of produce covered by this rule by applying that percentage to the data on average cash rent per acre from USDA.

For each state, the per acre cash rent is multiplied by the number of acres to which manure is applied in that state to calculate an average weighted cash rent per acre, per state. The sum of these amounts provides the estimated average cash rent per acre ($359). These estimates are presented in Table 67. The estimated opportunity cost of limiting raw manure application to every 9 months between application and harvest is based on this rent. Because the estimated average cash rent per acre is calculated as an annual average rent, a rent for a nine month time period must be calculated. Therefore, $359/52 weeks = $6.90 rent per week and $6.90 per week x 36 weeks = $249 average rent. It is estimated that 20% of this rent is recovered through the rotation of cover crops, such as alfalfa, onto land used to grow covered produce. Therefore, the average net rent is $199 per acre ($249 - $50 = $199). Table 67 presents the total average costs of limiting the interval for raw manure to 12 months between application and harvest, by farm size.

Table 67—Average Cash Rents, Per Acre, by State					
	Average cash rent per acre (all crops 2010)	Vegetable acre cash rent	weighted average cash rent/vegetable acre	Total Produce or manure acres	percent prod manure acres
AL	48	89.2032	0.23	3121.4	0.26%
AK		0	-	85.5	0.01%
AZ	160	297.344	12.15	49187	4.09%
AR	86	159.8224	0.56	4190.8	0.35%
CA	345	641.148	225.35	422961.8	35.15%
CO	62.5	116.15	1.62	16810	1.40%
CT		0	-	2982.7	0.25%
DE	66	122.6544	1.90	18663.4	1.55%
FL	43	79.9112	0.64	9584.6	0.80%
GA	80	148.672	3.03	24492.9	2.04%
HI		0	-	3126.8	0.26%
ID	132	245.3088	18.65	91471.1	7.60%
IL	169	314.0696	2.29	8756	0.73%
IN	141	262.0344	1.63	7471.3	0.62%
IA	176	327.0784	0.76	2778.4	0.23%
KS	50	92.92	0.07	957.4	0.08%
KY	103	191.4152	0.50	3143.7	0.26%
LA	74.5	138.4508	0.09	823.4	0.07%
ME		0	-	4751.8	0.39%
MD	65	120.796	1.41	14062.3	1.17%
MA		0	-	5583.8	0.46%
MI	80.5	149.6012	6.00	48230	4.01%
MN	121	224.8664	13.76	73629.4	6.12%
MS	87.5	162.61	0.54	3974.6	0.33%
MO	94	174.6896	1.06	7293	0.61%
MT	47	87.3448	0.09	1275.4	0.11%
NE	135	250.884	0.21	1030.3	0.09%
NV	125	232.3	0.17	859.5	0.07%
NH		0	-	1546.4	0.13%
NJ	55	102.212	0.57	6727.9	0.56%
NM	50	92.92	1.23	15961.6	1.33%
NY	56.5	104.9996	5.56	63762.5	5.30%
NC	63	117.0792	1.96	20096.9	1.67%
ND	46.5	86.4156	0.13	1789.7	0.15%
OH	101	187.6984	1.37	8774.6	0.73%
OK	28	52.0352	0.31	7085	0.59%
OR	137	254.6008	6.80	32130.6	2.67%
PA	56.5	104.9996	2.32	26532.2	2.20%
RI		0	-	450	0.04%
SC	63	117.0792	0.53	5497.8	0.46%
SD	71.5	132.8756	0.10	907.3	0.08%

TN	78	144.9552	0.17	1437.4	0.12%
TX	36	66.9024	0.92	16503.2	1.37%
UT	173	321.5032	0.53	1971.1	0.16%
VT		0	-	1445.5	0.12%
VA	45	83.628	0.56	7991.6	0.66%
WA	245	455.308	35.13	92851.2	7.72%
WV	32	59.4688	0.10	2013.6	0.17%
WI	92	170.9728	8.01	56381.3	4.69%
WY	31	57.6104	0.01	196.3	0.02%
			359.00	1,203,352	1

Table 68—Average Cost of Limiting the Interval Between Raw Manure Application and Harvest to 12 Months, by Farm Size			
Farm Size	Average rent per acre	Estimated Recovered Rent	Estimated Average Net Rent
Very Small	$249	$50	$199
Small	$249	$50	$199
Large	$249	$50	$199

Costs to Livestock / Produce Farms

The costs of restricting the use of untreated biological soil amendments of animal origin, including raw manure, as a soil amendment for fresh produce crops can include: the costs of setting up an on-farm composting operation, switching from raw manure to purchased compost, switching from raw manure to synthetic fertilizer, or limiting the interval between manure application and harvest to 9 months.

Cost of producing compost

The costs of producing compost are estimated in this section as it is estimated that this option is only available to livestock/produce farms. Very little data are available addressing the costs of starting an on-farm composting operation. However, hypothetical data on setting up an equine composting operation are available (Ref.67). It is estimated that these hypothetical costs are comparable to those incurred when setting up a composting operation on a livestock/produce farm. The Agency invites comments on the costs of setting up a composting operation. Table 69 presents the hypothetical costs. For each scenario, annual fixed and annual variable costs are presented, along with capital expenditures. Capital expenditures are incurred in the first year only.

In the data, the number of tons of manure produced annually is 12 tons per animal (it is estimated this is comparable to the amount produced by cattle; this estimation would decrease with animal size) annually and compost produced is estimated to be 75% of generated manure. For example, for a composting operation with five large animals, the estimated number of tons of manure is 60 (5 animals x 12 tons of manure/animal = 60) and the estimated number of tons of compost produced is 45 (60 tons of manure x .75 = 45 tons of compost). For the same farm with five large animals, the average first year cost of producing compost is $5,475/45 = $122 per ton of compost and the average annual cost of producing compost is $4,350/45 = $96 per ton of compost. These calculations are performed for the other potential compost operation sizes in Table 69, and a midpoint is derived from these ranges of costs. The midpoint of average annual costs is $45 per ton of compost and the midpoint of average first-year costs is $65 per ton. These midpoints are used to calculate average costs of starting up a composting operation for livestock/produce firms.

Table 69--Sample Costs of Starting and Operating an On Farm Composting Operation, by Number of Animals

Number of Animals	Manure Produced (Tons)	Total Capital Expenditure	Total Annual Fixed	Total Annual Variable	**Total Annual Costs**	**Total First Year**	Compost Produced Per Year	**Cost Per Ton of Compost**	**Cost Per Ton of Compost**

			Cost	Costs		**Costs**		**(Annual)**	**(First Year)**
5	60	$1,125	$50	$4,300	$4,350	$5,475	45	**$96**	**$122**
20	240	$3,125	$150	$7610	$7,760	$10,885	180	**$42**	**$60**
40	480	$6,895	$985	$8,970	$9,955	$16,850	360	**$25**	**$47**
75	900	$3,125	$150	$12,429	$12,579	$15,704	675	**$18**	**$23**
Midpoint								**$45**	**$65**

Tables 70 and 71 present the average first year cost of compost production and average annual cost of compost production, respectively, by farm size. The average costs are calculated assuming 5 tons of compost is needed for every produce acre. For example, for small farms, the average first year cost is $7,020 (12 average untreated manure acres x 5 tons of compost needed per acre = 60 required tons of compost and 60 required tons of compost x $65/ton of compost = $3,900).

Table 70—Cost of Compost Production in the First Year, by Livestock/Produce Farm Size			
Farm Size	**Average Untreated Manured Produce Acres**	**Average Cost of Compost Production Per Ton of Compost**	**Total Average Cost**
Very Small	12.08	$65	$3,925
Small	51.02	$65	$16,581
Large	136.87	$65	$44,482

Table 71—Annual Cost of Compost Production, by Livestock/Produce Farm Size			
	Average Untreated Manured Produce Acres	**Average Cost of Compost Production Per Ton of Manure**	**Total Average Cost**
Very Small	12.08	$45	$2,717
Small	51.02	$45	$11,479
Large	136.87	$45	$30,795

Total costs of this subpart livestock/produce farms are estimated as the minimum cost alternative that is applicable by farm size and is added together. For example, for all livestock/produce farms that have been using untreated biological soil amendments of animal origin, including raw manure, the least cost alternative is purchasing compost.

Table 72 presents all cost alternatives, by farm size, and Table 73 presents the least cost alternatives for each farm size, for livestock/produce farms. The total cost of switching away from untreated biological soil amendments of animal origin, including raw manure, for covered farms with livestock and produce, is estimated to be about $3 million.

Table 72—Livestock Produce Farm cost comparison of soil amendment options and 9 month interval between application and harvest

	Number of Farms with Livestock and Produce Production	Costs Per Farm of Purchasing Compost and Hauling Manure	Cost Per Farm of Producing Compost	Cost Per Farm of Using Synthetic Fertilizer and Hauling Manure	Cost Per Farm of 9 month restriction between manure application and harvest ($199/acre x average acres)
Very Small	337	$1,583.46	$3974	$3,346	$2,404
Small	66	$6,645	$15,748	$14,081	$10,152
Large	121	$17,250	$40,214	$37,638	$27,237

Table 73 -- Total Costs for Livestock/Produce Farms to Switch to Commercial Compost

Farm Size	Number of Farms with Livestock and Produce Production	Cost Per Farm of Purchasing Compost and Hauling Manure	Total Costs
Very Small	337	$1,573	$533,625
Small	66	$6,645	$438,570
Large	121	$17,250	$2,087,204
	524		**$3,059,398**

Costs to Organic Produce Farms

Costs incurred by organic produce farms are estimated the same way as for livestock/produce farms. However, the costs of producing compost are not estimated here because it is estimated that, without a source of manure, organic produce farms are unable to produce compost. Furthermore, the costs of switching to synthetic fertilizer are not estimated here due to the USDA's prohibition of the use of synthetic fertilizer in organic farming. Therefore, only the cost of purchasing compost and the cost of restricting the interval between raw manure application and harvest to 9 months are estimated here. Table 74 compares the costs of purchasing compost to the cost of restricting the interval between raw manure application and manure to 9 months, and Table 75 presents the estimated cost for organic farms to switching to commercial compost, about $1.2 million. We seek comment on our assumptions about how organic farms would respond to the proposed rule..

Table 74 - Costs to Organic farms of Switching to Compost or Restricting the Interval Between Raw Manure Application to Harvest to 9 Months

Farm Size	Number of Organic Farms Using Untreated Manure	Average number of untreated manure acres, per organic farm	Average cost per farm of Purchasing Compost ($25/ton)	Cost Per Farm of Restricting the Interval Between Application of Manure and Harvest to 9 months ($199/acre)
Very Small	74	10.13	$1,329	$2,017
Small	10	62.14	$8,094	$12,367
Large	24	327	$42,279	$65,024

Table 75--Total Costs to Organic Farms of Switching to Commercial Compost

Farm Size	Number of Organic Farms Using Untreated Manure	Average Cost Per Farm of Purchasing Compost ($25/ton)	Total Costs to Organic Farms
Very Small	74	$1,329	$98,313
Small	10	$8,094	$80,944
Large	24	$42,279	$1,014,692
Total			**$1,193,949**

Costs to Remaining Produce Farms

Finally, the costs of switching to synthetic fertilizer, purchasing commercial compost, or restricting the interval between raw manure applications to harvest to 9 months are estimated for remaining produce farms. As with organic farms, the costs of producing compost are not estimated here because these farms are not estimated to have an on-farm manure source.

According to the estimates in Table 76, the cost of switching to compost is lower for all remaining farms, regardless of size. Table 77 estimates the total average costs for all remaining farms, which are estimated to switch to commercial compost. Table 78 summarizes estimated costs for livestock/produce farms, organic farms and other produce farms of switching away from raw animal manure, and from the requirement to allow 9 months between application of raw manure and harvest.

Table 76--Costs to Remaining Farms of Switching to Commercial Compost, Fertilizer, or Restricting the Interval Between Raw Manure Application to Harvest to 9 Months

Farm Size	Number of Remaining Produce Farms	Average Cost of Switching to Compost ($25/ton)	Average Cost of Switching to Fertilizer	Average Cost of Restricting Interval between Raw Manure Application and Harvest to 9 Months ($199/acre)
Very Small	97	$4,145	$8,759	$6,292
Small	28	$15,296	$32,412	$23,370
Large	63	$62,399	$132,621	$95,969

Table 77-Total Averge Costs to Remaining Farms of Switching to Commercial Compost, Fertilizer, or Restricting the Interval Between Raw Manure Application to Harvest to 9 Months

Farm Size	Number of Remaining Produce Farms	Average Cost of Switching to Compost	TotalCost
Very Small	97	$4,145	$404,155
Small	28	$15,296	$432,952

Large	63	$62,399	$3,936,466
			$4,773,574

Table 78--Summary of Costs to Produce Farms Switching Away From Raw Manure to Commercial Compost, by Farm Size			
Farm Size	**Number of Farms**	**Total Cost**	**Average Cost Per Farm**
Very Small	508	$1,036,093	$2,040
Small	104	$952,466	$9,158
Large	208	$7,038,362	$33,838
Total	**820**	**$9,026,921**	**$11,008**

Microbial Standards for Soil Amendments

This proposed rule outlines acceptable processes for treating biological soil amendments of animal origin. They include any scientifically valid controlled physical, chemical, combination physical and chemical process, or composting that has been demonstrated to satisfy the applicable microbial standards in 112.55 for *Listeria monocytogenes*, *Salmonella*, *E coli* O157:H7, and/or fecal coliforms, as applicable. Growers of covered produce will comply with this requirement, and not be required to conduct any testing, if a scientifically sound treatment is used on a biological soil amendment of animal origin, for example, if the validated protocol is published in a peer-reviewed journal or made available by a trade association. It is estimated that such methods are widely available to growers; therefore, no testing costs are estimated for this requirement. The Agency acknowledges uncertainty in this estimation and requests comment on any costs that may be associated with the soil amendment treatment validation requirements in this proposed rule.

Recordkeeping

This proposed rule specifies the records covered produce farms must establish and keep regarding biological soil amendments of animal origin. For any biological soil amendments used in growing covered produce, produce farms must keep: 1) documentation of the date of application of any untreated biological soil amendment of animal origin or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil after application of the soil amendment; 2) for a treated biological soil amendment of animal origin received from a third party, documentation (such as a Certificate of Conformance) that: i) The process used to treat the biological soil amendment is a scientifically valid process that has been carried out with appropriate process monitoring; ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to satisfy the applicable microbial standard in § 112.55, including the results of such periodic verification testing; and iii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in-process biological soil amendment of animal origin; 3) For a treated biological soil amendment of animal origin growers produce for their own covered farms, documentation that process controls (for example, time, temperature and turnings) were achieved; 4) scientific data or information relied on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3); and 5) scientific data or information relied on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b).

Estimates of hourly burdens from recordkeeping area are partially taken from 'Evaluation of Recordkeeping Costs for Food Manufacturers' (Ref.16) and are presented in Table 79. Table 80 presents recordkeeping costs. For very small and small facilities, we value the recordkeeping burden by the mean hourly wage for a farm operator reported in the BLS under the heading of Farmers, Ranchers and Other Agricultural Managers ($47.40) multiplied by 1.5 to account for overhead, for a total of $71.10 per hour. For large farms, we use the mean hourly wage for first-line supervisors/managers of farming, fishing, and forestry workers ($30.26), multiplied by 1.5 to account for overhead, for a total wage of $45.39 per hour. We do not have information on the number of farms that would be required to adjust recordkeeping practices to comply with this rule; therefore, it is estimated that the number of farms that will incur costs to comply with the recordkeeping requirements is the same as those estimated to incur costs to adjust practices related to the use of biological soil amendments. The Agency acknowledges the uncertainty in these estimation and requests comment on the hourly burden of the recordkeeping requirements associated with soil amendments in addition to the estimated number of farms that will be required to change recordkeeping practices as a result of these requirements.

Table 79 – Recordkeeping Hourly Burden Per Farm, Soil Amendments

Provision	Very Small	Small	Large
§112.60(b)(1)- Documentation of the date of application of any untreated biological soil amendment of animal origin (inc. raw manure) or any biological soil amendment of animal origin treated by composting and date of harvest from growing area, except	.5	.5	.5

when covered produce does not contact the soil after application of the soil amendment			
§112.60(b)(2) - Certificate of Conformance documentation for soil amendments acquired from a third party	0	0	0
§112.60(b)(3)-For a treated biological soil amendment of animal origin produced for a grower's covered farms, documentation that process controls (time, temperature, etc) were achieved.	.5	.5	.5
Annual Burden Hours	1	1	1
One-Time Burdens			
§112.60(b)(4)-Scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54 (c)(3)	2	2	2
§112.60(b)(5)- Scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b)	2	2	2
One Time Burden Hours	4	4	4

This proposed rule requires growers of covered produce to document the date of application of any untreated biological soil amendment of animal origin, including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest from that growing area. It is estimated that this annual burden to be approximately 29 minutes, or .5 hour (the midpoint of the reported range of 10 minutes to 48 minutes for process validation records.

For soil amendments acquired from a third party, this proposed rule requires a Certificate of Conformance, or comparable documentation. A Certificate of Conformance is provided by a third party supplier, is typically printed on an invoice, and provides assurances that the material in question meets requirements of, for example, state regulations. This does not typically involve a third party audit. If it is the case that a third party supplier cannot provide a Certificate of Conformance, a grower must find a supplier that can provide such assurances in order to comply with this proposed rule. It is not known how common a business practice it is to provide such an assurance, but it is estimated that this search is at a negligible cost to growers, as third party suppliers have an incentive to provide such assurances as a general business practice. Therefore, there is no hourly burden estimated for this provision.

This proposed rule requires growers of covered produce to document, for a treated biological soil amendment of animal origin produced for a grower's covered farms, documentation that process controls (time, temperature, etc) were achieved. It is estimated that this annual burden to be approximately 29 minutes, or .5 hour (the midpoint of the reported range of 10 minutes to 48 minutes for process validation records.

This proposed rule requires that growers of covered produce keep scientific data or information relied on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54 (c)(3) and scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b). Because of variations in crops and geography it is possible that some growers adjusting soil amendment practices will seek to use alternative composting processes or alternative minimum application intervals. It is not known how many farms will do so, however, it is estimated that 50% of the farms estimated to have to adjust soil amendment practices will also seek to use alternative composting processes or minimum application intervals. It is estimated that such scientific data or information will require two hours of search and that this search represents a one-time burden to these growers. The Agency requests comment on the number of farms that may choose to use alternative composting methods or alternative application intervals.

Table 80—Estimated Recordkeeeping Costs Related to Subpart F			
Annual Recordkeeping Costs	**Very Small**	**Small**	**Large**
Number of Farms	508	104	208
Annual Hourly Burden	1	1	1
Hourly Cost Per Farm Size Category	$71.40	$71.40	$47.40
Total Cost Per Farm	$71.40	$71.40	$47.40
Total Annual Cost Per Size Category	$36,271	$7,426	$9,859
Total Annual Recordkeeping Costs	**$53,556**		
One Time Recordkeeping Costs	**Very Small**	**Small**	**Large**
Number of Farms	254	52	104
One Time Hourly Burden	2	2	2
Hourly Cost Per Farm Size Category	$71.40	$71.40	$47.40
Total Cost Per Farm	$142.80	$142.80	$94.80
Total One-Time Cost Per Size Category	$36,271	$7,426	$9,859
Total One-Time Recordkeeping Costs	**$53,556**		

Table 81-Total Costs of Subpart F						
Farm Size	**Number of Farms**	**Total Annual Non-Recordkeeping Cost**	**Total One-Time Recordkeeping Cost**	**Total Annual Recordkeeping Cost**	**Total Annual Cost**	**Average Cost Per Farm**
Very Small	508	$1,036,093	$36,271	$36,271	$1,108,635	$2,182
Small	104	$952,466	$7,426	$7,426	$1,037,318	$9,974
Large	208	$7,038,362	$9,859	$9,859	$7,058,080	$33,933
Total	**820**	**$9,026,921**	**$53,556**	**$53,556**	**$9,204,033**	**$11,224**

Table 81 presents total estimated costs associated with Subpart F. The total annual cost is estimated to be about $9.2 million, or about $11,000 per estimated affected farm, annually.

4. Domesticated and Wild Animals

The proposed animal controls include measures for farms that allow grazing or working animals in fields used to grow covered produce and requirements for farms to monitor for evidence of animal intrusion if there is a reasonable probability that working animals, grazing animals or animals intruding onto the farm would contaminate the covered produce. Farms that allow grazing or working animals in fields where covered produce is grown would be required to wait an adequate period of time between grazing and time to harvest if there is a reasonable probability that grazing or working animals would contaminate the covered produce. When working animals are used in fields where covered produce has been planted, farms would be required to take measures to prevent the known or reasonably foreseeable hazards into or onto covered produce if there is a reasonable probability that working animals would contaminate the covered produce. This section also addresses the requirements regarding domesticated animals in and around fully enclosed buildings covered by this proposed rule. Finally, in circumstances where there is a reasonable probability that animal intrusion will contaminate covered produce, the proposed rule would require monitoring areas that are at risk for animal intrusion as needed during the growing season and immediately prior to harvest, and, if animal intrusion occurs, evaluating whether the covered produce can be harvested in accordance with the requirements of this proposed rule.

Current Industry Practices

We estimate current rates of industry practice with the proposed provisions using a framework of adherence to the state-wide marketing agreements and regulations, the California and Arizona Leafy Greens Marketing Agreements (CA and AZ LGMA) and the Florida Tomato Rule (FTR) (Ref.11;Ref.12;Ref.13), . The CA AZ LGMA require that member growers develop a monitoring plan and monitor fields for animal intrusion prior to the season, before harvest, and at the time of harvest. Moreover, detailed descriptions of indicators of animal intrusion that must be monitored are made explicit in the marketing agreements (Ref.11;Ref.12). The FTR also has comprehensive requirements with regards to excluding livestock from fields, taking measures to minimize animal intrusion, and corrective actions when there is evidence of potential contamination due to animal intrusion (Ref.10). The numbers of growers that are members of the FTR and the CA and AZ LGMA were estimated earlier in the section entitled "Economic Analysis Costs: Overview of Cost Conventions and Farms Covered" and we estimate that these growers would incur no additional cost from the animal provisions of the proposed regulation.

Costs for monitoring for animal intrusion

The requirements of the proposed rule are to monitor covered areas as needed based on your experience and observations made during the season, and immediately prior to harvest if there is a reasonable probability that animal intrusion would contaminate the covered produce. We estimate that these farms will monitor 3 times per production season (once at the beginning of the season, once "as needed" during the season, and once immediately prior to harvest). We estimate an average of 2 production seasons per year based on data from the 2007 NASS Census of Agriculture (Ref.3).

We do not have information on the number of farms that would have to monitor for animal intrusion (or take the other steps described in this section 4) because of a reasonable probability that animals would contaminate the covered produce. For example, covered produce grown entirely underground may not face a reasonable probability of contamination by intruding animals. However, farms that grow such crops may also grow other covered produce crops on or above ground level which may face a reasonable probability of being contaminated if animals were to intrude. For purposes of this analysis we assume that field monitoring would be required of all covered produce farms. This may overstate the number of farms subject to monitoring requirements to the extent that there are farms where there is not a reasonable probability that intruding animals would contaminate the covered produce. We ask for comment on the number of farms that grow covered produce that would be subject to the monitoring requirements.

In Table 82 below, we report the numbers of produce farms by size category estimated from 2007 NASS Census of Agriculture and adjusted by the percentage of growers that would be members of the CA or AZ LGMA or FTR, as described in the section entitled "Economic Analysis Costs: Overview of Cost Conventions and Farms Covered". We use the estimates from a survey reported by Hardesty and Kusunose of the field monitoring costs incurred by grower operations in California's central coast region from membership in the CALGMA and other food safety programs to estimate the costs from the proposed requirements (Ref.8). Hardesty and Kusunose report findings of the costs incurred by leafy greens grower operations before (2006)-and-after (2007) becoming members of the CALGMA (Ref.8). They found the mean per-acre costs of monitoring for wildlife intrusion prior to becoming members in CA LGMA were approximately 55 percent of the monitoring costs that were incurred after they became members ($4.12 before becoming members versus $7.48 after becoming members), or an increase in $3.36 per acre.

The size distribution of grower operations reflected in the Hardesty and Kusunose report is not representative of growers nationwide. For example, in the survey reported by Hardesty and Kusunose, approximately 80 percent of the respondents reported gross revenues of more than $1M. This is much larger than the percentage of produce growers nation-wide who earn gross revenues of more than $1M. Consequently, the use of Hardesty and Kusunose results for estimating the monitoring costs of the proposed rule may be biased – especially if there are economies of scale in monitoring.

We do not have much information on the monitoring costs that would be incurred from the proposed monitoring requirements by farms of different sizes. If there are economies of scale, the per-acre costs of monitoring for large farms would be less than the per-acre costs of monitoring for small farms and very small farms, and the mean per-acre monitoring costs obtained by Hardesty and Kusunose would underestimate the mean per-acre monitoring costs from the proposed monitoring requirements. However, while finding that increases in total food safety costs per-acre were lowest for the largest group of growers in their survey (i.e., growers earning more than $10M in gross revenues), Hardesty and Kusunose found no statistical difference between the increase in per-acre monitoring costs for the largest and smallest groups (i.e., growers earning less than $1M in gross revenues) (Ref.8). This provides limited evidence that the estimated mean increase in per-acre monitoring costs may be reasonable as an estimate of the costs of the proposed monitoring requirements across all farm sizes. We request comment on the evidence suggesting that the increase in monitoring costs of $3.35 per acre is a reasonable estimate for all farm sizes.

We use of the mean increases in per-acre monitoring costs found by Hardesty and Kusunose ($3.36 per acre) to estimate the increase in monitoring costs that would be incurred for very small, small and large farms in this analysis. We estimate the costs for each farm size category defined earlier in the analysis by multiplying the estimated costs per acre by the midpoint of the acreage that defines each farm size category (112.5 acres, 375 acres, and 750 acres for very small, small and large respectively), and again by the number of farms covered in each category to obtain the total costs of the monitoring provision. These may overstate the costs of the proposed monitoring requirements if the frequency of required monitoring in CA LGMA is greater than that implied in the proposed rule. Moreover, the findings from Hardesty and Kusunose may reflect short run exaggerated responses by leafy greens growers to questions about monitoring costs made shortly following a large outbreak associated with leafy greens, and long run cost estimates may actually be lower. We ask for comment on the appropriateness of using this estimate of monitoring costs given these considerations. We report the annual monitoring costs in Table 82.

Table 82: Monitoring for animal intrusion

	Very small	Small	Large
# produce farms	26,610	4,644	8,437
Per-acre monitoring cost increase	3.36	3.36	3.36
Increase in cost per affected farm	$378	$1,260	$2,520
Total cost per category	$10,058,658	$5,851,553	$21,260,737
Total cost for the requirement	$37,170,949		

Costs for requiring an adequate period between harvest and grazing, and measures to prevent contamination when grazing or working animals are allowed on fields where covered produce is grown

We estimate that farms that produce both livestock products and covered produce may incur monitoring costs associated with the requirements for farms that allow grazing on fields where covered produce is to be harvested. We use information from the 2007 Census of Agriculture on the number of produce farms that use management intensive grazing to estimate of the number of farms that would incur costs from the proposed requirements for farms that allow grazing on fields where covered produce is to be harvested (Ref.3). We do not have information on the number of farms that use working animals and that would not be included in the number of farms that allow animals to graze on fields where covered produce is grown. We assume that farms that use working animals in fields planted with covered produce would be included in the number of farms that allow animals to graze on fields where covered produce is grown. In Table 83 we report the number of produce farms that use management intensive grazing, less the fraction that would also be members in the CA or AZ LGMA or FTR and would therefore not incur costs from the proposed provisions.

We do not have any information on costs from the requirements that would be incurred by farms that allow grazing or working animals on fields where covered produce is grown. However, we estimate that farms that allow livestock to graze on fields or allow working animals on fields where covered produce is grown would incur the cost equivalent of one additional monitoring activity over and above that incurred by farms that do not allow livestock to graze or working animals in fields where covered produce is grown. We estimate the cost of requiring an adequate waiting period for farms that allow animals to working animals in fields planted in covered produce would fall within the costs of one additional monitoring activity. We ask for comment on this estimate. We also ask for comment on the costs of measures to prevent contamination when grazing or working animals are allowed in the field where covered produce is grown.

The CA and AZ LGMA require 3 monitoring activities: pre-season, pre-harvest, and harvest monitoring. We estimate that produce farms that also allow grazing or working animals on fields planted in covered produce would incur the costs comparable to an additional monitoring activity, or 33 percent additional monitoring costs over and above the monitoring required by other produce farms that do not allow grazing or working animals on their fields. The costs from the measures for produce farms that also allow grazing on fields where produce is to be harvested are reported in Table 83 below.

Table 83: Costs for requiring an adequate period between harvest and grazing, and measures to prevent contamination when grazing or working animals are allowed on fields where covered produce is grown

	Very small	Small	Large
# produce farms that graze animals[1]	2,064	257	281
increase in per-acre cost	$1.12	$1.12	$1.12
cost per affected farm	$126	$420	$840
Total cost per category	$260,004	$108,094	$236,312
Total cost for the requirement	$604,411		

[1] Derived from data obtained from (Ref.3)

The proposed rule would require the evaluation of whether the covered produce can be harvested in accordance with the requirements of this proposed rule if there is evidence of animal intrusion. We estimate that this proposed rule will serve to focus producers' attention on the possibility of harvesting produce if there is evidence of animal intrusion but do not estimate the additional amount of evaluation that would occur as a result of this proposed rule. We also estimate that this proposed rule will serve to focus producers' attention on taking precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully enclosed buildings from domesticated animals. We ask for comment on the costs of these requirements. The total costs of the animal provisions are summarized in Table 84.

Table 84: Total Cost of the Animal Provisions

Description	Very small	Small	Large
Monitoring for Animal Intrusion	$10,058,658	$5,851,553	$21,260,737
Adequate waiting period between harvest and grazing, and measures when grazing or working animals on planted fields	$260,004	$108,094	$236,312
Cost by size category	$10,318,663	$5,959,647	$21,497,050
Total cost of the animal provisions	$37,775,360		

5. Growing, Harvesting, Packing, and Holding Activities

The proposed rule would require that all covered farms that grow, harvest, pack, or hold both covered and excluded produce (where the excluded produce is not grown, harvested, packed, or held in compliance with the standards in the proposed rule) take measures during covered activities to keep covered produce separate from excluded produce and adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such surfaces for covered produce. The proposed rule would also require covered farms to take steps reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated (such as if it is visibly contaminated with animal excreta), and to handle harvested covered produce in a manner that protects against contamination. The proposed rule would also prohibit covered farms from distributing dropped covered produce unless it is destined for commercial processing that adequately reduces microorganisms of public health concern. The proposed rule would also require farms to package covered produce in a manner that prevents the formation of Clostridium botulinum toxin where it is a known or reasonably foreseeable hazard (such as for mushrooms), and require food-packing material to be adequate for its intended use and, if reused, adequately clean and sanitized as necessary (clean liners may also be used).

Current Industry Practices

We estimate that farms are currently in compliance with multiple provisions of this subpart, and thus these will present no new costs to the industry. Currently, we estimate that all farms guard against contaminated produce, such as covered produce that is covered with animal excreta, and exclude this product to protect from further contamination. Additionally, we estimate that farms do not currently harvest dropped produce if it is not headed for kill step processing. Lastly, the mushroom industry is aware of the serious health hazard that Clostridium botulinum toxin poses, and therefore is currently taking steps to prevent against any illnesses due to their packaging. We ask for comment on the industry's compliance with these food handling practices. In addition, we estimate no additional costs for the proposed requirement to take measures to keep covered produce separate from produce not grown, harvested, packed, or held in compliance with the proposed rule and to clean and sanitize food contact surfaces that have contacted such produce before using such surfaces for covered produce beyond the costs estimated for cleaning and sanitizing tools and equipment in the section of this document titled "Equipment, Tools, Buildings, and Sanitation."

Because the remaining requirements in this section (cleaning and sanitizing reusable food-packing materials) apply primarily during harvest, packing, and storing activities, we are only concerned with farms that have some sort of postharvest operations. Table 85 presents the estimated number of farms which conduct these operations. Based on survey results from the Fruit and Vegetable Agricultural Practices Survey (Ref.6), we estimate that 12,429 very small, 2,187 small, and 4,012 large farms conduct some harvest, packing, or storing activity, and thus will fall under the requirements of this section. We have eliminated all farms that fall under the CA Tomato Farmer's Agreement, as they should already be cleaning their reusable food harvesting and packing materials daily. This specific subset of farms is used for all further estimations of standards directed to growing, harvest, packing, and storing activities.

Table 85. Number of farms with Postharvest Operations			
	very small	small	large
Number of Farms	27,021	4,753	8,722
% with on farm post-harvest	46%	46%	46%
Farms with postharvest	12,429	2,187	4,012

<u>Costs</u>

The cost of cleaning and sanitizing all reusable food harvesting and packing material is presented in table 86. We start with the estimated number of farms that perform some harvest, packing, or storing activities, as laid out in the baseline practices section of this provision. Of those farms, we estimate that 18 percent of farms are utilizing some form of reusable food contact surfaces (such as bins, pails, or trailers) which must be washed and sanitized before reuse (Ref.6).[37] Applying these percentages yields 2,237 very small, 394 small, and 722 large farms with cleanable food contact surfaces. Furthermore, we estimate that 70 percent of these farms are not properly cleaning and sanitizing all of their food contact surfaces to the level that this subpart requires (Ref.6). Applying this percentage to the number of farms with reusable food contact surfaces yield the number of farms that will need to do additional cleaning in

[37] All other farms are estimated to be using disposable or one time use containers, such as boxes, which do not need to be reconditioned under the requirements of this subpart.

order to be in compliance with this regulation. In total, we estimate that 1,566 very small, 276 small, and 506 large farms will need to do additional cleaning and sanitizing of reusable food harvesting and packing materials.

Next, we estimate the individual farm cost of cleaning and sanitizing all reusable food harvesting and packing materials used in harvest, packing, or storing activities. Based on a survey of food industry experts, we estimate that it will take a very small farm approximately ten minutes to clean and sanitize its food harvesting and packing materials. The time estimates rise from there, based on farm size, up to 15 minutes for large farms (Ref.68). This time estimate is an approximation that assumes the time to clean reusable food harvest and packing materials is equal to the amount of time it takes to clean a single piece of machinery. We request comment, supported by data, on this time estimate. Multiplying this time by the average farm workers wage rate from the BLS with fifty percent overhead applied, $14.00 (Ref.2), yields the daily labor cost of cleaning/sanitizing. Additionally, based on prices from National Chemicals, Inc., we estimate farms will use approximately one gallon of sanitizer fluid costing $0.05 (Ref.55), daily. The cost of labor plus the cost of sanitizer equals the daily cost to clean/sanitize; we estimate that cleaning and sanitizing will cost very small farms $2.43 (0.17 x 14.00 + .05) and small and large farms $3.55 (0.25 x 14.00 + .05).

The daily cost to farms times the number of operational harvest days equals the annual per farm cost to clean and sanitize food harvesting and packing materials. Annually, cleaning and sanitizing food harvesting and packing materials will cost very small farms $109.35 (2.43 x 45) and small and large farms $319.50 (3.55 x 90). Multiplying this annual cost by the number of farms that need to clean and sanitize more yields the total cost to clean and sanitize food packing materials used for growing, harvest, packing, and storing activities, by farm size. In total, we calculate the cost to very small farms $171,255 (109.35 x 1,566), small farms $88,024 (319.50 x 276), and large farms $161,509 (319.50 x 506). This represents a total cost of $420,788 to the industry as a whole.

Table 86. Cost of Cleaning and Sanitizing Food Contact Surfaces

	very small	small	large
Farms with postharvest	12,429	2,187	4,012
% with reusable fcs	18%	18%	18%
Farms with reusable fcs	2,237	394	722
% that do not clean	70%	70%	70%
Farms that need to clean/sanitize fcs	1,566	276	506
time to clean/sanitize	0.17	0.25	0.25
Wages	$14.00	$14.00	$14.00
labor cost to clean/sanitize a fcs	$2.38	$3.50	$3.50
cost of sanitizer per farm job	$0.05	$0.05	$0.05
daily per farm cost to clean/sanitize	$2.43	$3.55	$3.55
operational harvest days	45	90	90
annual per farm cost to clean/sanitize fcs	$109.35	$319.50	$319.50
total cost to clean/sanitize fcs	$171,255	$88,024	$161,509
Total Cost	**$420,788**		

Summary

In total we estimate that the cost of compliance for standards directed to growing, harvest, packing, and storing activities will be approximately $420,788. We estimate that, annually, it will cost very small farms $109 and small and large firms $320 per farm. Both the marginal and total costs of this provision are increasing with the size of the farm. We believe, based on the current literature, that grow, harvest, packing, and storing activities have the potential for contaminating covered produce, but proper controls can potentially help reduce the human health burden that is currently attributable to all produce.

6. Equipment, Tools, Buildings, and Sanitation

a. Equipment, Tools, and Buildings

Standards directed to equipment, tools, and buildings require that all farms take measures to prevent contamination of covered produce. To accomplish this, farms will be expected to maintain, clean, and monitor all equipment and tools intended to, or likely to, contact covered produce to protect against contamination. All equipment and tools intended to, or likely to, contact covered produce must be of adequate design, construction, and workmanship, so that they can be properly cleaned and maintained. All instruments used to measure, regulate, or record temperatures must be accurate and adequately maintained. Buildings must be suitable in size, construction, and design to facilitate sanitary operations. These requirements will ensure that the opportunity to introduce any microorganisms to covered produce through contact with equipment and tools, packing, holding, or cross-contamination that occurs within a building will be minimized, thus reducing the probability of unsellable product, wasted labor hours, or a serious foodborne event.

b. Sanitation

The sanitation provisions require all farms to provide workers with toilet facilities that are adequate and readily accessible with a nearby hand-washing facility during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities. Adequate is defined as "that which is needed to accomplish the intended purpose in keeping with good public health practice." Toilet facilities can be permanent, such as the toilet in a farm owner's home, or portable temporary structures. They must be cleaned regularly, stocked with toilet paper, have a trash bin, and must be serviced when necessary. The toilet facilities are also required to be readily accessible to workers.

The hand-washing facilities must also be adequate and readily accessible. They must be stocked with soap, have running water that shows no detectable generic *E.coli*, and be equipped with paper towels, single-use drying rags, or an air drying device. Hand-washing facilities must be located close to the workers and must be kept clean and sanitary. Farms must also provide for proper disposal of waste, such as waste water and towels.

The plumbing and toilet sewage systems must be maintained to prevent contamination of water, covered produce, or food-contact surfaces. Sewage must be disposed of adequately, and leaks or spills must be managed to prevent contamination. If a significant event occurs, such as an earthquake or a flood, the farm must make sure that the sewage system is still intact and that there is no risk of contamination.

Farms are also required to implement pest controls which protect covered produce, food-contact surfaces, and food-packing materials from contamination by pests in buildings, be they fully or partially enclosed. As well, all farms must control and dispose of litter and waste, and adequately control the waste of domesticated animals.

<u>Current Industry Practices</u>

a. Equipment, Tools, and Buildings

The agricultural industry relies heavily on tools and machinery, especially in harvesting operations, to cut, sort, dry, and clean its product. Most farms with hired labor operate using at least one hand tool per worker. Fifty-four percent of all produce farms are ensuring that their workers are sanitizing these tools (Ref.6). Additionally, of the farms that have machinery, whether it is for harvesting, hauling, or storage on the farm which comes into contact with food products, sixty-two percent are ensuring that this machinery is accurate and well maintained, properly cleaned, and monitored to check for any flaws in either product or function.

Because a portion of this section deals with buildings, we are concerned with the particular subset of farms that have enclosed structures onsite. Table 87 presents the estimated number of farms with on farm buildings. Based on survey results from the FVAP (Ref.6), we estimate that 4,594 very small, 1,046 small, and 1,919 large farms have buildings which will fall under the requirements of this section. This specific subset of farms is used for all further estimations of preventative controls directed to buildings.

Table 87. Number of farms with Buildings

	very small	small	large
Number of Farms	27,021	4,753	8,722
% with on farm packing facility	17.00%	22.00%	22.00%
Number of Farms with Buildings	4,594	1,046	1,919

To estimate further current industry practices, we employ a number of data sources that speak to specifically the individual aspect of the agricultural industry. Additionally, we estimate that most farms currently operating a building on the farm have ensured that it is of proper size, construction, and design with regards to cleaning.

b. Sanitation

To estimate the current practices associated with excluding pests from buildings, we rely on information from a survey of fruit and vegetable producers (Ref.6). All farms will be subject to compliance with the pest control and exclusion requirements of this proposed rule, and, according to this study, 79 percent of all farms already have pest controls in place to prevent the spread of contamination to covered produce.

We use survey data, current regulations, and food safety program information to estimate the current practices that pertain to the provisions in this section. Farms that currently implement food safety programs will already be in compliance with cleaning the toilet and hand-washing facilities. Farms are currently subject to field sanitation regulations from OSHA (Ref.57). The relevant regulations require employers that hire eleven or more field workers to provide toilet and hand-washing facilities and to provide each employee reasonable use of them. Current regulations require toilets to be maintained in accordance with “public health sanitation practices including…toilets being kept clean, sanitary, and operational…and the prevention of any unsanitary conditions through waste disposal” (Ref.57). Hand-washing facilities are required to be filled with potable water and to be kept clean and sanitary. Employers are required to refill the facility as necessary and to prevent any unsanitary conditions through the disposal of waste. Similar requirements for toilets and hand washing facilities in permanent structures, or buildings, exist under OSHA, and thus, we estimate that farms with toilets in buildings will already be complying with this provision (Ref.57).

Most farms in the U.S. are complying with OSHA regulations, and therefore, there are few farms that do not currently provide toilets or hand-washing facilities. Approximately 96.4 percent of workers report that employers provide both a toilet and a hand-washing facility (Ref.13). Of those without reasonable facilities, 2.1 percent report that neither is provided, 0.6 percent report that only a hand-washing facility is provided, and 0.97 percent report that only a toilet is provided (Ref.13).

In the National Agricultural Workers Survey, approximately 30 percent of workers that report use of the toilet that is provided by the employer stated that they went to the bathroom in the field, and 80 percent of these workers stated that the reason was because the toilet was too far away (Ref.45). This implies that 24 percent of workers (0.30 x .80) consider the toilets not readily accessible. However, it is uncertain what is meant by being too far away. OSHA standards require toilets to be within a quarter mile of agricultural employees. This standard could still be too far for these employees, or they could be reporting that the toilet is placed farther than what is required by the OSHA standard.

Toilets and hand-washing facilities must be stocked with toilet paper, soap, and paper towels or other suitable drying device. Workers report that toilets are cleaned three times a week (Ref.45), and farms report cleaning their toilets an average of 5.2 times a week and at a higher frequency during peak harvest season (Ref.66) for an average of 4.11 cleanings a week [(5.22 + 3)/2]. We expect that hand-washing facilities are cleaned at the same frequency. Since current OSHA regulations require toilet and hand-washing facilities to be kept clean and sanitary, we expect that the 4.11 cleanings a week are sufficient, and that farms will not have to change practices to comply with this provision. We seek comment on whether the toilet cleaning frequency estimate of 4.11 times a week is sufficient to ensure compliance to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste.

Toilet contracting companies include cleaning and servicing the toilet 3 times a week in their costs (Ref.28;Ref.35). Servicing portable toilets requires the disposal of sewage. If the toilet is not working, then the toilet contracting company replaces the toilet. For farms that do not contract their toilets and either have them in their own home or own portable toilets, it is expected that they also are complying with servicing their toilets, but it is uncertain. We seek comment on the frequency at which private toilets are serviced.

Since OSHA requires the potable water standard for hand-washing water, it is expected that all farms are in compliance with this standard. Farms must also provide for the disposal of gray water from the facility. It is expected that since hand-washing facilities are serviced similarly as toilets, where the contracting company must have access to them, then farms that contract their hand-washing facilities are already complying with this part. For farms that do not contract their hand-washing facilities, we expect that they are complying with the disposal of gray water, but it is uncertain. We seek comment on the frequency of this practice. We expect that all farms are currently complying with providing for the disposal of paper towels since OSHA requires hand-washing facilities to be maintained to prevent any unsanitary conditions through the disposal of waste. We seek comment on whether hand-washing facilities are currently readily accessible to workers.

We currently have no information regarding the monitoring of toilet or hand-washing facilities after a significant event. The probability of an earthquake or a flood in the U.S. varies by location. The probability of a serious earthquake in San Francisco in any given year is 1 percent, and in Maryland is near zero percent (Ref.69). We take the average and approximate that the probability of a significant earthquake in a given year in the U.S. is 0.5 percent. The probability of a flood that can cause damage in the U.S. is 1 percent (Ref.69). Therefore, we estimate that farms will have to comply with the provision of monitoring toilet and hand-washing facilities with a 1.5 percent probability every year.

We expect that farms already have a trash collecting service in the field in order to comply with OSHA regulations. However, we estimate that all farms must monitor in order to prevent contamination from trash, litter, or waste in any area used for a covered activity. We do not estimate the costs of controlling waste from domesticated animals since we are unaware of the frequency of this practice. We seek comment on the number of farms that currently follow this practice and the frequency at which this occurs.

Costs

a. Cost Related to Tools, Equipment, and Buildings

The cost of requirements directed to cleaning worker tools intended to, or likely to, contact covered produce are presented in Table 88 through 90.

In Table 88, we begin by estimating the cost of cleaning tools for all farms with hired labor. The universe of farms who hire labor is given on line one. We estimate that 47 percent of these farms are not already in compliance with regulation (Ref.6), and the total numbers of farms that will incur a new cost are listed on line 3. We estimate that 12,700 very small, 2,234 small, and 4,099 large farms will need to clean their worker tools more thoroughly. Each farm is estimated to have between 7 and 70 hired jobs, depending on farm size (Ref.3). We estimate that each job will require its own separate tool. Multiplying average number of farm jobs by the number of farms that need to come into compliance gives the total number of tools that will need to be cleaned. We estimate there will be 100,248 (12700 x 7.9) very small farm tools, 40,546 (2234 x 18.1) small farm tools, and 287,084 (4099 x 70.0) large farm tools. We estimate that on average workers will require 1 minute cleaning each tool. The estimated and hourly wage rate per farm worker is $14. We estimate that it costs a farm $0.23 ($14.00 x 0.02) in labor to clean their tools. Additionally, based on prices from National Chemicals, Inc., we estimate farms will use approximately $0.05 (Ref.55) of cleaner per farm tool. Multiplying the labor and materials cost of cleaning by the average number of farms tools, yields the daily cost of cleaning per farm, which we estimate at $2.24 (0.27 x 99937) for very small farms, $5.14 (0.27 x 40034) for small farms, and $19.84 (0.27 x 282113) for large farms. This, multiplied by the number of farms yields the total daily cost of cleaning. We estimate the daily cost of cleaning to be $28,403 (2.24 x 12700) for very small farms, $11,488 (5.14 x 2234) for small farms, and $81,338 (19.84 x 4099) for large farms. The daily cost of cleaning times operational days, which we estimate at 45 for small farms and 90 for all others, yields the total cost of cleaning worker tools. In total we estimate that cleaning worker tools will cost very small farms $1.28 million (45 x 28403), small farms $1.03 million (90 x 11488), and large farms $7.32 million (90 x 79930), annually; representing a total of $9.63 million.

Table 88. Cost of Sanitizing Tools

	very small	small	large
farms with hired labor	27,021	4,753	8,722
% not already cleaning/sanitizing	47.00%	47.00%	47.00%
farms that need to clean/sanitize	12,700	2,234	4,099
avg. jobs per farm	7.9	18.1	70.0
number of tools on farm	100,248	40,034	282,113
time to clean/sanitize	0.02	0.02	0.02
Wages	$14.00	$14.00	$14.00
labor cost to clean/sanitize a single tool	$0.23	$0.23	$0.23
cost of sanitizer per farm job	$0.05	$0.05	$0.05
daily cost to clean/sanitize per farm	$2.24	$5.14	$19.84
total daily cost to clean/sanitize	$28,403	$11,488	$81,338
operational days	45	90	90
total cost to clean/sanitize tools	$1,278,120	$1,033,894	$7,320,396
Total	**$9,632,410**		

In table 89, we estimate the cost of cleaning all farm equipment intended to, or likely to, contact covered produce. We estimate that all farms in scope of this rule will have some type of machinery, and, based on survey information (Ref.6), we estimate that approximately 38.5% of those farms are not cleaning thoroughly enough for this rule. There are approximately 10,403 (27021 x .385) very small, 1,830 (4753 x .385) small, and 3,358 (8722 x .385) large farms that will need to do more cleaning. We observe the average number of machines on farm (Ref.3), by size category and, based on a survey of industry experts, estimate that it takes approximately 15 minutes to clean a single piece of machinery (Ref.68). The number of machines multiplied by the time to clean and the average wage rate equals the per farm labor cost to clean. We estimate that it costs a very small farm $9.69 (2.27 x .25 x 14.00), a small farm $16.12 (4.61 x .25 x 14.00), and large farms $29.68 (8.48 x .25 x 14.00) in labor to clean their machinery. Additionally, there will be a cleaner cost between $0.30 and $0.45 to clean each piece of machinery (Ref.55). This brings the daily per farm cost of cleaning to $10.52 (.30 x 2.77 + 9.69) for very small farms, $18.20 (.45 x 4.61 + 16.12) for small farms, and $33.49 (.45 x 8.48 + 29.68) for large farms. Multiplying daily cost of cleaning by the total number of farms that need to clean yields the total daily cost of cleaning machinery, which we estimate at $109,451 (10.52 x 10403) for very small farms, $33,298 (18.20 x 1830) for small farms, and $10,122,287 (33.49 x 3358) for large farms. This is then multiplied by the number of operational harvest days to get the total cost of cleaning machinery. Together, this represents a cost of $4.92 ($109,451 x 45) million for very small farms, $3.00 ($33,298 x

90) million for small farms, and $10.12 ($10,122,287 x 90) million for large farms. In total, we estimate that cleaning will cost about $18.04 Million.

Table 89. Cost of Cleaning/Sanitizing Machinery			
	very small	small	large
farms with machinery	27,021	4,753	8,722
% not already cleaning	38.50%	38.50%	38.50%
farms that need to clean machinery	10,403	1,830	3,358
average number of machines	2.77	4.61	8.48
time to clean	0.25	0.25	0.25
Wages	$14.00	$14.00	$14.00
per farm labor cost to clean machinery	$9.69	$16.12	$29.68
cost of sanitizer	$0.30	$0.45	$0.45
daily cost to clean machinery per farm	$10.52	$18.20	$33.49
total daily cost to clean machinery	$109,451	$33,298	$112,470
operational days	45	90	90
total cost to clean machinery	$4,925,294	$2,996,812	$10,122,287
Total	**$18,044,393**		

We estimate that most farms are currently using tools and machinery that are properly designed, installed, stored, and bonded as appropriate. We request comment on industry's adoption of proper equipment and tools.

b. Costs related to sanitation

Table 90 presents the cost of excluding pests from all farm buildings.[38] The FVAP states that somewhere between 21 percent of fruit and vegetable producers have absolutely no pest control in place (Ref.6). Applying this percentage to the total number of farms with buildings onsite yields the number of farms that will need to implement some form of pest control. We estimate that 965 (4594 x .21) very small, 220 (1046 x .21) small, and 403 (1919 x .21) large farms will need to begin a pest control program to satisfy the requirements of this provision.

[38] We estimate that all buildings that have animals in or around them would be control for during the traditional regimen of excluding pests from the premises,

Based on an expert elicitation of produce packers and wholesalers, we estimate that a weekly regimen of 1 to 3 hours (Ref.39;Ref.40), depending on the farm size, would be required to ensure that all pest controls are properly functional and maintained. This time estimation may be slightly high, because it is meant to also capture any material costs that will be associated with the pest control. Because pest control is widely variable by the materials (which may include such things as pesticides, traps, spays, screens, etc.), line of production, season, time of production, and geographical area we included their costs in the labor estimate rather than attempting to estimate all of these separately. It may be that our estimate is an underestimate for some farms, but it is just as likely that our estimate overstates the cost to others.[39] We request comment on this cost estimate of pest control options. Pest control can be performed by the average farm worker, and multiplying their wage rate by the number of hours needed to perform the task gives the weekly cost of pest control monitoring. We estimate that pest control will cost very small farms $14.00 (1 x 14.00), small and large farms $42.00 (3 x 14.00) to perform weekly pest control. The weekly cost times the total number of operational weeks, 50, gives us the annual cost of pest control, per farm. We estimative this provision will cost very small farms $700 (14.00 x 50) and small and large farms $2100 (42.00 x 50), annually. This number multiplied by the number of farms that need to come into compliance yields the total cost of pest control by farm size; we estimate a cost of $675,245 (700 x 965) for very small farms, $461,171 (2100 x 220) for small farms, and $846,173 (2100 x 403) for large farms. In total, we estimate that the cost of excluding pests from farm buildings is $1.98 million, annually. This time estimation may be slightly high, because it is meant to

[39] Additionally, there is some evidence that suggests that most farms will contract out their pest control to a third party (Ref.68). We believe that our annual cost estimate of $700-$2100 captures this possibility.

also capture any material costs that will be associated with the pest control, as well as any monitoring for domestic animals in or around on farm buildings.

Table 90. Cost of Excluding Pests			
	very small	small	large
Number of Farms with Buildings	4,594	1,046	1,919
% with no pest control	21.00%	21.00%	21.00%
Farms that need pest control	965	220	403
time to monitor pest control per week	1	3	3
wage rate	$14.00	$14.00	$14.00
Weekly cost of pest control monitoring	$14.00	$42.00	$42.00
operational weeks	50	50	50
annual cost of pest control	$700	$2,100	$2,100
Total Cost of pest control	$675,245	$461,171	$846,173
Total	**$1,982,590**		

The costs to farms of the sanitation provisions will be incurred for all farms with workers on the field and in buildings during covered harvest, packing, and holding activities. Since very few commodities are grown and harvested in buildings, we estimate that the buildings are mainly used for packing and holding activities, and that farms with buildings will still need to provide harvest workers in the field with proper sanitation facilities. Additionally, farms with buildings (i.e. permanent structures) are likely to have toilets and hand-washing facilities in their buildings since they are required by OSHA (Ref.57). In order to not double-count the number of portable toilets on the field and the toilets in the buildings, we account for the post-harvest workers in buildings in this section by first subtracting these workers from the total number of workers on farms. We then convert the survey baseline practices information from the previous section, which is based on farm worker responses, into the number of farms that will be affected using the average number of workers employed per farm.

There are 4,581 very small farms, 1,033 small farms, and 1,886 large farms that conduct post-harvest activities in buildings as will be discussed in the next section. The very small farms employ 4,084 workers (4,581 x 0.9 average workers), the small farms employ 2,118 (1,033 x 2 average workers), and large farms employ 14,919 (1,886 x 7.9 average workers). We subtract these numbers from the total number of workers that conduct harvest and post-harvest activities on very small, small, and large farms to obtain the total number of workers that are on the field during harvest and post-harvest activities. There are 109,430 workers on very small farms (113,514 workers during harvest and post-harvest – 4,084 worker in buildings during post-harvest), 43,339 workers on small farms (45,457 workers during harvest and post-harvest – 2,118 worker in buildings during post-harvest), and 305,405 workers on large farms (320,324 workers during harvest and post-harvest – 14,919 worker in buildings during post-harvest).

We estimate the costs to the toilet and hand-washing facilities provisions by first calculating the total number of workers that report not having them. Since 2 percent of workers do not have access to neither a toilet nor a hand-washing facility, we estimate that this is 2,256 workers on very small farms (0.02 x 109,430), 894 workers on small farms (0.02 x 43,339), and 6,298 workers on large farms (0.02 x 305,405). We divide the number of workers by the average number of workers employed per farm to estimate the number of farms affected. We estimate that this accounts for approximately 536 very small farms (2,256/4.2), 92 small farms (894/9.7), and 168 large farms (6,298/37.4) that will need to provide both a toilet and hand-washing facility to their workers.

We estimate that since 0.6 percent of workers has access to a hand-washing facility but not a toilet, this accounts for 657 workers (0.006 x 109,430) on very small farms, 260 workers (0.006 x 43,339) on small farms, and 1,834 workers (0.006 x 305,405) on large farms. Dividing these numbers by the average number of workers on farms, we estimate that 156 very small farms (657/4.2), 27 small farms (260/9.7), and 49 large farms (1,834/37.4) will need to provide a toilet to their workers. For the .97 percent of workers with access to a toilet, but not a hand-washing facility, we estimate that this is 1,058 workers (0.097 x 109,430) on very small farms, 419 workers (0.097 x 43,339) on small farms, and 2,953 workers (0.097 x 305,405) on large farms. We estimate that this accounts for 251 very small farms (1,058/4.2), 43 small farms (419/9.7), and 79 large farms (2,953/37.4) that will need to provide a toilet to their workers. We expect that none of these farms are currently implementing a food safety program on their farm.

Although 96.4 percent of workers reported having a toilet provided to them by their employer, 24 percent of workers do not believe that they are accessible. It is possible that the toilets that are provided are too far away and that additional toilets are needed. In order for farms to comply with the provision for readily accessible toilets, we estimate that the 24 percent of workers that report toilets as being too far away from their work facility will receive a toilet that is close enough. We estimate that this is 26,263 workers on very small farms (0.24 x 109,430), 10,401 workers on small farms (0.24 x 43,339), and 73,297 workers on large farms (0.24 x 305,405). This accounts for 6,234 very small farms (26,263/4.2), 1,074 small farms (10,401/9.7), and 1,961 large farms (73,297/37.4).

Workers reported that toilets are usually cleaned three times a week, and farms report cleaning toilets approximately 5.22 times a week for an average of 4.11 cleanings per week. Additionally, toilet contracting companies include the costs to cleaning the toilet and hand washing facilities 3 times a week. We estimate that all farms are in compliance with this provision except for farms that will have to rent toilets and/or hand washing facilities because they don't currently provide them or due to their inaccessibility. Adding the numbers estimated previously of the farms that will have to provide toilets and hand washing facilities, we estimate that 7,177 very small farms, 1,236 small farms, and 2,258 large farms will have to clean and maintain the toilets and hand washing facilities. The cost to farms with additional bathrooms in buildings will be estimated in the next section.

In order for a farm to comply with providing for sanitary disposal of toilet paper, they must purchase trash bins for the inside of their portable toilets. We estimate that all farms must do this: 26,947 very small farms, 4,693 small farms, and 8,571 large farms. This is potentially an overestimate since farms with personal bathrooms will already be complying with this provision. However, we are unaware of the number of farms that currently follow this practice, and we estimate the cost to all, but we seek comment.

We now calculate the costs per farm of complying with the toilet and hand-washing facilities provisions. It costs an average of $164 per month in the U.S. to rent toilets accommodating ten people that also include a hand-washing unit with running water (Ref.32;Ref.33). A double toilet which accommodates twenty people costs $260 per month, a triple toilet which accommodates thirty people costs $346 per month, and a quadruple toilet which accommodates forty people costs $433 per month (Ref.32;Ref.33). The cost for only a toilet is $92 per month, and for only a hand-washing facility is $104 per month.[40] The cost includes pumping out the toilet, recharging it with fresh chemicals,

[40] All costs that are available only from one California source were adjusted to account for differences in prices across the U.S. Since we only have information on non-California costs for a single-unit toilet with

washing the inside, restocking it with supplies, pumping out the sinks and refilling them with fresh water, and restocking the hand-washing facility with paper towels and soap.

We estimate that very small farms will need a single toilet with adjacent hand-washing facility at a cost of $164 per month since they hire an average of 6 workers during harvest and post-harvest. Small farms will need a double-unit at a cost of $260 per month since they hire an average of 13 workers, and large farms will need a quadruple unit and a double unit at a total cost of $693 per month ($433 quadruple + $260 double) since they hire an average of 52 workers during harvest and post-harvest. Note that to calculate the costs accrued to farms, we use the number of farm jobs they fill per year, and not the number of workers on farms. Since farms will need the facilities for harvest and post-harvest activities, which is 68 days for very small farms and 135 days for small and large farms, we estimate that the cost per farm per year is $370 per very small farm [$164 x (68/30)], $1,168 per small farm [$260 x (135/30)], and $3,116 per large farm [$693 x (135/30)].

For farms that must supply toilet facilities but no hand-washing facility, it will cost each very small farm $92 per month, each small farm $184 per month ($92 x 2) and each large farm $551 per month ($92 x 6). We estimate that the cost per year is $206 for a very small farm [$92 x (68/30)], $826 per small farm [$189 x (135/30)], and $2,477 per large farm [$551 x (135/30)]. For farms that need a hand-washing facility and not a toilet, it will cost $104 per very small farm, $208 per small farm ($104 x 2), and $623 per large farm ($104 x 6). We estimate that the cost per year is $234 for a very small farm

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adjacent hand-washing facility, we adjust all California costs by first taking the average rent of single-unit toilets in the U.S. ($95/month in California + $254/month Michigan + $144/month central California), to obtain $164. We then estimate the percentage mark-up of 70 percent [(164-95)/95] and multiply it by the costs in California to obtain the average cost in the U.S.

[$104 x (68/30)], $935 per small farm [$208 x (135/30)], and $2,804 per large farm [$623 x (135/30)].

We estimate that farms that will need to rent a toilet and/or hand washing facility will have to increase their cleaning frequency by 1.11 days a week during the harvest and post-harvest operations. Although the toilet contracting company includes 3 days of cleaning in their costs, on average farms clean their toilets 4.11 times a week, and therefore, these farms will have to increase their cleaning frequency by 1.11 times a week. This indicates an additional 11 cleanings per very small farm [1.11 x (68 days/7 days)], and an additional 21 cleanings for small and large farms [1.11 x (135 days/7 days)]. The cost to clean the toilet and hand-washing facilities consists of the increase in time to clean the units which involves stocking with toilet paper and paper towels, disposing of the trash, and cleaning the surfaces to keep them sanitary (wiping toilet seat, wiping sink, etc). We expect that one worker will clean the units for 30 minutes on very small farms at a cost of $7 [($14/60) x 30], 45 minutes on small farms at a cost of $10.50 [($14/60) x 45], and 90 minutes on large farms at a cost of $21 [($14/60) x 90] since they have a quadruple unit and a double unit.

Materials for cleaning the toilet and hand-washing facilities include gloves, multipurpose rags, cleaning solution, trash bags, toilet paper, paper towels, and soap. A pair of disposable gloves and one rag is expected to be used per cleaning at a cost of $0.09 and $0.10, respectively (Ref.52). The cost of cleaning solution and trash bags will vary by the number of toilet units on the farm. We estimate that it will cost $0.04 per trash bag and $1.46 per gallon of cleaning solution, which will be used per cleaning (Ref.52). Therefore, the cost of trash bags and solution per cleaning for all units on the farm will be $1.5 for very small farms ($0.04 + $1.46), $3 for small farms [2 x ($0.04 + $1.46)], and $9 for large farms [6 x ($0.04 + $1.46)].

The costs of toilet paper, paper towels, and soap will vary by the number of workers that use the materials, and the number of times they are used in one day. We estimate that each worker uses the toilet twice in one day, and washes their hands four times in one day. This is consistent with the estimates in the standards directed to health and hygiene section. For each use, the cost of toilet paper is $0.03, paper towels are $0.016, and soap is $0.023 (Ref.52). The cost to very small farms to re-stock toilet paper per cleaning is $0.34 ($0.03 x 6 workers x 2 uses per day); the cost to small farms is $0.78 ($0.03 x 13 workers x 2 uses per day), and the cost to large farms is $3 ($0.03 x 52 workers x 2 uses per day). The total cost to very small farms to re-stock paper towels per cleaning is $0.36 ($0.016 x 6 workers x 4 uses per day); the cost to small farms is $0.83 ($0.016 x 13 workers x 4 uses per day), and the cost to large farms is $3.2 ($0.016 x 52 workers x 4 uses per day). The total cost to very small farms to re-stock soap per cleaning is $.53 ($0.023 x 6 workers x 4 uses per day); the cost to small farms is $1.2 ($0.023 x 13 workers x 4 uses per day), and the cost to large farms is $4.7 ($0.023 x 52 workers x 4 uses per day).

We estimate the per cleaning cost on very small farms to clean the toilet with adjacent hand-washing facility is $10 ($7 + $0.09 + $0.10 + $1.5 + $0.34 + $0.36 + $0.53); the cost to small farms is $16.5 ($10.5 + $0.09 + $0.10 + $3 + $0.78 + $0.83 + $1.2), and the cost to large farms is $41.1 ($21 + $0.09 + $0.10 + $9 + $3 + $3.2 + $4.7). We multiply these costs by the number of cleanings required on very small, small, and large farms of 11, 21, and 21, respectively. We estimate that the annual per farm cost to clean the toilets and hand-washing facilities on the field are $106 for very small farms ($10 x 11), $354 for small farms ($16.5 x 21), and $881 for large farms ($41.1 x 21). Additionally, we estimate that it costs $6 to supply one trash bin for each toilet (Ref.55), and that all farms are required to supply a trash bin in order to comply with this provision. Therefore, we estimate that it will cost each very small farm $6 to supply a trash bin, each small farm $12 ($6 x 2), and each large farm $36 ($6 x 6).

Table 91 summarizes the total costs to comply with the toilet and hand-washing facilities provisions. We estimate that it will cost farms $0.83 million to obtain a toilet with adjacent hand-washing facility: $0.20 million for very small farms ($370 x 536), $0.11 million for small farms ($1,168 x 92), and $0.53 million for large farms ($3,116 x 168). To obtain only toilet facilities, we estimate a total cost of $0.18 million: $0.03 for very small farms ($206 x 156), $0.02 million for small farms ($826 x 27), and $0.12 million for large farms ($2,477 x 49). To obtain only hand-washing facilities, we estimate a total cost of $0.32 million: $0.06 million for very small farms ($234 x 251), $0.04 million for small farms ($935 x 43), and $0.22 million for large farms ($2,804 x 79). To obtain additional toilet with adjacent hand washing facilities due to their inaccessibility, we estimate a total cost of $9.7 million: $2.3 million for very small farms ($370 x 6,234), $1.3 million for small farms ($1,168 x 1,074), and $6.1 million for large farms ($3,116 x 1,961). It will cost a total of $3.2 million to clean and maintain toilets: $0.76 million for very small farms ($106 x 7,177), $0.44 million for small farms ($354 x 1,236), and $2 million for large farms ($881 x 2,258). Last, it will cost $0.53 million to obtain trash bins: $0.16 million for very small farms ($6 x 26,947), $0.06 million for small farms ($12 x 4,693), and $0.31 million for large farms ($36 x 8,571). The total cost to farms to comply with the toilet and hand-washing provisions is $14.2 million ($0.83 million + $0.18 million + $0.32 million+ $9.7 million + $3.2 million + $0.53 million). The cost per average farm is $353.We seek comment on our estimates about current toilet access, cleaning and disposal and our assumptions about costs by farm size.

Table 91: Costs to Provide Toilets & Hand-washing Facilities				
	Very Small	Small	Large	Total
Number of Farms				
Toilets and hand-washing needed	536	92	168	796
Only toilets needed	156	27	49	232
Only hand-washing needed	251	43	79	373
Toilet accommodations not accessible	6,234	1,074	1,961	9,270
Maintain and clean toilet	7,177	1,236	2,258	10,671
Sanitary disposal of toilet paper	26,947	4,693	8,571	40,211
Costs per farm per year				
Cost of Toilet with adjacent Hand-washing facility	$370	$1,168	$3,116	
Cost of only a Toilet	$206	$826	$2,477	
Cost of only a Hand-washing facility	$234	$935	$2,804	
Cost of cleaning the toilet & hand-washing facility	$106	$354	$881	
Cost of trash bin	$6	$12	$36	
Total Costs (in millions)				
Toilets and hand-washing needed	$198,192	$107,810	$525,004	$831,007
Only toilets needed	$32,199	$22,186	$121,545	$175,930
Only hand-washing needed	$58,694	$40,442	$221,557	$320,693
Toilet accommodations not accessible	$2,306,744	$1,254,797	$6,110,485	$9,672,026
Maintain and clean toilet	$763,000	$437,607	$1,988,018	$3,188,626
Sanitary disposal of toilet paper	$161,410	$56,226	$308,029	$525,665
Total Costs Accrued to Farms (Annual cost)	$3,358,830	$1,862,843	$8,966,609	$14,188,282
Costs per affected farm	$125	$397	$1,046	$353
Costs per farm	$125	$397	$1,046	$353

The costs to ensure that a sewage or septic system does not become a source of contamination after a significant event is based on the time farm operators or supervisors take to monitor each toilet unit after the event occurs. We estimate that all farms must comply with this provision including those that are currently in food safety programs. The probability of a significant event occurring in any given year was estimated previously in the industry practices section at 1.5 percent. We estimate that it will take the farm operator or supervisor approximately 2 minutes per toilet unit to check and ensure that the toilet unit has not leaked or been compromised. We estimate that it will take an additional hour to manage any leaks or spills that have occurred, and to remove the toilet unit either by having to do it themselves or to call the contracting firm and monitoring them to do so. Since it is uncertain whether a toilet unit will be compromised after a significant event, we estimate that this occurs only half of the time, therefore, with probability 0.75 percent.

We estimate that the farm operator will check the toilet after a significant event on very small and small farms, and that one farm supervisor will do this on large farms. The cost to very small farms of having the operator monitor the toilet unit is $1.6 [($47/60) x 2 minutes]. For small farms, the cost is $3 [($47/60) x 2 minutes x 2 toilets], and for large farms, the cost is $6 [($30/60) x 2 minutes x 6 toilets]. The cost to very small farms of managing leaks and removing the toilet is $47 on very small farms ($47 x 1 toilet), $95 on small farms ($47 x 2 toilets), and $182 on large farms ($30 x 6 toilets). We multiply the cost of monitoring the toilets by the 1.5 percent chance of the event occurring, and we multiply the cost of managing leaks and removing the toilet by the 0.75 percent chance of the event occurring. We do this in order to accurately measure the cost by not having to assume that a significant event will happen every year. Therefore, the cost per farm to comply with this provision is $0.38 per very small farm [(0.015 x $2) + (0.0075 x $47)], $0.76 per small farm [(0.015 x $3) + (0.0075 x $95)], and $1.45 per large farm [(0.015 x $6) + (0.0075 x $182)].

Table 92 summarizes the total costs to farms of ensuring that the sewage or septic system has not been negatively impacted by a significant event. Multiplying the costs per farm by the number of farms that must comply, we estimate that it will cost very small farms a total of $10.2K ($0.38 x 26,947), small farms $3.6K ($0.76 x 4,693), and large farms $12.4K ($1.45 x 8,571). The total cost is approximately $26.2K ($10.2K + $3.6K + $12.4K).

Table 92: Costs to Prevent Contamination from Sewage after a Significant Event

	Very Small	Small	Large	Total
Number of farms	26,947	4,693	8,571	40,211
Operator/Supervisor cost to monitor after event	$2	$3	$6	
Operator/Supervisor cost to remove port-a potty after event	$47	$95	$182	
Probability that event happens in one year	1.5%	1.5%	1.5%	
Probability that sewage is negatively impacted in one year	0.75%	0.75%	0.75%	
Total Costs (annual cost)	$10,218	$3,559	$12,447	$26,224
Costs per affected farm	$0.38	$0.76	$1.45	$0.53
Costs per farm	$0.38	$0.76	$1.45	$0.53

We estimate that all farms will have to monitor their land in order to prevent contamination from trash, litter, or waste, and that they will do this the entire production season in order to protect against contamination of areas used for a covered activity. We estimate that it will take approximately 2 seconds per acre per day to ensure that there is no trash, litter, or waste. We make this estimate based on the assumption that most farms are already monitoring for trash, litter, and waste, and that most farms will have increase their efforts very little. We request comment on this estimate. There are an average of 17 produce acres on very small farms, 83 produce acres on small farms, and 424 produce acres on large farms. The total seconds required to monitor per farm per day are 33 seconds (2 x 17) on very small farms, 166 seconds (2 x 83) on small farms, and 923 seconds (2 x 424) on large farms. Converting this to minutes, we obtain 0.6 minutes per very small farm per day (33 seconds/60 seconds), 2.8 minutes per small farm per day (166 seconds/60 seconds), and 15.4 minutes per large farm per day (923 seconds/60 seconds).

We estimate that the farm operator will monitor on very small and small farms, but that one farm supervisor will monitor on large farms. Multiplying the number of minutes needed to monitor by the labor time cost, we obtain a daily cost of $0.4 on very small farms [($47/60) x 0.6], $2.2 on small farms [($47/60) x 2.8], and $7.8 on large farms [($30/60) x 15.4]. The total number of operating days is 90 on very small farms, and 180 days on small and large farms. Multiplying the daily cost to monitor by the number of days required to monitor, we estimate that it will cost approximately $39 per very small farm ($0.4 x 90), $393 per small farm ($2.2 x 180), and $1,396 per large farm ($7.8 x 180).

Table 93 summarizes the costs to farms of ensuring trash, litter, or waste does not contaminate covered produce, food-contact surfaces, areas used for a covered activity, water sources, or water distribution systems with hazards. The cost for all very small farms is $1.1 million ($39 x 26,947), for small farms is $1.8 million ($393 x 4,693), and for large farms is $12 million ($1,396 x 8,571). The total cost to comply with this provision is $14.9 million, and the average cost per farm is $202.

Table 93: Costs to Prevent Contamination from Trash, Litter, or Waste				
	Very Small	Small	Large	Total
Number of farms	26,947	4,693	8,571	40,211
Average Produce Acres per farm	17	83	462	
Operator/Supervisor time to monitor for this (sec/daily)	33	166	923	
Operator/Supervisor time to monitor for this (minutes per day)	1	3	15	
Operating Days – ALL	90	180	180	
Operator/Supervisor time cost to monitor for this (per day)	$0.4	$2	$8	
Cost per farm (annual)	$39	$393	$1,397	
Total Costs (annual cost in millions)	$1.1	$1.8	$12	$14.9
Costs per affected farm				$202
Costs per farm	$39	$393	$1,397	$202

Table 94 presents the cost of providing proper trash disposal at in all on-farm buildings. We estimate that only about 1.5 to 1 percent of on-farm buildings do not already properly dispose of their trash. Applying this percentage to the total number of farms with buildings onsite yields the number of farms that will need to hire trash removal services. We estimate that 69 (4581 x 0.015) very small, 10 (1033 x 0.01) small, and 19 (1886 x 0.01) large farms will need to begin a trash removal to satisfy the requirements of this provision. Based on a number of trash removal services, we estimate that it will cost farms between $1,000 and $1,400, annually, to hire a waste removal company. Multiplying the cost by the number of farms that will need to come into compliance yields the cost of trash removal to industry. We estimate that this will cost very small farms $68,903 (1000 x 69), small farms $12,549 (1200 x 10), and large farms $26,863 (1400 x 19). This represents a total cost to industry of $108,314. We seek comment on these estimates.

Table 94. Cost of Trash Removal			
	very small	Small	large
Number of Farms with Buildings	4,594	1,046	1,919
% not properly handling trash disposal	1.5%	1.0%	1.0%
Farms that will need to change behavior	69	10	19
annual per farm cost of industrial trash removal	$1,000	$1,200	$1,400
total cost of trash removal	$68,903	$12,549	$26,863
Total	**$108,314**		

c. Recordkeeping Burden for Cleaning of Certain Equipment

Additionally, Subpart L requires that all farms keep records of their cleaning activities associated with equipment subject to that subpart used in (1) growing operations for sprouts, and (2) covered harvesting, packing, and holding activities.

Table 95 presents the annual cost of tool cleaning records. All farms not currently keeping records on these cleaning activities will incur an additional cost. We estimate that the number of firms that must do additional cleaning in order to be in compliance with this subpart will also need to keep additional records; in addition, between 0 and 100 percent of all farms currently cleaning tools would need to keep additional records. Without further information we assume that a uniform distribution between 0 and 100 percent, with a mean of 50 percent, of the remaining farms would need to begin keeping records. The average annual hours required to keep cleaning records for worker tools is obtained from an ERG survey of manufacturers (Ref.16). This estimate is scaled down to account for the abbreviated calendar that farms are operating on. We estimate that farms will spend between 8 and 25 hours annually recording these activities, depending on farm size. This job will likely be performed by an average farm worker, whose wage we estimate at $14.00 per hour (Ref.2). Multiplying the hours by the wage rate gives the annual cost of recordkeeping for a single farm. We estimate this will cost very small farms $112 (8 x 14.00) and small and large farms $350 (25 x 14.00). The per farm cost times the number of farms affected yields the cost of recordkeeping by farm size; $2.22 million (112 x 19861) for very small, $1.22 million (350 x 3494) for small, and $2.24 million (350 x 6411) for large. In total, we estimate this will cost the industry an additional $5.69 million, annually.

Table 95. Recordkeeping Cost of Cleaning Worker Tools

	very small	small	large
farms that need to keep tool records	19,861	3,494	6,411
annual hours to record	8	25	25
Wages	$14.00	$14.00	$14.00
annual cost of record keeping per farm	$112	$350	$350
total cost of recordkeeping	$2,224,376	$1,222,725	$2,243,675
Total	**$5,690,776**		

Table 96 presents the annual cost of machinery cleaning records. We estimate that the number of farms that must do additional cleaning in order to be in compliance with this subpart will also need to keep additional records; additionally, 50 percent (between 0-100) of the remaining farms will also need to do additional recordkeeping. The average annual hours required to keep cleaning records for machinery is obtained from an ERG survey of manufacturers (Ref.16). This estimate is scaled down to account for the abbreviated calendar that farms are operating on. We estimate that farms will spend between 8 and 25 hours annually recording these activities, depending on farm size. This job will likely be performed by an average farm worker, whose wage we estimate at $14.00 per hour (Ref.2). Multiplying the hours by the wage rate gives the annual cost of recordkeeping for a single farm. We estimate this will cost very small farms $112 (8 x 14.00) and small and large farms $350 (25 x 14.00). The per farm cost times the number of farms affected yields the cost of recordkeeping by farm size; $2.10 million (112 x 18712) for very small, $1.15 million (350 x 3292) for small, and $2.11 million (350 x 6040) for large. In total, we estimate this will cost the industry an additional $5.36 million, annually.

Table 96. Recordkeeping Cost of Cleaning Machinery

	very small	small	large
farms that need to keep equipment records	18,712	3,292	6,040
annual hours to record	8	25	25
Wages	$14.00	$14.00	$14.00
annual cost of record keeping per affected farm	$112	$350	$350
total cost of recordkeeping	$2,095,744	$1,152,025	$2,114,000
Total	**$5,361,769**		

<u>Summary</u>

In total we estimate that the cost of compliance for preventive controls directed to Equipment, Tools, Buildings, and Sanitation will be approximately $65.49 million. The individual costs by provision, separated by farm size, are laid out in Table 97. Costs are separated into physical costs, which included cleaning, monitoring, etc., and recordkeeping costs, which involve only the paperwork portion of the provision. From the table, we see that physical costs account for about $58.87 million, or about 85% of the total burden. All recordkeeping activities cost about $11.05 million. The most costly provision is cleaning all on farm machinery, followed by the providing toilets and hand washing facilities. Although, they are the most costly provisions, we also estimate these will be the most beneficial in reducing the human health burden, as they directly contact produce.

Table 97. Summary of Total Costs (in Millions)

Physical costs	very small	small	large	**Total**
total cost to clean/sanitize tools	$1.28	$1.03	$7.32	**$9.63**
total cost to clean machinery	$4.93	$3.00	$10.12	**$18.04**
Total cost of pest control	$0.68	$0.46	$0.85	**$1.98**
total cost of trash removal	$0.07	$0.01	$0.03	**$0.11**
total cost to provide toilets and hand washing	$3.35	$1.86	$8.97	**$14.18**
total cost to prevent sewage contamination	$0.01	$0.01	$0.01	**$0.03**
total cost to dispose litter and land drainage	$1.06	$1.85	$11.97	**$14.88**
TOTAL PHYSICAL COSTS	**$11.38**	**$8.22**	**$39.27**	**$58.87**
Recordkeeping costs				
total cost to clean/sanitize tools	$2.22	$1.22	$2.24	**$5.69**
total cost to clean machinery	$2.10	$1.15	$2.11	**$5.36**
TOTAL RECORDKEEPING COSTS	**$4.32**	**$2.37**	**$4.35**	**$11.05**
TOTAL COSTS	**$15.70**	**$10.59**	**$43.62**	**$69.92**

Additionally, provided in Table 98 are the average per farm costs of each provision. From this table, we estimate a firm completely non-compliant would incur a cost of $581 for very small farms, $2,228 for small farms, and $5,001 for large farms.

However, it is unlikely that any one farm will need to do all of these activities to be compliant. More realistically, they will have one or two provisions that apply to them individually. We seek comment on these estimates including how to estimate per farm costs given that it is likely that farms currently comply with some of these provisions.

Table 98. Summary of Per Farm Costs

Physical costs	very small	small	large
cost to clean/sanitize tools	$47	$217	$839
cost to clean machinery	$182	$631	$1,160
cost of pest control	$25	$97	$97
cost of trash removal	$3	$2	$3
cost of toilets and handwashing	$124	$391	$1,028
cost of sewage controls	$0	$2	$1
cost of field trash disposal	$39	$389	$1,372
PHYSICAL COSTS	**$421**	**$1,729**	**$4,502**
Recordkeeping costs			
cost to clean/sanitize tools	$82	$257	$257
cost to clean machinery	$78	$242	$242
RECORDKEEPING COSTS	**$160**	**$499**	**$499**
TOTAL COSTS	**$581**	**$2,228**	**$5,001**

7. Sprouts

Sprout producers would have to comply with all of the provisions of this proposed rule, as applicable. There are also proposed provisions that are specifically required of sprouts producers. Sprouts producers would be required to grow, harvest, pack, and hold sprouts in a fully-enclosed building; clean and sanitize food-contact surfaces used to grow, harvest, pack, and hold sprouts before contact with sprouts or with seeds or beans for sprouting; treat each batch of seeds or beans for sprouting using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance; test spent sprout irrigation water for each production batch of sprouts (or test each production batch of in-process sprouts when not practicable to test spent irrigation water) for *Salmonella* and *E.* coli O157:H7 using a sampling plan that meets the requirements in the proposed rule; and establish and implement an environmental monitoring plan (including a sampling plan) that is designed to find *L*. monocytogenes if it is present in the growing, harvesting, packing, or holding environment by testing for Listeria spp. or L. monocytogenes. Sprouters would also be required to take certain corrective steps if they detect *Listeria* spp. or *L.* monocytogenes in the growing, harvesting, packing, or holding environment (discussed in section VI.G.9 of this document). The proposed recordkeeping requirements include, documentation of the farm's required treatment of seeds or beans used for sprouting, the written environmental monitoring plan (including its sampling plan), the written sampling plan for testing of spent irrigation water or in-process sprouts, documentation of all analytic test results, any analytical methods that are used as substitutes for the proposed methods, and the testing method used to test spent irrigation water or in-process sprouts. The proposed rule also requires that covered farms that grow seeds or beans for their own sprouting purposes to take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto seeds or beans for sprouting. The proposed rule also requires sprouters, if they know or have reason to believe that a lot of seeds or beans have been associated with foodborne illness, not use that lot of seeds or beans for sprouting; and requires sprouters to visually examine seeds or beans for sprouting and the packaging materials used to ship them for signs of potential contamination.

Current Business Practice

The FDA guides "Reducing Microbial Food Safety Hazards for Sprouting Seeds" (Ref.70) and "Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production" (Ref.71) were both published in 1998 and many of the recommendations have been adopted by industry. When estimates of rates of current business practice are not found elsewhere in the literature, we estimate that provisions in the proposed rule that correspond to similar recommendations in published guidance are already currently practiced by 50 percent of sprout producers. We ask for comment on this estimate.

There are few estimates of the number of sprout producers as well as the size of the market for sprouts. The number of farms that grow sprouting seeds and beans for their own production is highly uncertain. We have very little knowledge of the number of seed and bean farms that would need to be in compliance with the proposed requirements. We estimate that the number of farms that grow seeds and beans for their own sprout production is very small, and that many would be exempt from this proposed rule because their small size. We ask for comment on the number of sprout producers that also grow seeds and beans and the extent to which these farms would be covered by this proposed rule.

The proposed rule would require sprout producers to use only fully enclosed buildings for producing sprouts. We do not have information on the number of sprout producers that do not use fully enclosed buildings. We assume that these are small producers and would qualify for an exemption to this proposed rule. We ask for comment on the number of sprout producers that do not use fully enclosed buildings that would be covered by this proposed rule.

Quantities of sprouting seed and sprouts produced annually

There are many types of sprouts and there are different ways of producing each type of seed. One estimate from an industry expert suggests that approximately two-thirds of all sprouting seed sold are either mung beans or soy beans, and production for those is largely foreign-based (Ref.72). With regard to green sprouting seed (non-bean sprouting seed), alfalfa sells more than any other and is estimated to account for 75 to 80 percent of the green sprout market (Ref.73). According to correspondence with an industry expert, the alfalfa seed used for sprouting purposes currently comes from the US, Canada, Australia and Italy (Ref.72).

A USDA report on the environmental impact statement on alfalfa estimates that in 1998 domestic alfalfa sprout producers purchased 1.5 to 1.8 million pounds of alfalfa seeds, and produced 15 to18 million pounds of alfalfa sprouts (Ref.74). We use the estimate reported above that alfalfa represents between 75 and 80 percent of the green sprouting seed market (Ref.72) to estimate that there are between 1.94 to 2.32 million lbs of green sprouting seeds used by domestic sprout producers (1.5 million lbs. / 0.775 and 1.8 million lbs. / 0.775, using the midpoint of the range between 75 and 80 percent). We use the estimate that beans represent two-thirds of all sprouting seed sold to estimate that between 5.87 and 7.04 million lbs, with a midpoint of 6.45 million lbs, of sprouting seed (green sprouting seed and beans for sprouting) are used by the domestic sprouting industry. We request comments on this estimate. Using a ratio of 10 lbs of sprouts from 1 lb of sprouting seed (Ref.74), and assuming that this ratio holds true for beans for sprouting as well, we estimate that between 49.85 and 59.82 million lbs of sprouts, with a midpoint of approximately 55 million lbs, are produced domestically each year. We request comments on this estimate.

Table 99: Industry-wide quantities of sprouting seed and beans used by sprout producers		
	low	High
Green sprouting seed	1.94	2.32
Green sprouting seed + beans for sprouting (assuming 67 percent of sprout market is beans)	5.87	7.04
Quantities of sprouts produced		
All sprouts (lbs.)	49,850,000	59,820,000
Mean estimate of all sprouts (lbs.)	54,838,710	

Annual Number of Sprout Production Batches

Estimates of the costs of the proposed requirements for testing spent irrigation water or sprouts, and treatment of seeds for sprouting depend on the number of production batches of sprouts that are produced. We use expert testimony from the transcripts of FDA's 1998 and 2005 Public Meetings on sprouts to estimate the average size of a batch, and the number of batches per year. We then divide the total quantity of sprouting seed estimated earlier by the estimate of the average batch size to obtain an estimate of the number of batches of sprouts produced annually.

Equipment available for sprouting beans called a "bin" can be used to sprout 1,700 lbs. of finished bean sprouts from 170 lbs. of seed (Ref.73) using a ratio of 10 to 1 of sprouts to beans. A rotary drum is typically used to produce green sprouts (alfalfa, onion, broccoli, etc.) (Ref.72). These drums produce approximately 500 lbs. of sprouts from approximately 50 lbs. of seed, using a ratio of 10 to 1 of sprouts to seed.

Based on these descriptions of the equipment used, we estimate that a typical "batch" of bean sprouts is approximately 170 lbs of beans for sprout producers earning the mean reported gross revenue, and that a batch of green sprouts is approximately 50 lbs. of seed for the sprout producers earning the mean gross revenue. We weigh each batch size by the corresponding share of the market for green sprouts (33 percent of the sprout market x 50lbs of green sprouting seed in a typical batch) and bean sprouts (67 percent of the sprout market x 170 lbs. of beans in a typical batch) and estimate a weighted average batch size of approximately 130 lbs. of seeds and beans for the sprout producer earning the mean gross revenue.

We estimate that the average size of a batch for sprout producers that earn less than the mean gross revenue would be less than 130 lbs. of seed, in proportion to the revenue earned relative to the mean. We estimate that the average size of a batch for the sprout producers that earn more than the mean gross revenue is constrained by the equipment size (170 lbs. and 50 lbs. for beans and seeds, respectively) and would be the same as the batch size for producers that earn the mean revenue. Dividing the total quantity of seeds (6,450,000 lbs.) by the average batch size (130 lbs.) yields an estimated 50,000 (49,628 rounded up) batches per year produced in the sprouting industry.

There is little information on the size and structure of the sprout producing sector. According to testimony by representatives of the International Sprout Growers Association (ISGA) at a public meeting held at FDA in 1998 there are approximately 475 domestic commercial sprout producers (Ref.73). The distribution of gross annual sales across sprout producers was reported in the FDA's 1998 Field Assignment report from a sample of 83 sprout producers (Ref.75). We apply this distribution to the total number of sprout producers (475) and calculate the numbers of sprout producers by category of gross annual sales reported in Table 100. We estimate the weighted average revenue of sprout producers by multiplying the midpoint of each revenue category by the percent of sprout producers in the corresponding category and add them all together ($12.5K x 0.04 + $37.5K x 0.06 +…+$17.5M x 0.025). The weighted average revenue estimated for sprout producers is approximately $1.01 million ($1,014,440, rounded to the near 10 thousand).

Table 100: Distribution of Sprouting Firms by Gross Annual Sales

Gross annual sales	0-$25k	$25k-$50k	$50k-$100k	$100k-$500k	$500k-$1M	$1M-$5M	$5M-$10M	$10M-$25M
Number of sprouting firms	19	29	48	228	107	29	5	12
Fraction of all sprout producers	0.04	0.06	0.10	0.48	0.225	0.06	0.01	0.025

We do not know how many sprout producers would qualify for an exemption from this proposed rule or would not be covered by this rule based on their size. We estimate the number of firms that would be eligible for the qualified exemption from this proposed rule based on average annual value of food sold and direct farm marketing (proposed § 112.5) by applying the same distribution used to estimate the number of non-sprout produce farms that would be eligible for that qualified exemption from this proposed rule to the distribution of sprout producers obtained from the 1998 Field Assignment, but taking into account only the TVP proportions of the size definitions. The percentages of sprout producers by size that we estimate to be eligible for this qualified exemption are reported in Table 101. We apply this distribution to the industry-wide numbers of batches and sprout producers used to estimate costs of the sprouts provisions in the remainder of the analysis.

Table 101: The distribution of qualified exempt status under proposed § 112.5 by size

Farm Size ("Food" TVP) & Acres)	Percent Exempt
< $25K TVP	76 percent
< $250K TVP	57 percent
< $500K TVP	55 percent

> $500K TVP	1 percent

Costs of requiring farms that grow seeds or beans for their own sprouting to take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto seeds or beans and visually examine seeds or beans and packaging materials for signs of potential contamination, and not using lots of seeds or beans you know/suspect to be associated with foodborne illness.

We estimate the number of farms that grow seeds or beans for their own sprouting is very small and do not estimate costs for these seed producers in the remainder of the analysis. We ask for comment on the number of farms that grow seeds or beans for purposes of their own sprouting. We estimate that all sprout producers would need to take some time to visually examine seeds or beans and packaging materials. We estimate that all sprout producers visually examine seeds or beans and packaging materials they arrived in to some extent, and do not estimate the increment of time spent by sprout producers visually examining seeds or beans and packaging materials for signs of potential contamination due to this proposed rule. We assume that this time increment is small and we ask for comments on the additional costs associated with visually inspecting seeds or beans and packaging materials due to this proposed rule.

We estimate that all sprout producers currently refrain from using lots of seeds or beans that are associated with foodborne illness. We estimate that this proposed rule will serve to focus sprout producers' attention on the possibility of using lots of seeds or beans that are associated with foodborne illness, but do not estimate the additional quantity of seeds that might otherwise be used if this proposed rule were not to become final. Moreover, the public health benefits of refraining to use lots of seed associated with foodborne illness clearly outweigh any cost of doing so, further justifying our omission of the cost consideration associated with this requirement.

Seed disinfection costs and costs for cleaning and sanitizing food contact surfaces

The costs of the requirement to clean and sanitize food contact surfaces that touch sprouts or seeds or beans for sprouting are included in the general cost estimate in the section entitled "Worker Tools and Equipment" that addresses food contact surfaces for all covered entities. The proposed rule would require sprout farms to treat seeds or beans for sprouting using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Prior treatment conducted by a grower, handler, or distributor of seeds or beans other than the covered farm would not relieve the covered farm from the responsibility to perform this treatment at the farm. We use the costs of calcium hypochlorite treatment, which is mentioned in FDA's "Guidance for industry: Reducing Microbial Food Safety Hazards for Sprouting Seeds" (Ref.70) to estimate the costs of this requirement, although there may be other approved treatments that would satisfy this requirement as well. We ask for comment on the extent of use of treatments other than calcium hypochlorite that would satisfy the requirement to disinfect sprouting seed. In addition to the cost of calcium hypochlorite, the costs of seed disinfection include the labor costs of preparing, administering and monitoring treatment for each batch for a significant amount of time, and then rinsing the seeds to ensure that no calcium hypochlorite remains during sprouting. Based on FDA's 1998 public meeting testimony, seeds can soak in treated water for up to 4 to 8 hours before being rinsed prior to sprouting (Ref.71). We estimate that the cost of calcium hypochlorite would depend on the quantity of seeds to be treated, and that the labor costs for the treatment would be incurred by batch.

Based on correspondence with an industry expert, 3,000 lbs. of seed would require approximately $238 of calcium hypochlorite (at the time of the correspondence), or approximately $0.08 of hypochlorite per lb. of seed (Ref.72). This implies that 6,450,000 lbs. of seed would require approximately $516,000 of calcium hypochlorite to treat (i.e., $516,129 rounded down), based on the FDA recommended concentration, and with a seeds-to-water ratio of 5 lbs. of seed to 1 gallon of water. This may underestimate the costs of calcium hypochlorite to the extent that time for purchase and storage of the chemical are not included.

We estimate that calcium hypochlorite costs would be distributed across sprout producer firm sizes based on their share of total revenue. Each size category of sprout producers would incur calcium hypochlorite costs based on the share of revenue represented by that category multiplied by $516,129. For example, since very small facilities earn 15.14 percent of total industry revenue they would incur 15.14 percent of the industry-wide costs of the chemical used for treatment. We then multiply the resulting cost by the percentage of production that is estimated to be exempt. The costs are reported in Table 102.

Since labor costs for treatment are incurred by batch, we estimate that each batch would require on average of 1 hour of labor to prepare, administer, and monitor the treatment. We estimate the hourly wage for this task to be $30.25, which is the mean hourly wage reported in the BLS for 2010 for first-line supervisors for farming of $20.17, multiplied by 1.5 to account for overhead (Ref.2). Based on industry-wide estimates of the number of batches (50,000 batches), we estimate total industry labor costs for preparing, administering and monitoring treatment would be approximately $1,512,500, before accounting for exemptions.

We estimate that labor costs for seed treatment would be distributed across sprout producer firm sizes based on the number of batches in each size category, with the constraint that the numbers of batches sum to 50,000. We estimate that very small and small sprout farms would each grow approximately 1 batch of sprouts per week while large facilities would produce the remaining number of batches. For example, 323 very small, small, and medium sized sprout farms would produce 16,150 batches of sprouts per year (323 sprout producers x 50 batches per year, and large sprout producers would produce 33,850 batches of sprouts per year (50,000 batches industry-wide minus 1,650 - the number of batches produced by very small and small firms). We then adjust the industry-wide estimate of the number of batches to account for qualified exemptions by applying the percentage of producers (and batches) in each size category reported in the section entitled "Annual Number of Sprout Batches." The labor costs for treatment are reported by size category in Table 101.

We use information obtained from the 1998 Field Assignment and acknowledge similar provisions in FDA guidance documents to estimate the rate of current industry practice of treating each batch of seeds for sprouting. According to 1998 Field Assignment, 89 percent of sprouting firms soaked seeds and beans in some form of chlorinated water. This practice is also recommended in the current FDA guidance entitled "Reducing Microbial Food Safety Hazards for Sprouting Seeds." Based on this framework, FDA estimates that 90 percent of sprout producers currently adhere to this practice. We ask for comment on current rates of seed disinfection in the sprouting industry. Total costs for seed treatment by size category are reported in Table 102.

Table 102: Costs to treat seeds or beans that will be used to grow sprouts

	Very small	Small	Large
# sprout producers	74	60	151
# Batches	3,710	2,976	33,623
Calcium hypochlorite costs	$7,004	$3,414	$487,273
Labor costs	$112,223	$90,020	$1,017,102
Estimated rate of industry practice	90%	90%	90%
Costs per size category	$11,923	$9,343	$150,438
Cost of the provision	$171,704		

Spent irrigation water and sprouts testing costs

The proposed rule requires that sprout farms test spent sprout irrigation water from each production batch of sprouts for *E. coli* 0157:H7 and *Salmonella* spp., or when testing spent sprout irrigation water is not practicable (such as for soil-grown sprouts), test each production batch of sprouts at the in-process stage for the same microorganisms. For either kind of testing the sprout farm must follow a sampling plan that meets the requirements of the proposed rule. We estimate that each test of sprouts or spent irrigation water requires labor for sample collection, shipping costs, and laboratory analysis costs to test for the pathogens *E.* coli O157:H7 and *Salmonella,* sp. We modify the costs for in-house water sample collection described in the section entitled "Agricultural Water" to account for the laboratory analysis of two pathogens (*Salmonella* and *E.* coli O157:H7) rather than generic *E*. coli. From FDA's "*Guidance for Industry: Sampling And Microbial Testing Of Spent Irrigation Water During Sprout Production"* (Ref.71) we estimate that the same sample of water could be analyzed for both pathogens.

From correspondence with a private laboratory, the cost for analyzing for *Salmonella,* sp is $30, and the cost for analyzing for *E.* coli O157:H7 is $35 (Ref.76). We estimate the sample collection supplies, shipping costs and the costs for shipping supplies would be the same as those reported in the section entitled "Agricultural Water" ($5 for sample collection supplies, $41 for overnight shipping and $21 for shipping supplies), and that ½ hour of labor would be required to collect a sample of the spent irrigation water, consistent with that reported in the section entitled "Agricultural Water" for a labor cost of ($15.05). The total costs incurred to collect, ship and analyze a sample of spent irrigation water or sprouts are estimated to be $148 ($30.for *Salmonella* testing + $35 for *E.* coli O157:H7 testing + $5 for sample collection supplies + $21 for shipping supplies + $41 for overnight shipping + $15.02 for labor costs) We multiply $148 by the number of batches in each size category reported in Table 103.

We do not have recent estimates of current industry practice and for purposes of this analysis we use information from the FDA 1998 Field Assignment Report to estimate the rate of the industry practice of testing spent irrigation water or sprouts. We acknowledge that information from the 1998 Field Assignment may be somewhat dated; however, we justify its use by the similarity of testimonies by ISGA representatives characterizing the number of sprout producers at public meetings in both 1998 and 2005. In both testimonies ISGA participants report that there are 475 sprout producers in the domestic industry - an indication that the sprout industry had not undergone dramatic changes between 1998 and 2005. We ask for comment on the applicability of using information on sprouting practices in 1998 to estimate current sprouting practices.

We do not have good information on the practice of testing spent irrigation water or in-process sprouts for *Salmonella* and *E.* coli O157:H7. The 1998 Field Assignment of sprout producers did not address the practice of testing spent irrigation water or testing in-process sprouts for *Salmonella* and *E.* coli O157:H7. However, it did address the practice of finished produce testing, and we use the findings from the Field Assignment report on finished product testing for *Salmonella* and *E.* coli to estimate the rates of current practice of testing spent irrigation water or in-process sprouts for these pathogens. We ask for comment on the appropriateness of using finished product testing to estimate current practice of spent irrigation water testing or for testing in-process sprouts.

According to the 1998 Field Assignment report, 28 percent of sprouting firms conducted finished product testing for *Salmonella* and *E*. coli O157:H7. However, product testing was very infrequent and only 9 percent (the highest percentage that reported a frequency of testing) reported testing their product quarterly. We estimate that 9 percent of all producers in all size categories test their product quarterly. From the earlier discussion of the annual number of batches produced by farm size, we estimate that each very small and small sprout farm produces 1 batch per week or approximately 50 batches of sprouts annually, and each large facility produces approximately 220 batches annually. Consequently, we estimate that current rates of batch testing are 1 percent for very small and small producers (4 batches tested / 50 batches produced per year x 9 percent) and 0.2 percent for large producers (4 batches tested / 220 batches produced annually x 9 percent) assuming that large producers currently test one batch every 3 months. Spent irrigation and sprout testing costs are reported in Table 103.

Table 103: Costs to test each batch of sprouts for *E. coli* O157:H7 and *Salmonella,* sp.

Firm size	Very small	Small	Large
# sprout producers	74	60	151
# Batches	3,710	2,976	33,623
Testing costs	$549,057	$440,430	$4,976,234
Rate of industry practice	1%	1%	0.2%
Total cost by size category	$545,104	$437,258	$4,968,190
Total cost for the provision	$5,950,552		

Costs to establish and implement a written environmental monitoring plan

The proposed rule requires the establishment and implementation of a written environmental monitoring plan, including a sampling plan, for testing the sprout growing, harvesting, packing, and holding environment to find L. monocytogenes if it is present by testing for either Listeria spp. or L. monocytogenes. The number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces. Facilities should determine the points to sample and the frequency of sampling, and the frequency of sampling must be no less than monthly.

For our base case costs of environmental testing, we estimate that: Testing will occur once per month, The farm will collect 5, 10, or 15 samples per occasion, depending on facility size, and The farm will send the samples to an outside laboratory for analysis. To undertake environmental sampling on a routine basis, we estimate that farms will need to buy the following supplies: Sampling sponges or swabs, Neutralizing buffer broth, Sample collection bags, Sterile gloves, Cooling medium (e.g. gel packs) for samples, Coolers, and Sterile tool to scrape debris out of cracks.

We assume that the one-time costs of establishing an environmental monitoring plan are small compared to the implementation costs and are incorporated into the estimated costs of implementing an environmental monitoring plan. We ask for comment on this assumption.

We estimate that it will take 15 minutes to collect each sample; each sample will be collected by an environmental science and protection technician (BLS food manufacturing code 19-4091) earning an hourly wage rate of $23.34 including overhead. The number of samples taken depends on the farm set-up and the age of the structure. We estimate that it is likely that smaller farms will need to take fewer samples per sampling occasion than larger farms.

We obtained information from a private laboratory on the testing costs per swab for *Listeria* (Ref.77). For *Listeria* genus, we use the pricing for the 48 hour Enzyme Linked Fluorescent Assay (ELFA) test with no confirmation. For the environmental testing costs presented here we do not include the costs of confirmation of a presumptive positive sample. If a presumptive positive swab is found based on the environmental testing conducted, additional environmental testing and even product testing by the farm is likely to be undertaken in an effort to find the source of the contamination. The costs of such activities would be covered under the corrective actions costs as analyzed in the corrective actions section of this analysis.

Samples will be collected using sponges, buffer broth, gloves, and collection bags ($2.33 for a sponge pre-moistened with buffer broth, sterile gloves and sample bag.) (Ref.76). We also include the cost of disposable sterile sampling spatulas ($1.04 per spatula) (Ref.77). For shipping supplies, we estimate the costs of an insulated shipping carton and gel packs to keep samples at the appropriate refrigerated temperature until they can be analyzed by the laboratory ($18.86 per carton + $2.90 per gel pack+ $37.75 for overnight delivery).

Table 104 shows the annual costs of environmental testing per farm for *Listeria* sp. based on 15 samples per month as an example. Farms that send a high volume of samples to a laboratory can negotiate lower pricing per sample for testing than can farms sending a lower volume of samples. We show the difference in the annual costs by number of samples and volume-based pricing Tables 104 and 105.

Table 104: Annual costs of environmental monitoring for 15 samples per month for high and low volume pricing

-	Low Volume pricing	High Volume Pricing
-	*Listeria*	*Listeria*
Hourly labor cost (includes overhead)	$23.34	$23.34
Time to collect each sample (hours)	0.25	0.25
Number of samples	15	15
Total labor cost	$88	$88
-	-	-
Cost of sampling supplies per sample	$3.37	$3.37
Number of samples	15	15
Total sampling supplies cost	$51	$51
-	-	-
Cost of shipping supplies	$21.76	$21.76
FedEx Standard Overnight	$37.75	$37.75
Total cost of shipping	$60	$60
-	-	-
Lab analysis cost per swab	$26.00	$17.50
Number of samples	15	15
Total cost of laboratory analysis	$390	$263
-	-	-
Total Cost Per Shipment	$588	$460
Number of shipments annually	12	12
Annual testing costs per facility	$7,051	$5,521
Mean testing cost per facility for 15 samples per monthly shipment	$6,511	

We estimate that the numbers of samples collected per monthly shipment would depend on the size of facility and that large farms would collect 15 environmental samples per shipment, small farms would collect 10 environmental samples per shipment, and very small farms would collect 5 environmental samples per shipment.

Table 105: Annual environmental monitoring testing costs by sample size, and volume pricing	
	Listeria
Low volume pricing	
5 samples	$2,826
10 samples	$4,939
15 samples	$7,051
High volume pricing	
5 samples	$2,316
10 samples	$3,919
15 samples	$5,521
Mean price	
5 samples	$2,571
10 samples	$4,429
15 samples	$6,286

The 1998 field assignment did not identify the use of environmental monitoring plans as a practice to observe during visits to sprout farms, and we do not have information on the current rates of practice of establishing and implementing an environmental monitoring plan. Moreover, the proposed requirement to establish and implement an environmental monitoring plan is not contained as a recommendation in any FDA sprout guidance, and we estimate that currently adherence to the proposed practice of establishing and implementing an environmental monitoring plan to be 0 percent. We ask for comment on the current practice of establishing and implementing an environmental monitoring plan. The costs for establishing and implementing an environmental monitoring plan are reported in Table 106.

Table 106: Costs to implement an environmental monitoring plan			
Facility size	Very small	Small	Large

No. sprout producers	74	60	151
Annual environmental testing costs per firm	$2,571	$4,429	$6,286
Estimated rate of industry practice	0%	0%	0%
Costs by size category	$190,760	$263,603	$949,070
Total cost of the provision	$1,403,434		

Costs of learning a specified protocol to collect environmental samples and test for *L.* sp., or *L.* monocytogenes

The proposed provision requires a specified protocol (proposed § 112.152) for collecting environmental samples and testing for *Listeria* sp. or L. monocytogenes. We estimate that there would be a one-time cost of learning the specific collection and testing protocol required by the proposed rule. We estimate that 1 scientist would incur half a day to learn the protocol and consider how best to implement it. We use the mean hourly wage of environmental science and protection technician (May 2010 BLS food manufacturing code 19-4091) earning an hourly wage rate of $23.34 including overhead) and multiply by 4 hours (half a day) to obtain a one-time learning cost of $93.36, which is equivalent to an annualized cost of $17 assuming an annual rate of interest of 7 percent payable over 7 years. We do not have information on the rates of current industry adherence to this practice and it is not contained as a recommendation in either of FDA's sprout guides. Consequently, we estimate that the rate of current practice is 0 percent.

Table 107: Costs of leaning a specified protocol to collect environmental samples and test for *L.* sp., or *L.* monocytogenes			
Facility size	Very small	Small	Large
No. sprout producers	74	60	151
One-time learning cost per firm	93.36	93.36	93.36
Annualized cost per firm (7 years at 7 percent)	$17	$17	$17
Estimated rate of industry practice	0%	0%	0%
Total cost by size category	$1,285	$1,031	$2,615
Total cost of the provision	$4,932		

Costs to establish and implement a written sampling plan for testing spent sprout irrigation water or in-process sprouts

The proposed provision requires the establishment and implementation of a written sampling plan for testing spent sprout irrigation water or in-process sprouts. We estimate the cost for establishing a sampling plan is a one-time cost. The recurring costs of implementing the sampling plan were reported in the section entitled "Spent irrigation water and sprouts testing costs" and we assume that the one-time costs of establishing a sampling plan are small compared to the implementation costs and are incorporated into the costs estimated for implementing a sampling plan. We ask for comment on this assumption. The total costs of the sprouts provisions are reported in Table 108.

Table 108: Cost of the Sprouts Provisions

Description	Very small	Small	Large
costs for cleaning and sanitizing food contact surfaces	Estimated in section entitled "Worker, Tools, and Equipment"	Estimated in section entitled "Worker, Tools, and Equipment"	Estimated in section entitled "Worker, Tools, and Equipment"
Seed disinfection costs	$11,923	$9,343	$150,438
Costs to test each batch of sprouts for *E. coli* O157:H7 and Salmonella, sp.	$545,104	$437,258	$4,968,190
Costs to implement an environmental monitoring plan	$190,760	$263,603	$949,070
Costs for a specified protocol for collecting environmental samples and testing for L. sp., or L. monocytogenes	$1,285	$1,031	$2,615
Total cost by size category	$749,072	$711,236	$6,070,313
Total cost of the sprouts provisions	$7,530,621		

Recordkeeping costs

Documentation of a sprout farm's treatment of their seeds or beans for sprouting, a written environmental monitoring plan (including a sampling plan), a written sampling plan for each production batch of sprouts, test results, documentation of any analytical methods that are used as substitutes for the proposed methods, and the testing method used to test spent irrigation water or in-process sprouts all would require records. We use the recordkeeping burdens reported in the *Evaluation of Recordkeeping Costs for Food Manufacturers* (ERCFM) as described in the section entitled "Economic Analysis Costs: Overview of Cost Conventions and Farms Covered." For very small and small sprouting operations, we value the recordkeeping burden by the farm operator or manager mean wage rate described in the section entitled "Economic Analysis Costs: Overview of Cost Conventions and Farms Covered" of $47.40 to estimate the hourly costs. For large sprouting operations we use the Farm Supervisor Mean Wage Rate described in the section entitled "Economic Analysis Costs: Overview of Cost Conventions and Farms Covered" of $30.26 to estimate the hourly costs.

All covered sprout farms would be required to sample and analyze each batch of spent irrigation water or sprouts and also sample and analyze environmental samples at frequencies specified in their environmental monitoring plans. Consistent with findings reported in ERCFM, we estimate the per-activity recordkeeping burden for sampling and testing spent irrigation water or the production environment to be approximately 9 minutes (the midpoint of the reported range of between 5 and 13 minutes for sampling and testing records). We estimate the per-activity burden for recording the analytic results of the spent irrigation water, sprouts, or environmental samples to be approximately 10 minutes (the midpoint of the reported range of between 6 and 15 minutes for analytic testing records).

All covered sprout producers would need to document seed treatment done at their farms. The proposed rule requires sprout producers to treat their seeds. Consistent with the description of the sprout production process from testimony at the 1998 public meeting on sprouts (Ref.73), we estimate that treatment will be administered by production batch. We use the average minutes spent keeping production process records reported in ERCFM of between 6 and 17 minutes, with a midpoint of 12 minutes to estimate the per-activity burden for keeping seed treatment records.

All sprout producers would be required to maintain records of their written environmental monitoring plan and their sampling plan for spent irrigation water or in-process sprouts. We estimate that the one-time burden for establishing an environmental monitoring plan is similar to the burden for writing SOPs for environmental monitoring records reported in ERCFM of 7 hours, 12 hours and 17 hours for very small, small and large operations. We estimate that the one-time burdens for establishing a sampling plan is similar to the burden for writing SOPs for sampling and testing records reported in ERCFM of 9 hours, 18 hours and 24 hours for very small, small and large operations.

We assume that all spout farms will also incur burden for plan updates, and we estimate that the burden for updating an environmental monitoring plan is similar to the burden for updating SOPs for environmental monitoring records reported in ERCFM of 2 hours, 4 hours and 6 hours for small, medium and large operations. We estimate that the burden for updating a sampling plan is similar to the burden for updating SOPs for sampling and testing records reported in ERCFM of 3 hours, 6 hours and 8 hours for very small, small and large operations.

We estimate the costs of keeping a record of any analytical methods that are used as substitutes for the proposed methods, and the testing method used to test spent irrigation water or in-process sprouts as one-time costs. However, we do not know the extent to which these records will be needed, and ask for comments on the extent to which substitutes to the proposed analytical and testing methods will be used. The recordkeeping burdens, one time recordkeeping costs, and recurring recordkeeping costs of the sprouts provisions are reported in Tables 109, 110, and 111.

Table 109: Recordkeeping burdens for very small, small, and large sprout producers

Recordkeeping cost description	Per-activity hourly burden	Frequency for very small firms[1]	Frequency for small firms[1]	Frequency for large firms[1]	Total burden for very small firms	Total burden for small firms	Total burden for large firms
Documentation of seed treatment at sprouting facility	0.20	3,710	2,976	33,623	742	595	6,725
Environmental monitoring plan (one-time)					7	12	17
Environmental monitoring	0.15	60	120	180	9	18	18
Environmental monitoring test results	0.17	60	120	180	10	20	20
Irrigation water sampling plan (one-time)					9	18	24
Irrigation water sampling	0.15	3,710	2,976	33,623	557	446	557
Spent irrigation water test results	0.17	3,710	2,976	33,623	618	496	618

[1]The frequencies include the aggregate for all firms in the corresponding size category

Table 110: One-time Recordkeeping costs

One-time recordkeeping costs	Very small firms	Small firms	Large firms
No of firms	74	60	151
Environmental monitoring plan (one-time)	$24,619	$33,854	$79,131
Irrigation water sampling plan (one-time)	$31,652	$50,780	$111,714
Total one-time recordkeeping costs by size category	$56,271	$84,634	$190,845
Annualized one-time recordkeeping costs by size category (7 % for 7 years)	$10,441	$15,704	$35,412
Total one-time recordkeeping costs for the sprouts provision	$331,750		
Annualized one-time recordkeeping costs for the sprouts provision (7 % for 7 years)	$61,557		

Table 111: Recurring Recordkeeping costs			
Recurring recordkeeping costs	Very small firms	Small firms	Large firms
Documentation of seed treatment at sprouting facility	$35,171	$28,212	$207,319
Environmental monitoring	$427	$853	$555
Environmental monitoring test results	$474	$948	$617
Irrigation water sampling	$26,378	$21,159	$17,157
Spent irrigation water test results	$29,309	$15,292	$19,063
Total recurring recordkeeping costs for by size category	$91,759	$66,465	$244,711
Total recurring recordkeeping for the sprouts provision	$402,934		

8. Administrative Provisions

The personnel qualifications and training provisions impose training requirements on all farm operators, supervisors, and other farm workers that handle (contact) covered produce or food-contact surfaces. The training curriculum must include topics on food hygiene and food safety, worker and visitor health and hygiene, the standards established in the proposed rule applicable to the employee's job responsibilities. For workers who conduct harvesting activities there are additional training curriculum requirements including recognizing covered produce that should not be harvested, inspecting harvest containers and equipment, and correcting problems with harvest containers or equipment and reporting such problems, as appropriate to the person's job responsibilities. Training must be conducted in an easily understood manner, and all workers must be trained upon hiring, at the beginning of the season, and periodically thereafter.

At least one supervisor or operator on the farm is required to successfully complete food safety training at least equivalent to that received under standardized curriculum recognized as adequate by FDA. FDA intends to recognize curriculums that are based on the Produce Safety Alliance's (PSA) training materials or that are comparable. University cooperative extension programs, USDA programs, or other courses or materials can be used as long as they are equivalent to what FDA approves.

All personnel who handle covered produce or food-contact surfaces, or who are engaged in the supervision thereof, must have the education, training, or experience to do so in a manner that ensure compliance with the rule. Covered farms must assign or identify personnel to supervise or otherwise be responsible for the farm's operations to ensure compliance with the rule. Farms must also establish and keep records that document the required training, including the date of training, topics covered, and the persons trained.

Current Industry Practices

Food safety training on farms can vary significantly by topics covered, training method, and frequency of training. In the mushroom industry, farm worker training varies from receiving a list of official food safety rules with no reinforcement to attending training sessions with drawings and videos (Ref.78). In 1999, 86 percent of fruit and vegetable farms reported training workers on food safety, but the topic covered with the highest frequency was produce quality (Ref.6). The majority of training on these farm operations is usually conducted by the farm operator or manager followed by the labor crew supervisor (Ref.6). In New England, 50 percent of growers reported having a food safety and sanitation training program in 2001 (Ref.7). It is uncertain how detailed the training programs implemented on these farms are and whether they cover all of the information in the standardized curriculum that would be recognized by the FDA.

Farm operations currently implementing food safety programs require training on hygiene and sanitation procedures and for training to be conducted at the time of hire and periodically throughout the growing season when appropriate. Most of these food safety programs require training on topics regarding glove use, container and equipment contamination, and proper hand washing procedures. For example, the CA LGMA requires training on "appropriate and effective hand washing, glove use and replacement…" (Ref.10). However, the training requirements in the proposed rule cover additional topics than the requirements imposed by farms that have food safety training programs in place.

Farms are currently required by OSHA to train farm workers on health and hygiene issues to minimize worker exposure to hazards in the field (Ref.57). Relevant OSHA requirements that are similar to the provisions in the proposed rule only include training on hand-washing before and after using the toilet. Therefore, OSHA requirements are not considered as sufficient to ensure compliance with the training provisions in this proposed rule. It is uncertain how many farm operations currently have at least one supervisor with outside training equivalent to a standardized curriculum, and we seek comment on the number of farms this accounts for.

Costs

The cost for at least one supervisor or responsible party to receive training will be incurred by all 40,496 covered farms. Farms that have previously received training may be required to comply with this provision since it is uncertain at this time whether the course met the standards that will be recognized by the FDA. It is estimated that the farm operator will be responsible for attending the course across all farm sizes, and that the average farm operator will travel approximately 55 miles to and from the course taking approximately one hour of total travel time. Since operators will have different travel options to and from the course (e.g. driving, flying, or none if done online), we estimate that the 55 miles is a good approximation, but it could be an under or overestimate. Additionally, the farm supervisor or responsible party is not required to take the course from an outside party, but it is possible that he must still incur a travel cost. The total cost for a farm operator to travel to and from the course is $75 since an hour of his time costs $47.4 plus the cost of mileage at $0.51 per mile (Ref.79) for 55 miles [(1 hour x $47.4) + (55 miles x $0.51) = $75].

We base the cost of the training course on the average price of three food safety training courses we are aware of. Currently, the Cornell GAPs Online Produce Safety course costs $50 (due to a grant from the USDA) and takes approximately 12 hours to complete (Ref.32). In Arizona, the Department of Agriculture sponsors an LGMA workshop that costs nothing and takes 4 hours (Ref.80). However, training kits for the course cost $180, and although are not necessarily required for the course, are an approximate cost of the course itself. In early 2011, Pennsylvania State University provided GAPs training to growers across the state at a cost of $30 (due to grants from USDA, PA Department of Agriculture, and the PA Vegetable Growers Association) that took approximately 5 and a half hours (Ref.78). We estimate that the training courses available to comply with this requirement will cost on average $87 [($50+$180+$30)/3] for registration including materials, and will take 7.2 hours [(4+12+5.5)/3] on average to complete. The cost of the farm operator’s time while in the course will be $340 ($47.4 x 7.2 hours).

Table 112 shows the total farm costs of taking the training course. All 40,496 farms will need to comply at a cost of approximately $502 per farm ($75 travel cost + $87 course cost + $340 time cost) to take the course. Multiplying the number of farms with the cost per farm by farm size, we estimate that the total onetime cost to farms of this requirement is approximately $20.3 million [($502 x 27,021) + ($502 x 4,753) + ($502 x 8,722)]. This assumes that each farm will train someone that does not leave the operation in the foreseeable future. Because this training takes place at the managerial level we do not expect that turnover would greatly increase this cost. We request comment on this assumption. Annualizing the cost at 7 percent over 7 years, we estimate that the total annual cost is $3.8 million and that the cost per farm is $93.

Table 112: Provision for Food Safety Training by one supervisor or responsible party on the Covered Farm

	Very Small	Small	Large	Total
Number of Farms	27,021	4,753	8,722	40,496
Marginal costs				
Operator Travel Cost (Time cost of one hour + mileage @ $.51/mile)	$75	$75	$75	$75
Course Cost	$87	$87	$87	$87
Operator Time Cost (7 hours @ $47.40)	$340	$340	$340	$340
Total per farm cost	$502	$502	$502	$502
Total Costs Accrued to Farms (One time cost)	$13,559,399	$2,385,316	$4,376,662	$20,321,377
Total Costs Discounted at 7% over 7 years (annualized)	$2,515,990	$442,603	$812,104	$3,770,697
Costs per farm (annualized)	$93	$93	$93	$93

The cost of training management personnel and workers on the food safety topics outlined in the proposed rule will be incurred by all produce farms since it is uncertain how many farms currently have a training program that is equivalent to what is required in the proposed rule. For farms that either have a training program in place or are implementing a food safety program, we estimate that it will take less time to train their personnel than it would for other farms that do not since they will likely only have to change a few topics in their training programs in order to have equivalent programs to that in the standard curriculum. As estimated in the current industry practices section, there are approximately 1,117 farms with measurable food safety programs in place.

We estimate that approximately 68 percent of farms are currently providing food safety training in addition to those that have food safety programs. This is the average percentage from what was reported in the Fruit and Vegetable Agricultural Survey of 86 percent, and the percentage reported in the New England Survey of 50 percent. After subtracting the farms with food safety programs from the total number of farms by size, we multiply the 68 percent with the number of farms without food safety programs to obtain that 17,929 very small farms (0.68 x 26,366), 3,161 small farms (0.68 x 4,649), and 5,687 large farms (0.68 x 8,364) will not bear the full cost to train workers. The remaining 9,092 very small farms (27,021 - 17,929), 1,592 small farms (4,753 – 3,161), and 3,034 large farms (8,722 – 5,687) that do not have any food safety training in place will bear the full cost.

To estimate the number of hours that it will take to train other management personnel and farm laborers, we use an estimate obtained from a survey of CA LGMA growers of the additional training time needed to train personnel in the food safety topics covered by the LGMA. The survey, conducted by Hardesty and Kusunose (Ref.8), asks growers to report personnel training time before and after the implementation of the LGMA. The LGMA requires worker training on similar food safety topics that are required in the proposed regulation. However, the LGMA training standards are possibly not equivalent to the training materials approved by the FDA, but do serve as a measure of personnel's time that is spent in training devoted to food safety topics. It is possible that the additional training time reported by the LGMA farms is an underestimate of the time that it will take farms to comply with the training requirements since it is possible that farms with LGMA audits were already conducting similar training prior to LGMA indicating that they did not start from a zero baseline. We expect that the estimate obtained here is an indicator of the amount of time it will take farms without food safety training to train workers and that it will take half as long for farms with training in place.

In order to implement the LGMA training standards, it took growers an additional 31.44 hours of personnel training from before and after implementation (Ref.8). To obtain the average training time required per worker per year, we take the 31.44 hours of additional training time and divide by the average number of workers employed by the LGMA farms surveyed. The average LGMA farm employs 49 workers indicating that each worker is devoted 0.64 hours (31.44 hours/49 employees) of training per year. This estimate includes the aggregate time from training workers when hired, at the beginning of the season, and throughout the season. We expect that the time it takes to make the training easily understood by employees is also included. We estimate that the same time is required to train management personnel on the farm as it takes to train farm laborers. We seek comment on our estimate that training requirements in this rule will result in 38 minutes (0.64 hours) of training per worker for farms without food safety programs and 19 minutes (0.32 hours) of training per worker for those with an existing food safety program.

The cost of training consists of the operator and supervisor’s time to train as well as the employee’s (operator, supervisor, or laborer) loss of production time while in training. We use the hourly wage plus 50 percent overhead of $47.4 for farm operators,

$30.26 for supervisors, and $14 for farm workers as the per hour cost. Since we expect that farm operators will take the training course that is equivalent to FDA-recognized standard curriculum, we estimate that these operators will train other operators on the farm and all supervisors on large farms. Very small farms have on average 1.6 farm operators indicating that some very small farms have one farm operator, others have two farm operators, and some (but few) might even have three farm operators. Since every farm operator on the farm must be trained in addition to the operator that takes the FDA-recognized training course or equivalent, then we estimate that on average, very small farms must train an additional 0.6 operators (1.6 – 1 operator that took the FDA-recognized training course or equivalent). Although there is no such thing as 0.6 of an operator, this considers that the average farm has more than one operator that will have to be trained. Using the same logic for small and large farms, we estimate that small and large farms will train an additional 0.7 (1.7 – 1) and 1.1 (2.1 – 1) operators, respectively. We estimate that supervisors are only employed on large farms since it is expected that one supervisor oversees 20 employees indicating that employees on very small and small farms are overseen by the farm operator while workers on large farms are overseen by 4 supervisors.

On very small farms without food safety training programs, it costs $18 ($47.4 x 0.64 hours x 0.6 additional operators) for an operator to be trained. Since small and large farms have slightly more operators, the costs to train additional operators on these farms are $22 ($47.4 x 0.64 hours x .7 additional operators) and $33 ($47.4 x 0.64 hours x 1.1 additional operators), respectively. The cost of the operator's time to conduct the training is estimated at $30 on all farms ($47.4 x 0.64 hours x 1 operator). Therefore, the total per farm cost to train other operators is $49 on very small farms ($18 operator time to take training + $30 operator time to conduct training), $52 on small farms ($22 operator time to take training + $30 operator time to conduct training), and $66 on large farms ($33 operator time to take training + $30 operator time to conduct training). The costs to farms that have food safety training are half of the costs to farms that do not have training.

The cost of an operator's time to train supervisors is only incurred by large farms. Since they have 4 supervisors, we estimate that the cost of the supervisor's time spent in training is $78 ($30.26 x 0.64 hours x 4 supervisors), and that the cost of the operator's time to train supervisors is $30 ($47.4 x 0.64 hours) since we expect for one farm operator to train all supervisors at the same time. The total costs on large farms of training operators and supervisors on farms with no food safety training in place is therefore $171 ($66 operator's time to train operator and to be trained + $30 operator's time to train supervisors + $78 supervisor's time to be trained). Again, the costs to farms that have food safety training are half of the costs to farms that do not have training.

Table 113 describes the costs of operator and supervisor training on all produce farms. Multiplying the per farm costs to provide training by size, we estimate that it will cost very small farms $0.88 million [($49 x 9,092) + ($24 x 17,929)], small farms $0.17 million [($52 x 1,592) + ($26 x 3,161)], and large farms $1 million [($171 x 3,034) + ($86 x 5,687)]. Adding these costs, we estimate that the total cost to train management personnel is $2.05 million, and the average per farm cost is $51.

Table 113: Provision for Operator/Supervisor Food Safety Training				
	Very Small	Small	Large	Total
Number of Farms not training personnel	9,092	1,592	3,034	13,718
Number of Farms already training personnel	17,929	3,161	5,687	26,777
Marginal costs				
Farms not training personnel				
Operator time cost to train operator and to be trained	$49	$52	$63	
Operator time cost to train supervisor	-	-	$30	
Supervisor time cost to be in training	-	-	$78	
Total cost per farm not training personnel	$49	$52	$171	
Farms already training personnel				
Operator time cost to train operator and to be trained	$24	$26	$32	
Operator time cost to train supervisor	-	-	$15	
Supervisor time cost to be in training	-	-	$39	
Total cost per farm training personnel	$24	$26	$86	
Total costs accrued on farms not training personnel	$442,419	$82,809	$520,086	$1,045,314
Total costs accrued on farms already training personnel	$436,221	$82,213	$487,398	$1,005,833
Total Costs Accrued to Farms (Annual cost)	$878,641	$165,022	$1,007,484	$2,051,147
Costs per affected farm	$33	$35	$116	$51
Costs per farm	$33	$35	$116	$51

The cost of training personnel consists of the operator or supervisor’s time conducting the training, and the laborer’s time in the training. We estimate the same hourly training time is spent per laborer as is spent training management personnel of 0.64 hours and 0.32 hours per worker for farms without and with food safety training, respectively (Ref.8). The costs per farm size vary since the average number of farm workers per farm by size varies from 3.5 to 70 workers. The operator’s time costs the same as when the operator trains other operator’s or supervisors on the farm of $30 on very small and small farms. This estimate is based on all workers being trained at the same time throughout the production season. We estimate that each supervisor trains a group of workers on large farms. The supervisor’s time to train workers on large farms costs $78 ($30.26 x 0.64 hours x 4 supervisors). On very small farms without training, the time costs for all workers are $71 ($14 x 0.64 hours x 7.9 workers); on small farms, the workers' time costs are $163 ($14 x 0.64 hours x 18.1 workers); and on large farms, the workers' time cost are $629 ($14 x 0.64 hours x 70 workers). For farms that have food safety training, the farm costs by size are half.

Table 114 describes the costs of non-management personnel training on all produce farms. On very small farms without food safety training, the cost per farm is $101 ($30 operator's time to train + $71 workers' time to be trained); on small farms, the cost per farm is $193 ($30 operator's time to train + $163 workers' time to be trained), and on large farms, the cost per farm is $707 ($78 supervisor's time to train + $629 workers' time to be trained). Farms with food safety training will incur half of these costs. Multiplying the per farm costs to provide training by the number of farms that need to comply by size, we estimate that it will cost very small farms a total of $1.8 million [($101 x 9,092) + ($51 x 17,929)], small farms $0.61 million [($193 x 1,592) + ($97 x 3,161)], and large farms $4.2 million [($707 x 3,034) + ($353 x 5,687)]. The total cost to train non-management personnel is then $6.6 million ($1.8 million + $0.61 million + $4.2 million), and the cost per farm is $163.

Table 114: Provision for Personnel Food Safety Training				
	Very Small	Small	Large	Total
Number of farms not training personnel	9,092	1,592	3,034	13,718
Number of farms already training personnel	17,929	3,161	5,687	26,777
Marginal costs				
Farms not training personnel				
Operator time to train worker	$30	$30	-	
Supervisor time to train worker	-	-	$78	
Worker time cost	$71	$163	$629	
Total cost per farm not training personnel	$101	$193	$707	
Farms already training personnel				
Operator time to train worker	$15	$15	-	
Supervisor time to train worker	-	-	$39	
Worker time cost	$35	$81	$314	
Total cost per farm training personnel	$51	$97	$353	
Total costs accrued on farms not training personnel	$920,965	$307,885	$2,143,880	$3,372,730
Total costs accrued on farms already training personnel	$908,063	$305,671	$2,009,139	$3,222,872
Total Costs Accrued to Farms (Annual cost)	$1,829,028	$613,556	$4,153,019	$6,595,603
Costs per affected farm	$68	$129	$476	$163
Costs per farm	$68	$129	$476	$163

In addition to training workers, management personnel must supervise or otherwise be responsible for the farm's operations to ensure compliance with the requirements of the proposed rule, which we assume will be achieved in part by monitoring farm workers. To estimate monitoring time, we use the time reported by the CA LGMA growers in the Hardesty and Kusunose (Ref.8) survey. In implementing the LGMA, growers stated that field monitoring for compliance with food safety training increased by approximately 8.11 hours (486.6 minutes) per week (Ref.8). Monitoring includes the time it takes for supervisors to watch their employees, and does not include the time it can take for a corrective action.

To obtain the average monitoring time required per worker per week, we take the 486.6 minutes of additional monitoring time and divide by the average number of workers on LGMA farms of 49 workers. This indicates that LGMA farms increased their monitoring time by approximately 9.93 minutes (486.6/49) per week per person. Although the estimate is solely for field monitoring, we estimate that it will also take an additional 9.93 minutes per worker to monitor during pre- and post-harvest. To convert the weekly number to a yearly estimate, we multiply the time to monitor by the number of operating weeks in a year for all farms by farm size. For very small farms with 90 operating days, the annual monitoring time per worker is 128 minutes [(90 days/7) x 9.93 minutes)]. For small and large farms with 180 operating days, the monitoring time per worker is 255 minutes [(180 days/7) x 9.93 minutes)] for the year. Similarly as with personnel training, we estimate that the monitoring time represents farms that currently do not have food safety training in place, and the monitoring time for farms with training is half or 64 minutes per worker annually on very small farms and 128 minutes per worker on small and large farms annually.

The cost of monitoring workers consists of the time cost of the operator on very small and small farms and the supervisor on large farms. On very small farms with no food safety training, it costs $796 per farm [($47.4/60) x 128 minutes x 7.8 workers] for the operator’s time to monitor all workers per year. On small farms, it costs $3,661 [($47.4/60) x 255 minutes x 18.8 workers], and on large farms, it costs $9,018 [($30.26/60) x 255 minutes x 70 workers]. For farms that have food safety training, the farm costs by size are half of the costs to farms without training.

Table 115 summarizes the costs to farms to ensure worker compliance with the training that they have received. Multiplying the number of farms that need to comply by the cost per farm, we obtain that the total cost for very small farms to monitor is $14.4

million [($796 x 9,092) + ($398 x 17,929)], for small farms is $11.6 million [($3,661 x 1,592) + ($1,831 x 3,161)], and for large farms is $53 million [($9,018 x 3,034) + ($4,509 x 5,687)]. The total cost to monitor all workers is therefore $79 million annually, and the cost per farm is $1,951.

The findings from Hardesty and Kusunose may reflect short run overestimated cost responses by leafy greens growers to questions about monitoring costs made shortly following a large outbreak associated with leafy greens, and long run cost estimates may actually be lower. Additionally, it is likely that these estimates may overstate the true burden that will be incurred by industry, as some of these costs could be absorbed in the everyday monitoring of manager on the farm, which are preformed currently. We ask for comment on the appropriateness of using monitoring costs incurred by members of the CA LGMA and the likelihood that farms may not incur new costs due specifically to these requirements.

Table 115: Provision for Ensuring Personnel Compliance with Training

	Very Small	Small	Large	Total
Number of Farms not training personnel	9,092	1,592	3,034	13,718
Number of Farms already training personnel	17,929	3,161	5,687	26,777
Marginal costs				
Operator/Supervisor time cost on farms with no training	$796	$3,661	$9,018	
Operator/Supervisor time cost on farms already training	$398	$1,831	$4,509	
Total costs accrued on farms not training personnel	$7,239,016	$5,829,017	$27,363,713	$40,431,746
Total costs accrued on farms already training personnel	$7,137,600	$5,787,104	$25,643,917	$38,568,621
Total Costs Accrued to Farms (Annual cost)	$14,376,615	$11,616,121	$53,007,630	$79,000,367
Costs per affected farm	$532	$2,444	$6,078	$1,951
Costs per farm	$532	$2,444	$6,078	$1,951

Summary

Table 116 describes the total costs of the provisions in the personnel and qualifications training section excluding the recordkeeping costs. The total costs of the provisions for very small farms are $19.6 million ($2.5 million + $0.88 million + $1.8 million + $14.4 million), for small farms are $12.8 million ($0.44 million + $0.17 million + $0.61 million + $11.6 million), and for large farms are $58.98 million ($0.81 million + $1 million + $4.2 million + $53 million). Large farms have the highest costs since they employ the largest number of workers. The total cost for all farms to comply with the provisions is $91.4 million, and the cost per farm is $2,257.

Table 116: Total costs for personnel qualifications and training				
	Very Small	Small	Large	Total
Outside Training	$2,515,990	$442,603	$812,104	$3,770,697
Management Personnel Food Safety Training	$878,641	$165,022	$1,007,484	$2,051,147
Personnel Food Safety Training	$1,829,028	$613,556	$4,153,019	$6,595,603
Ensuring Personnel Compliance with Training	$14,376,615	$11,616,121	$53,007,630	$79,000,367
Total Costs Accrued to Farms (Annualized)	$19,600,274	$12,837,302	$58,980,237	$91,417,813
Costs per farm	$725	$2,701	$6,763	$2,257

Records

Farms are required to keep records of training that is conducted. The documentation must include the topics covered during the training event, the date of the training, and the group or person trained. All 1,117 farms implementing food safety programs are currently following this provision. In addition, approximately 33 percent of farms currently keep worker training records (Ref.7). We recognize that this is potentially an overestimate since it is uncertain whether the training records kept include all of the information required to be maintained under this proposed rule. However, it is possible that it is an underestimate since industry practices could have changed since 2001 when the survey was taken. After subtracting the number of food safety program farms from the total and multiplying the remainder by 67 percent, we obtain that there are 17,665 very small farms [(27,021 – 655) x 0.67], 3,115 small farms [(4,753 – 104) x 0.67], and 5,604 large farms [(8,722 – 358) x 0.67] that will incur the costs of worker training recordkeeping.

Food manufacturers keep worker records for approximately 3 to 12 hours a year for initial training and 3 to 11 hours for refresher training (Ref.13). The records include employee background records, employee training, employee training audits, and employee performance reviews. Since we are only interested in employee training records, we estimate that the number of hours required to comply with this provisions is one-fourth of the total time since employee training is one of the four records kept during the time reported. We take the midpoint of the 3 to 12 hours for initial training, 7.5 hours, and multiply by 60 minutes and divide by 4 to obtain that it will take 113 minutes [(7.5 hours x 60 minutes)/4] for initial training. Similarly, for refresher training we take the midpoint of 3 to 11 hours, 7 hours, and multiply by 60 minutes and divide by 4 to obtain that it will take 105 minutes [(7 hours x 60 minutes)/4].

We expect that farm operators will fill out the training records on very small and small farms at a cost of $47.4 an hour, but that farm supervisors will do so on large farms at a cost of $30.26 an hour. Therefore, very small farms will incur a recordkeeping cost per farm of $172 [(113 minutes + 105 minutes) x ($47.4/60)], small farms will incur a cost per farm of $172 [(113 minutes + 105 minutes) x ($47.4/60)], and the cost for large farms will be $439 per farm [(113 minutes + 105 minutes) x ($30.26/60) x 4 supervisors]. Multiplying the cost per farm by the number of farms that must comply, we estimate that the cost to keep worker training records is $3.04 million on very small farms ($172 x

17,665), $.54 million on small farms ($172 x 3,115), and $2.46 million on large farms ($439 x 5,604) for a total of $6.03 million. Table 117 summarizes the costs to keeping training records.

Table 117: Provision for Recordkeeping Associated with Training Personnel				
	Very Small	Small	Large	Total
Number needed for Compliance	17,665	3,115	5,604	26,384
Marginal costs				
Operator/Supervisor time cost	$172	$172	$439	$229
Total Costs Accrued to Farms (Annual cost)	$3,035,319	$535,198	$2,458,307	$6,028,824
Costs per affected farm	$172	$172	$439	$229
Costs per farm	$112	$113	$282	$149

In addition to the training costs relating to food safety practices, produce farms will incur training costs to learn about the rule requirements in order to comply with the rule provisions. FDA estimates that this additional training will take very small farms one individual at the level of a farm operator or manager about 40 hours to review and assess the requirements. For small and large farms, FDA estimates that, in addition, a legal analyst will also spend about 40 hours analyzing the rule requirements. We also estimate that out of scope or exempt farms that will not be subject to the requirements of this rule could take up to 10 hours to verify that they are exempt and to know how to change the labeling on their produce.[41] We request comment on the cost to exempt farms to learn about the rule.

Wage rates are from the May 2010 BLS Occupational Employment Statistics for a Farm Operator or Manager Mean Wage Rate and a lawyer and include overhead (Ref.2). In the case of qualified farms, using an estimated training cost per farm of $474, we expect out of scope/exempt, very small, small, and large farms to incur training costs of

[41] This estimate may be an overestimate for numerous farms that can readily tell they are out of scope of this rule. Specifically, we count seed producers for non-human consumption, and farms such as these will likely not spend much time learning about this rule.

about $54.2 million, $12.6 million, $2.1 million, and $2.3 million, respectively. For non-qualified farms, we estimate training costs per farm to be about $1,896 for very small farms and $5,727 for small and large farms, which amounts to $51.1 million, $26.9 million, and $49.1 million for very small, small, and large farms, respectively. Qualified and non-qualified farms taken together, we estimate a total one-time training cost related to the requirements of this rule of $54.2 million, $63.7 million, $29.0 million, and $51.4 million for out of scope/exempt, very small, small, and large farms, respectively. The costs annualized over 7 years are then estimated to be $10.1 million, $11.8 million, $5.4 million, and $9.5 million for out of scope/exempt, very small, small, and large farms, respectively.

9. Corrective Steps

The proposed rule would require farms to take certain corrective steps at specific times. These steps are intended to ensure that the farm identifies and corrects the cause of the problem, thereby minimizing the risk of serious adverse health consequences or death associated with covered produce.

If water that is used as sprout irrigation water, to directly contact covered produce during or after harvest activities (including as ice), to make a treated agricultural tea, to directly contact food-contact surfaces (including as ice), or for washing hands during or after harvest tests positive for generic *Escherichia coli* (*E. coli*) in 100 ml agricultural water, the producer must stop using the water for those uses. In order to use the same water source for the uses prescribed without treatment, the producer must re-inspect the agricultural water system under the farm's control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces, make necessary changes, and retest the water to determine if the changes were effective and to ensure that the microbial requirement is met. The farm can also choose to treat the water. If water used during growing activities for covered produce other than sprouts using a direct application method is found to have more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic *E. coli* per 100 ml for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 ml of water, then the producer must take the same steps as described before (or has the option of treating the water).

Sprout producers are required to collect environmental samples and test them for *Listeria* species or *L. monocytogenes*. If a sample tests positive for either organism, then the producer is required to conduct additional microbial testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem. Following these additional tests, the producer must clean and sanitize the affected surfaces and surrounding areas, conduct additional microbial testing to determine whether *Listeria* species or *L. monocytogenes* has been eliminated, conduct finished product testing when appropriate, and perform any other actions necessary to prevent reoccurrence of the contamination.

In order to estimate the costs associated with the corrective steps needed in these circumstances, we must know the annual frequency of occurrence of these circumstances and the corrective step that is implemented for such circumstances. The CTF cooperative granted FDA access to their audit database, which provides information on the number of cooperative member farms that have had to take necessary corrective steps when one of their standards failed while an auditor was present, the specific standard that failed, and the corrective step that was taken in order to identify and correct the problem. As was explained in the current industry practices section, CTF members follow the food safety standards in the Tomato Audit Protocol and are audited by the USDA. We expect that the audit database provides a reasonable estimate of the frequency and type of corrective steps that will result from agricultural water testing. Since sprouting operations are very different from tomato farms, we use the frequency of corrective actions estimated for manufacturing operations to estimate the frequency that the growing environment for sprouts tests positive for *Listeria* species or *L. monocytogenes.*

The CTF database shows that of the 98 member farms, 1 farm (approximately 1 percent) had agricultural water not meet the appropriate standard during either an announced or unannounced audit from May 2011 to November 2011. The members of the CTF have either been implementing standards for several years, or are new members of the cooperative who have just started. We use the frequency of 1 percent estimated from the CTF database and apply it to covered farms in the proposed rule to measure the frequency in which agricultural water on covered farms will not meet the standard imposed by the proposed rule. We recognize that the rate at which these standards are not met is likely to vary across region, commodity, and other farm attributes. However, for the purposes of this analysis, we treat the rates as similar across all farms. We also recognize that the frequency of which standards are not met is possibly an underestimate of the corrective steps that will take place in the implementation year of the rule since many covered farms have limited experience implementing controls.

For the failed standard of when the water does not meet the quality standard, we estimate that 272 very small farms (0.01 x 26,947), 47 small farms (0.01 x 4,693), and 87 large farms (0.01 x 8,571) will need to re-inspect the agricultural water system, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards, make necessary changes, including water treatment, and re-test the water. We estimate that it costs $723 for very small and small farms and $470 for large farms to re-inspect the agricultural water system, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards, and make necessary changes. This is the same cost of inspecting agricultural water sources and distribution systems estimated in the agricultural water section. We also estimate that it costs $87 to re-test the water, which includes the cost of laboratory water sample collection and in-house collection with subsequent shipment to a laboratory for analysis as estimated in the agricultural water section. Moreover, pending the results of the re-test, 50 percent of farms will opt to treat their water at a per-farm cost of $1,720, $3,166, and $5,098 for very small, small and large farms, respectively. Adding these costs, we obtain a total of $810 for each very small and small farms to implement the corrective action, and $1,720 and $3,166 for 50 percent of very small and small farms to implement the corrective action. We estimate that $557 for each large farm to implement the corrective steps necessary when a water test is positive and $5,098 for 50 percent of large farms to implement the corrective steps necessary when a water test is positive. Multiplying the cost per farm by the number of farms and adding together, we estimate that it costs $454,240 for very small farms (272 farms x $810 + 136 x $1,720), $129,883 for small farms (47 x $810 + 29 x $3,166), and $298,261 for large farms (87 x $557 + 49 x $5,098). Table 119 summarizes the costs to farms that have to implement a corrective step for agricultural water that does not meet the appropriate standard in the proposed rule.

Table 119: Costs for Corrective Steps due to Standards Not Met Directed to Agricultural Water				
	Very Small	Small	Large	Total
Number of Farms				
Agricultural water must meet appropriate standard	272	47	87	406
Corrective Steps cost per farm				
Re-inspect the agricultural water system, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards, make necessary changes, and re-test the water	$810	$810	$557	
Cost of treatment incurred by 50 percent of farms to implement corrective steps	$1,720	$3,166	$5,098	
Total Costs (annual)	$454,240	$129,883	$298,261	$882,385
Costs per affected farm	$1,670	$2,763	$3,428	$2,173
Costs per farm	$17	$28	$35	$22

We do not use the CTF database to estimate the annual frequency of corrective steps that are implemented in sprouts operations since tomato farms are very different from sprouts operations. We use information from an expert elicitation that was conducted through an FDA contract (Ref.81). The expert elicitation shows that facilities with less than 20 employees will have approximately 2 corrective steps per year, and that farms with between 20 and 100 employees will have approximately 4. We estimate that very small and small sprouts operations will have an average of 2 corrective steps per year, and that large farms will have 4 per year due to a positive test for *Listeria* species or *L. monocytogenes*.

Problems with environmental pathogen control can take from 1 to 15 hours to correct (Ref.81). We estimate that it will take an average of 7 hours, the midpoint of 1 to 15 hours, to properly implement the corrective step. This requires the operator's time to make sure that the appropriate measures are being taken such as conducting additional microbial testing, cleaning and sanitizing the affected surfaces and surrounded areas, conducting additional microbial testing to determine whether *Listeria* species or *L. monocytogenes* has been eliminated, and conducting finished product testing when appropriate. According to the expert elicitation, corrective steps do not usually affect the production schedule. If finished product testing results in a positive pathogen result, the product batch is often destroyed.

The cost of the corrective step is estimated as the cost of the operator's time to ensure the corrective step is properly implemented, the cost to conduct additional microbial testing, cleaning and sanitizing the affected surfaces, and conducting finished product testing when appropriate. We do not estimate a cost for destroyed batches of sprouts since we are uncertain of the frequency at which this occurs, but we seek comment on whether this is appropriate. We estimate that the cost of the operator's time is $332 per corrective step event ($47.4 x 7 hours). We estimate that it costs $214 for very small farms, $369 for small farms, and $524 for large farms to conduct the additional microbial testing. These costs were estimated in the sprouts section and are the total costs of environmental testing for *Listeria* species and *L. monocytogenes.* The sprouting facility will incur this cost twice per corrective step: once immediately following the initial positive test result, and another time after cleaning and sanitizing the affected areas. We estimate that it costs $2.43 on very small farms, $3.55 on small farms, and $3.55 on large farms to clean and sanitize affected areas. This was estimated in the growing, harvesting, packing, and holding section of the analysis and accounts for one day of cleaning for 10 minutes by a general worker. Finally, we estimate the cost for finished product testing as $306 for all farms, which includes the lab analysis, sampling, shipping, and labor costs. In order to account for the requirement that this is conducted only when appropriate, we estimate that sprouts operations will only incur this cost half of the time, for a cost of $153 ($306/2).

Table 120 summarizes the costs to sprouts operations of implementing corrective steps. The annual cost per very small farm is $1,831 ($332 + $214 + $2.43 + $214 + $153), per small farm is $2,453 ($332 + $369 + $3.55 + $369 + $153), and per large farm is $6,144 ($332 + $524 + $3.55 + $524 + $153). Multiplying the number of sprouts operations by the cost per farm by size, we estimate that the total costs to very small farms are $136K (74 x $1,831), to small farms are $147K (60 x $2,453), and to large farms are $927.8K (151 x $6,144). The total costs are estimated at $1.2 million ($135K + $147K + $927.8K).

Table 120: Costs for Corrective Steps due to Standards Not Met Directed to Sprouts				
	Very Small	Small	Large	Total
Number of Farms				
Positive Listeria or L. monocytogenes Test	74	60	151	285
Corrective Steps cost per farm				
Frequency of corrective steps	2	2	4	
Operator time spent implementing corrective step	7	7	7	
Farm operator time costs	$332	$332	$332	
Microbial testing	$214	$369	$524	
Cleaning and sanitizing affected surfaces	$2.43	$3.55	$3.55	
Microbial testing	$214	$369	$524	
Finished product testing	$153	$153	$153	
Total cost per farm (annual)	$1,831	$2,453	$6,144	
Total Costs (annual)	$135,528	$147,182	$927,754	$1,210,464
Costs per affected sprouts facility	$1,831	$2,453	$6,144	$4,247
Average costs per sprouts facility	$1,831	$2,453	$6,144	$4,247

Table 121 summarizes the total costs of the corrective steps section. The total cost for very small farms is $356K ($220.5K + $136K), for small farms is $185.6K ($38.4K + $147.2K), and for large farms is $976K ($48.3K + $927.8K). The total cost for the corrective steps section is $1.5 million.

Table 121: Summary Costs of Corrective Steps				
	Very Small	Small	Large	Total
Failed standards Directed to Agricultural Water	$220,472	$38,400	$48,259	$307,131
Failed standards Directed to Sprouts	$135,528	$147,182	$927,754	$1,210,464
Total Costs of Corrective Steps (annual)	$356,000	$185,582	$976,013	$1,517,595
Cost per farm	$13	$40	$114	$20

The benefits of implementing corrective steps are that they improve a farm's food safety system, and are critical in preventing the likelihood of contamination. The CA LGMA members have a similar auditing process as the CTF cooperative, and find that corrective steps "…drive continuous improvements in food safety on leafy greens farms" (Ref.11). Corrective steps provide information to farm operators and supervisors on the standards that require more training in order to prevent their failure. Corrective steps allow for farms to address food safety problems based on their experience, and minimizes the likelihood that risky product enters commerce.

10. Variances

This provision would allow states and foreign countries to petition FDA for a variance from the proposed rule or certain of its provisions. To accomplish this they would have to submit a petition stating that the state or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements prescribed by the proposed rule; describing with particularity the variance requested, including the persons to whom it would apply and the provisions of the rule to which it would apply; and presenting information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the FD&C Act and to provide the same level of public health protection as the requirements prescribed by the proposed rule. If FDA approves a variance petition, the persons to whom it applied would be allowed to grow, harvest, pack, or hold covered produce using the alternative method in the approved variance.

Current Industry Practices

We recognize that the growing practices in many states and foreign countries may not exactly line up with those outlined in this proposed rule. For this reason, we believe some states and countries may find it advantageous to petition FDA for a variance from some of the specific requirements in this proposed rule. We expect states and countries that wish to petition FDA for variances from certain requirements of this proposed rule have already completed a risk assessment and put risk management strategies into place, forgoing the need for any further studies or data collection to support their variance request. We request comment on this estimation.

A report from the USDA (Ref.82) states that Mexico and Canada accounted for over 85 percent of total fresh vegetable imports into the US between 1998 and 2007. This was followed by Peru, and other Central and South American countries, whose totals were not over 2 percent each. Additionally, Mexico, Chile, Costa Rica, Guatemala and Ecuador accounted for the largest share of total fresh fruit and nuts shipped into the US during the same time period. That these countries make up most the fresh produce imports to the US, is not surprising given their relatively proximity to the US, the perishability of fresh produce, and the significant trade agreements in place.

Costs

The total cost of filing a petition for a variance is presented in Table 122. We estimate that it will take a person 80 hours to compile all the relevant information and complete the petition to FDA. This person will likely be a state or foreign government employee with an hourly wage of roughly equivalent to that of a GS grade 14 step 1, $75.62 (with 50 percent overhead included). We estimate that it will cost about $6,049 (80 x 75.62) to complete the petition. Additionally, it is likely that a supervisor will need to evaluate and review the petition before it is submitted. We estimate that it will take 40 hours to review, and the supervisor would have a wage roughly equivalent to GS grade 15 step 13, $94.88 (with overhead). Multiplying the hours by wages yields a cost of review of about $3,765 (40 x 94.88). In total, this represents a onetime cost of $9,844 (6049 + 3765) to complete a petition and have it reviewed internally.

Once the petition is received by FDA, it will need to be reviewed in some detail. We estimate that it will take an additional 80 hours for an FDA employee to evaluate all the claims involved in the petition. This employee's wage is likely to be $76.79 (GS grade 13 step 7, with overhead). The cost of FDA review, then, is $6,143 (80 x 76.79). Together with the cost of preparing the petition, we estimate a total, individual cost of submitting a petition for a variance to FDA of approximately $15,987 (9844 + 6143).

Because we have limited information on how many states or foreign countries will file a petition for a variance with FDA, we estimate there may be as many as six in a single year. This is based on the fact than an overwhelming majority of fresh fruits and vegetables are provided by a limited number of countries, primarily located in the western hemisphere. This gives a total cost of preparing and reviewing petitions for variances of $95,922 (6 x 15,987).[42]

Table 122. Cost to Prepare and Review Initial Petition	
hours to complete petition	80
wage (GS 14.1)	$75.62
cost to complete petition	$6,049
hours to internally review	40
wage (GS 15.3)	$94.88
cost to internally review petition	$3,795
cost to complete & review	$9,844
hours for FDA review	80
wage (GS 13.7)	$76.79
cost for FDA review	$6,143
total individual cost of petition	$15,987
potential number of applicants	6
Total Cost	**$95,922**

In total, we estimate that this provision could cost about $96,000. Although we do not attempt to quantify cost savings to states or foreign entities, it is highly unlikely that any petition will be filed unless it represents a substantial, state or nationwide cost savings to the agricultural industry. In fact, we believe that this subpart will not only cover the $96,000 cost, but it should also serve to reduce the costs far beyond this amount. Additionally, we expect that this subpart will increase the availability of certain covered produce, which may not grow as well domestically, for sale in the United States.

11. Costs for Foreign Entities and Trade Effects

The proposed rule covers all farms that supply fresh produce to U.S. consumers. In this section, we discuss the effects of the implications of the proposed rule for both international trade and costs borne by U.S. consumers of fresh produce.

a. Trade and WTO Obligations

[42] This may be an overestimate of the costs associated with filing a variance, specifically because the number of foreign countries that file is likely to subside over time and eventually reach zero. However, due to the large amount of uncertainty associated with this provision, we assume a recurring number of filers.

To assess the proposed rule's impact on foreign trade, we consider whether the proposed rule: 1) is consistent with widely adopted international food safety guidelines of the Codex Alimentarius Commission (Codex) specifically the Codex General Principles of Food Hygiene (Ref.83); 2) is consistent with World Trade Organization (WTO) treaty obligations (Ref.84) ; 3) is consistent with Global GAP requirements; and 4) would create a non-tariff or technical trade barrier to imported goods, adversely affect the demand for exported FDA-regulated foods or in other ways disrupt the international flow of FDA-regulated foods. If the proposed rule is consistent with Codex General Principles of Food Hygiene and WTO obligations, does not create a technical barrier to trade, and if most farms are generally already performing the food safety practices that are being proposed, then the proposed rule should not have a substantial adverse effect on the international trade of FDA-regulated food (Ref.20).

Our analysis predicts that at least some foreign farms from all regions of the world, including our largest trading partners, Mexico and Canada, as well as farms of other nations (especially their smaller farms) would have to incur the cost to change at least some of their practices to comply with the proposed rule. Farms located in the developing world are less likely to already be in compliance with the proposed requirements and will incur the costs to comply (Ref.13). The proposed rule is consistent with Codex guidelines, WTO obligations, and Global GAPs and it would not act as a non-tariff or technical barrier to trade. Any price increases that would be incurred as compliance costs are likely to be passed on to both domestic and foreign customers. We do note that an increase in costs and thus prices would likely impact trade; however, any contraction experienced in the marketplace should be experienced by domestic and international parties equally, thereby not creating a significant barrier to trade.

Current international trade in FDA-regulated foods is extensive. In 2009, the most recent complete year for which international trade data is available, total domestic food exports amounted to about $43.8 billion (as measured in dollar value), of which about $26.5 billion were of FDA-regulated foods. Total foods imported to the U.S. for consumption amounted to about $36.1 billion (as measured in dollar value) of which FDA-regulated foods imported to the U.S. were valued at about $28.6 billion. Total domestic produce sales in the U.S. are valued at about $42.5 billion (Ref.3). The long-term trend in international trade between the U.S and its trading partners for food products, including FDA-regulated foods, points to ever increasing volumes (Ref.85). For most of the last 10 years, international trade in food products has grown by at least 10 per cent per year and in some years by over 20 per cent as measured in their dollar value (Ref.3). Although most categories of food, including FDA-regulated imported and exported foods, experienced a decline of about 11% between 2008 and 2009, the decline was probably due to the sharp world-wide economic downturn and not a reversal of the long-term trend (Ref.3).

To determine the ability of foreign farms to meet the proposed requirements, we compared the proposed rule to Codex guidelines, which are the basis for our major trading partners' food safety regulations to determine how consistent they are to each other. Ensuring that the proposed rule is consistent with Codex guidelines promotes the equal treatment of domestic and foreign producers.

The Codex General Principles of Food Hygiene promotes measures that are consistent with the proposed requirements as described in the Preamble. In 2003, the

Codex Alimentarius Commission published food safety practices for growers and packers of fresh fruits and vegetables (Ref.83). These principles have been widely adopted as regulatory requirements for many countries around the world, including Canada (our largest trading partner for FDA-regulated food products), the European Union countries, and many other countries as foundational principles for ensuring food safety. Codex principles are designed to promote science-based food safety practices to prevent, reduce or eliminate potential biological, chemical and physical food safety hazards (Ref.83). Taken together, these Codex guidelines call for training in food hygiene, sanitation programs, hazard analysis, effective monitoring procedures, procedures for corrective actions, for effective verification and for recordkeeping and documentation. While not identical, the provisions of the proposed rule are consistent with the corresponding Codex principles. We do not estimate the number of international farms that are potentially in compliance with these standards; however, it is likely that numerous trading partners in developed nations are currently already following the food safety practices set forth in Codex guidelines.

The international trade obligations for FDA-regulated food products are overseen by the World Trade Organization Agreement (WTO), which governs the international rules of trade for member states, including the U.S. as a member state. WTO obligations for member states include three essential responsibilities; 1) the equal treatment of domestic and foreign entities; 2) that trade between WTO members be conducted without discrimination, which precludes granting special favors to some countries or regions but not to other countries or regions, and 3) that domestic regulations, standards, testing and certification procedures not create unnecessary regulatory impediments. Domestic regulations, standards, testing and certification procedures are not to be developed arbitrarily, without a scientific basis or for the purpose of creating a trade barrier (Ref.84). If a proposed rule meets these conditions, then it is consistent with WTO obligations. The proposed rule does not distinguish among countries or between domestic and foreign farms, nor does it create special favors. In addition, the proposed rule provides a scientific basis and rationale for each of the proposed provisions based on the best available scientific knowledge and in response to a critical public health need. Therefore, the proposed rule is consistent with WTO obligations.

The Global Good Agricultural Practices (GLOBALG.A.P.) standards were developed in partnership with agricultural producers and retailers to harmonize food safety standards, and to develop certification that would be valid worldwide (GLOBALG.A.P. 2010). Agreements with independent Certified Bodies (CBs), which are auditing companies, allow for audits to be conducted on behalf of the GLOBALG.A.P. entity. The GLOBALG.A.P. standards have similar requirements as other food safety standards for water, worker health and hygiene, and soil amendments.

b. Costs for foreign entities

Although the proposed rule is consistent with Codex guidelines, WTO obligations, and Global GAP, as in the U.S. a significant number of foreign farms are not currently performing in accordance with all of the proposed requirements and their cost of compliance is high. To estimate the costs for foreign farms, we first consider how their practices compared with current U.S. practices.

To better understand the impact on foreign food farms, we examined the actual practices of foreign farms to determine on average how similar current international practices are with what would be required under the proposed rule. We examined their actual practices because some farms might already voluntarily meet our proposed requirements; conversely despite comparable local requirements and Codex principles, some exporters to the U.S. might be deficient and might not meet our proposed requirements.

We lack a survey based on a statistically representative sample of foreign farms to give us reliable evidence of baseline foreign food safety practices. In the absence of a statistical survey, we look at the current requirements placed on the two countries that account for by far the largest part of fresh produce import to the U.S., and how these correspond to the provisions of the proposed rule.

Mexico is the leading foreign supplier of RACs that are exported as produce to the U.S. A USDA report (Ref.82) indicates that Mexico accounted for about 70 percent of all fresh vegetables and 30 percent of the total value of fruits (including nuts) imported into the U.S. as recently as 2007.

Mexico is a member of the WTO, and approximately 300 of its producers were GLOBALG.A.P. certified as of 2011. Additionally, all farms are subject to the National Health Service, Food Safety and Food Quality's Contamination Risk Reduction System. This program, designed by the General Management of Agro-Food Safety, Aquaculture and Fisheries, is designed to "minimize the degree of exposure of agricultural products to substances and surfaces that could contaminate them and thereby reduce the risk of contamination". More specifically, this is a comprehensive food safety system which has 15 specific provisions that are comparable to many of the provisions described in this proposed rule, such as: hygiene, water handling, training, harvesting, and packing. With these systems already in place in Mexico, it is unlikely that this proposed rule will impose a significantly larger burden on Mexican produce exporters relative to domestic U.S. producers.

Canada is the U.S.' second largest foreign supplier of produce RACs, accounting for about 15 to 20 percent of all fresh vegetable imports (Ref.82). Canada is a member of the WTO and ascribes to the Codex General Principles of Food Hygiene. Ascribing to the Codex guidelines likely means that most Canadian farms would have to do little or nothing to come into compliance with many of the provisions of this proposed rule; especially in the areas of maintenance and sanitation, personal hygiene, transportation, and training. Therefore, we tentatively conclude that this proposed rule will not represent a substantial burden to the Canadian produce exporters compared with domestic U.S. producers.

Other produce RACs come from numerous smaller and less well developed Central and South American countries. Chile, Costa Rica, Guatemala, Ecuador, Peru, and others all export produce RACs to the US; however, their shares are all relatively small compared with that of Mexico or Canada. The largest foreign supplier outside of the Americas is China. China accounted for about 2 percent of the total value of fresh vegetable imports in 2007.

In total, there are about 100,000 GLOBALG.A.P. compliant farms worldwide, and Chile, Costa Rica, Guatemala, Ecuador, Peru, and China are all Codex members. It is unlikely that these farms perfectly overlap with the farms who export produce RACs to the US. However, it is reasonable to assume that a vast majority already have some formal food safety training whether through supplier audits or organized food safety programs. Considering all of the existing international food safety programs and the likelihood that most farms participate at some level, the cost of compliance for most farms already exporting covered produce to the U.S. will likely be minimized, thereby reducing the opportunity for any significant trade barriers to arise.

We tentatively conclude that the food safety practices of foreign farms that export fresh produce to the U.S. are comparable to current practices of U.S. farms. Assuming that to be the case, we can estimate the costs of the proposed rule for foreign farms by simply multiplying the number of affected foreign farms by the average cost of compliance for U.S. farms. If the practices of affected foreign farms are not similar to U.S. farms, then our procedure underestimates costs if foreign food safety practices are less comprehensive and overestimates costs if foreign food safety practices are more comprehensive. We ask for comments on the assumption of approximately similar food safety practices.

We estimate there are currently 40,211 domestic and 14,927 foreign farms[43] that will be covered by the proposed rule. Because we do not have direct estimates of the costs likely to be borne by the affected foreign farms, we indirectly estimate those costs by assuming that on average costs are the same for foreign farms as for domestic farms. Applying the average cost of the proposed rule to domestic farms ($11,430) to the estimated number of foreign farms covered (14,927) yields an estimated cost to foreign farms of $171 million.

Some fraction of these costs will be passed through to the U.S. in the form of higher prices for imported produce and therefore should be considered U. S. domestic

[43] We arrive at this estimate by estimating the percentage of domestic farms that are covered by this proposed rule (21%), as estimated from the 2007 Census of Agriculture, and applying it to the total number of international farms (70,395) from OASIS.

costs. At the limit, if all costs (including quasi-fixed costs) are passed through, then the entire $171 million cost will be borne by U.S. consumers. This would be the case if the supply of fresh produce to the U.S. is completely elastic. If some part of these costs are borne by foreign farms and not passed through, then this procedure overstates costs to the U.S. In this analysis of costs, however, we assume complete pass through.

12. Inspection Costs

We assume that the FDA and states will face no increased inspection costs as a result of the rule. We believe that the rule's benefits of reduced produce contamination can be achieved without adding any additional resources to inspection to ensure compliance with the rule. We seek comment on this assumption.

H. Summary of Benefits and Costs of the Proposed Rule

1. Summary of Costs and Benefits

This section summarizes the costs and potential benefits of the proposed rule. Approximately 189,636 domestic farms grow produce for sale excluding sprouts, and approximately 475 farms grow sprouts. Of these farms, 119,449 non-sprout farms and 19 sprouts farms are not covered by the proposed rule since they either exclusively grow commodities rarely consumed raw, or they generate an average annual monetary value of food sold of $25,000 or less (on a rolling basis). Additionally, there are 29,976 non-sprout farms and 117 sprouts farms eligible for qualified exemptions due to either the monetary value of all food sold and direct marketing of the food, or due to covered produce that is destined for commercial processing that adequately reduces the presence of microorganisms of public health significance. There are 40,211 non-sprout farms and 285 sprouts farms that are fully covered and that would have to implement all of the standards outlined in the proposed rule.

The total costs by standard in the proposed rule and other sections are summarized in Table 123 by farm size. The "not covered" category only includes the 113,870 non-sprout farms and 19 sprouts farms that generate an average annual monetary value of food sold of $25,000 or less. All farms either covered or not by the proposed rule would incur the costs to learn the rule. In addition to learning the rule, the 40,496 covered farms (40,211 non-sprout farms + 285 sprouting farms) covered by the proposed rule would incur the costs of implementing the standards directed to health and hygiene; agricultural water; biological soil amendments of animal origin and human waste; 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, but in the case of the qualified exemption for monetary value of all food sold and direct marketing, also costs to change labels if necessary or otherwise disclose their name and complete business address at the point of sale; and in the case of the qualified exemption for covered produce that is destined for commercial processing that adequately reduces the presence of microorganisms of public health significance, costs to keep documentation of the identity of the recipient of the produce who applies the processing. The costs to qualified exempt farms of these proposed requirements are included in the total recordkeeping costs of the rule.   We do not estimate a cost for a withdrawal of an exemption since we do not have sufficient information about the frequency that this will occur. We additionally do not estimate any costs to farms for the compliance and enforcement provisions since we expect that these costs will be FDA operational costs that will not fall on farms.

The estimates in Table 123 are reported in millions for ease of readability with the exception of the average cost per farm estimates, which are reported with no abbreviation. We estimate that the annualized costs of the proposed rule would be approximately $459.66 million per year using a discount rate of 7 percent for all future years as shown in Table 123. The average cost per covered farm is $11,430. 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. Although not reported in the table, the estimate using a discount rate of 3 percent for all future years is $419.28 million. We discuss our use of the 3 and 7 percent discount rates and our use of a 7 year time preference in accordance with OMB Circular A-4 in our section that describes cost conventions. The total cost of implementing the proposed rule for very small farms is $126.56 million, for small farms is $60.88 million, and for large farms is $261.96 million.

The total cost of the rule, including foreign costs would be $630.18 million; however, we do not believe this to be a fair comparison to only the domestic benefits estimated. Because we are not estimating benefits accrued by foreign citizens who consume safer produce on farms within their countries that are covered by the rule or consume relatively safer exported US produce, we present these cost estimates without their associated benefits.

Table 123: Summary of Costs for Proposed Produce Safety Rule (in millions)					
Annual Costs estimated at 7% over 7 years					
Cost Sections	Not Covered	Very Small	Small	Large	Total
Administrative cost to learn the rule	$10.06	$11.82	$5.38	$9.53	$36.79
Health and Hygiene	$0.00	$27.18	$15.06	$95.97	$138.21
Agricultural water	$0.00	$27.45	$7.09	$14.00	$48.55
Biological soil amendments of animal origin	$0.00	$1.11	$1.04	$7.06	$9.20
Domesticated and wild animals	$0.00	$10.32	$5.96	$21.50	$37.78
Growing, harvesting, packing, and holding activities	$0.00	$0.17	$0.09	$0.16	$0.42
Equipment, tools, buildings, and sanitation	$0.00	$11.38	$8.22	$39.27	$58.87
Sprouting operations	$0.00	$0.75	$0.71	$6.07	$7.53
Personnel Qualifications and training	$0.00	$19.60	$12.84	$58.98	$91.42
Corrective steps	$0.00	$0.59	$0.28	$1.23	$2.09
Variances	$0.00	$0.00	$0.00	$0.00	$0.10
Recordkeeping	$0.00	$16.19	$4.21	$8.19	$28.60
Total Costs (annual in millions)	$10.06	$126.56	$60.88	$261.96	$459.56
Average Cost per farm	$88.33	$4,697.19	$12,972.36	$30,566.23	$11,429.70
Total Cost to Foreign Farms					$170.62

Table 124 summarizes the total costs to farms in the first year of implementing the rule (if the compliance period were to be the same for all farms, with no staggered compliance), and Table 125 summarizes the recurring costs after the initial year. Total costs to farms in the first year would be approximately $699.79 million. The cost to learn the rule would be incurred in only the first year of implementation, and would be zero afterwards. Farms that are not covered would therefore not incur any recurring costs of the proposed rule unless their qualified exempt or coverage status changes. Total recurring costs would be $365.65 million per year.

Table 124: Summary of Costs for Proposed Produce Safety Rule (in millions)

First Year Costs – Initial and Recurring					
Cost Sections	Not Covered	Very Small	Small	Large	Total
Administrative cost to learn the rule	$54.21	$63.68	$29.02	$51.35	$198.26
Health and Hygiene	$0.00	$27.18	$15.06	$95.97	$138.21
Agricultural water	$0.00	$60.57	$16.70	$33.50	$110.76
Biological soil amendments of animal origin	$0.00	$1.11	$1.04	$7.06	$9.20
Domesticated and wild animals	$0.00	$10.32	$5.96	$21.50	$37.78
Growing, harvesting, packing, and holding activities	$0.00	$0.17	$0.09	$0.16	$0.42
Equipment, tools, buildings, and sanitation	$0.00	$11.38	$8.22	$39.27	$58.87
Sprouting operations	$0.00	$0.75	$0.71	$6.07	$7.53
Personnel Qualifications and training	$0.00	$30.64	$14.78	$62.54	$107.97
Corrective steps	$0.00	$0.59	$0.28	$1.23	$2.09
Variances	$0.00	$0.00	$0.00	$0.00	$0.10
Recordkeeping	$0.00	$16.19	$4.21	$8.19	$28.60
Total Costs (annual in millions)	$54.21	$222.58	$96.07	$326.83	$699.79
Average Cost per farm	$476	$8,260	$20,470	$38,133	$17,403
Total Cost to Foreign Farms					$259.77

Table 125: Summary of Costs for Proposed Produce Safety Rule (in millions)					
Recurring Costs					
Subpart	Not Covered	Very Small	Small	Large	Total
Cost Sections					
Administrative cost to learn the rule	$0.00	$0.00	$0.00	$0.00	$0.00
Health and Hygiene	$0.00	$19.68	$8.96	$52.82	$81.47
Agricultural water	$0.00	$27.47	$7.09	$14.03	$48.59
Biological soil amendments of animal origin	$0.00	$1.11	$1.04	$7.06	$9.20
Domesticated and wild animals	$0.00	$10.32	$5.96	$21.50	$37.78
Equipment, tools, buildings, and sanitation	$0.00	$11.38	$8.22	$39.27	$58.87
Sprouting operations	$0.00	$0.75	$0.71	$6.07	$7.53
Personnel Qualifications and training	$0.00	$19.60	$12.84	$58.98	$91.42
Corrective steps	$0.00	$0.59	$0.28	$1.23	$2.09
Variances	$0.00	$0.00	$0.00	$0.00	$0.10
Recordkeeping	$0.00	$16.19	$4.21	$8.19	$28.60
Total Costs (annual in millions)	$0.00	$107.09	$49.31	$209.14	$365.65
Average Cost per farm	$0.00	$3,974.01	$10,507.62	$24,401.02	$9,093.36
Total Cost to Foreign Farms					$135.74

There are approximately 3.1 million illnesses each year that are attributable to produce. The total potential benefits of eliminating all foodborne illnesses associated with contamination of produce is $1.88 billion. The proposed regulation covers produce responsible for about $1.61 billion of this total estimate. We do not expect that we will eliminate all dollars' worth of foodborne illness. The effectiveness of this regulation and the corresponding reduction in food contamination and foodborne illness will depend on how successfully the standards are implemented. In total, we estimate that this rule, if implemented correctly, would reduce the human health burden associated with produce by about 64.77%, about $1.04 billon, annually. Table 126 summarizes the costs per covered farm (excluding the costs to farms that are not covered), and the public health burden.

Table 126: Summary of Costs and Benefits by Contamination Pathway and by Commodity			
	Total Benefits (in millions)	**Total Costs (in millions)**	**Net Benefits (in millions)**
Total Domestic Costs and Benefits	**$1,036.40**	**$459.56**	**$576.84**
Total Foreign		$170.62	
Total	$1,036.40	$630.18	$576.84
Pathway			
Health and Hygiene	$343.83	$138.21	$205.63
Agricultural water	$309.03	$48.59	$260.44
Biological soil amendments of animal origin	$144.97	$9.20	$135.77
Domesticated and wild animals	$130.82	$37.78	$93.04
Equipment, tools, buildings, and sanitation	$107.74	$58.87	$48.87
Other	N/A	$166.95	N/A
Total	**$1,036.40**	**$459.56**	**$576.84**
Commodity			
Herbs	$42.35	$4.07	$38.28
Leafy Greens	$131.95	$50.00	$81.95
Melons	$109.00	$28.19	$80.82
Sprouts	$16.59	$5.47	$11.11
Tomatoes	$353.02	$48.87	$304.15
Other	$379.15	$312.83	$66.32
Total*	**$1,032.07**	**$449.44**	**$582.63**

* Commodity totals do not match pathway or overall totals due to differences in estimation methodology and slight rounding errors.

Overall, we estimate the total net benefit of the proposed rule is about $576.80 million. Additionally, we present cost and benefits information by contamination pathway and commodity group.

Because estimated costs are not separable between harvest, growing, and post-harvest activities, we present benefits of each pathway as a whole to perform a cost-benefit comparison. All contamination pathways are estimated to have a positive net benefit, the lowest of which is Equipment, Tools, Buildings, and Sanitation. This is entirely due to the relatively low weight given to the specific contamination pathway, estimated in Table 23. Additionally, there is an additional $166 million in 'other costs.' These are things like administrative costs to learn the rule, personnel qualifications and training, corrective steps, variances, and recordkeeping, which are important aspects of the rule that are not captured in this analysis of specific contamination pathways.

Additionally, all farm types are estimated to have positive net benefits. Tomato farms are estimated to have the largest overall net benefits, as they are estimated to have relatively large benefits and relatively smaller costs. This is followed by leafy green and melon farms. Taken wholly, considering all costs,[44] we expect to see positive net benefits across all farms. Further, the large benefits accruing from preventing relatively random outbreaks provides strong evidence that the most effective produce rule is one that covers a wider range of commodities than only those most frequently associated with contamination in outbreak data.

[44] This calculation does include all costs of the rule; some of which were previously excluded in the estimation of contamination pathway benefits.

2. Summary of Records

The proposed rule would require that documentation be established and kept for certain purposes described in the proposed rule. These records must include, as applicable, the name and location of the farm, actual values and observations obtained during monitoring, an adequate description of covered produce applicable to the record, the location of the growing area applicable to the record, and the date and time of the activity being documented.

These records must be created when the activity is performed or observed, be accurate, legible, and indelible, and be dated and signed by the person who created the record. Farms must also establish and keep records of actions taken when a standard associated with a covered activity is not met. For certain records, a farm operator or supervisor must review, date, and sign the record within a reasonable time after the records are made. Farms would be required to store records onsite for 6 months after the document was created and offsite after 6 months only if the record can be provided onsite within 24 hours. All records must be kept for two years after they are created, or, for records that relate to the general adequacy of the equipment or processes being used, must be kept for two years after the use of such equipment or processes is discontinued. Originals, true copies, or electronic records can be kept. Farms must provide records required under the proposed rule to FDA for inspection and copying during the retention period upon oral or written request and are subject to FDA's regulations in 21 CFR part 20 with regard to disclosure by FDA.

Farms are currently required to keep records under a number of regulations and programs. The National Organic Program (NOP) requires certified operations to keep records concerning the production of organic products, and these records must be kept for 5 years beyond their creation (Ref.5). Country of Origin Labeling (COOL) regulations require farms that supply, either directly or indirectly, a covered commodity to a retailer to maintain records that establish and identify the immediate previous source and immediate subsequent recipient, and must keep these records for one year (Ref.7;Ref.86). OSHA requires farms to keep injury and illness records, and must be provided to an authorized government representative within 4 hours when asked (Ref.87). The food safety programs discussed in the current industry practices section (section IV.D.3.) require farms to keep a variety of food safety records.

In addition to the regulations and programs listed, farms keep records for tax compliance, financial reporting, management analysis, and budgeting (Ref.88). We do not estimate additional costs for keeping and maintaining records for two years after the date the record was created, or for storage of the documents since farms currently keep records for other purposes. We expect that the additional records that would be required by the proposed rule would not require an additional storage burden, but we seek comment on whether this is reasonable. We are uncertain whether all farms keep this documentation for two years. We also seek comment on the current industry practices for the length of recordkeeping, and the cost of having to keep a record for two years.

Table 127 summarizes the records that would be required by the proposed rule per recordkeeping activity and by farm size. The costs associated with each recordkeeping activity were estimated in the section for which the documentation is created. We estimate all record costs using FDA’s ERCFM report adapted to farm operations (Ref.16). The total cost for all records is $28.6 million, and the average cost per covered farm is approximately $711.

Farms that are qualified exempt because of value of food sold and direct farm marketing would be required to include their name and complete business address on the label of their product if a label is required, or otherwise disclose this information at the point of sale, and other qualified exempt farms will need to have documentation that identifies the processor of their product, which would cost a total of $3.8 million. Farms must also keep documentation on findings from agricultural water system inspections, analytic test results, the results of water treatment monitoring, documentation from public water suppliers if applicable, and scientific data or information relied upon to support an alternative water standard for non-sprout direct application irrigation water or the adequacy of a farm's treatment method if applicable. The total recordkeeping costs associated with the agricultural water section are $7.2 million.

The costs to farms of keeping records associated with biological soil amendments of animal origin and human waste are $54 thousand. Farms that use biological soil amendments of animal origin must keep documentation of the date of application of untreated biological soil amendments of animal origin or biological soil amendments treated by a composting process to a growing area and the date of harvest (except when covered produce does not contact the soil after application of the soil amendment), certain listed documentation for treated biological soil amendments of animal origin received from a third party, documentation that process controls were achieved for a treated biological soil amendment of animal origin the farm produces itself, and scientific data that the farm relies upon to support any alternative composting process or application interval if applicable. Farms must also keep records for cleaning and sanitizing equipment used in growing operations for sprouts and covered harvesting, packing, or holding activities, which will cost $11.1 million. The costs for additional records on sprouts farms would be $464 thousand. Farms would also be required to keep records on training that is conducted, which would cost a total of $6 million.

Table 127: Summary of Recordkeeping Costs (annual in thousands) estimated at 7% over 7 years				
Recording activity	Very Small	Small	Large	Total
Qualified exempt farms labeling and documentation	$3,503	$313	$14	$3,830
Agricultural water	$5,195	$905	$1,075	$7,174
Biological soil amendments of animal origin	$36	$7	$10	$54
Equipment, tools, buildings, and sanitation	$4,320	$2,370	$4,350	$11,050
Sprouting operations	$102	$82	$280	$464
Training that is conducted	$3,035	$535	$2,458	$6,029
Total cost (annual in thousands)	$16,191	$4,212	$8,187	$28,601
Average costs per farm (annual in thousands)	$0.6	$0.9	$1.0	$0.7
Total Cost to Foreign Farms				$10,499

Inspection Costs

We assume that the FDA and states will face no increased inspection costs as a result of the rule. We believe that the rule's benefits of reduced produce contamination can be achieved without adding any additional resources to inspection to ensure compliance with the rule. We seek comment on this assumption.

3. Analysis of Uncertainty

a. Benefits

We estimate the benefits of this rule to be approximately $1.00 billion for preventing 65% of all illnesses associated with covered FDA-regulated produce. As we explain in the previous section, the number of illnesses may understate the true total. In this section, we show the effect of a less restrictive assumption about baseline illnesses. Also, we have been estimating benefits using single values per illness prevented. In this section, we show the effects of using a range of potential values per illness, included values from a recent study of consumers' stated preferences.

As stated, our estimate of the baseline burden of illnesses attributable to produce is potentially underestimated because it omits home and retail mishandling which may have been prevented by better manufacturing practices and includes only those outbreaks FDA was directly involved in.[45] To relax both of these assumptions, we estimate the overall number of outbreak related illness that could potentially be due to produce. Eliminating all illnesses due to meat, processed foods, seafood, etc., we estimate that there are approximately 2.367 identified illnesses and 213 unidentified illnesses, annually that may be attributable to FDA regulated produce. Since these illnesses are not separable by pathogen we assume a weighted cost per illness, of $4,531, for the identified illnesses attributable to produce and $214 for unidentified illnesses. These values range from $1,507 to $6,189 for identified illnesses and $135 to $296 for unidentified illnesses, assuming varying VSLs and QALDs. Assuming all contamination was due to on farm contamination there would be a total preventable burden of $2.74 ($0.98 to $7.66) billion. However, not all of these illnesses are likely to be attributable to problems on the farm. Common sources of post-production contamination include improper handling, storage, or preparation methods; therefore, we estimate that approximately 47.4% of the contamination occurs at the farm level (Ref.28). This yields 1,112 identified and 100 unidentified illnesses potentially attributable to FDA regulated farms. In total, this gives a

[45] Outbreaks associated with FDA-regulated produces have an average of 121 illnesses; while, all outbreaks have an average of 20 illnesses. This could indicate that many of the smaller outbreaks, which are associated with no identified food vehicle or pathogen, and thus excluded from our counts, could be attributable to FDA regulated produces.

potential preventable human health burden of approximately $1.29 ($0.46 to $3.60) billion.

An interesting but limited recent stated preference survey intended to estimate the relationship between the severity and duration of hypothetical food-borne illnesses generated WTP numbers similar to the WTP numbers in our model. Haninger and Hammitt (Ref.89) use an experimental study, valuing acute foodborne illness, to estimate how WTP varies with severity and duration of illness and other observable characteristics. Their study indicates that the marginal WTP is decreasing over severity of the illness, duration of the illness, respondent's age, wealth, and other characteristics. They find that individuals do not have one stated WTP per QALY, so the uniform application of these is likely incorrect. Their results imply that our estimates of the value of preventing foodborne illness may understate the value of preventing an illness with low severity and duration and overstate the value of preventing an illness that is more severe and drawn out. Future work could address the issue by allowing the WTP for health endpoints to vary separately with illness severity and duration, rather than with the combination of the two. In the meantime we allow the burden of illness estimates to vary over the plausible range of VSL and QALD values, thus accounting for potential underestimation or overestimation bias.

Table 128 presents the values of the human health burden potentially attributable to FDA regulated produce if we allow VSLs and QALDs to vary. Altogether, this provides a range of between $0.46 and $1.44 billion, annually.

Table 128. Estimated Dollar Burden Attributable to FDA-Regulated Produce

	$293 QALD	$586 QALD	$882 QALD
$1.2 Million VSL	$0.46	$0.69	$0.91
$7.9 Million VSL	$0.79	$1.00	$1.24
$12.2 Million VSL	$1.00	$1.22	$1.44

Additionally, using this alternative willingness to pay (WTP) measure of foodborne illness from Haninger and Hammitt (Ref.89), we re-estimate the hypothetical maximum health benefits from by this rule. Applying their price a consumer is willing to pay to avoid a foodborne illness, $5,130 to $7,750 (compared to FDA's estimated range of $1,507 to $6,189, and a mean estimate $4,531 per illness attributable to produce), to the total number of identified illnesses that may be preventable by this rule yields $1.4 to $2.1 billion, annually. We do not apply these illness estimates to unidentified illnesses because the Haninger and Hammitt study design, although it uses generic illness descriptions, attempts to find stated willingness to pay to avert recognizable foodborne illnesses. Indeed, many respondents' estimates were at least partly based on their previous experience with known foodborne illness -- as well as the information provided by the survey. Since most unidentified illnesses we consider are not easily recognized by the public as foodborne, it is highly unlikely that these illnesses were taken into consideration for this survey. Instead, keeping a cost per unidentified foodborne illness of $214, because these illnesses are demonstrated to be much less severe (Ref.90), with the Haninger and Hammitt estimates we generate a total potential health saving from this rule of between $2.0 and $2.7 billion, annually. This is in line with, but somewhat larger than, the $1.00 billion ($0.46 -$1.44 billion) we estimated previously. We seek comment on these estimates.

b. Costs

We use two main sources to identify current produce safety practices, or baseline practices: the 1999 FVAP Survey (Ref.6) and a 2001 New England farm food safety survey (Ref.7). After accounting for farms in measurable food safety programs (i.e. GAPs audits, CA LGMA, AZ LGMA, etc.) we apply the information in these surveys to farms not in measurable programs to obtain information on which practices are the most prevalent in order to accurately measure the costs to farms of the proposed rule. While we believe that the 1999 FVAPS and the 2001 NEFFSS provide the best data available, there is a degree of uncertainty in the industry practices estimates since both of these surveys predate a modern movement towards safer practices on produce farms. The uncertainty stemming from these estimates are the primary driver of the uncertainty in the cost model. Since we expect that the use of these surveys will underestimate, sometimes significantly, the current application of food safety practices, we account for the uncertainty by estimating that of the farms that are not implementing a specific food safety practice, as measured by these surveys, half of them are complying today.

Table 129 describes the practices in the analysis for which either the 1999 FVAPS or the 2001 NEFFSS were used to determine baseline practices. In cases where the surveys provided information not correlated with food safety practices, such as the percentage of farms with post-harvest operations, with buildings, that utilize reusable food contact surfaces, or that use a municipal water source, the farm percentages were not changed since we do not expect that the movement towards safer food practices on farms would also change these practices. For soil amendment practices, the FVAPS shows that 14 percent of acres were covered with a biological soil amendment of animal origin and that 18.5 percent of farms use an either an untreated or treated biological soil amendment of animal origin. Since we expect that manure use changed over time due to changes in food safety practices that we cannot measure with another survey, we estimate that half of these farms changed their practices. This indicates that 7 percent of acres and 9 percent of farms use untreated manure. Similarly, we estimate the current industry practices percentages for provisions in the growing, harvesting, packing, and holding; equipment, tools, buildings, and sanitation; health and hygiene; and records sections.

Table 129: Estimates of Current Industry Practices in 1999 FVAPS and 2001 NEFFSS		
1999 Fruit and Vegetable Agricultural Practices Survey	Percentage of farms	Half as likely to not be following practice today
Biological soil amendments of animal origin		
Produce acres to which biological soil amendments of animal origin is applied, including manure	14%	7%
Farms that use biological soil amendments of animal origin, including manure (untreated and treated)	18.5%	9%
Growing, Harvesting, Packing, and Holding		
Farms that are not properly cleaning and sanitizing food harvest and packing materials	70%	35%
Equipment, Tools, Buildings, and Sanitation		
Farms that are not ensuring their workers are cleaning/sanitizing their tools	47%	24%
Farms with equipment that are not ensuring that it is adequately cleaned	39%	19%
Farms that do not have pest control	21%	11%
Training Records		
Farms that do not keep worker training records	67%	34%
2001 New England Practices Survey	Percentage of farms	Half as likely to not be following practice today
Agriculture Water Records		
Farms that do not keep water testing records	59%	30%
Health and Hygiene		
Do not exclude ill workers from handling produce directly	22%	11%
Do not exclude domesticated animals from being in produce fields	9%	5%
Do not exclude pets from being in produce fields	52%	26%
Both surveys	Percentage of farms	Half as likely to not be following practice today
Farms that do not have a food safety training program	32%	16%

Additionally, because these surveys of industry baseline practices are primarily from the 14 largest producing states, they may overstate the amount of industry adoption in the remaining states. In the absence of more current or more comprehensive data on this subject, we assume that the same margin of error calculated to generate a lower total cost in this sensitivity analysis could apply to estimate a higher total cost of industry compliance.

Table 130 summarizes the costs after accounting for the uncertainty in the industry practices estimates described in Table 129. It shows costs annualized at 7 percent and at 3 percent over 7 years. We estimate that the costs of the proposed rule are $416.09 million after accounting for uncertainty and annualized at 7 percent compared to $459.60 million as estimated in the analysis of the proposed rule. We estimate that the costs of the proposed rule are $383.28 million after accounting for uncertainty and annualized at 3 percent compared to $419.28 million as estimated in the analysis of the proposed rule. The average costs per covered farm range from $9,532, after accounting for uncertainty and annualized at 3 percent over 7 years, to $11,430 not accounting for uncertainty and annualized at 7 percent over 7 years.

Table 130: Range of Cost Estimates

	Low Costs		Estimated Costs		High Costs	
	Annualized at 7% over 7 years	Annualized at 3% over 7 years	Annualized at 7% over 7 years	Annualized at 3% over 7 years	Annualized at 7% over 7 years	Annualized at 3% over 7 years
Total costs accounting for uncertainty (in millions)	$570.55	$525.56	$630.21	$574.92	$689.87	$624.29
Average Cost per Farm	$10,348	$9,532	$11,430	$10,427	$12,512	$11,322

c. <u>Net Benefits</u>

Finally, we compare the range of estimate benefits to the range of estimate costs. This information is presented in Table 131.

Table 131. Sensitivity Analysis of Net Benefits (in millions)			
	Minimum	Mean	Maximum
Benefits	$816.10	$1,036.40	$1,158.04
Costs	$525.56	$630.21	$689.87
Net Benefits	$126.23	$406.19	$632.48

Benefits range from $816.10 million to $1.16 billion annually, with a mean estimate of $1.04 billion. Cost range from $525.56 to $689.87 million, with a mean estimate of $630.21 million. This yields a mean estimate of net benefits of about $406.19 million; a maximum estimate of net benefits of $632.48 million ($1,158.04 - $525.56), and a minimum estimate of $126.23 ($816.10 - $689.87)

V. PRELIMINARY REGULATORY FLEXIBILITY ANALYSIS

A. Introduction

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency believes that this proposed rule will have a significant economic impact on a substantial number of small entities.

B. Economic Effects on Small Entities

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 believes that the proposed rule will have a significant economic impact on a substantial number of small entities.

1. Regulated Entities

a. Number of small entities affected

The Small Business Administration defines farms involved in crop production as "small" if their total revenue is less than $750,000 (Ref.1). Approximately 95 percent of all farms that grow covered produce are considered small by the SBA definition, and these farms account for 33 percent of covered produce production. Accounting for the proposed exemptions for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, farms that are eligible for a qualified exemption based on average annual value of food sold and direct farm marketing, and produce and farms that are otherwise not covered by the rule, 80 percent of farms would fit within the SBA definition of small, and these farms would account for approximately 19 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 proposed rule-making, FDA has proposed to defined a small business in part 112 as a farm that is covered by the proposed rule whose average annual monetary value of food, 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[46]. FDA proposes to define a very small business in part 112, as a farm that is covered by the proposed rule and whose average annual monetary value of food, on a rolling basis, sold during the previous three-year period is no more than $250,000. As proposed, the definitions for small business and very small

[46] The $500,000 threshold is based on the legislative cut off for exemptions.

business exclude farms that are not subject to the proposed rule per proposed § 112.4(a), that is, farms with $25,000 or less in average annual monetary value of food sold. Approximately 12 percent of farms that are covered by the proposed rule are considered small businesses under the proposed rule, and these farms account for 8 percent of covered produce. Approximately 67 percent of farms that are covered by the proposed rule are considered very small businesses under the proposed rule, and these farms account for 9 percent of covered produce.

The proposed 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 (proposed § 112.5). The proposed rule additionally reduces the burden on small entities by excluding from the scope of the rule farms with $25,000 or less of average annual monetary value of food sold (proposed § 112.4(a)). These farms account for approximately 1.5 percent of produce that would otherwise be covered by this proposed rule, after accounting for farms eligible for a qualified exemption or other exemptions.

The proposed rule additionally provides all farms flexibility for alternative practices to be used for certain listed requirements with adequate scientific support. The proposed rule also provides for States and foreign countries to submit a request for a variance for one or more requirements of the proposed 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 proposed rule.

Farms defined as small businesses have an additional 2 years to comply with most provisions of the rule after the effective date of FDA's final rule, and farms defined as very small businesses have an additional 3 years. There is also an extended 2-year compliance period for certain proposed provisions for water quality in § 112.44 and related provisions in §§ 112.45 and 112.50 (specifically, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)). The extended compliance dates for these specific water quality standards would then be four years from the effective date for small businesses and five years from the effective date for very small businesses.

Table 132 summarizes the total number of domestic farms covered by the proposed 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. We estimate that a total of 31,640 domestic farms (26,947 very small + 4,693 small), 79 percent (31,640/40,211), are small entities after accounting for farms not covered, farms that exclusively grow covered produce destined to commercial processing, and farms eligible for a qualified exemption based on annual average value of food sold and direct farm marketing. Collectively, these entities account for 17 percent (9% very small + 8% small) of covered produce.

Table 132: Covered Farms in the Proposed Rule				
	Very Small	Small	Large	Total
Number of covered farms	26,947	4,693	8,571	40,211
Percentage of covered farms	67%	12%	22%	100%
Percentage of produce acres	9%	8%	83%	100%
Average annual monetary value of food	$75,279	$320,696	$2,638,384	$656,108

b. <u>Costs to small entities.</u>

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

Table 133 shows the average costs of implementing the requirements in the proposed rule (annualized at 7 percent over 7 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. The table shows that the average costs to very small farms are $4,698 and that the average costs to small farms are $12,972, which are both significantly lower than the average cost to large farms of $30,566. Average costs make up 6 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 proposed requirements will incur a larger cost than the average shown. We lack information about how many requirements any one particular farm will need to implement.

Table 133: 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	$4,697.19	$12,972.36	$30,566.23	$11,429.70

Average annual monetary value of food sold	$75,279	$320,696	$2,638,384	$656,108
Average costs percentage of average annual monetary value of food sold	6%	4%	1%	2%

We contracted with RTI International to develop a model that provides the percentage of farms by size (Ref.91). Since the model includes all farms that grow produce, it does not account for farms that are excluded from the scope of the rule or that are eligible for a qualified exemption. We believe that some farms will choose to switch farming operations, but that choice depends on many variables that make the quantification intractable at this time: regional geography (including soil nutrients and climate), capital requirements, supply chain, alternative produce market elasticity, and acreage requirements, as well as land prices. We request comment on likely farm business impacts as a result of this proposed rule as well as the ability to switch farming operations.

FDA believes farm operators are likely to make behavioral adjustments that would alleviate the impact of a regulation on their net returns. Farm operators may decide to increase their off-farm income (that is, income coming from a source other than the farm, for example, if the farm operator has an additional occupation) in order to provide more total income to the farm operation. Farms may also learn to comply with the regulation more cost-effectively over time. We lack data to account for these aspects of operators' behavior.

We seek comment on the impact and likely response of farms to the proposed rule.

The regulatory costs of this proposed rule may discourage at least some new small entities from entering the industry. The agriculture industry is characterized by substantial entry of small entities. Although we cannot quantify how much that will change, we expect that the rate of entry of very small and small businesses will decrease.

C. Regulatory Flexibility Options

1. Exemptions for Small Entities

One option to reduce the impact on small entities would be to exempt all small entities from the proposed rule. As mentioned previously, under the SBA size standards the vast majority of entities affected by the proposed rule are small. Additionally, under the definition in the proposed rule, we estimate that 31,774 out of a total of 40,496 farms, or about 79 percent, are small and collectively account for 17 percent of covered produce. Exempting small entities would substantially reduce the expected benefit of the rule.

The proposed rule includes a qualified exemption for certain small entities based on average monetary value of food sold and direct sales to qualified end users. This qualified exemption is mandated by Section 419(f) of the FD&C Act. Farms would be eligible for a qualified exemption if during the previous 3-year period preceding the applicable calendar year, the average annual monetary value of all food sold directly to qualified end-users exceeded the average annual monetary value of the food sold to all other buyers, and the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation. Approximately 76,000 farms are eligible for this exemption, and all of these entities are considered very small and small businesses as defined in the proposed rule.

The proposed rule further excludes from its scope farms with $25,000 or less of average annual monetary value of food sold. Although approximately 46 percent of farms that grow covered produce fall under this threshold, these farms account for approximately 1.5 percent of produce after accounting for farms eligible for a qualified exemption and farms that are otherwise exempt. If the proposed rule were to cover these farms, then the total cost to these farms would be approximately $144.7 million (34,452 x $4,201) using the same average cost that would be incurred on very small farms of $4,201. Additionally, since the average farm generates approximately $6,663 in annual monetary value of food sold, then the average cost per farm would make up 63 percent of the average per farm revenue $4,201/$6,663).

2. Longer compliance periods

Small entities may find it more difficult to learn about and implement the proposed requirements than it will be for large entities. Lengthening the compliance period provides some regulatory relief for small businesses 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 train workers to fully understand produce safety principles, implement appropriate practices consistent with the proposed requirements, set up record keeping, 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.

We are proposing that the compliance dates for persons subject to the rule would be based on the size of a farm and the effective date of the requirement, with additional flexibility for compliance with proposed provisions for water quality in § 112.44 and related provisions in §§ 112.45 and 112.50 (specifically, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7)).

The compliance date for very small businesses (as defined in proposed § 112.3(b)(1)) would be three years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The compliance date for very small businesses would not be in conflict with the requirement in section 419(b)(3)(B) of the FD&C Act for the regulations promulgated under section 419 to apply to very small businesses "after the date that is 2 years after the effective date of the final regulation…." because this requirement specifies that the regulations shall apply after, not on, the date that is 2 years after the effective date. To provide additional flexibility to small businesses, we would provide one more year for very small businesses to comply with the rule than is required under section 419(b)(3)(B). Providing an extended compliance period to very small businesses as a means of providing additional flexibility is consistent with our approach to compliance dates in recent rules directed to food safety. (See, e.g., 74 FR 33029 at 33034 and 72 FR 34751 at 34752.)

The compliance date for small businesses (as defined in proposed § 112.3(b)(2)) would be two years from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The compliance date for small businesses would not be in conflict with the requirement in section 419(b)(3)(A) of the FD&C Act for the regulations promulgated under section 419 to apply to small businesses "after the date that is 1 year after the effective date of the final regulation…." because this requirement specifies that the regulations shall apply after, not on, the date that is 1 year after the effective date. To provide additional flexibility to small businesses, we would provide one more year than is required under section 419(b)(3)(A). Providing an extended compliance period to small businesses as a means of providing additional flexibility is consistent with our approach to compliance dates in recent rules directed to food safety. (See, e.g., 74 FR 33029 at 33034 and 72 FR 34751 at 34752.)

The compliance date for all other farms subject to the rule would be one year from the effective date (with the exception of compliance with §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7), as discussed below). The one year compliance period for farms other than small and very small businesses is consistent with compliance dates in recent FDA rules directed to food safety. (See, e.g., 74 FR 33029 at 33034 and 72 FR 34751 at 34752.)

The compliance dates for water quality requirements in proposed § 112.44 and related provisions in §§ 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) would be two years beyond the compliance date for the rest of the final rule applicable to the farm based on its size. We recognize that farms may need additional time to cope with implementation of the water quality testing, monitoring, and related record-keeping provisions. This additional compliance period would also be expected to permit farms to consider identifying alternatives to the standard in proposed § 112.44(b) and developing adequate scientific data or information necessary to support a conclusion that the alternative would provide the same level of public health protection as the standard that would be established in this part, and would not increase the likelihood that the covered produce will be adulterated under section 402 of the FD&C Act, in light of the farm's covered produce, practices, and conditions. The extended compliance dates for the water quality testing, monitoring, and related record keeping requirements in proposed §§ 112.44, 112.45, 112.50(b)(5), 112.50(b)(6), and 112.50(b)(7) would then be five years from the effective date for very small businesses, four years from the effective date for small businesses, and three years from the effective date for all other farms subject to the rule.

The compliance dates would apply to all farms subject to the rule, including those farms that satisfy the requirements in proposed § 112.5 for an exemption from most requirements of the rule, because such farms have modified requirements (proposed § 112.6) to which they would be subject on the relevant compliance date.

We seek comment on these proposed implementation periods. In addition, given that activities related to produce production, harvesting, packing, and holding may be affected by the produce growing season, we seek comment on whether these compliance dates sufficiently address any issues related the seasonal nature of produce-related activities.

FDA plans to publish small entity compliance guidance to help inform and educate small businesses about the requirements of the proposed rule. Section 419(e) of the FD&C Act requires FDA to develop guidance "for the safe production and harvesting of specific types of fresh produce under [section 419]" and to hold at least three public meetings in diverse geographical areas of the U.S. as part of an effort to conduct education and outreach regarding the guidance. Consistent with this statutory provision, FDA plans to develop guidance materials, including additional commodity-specific guidances, as needed and informed, in part, by stakeholder input, including that received during public meetings. We plan to use guidance to the extent feasible as a vehicle to identify areas where compliance can be achieved through flexible approaches that mitigate the financial impact of the proposed rule while preserving the public health benefits of the proposed rule.

FDA has together with USDA AMS, established a jointly-funded Produce Safety Alliance (PSA), a public-private partnership that will develop and disseminate science- and risk-based training and education programs to provide produce growers and packers with fundamental food safety knowledge. A first phase of PSA's work is intended to assist farms, especially small and very small farms, in establishing food safety programs consistent with the GAPs Guide and other existing guidances so that they will be better positioned to comply when we issue a final produce safety rule under section 419 of the FD&C Act. FDA intends to work with federal, State, and local officials, industry, and academia through the PSA to assist farmers to implement measures necessary to minimize the risk of serious adverse health consequences or death from consumption of covered produce.

D. Description of Recordkeeping and Recording Requirements

The Regulatory Flexibility Act requires a description of the recordkeeping required for compliance with this proposed rule. Documentation must be established and kept for the certain purposes described in the proposed rule. Qualified exempt farms (based on average annual value of food sold and direct farm marketing) are required to include their name and complete business address on the label of their product if a label is required, or otherwise disclose this information at the point of sale, and farms that are exempt because they exclusively grow covered produce that receives commercial processing will need to have documentation that identifies the processor of their product. Covered farms are required to keep and establish documentation of required training, findings from agricultural water system inspections, analytical test results, the results of water treatment monitoring, documentation from public water suppliers if applicable, and scientific data or information relied upon to support an alternative water standard for non-sprout direct application irrigation water or the adequacy of a farm's treatment method if applicable. Covered farms that use biological soil amendments of animal origin must keep documentation of the date of application of untreated biological soil amendments of animal origin or biological soil amendments of animal origin treated by a composting process to a growing area and the date of harvest (except when covered produce does not contact the soil after application of the soil amendment), certain listed documentation for treated biological soil amendments of animal origin received from a third party, documentation that process controls were achieved for a treated biological soil amendment of animal origin the farm produces itself, and scientific data that the farm relies upon to support any alternative composting process or application interval if applicable. Farms must also keep records for cleaning and sanitizing certain equipment used in growing operations for sprouts and covered harvesting, packing, or holding activities. Additionally, sprouting operations must establish and keep documentation of treatment of seeds or beans at the farm, a written environmental monitoring plan, a written sampling plan for each production batch of sprouts, the results of all testing conducted, any alternative test method used in lieu of the environmental testing method incorporated into the rule, and the testing method used to test spent irrigation water or sprouts. The cost of recordkeeping is shown in section IV.H.2. (Summary of Records).

VI. UNFUNDED MANDATES

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this proposed rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on:Future costs; particular regions, communities, or industrial sectors; national productivity; economic growth; full employment; job creation; and exports.

The issues listed above are covered in detail in the cost benefit analysis of the preceding sections.

VII. SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule is a major rule for the purpose of congressional review.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the following paragraphs with an estimate of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: Section 105 of the FDA Food Safety and Modernization Act requires that " not later than 1 year after the date of enactment, …shall publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death…"

Description of Respondents: The proposed regulation applies to farms that grow produce, meaning fruits and vegetables such as berries, tree nuts, herbs, and sprouts. There are 40,211 farms in the U.S., the District of Columbia, and the Commonwealth of Puerto Rico, excluding sprouting operations (Ref 3), that would be covered by the proposed rule. We estimate that there are approximately 285 sprouting operations covered by this proposed rule.

Qualified Exemptions

The proposed rule identifies certain farms and produce that are eligible for qualified exemptions. A qualified exemption is established under two criteria: the monetary value of all food sold and direct marketing of the food, and covered produce that is destined for commercial processing that adequately reduces the presence of microorganisms of public health significance (i.e., a microbial kill-step). Farms that qualify for a qualified exemption are subject to a subset of the proposed regulation.

Information Collection Burden Estimate

The estimated hourly burden is 8,493 one-time hours, and 1,289,959 annual hours.

Furthermore, the estimated one-time third-party disclosure burden is 1,083 hours and the estimated annual third-party disclosure burden is 395,746 hours. FDA estimates the burden for this information collection as follows:

Section 112.2(b)(2) requires documentation of the identity of the recipient of the covered produce that performs the commercial processing that adequately reduces microorganisms. We believe that producers currently possess documentation on the recipient of their produce that will meet these requirements. We assume that no additional burden will be incurred. We ask for comment on our assumption that the proposed requirements are standard business practice and impose no additional burden.

Section 112.30(b) requires the establishment and maintenance of records of training documenting required training of personnel, including the date of training, topics covered, and the persons(s) trained. As described in the Regulatory Impact Analysis, we assume all 1,117 farms implementing voluntary food safety programs are currently meeting the proposed standard and recordkeeping requirements and approximately 33 percent of farms currently keep worker training records; therefore, we assume that no additional burden will be incurred for those 1,117 farms. We ask for comment on our assumption that the proposed requirements are standard business practice for these 1,117 farms and impose no additional burden.

After subtracting the number of these farms from the total and multiplying the remainder by 67 percent, we calculate that there are a total of 26,384 farms that will incur the costs of worker training recordkeeping. Therefore, it is estimated that one recordkeeper on each of 26,384 farms will spend an average of 7.25 hours per year on recordkeeping related to training requirements (recording and maintaining the dates and topics of training, and person(s) trained) of this proposed rule. Therefore, 26,384 recordkeepers x 7.25 average hours per recordkeeper = 191,284 hours to meet the requirements of § 112.30 (b). We ask for comment on the estimation of farms that will be affected by the requirements of proposed § 112.30(b).

Section 112.44 of this proposed rule outlines certain requirements for agricultural water, including § 112.44(a) and (b), which outline requirements to test water for certain uses for generic *E. coli*, and § 112.50, which requires recordkeeping related to those tests. For all testing burdens estimated for § 112.44(a) and (b), it is estimated that each test will represent a burden of one half hour, or 30 minutes. As discussed in the Regulatory Impact analysis, of the 40,496 non-sprout farms subject to these requirements, we assume that 46 percent of covered produce farms have post-harvest operations and that 50 percent of farms with post-harvest operations (the midpoint between 0 and 100 percent) use water in their harvest or post-harvest operations. We assume that all surface water used for harvest and post-harvest uses is currently treated and that 47 percent of farms use groundwater sources for water or ice in direct contact with covered produce during or after harvest activities, water for hand-washing during and after harvest, water or ice for direct contact with food-contact surfaces, water for treated agricultural teas. Finally, we assume 26 percent of covered farms would not be subject to the proposed testing requirements because water for these purposes is obtained from a municipal source using findings from a 2001 survey of New England produce growers (Ref 7). Consequently, we estimate that 3,216 farms that apply water or ice in direct contact with covered produce during or after harvest activities, water for hand-washing during and after harvest, water or ice for direct contact with food-contact surfaces, and water for treated agricultural teas would incur a testing burden, with the magnitude of the burden dependent on the initial test results and the availability of alternative water sources. We estimate that 1,608 non-sprout farms (i.e., 50 percent of 3,216 non-sprout farms) would incur a testing burden twice annually (i.e., once every 3 months during the production season), 804 non-sprout farms (i.e., 25 percent of 3,216 non-sprout farms) would incur a testing burden once annually (i.e., those with positive test results that would then opt to treat their water), and 804 non-sprout farms (i.e., 25 percent of 3,216 non-sprout farms) would incur a testing frequency of 3 times annually (i.e., those with initial positive analytic findings that would then switch water sources and test two more times that year). It is estimated that the burden of each test (the time to collect and prepare each sample) is 30 minutes. We ask for comment on our estimates of the number of respondents and the amount of time required to collect and prepare the sample.

The burdens estimated here include the farms that apply water in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities, (a)(2); use water used to make a treated agricultural tea, (a)(3); and use water to contact food-contact surfaces, or to make ice that will contact food-contact surfaces, (a)(4). As explained in the RIA we request comment on the number of farms that use water to make a treated agricultural tea and water used to contact food-contact surfaces or make ice that will contact food contact surface. We assume that the number of farms that use groundwater during or after harvest activities also includes farms that use water to make agricultural teas as well as water to contact food contact surfaces, including as ice.

Therefore, it is estimated that 804 non-sprout farms that use groundwater sources as outlined in the discussions of § 112.44(a)(2), § 112.44(a)(3) and § 112.44(a)(4) above would sample and test 1 time annually and then opt to treat water. The burden associated with testing is estimated to take one half hour per test. Therefore, 804 farms x .5 hour = 402 total annual hours to comply with § 112.44(a)(2), § 112.44(a)(3) and § 112.44(a)(4).

Section § 112.50(b)(5) requires records of the results of water testing you perform to satisfy the requirements of Section § 112.44. For the farms using groundwater sources during or after harvest activities that would sample and test one time and then opt to treat, this recordkeeping will require one recordkeeper for each of 804 farms to maintain a record one time a year, consisting of recording the result of the test and decision to treat. It is estimated that each record will take .33 hour annually and will consist of one recordkeeper per estimated farm recording the results of the water test. Therefore, 804 farms x 1 records = 804 records and 804 x .33 = 265.3 annual hours for these farms to comply with § 112.50(b)(5). The burden of complying with § 112.44(a)(2), § 112.44(a)(3) and § 112.44(a)(4) also extends to operating costs above any labor hours spent collecting for the test (laboratory analysis, shipping and collection supplies, and any laboratory travel). This additional operating cost is an average of $87.30 per test (a range of $80 – $94.60). Therefore, 804 tests x $87.30 = $70,189 for additional operating costs.

It is estimated that 1,608 of non-sprout farms that use groundwater sources for as outlined in the discussion of § 112.44(a)(2), § 112.44(a)(3) and § 112.44(a)(4) above during or after harvest would sample and test would sample and test 2 times annually. Therefore, 1,608 farms x 2 tests = 3,216 annual tests and 3,216 tests x .5 hour per test =

1,608 annual hours to comply with § 112.44(a)(2), with additional recordkeeping burden of 2,825 annual hours (3,216 records x .33 = 1,061 annual hours) to comply with § 112.50(b)(5) and operating costs of $280,757 (3,216 tests x $87.30 per test).

It is estimated that 804 of non-sprout farms that use groundwater sources as outlined in § 112.44(a)(2), § 112.44(a)(3) and § 112.44(a)(4) would sample and test 1 time and then take corrective actions (e.g., switch wells) and sample 2 more times (for a total of 3 times annually). Therefore, 804 farms x 3 tests = 2,412 tests and 2,412 tests x .5 hour = 1,206 hours annually to comply with § 112.44(a)(2)), with additional recordkeeping burden of 796 annual hours (2,412 records x .33 = 796 annual hours) to comply with § 112.50(b)(5) and operating costs of $210,567 (2,412 tests x $87.30 per test).

In summary, we estimate that the water testing requirements associated with § 112.44(a)(2), § 112.44(a)(3) and § 112.44(a)(4) will require 3,216 respondents to maintain records and the respondents will incur .5 hour of burden as they test between 1 and 3 times annually for a total of 6,432 records and a burden of 3,216 hours. Compliance with § 112.50(b)(5) will impose an additional burden of 5,893.3 hours. There will also be operational costs associated with these tests of $140,379. We ask for comment on these estimates.

As discussed in our regulatory impact analysis, 74 percent of the respondents to a 1998 survey of California sprout growers reported using municipal water as the source for growing sprouts; the remaining sprout growers reported using ground water sources. We are proposing that only those sprout growers that do not use municipal water would have to test their water to determine whether it satisfies the water quality criterion of no detectable generic E. coli per 100ml water sample. Therefore, we assume that 37 (or 50% of the 74 sprout growers who do not use municipal water sources) who use groundwater for irrigation water would sample and test 1 time annually and opt to treat as a corrective action, in accordance with § 112.44(a)(1). Therefore 37 growers x .5 hour for testing = 18.5 hours annually to comply with § 112.44(a)(1). Section § 112.50(b)(5) requires records of the results of water testing you perform to satisfy the requirements of Section § 112.44. It is estimated that each record will take .33 hour annually and will consist of one recordkeeper per estimated farm recording the results of the water test. Therefore 37 records x .33 hour = 12.2 hours annually for sprout growers to comply with § 112.50(b)(5). The burden of complying with § 112.44(a)(1) also extends to operating costs above any labor hours spent collecting for the test (laboratory analysis, shipping and collection supplies, and any laboratory travel). This additional operating cost is an average of $87.30 per test (a range of $80 - $94.60). Therefore, 37 tests x $87.30 = $1,571 for additional operating costs.

Furthermore, it is estimated that 37 sprout growers who use groundwater for irrigation water would sample and test quarterly in accordance with § 112.44(a)(1). Therefore, 37 growers x 4 tests = 148 annual tests, and 148 tests x .5 hour per test = 74 hours to comply with § 112.44(a)(1). Section § 112.50(b)(5) requires records of the results of water testing you perform to satisfy the requirements of Section § 112.44. It is estimated that sampling and testing quarterly will generate four records per year each, consisting of one recordkeeper per estimated farm recording the results of the water test. It is estimated that each record will take .33 hour annually and will consist of one recordkeeper per estimated farm recording the results of the water test. Therefore, 148 records x.33 hour = 49 hours for these sprout growers to comply with § 112.50(b)(5). The burden of complying with § 112.44(a)(1) also extends to operating costs above any labor hours spent collecting for the test (laboratory analysis, shipping and collection supplies, and any laboratory travel). This additional operating cost is an average of $87.30 per test (a range of $80 - $94.60). Therefore, 148 tests x $87.30 = $12,920, for additional operating costs.

Farms that use water other than municipal water or treated water for hand washing during and after harvest would be subject to the sampling and testing requirement for purposes of hand washing during and after harvest (§ 112.44(a)(5), with related recordkeeping requirements in § 112.50(b)(5)). To obtain an estimate of the number of farms that would be required to test and maintain records, we multiplied the total number of farms, 40,496 by 47 percent (the fraction of irrigated farms that use groundwater estimated from 2008 Farm and Ranch Irrigation Survey) and then subtracted our estimate of the number of farms using municipal water for post-harvest uses (26 percent). Based on this calculation, 14,085 of all farms that use groundwater sources for handwashing would sample and test their water[47]. We assume the water will be sampled and tested 2 times annually consistent with a frequency of every three months during the production season, which is estimated to average 6 months. Therefore, 14,085 farms x 2 tests = 28,170 annual tests and 28,170 tests x .5 hour per test = 14,085 annual hours to comply with § 112.44(a)(5), with additional operating costs of $2,459,241 (28,170 tests x $87.30 per test). Section § 112.50(b)(5) requires records of the results of water testing you perform to satisfy the requirements of Section § 112.44. It is estimated that, for

[47] It is estimated that water used for hand washing will come from a different source than water used for harvest and postharvest activities. Therefore, the information collection burdens are estimated separately.

records of sampling and analytic test results for farms using groundwater for hand-washing during and after harvest activities, this recordkeeping will require one recordkeeper for each of about 14,085 farms to maintain a record 2 times a year, and it is estimated that this burden consists of recording the results of the sampling and analytic test results and that each record will take .33 hour annually. Therefore, 14,085 farms x 2 records = 28,170 records and 28,170 x .33 hour per record = 9,296 annual hours for these farms to comply with § 112.50(b)(5).

Section § 112.44(c) outlines requirements to test water for generic *E. coli* when water is used during growing activities for covered produce (other than sprouts) using a direct water application, and § 112.50 requires recordkeeping related to those tests.[48] This burden is estimated to vary across farms. It is estimated that the collection burden associated with § 112.44(c) is one half hour per test, which is estimated to consist of the time needed to collect and prepare the sample. In the analysis that follows, this collection burden applies to all testing burdens estimated for § 112.44(c). The burden is estimated to vary across farms and is dependent on use and source of the water. We ask for comment on these estimations.

Using data on irrigated farms from the 2008 FRIS survey on farms that use surface water and groundwater as their primary sources for irrigation, it is estimated that, out of 40,496 total farms subject to this regulation, 7,435 irrigated farms apply water using a direct application method and would incur a testing burden. As discussed in the Regulatory Impact Analysis we estimate that 289 of these farms would incur a testing burden once annually and opt to treat their water to meet the standard, and that 50 percent

[48] While this proposed rule addresses water used for agricultural teas, it not estimated that agricultural teas are commonly used in produce growing. Therefore, there is no estimated burden for water used for agricultural teas in this analysis.

of the remaining irrigated farms that apply water using a direct application method (i.e., 3,573 of these farms) would incur a testing burden weekly during the production cycle, or 26 times annually, and 50 percent (i.e., 3,573 of these farms) would incur a monthly testing burden during the production cycle, or six times annually.

It is estimated that 289 farms would test one time annually, in accordance with § 112.44(c). Therefore, 289 growers x .5 hour per test = 144.5 annual hours to comply with § 112.44(c), with additional operating costs of $25,230 (289 tests x $87.30 per test). It is estimated that 3,573 farms would test surface water on a weekly basis during the production season, or about 26 times. Therefore, 3,573 farms x 26 weekly tests = 92,898tests and 92,898 tests x .5 hour per test = 46,449 annual hours to comply with § 112.44(c), with additional operating costs of $8,109,995 (71,460 x $87.30). It is estimated that 3,573 farms would test surface water on a monthly basis for six months. Therefore, 3,573 farms x 6 annual tests = 21,438 tests and 21,438 tests x .5 hour per test = 10,719 annual hours to comply with § 112.44(c), with additional operating costs of $1,871,537 (42,876 tests x $87.30 per test).

As discussed above, Section § 112.50(b)(5) requires records of the results of water testing you perform to satisfy the requirements of Section § 112.44. It is estimated that, for farms that directly apply surface water to covered produce other than sprouts during growing, § 112.44(c) will require one recordkeeper to record the result of the test and the decision to treat. We estimate that the recordkeeper will incur a burden of .33 hour for each record. As a result, the 289 farms that test one time, then opt to treat, will maintain a record one time a year, consisting of recording the result of the test and decision to treat, resulting in 95 annual hours (289 records x .33) for these farms to comply with § 112.50(b)(5). For the 3,753 farms directly applying surface water to covered produce other than sprouts during growing and then testing weekly during the production cycle (26 weeks), one recordkeeper for each farm will be required to maintain a record of the test results 26 times a year, resulting in 30,656 annual hours (3,573 farms x 26 records x .33) for these farms to comply with § 112.50(b)(5). For the 3,573 farms directly applying surface water to covered produce other than sprouts during growing and testing monthly (for six months), one recordkeeper for each farm will be required to maintain a record of the sampling and testing results one time a month, for six months, resulting in 7,074.5 annual hours (3,573 farms x 6 records x .33) for these farms to comply with § 112.50(b)(5).

In the aggregate, we estimate that the testing required by § 112.44(c) would impose 57,312.5 hours of burden on 7,435 respondents and impose additional operating costs of $10,006,762. Compliance with § 112.50(b)(5) will impose an additional burden of 37,825.5 hours. We ask for comment on these estimates.

Section § 112.50 outlines recordkeeping requirements related to agricultural water. Section § 112.50(b)(1) requires records of findings of the inspection of a farm's agricultural water system under § 112.42(a). According to the 2007 Census of Agriculture (Ref 3), there are 26,431 farms that use irrigation water. We estimate that it will take .8 hour to record the information related to findings of the agricultural water inspection. We assume there will be an average of 6 agricultural water inspections a year because of potential variation across crops and growing seasons. It is estimated that recordkeeping related to findings of the agricultural water inspection will require one recordkeeper for each of 26,431 farms to maintain a record containing the results of the agricultural water inspection 6 times a year. Therefore 26,431 farms x 6 records = 158,586 annual records x .8 hour per records = 126,869 annual hours to comply with § 112.50(b)(1). We ask for comment on these estimates.

Section § 112.50(b)(2) requires records of analytical test results for any tests conducted to determine whether agricultural water is safe and of adequate sanitary quality for its intended use. Farms may test their water as part of corrective steps because of a determination or reasonable belief that the water is not safe and of adequate sanitary quality for its intended use (see § 112.42(d)). Based on the California Tomato Farmer (CTF) database that indicates that approximately 1 percent of member farms had agricultural water that did not meet the appropriate standard during an audit between May 2011 and November 2011, we assume that 1 percent of farms would test their water as part of corrective steps. Therefore, after accounting for farms not covered by the proposed rule we use 2008 FRIS data to estimate that 26,431 irrigated farms x 1 percent = 264 farms and 264 x .33 hour per record = 87 hours to record and maintain records of test results to comply with Section § 112.50(b)(2). We ask for comment on these estimations. In addition, we include the estimated burden of the test itself. it is estimated that 264 farms would incur a testing burden once per year from this provision. Therefore, 264 times 1 test = 264 tests and 264 tests x .5 hour per test = 132 annual hours to comply with § 112.50(b)(2), with additional operating costs of $23,047.20 (264 tests x $87.30 per test).

Section 112.50(b)(3) requires documentation of scientific data relied on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)(1). We estimate that the number of farms that would rely on documentation of scientific data to support the adequacy of a method used to satisfy these requirements is 50 percent of the number of that would treat and monitor their water as described above. Consequently, we estimate that 2,397 farms (i.e., (4,468 non-sprout farms that would choose to treat water used during and after harvest activities+ 289 non-sprout farms that would choose to treat water directly applied during growing operations +37 sprout farms that would choose to treat irrigation water) x 50 percent = 2,397 farms) would rely on documentation of scientific data to support the adequacy of a method used to satisfy these requirements. It is estimated that one recordkeeper for each of 2,397 farms will spend .5 hour one-time on this documentation, estimated to consist of gathering and maintaining the documentation of scientific data. Therefore, 2,397 x .5 = 1,199 one-time hours to meet the requirement of § 112.50(b)(3). We ask for comment on these estimates.

Section 112.50(b)(4) requires documentation of the results of monitoring water treatment under § 112.43(c)(2). We estimate there are 289 non-sprout farms that directly apply surface water and would opt to treat their water in the Regulatory Impact Analysis using surface water quality information from EPA (Ref 58), data from the 2007 Agricultural Census (Ref. 3) on average farm sizes, and by assuming that 50 percent of farms that would irrigate with substandard water would have an alternative water source available to use instead of opting to treat. We ask for comment on these estimations.

Furthermore, we estimate that all farms that use surface water during and after harvest activities , to contact food contact surfaces including as ice, for treated agricultural teas and for sprout irrigation would opt to treat their water unless it comes from a municipal source[49]. As discussed in the Regulatory Impact analysis, of the

[49] It is assumed that 26 percent of covered farms that would otherwise use a surface water source and 26 percent of covered farms that would otherwise use a groundwater source use a municipal source.

40,211 farms subject to the regulation, we assume that 46% are estimated to have post-harvest operations on their farm. We further estimate that 50 percent of these farms use water in their post-harvest operations. We then apply the fraction of farms that use a groundwater source (47 percent), obtained from the 2008 Farm and Ranch Irrigation Survey (Ref 17), and estimate that 25 percent, or 4,757 farms that use groundwater during and after harvest activities, including for ice and hand washing and for sprout irrigation would opt to treat their water and would incur a monitoring burden. Therefore, it is estimated that 1 recordkeeper for each of 4,757 farms (289+4,468) will spend .98 hour annually recording the results of water monitoring. Therefore 4,757 farms x .98 hour per year = 4,662 hours for farms to comply with § 112.50(b)(4).   We ask for comment on these estimates.

Proposed § 112.50(b)(6) requires documentation of scientific data or information relied on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method. It is not known how many covered farms will seek to use some alternative to the requirements in § 112.44(c); however, it is estimated that the number of farms that would rely on documentation of scientific data to support such an alternative is 50% of farms that use a direct application method and would be subject to weekly testing requirements (3,573 x .5 = 1,787 farms). Therefore, it is estimated that 1,787 farms that would be subject to weekly testing requirements will seek some alternative to the requirements in § 112.44(c), and each farm will work 1 hour, estimated to consist of searching for and creating documentation, to fulfill this requirement. Therefore, 1,787 farms x 1 hour = 1,787 annual hours for these farms to comply with § 112.50(b)(6). We ask for comment on these calculations and assumptions. We ask for comment on these estimates.

Section 112.50(b)(7) requires annual documentation of the results or certificates of compliance from a public water system under 112.45(a)(1) or (2), if applicable. We estimate the number of covered farms that use water or ice in direct contact with covered produce during and after harvest activities, water for hand-washing during and after harvest, water or ice for direct contact with food-contact surfaces, and water for treated agricultural teas that obtain their water from a municipal source using findings from a 2001 survey of New England produce growers. In that survey 26 percent of respondents reported using municipal water as the source for the farm's drinking water. We use this information to estimate that 26 percent of covered farms, or 5,052, apply municipal water for the uses of water subject to the requirement of 0 detectable generic *E.* coli per 100 ml, and information from a 1998 survey of California sprout growers (Ref 53) that reports that 74 percent of sprout growers, or 211, use municipal water as the source for growing sprouts as a basis for assuming that 5,253 farms that would incur a burden from maintaining documentation showing their water is from a municipal source. We estimate that these farms will spend .33 hour annually to obtain and maintain this documentation. Therefore, 5,253 records x .33 hour = 1,733 annual hours for farms to comply with this requirement. We ask for comment on these estimates.

Section 112.60(b) of this proposed rule specifies the records that covered produce farms must establish and keep regarding biological soil amendments of animal origin. Section 112.60(b)(1) of this proposed rule requires covered farms to document the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated by composting to a growing area and the date of harvest from that growing area, except when covered produce does not contact the soil after application of the soil amendment. In part G(3) of the Regulatory Impact Analysis, using data from the NASS (Ref 3), it is estimated that there are 820 (523 livestock/manure farms + 109 organic farms+ 188 other farms = 820) produce farms that will change practices related to the use of soil amendments as a result of this proposed rule. This total is based on estimated current practices with respect to soil amendments of animal origin and is estimated to be the number of farms using untreated manure. The estimate does not include farms estimated to use treated manure or commercial compost. Please see the Regulatory Impact Analysis for further detail.

In part G(3) of the Regulatory Impact Analysis, it is estimated that the lowest cost option for any covered produce farm currently estimated to use untreated biological soil amendment of animal origin (including raw manure) is to switch to commercial compost. While it is still possible that some farms may choose to continue to use untreated biological soil amendments of animal origin (including raw manure), the data do not exist to estimate how many of these farms may choose to do so. For the purposes of this analysis, it is estimated that 5% of the covered produce farms currently estimated to use untreated biological soil amendments of animal origin (including raw manure) will continue with this practice, and thus be subject to the recordkeeping requirement of § 112.60(b)(1) (820 x .05 = 41 farms) unless the covered produce does not contact the soil after application. It is estimated that that one recordkeeper for each of these 41 estimated farms will spend .5 hour annually to meet this requirement, estimated to consist of recording any application dates. Therefore, 41 recordkeepers x .5 hour = 20.5 annual hours.

For treated soil amendments acquired from a third party, proposed § 112.60(b)(2) requires documentation that certain criteria have been met, namely that (i) the process used to treat the biological soil amendment of animal origin is a scientifically valid process carried out with appropriate process monitoring; (ii) the application treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in section 112.55, including the results of such periodic testing; and (iii) the biological soil amendment of animal origin has been handled, conveyed, and stored in a manner and location to minimize the risk of contamination by an untreated or in-process biological soil amendment of animal origin. Current EPA regulations, as well as many states, require documentation that certain criteria have been met for treated soil amendments acquired from a third party. Therefore, it is estimated that, for any covered produce farm already using treated biological soil amendments from a third party, this requirement does not represent a new recordkeeping burden. However, in part G(3) of the Regulatory Impact Analysis, it is estimated that the lowest cost option for any of the 820 covered produce farms currently estimated to use untreated biological soil amendments of animal origin (including raw manure) is to switch to commercial compost (again, these 820 farms are derived from NASS data). However, the data do not exist to estimate what percentage of the 820 farms would actually choose to switch to treated soil amendments from a third party. Furthermore, to account for the possibility that this may still be a new recordkeeping burden for farms using soil amendments acquired from a third party, it is estimated that this requirement will be a new recordkeeping burden for an additional 10% of remaining covered farms (40,211 – 820 =

39,372 and 39,372 x .10 = 3,937) Therefore, for the purposes of this analysis, it is estimated that one recordkeeper for each of a maximum of 4,757 (3,937 + 820) farms will spend .25 hour annually to meet this requirement, estimated to consist of the act of acquiring and maintaining documentation. Therefore, 4,757 recordkeepers x .25 hour = 1,189.25 annual hours. Section 112.60(b)(3) of this proposed rule requires covered farms to document, for a treated biological soil amendment of animal origin produced by the covered farm, documentation that process controls (for example, time, temperature, and turnings) were achieved. NASS data do not exist that would make it possible to estimate how many covered farms would choose to produce treated biological soil amendments for use on their own farms. However, using the USDA's 1999 Fruit and Vegetable Survey (Ref. 6), it is estimated that 10.5% of farms that claim to use manure also claim that the manure is composted on farm. Furthermore, using data from NASS, the Regulatory Impact Analysis estimates that a total of 4,438 covered produce farms use manure. For the purposes of this analysis, we assume, as an upper bound, that 466 covered farms (4,438 x .105 = 466) choose to produce treated biological soil amendments of animal origin for their own farms, and that one recordkeeper for each of the 466 farms will spend .5 hour annually on this requirement, estimated to consist of recording confirmation of process control achievement. Therefore, 466 recordkeepers x .5 hour = 233 annual hours. We ask for comment on these estimations.

Sections 112.60(b)(4) of this proposed rule requires that covered farms keep scientific data or information relied on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of § 112.54(c)(3). Covered farms are subject to this requirement only if they opt to use an alternative composting process; however, data do not exist to estimate the number of farms that would opt to do so. However, for the purposes of this analysis, it is estimated that 5% of farms estimated to choose to produce treated soil amendments for use on their own covered farms (4,757 estimated for § 112.60(b)(3) x .05 = 238 farms) would also choose to use an alternative composting process and would be subject to the requirement of § 112.60(b)(4). Therefore, one recordkeeper for each of 238 farms will spend two hours to search for information on alternative composting processes and this represents a one-time burden. Therefore 238 recordkeepers x 2 hours = 476 one time hours. We ask for comment on these estimations.

Section 112.60(b)(5) requires covered farms to keep scientific data or information relied on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b). Covered farms are subject to this requirement only if they choose to use an alternative application interval in accordance with § 112.56(b); however, the data do not exist to estimate the number of farms that would choose to do. However, for the purposes of this analysis, it is estimated that 10% of farms estimated to choose to continue to use raw manure (41 farms estimated for § 112.60(b)(1) x .1 = 4 farms) would also choose to use an alternative application interval and would thus be subject to the requirement of § 112.60(b)(5). Therefore, one recordkeeper for each of 4 farms will spend two hours to search for information to support minimum application intervals and this represents a one-time burden. Therefore 4 recordkeepers x 2 hours = 8 one time hours. We ask for comment on these estimations.

Section 112.140(b) requires the establishment and maintenance of records documenting the date and method of cleaning and sanitizing of certain equipment used in: (1) Growing operations for sprouts; and (2) Covered harvesting, packing, or holding activities. For both the recordkeeping burden of cleaning worker tools and cleaning machinery, we assume that all farms which are not currently performing these cleaning activities will be required to start keeping records. That is, 12,700 very small, 2,234 small, and 4,099 large farms will need to keep records on cleaning worker tools, and 10,403 very small, 1,830 small, and 3,358 large farms will need to keep records on cleaning machinery. Additionally, of the farms already performing these cleaning activities to the requirements of this proposed rule, we estimate that 50 (between 0-100) percent will have to start keeping records on this activity. In total, we estimate that 29, 766 farms (19,861 very small, 3,494 small, and 6,411 large farms) will need to begin keeping records on cleaning worker tools. Similarly, we estimate that 28,044 farms (18,712 very small, 3,292 small, and 6,040 large farms) will need to begin keeping records on cleaning machinery. We ask for comment on these estimates.

Hourly burdens for these requirements are estimated for two activities: cleaning worker tools and cleaning machinery[50]. It is estimated that one recordkeeper for each of 19,861 very small farms will have to spend an average of 8 hours annually on recordkeeping related to cleaning worker tools, estimated to consist of recording the date and method of cleaning and sanitizing equipment. Therefore, 19,861 recordkeepers x 8

[50] All record keeping times are from an ERG exert elicitation of recordkeeping costs for food manufacturers. We use these estimates as an approximation for the time it takes a farm to keep similar records. However, we make some adjustments downwards, as it is unlikely that farms will need to spend the same amount of time that industrial food processors do, especially on things like machinery. First, ERG estimates the costs for a small, medium, and large food processor; however, we do not believe that any farm will be performing cleaning activities or monitoring on the same scale as a large food processor, so we omit these results from our analysis. This leaves us with only two time estimates, small and medium. Because we have essentially estimated four size categories, not covered, very small, small, and large, we draw the line between these categories in the middle. Therefore, we estimate not covered (although they have no costs in these sections) and very small farms are roughly equivalent to a small food processor, and small and large farms are equivalent to a medium size food processor, in terms of hours needed to keep records.

average hours = 158,888 hours. It is estimated that 3,494 small farms and 6,411 large farms, for a total of 9,905 farms, will each spend 25 hours annually on recordkeeping related to cleaning worker tools, estimated to consist of recording the date and method of cleaning the worker tools. Therefore, 9,905 x 25 hours = 247,625 hours. It is estimated that one recordkeeper for each of 18,712 very small farms will spend an average of 8 hours annually on recordkeeping related to cleaning machinery, estimated to consist of recording the date and method of cleaning the machinery. Therefore, 18,712 recordkeepers x 8 hours = 149,696 annual hours on recordkeeping related to cleaning machinery. It is estimated that 3,292 small and 6,040 large, for a total of 9,332 farms, will each spend 25 hours annually on recordkeeping related to cleaning machinery. Therefore, 9,332 recordkeepers x 25 hours = 233,300 annual hours on recordkeeping related to cleaning machinery.

Sections 112.143 and 112.150 of this proposed rule outline certain requirements related to sprout farming. A detailed description of the method for estimating the number of covered sprout farms and covered sprout batches is provided in the RIA. To summarize, we estimate that there are 285 sprout farms (74 very small, 60 small, and 151 large) based on information obtained from the International Sprout Growers Association (Ref. 24) and from the distribution of firm sizes obtained from a 1998 field assignment (Ref. 75).

Sections 112.143(a) and 112.144(d) outline testing requirements for testing the sprout growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*, and § 112.150(b)(4) requires recordkeeping related to those tests . This burden is estimated to vary across farm size. It is estimated that the burden associated with testing is .15 hour to collect and prepare each sample. We expect that all firms will sample on a monthly basis; it is also expected that the number of samples will vary with the size of the farm. We expect very small farms to average five samples for each test; small farms to average ten samples per test; and large farms to average 15 samples. More samples are expected as the size of the farm increases because we estimate that the number and location of sampling sites, including appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces would increase as the facility size increases. It is estimated that one recordkeeper from each of the farms will be responsible for collecting samples. Therefore, to comply with the requirements of § 112.143(a) and § 112.144(d), 74 very small farms will incur a total of 666 hours of burden annually (74 farms x 5 samples x 12 annual tests x .15 hour per sample); 60 small farms will incur a total of 1,080 hours annually, (60 farms x 10 samples x 12 annual tests x .15 hour per sample); and 151 large farms will incur a total of 4,077 hours ((151 farms x 15 samples x 12 annual tests x .15 hour per sample).

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of §§ 112.143 and 112.144. To comply with this, records of testing for *Listeria* species or *L. monocytogenes* will be kept, and it is estimated that each such record will represent a burden of .17 hour, estimated as the time needed to record the results of the tests, but the number of records will vary across farm sizes. For 74 very small farms, it is estimated that a total of 4,440 records will be kept annually (or an average of 60 per firm) with respect to testing for *Listeria* species or *Listeria monocytogenes*. Therefore, 4,440 records x .17 hour per record = 755 total annual hours for small farms to comply with § 112.150(b)(4) with respect to testing for *Listeria* species or *L. monocytogenes*. For 60 small farms, it is estimated that a total of 7,200 records will be kept annually (or an average of 120 per firm). Therefore, 7,200 records x .17 hour per record = 1,224 total annual hours for small farms to comply with § 112.150(b)(4) with respect to testing for *Listeria* species or *L. monocytogenes*. For 151 large farms, it is estimated that a total of 27,180 records will be kept annually (or an average of 180 per farm). Therefore, 27,180 records x .17 hour per record = 4,620.6 total annual hours for large farms to comply with § 112.150(b)(4) with respect to testing for *Listeria* species or *L. monocytogenes*.

Sections § 112.143(b) and § 112.146 outline requirements related to testing spent sprout irrigation water from each production batch for *E. coli* O157: H7 and *Salmonella* species or testing of each production batch of sprouts at the in-process stage for *E. coli* O157: H7 and *Salmonella* species, and § 112.150(b)(4) requires recordkeeping related to those tests. This burden is estimated to vary across farm size. It is estimated that the burden associated with testing is an average of .5 hour per test. This time burden is estimated to include collecting and preparing the sample. We estimate the number of covered sprout batches from information obtained from minutes of the 1998 and 2005 FDA Public Meetings regarding different kinds of sprouting equipment that are typical in the sprouting industry, the total quantities of seed used in the industry, as well as from conversations with sprout industry experts (Ref. 72) on the different markets for sprouts. We obtain an estimate of the total number of sprout batches produced in the industry annually, and estimate that very small and small sprout farms produce 1 batch per week (50 batches per year), while large sprout farms would produce the remaining number of batches. As a result, we estimate that 74 very small sprout farms produce 3,710 batches, 60 small sprout farms produce 2,976 batches, and 151 large sprout farms produce 33,623 batches. Each farm will have one recordkeeper for each test. Small and very small farms will average 50 tests per farm; large farms will average 223 tests. .

It is estimated that a total of 3,710 batches of sprouts will be tested annually for *E coli* and *Salmonella* across 74 very small farms (one recordkeeper for each farm and an average of about 50 [50.13] tests per farm). Therefore, 3,710 tests x .5 hour per test = 1,855 annual hours for very small farms to comply with § 112.143(b) and § 112.146. It is estimated that a total of 2,976 batches of sprouts will be tested annually across 60 small farms (one recordkeeper for each farm and an average of about 50 [49.6] tests per farm). Therefore 2,976 tests x .5 hour per test = 1,488 annual hours for small farms to comply with § 112.143(b) and § 112.146. It is estimated that 33,623 batches of sprouts will be tested annually across 151 large farms (one recordkeeper per farm and an average of about 223[222.6] tests per farm). Therefore, 33,623 test x .5 hour per test = 16,811.5 annual hours for large farms to comply with § 112.143(b) and § 112.146.

Section 112.150(b)(4) requires records of all testing conducted in accordance with the requirements of §§ 112.143 and 112.144. To comply with this, records of testing for *E. coli* O157:H7 and *Salmonella* species will be kept, and it is estimated that each such record will represent a burden of .15 hour, estimated as the time needed to record the results of the tests, but the number of records will vary across farm sizes. For 74 very small farms testing for *E. coli* and *Salmonella*, it is estimated that 3,710 total records will be generated annually (or an average of 50.13 per firm). Therefore, 3,710 x .15 = 556.5 annual hours for very small farms to comply with § 112.150(b)(4). For 60 small farms it is estimated that 2,976 total records will be generated annually (or an average of about

49.6 per firm). Therefore, 2,976 records x .15 hour per record = 446 annual hours for small farms to comply with § 112.150(b)(4) with respect to testing for E. coli and Salmonella. For 151 large farms it is estimated that 33,623 total records will be generated annually (or an average of about 222.6 per firm). Therefore, 33,623 records x .15 hour per record = 5,043 annual hours for large farms to comply with § 112.150(b)(4) with respect to testing for E. coli and Salmonella.

Section 112.150 of this proposed rule outlines recordkeeping requirements related to sprout farming. Section 112.150(b)(1) requires documentation of treatment of seeds or beans. This burden is expected to vary across farms; however, this documentation burden is estimated to be .2 hour per activity, estimated to consist of the time needed to record the treatment of seeds or beans. It is estimated that one recordkeeper per very small farm will document this activity 50 times annually. Therefore, 74 very small farms x 50 records = 3,710 records and 3,710 records x .2 hours per record = 742 hours for very small farms to comply with § 112.150(b)(1). It is estimated that one recordkeeper per small farm will document this activity 50 times annually. Therefore, 60 small farms x 50 records = 3,000 records and 3,000 records x .2 hours per record = 600 hours for small farms to comply with § 112.150(b)(1). It is estimated that one recordkeeper per large farm will document this activity about 223 times annually. Therefore, 151 very small farms x 223 records = 33,623 records and 33,623 records x .2 hours per record = 6,735 hours for large farms to comply with § 112.150(b)(1).

Section 112.150(b)(2) requires sprout growers to establish and keep a written environmental monitoring plan in accordance with § 112.144. There is a one-time burden estimated for the establishment of this plan and an annual burden estimated for the maintenance of this plan. For 74 very small farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan and developing a template for the plan) record is a one-time burden of 7 hours. Therefore, 74 farms x 7 hours = 518 one-time hours to comply with § 112.150(b)(2). For 60 small farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan and developing a template for the plan) is a one-time burden of 12 hours. Therefore, 60 farms x 12 hours = 720 one-time hours to comply with § 112.150(b)(2). For 151 large farms, it is estimated that the establishment of this environmental monitoring plan (that is, determining the information needed to be included in the monitoring plan and developing a template for the plan) is a one-time burden of 17 hours. Therefore, 151 farms x 17 hours = 2,567 one-time hours to comply with § 112.150(b)(2). For annual burdens, it is estimated that each record will require one recordkeeper to work .15 hour to maintain the environmental monitoring plan (such as updating or making needed changes to the plan), across all farm sizes. For 74 very small farms, it is estimated that 60 total records will be generated annually (or an average of .81 per firm). Therefore, 60 records x .15 hour per record = 9 total annual hours for very small farms to comply with § 112.150(b)(2). For 60 small farms, it is estimated that 120 total records will be generated annually (or an average of 2 per firm). Therefore, 120 records x .15 hour per record = 18 total annual hours for small farms to comply with § 112.150(b)(2). For 151 large farms, it is estimated that 180 total records will be generated annually (or an average of 1.2). Therefore, 180 records x .15 hour per record = 27 total annual hours for very small farms to comply with § 112.150(b)(2).

Section 112.150(b)(3) requires the documentation of the written sampling plan for each production batch of sprouts in accordance with § 112.146(a). It is estimated that there is a one-time burden to establish this record (that is, determining the information needed to be included in the sampling plan and developing a template for the plan) and an annual burden to maintain this record(such as updating or making needed changes to the plan); For each of 285 sprout farms, it is estimated that the one-time burden to establish a written sampling plan is 8. Furthermore, it is estimated that there will be an annual burden of 1 hour per farm to update and make needed changes to the plans. Therefore, 8 hours x 285 sprout farms = 2,280 one-time burden hours and 285 sprout farms x 1 hour = 285 annual hours for sprout farms to comply with § 112.150(b)(3).

Proposed § 112.150(b)(5) requires sprout growers to have documentation of any analytical methods used in lieu of the methods that are incorporated by reference in § 112.152. It is not known how many sprout growers will use other analytical methods; however, it is estimated that one recordkeeper will work a total of 5 hours one-time to fulfill this requirement, estimated as the time needed to search for and collect the documentation of the alternative analytical methods.

Proposed § 112.150(b)(6) requires sprout growers to document the testing method used in accordance with the requirements of § 112.146(b). It is estimated that sprout growers will each spend 15 minutes on this requirement, estimated as the time needed to record the testing method used, annually. Therefore, 285 total sprout growers x .25 hour annually = 71.25 annual hours to meet the requirement of § 112.150(b)(6).

Under § 112.161(b), farms are required to establish and keep documentation of actions taken when a standard in Subparts C, E, F, L, and M are not met. In the

Regulatory Impact Analysis, costs of corrective actions with respect to employee training (Subpart C), soil amendments (Subpart F) and equipment and machinery (Subpart L) and are built into the cost of complying with those Subparts. It is not possible to know when or how often records of corrective actions taken with respect to these Subparts will occur. However, for the purposes of this PRA analysis, it is estimated that one recordkeeper from 10% of all covered farms (40,211) will each spend 30 minutes annually on recordkeeping related to any corrective actions taken with respect to employee training, soil amendments, and equipment and machinery, which is estimated to consist of recording the action taken to correct a standard that was not met. Therefore, 4,021 recordkeepers x .5 hour = 2,011 hours to comply with § 112.161(b) for Subparts C, F, and L. For Subpart E (Standards Directed to Agricultural Water) and Subpart M (Standards Directed to Sprouts), the burden associated with § 112.161(b) is covered by burdens estimated for corrective actions taken with respect to § 112.44 and § 112.50 (Subpart E) and § 112.143 and § 112.150 (Subpart M). Therefore, no additional burden is estimated here. We ask for comment on these estimates.

Section 112.161(c) requires that records required under §§ 112.50(b)(4), 112.50(b)(5), 112.60(b)(1), 112.60(b)(3), 112.140, 112.150(b)(1), 112.150(b)(4), and 112.161(b), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party. It is not possible to estimate how many covered farms do not have practices aligned with this requirement, therefore, it is estimated that one recordkeeper from each of 10% of all covered farms (40,211 x .1 = 4,021 farms) will spend an hour annually reviewing, dating, and signing records required under §§ 112.50(b)(4), 112.50(b)(5), 112.60(b)(1), 112.60(b)(3), 112.140, 112.150(b)(1), 112.150(b)(4), and 112.161(b). Therefore, 4,021 x 1 hour = 4,021 annual hours to comply with § 112.161(c). We ask for comment on these estimates

Section 112.171 of this proposed rule allows states and foreign countries to petition FDA for a variance from one or more requirements of the proposed rule. Section 112.172 requires the competent authority (e.g., the regulatory authority for food safety) for a State or a foreign country to submit a petition to seek a variance and section 112.173 describes what must be included in the Statement of Grounds in a petition requesting a variance.

Data on the number of hours needed to assemble the information required for a petition are not available. However, it is estimated that it will take one recordkeeper 80 hours to compile the relevant information and submit the petition to FDA. Furthermore, it is estimated that an additional recordkeeper (for example, a supervisor) will evaluate and review the petition before it is submitted. We estimate that it will take an additional 40 hours for the additional recordkeeper to review the submission Therefore, it is estimated that a state or foreign government would spend a total of 120 hours on a petition, and this would be a one-time burden. Data do not exist to estimate how many petitions FDA may get in a year; however, for the purposes of this analysis, it is estimated that FDA may receive six petitions from state or foreign governments. Therefore, 120 hours x 6 petitions = 720 hours to comply with the requirements of § 112.173. We request comment on these estimations.

Table 1 shows the estimated one-time and annual recordkeeping burdens associated with this proposed rule.

Table 1- Recordkeeping Hourly Burdens

One-Time Hourly Burden

21 CFR	No. Of Recordkeeper s	No. of Records	Total Record s	Average Hourly Burden	Total Hours	Operating Costs (related to testing burdens)
Agricultural Water—Documentation of Scientific Data						
112.50(b)(3)	2,397	1	2,397	0.5	1,199	
Recordkeeping Related to Soil Amendments						
112.60(b)(4)	238	1	238	2	476	
112.60(b)(5)	4	1	4	2	8	
Sprouts-Establishment of Environmental Monitoring Plan						
112.150(b)(2), Very Small Farms	74	1	74	7	518	
112.150(b)(2), Small farms	60	1	60	12	720	
112.150(b)(2), Large farms	151	1	151	17	2,567	
112.150(b)(5)	1	1	1	5	5	
Sprouts-Establishment of Sampling Plan						
112.150(b)(3), 112.146(a)	285	1	285	8	2,280	
Variances						
112.173	6	1	6	120	720	
Total One-Time Hourly Burden					8,493	N/A
Annual Hourly Burden						
21 CFR	**No. of Recordkeeper s**	**No of Records**	**Total Annual Record s**	**Avg. Hourly Burden**	**Total Hours**	**Operating Costs**
Training						
112.30 (b)	26,384	1	26,384	7.25	191,284	
Testing Requirements for Agricultural Water						
Testing for 0 Detectable Generic E. coli - Applicable Water Uses Other Than Hand Washing						
112.44(a)(1)	37	1	37	0.5	18.5	$3,230
112.44(a)(1)	37	4	148	0.5	74	$12,920
112.44(a)(2), (a)(3), (a)(4)	804	1	804	0.5	.5	$70,189
112.44(a)(2), (a)(3), (a)(4)	1,608	2	3,216	0.5	1,608	$280,757
112.44(a)(2),(a)(3), (a)(4)	804	3	2,412	0.5	1,206	$210,567
Testing for 0 Detectable Generic E. coli - Water Used For Hand Washing						

112.44(a)(5)	14,085	2	28,170	0.5	14,085	$2,459,241
Testing for 235 CFU/MPN Generic E. coli - Water Used For Direct Application Irrigation of Non-Sprout Covered Produce						
112.44(c)	289	1	289	1	144.5	$25,230
112.44(c)	3,573	26	92,898	0.5	46,449	$8,109,995
112.44(c)	3,573	6	21,438	0.5	10,719	$1,871,537
Analytical Testing as Part of Corrective Steps						
112.42(d)	264	1	264	.5	132	$23,047
Recordkeeping Related to Agricultural Water						
Findings of Water System Inspection						
112.50(b)(1)	26,431	6	158,586	0.8	126,869	
Records of Analytical Test Results as Part of Corrective Steps						
112.50(b)(2)	264	1	264	0.33	87	
Documentation of Monitoring Water Treatment						
112.50(b)(4)	4,757	1	4,757	0.98	4,662	
Records of Testing for 0 Detectable Generic E. coli - Applicable Water Uses Other Than Hand Washing						
112.50(b)(5)	804	1	804	0.33	265.3	
112.50(b)(5)	1,608	2	3,216	0.33	1,061	
112.50(b)(5)	804	3	2,412	0.33	796	
112.50(b)(5)	37	1	37	0.33	12.2	
112.50(b)(5)	37	4	148	0.33	49	
Records of Testing for 0 Detectable Generic E. coli - Water Used for Hand Washing						
112.50(b)(5)	14,085	2	28,170	0.33	9,296	
Records of Testing for 235 CFU/MPN Generic E. coli - Water Used For Direct Application Irrigation of Non-Sprout Covered Produce						
112.50(b)(5)	289	1	289	0.33	95	
112.50(b)(5)	3,573	26	92,898	0.33	30,656	
112.50(b)(5)	3,573	6	21,438	0.33	7,074.5	
Documentation to Support Alternative to Requirements of 112.44(c)						
112.50(b)(6)	1,787	1	1,787	1	1,787	

Documentation from Public Water Systems						
112.50(b)(7)	5,253	1	5,253	0.33	1,733	
Recordkeeping Related to Soil Amendments						
112.60(b)(1)	41	1	41	0.50	20.5	
112.60(b)(2)	4,757	1	4,757	.25	1,189.25	
112.60(b)(3)	466	1	466	0.5	233	
Recordkeeping Related to Cleaning and Sanitation						
112.140(b) Cleaning worker tools, very small farms	19,861	1	19,861	8	158,888	
112.140(b) Cleaning worker tools, small and large farms	9,905	1	9,905	25	247,625	
112.140(b) Cleaning machinery, very small farms	18,712	1	18,712	8	149,696	
112.140(b) Cleaning machinery, small and large farms	9,332	1	9,332	25	233,300	
Testing Requirements for Sprouts						
Testing for *E. coli* and *Salmonella*						
112.143(b), 112.146, very small farms	74	50.13	3,710	0.5	1,855	
112.143(b), 112.146, small farms	60	49.6	2,976	0.5	1,488	
112.143(b), 112.146, large farms	151	222.6	33,623	0.5	16,811.50	
Testing for *Listeria* species or *L. monocytogenes*						
112.143(a), 112.144(d), very small farms	74	60	4,440	0.15	666	
112.143(a), 112.144(d), small farms	60	120	7,200	0.15	1,080	
112.143(a), 112.144(d), large farms	151	180	27,180	0.15	4,077	
Recordkeeping Related to Sprouts						
Documentation of Treatment of Seeds or Beans						
112.150(b)(1), very small farms	74	50	3,710	0.2	742	
112.150(b)(1), small farms	60	50	3,000	0.2	600	
112.150(b)(1), large farms	151	223	33,673	0.2	6,735	
Environmental Monitoring Plan						
112.150(b)(2), very small farms	74	0.81	60	0.15	9	
112.150(b)(2), small	60	2	120	0.15	18	

farms						
112.150(b)(2), large farms	151	1.2	180	0.15	27	
Sampling Plan						
112.150(b)(3)	285	1	285	1	285	
Records of Testing for *E.coli* and *Salmonella*						
112.143(b), 112.146, very small farms	74	50.13	3,710	0.15	556.5	
112.143(b), 112.146, small farms	60	49.6	2,976	0.15	446	
112.143(b), 112.146, large farms	151	222.6	33,623	0.15	5,043	
Records of Testing for *Listeria* species or *L. monocytogenes*						
112.150(b)(4), very small farms	74	60	4,440	0.17	755	
112.150(b)(4), small farms	60	120	7,200	0.17	1,224	
112.150(b)(4), large farms	151	180	27,180	0.17	4,620.6	
Records of testing method used in *E. coli* and *Salmonella* testing						
112.150(b)(6)	285	1	285	0.25	71.25	
Recordkeeping Related to Corrective Actions						
112.161(b)	4,021	1	4,021	1	4,021	
Review of Records						
112.161(c)	4,021	1	4,021	1	4,021	
Annual Hourly Burden					1,228,959	
Operating Costs						$11,171,606

<u>Third Party Disclosure Burden</u>

Under § 112.6 certain qualified exempt farms (those that would otherwise be covered by the rule but that meet the criteria in § 112.5) must comply with certain food labeling or disclosure requirements. A total of 75,716 non-sprout farms are estimated to be eligible for the qualified exemption in § 112.5. After subtracting the number of farms that are not covered by the rule because have annual monetary value of food sold of $25,000 or less (62,194 farms), 13,522 non-sprout farms remain that must comply with § 112.6. Furthermore, 191 sprout farms would also be eligible for the § 112.5 exemption, for a total of 13,713 farms that would need to comply with § 112.6. There are 11,816 very small farms, 1,763 small farms, and 134 large farms that are required to comply with the food labeling/disclosure requirements of this proposed rule. It is estimated that 26 percent of very small, 16 percent of small, and 9 percent of large farms sell some of their covered produce direct to consumers (i.e. roadside stands, and farmers markets) (Ref 3). This is approximately 3,082 very small farms (.26 x 11,816), 275 small farms (.16 x 1,763), and 12 large farms (.09 x 134), for a total of 3,333 farms, that will display the name and complete business address of their farm at the point of purchase. It is not expected that these farms will provide their name and complete business address in documents accompanying the covered produce.

It is estimated that it will take the farm operator approximately 5 minutes to buy and prepare one poster board. It is also estimated that the operator will buy posters bi-weekly.[51] The total annual time required to buy and prepare a poster board is 24 hours [(60 minutes x 24)/60]. Therefore, 3,333 farms x 24 annual hours = 79,992 annual hours for these farms to comply with the requirement of § 112.6(b)(2).

It is estimated that farms with other marketing channels will provide their name and complete business address on an invoice or receipt that accompanies their product. We estimate that 95 percent of very small, 98 percent of small, and 99 percent of large farms will provide an invoice or receipt. Multiplying the percentages by the number of farms required to comply with § 112.6, we obtain 11,216 very small farms (.95 x 11,816), 1,727 small farms (.98 x 1,763), and 133 large farms (.99 x 134), for a total of 13,542 farms. It is estimated that these farms already provide an invoice that

[51] Farms may choose other ways to comply. For example, a farm may choose to use a sturdier, more permanent sign, even though the initial cost may be more than for poster board. We request comment on what farms will actually do in response to this requirement.

accompanies their product, but that it does not include the full information required by the proposed rule. It is estimated that it will take a farm operator 5 minutes (.08 hour) to change this template for new invoices, and that this is a one-time burden. Therefore, 13,542 x .08 hour = about 1,083 hours to comply with § 112.6 (b)(2). We ask for comment on these estimations.

Under § 112.31(b)(2), covered farms are required to instruct personnel to notify their supervisor(s) if they are have, or if there is a reasonable possibility that they have an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea). The number of farms that will need to implement this disclosure is based on the estimated number of farms that are not currently implementing the requirements imposed by the proposed rule in the Regulatory Impact Analysis. In the RIA, it is estimated that 22 percent of farms need to exclude ill workers since 78 percent of farms are already estimated to either exclude workers from the entire operation or from handling produce directly. We also consider the 1,117 farms that are currently implementing a food safety program that covers this provision. We subtract the 1,117 farms in food safety programs by size to obtain 39,379 total farms where 26,366 are very small (27,021-655), 4,649 are small (4,753-104), and 8,364 are large (8,722-358). The estimated percentage of farms not in compliance, 22 percent, is then applied to each farm size category, as the data needed to refine this estimate is not available. We then apply the percentage of farms not complying, 22 percent, to all farms across size categories to obtain a total of 8,663 farms, where 5,801 very small farms (.22 x 26,366), 1,023 small farms (.22 x 4,649), and 1,840 large farms (.22 x 8,364), that will need to comply with the third party disclosure requirement of § 112.31(b)(2). Therefore it is estimated that one worker from each of 8,663 farms will spend 5 minutes annually to comply with § 112.31(b)(2), which will consist of the employer giving verbal instructions to employees. Therefore, 8,663 x 5 minutes = 722 hours to comply with § 112.31(b)(2). We ask for comment on these estimations.

Under § 112.33(b), covered farms must make visitors aware of policies and procedures to protect covered produce and food-contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures. It is estimated that farms with voluntary food safety programs in place will already have practices aligned with this provision; therefore no burden is estimated for those farms. After subtracting these farms, it is estimated that § 112.33(b) represents a third-party disclosure requirement for 26,366 very small farms, 4,649 small farms, and 8,364 large farms, for a total of 39,379 farms.

We estimate that it will take 8 hours annually for the operator to inform visitors of the farm policies, including showing them where the restrooms are, and to take reasonable steps to ensure their compliance, such as monitoring visitors to ensure they are following the policies and procedures. Therefore, 39,379 farms x 8 hours per farm = 315,032 annual hours to comply with § 112.33(b). We ask for comment on these estimations.

Table 2- Estimated Third Party Disclosure Burden[1]					
One Time Third Party Disclosure Burden					
20 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Hours

112.6(b)(2) Documentation	13,542	1	13,542	.08	1,083
Total One-Time Burden					1,083
Annual Third Party Disclosure Burden					
20 CFR Section (Or FDA Form #)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
112.6(b)(2) Posting signage	3,333	24	79,992	1	79,992
112.31(b)(2)	8,663	1	8,663	.08 (5 minutes)	722
112.33(b)	39.379	1	39,379	8	315,032
Total annual burden hours					395,746

APPENDIX A

1. Total FDA-Regulated Risk of Foodborne Illness

To estimate the burden of illness associated with each individual FSMA regulation, we first determine the total burden of foodborne illness that can be attributed to all FDA regulated commodities. The text laid out here, makes no estimation of the efficacy of the individual rules; rather, we simply explain the methodology employed and data sources utilized, to estimate the full human health burden attributable to FDA regulated foods.

Estimation of the total burden of foodborne illness associated with FDA regulated commodities is a multistep process: starting with a subset of outbreaks we can identify as attributable to FDA regulated commodities; extrapolating these outbreak illnesses up to a total number of annual foodborne illnesses; applying a pathogen specific cost to each of these illnesses, to get the annual burden that these foodborne illnesses represent; and, finally, summing over all pathogens to get the total annual burden of foodborne illness attributable to FDA regulated commodities.

From the total we estimate in this appendix, we can further partition the data by food commodity attributable to each proposed regulation to determine what percentage of the estimated human health burden is attributable to food covered by the regulation.

Below, we explain in detail our full methodology, with its associated data sources, assumption, and caveats.

a. Measuring total foodborne illness from available outbreak data

To estimate the total number of illnesses attributable to FDA-regulated foods, we utilize a combination of CDC's OutbreakNet: Foodborne Outbreak Online Database and FDA's own epidemiological assessment of those outbreaks (Ref.36). Table 137 presents all outbreaks, organized by agent, which can be linked to FDA-regulated foods based on illnesses recorded in FDA's outbreak database. We have only included those illnesses (and the causative agents) that were the result of contamination of the food during production; we did not include any outbreaks where the contamination of the food was attributable to retail or home mishandling of food.[52]

In total, there are 10,440 illnesses from 157 separate outbreaks that are linked to FDA-regulated foods for the years 2003-2008; this data represents only reported and laboratory confirmed illnesses from outbreaks, therefore this data represents only a small portion of the actual illnesses associated with FDA foods.

Table 137. Complete FDA-Regulated Food Outbreaks from Known Pathogens 2003-2008

Agent	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
C. Botulinum	3	13	12	1
Campylobacter jejuni	1	268	7	0

[52] This omission excludes a vast majority of the outbreak illnesses, because most (approximately 60 percent) are linked to retail or home mishandling.

Ciguatera	8	80	1	0
Cryptosporidium	1	144	3	0
Cyclospora	6	891	3	0
E. coli non-0157 STEC	1	212	14	0
E. Coli O157:H7	17	789	244	6
E. coli, Enterotoxigenic and other diarrheogenic	2	15	1	0
Hepatitis A	2	958	131	3
Listeria monocytogenes	9	54	31	1
Mycobacterium bovis	1	35	0	0
Norovirus	5	119	1	0
Other chemical	2	203	69	0
Other fungal	2	31	0	0
Other parasitic	1	18	2	0
Plant toxin	1	8	0	0
Salmonella	56	6113	885	15
Scombroid	26	154	4	0
Seafood poison	3	5	0	0
Shigella sonnei	1	56	3	0
Vibrio cholerae	2	5	0	0
Vibrio parahaemolyticus	7	269	2	0
TOTAL	**157**	**10,440**	**1,413**	**26**

While Table 138 accounts for FDA-confirmed illnesses, it is important to note that many foodborne illnesses go unconfirmed for a variety of reasons. To determine the total cost of foodborne illness, it is important to attempt to account for these unconfirmed illnesses. To estimate the total burden of foodborne illness, we need to account for numerous factors including: the underreporting of foodborne illnesses, foodborne illnesses not diagnosed as such, and foodborne illnesses for which the causative agent was not identified.

Table 138 presents our estimate of the total number of illnesses attributable to FDA-regulated foods. In order to account for unconfirmed illnesses we adjust the number of illnesses in the FDA outbreak data, based on estimates in Scallan et al. (Ref.37;Ref.90). In Scallan et al. cases of undiagnosed foodborne illnesses caused by 31 known pathogens are estimated using multipliers. Scallan et al. also provides an estimate of the number of foodborne illnesses caused by unidentified pathogens—those not caused by any of the 31 pathogens identified in their 2011 paper.[53] Scallan, et al. estimates that about 80 percent of all foodborne illnesses are in fact attributable to as yet "unidentified" pathogens.

Column one shows agent. Column two shows the total number of illnesses attributable to each individual pathogen, using raw FDA outbreak data. Column three presents the total illnesses attributable to each individual pathogen in the CDC outbreak data.

We exclude all CDC outbreak illnesses that do not have an identified food vehicle. When no food vehicle is identified as a source of contamination, we cannot definitively say anything about the food product that caused the contamination; the resulting illnesses could be due to FDA-regulated food or any other type of food product. By this omission, we make no assumption on the unobserved data and are able to calculate a percentage of baseline illnesses attributable to FDA-regulated foods which may represent the true number of illnesses attributable. This method is appropriate because: First, there are numerous outbreaks with no associated vehicle, and it is highly likely that at least some of these outbreaks are due to some kind of FDA-regulated product. Second, including these outbreaks in the denominator of our percentage attributable but explicitly excluding them from the numerator would artificially force the calculated percentage down. By excluding these outbreaks altogether, we estimate the percentage based solely on the fully observed data, and then estimate that the unobserved food vehicles are distributed accordingly.

CDC data differs from FDA data in a few key ways. First, the CDC illnesses can

[53] "Unidentified" should not be confused with "undiagnosed." Any illnesses attributed to unidentified pathogens do not include undiagnosed cases of Salmonella spp. or E. coli, for example.

be attributed to any food vehicle; meaning that these illnesses could be from FDA-regulated food or USDA-regulated foods, such as meat. Second, these illnesses could be due to retail or home mishandling and contamination of food. In other words, the FDA illnesses are a subset of the CDC (total) illnesses. From these two columns, we compute a percentage of illnesses caused by a specific pathogen that are attributable to only FDA-regulated food (FDA Outbreak Cases / Total Outbreak Cases = Percentage Attributable to FDA Food). This percentage of total illnesses attributable to FDA regulated foods can be found in the fourth column.

We use a different methodology to estimate the percentage of illnesses due to unidentified pathogens. In this case, there is no data linking these illnesses to a specific food source or pathogen. This is because these illnesses are due to other, emerging agents not included in the 31 well known and regularly tested for agents. Because we have no data on these illnesses, but overall estimates suggest that they may be a large portion of the health burden from reducing foodborne illness, we assume that the proportion of foodborne illnesses attributable to FDA-regulated food is the same for 'unidentified' illnesses as for identified illnesses. We estimate the unidentified percentage attributable as the total number of identified FDA related illnesses divided by the total number of identified illnesses that appear in the outbreak data. As shown in table 138, we estimate that all FDA-regulated foods account for 13.16% of all identified illnesses. Lacking further information, we apply this percentage to Scallan, et al.'s total estimated number of 'unidentified' illness to determine the total number of illnesses attributable to FDA-regulated products. We recognize that this assumption is based on limited information, and request comment on it.

Next, we multiply the estimated shares of illness attributable to FDA-regulated foods by the total, annual estimated number of foodborne illnesses attributable to each pathogen estimated by Scallan et al. (Ref.37;Ref.90). Scallan reaches this estimate by using both active and passive illness surveillance data to estimate the annual occurrence of each of the 31 major foodborne pathogens. Laboratory and hospital confirmed and documented cases of each illness are compared with survey data of the national incidence of each pathogen. From this information, they are able to extrapolate the cases confirmed to a national total that accounts for under reporting and under diagnosis for all illnesses. In total, Scallan et al. estimate that 9.4 million episodes of foodborne illness occur in the US each year due to these 31 pathogens.

However, this does not account for all foodborne illness in the US. Scallan further estimates that as many as 80% of foodborne illnesses are due to unidentified pathogens. This is estimated by examining nationally representative survey data on foodborne illnesses in the US. From this survey, the occurrence total foodborne illnesses episodes are estimated to be about 47.78 million, annually. Having previously estimated that 9.4 million of these are due to the 31 major pathogens, the authors are able to conclude that approximately 38.39 million foodborne illnesses each year are due to ‘unidentified’ pathogens. That is, pathogens that have not yet been fully identified by scientists, and are still very difficult to observe, test for, or link to any specific food or outbreak.

To capture not only the illnesses associated with foodborne outbreaks, but also those sporadic cases of foodborne illness, we apply the previously calculated percentage to the estimated number of annual foodborne illnesses in the U.S. as estimated in Scallan et al. (Ref.37). These estimates of foodborne illness take into account that foodborne illnesses are likely to be underreported or not diagnosed as foodborne illnesses (Ref.37). By applying the percentage of outbreak-related illnesses attributable to FDA-regulated food products in column four to the estimated annual number of total foodborne illnesses in column five we are able to ascertain the total annual burden of baseline illnesses that are associated with FDA-regulated food due to both outbreak and sporadic illnesses. In total, we estimate that 5,741,212 foodborne illnesses occur every year due to FDA-regulated foods.

We also explored an alternative methodology for estimating the number of illnesses caused by unknown pathogens attributable to FDA-regulated produce. This methodology makes use of Scallan, et al.'s estimate that illnesses due to unknown pathogens are equal to 80% of illnesses and applies this to our estimated number of illnesses due to known pathogens. Summing the number of identified illnesses in Column 6 of Table 138, we get a total of 689,731 illnesses due to known pathogens that are attributable to FDA-regulated food. If Scallan, et al. are correct and this is 20% of the total illnesses (100% minus 80%), then illnesses due to unknown pathogens would be equal to 2,758,924 (8/2 times 689,731). This is considerably smaller than the estimate obtained using our assumption that the proportion of attributable illnesses is equal across identified and unidentified pathogens—5,051,481. We seek comments on these alternative estimates and which is more likely to be correct.

Table 138- Estimated Number of Illnesses Attributable to FDA-Regulated Foods					
Agent	**FDA Cases (2003-2008)**	**CDC Identified Cases (2003-2008)**	**Percentage Attributable to FDA Products**	**Estimated Annual Foodborne Illnesses**	**Estimated Illnesses Attributable to FDA Products**
C. Botulinum	13	56	23.20%	55	13
Campylobacter jejuni	268	3,448	7.80%	845,024	65,681
Ciguatera	80	353	22.70%	2,100	476
Cryptosporidium	144	149	96.60%	57,616	55,683
Cyclospora	891	919	97.00%	11,407	11,059
E. coli non-0157 STEC	212	481	44.10%	112,752	49,695
E. Coli O157:H7	789	2,452	32.20%	63,153	20,321
E. coli, Enterotoxigenic and other diarrheogenic	15	481	3.10%	11,982	374
Hepatitis A	958	1,086	88.20%	1,566	1,381
Listeria monocytogenes	54	72	75.00%	1,591	1,193
Mycobacterium bovis	35	35	100.00%	60	60
Norovirus	119	24,570	0.50%	5,461,731	26,453
Other chemical	203	506	40.10%	159	64
Other fungal	31	93	33.30%	19	6
Other parasitic	18	18	100.00%	4	4
Plant toxin	8	21	38.10%	4	2
Salmonella	6,113	14,709	41.60%	1,027,561	427,050
Scombroid	154	581	26.50%	20,000	5,301
Seafood poison	5	60	8.30%	360	30
Shigella sonnei	56	667	8.40%	131,254	11,020
Vibrio cholerae	5	14	35.70%	84	30
Vibrio parahaemolyticus	269	674	39.90%	34,664	13,835
Total Identified	10,440	79,347*	13.16%		
Unidentified**			13.16%	38,392,704	5,051,481
TOTAL	**20,880**	**130,792**	**15.96%**		**5,741,212**

*This total includes 27,902 illnesses due to known pathogens other than those included in the table. There were no illnesses in FDA-regulated foods caused by these pathogens.
** The percentage attributable to unidentified illnesses is calculated as the total number of observed FDA attributable illnesses divided by the total number of observed illnesses from all 31 identified pathogens. This methodology assumes that the percentage of observed illnesses attributable to FDA products is equal to the percentage of unidentified pathogen illnesses attributable to FDA products.

b. Measuring the burden of illness associated with foodborne contaminants

In measuring the economic impact of illness due to the consumption of FDA-regulated foods, it is important that we include all of the effects of the foodborne illness on human health. The preferred estimates should therefore be based on the willingness to pay to reduce the risk of foodborne illness, based on either revealed preference (i.e., market evidence) or stated preference (i.e., survey evidence) studies. Because few such studies exist, as an alternative to direct estimates, we use indirect estimates of willingness to pay based on values of risk reduction estimated for other hazards.[54] The method involves combining estimated values of statistical lives and life years with the estimated losses of life-years and quality-adjusted life years associated with foodborne illnesses. In the following sections, we explain the steps used to calculate the effects.

i. <u>The consequences of foodborne illness</u>

The acute illness that results from the ingestion of pathogens in food generally causes gastrointestinal symptoms ranging from mild to severe and may include stomach cramping, vomiting, diarrhea, fever, aches, and chills. The exact symptoms of each illness depend on the type of foodborne pathogen involved. The severity of a foodborne illness is often dictated by the overall health of the individual; the elderly, immuno-compromised, and young children often experience more severe symptoms from foodborne illness than those that would be experienced by an otherwise healthy adult. Death as an outcome of a foodborne illness is relatively rare and also depends on foodborne illness type and the overall health of the affected individual. However, there are several types of foodborne illnesses that do carry a significant risk of death, e.g. a case of listeriosis during pregnancy could result in the death of the fetus.

Table 139 includes the medical outcomes of foodborne illness, the duration of

[54] The general method of plugging in values from other studies is known as benefit transfer.

conditions acquired due to illness, and the probability of occurrence for each condition with a given level of severity (non-hospitalized or hospitalized). We only include cost estimates in this section for foodborne illnesses that were identified as having caused outbreaks related to FDA-regulated foods that occurred during the years 2003-2008.

The percentage of cases by severity for each illness is based on Scallan et al for most illnesses except for marine toxin poisonings. The case severity breakdown for marine toxin poisonings comes from CDC data. The duration of illness for each illness type was determined by reviewing peer-reviewed published medical journal articles on outbreaks associated with a particular pathogen (e.g. an outbreak where Campylobacter was the identified agent) and general articles on symptoms associated with a particular foodborne illness (e.g. patient observation studies; epidemiological and clinical features of an illness articles). Reviewing the journal articles on the different types of foodborne illness gave us information on the typical symptoms associated with each illness and the usual duration for each illness depending on the illness severity.

Table 139 - Foodborne Illness: Acute Illness by Cause, Duration and Severity		
Gastrointestinal Illness	Duration (days per year)	Percent of Cases
Campylobacter spp.		
nonhospitalized	2 to 10	99.00%
hospitalized	5 to 10	1.00%
Death		0.01%
Clostridium botulinum		
nonhospitalized	14 to 90	23.64%
hospitalized	14 to 210	76.36%
Death		16.36%
E. coli O157:H7		
nonhospitalized	5 to 10	96.61%
hospitalized	5 to 15	3.39%
Death		0.03%
E. coli non-0157 STEC		
nonhospitalized	5 to 10	99.76%
hospitalized	5 to 15	0.24%
Listeria monocytogenes		
nonhospitalized	3 to 7	8.55%
hospitalized	14 to 42	91.45%
Death		16.03%
Tuberculosis caused by *M. bovis*		
nonhospitalized	270	48.33%
hospitalized	270	51.67%
Death		5.00%
Salmonella spp., Nontyphoidal		
nonhospitalized	4 to 7	98.12%
hospitalized	7 to 14	1.88%
Death		0.04%
Shigella, spp.		
nonhospitalized	4 to 10	98.89%
hospitalized	5 to 14	1.11%
Death		0.01%
Vibrio cholerae, Toxigenic		
nonhospitalized	3 to 6	97.62%
hospitalized	7 to 14	2.38%
Vibrio vulnificus		
nonhospitalized	2 to 8	3.13%
hospitalized	30 to 60	96.88%
Death		37.50%
Vibrio parahaemolyticus		
nonhospitalized	2 to 7	99.71%
hospitalized	15 to 30	0.29%
Death		0.01%

Cryptosporidium parvum		
nonhospitalized	1 to 14	99.64%
hospitalized	7 to 60	0.36%
Death		0.01%
Cyclospora cayetanensis		
nonhospitalized	5 to 30	99.90%
hospitalized	5 to 60	0.10%
Norovirus		
nonhospitalized	1 to 2	99.73%
hospitalized	1 to 7	0.27%
Hepatitis A		
nonhospitalized	7 to 21	93.68%
hospitalized	1 to 100	6.32%
Death		0.45%
Ciguatera toxin poisoning		
nonhospitalized	3 to 10	87.36%
hospitalized	10 to 28	12.64%
Death		0.14%
Scombroid toxin poisoning		
nonhospitalized	1 to 2	96.10%
hospitalized	2 to 3	3.90%
Food Allergic Reaction		
nonhospitalized	1	90.55%
hospitalized	1 to 2	9.46%
Death		0.01%
Foodborne illness, Unknown agent		
nonhospitalized	1 to 2	99.81%
hospitalized	2 to 3	0.19%

We divide our estimates of illness burden into illnesses that are not severe in nature (non-hospitalized illnesses) and those that are severe enough to require hospitalization. We choose this illness severity breakdown for its practicality and usefulness in illustrating where the costs of foodborne illness differentiate. For a mild to moderately severe foodborne illness, the duration of the illness is likely to be similar, and depending on individual's tolerance for discomfort, these persons will likely either treat the symptoms themselves or perhaps visit a family doctor. Hospitalization as a result of a foodborne illness is rarer and more expensive to treat; the duration of the illness may also be longer than the milder version.

Most acute symptoms of foodborne illness last from a few hours (for some toxins) to a few days to several weeks. However some foodborne illnesses carry a risk of secondary or long-term complications that must be accounted for. For example, a case of foodborne illness caused by *Salmonella* spp. in the short term can cause gastroenteritis; in the long term, the residual effects of the illness may include reactive arthritis. In table 140 we outline the list of secondary complications from foodborne illnesses by pathogen type that we account for in this analysis. As with the acute foodborne illnesses, for secondary complications we used information from a review of the medical literature to determine the typical duration of the complication.

Table 140 - Foodborne Illness Secondary Complications by Cause, Duration and Severity		
Gastrointestinal Illness Secondary Complications	Duration	Percent of Cases
Campylobacter spp.		
Guillain-Barre Syndrome (GBS)	30 to 180 days	0.08%
GBS long-term disability	rest of life	0.02%
reactive arthritis	30 to 365 days	1% to 4%
GBS related death		0.00002% to 0.00003%
E. coli O157:H7 and non-O157 STEC		
mild/moderate renal disease	rest of life	0.00089% to 0.00019%
End Stage Renal Disease	1 to 5 years	0.00002% to 0.00008%
Hypertension	rest of life	0.00021% to 0.00210%
Death from ESRD		0.00016% to 0.00144%
Salmonella, Nontyphoidal		
reactive arthritis	30 to 365 (1 year only)	1% to 4%
Shigella, spp		
reactive arthritis	30 to 365 (1 year only)	1% to 4%
Ciguatera toxin poisoning		
post acute illness symptoms	90 to 180	65%

ii. Quality adjusted life years (QALYs)

One approach to estimating health benefits involves the use of QALYs. QALYs can be used to measure the loss of well-being that an individual suffers due to a disease or condition. QALYs do not include the value of health expenditures caused by the condition in question; we estimate health expenditures separately. QALYs range from 0 to 1, where 0 is equivalent to death and 1 is equivalent to perfect health for one year. Because most foodborne illness last for days or weeks rather than years, the value between 0 and 1 of a QALY (the individual's health state) is more useful if expressed as a daily health state, or quality adjusted life day (QALD). We use a starting QALD value of 0.87 to represent the average health score based on the U.S. population (Ref.92). We seek comment on the use of this measure to assess the health benefits of the proposed rule.

A number of methods have been constructed to measure QALYs (and QALDs). For this analysis, for both acute and secondary complications from foodborne illnesses, we use the EQ-5D health index adjusted for U.S. health status preference weights (Ref.93) to calculate QALD value lost. The EQ-5D index allows us to estimate an individual's disutility from being ill due to a food-related illness in terms of the number of QALDs lost due to that illness. As shown in table 141, the EQ-5D scale consists of five domains, with 3 levels for each domain, that assess an individual's mobility, ability to perform self-care activities, ability to perform usual activities (such as going to work or school), level of pain and discomfort, and level of anxiety and depression as a result of their medical condition.

Estimates of QALD loss for any illness are subjective as different individuals experience illness and its related symptoms on an individual level. Attempts have been made to create nationally accepted estimates of QALY loss for some chronic medical conditions, such as cancer, but there are no nationally recognized estimates for QALD losses due to foodborne illnesses. Since there are no national estimates of QALD Loss for foodborne illnesses by causal agent, we have created a daily QALD loss per illness type based on the profile of each illness.

We use the information on symptoms of foodborne illnesses from our review of the literature to guide us in estimating the quality of life lost from that particular illness type. For example, the medical literature on outbreaks caused by Salmonella and clinical features of Salmonellosis allow us to make a determination on whether the typical person suffering from a case of Salmonellosis can perform self-care activities or work activities while they are ill (e.g. is their ability while ill at the 1, 2, or 3 level for each EQ-5D domain). Once we have made the determination about the level of ability of the person while ill, we can use the numbering generated by the EQ-5D index (e.g. 12221) to look up the associated value loss as adjusted for U.S. health status preference weights (e.g. 12221 is associated with a quality of life value of 0.748).[55]

We use a non-hospitalized case of shigellosis to give an example of how we calculate QALD loss using the five domains of EQ-5D scale and the associated values for the EQ-5D scaled to the U.S population. The CDC website indicates that shigellosis results in diarrhea, fever, and stomach cramps starting a day or two after an individual has been exposed to the bacteria; the diarrhea is often bloody. The illness usually resolves in 5 to 7 days; persons with shigellosis in the United States rarely require hospitalization.

[55]The values for each EQ-5D score are given in Shaw et al. (Ref.93).

Given this information, we determined that a person with a non-hospitalized case of shigellosis would: have some problems walking about, have some problems washing and dressing themselves, have some problems performing their usual activities, have moderate pains or discomfort, and would not be anxious or depressed. This health determination results in an EQ-5D index score of 22221 which equals a quality of life value of 0.689. This means that instead of having a quality of life value of the normal population average of 0.87, the person who is suffering from a non-hospitalized case of shigellosis now only has a quality of life score of 0.689. So, there is a quality of life health loss of 0.181 for every day that the person is ill with a case of non-hospitalized shigellosis.

Table 141 - EQ5D Health Status Classification System

Domain	Attribute Level	Description
Mobility	1	I have no problems walking about
	2	I have some problems walking about
	3	I am confined to bed
Self-Care	1	I have no problems with self-care
	2	I have some problems washing or dressing myself
	3	I am unable to wash or dress myself
Usual Activities	1	I have no problems with performing my usual activities
	2	I have some problems with performing my usual activities
	3	I am unable to perform my usual activities
Pain/Discomfort	1	I have no pain or discomfort
	2	I have moderate pain or discomfort
	3	I have extreme pain or discomfort
Anxiety/Depression	1	I am not anxious or depressed
	2	I am moderately anxious or depressed
	3	I am extremely anxious or depressed

Table 142 lists daily QALD loss we have estimated for each illness type and severity. Table 142 then shows the range QALD values for non-hospitalized and hospitalized cases of foodborne illnesses based on expected illness duration as researched from the medical literature on foodborne illnesses. We present the possible QALD loss for both acute and secondary complications of illness. In instances where the residual effects of a foodborne illness last longer than one year; the health loss is discounted at the 3 percent discount rate.[56]

Table 142 - Estimated EQ-5D Determination, QALD and QALY loss for Food-related Illnesses by Pathogen Type				
Gastrointestinal Illness	EQ-5D determination	QALD Loss per day	Duration (days per year)	Total Burden per Illness
Campylobacter spp.				
nonhospitalized	22221	0.181	2 to 10	0.362 to 1.81
hospitalized	22332	0.607	5 to 10	3.035 to 6.07
Clostridium botulinum				
nonhospitalized	22221	0.181	14 to 90	0.724 to 16.29
hospitalized rate part 1	33322	0.752	14 to 30	10.528 to 22.56
hospitalized rate part 2	22221	0.181	31 to 180	5.611 to 32.58
E. coli O157:H7 and non-0157 STEC				
nonhospitalized	22221	0.181	5 to 10	0.905 to 1.81
hospitalized	22332	0.607	5 to 15	3.035 to 9.105
E. coli, Enterotoxigenic and other diarrheogenic				
nonhospitalized	22221	0.181	1 to 5	0.181 to 0.905
hospitalized	22332	0.607	5 to 15	3.035 to 9.105
Listeria monocytogenes				
nonhospitalized	21221	0.092	3 to 7	0.276 to 0.644
hospitalized	33332	0.91	14 to 42	12.74 to 38.22
Tuberculosis due to *M. bovis*				
nonhospitalized	11211	0.01	270	2.70
hospitalized rate part 1	22222	0.273	14	3.822
hospitalized rate part 2	11211	0.01	255	2.55
Salmonella, Nontyphoidal				
nonhospitalized	22221	0.181	4 to 7	0.724 to 1.267
hospitalized	22332	0.607	7 to 14	4.249 to 8.498
Shigella, spp				
nonhospitalized	22221	0.181	4 to 10	0.724 to 1.81
hospitalized	22332	0.607	5 to 14	3.035 to 8.498

[56]Only Campylobacter, E. coli O157:H7 and E. coli non-O157 STEC have chronic complications that need to be discounted. We examined how the costs of secondary complications associated with these illnesses change using the 7 percent discount rate as well. Cost changes due to changes in the discount rate are small because the percentage of illnesses that result in secondary complications are small. Thus, varying the discount rate from 3 percent to 7 percent does not change the overall average cost of an illness in a significant way.

Vibrio cholerae, Toxigenic				
nonhospitalized	22221	0.181	3 to 6	0.543 to 1.086
hospitalized	22332	0.607	7 to 14	4.249 to 8.498
Vibrio vulnificus				
nonhospitalized	22221	0.181	2 to 8	0.362 to 1.448
hospitalized	22332	0.607	30 to 60	18.21 to 36.42
Vibrio parahaemolyticus				
nonhospitalized	22221	0.181	2 to 7	0.362 to 1.267
hospitalized	22332	0.607	15 to 30	9.105 to 18.21
Cryptosporidium parvum				
nonhospitalized	22221	0.181	1 to 14	0.181 to 2.534
hospitalized	22332	0.607	7 to 60	4.249 to 36.42
Cyclospora cayetanensis				
nonhospitalized	22221	0.181	5 to 30	0.905 to 5.43
hospitalized	22332	0.607	5 to 30	3.035 to 18.21
Norovirus				
nonhospitalized	22221	0.181	1 to 2	0.181 to 0.362
hospitalized	22332	0.607	1 to 7	0.607 to 4.249
Hepatitis A				
nonhospitalized	22221	0.181	7 to 21	1.267 to 3.801
hospitalized rate part 1	22332	0.607	1 to 10	0.607 to 6.07
hospitalized rate part 2	22221	0.181	11 to 90	1.991 to 16.29
Ciguatera toxin poisoning				
nonhospitalized	12222	0.192	3 to 10	0.576 to 1.92
hospitalized	22322	0.433	10 to 28	4.33 to 12.124
Scombroid toxin poisoning				
nonhospitalized	11221	0.054	1 to 2	0.054 to 0.108
hospitalized	22322	0.433	2 to 3	0.866 to 1.299
Food Allergic Reaction				
nonhospitalized	12221	0.122	1	0.122
hospitalized	32322	0.654	1 to 2	0.654 to 1.308
Foodborne illness, Unknown agent				
nonhospitalized	22221	0.181	1 to 2	0.181 to 0.362
hospitalized	22332	0.607	2 to 3	1.214 to1.821
QALD and QALY loss for Secondary Complications from Food-Related Illness				
Campylobacter spp.				
Guillain-Barre Syndrome (GBS)	33322	0.752	30 to 180 days	26.46 to 158.76
GBS long-term disability	22222	0.273	rest of life	1987.00
reactive arthritis	21221	0.092	30 to 365 days	6.66 to 81.03
E. coli O157:H7 and non-0157 STEC				
mild/moderate renal disease	21222	0.162	rest of life	1401.46
End Stage Renal Disease	21222	0.162	1 to 5 years	59.13 to 295.65
Salmonella, Nontyphoidal				

reactive arthritis	21221	0.092	30 to 365 days	2.76 to 33.58
Shigella, spp				
reactive arthritis	21221	0.092	30 to 365 days	2.76 to 33.58
Ciguatera toxin poisoning				
post acute illness symptoms	11222	0.10	90 to 180 days	9.0 to 18.0

iii. Valuation of foodborne illnesses

Table 143 illustrates how we calculate the total dollar value burden of a case of food-related illness. The first column lists the type and severity of ailment. The second and third columns are taken from tables 140, 141, and 142 of this document; for table 143 we present the mean estimates when there is a range of possible values. The health loss per case, shown in the fourth column, is calculated by multiplying the value of a QALD by the actual number of QALDs lost, and then discounting where appropriate. The values in this column will vary depending upon the particular estimates used for the value of a statistical life (VSL), the value of a QALD, and the discount rate. The VSL of $7.9 million in 2010$ is based on EPA National Center for Environmental Economics estimate of $7.4 million in 2006 dollars. The VSLY range $107,000, $214,000, and $322,000 in 2010 dollars, from which we calculate the daily QALD value, is based on VSLY and Cost Effectiveness Analysis (CEA) literature which often cites $100,000, $200,000 and $300,000 as values (base year 2006) (Ref.92;Ref.94). We use $7.9 million for the VSL, $214,000 for the VSLY ($586 per QALD), and a 3 percent discount rate.

The fifth column shows the direct medical costs of each condition. We use data from the Healthcare Cost and Utilization Project (HCUP) to estimate the costs of hospitalization and visits to the emergency room; HCUP data collects national hospital care data on patient stays by specific diagnosis (Ref.94). We use a publication called Medical Fees in the United States to determine the usual, customary, and reasonable doctors' fee schedules for hospitalized visits, office visits, and emergency room treatment based on the current procedural terminology (CPT) codes (Ref.95). We seek comment on these methods.

The sixth column shows the weighted dollar loss per outcome caused by each food-related illness. The weighted dollar loss per case is calculated by multiplying the probability of getting an illness of a particular severity by the health loss plus the medical costs per case. The weighted dollar values in column 6 are then summed to calculate the total expected loss associated with each type of food-related illness. For the weighted cost per case, we include any chronic complication burden resulting from the foodborne illness. The weighted cost of the secondary complication is added to the weighted cost burden of the acute illness.

To give an example of how the total burden of a specific type of foodborne illness is calculated we can look at Shigella. We expect that 98.89 percent of the cases of shigellosis will not result in hospitalization. We have estimated that the quality of life lost from this non-hospitalized illness will be 1.267 days; at a $586 per day value of life, then the dollar burden associated with this health equals $742. In twenty percent of the cases of non-hospitalized foodborne illness cases, the ill person visits the doctor; the expected value of this visit is $17 ($87 x 0.20) (Ref.96). Thus the weighted cost per non-hospitalized case of shigellosis is 0.9889($742 + $17) = $751 because we expect that 98.89 percent of all cases of shigellosis will result in this burden outcome.

Scallan et al reports that 1.11 percent of all shigellosis cases result in hospitalization. We have estimated that the quality of life lost from the hospitalized version of this illness to be 5.767 days; at a $586 day value we get that the monetary burden of the health loss will be $3,379. Doctors' fees and hospital charges for a hospitalized case of shigellosis amount to $16,282 per case. Thus, the weighted cost per hospitalized case of shigellosis is 1.11($3,379 + $16,282) = $218. The weighted cost per case is less for a hospitalized case of shigellosis than for a case of non-hospitalized case of shigellosis because most likely a person who gets shigellosis will experience the burden of the non-hospitalized case. In 0.01 percent of shigellosis cases, a death results; using the VSL of $7.9 million, we have a weighted death per case cost of 0.01($7,900,000) = $790.

Finally, after an acute case of shigellosis, a person has about 2.5 percent chance of experiencing arthritis as a secondary complication (Ref.97). This burden would be in addition to the burden already incurred due to the acute phase of the shigellosis illness. Here we estimate that should a person have the arthritis complication, they will have the condition for one year; this results in a quality of life lost of 20.93 days; at $586 a day value, which results in a health loss of $12,265. However, given that only 2.5 percent of persons experience arthritis after a case of shigellosis, the weighted cost of this secondary complication is 2.5($12,265) = $307.

The total weighted cost per case of shigellosis, then, is the sum of the weighted cost per case for each severity of illness weighted by its likelihood of occurrence: $751 + $218 + $790 + $307 = $2,066.

Table 143 - Total Costs of Foodborne Illnesses Identified as Associated with FDA Outbreaks					
Gastrointestinal Illness	Case Breakdown	Total QALDs Lost per Illness (based on mean)	Health Loss per Case	Medical Costs per Case	Weighted Dollar Loss per Case
Campylobacter jejuni					
nonhospitalized	99.00%	1.086	$636	$17	$647
hospitalized	1.00%	4.553	$2,668	$22,270	$249
Death	0.01%		$7,900,000		$790
Guillain-Barre Syndrome (GBS)	0.08%	78.960	$46,271	$122,132	$135
GBS long-term disability	0.02%	2361.722	$1,383,969	$65,319	$290
GBS-related death	0.00%		$7,900,000		$198
reactive arthritis	2.50%	18.170	$10,648	$486	$278
total expected loss per case					$2,587
Clostridium botulinum					
nonhospitalized	23.64%	9.412	$5,515	$17	$1,308
hospitalized	76.36%	35.640	$20,885	$165,274	$142,151
Death	16.36%		$7,900,000		$1,292,440
total expected loss per case					$1,435,899
E. coli O157:H7					
nonhospitalized	96.61%	1.358	$795	$17	$785
hospitalized	3.39%	6.070	$3,557	$56,167	$2,025
Death	0.03%		$7,900,000		$2,370
mild/moderate renal disease	0.22%	1401.461	$821,256	$32,611	$1,879
End Stage Renal Disease (ESRD)	0.01%	164.964	$96,669	$750,133	$85
death from ESRD	0.005%		$7,900,000		$395
hypertension	0.12%			$7,479	$9
total expected loss per case					$7,547
E. coli non-0157 STEC					
nonhospitalized	99.76%	1.358	$813	$17	$828
hospitalized	0.24%	6.070	$59,724	$56,167	$278
mild/moderate renal disease	0.02%	1401.461	$821,256	$32,611	$171
End Stage Renal Disease (ESRD)	0.001%	270.798	$96,669	$750,133	$8
death from ESRD	0.0003%		$7,900,000		$24
hypertension	0.12%			$7,479	$9
total expected loss per case					$1,318
E. coli, Enterotoxigenic and other diarrheogenic					
nonhospitalized	99.93%	0.543	$318	$17	$335
hospitalized	0.07%	6.070	$3,557	$22,065	$18
total expected loss per case					$353
Listeria monocytogenes					
nonhospitalized	8.55%	0.460	$270	$17	$25
hospitalized	91.45%	25.480	$14,931	$87,499	$93,672
Death	16.03%		$7,900,000		$1,266,370
total expected loss per case					$1,360,067
Mycobacterium bovis					

nonhospitalized	48.33%	2.700	$1,582	$17	$773
hospitalized	51.67%	6.236	$3,654	$76,935	$41,640
Death	5.00%		$7,900,000		$395,000
total expected loss per case					$437,413
Salmonella spp. (non-typhoidal)					
nonhospitalized	98.12%	0.996	$583	$17	$589
hospitalized	1.88%	6.374	$3,735	$26,343	$565
Death	0.04%		$7,900,000		$3,160
reactive arthritis	2.50%	20.930	$12,265		$307
total expected loss per case					$4,622
Shigella spp.					
nonhospitalized	98.89%	1.267	$742	$17	$751
hospitalized	1.11%	5.767	$3,379	$16,282	$218
Death	0.01%		$7,900,000		$790
reactive arthritis	2.50%	20.930	$12,265		$307
total expected loss per case					$2,066
Vibrio cholerae					
nonhospitalized	97.62%	0.815	$477	$17	$483
hospitalized	2.38%	6.374	$3,735	$8,429	$289
total expected loss per case					$772
Vibrio vulnificus					
nonhospitalized	3.13%	0.905	$530	$17	$17
hospitalized	96.88%	27.315	$16,007	$530,317	$529,278
Death	37.50%		$7,900,000		$2,962,500
total expected loss per case					$3,491,795
Vibrio parahaemolyticus					
nonhospitalized	99.71%	0.815	$477	$17	$493
hospitalized	0.29%	13.658	$8,003	$21,567	$86
Death	0.01%		$7,900,000		$790
total expected loss per case					$1,369
Cryptosporidium parvum					
nonhospitalized	99.64%	1.358	$795	$17	$810
hospitalized	0.36%	20.335	$11,916	$19,885	$114
Death	0.01%		$7,900,000		$790
total expected loss per case					$1,714
Cyclospora cayetanensis					
nonhospitalized	99.90%	3.168	$1,856	$17	$1,872
hospitalized	0.10%	10.623	$6,225	$10,900	$17
total expected loss per case					$1,889
Norovirus					
nonhospitalized	99.73%	0.272	$159	$17	$176
hospitalized	0.27%	2.428	$1,423	$26,580	$76
total expected loss per case					$252
Hepatitis A					
nonhospitalized	93.68%	2.534	$1,485	$17	$1,407
hospitalized	6.32%	12.479	$7,313	$28,090	$2,237
Death	0.45%		$7,900,000		$35,550
total expected loss per case					$39,195

Ciguatera toxin poisoning					
nonhospitalized	87.36%	1.248	$731	$204	$817
hospitalized	12.64%	8.227	$4,821	$15,851	$2,613
Death	0.14%		$7,900,000		$11,060
post acute illness symptoms	65%	13.770	$8,069	$391	$5,499
total expected loss per case					$19,989
Scombroid toxin poisoning					
nonhospitalized	96.10%	0.081	$47	$204	$242
hospitalized	3.90%	1.083	$634	$14,526	$591
total expected loss per case					$833
Food Allergic Reaction					
nonhospitalized	90.55%	0.122	$71	$204	$249
hospitalized	9.46%	0.981	$575	$13,256	$1,308
Death	0.01%		$7,900,000		$790
total expected loss per case					$2,347
Foodborne illness, Unknown Agent					
nonhospitalized	99.51%	0.272	$159	$17	$176
hospitalized	0.19%	1.518	$889	$19,497	$39
total expected loss per case					$214

iv. The economic impact of illness from FDA-regulated foods

We estimate the total benefits of eliminating foodborne illnesses from FDA-regulated products by multiplying the estimated annual number of illnesses per pathogen by the estimated cost per case. Table 144 presents the total estimated burden of illness associated with FDA-regulated foods. Column 2 contains the total number of FDA illnesses attributable to outbreaks, previously calculated in Table 138. This is multiplied by the expected dollar loss per case, in column 3, to give the annual cost of each pathogen in the US population, presented in column 4. Summing over all pathogens, we estimate a potential annual cost savings of approximately $5.34 billion dollars if all illnesses attributable to FDA-regulated foods were eliminated.

Table 144 - Estimated Dollar Burden Attributable to All FDA-regulated Foods			
Agent	**Estimated Attributable Illnesses**	**Expected Dollar Loss per Case**	**Dollar Burden**
C. Botulinum	13	$1,435,899	$18,333,349
Campylobacter jejuni	65,681	$2,587	$169,918,469
Ciguatera	476	$19,989	$9,513,321
Cryptosporidium	55,683	$1,714	$95,464,676
Cyclospora	11,059	$1,889	$20,889,089
E. coli non-0157 STEC	49,695	$1,318	$65,515,401
E. Coli O157:H7	20,321	$7,547	$153,367,257
E. coli, Enterotoxigenic and other diarrheogenic	374	$353	$132,011
Hepatitis A	1,381	$39,195	$54,128,295
Listeria monocytogenes	1,193	$1,360,067	$1,622,899,591
Mycobacterium bovis	60	$437,413	$26,244,795
Norovirus	26,453	$252	$6,656,158
Other chemical	64	$214	$13,657
Other fungal	6	$214	$1,329
Other parasitic	4	$214	$772
Plant toxin	2	$214	$343
Salmonella	427,050	$4,622	$1,973,633,824
Scombroid	5,301	$833	$4,414,540
Seafood poison	30	$833	$24,982
Shigella sonnei	11,020	$2,066	$22,770,087
Vibrio cholerae	30	$772	$23,172
Vibrio parahaemolyticus	13,835	$1,369	$18,939,883
Unidentified	5,051,481	$214	$1,081,016,934
TOTAL	5,741,212		$5,343,901,935

If we use the alternative estimate of the number of illnesses due to unknown pathogens that are attributable to the FDA-regulated foods, we obtain a somewhat smaller estimate of the burden of foodborne illnesses. The number of illnesses due to unknown pathogens estimated using this methodology is 2,758,924. Multiplying this by a cost per illness of $214 gives an estimated burden due to illnesses from unidentified pathogens of $590,409,735 and an estimated total burden from all foodborne illnesses attributable to FDA-regulated food of $4.85 billion.

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