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IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. OMB has determined that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because facilities with less than 20 employees (both qualified and non-qualified) facilities 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

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Deleted: FDA has developed a comprehensive preliminary regulatory impact analysis (PRIA); the PRIA is available at http://www.regulations.gov Docket No. 2004-0448, 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
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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

This regulation is required by the FDA Food Safety Modernization Act, Section 103 of which states that FDA must establish through rulemaking, science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls.

Private markets operating within the framework of the legal system promote the health and safety of consumers. Limitations of both the marketplace and the legal system, however, can result in inadequate control of some health and safety hazards, and reduce societal welfare.

In an idealized perfectly competitive market in which consumers and producers both have sufficient information, the optimal level of production of foods that are manufactured, processed, packed or held by food facilities will be provided at an optimal level of safety. In real markets, however, consumers and producers may not have sufficient information on the safety attributes of foods. Although food facilities do have an incentive to put safety programs into place, the lack of awareness and information about the risks suggests that an inefficiently low demand may exist for food products that are produced using adequate measures to prevent foodborne illness, adulteration, or contamination. Because the demand for many manufactured or processed foods may not be sufficiently affected by safety considerations, incentives to invest in safety measures from farm to fork is diminished. Consequently, the market may not provide the incentives necessary for optimal food safety.

With sufficient information for consumers and producers, a legal system that awards compensation for harm done due to unsafe foods has the potential to remedy market

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Facilities acting in competitive markets can reasonably be expected to manufacture, process, package, or hold food ingredients or finished foods safely up to the point at which it is profitable, suggesting that facilities will adopt some preventive controls in the absence of any regulation. These facilities might rely on their reputation for food safety and general product quality, or they might be concerned about the economic harm from lost good-will or the high cost of legal liability and punitive damages as incentives to ensure the safety of their products and the satisfaction of the customers. Brand name, loss of goodwill, or the threat of a lawsuit contribute to the strength of market incentives but are unlikely to be sufficient to ensure a safe food supply as demonstrated by the large number of foodborne illnesses still reported to CDC each year (Ref CDC). ¶
The actions of manufacturers of food ingredients (suppliers) can also contribute to risk of adulteration throughout the distribution chain. If food ingredient suppliers have insufficient preventive controls, they can cause harm to food manufacturers that use their ingredients, spreading pathogens and other hazards. While many establishments will adopt what they believe are the necessary preventive controls to protect the public, not every establishment will adopt them throughout the supply chain. Foodborne hazards might be introduced at any point along sometimes long production and distribution chains, so that even well-intentioned distributors or their consumers might be vulnerable to the bad or insufficient practices of their suppliers. The problems can be compounded when ingredients are comingled with many products and it becomes difficult to identify the source of the ingredients or the source of the contamination. ¶
The high cost of private monitoring and auditing suppliers about the use of preventive controls along with the high cost of private dispute resolution makes the use and enforcement of private supplier agreements uneven and often, ineffective to ensure the use of adequate preventive controls. Moreover, consumer complaints may have to occur frequently before establishments realize there is a problem of adulteration that originates from their or their supplier's production or distribution practices. Most recalls are prompted by consumer complaints and government inspections, not by the actions of the offending establishments themselves (Ref. FDA Food GMP Modernization Working Group: ...

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imperfections by providing producers with incentives to provide the level of safety that is best for society. Currently, the legal system does not ensure the optimum level of safety for foods because consumers who become ill often do not know the reason for, or source of, their illness. Even in cases where consumers are aware that their illness was contracted from a specific food, it is often difficult to determine who is ultimately responsible for their illness, since the particular source of contamination is not known in many circumstances.

Markets characterized by branding may remedy market imperfections and result in optimum levels of safety, if the illnesses or adverse consequences from the foods can be linked to a brand or establishment. However, as noted above, in many cases it is difficult to determine the source of contamination. In addition, branding is not used universally across the food sector and investments in branding vary substantially across the food sector. As a result, it is unlikely that the existence of brands in the food sector creates the optimal level of safety for society.

In sum, the imperfect information about the risk associated with food covered by the regulation means that neither the legal system nor the marketplace may be able to provide adequate economic incentives for the production of safe food. The Government may therefore be able to improve social welfare through targeted regulation.

C. Summary of Proposed Rule Costs and Benefits

We summarize our estimate of the total burden of illnesses associated with covered foods, the costs of Option 1 of the proposed rule in Table 1a, Option 2 the co-proposal in Table 1b and Option 3 the co-proposal in Table 1c. Under Option 1 of the co-proposal, FDA is proposing to define the term "very small business" to mean, for the purposes of proposed part 117, a business that has less than $250,000 in total annual sales of foods, adjusted for inflation. This proposed definition uses a dollar amount that is, for practical purposes, the same as the

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dollar amount of sales by a qualified facility to end users other than those that would satisfy the definition of "qualified end users." Under Option 2, we are proposing to define the term "very small business" to mean a business that has less than $500,000 in total annual sales of foods, adjusted for inflation. Under Option 3, we are proposing to define the term "very small business" to mean a business that has less than $1,000,000 in total annual sales of foods, adjusted for inflation.

The three proposed definitions are informed by the findings of the food processing sector study that we conducted as required by section 418(l)(5) of the FD&C Act. The $250,000 definition of very small business adds approximately 34,600 facilities to the number of qualified facilities beyond the approximately 11,500 facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act. As a group, businesses with less than $250,000 in total annual sales of foods produce less than one-half of one percent of all food produced in the United States when measured by dollar value. The $500,000 definition of very small business adds approximately 45,900 facilities to the number of qualified facilities (in addition to the 11,500 facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act). As a group, businesses with less than $500,000 in total annual sales of foods produce less than one percent of all food produced in the United States when measured by dollar value. The $1,000,000 definition of very small business adds approximately 63,500 facilities to the number of qualified facilities (in addition to the 11,500 facilities that are qualified facilities under section 418(l)(1)(C) of the FD&C Act). As a group, businesses with less than $1,000,000 in total annual sales of foods produce less than two percent of all food produced in the United States when measured by dollar value. The food processing sector study is available in the docket established for this proposed rule (Ref. 32). We request comment on that study. We will consider comments regarding the

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study, as well as comments regarding our proposed definition for very small business, in any final rule based on this proposed rule.

We estimate that under Option 1 the total costs to domestic facilities in the first year, which will be the period when the industry incurs the largest cost, including both set up costs to implement the rule and the initial recurring monitoring and verification costs, will be approximately $775 million. We estimate that annually recurring costs after the first year will be $347 million. The annualized costs, which include annualized one-time set up costs and annually recurring costs will be approximately $475 million per year using a discount rate of 7 percent and discounted over 7 years. We estimate the total annualized cost to foreign facilities will be approximately $500 million.

We estimate that under Option 2 the total costs to domestic facilities in the first year, including both set up costs to implement the rule and the initial recurring monitoring costs will be approximately $717 million. We estimate that annually recurring costs after the first year will be $276 million. The annualized costs will be approximately $395 million per year again using a discount rate of 7 percent and discounted over 7 years. We estimate the total annualized cost to foreign facilities will be approximately $400 million.

We estimate that under Option 3 the total costs to domestic facilities in the first year, including both set up costs to implement the rule and the initial recurring monitoring costs will be approximately $686 million. We estimate that annually recurring costs after the first year will be $206 million. The annualized costs will be approximately $319 million per year again using a discount rate of 7 percent and discounted over 7 years. We estimate the total annualized cost to foreign facilities will be approximately $300 million.

We are not able to estimate the commensurate health benefits that would accrue to

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foreign citizens that consume safer foods that are produced within their countries because of this rule or that consume safer exported U.S. foods.

As discussed below, we lack sufficient information to fully estimate the proposed rule's likely benefits. Instead we attempt to estimate the total economic burden of the illnesses that could potentially be prevented by this rule. We do not expect that all of these illnesses will be prevented; rather, we expect that the rule would prevent some portion of them from occurring. We estimate that there are close to 1,000,000 illnesses each year that are attributable to FDA-Regulated food products that would fall under the scope of this propose rule. The monetized cost of these illnesses is estimated to be nearly $2 billion.

Ignoring the costs to foreign firms and the benefits to foreign consumers, for the proposed rule to break even, by which we mean for the proposed rule to reduce the health burden to consumers by approximately the same amount as the compliance costs to industry, the rule would have to reduce the monetized cost of the illnesses for Option 1 by about $475 million. We estimate that the average cost per illness is $2,063, so reducing the cost of illness by $470 million requires reducing the number of illnesses by at least 230,000 illnesses each year. This is roughly one quarter of the annual illnesses that we estimated, using our primary methodology, are attributable to foods covered by the rule, and roughly half of the illnesses that we estimated, using our alternative methodology, are attributable to foods covered by the rule. For Option 2 to break even, the rule would have to reduce the monetized cost of the illnesses by about $395 million. Reducing the cost of illness by $395 million requires reducing the number of illnesses by at least 191,000 illnesses each year. For Option 3 to break even the rule would need to reduce the monetized cost of the illnesses by at least $319 million. Reducing the cost of illness by $319 million requires reducing the number of illnesses by at least 155,000 illnesses each year.

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Deleted: Economic Analysis of Preventive Controls Benefits ¶ The primary benefit of the provisions in this rule would be an expected decrease in the incidence of illnesses relating to the manufacturing, processing, packing or holding human food. ¶ 1. Total FDA-Regulated Risk of Foodborne Illness¶

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Deleted: To estimate the total number of illnesses attributable to all FDA-regulated foods, we utilize a combination of CDC's OutbreakNet: Foodborne Outbreak Online Database (REF) and FDA's own epidemiological assessment of those outbreaks.

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Table 6- Foodborne Illness Secondary Complications by Cause, Duration and Severity ...

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Deleted: Shaw 2005) to calculate QALD value.

Moved down [16]: 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.

Deleted: Stewart et al 2007 and Jia et al 2011) ¶

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iii. Valuation of foodborne illnesses¶ ...

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The effectiveness of this regulation and the corresponding reduction in food contamination and foodborne illness will depend on how successfully preventive controls are

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Moved down [23]: Summing over all pathogens, we estimate a potential annual cost savings of approximately $6.32 billion dollars if all illnesses attributable to FDA-regulated foods were eliminated. [10,11]¶
¶

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The primary benefit of the provisions in this rule would be an expected decrease in the incidence of illnesses relating to the processed foods.[12] ¶
a. Foodborne illness attributable to FDA-regulated processed food¶
Previous estimates of foodborne illness incorporate all FDA-regulated food products, but this rule is specific to processed foods. To account for this we examine only a subset of the total illnesses that are directly linked with processed foods. To estimate the number of baseline illnesses attributable to only processed foods we utilize the same methodology previously outlined, but we begin with only those outbreaks we can directly attribute to FDA-regulated processed foods. Table 10 presents all outbreaks, organized by agent, which can be linked to processed foods based on illnesses recorded in FDA's outbreak database. In total, there are 2,194 illnesses from 27 separate outbreaks that are linked to processed foods for the years 2003-2008; this data represents only reported and laboratory confirmed illnesses from outbreaks,. ¶
Table 10. FDA Outbreak Data for Illnesses Attributed to Processed Foods¶ ...

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implemented and how effective the proposed provisions are at reducing contamination that leads to illness. Tables 1a, 1b and 1c summarize the annualized domestic costs using a discount rate of 7% and discounted over a 7 year period. The average annualized costs when discounted at 3% are only about 5% to 10% less than the average annualized costs when discounted at 7% and discounted over a 7 year period. Tables later in the analysis show estimates for the major provisions discounted at 3% and over a 7 year period.

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Table 1a: Preventive Control Rule Annualized Cost Summary for Domestic Firms at discount rate of 7% over 7 years Very Small Business defined as less than $250,000 Annual Revenue

Benefits are Qualitative Estimates: Fewer illnesses and deaths from potential reduction in adulteration

Provision	<20 employees	20 to 99 employees	100 to 499 employees	500 > employees	Total
Approximate Total Number of Domestic Facilities (Manufacturers, Warehouses and Wholesalers)	80,475	12,283	4,411	477	97,646
Approximate Number of Facilities subject to Subpart C Hazard Analysis and Risk-based Preventive Controls (Non-qualified Facility)	34,571	12,124	4,383	471	51,549
Approximate Number of Facilities exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls (Qualified Facility)	45,904	159	28	6	46,097
Learn about Rule	$47,269,991	$7,214,878	$5,726,708	$619,279	$60,830,856
Attest Qualified Status to FDA	$468,221	$1,622	$286	$71	$470,200
One-time Label	$14,999,555	$121,228	$39,647	$13,724	$15,174,154

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Total Subpart B Annualized Costs	$15,467,776	$122,850	$39,933	$13,795	$15,644,354
Subpart C Hazard Analysis and Risk-Based Preventive Controls					
Hazard Analysis	$55,325,358	$6,110,722	$1,141,367	$0	$62,577,447
Process Controls	$113,355,618	$13,802,902	$3,452,636	$0	$130,611,156
Allergen Controls					
Proper Usage	$4,385,110	$3,568,131	$2,407,116	$370,708	$10,731,065
Label Application Review	$758,130	$2,580,219	$2,368,359	$0	$5,706,708
Sanitation Controls					
Food Contact Surfaces	$10,530,034	$4,182,468	$2,905,185	$0	$17,617,687
Prevent Cross Contamination with Raw Ingredients	$6,931,179	$3,826,030	$1,828,195	$147,970	$12,733,374
Prevent Cross Contamination In Process/Production Areas	$5,903,972	$2,412,365	$1,549,329	$149,023	$10,014,689
Monitoring / Verification	$59,025,438	$15,767,194	$10,291,112	$0	$85,083,744
Corrective Actions	$21,067,636	$12,534,300	$18,733,455	$0	$52,335,391
Recall Plans	$8,783,463	$1,731,533	$344,645	$0	$10,859,641
Total Subpart C Annual Costs	$286,065,938	$66,515864	$45,021,399	$667,701	$398,270,902
Total Annualized Costs discounted at 7%	$348,803,705	$73,853,592	$50,788,040	$1,300,775	$474,746,112
Avg Annualized Cost per Facility exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls					$1,000/facility
Avg Annualized Cost per Facility subject to Subpart C Hazard Analysis and Risk-based Preventive Controls					$13, 000/facility
Total Annualized Cost to Foreign Facilities					$500 million

Table 1b summarizes our domestic cost estimate for our co-proposal where we use a definition for a very small business of $500,000 or less. The summary shows annualized costs using a discount rate of 7%.

Table 1b: Preventive Control Rule Annualized Cost Summary for Domestic Firms at discount rate of 7% over 7 years, Very Small Business defined as less than $500,000 Annual Revenue

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Benefits are Qualitative Estimates: Fewer illnesses and deaths from potential reduction in adulteration					
Provision	<20 employees	20 to 99 employees	100 to 499 employees	500 > employees	Total
Approximate Total Number of Domestic Facilities (Manufacturers, Warehouses and Wholesalers)	80,475	12,283	4,411	477	97,646
Approximate Number of Non-qualified Facilities subject to Subpart C Hazard Analysis and Risk-based Preventive Controls	23,379	12,009	4,378	469	40,235
Approximate Number of Qualified Facilities exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls	57,096	274	33	8	57,411
Learn about Rule	$47,269,991	$7,214,878	$5,726,708	$619,279	$60,830,856
Attest Qualified Status to FDA	$582,379	$2,795	$337	$82	$585,593
One-time Label Change	$18,656,644	$208,908	$46,727	$15,684	$18,927,963
Total Subpart B Annualized Costs	$19,239,023	$211,703	$47,064	$15,766	$19,513,556
Subpart C Hazard Analysis and Risk-Based Preventive Controls					
Hazard Analysis	$38,129,781	$6,049,344	$1,140,017	$0	$45,319,142
Process Controls	$70,400,208	$13,649,221	$3,449,113	$0	$87,498,542
Allergen Controls					
Proper Usage	$2,723,400	$3,528,404	$2,404,045	$369,057	$9,024,906
Label Application Review	$470,844	$2,551,546	$2,365,097	$0	$5,387,487
Sanitation Controls					
Food Contact Surfaces	$6,539,743	$4,135,901	$2,901,479	$0	$13,577,123
Prevent Cross Contamination Raw Ingredients	$4,304,652	$3,783,432	$1,825,863	$147,311	$10,061,258
Prevent Cross	$3,666,698	$2,385,505	$1,547,353	$148,359	$7,747,915

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Contamination In Process/Production Areas					
Monitoring / Verification	$56,302,871	$15,752,741	$10,290,776	$0	$82,346,388
Corrective Actions	$14,838,624	$12,422,419	$18,725,161	$0	$45,986,204
Recall Plans	$5,462,784	$1,712,372	$344,212	$0	$7,519,368
Total Subpart C Annual Costs	$202,839,605	$65,970,885	$44,993,116	$664,727	$314,468,333
Total Annualized Costs discounted at 7%	$269,348,619	$73,397,466	$50,766,888	$1,299,772	$394,812,745
Average Annualized Cost per Manufacturing Facility exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls					$1,000/facility
Average Annualized Cost per Manufacturing Facility subject to Subpart C Hazard Analysis and Risk-based Preventive Controls					$13,000/facility
Total Annualized Cost to Foreign Facilities					$400 million

Table 1c summarizes our domestic cost estimate for our co-proposal where we use a definition for a very small business of $1,000,000 or less. The summary shows annualized costs using a discount rate of 7%.

Table 1c: Preventive Control Rule Annualized Cost Summary for Domestic Firms at discount rate of 7% over 7 years, Very Small Business defined as less than $1,000,000 Annual Revenue

Benefits are Qualitative Estimates: Fewer illnesses and deaths from potential reduction in adulteration

Provision	<20 employees	20 to 99 employees	100 to 499 employees	500 > employees	Total
Approximate Total Number of Domestic Facilities (Manufacturers, Warehouses and Wholesalers)	80,475	12,283	4,411	477	97,646
Approximate Number of Non-qualified Facilities subject to Subpart C Hazard Analysis and Risk-based Preventive Controls	10,644	9,542	2,272	203	22,661

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Approximate Number of Qualified Facilities exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls	69,831	2,741	2,139	274	74,985
Learn about Rule	$47,269,991	$7,214,878	$5,726,708	$619,279	$60,830,856
Attest Qualified Status to FDA	$712,276	$27,958	$21,818	$2,795	$764,847
One-time Label Change	$22,817,923	$2,089,843	$3,028,731	$537,192	$28,473,689
Total Subpart B Annualized Costs	$23,530,199	$2,117,801	$3,050,549	$539,987	$29,238,536
Subpart C Hazard Analysis and Risk-Based Preventive Controls					
Hazard Analysis	$17,704,115	$4,934,205	$590,400	$0	$23,228,720
Process Controls	$40,870,754	$11,326,108	$1,763,311	$0	$53,960,173
Allergen Controls					
Proper Usage	$1,581,066	$2,927,866	$1,229,348	$159,347	$5,897,627
Label Application Review	$273,348	$2,117,270	$1,209,431	$0	$3,600,049
Sanitation Controls					
Food Contact Surfaces	$3,796,640	$3,431,966	$1,483,719	$0	$8,712,325
Prevent Cross Contamination Raw Ingredients	$2,499,060	$3,139,487	$933,685	$63,604	$6,635,836
Prevent Cross Contamination In Process/Production Areas	$2,128,697	$1,979,490	$791,265	$64,057	$4,963,509
Monitoring / Verification	$54,431,258	$15,534,254	$10,162,236	$0	$80,127,748
Corrective Actions	$10,556,524	$10,731,168	$15,552,150	$0	$36,839,842
Recall Plans	$3,180,002	$1,422,734	$178,443	$0	$4,781,179
Total Subpart C Annual Costs	$137,021,464	$57,544,548	$33,893,988	$287,008	$228,747,008
Total Annualized Costs discounted at 7%	$207,821,654	$66,877,227	$42,671,245	$1,446,274	$318,816,400
Average Annualized Cost per Manufacturing Facility exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls					$1,000/facility
Average Annualized Cost per Manufacturing Facility subject to Subpart C Hazard Analysis and Risk-based Preventive Controls					$13,000/facility

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Total Annualized Cost to Foreign Facilities	$300 million

D. Economic Analysis of the Cost of Illnesses that Could Potentially Be Prevented by Proposed Rule

The proposed rule would implement the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. The proposed rule would also modernize and update the language of the current CGMP requirements to clarify that certain CGMP provisions that require protection against contamination also require protection against cross-contact of food to address food allergens.

Specifically, the proposed rule would establish requirements for: a written food safety plan; hazard analysis; preventive controls for hazards that are reasonably likely to occur; monitoring; corrective actions; verification; and associated records. After accounting for exemptions, this rule will fully cover almost all of the processed food sales associated with our burden of illness estimate. 'Qualified' facilities would be subject to alternative requirements described in section E.2.b. Further, they would remain subject to Current Good Manufacturing Practices.

The primary benefit of this rule would be an expected decrease in the incidence of illnesses caused by the manufacturing, processing, packing or holding practices of human food. While quantification of the human health benefits derived from this rule is difficult and complex, for the purpose of this analysis, we develop a conceptual framework or qualitative assessment that describes how implementing this rule would likely reduce the level of foodborne illness. Estimating the human health benefits from the rule's reduction of foodborne illness would require the following: (1) a measure for the current risk of foodborne illnesses attributable to

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FDA-regulated food under the scope of this rule; (2) a measure of lost health as measured by morbidity and mortality effects attributable to foodborne illnesses; (3) a value of lost health due to foodborne illness; (4) the changes from baseline food manufacturing practices due to the rule; and (5) an estimate for the effectiveness of the preventive controls in preventing foodborne illnesses that would otherwise have occurred.

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1. Baseline Risk of Foodborne Illness

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a. Foodborne illness attributable to FDA-regulated food under the scope of this proposed rule

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To estimate the number of baseline illnesses attributable to only foods under the scope of this proposed rule-making we begin with only those outbreaks and food allergic reactions that we can directly attribute to FDA-regulated foods that are manufactured, processed, packed or held in food facilities.[16] Table 2 presents all outbreaks, organized by food commodity and agent which can be linked to foods under the scope of this proposed rule-making based on illnesses recorded in FDA's outbreak database. It does not include any outbreaks linked to handling or storage at retail establishments, restaurants, or homes. In total, for the years 2003-2008, there were 1,655 illnesses from 16 separate outbreaks that are linked to foods that fall under the scope of this proposed rule-making (Ref 1); this averages out to about 2.7 outbreaks, 276 illnesses, and 1.7 deaths per year. However, this data represents reported and laboratory confirmed illnesses from outbreaks. We provide more detailed data about those outbreaks associated with FDA-regulated foods in our Reference 1.

Table 2. FDA Outbreak Data for Illnesses Attributed to Foods Under the Scope of this Proposed Rule-Making

Commodity	Agent	Outbreaks	Cases	Hospitalizations	Deaths
CHEESE PRODUCTS	*Listeria monocytogenes*	6	36	15	1

[16] Appendix A provides estimates of foodborne illness attributable to all FDA-regulated food products.

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MILK, BUTTER, OR DRIED MILK	*Listeria monocytogenes*	1	3	0	0
MILK, BUTTER, OR DRIED MILK	*Mycobacterium bovis*	1	35	0	0
SNACK FOOD ITEMS	*Salmonella* spp.	1	33	12	0
BAKERY PRODUCTS	*Salmonella* spp.	1	26	11	0
CHEESE PRODUCTS	*Salmonella* spp.	2	71	6	0
NUT PRODUCTS	*Salmonella* spp.	2	1,342	171	9
PREPARED SALAD	*Salmonella* spp.	1	22	2	0
VEGETABLE PRODUCTS	*Salmonella* spp.	1	87	8	0
TOTAL		**16**	**1,655**	**225**	**10**

Table 3a presents our estimation of the total annual number of illnesses attributable to foods that would fall under the scope of this proposed rule-making based on FDA outbreak data combined with CDC outbreak data[17] (Ref 2) and adjusted for unidentified pathogens.

While the FDA database contains information on only 16 outbreaks during the 2003-2008 period attributable to foods covered by this proposed rule, it is likely that there are many more unidentified or unreported cases. To deal with this undercounting, we have developed a methodology to extrapolate from the number of reported outbreaks to an estimated total number of cases associated with the food covered by this rule. The methodology is described below.

First, for different pathogens we calculated the proportion of CDC outbreak illnesses represented by preventable outbreaks in the FDA database for foods that would fall under the scope of this rulemaking. This proportion varied by pathogen, up to a high of 100% for *Mycobacterium bovis* cases. Next, we applied these proportions to Scallan, et al.'s (Ref 3) estimates of the total annual number of foodborne illnesses to obtain an estimate of the number of illnesses attributable to food covered by this rulemaking for each pathogen.

To deal with the problem of illnesses caused by unknown pathogens, we needed to make

[17] CDC outbreak data does not allow us to differentiate outbreaks by the source of contamination. To that extent, CDC data possibly includes outbreaks related to contamination of FDA-regulated food that were linked to handling or storage at retail establishments, restaurants, or homes.

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some assumptions. There is very little information about which types of foods are responsible for illnesses caused by unknown pathogens, so we assumed that foods covered by this rulemaking are responsible for the same share of illnesses caused by unknown pathogens as by known pathogens. We calculated that foods covered by this rulemaking represented about 2.1% of the illnesses due to known pathogens in the CDC database. (See Appendix A for detail on this derivation.) Then we applied this proportion to Scallan, et al.'s estimate of about 39 million foodborne illnesses from unknown pathogens to come up with an estimate for the number of illnesses from unknown pathogens attributable to foods covered by this rule. Using this methodology, we estimate that there are about 917, 118 illnesses per year attributable to food under the scope of this rule. We seek comment on our assumption that the share of illnesses caused by unknown pathogens that are attributable to food covered by this rulemaking is equal to the share of illnesses caused by known pathogens that are attributable to food covered by this rulemaking.

We also explored an alternative methodology for estimating the number of illnesses caused by unknown pathogens attributable to FDA-regulated foods. 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 3a, we get a total of 110,871 illnesses due to known pathogens that are attributable to food under the scope of this rule. 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 443,484 (8/2 times 110,871). This is considerably smaller than the estimate obtained using our assumption that the proportion of attributable illnesses is equal across identified and unidentified pathogens—806,247. Using this alternative

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methodology, we estimate that the total annual number of illnesses attributable to foods covered by this rule is 554,355. We seek comments on these alternative estimates and which is more likely to be correct.

Table 3a- Estimated Annual Number of Illnesses Attributable to Food Under the Scope of this Proposed Rule-Making

Agent	FDA Cases (2003-2008)	Total Cases (2003-2008)	Percentage Attributable to FDA Products Under this proposed rule-making	Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to FDA Products Under this proposed rule-making
Listeria monocytogenes	39	72	54.2%	1,591	862
Mycobacterium bovis	35	35	100.0%	60	60
Salmonella spp.	1,581	14,709	10.7%	1,027,561	109,949
total identified	1,655	79,347	2.1%		
total unidentified**			2.1%	38,392,704	806,247
TOTAL					**917,118**

** The percentage attributable to unidentified illnesses is calculated as the total number of observed FDA attributable cases divided by the total number from all observed cases (1,655/79,347 = 2.1%). This methodology then assumes that the percentage of observed illnesses attributable to FDA products is equal to the percentage of unidentified pathogen illnesses attributable to FDA products. See Appendix A for further details on this methodology.

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Facilities producing foods containing allergenic ingredients (the eight major food allergens of milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) are subject to the proposed rule allergen controls; allergen controls are one of the preventive controls identified in the proposed rule.[18] Preventive controls must be written and must include, as appropriate to the facility and the food: (1) the parameters associated with the control of the

[18] Preventive controls are practices that must be implemented at each facility to provide assurances that hazards identified in the hazard analysis as reasonably likely to occur (in this case food allergens) will be significantly minimized or prevented and the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

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hazard, and (2) the maximum or minimum value, or combination of values, to which any biological, chemical, physical, or radiological parameter must be controlled to significantly minimize or prevent a hazard that is reasonably likely to occur. Allergen preventive controls specifically must include those procedures, practices, and processes employed for (1) ensuring protection of food from cross-contact, including during storage and use; and (2) labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

We used a different methodology to estimate food allergic reactions because food allergic reactions are not included in Scallan et al (Ref 3) as food allergens are not considered pathogens. First, we estimated the total food allergic reactions attributable to FDA-regulated products (see Appendix A for more detail on how this estimate was derived). Then since seafood producers do not have to comply with the enhancements to food allergen controls in the proposed rule, we reduced our estimate of the total number of allergic reactions that involve FDA-regulated products subject to this rule-making by an additional 24 percent based on Ross et al.'s (2008) (Ref 4) estimate of the share of food allergic reactions annually related to shellfish consumption (93,632 x 0.76 = 71,160).

Finally, to examine just those allergic reactions that are due to foods under the scope of this rule-making and those reactions that the proposed allergen controls may help reduce, we use information on unsolicited calls from consumers to the Food Allergy and Anaphylaxis Network (FAAN). (Ref 5) Out of 206 phone calls related to problems with packaged food, 28 percent of calls were due to a product that was cross-contaminated by an unlabeled allergen,[19] 26 percent

[19] Among the episodes of cross-contact, 65 percent were called to FAAN's attention because of otherwise unexplained reactions to the product and 35 percent were based on consumer initiated calls to the manufacturer. The potential for error was confirmed by the company in 88 percent of these incidents (e.g. shared processing

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were due to a visible ingredient in the product that was not disclosed on the label, and 7 percent were due to completely wrong contents in the package.[20] Thus, we estimate that on an annual basis this rule making could help reduce some portion of 43,408 allergic reactions ((71,160 x 0.28 = 19,925) + (71,160 x 0.26 = 18,502) + (71,160 x 0.07 = 4,981)). We request comment on this estimate.

Our estimate does not account for those first-time allergic reactions that occur when consumers are unaware that they are allergic to one or more of the eight major allergens. We lack data about how many annual reactions are due to consumers with first-time reactions. These first-time reactions are presumably not because of unintentional contamination, e.g., cross-contact, or undeclared allergens in their processed food, and therefore, presumably not avoidable by our proposed rule. We request comment on how to adjust our estimate for first-time reactions.

Table 3b- Estimated Number of Allergic Reactions Attributable to FDA-Regulated Foods Under the Scope of this rule-making

	Percent of cases annually	**Total Cases Annually**	**Average Annually**
Allergen reactions from 8 major food allergens due to packaged food [a]		28,359-158,904	93,632
Reactions due to seafood	24%	6,806-38,137	22,472
Reactions less seafood		21,553-120,767	71,160
Cross-contact from unlabeled allergen	28%	6,035-33,815	19,925
Visible ingredient in product not declared on label	26%	5,604-31,399	18,502
Wrong contents in	7%	1,509-8,454	4,981

equipment). (Ref 5)

[20]Other problems reported included, allergen newly disclosed on the label (22 percent), Outer package label different from individual package label inside (6 percent), ambiguous terminology (5 percent), reaction from milk product labeled "Pareve" (3 percent), label in English placed over foreign language label (1.5 percent), and different package sizes of same product have different ingredients (1.5 percent). (Ref 5)

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package			
Total reactions that may be reduced due to this proposed rule-making		**13,148-73,668**	**43,408**

[a] See Appendix A for the derivation of this estimate.

b. Economic burden of illnesses attributable to FDA-regulated foods under the scope of this proposed rule-making

We estimate the total cost of foodborne illnesses from foods that would fall under the scope of this proposed rule-making by multiplying the annual number of illnesses per agent by the estimated cost per case. The derivation of our costs per case estimates are presented in Appendix A. Table 4 presents the dollar burden of illness attributable to FDA-regulated foods under the scope of this proposed rule-making. Column 2 contains the total number of illnesses attributable to FDA-regulated foods under the scope of this proposed rule-making, as previously calculated in Table 3a and b. This is multiplied by the expected dollar loss per case, in column 3, to give the annual cost of each agent in the U.S. population, presented in column 4. Summing over all agents, we estimate an average cost per foodborne illness of $2,063 and a total cost of approximately $1.98 billion dollars.[21]

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We cannot expect facilities not covered under proposed 117 subpart C-Hazard Analysis and Risk-Based Preventive Controls, such as qualified facilities or exempt facilities (e.g. very small facilities or seafood facilities that already comply with seafood HACCP), to adjust their food manufacturing practices in response to this rule-making. Therefore we do not expect to see a reduction in contamination and foodborne illnesses from these facilities.

We have already adjusted our illness estimates to eliminate any illnesses caused due to

[21] Since none of the foodborne illnesses with chronic complications are attributed to foods under the scope of this proposed rule-making, the total annual dollar burden remains the same regardless of discount rate used.

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products produced by exempt facilities (e.g., we do not include illnesses due to contamination of seafood). To further adjust our estimate of illnesses to eliminate any illness that may be caused by a qualified facility we use data from Dun &Bradstreet (D&B). (Ref 6) D&B data show facilities with revenues of more than 99.5 percent of all food produced in the United States when measured by dollar value. Thus, less than 0.5 percent of the food sold will be from facilities that are likely to be "qualified under Option 1 of the co-proposal. D&B data indicate that facilities with more than $500,000 account for about 99 percent of the total industry sales. Thus, less than one percent of the food sold will be from facilities that are likely to be "qualified" under Option 2. D&B data show facilities with revenues of more than $1,000,000 account for more than 98 percent of the total sales. Thus, less than 2 percent of the food sold will be from facilities that are likely to be "qualified" under Option 3. Table 4 shows the estimated number of illnesses and the associated cost burdens under proposed Options 1, 2, and 3.

In the absence of better information, we assume that the potential for foodborne illness from facilities is equal to the facility's share of sales, because we lack data that definitively associates smaller facilities with a greater potential for outbreaks. However, we do have data that suggests smaller facilities are less likely to already be doing many of the things required by this rule. We ask for comment about our assumption.

Given that less than one-half of one percent, one percent, or less than two percent of industry sales, respectively, come from facilities that are likely to be "qualified" under Options 1, 2, and 3 of this proposed regulation, we reduce our foodborne illness total by these percentages to eliminate from consideration any potential illnesses caused by facilities that would be qualified under this proposed rule-making. We thus estimate that the illnesses attributable to FDA-regulated food products under the scope of this proposed rule-making to be close to 1

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million annually; the cost burden associated with these illnesses is nearly $2 billion dollars.

Table 4- Estimated Dollar Burden Attributable to FDA-Regulated Food Under the Scope of This Proposed Rule-Making

Agent	Estimated Illnesses Attributable to FDA-Regulated Food Products Under the Scope of this Proposed Rule-Making	Expected Dollar Loss per Case	Dollar Burden (in Millions)
Allergen	43,408	$2,347	$101,878,576
Listeria monocytogenes	862	$1,360,067	$1,172,377,754
Mycobacterium bovis	60	$437,413	$26,244,780
Salmonella	109,949	$4,622	$508,184,278
Unidentified	806,247	$214	$172,536,858
Total	960,526	$2,063	$1,981,222,246
Total Less 0.5% (VSB < $250,000)	**955,723**	**$2,063**	**$1,971,316,135**
Total Less 1% (VSB < $500,000)	**950,921**	**$2,063**	**$1,961,410,024**
Total Less 2% (VSB < $1,000,000	**941,315**	**$2,063**	**$1,941,597,801**

c. Potential Underestimation of the Burden of Foodborne Illness

It is important to note that the estimates of the cost burden attributed to foods under the scope of this proposed rule on an annual basis may not provide a full accounting of all costs for several reasons. First, we only have detailed information on illnesses caused by pathogens, viruses, and toxins. We do not have detailed information on injuries that might be the result of physical contaminants in manufactured food products. We also do not have information on foodborne illnesses or conditions that would be result of chronic exposure to a food contaminant such as pesticide residues, where illness would likely only result over time. While we note that

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the controls established in this rule are intended to prevent these sorts of contamination, we are aware of no evidence that would indicate that these are significant problems at this time.

Secondly, our starting point, the FDA outbreak database, represents only illnesses where the cause of the food contamination could be directly linked to foods under the scope of this proposed rule. This creates a smaller than probable weighting factor when estimating FDA-regulated foods' share of total foodborne illnesses from the CDC outbreak database. In some instances foodborne illnesses in the FDA outbreak database that we did not use in the estimation (i.e., the problem was attributed to retail or in the household) may have actually had a root cause at the manufacturing level. For example, consumer mishandling of a product that led to the sufficient growth of bacteria in a food to cause illness could have been ultimately caused by food contamination (and the bacteria's survival) during processing. We are unable to determine how significant this confounder may be.

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Finally, the FDA outbreak database is limited to cases where the FDA got involved in the outbreak. Again, this creates a smaller than possible weighting factor for estimating the total FDA-regulated foods' share of illnesses from the CDC outbreak database; 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 tracebacks at the request of CDC and/or the state and local health authorities. While intrastate outbreaks may only be responded to by state/local authorities and may be reported to CDC, if the outbreak was not reported to FDA and FDA was not requested to assist state/local authorities with a particular outbreak, FDA will not have information on that particular outbreak in our internal database. Consequently, we assume that the proportion of illnesses attributable to FDA-regulated products is the same for outbreaks in

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which FDA's involvement is requested as it is in outbreaks for which FDA's involvement is not requested. Outbreaks associated with FDA-regulated foods under the scope of this proposed rule-making have an average of 103 illnesses while all outbreaks have an average of 20 illnesses. This could indicate that many of the smaller outbreaks, which are not associated with an identified food vehicle or pathogen, and thus excluded from our counts, could be attributable to FDA-regulated foods under the scope of this proposed rule-making. It could also be that FDA's presence is most frequently requested when an outbreak is likely to be traced to products that we regulated. However, we lack the information to make any definitive determination and request comment on our assumption.[22]

We continue to work on methodologies and gather data that would allow us to improve our estimates of the illnesses associated with FDA foods under the scope of this proposed rule-making, and thus the potential direct health benefits from this rule. We welcome all comments and data relating to human illnesses related to foods that will be covered by this proposed rule. We also welcome comments related to the methodology that we used to extrapolate the total number of illnesses and the total cost burden of those illnesses.

2. Reduced Foodborne Illness due to Implementation of the Rule

As described in the preamble in greater detail, this rule establishes requirements for food safety plans; hazard analysis; preventive controls (including process controls, sanitation controls, allergen controls, and recall controls); monitoring; corrective actions; verification; and recordkeeping (including documentation). We develop a conceptual framework for evaluating

[22] Scallan et al (Ref 3) includes multipliers to account for the underreporting of all foodborne illnesses diagnosed in the U.S. If we have the correct proportion due to FDA foods, their numbers would appropriately reflect the burden of FDA products. However, we may be identifying an artificially low portion of illnesses due to FDA products because we are missing information. Because we are missing information, this means we may be taking an artificially low percentage of Scallan's full characterization on illnesses, making our numbers potentially lower than reality.

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The industry-wide adoption of the proposed rule across the entire supplier, manufacturer, processor, packer, holder, and distribution chain should reduce the volume of misbranded and adulterated foods that put the public at risk, which should reduce the volume of foods that are recalled. The immediate effect of adopting better preventive controls might be that establishments change their practices in-process or catch more of their adulterated products already in the food chain, which might lead to an initial spike in the number of recalled products. We recognize that not all recalls are caused by the failure or the absence of importer controls and that human error will still occur. Pharmaceuticals, despite having more stringent supplier controls requirements, still have recalls, although most drug recalls are not caused by the failure of supplier controls. Over time, once better supplier controls have been adopted for a sufficient period, there should be a lower initial risk of adulteration, along with a greater chance of catching any adulterated products earlier, which should cause fewer and smaller food recalls.¶
As described in the preamble, FDA reviewed its food recall records for recall actions that were classified I or II for fiscal years 1999 through 2003 to identify those recalls that took place because of problems that could have been prevented by CGMP-type preventive measures such as proper equipment sanitation, adequate training of employees, review of product labels for accuracy and agreement with the product formulation, and adequate preventive maintenance of equipment (Ref. summary of recall data 1999-2003). FDA conducted a similar review 5 years later, for the period 2008-2009 (Ref. summary of recall data 2008-2009). From the results of these two reports, the second most common reason for such recalls was microbiological contamination (Ref. FDA Recalls Rpts). Approximately 17 percent of such recalls during 1999-2003 and 24 percent of such recalls during 2008-2009 were linked to microbiological hazards. During 2008-2009, the two most commonly implicated pathogens in such recalls were L. monocytogenes (9.9 percent) and Salmonella (7.6 percent). In the 2010 annual report on the Reportable Food Registry, the three main pathogens associated with the reports received by the RFR were Salmonella (31.6 percent), L. monocytogenes (17.6 percent), and E. coli O157:H7 (3.2 percent). ¶
We do not believe that product recalls will fall to ...

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the potential cases of foodborne illness that would be prevented as a result of implementing this rule.

Our conceptual framework attempts to organize the available evidence regarding the interaction between food manufacturing practices, the prevalence of and exposure to pathogens, and foodborne illness. To illustrate the linkage between rule-induced changes in food manufacturing practices and the expected corresponding decrease in the annual risk of foodborne illness, we first describe the major provisions of this rule that are expected to have the largest impact on foodborne contamination at the processor level. For these key provisions, we then estimate the expected increase in compliance and discuss where we expect most improvements to occur relative to baseline manufacturing practices. Finally, we examine the available evidence regarding the likely risk reduction to occur as a result of improved food safety measures that would decrease the prevalence of and exposure to pathogens in FDA-regulated foods under the scope of this rule.

a. Key Preventive Controls Expected to Reduce Foodborne Pathogens – Qualitative Benefits Assessment

For the purpose of this analysis, we refer to the results of an Eastern Research Group (ERG) study, undertaken as part of FDA's GMP modernization efforts, which was conducted to identify several broad categories of preventive controls that would be expected to generate the most public health benefit (Ref. 7). The study consisted of an extensive literature review and an expert elicitation (a formal approach to the acquisition and use of expert opinions, in the absence of or to augment available data) of current food safety problems and the range of preventive controls needed to address them. The experts consulted for this analysis are identified in Ref. 7.

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The ERG study first identified the most common microbiological, chemical, and physical safety hazards cited in the literature, from which the experts each made their own determination of what they thought were the most significant of the food safety problems and the foods most at high risk from these problems as part of their qualitative evaluation of risk. Based on the number of votes by experts who participated in the elicitation, "deficient employee training" (94%); "contamination of raw materials" (75%); "poor plant and equipment sanitation" (75%); and "poor plant design and construction" (75%), were ranked as the top four food safety problems faced by food manufacturers.

These results are also generally consistent with more recent findings of major food safety problems. FDA's review of recalls during 2008-2009, found that major contributing factors to food safety problems include: lack of label controls, lack of supplier controls, deficiencies in employee training, lack of sanitation controls, poor processing controls, and lack of environmental monitoring (Ref. 8).

The food safety experts who participated in the ERG study then recommended a range of preventive controls that could address most of the food safety problems faced by the food processing industry. The most frequently mentioned preventive controls with broad applicability across sectors and food safety problems are summarized in Table 5.

Table 5. Experts' Qualitative Assessment - Most Recommended Preventive Controls by Food Safety Problem

Most Common Food Safety Problem	Experts' Most Recommended Preventive Controls		
Deficient employee training	Audits (third-party or in house) In-house training Bilingual training Use video tapes for training and other visuals Documentation of training		

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	activities		
Contamination of raw materials	Supplier audits Supplier qualification/certification Raw material and product specifications Testing or inspecting raw materials Segregation of storage		
Poor plant and equipment sanitation	Training Audits (third-party or in-house) SSOPs Documentation of sanitation activities and procedures Sanitation evaluation and monitoring		
Poor plant design and construction	Audits (third-party or in-house) Fix problems and reconfigure plant design Use outside consultants or others specialized in plant design Contract out repair and design work Correct, reconfigure, or repair equipment		
No preventive maintenance	Preventive maintenance programs Audits (third-party or in-house) Records/documentation of maintenance Assign accountability		
Difficult-to-clean equipment	SSOPs Training Environmental sampling and testing Audits (third-party or in-house) Repair, replace, or return equipment		
Post-process contamination at manufacturing plant	Audits (third-party or in-house) Environmental sampling SSOPs Training		
Contamination during processing	Sanitation practices Audits (third-party or in-house) Training Segregation or processes, products, and storage HACCP Equipment maintenance		
Poor employee hygiene	Training Audits (third-party or in-house) Adequate facilities and equipment Automated handwashing and towel dispensers		

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- a.
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b.

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The proposed rule identifies "qualified" facilities that are not required to comply with Part 110 subpart C of the proposed rule. A qualified facility as defined by §418(l) of the FD&C Act is a facility that has revenues of less than $500,000 on average annually and sells more than 50 percent of its product to consumers, restaurants, and retail food establishments that are not more than 275 miles from the manufacturing site. Additionally there will be facilities that are qualified as the result of being a very small business as defined by FDA. Section §418(l) states that very small businesses as defined by FDA are qualified facilities for the purpose of this rule-making. FDA is proposing to define a very small business as one with less than $250,000 annually in sales. ¶
i. Number of Qualified Facilities ¶
Table 16 shows the facility breakdown by manufacturers, warehouses, and wholesalers for facilities that are qualified under § 418(l) of the FD&C Act , and facilities that are not qualified under § 418(l) of the FD&C Act. ¶
We were able to employ data from D&B to estimate the number of manufacturers, warehouses, and wholesalers that reported annual sales of below $500,000 annually and $250,000 annually; D&B data was also used to estimate facilities' employee numbers. We were able to use raw data received directly from the National Agricultural Statistics Service's (NASS) 2008 Organic Production Surv ...

Moved down [54]: shows the total food manufacturers count according to D&B data. Row 2 shows the number of these facilities that report less than $500,000 in annual sales. Row 3 adjusts the information from row 2 to estimate the number of facilities that have less than $500,000 annually in ...

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Table 16 - Food Manufacturers, Warehouses, and Wholesalers: Total Number of Facilities and Qualified and Non-Qualified Facilities Breakdow ...

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Baseline Food Safety Practices for Key Categories of Controls

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Table22: Complete Responses to the Survey, by Size Class and Industry Group ...

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Table 25- Annual Training Costs Summary ...

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We expect that benefits, in the form of reduced foodborne illness, due to rule-induced improvements in manufacturing practices, will be generated in areas where voluntary compliance with the rule's provisions may be relatively low and in food sectors where the risk of food safety problems may be relatively high. Most of the rule's provisions fall into the several broad categories of controls that were identified in the previous section. For these major categories of controls, we provide a general overview of expected changes in food manufacturing practices likely to occur as a result of the rule based on the findings from the most recent Food GMP survey Report (Ref. 9). Overall, we expect this rule will increase compliance, especially for small and medium-sized food processors covered by the safety requirements of the rule as large firms have voluntarily adopted many of the related practices already. A more detailed analysis of baseline practices can be found in the appropriate cost sections. We seek comment on the accuracy of the Food GMP Survey Report in capturing current food safety practices.

Process Controls

Across the domestic food industry, about 66 percent of facilities have HACCP systems, although this varies greatly by facility size. Ninety-seven to one hundred (97 to 100) percent of facilities with more than 100 employees have HACCP systems compared with about 82 percent and 42 percent for facilities with 20-99 and fewer than 20 employees, respectively. Although various third parties provide HACCP system certification, as noted in the literature, 41 percent of facilities with HACCP systems do not certify their HACCP systems using a third party or agency, and less than 16 percent of HACCP systems are certified by any one agency, demonstrating a lack of standardization among food manufacturers for HACCP system

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Moved down [94]: of training programs for reducing microbial product contamination or for reducing the cases of consumer illness caused by contaminated processed foods. Most of the available research assesses worker hygiene practices, worker attitudes, work motivation and worker knowledge pre- and post- training. The studies that we are aware of demonstrate that worker training contributes to, along with other factors, better knowledge of personal hygiene as well as better self-reported and observed food safety practices and behaviors.

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The effectiveness of sanitation operations varies i...

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certification and evaluation processes. In addition, only about one percent of facilities have ISO 9000 or 22000 certification. FDA requests that commenters provide data on similar statistics for foreign facilities.

Sanitation Controls

Overall, 78 percent of facilities have written procedures for cleaning their food-contact surfaces and, as we have seen for most food safety practices, larger facilities are more likely to have these policies in place.[31] However, regardless of whether or not a facility has a written plan, 43 percent of facilities clean food-contact surfaces after each production run, 19 percent perform cleaning at least twice per shift and 25 percent clean food-contact surfaces daily (Ref. 9). Comments received also indicated that many facilities have variable cleaning schedules depending on the type of food, equipment, surfaces, and other factors.

Recordkeeping

[31] In this context, "cleaning" refers to surfaces that are visually free of dust, dirt, food residues, and other debris .

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Deleted: verify the efficacy of their sanitation operations (Ref. Blackburn and McClure, 2002). These activities impose a cost on facilities that do not already perform them. ¶
Sanitation workers should be trained before they start work at a food facility and they should receive at least annual refresher training. Training in the use of sanitation operations typically includes chemical safety and job specific training in the written procedures for which they are responsible. While some facilities use dedicated sanitation employees, in other facilities, much of the cleaning is performed by line operation personnel (Ref. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010). ¶
We believe the costs to facilities to comply with this section will be to those qualified manufacturing facilities that are not subject to proposed subpart C §110.135(d)(3) for training their employees in the proposed requirements for their sanitary operations, processes and controls. The impact to manufacturing facilities that are subject to subpart C §110.135(d)(3) sanitation controls are addressed in our section for sanitation controls. We estimate that the cost to the qualified facilities will be for training their employees in the proposed sanitation operations, processes and controls as described in the revised subpart B.¶
To estimate the costs we first determined the number of qualified manufacturing facilities. Our Table 17 identifies all facilities covered by the proposed rule, including qualified facilities. We estimate that it will take two hours per year for qualified manufacturing facilities to train their employees in the proposed ...

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Recordkeeping ensures that the processes and actions taken in the plant, such as sanitation and employee training, are documented so as to verify that they take place. As facilities increase in size, their tendency to maintain records increases. More than 99 percent of facilities with more than 500 employees maintain all the records that will be required. Most facilities with 100 to 499 employees (77 percent or more) maintain every type of record. Sixty-nine (69) percent or more of facilities with 20 to 99 employees maintain every type of record. In comparison, 42 percent or more of facilities with fewer than 20 employees maintain every type of record.

c. Effectiveness of Preventive Controls in Foods under the Scope of this Proposed Rule-Making

We do not expect that this proposed rule will eliminate the entire almost two billion dollars' worth of foodborne illness attributed to FDA-regulated foods under the scope of this proposed rule-making. Instead, we expect the new, improved proposed approach to food safety will prevent some portion of this illness burden from recurring. The effectiveness of this regulation and the corresponding reduction in food contamination and foodborne illness will depend on how successfully preventive controls address the sources of contamination and how well the controls are implemented.

We expect that components of the rule would work together as part of an interrelated system to reduce the risk of food contamination. (The rule also functions as one component of several food safety regulations required by FSMA.) Some of the rule's individual provisions may be partial substitutes for one another, while others complement each other. Although the

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activities required by the rule are distinct, the effects of each action are related. We lack sufficient data to estimate the likely risk reduction from the individual provisions, or from the rule as a whole. In addition, unobserved factors influencing how successfully the rule's provisions would be implemented, such as the attitude and commitment of management and employees, may vary across covered food facilities. These and other confounding factors make estimating the reduction in foodborne illness highly uncertain.

To quantify the risk reduction, representative sample data across the range of food products in the market place would be needed to analyze how much change in the prevalence and level of pathogens (e.g. measured as a change in pathogen load per serving) could be attributable to any specific intervention or group of actions. We expect this rule to reduce the prevalence and concentration of pathogens at the end of processing through improvements in manufacturing practices, which would lower the average risk of foodborne illness. However, isolating the effect of this rule on the risk of illness would be difficult because of potential changes in the prevalence of and exposure to contaminated food products between the end of production and the point of consumption, due to changes in factors that are outside the scope of this rule that would also impact the probability of foodborne illness.

Typically, complex models are used to describe the manufacturing process and distribution chain to show how contamination levels change over a food pathway from production to the point of consumption. The concentration of the food pathogen changes during the processing, transport, storage, and meal preparation, making it difficult to estimate the number of the microorganisms or the concentration of their toxins at the moment of ingestion by the consumer. In addition, the number of microorganisms can change as a result of physical moving, mixing of the food ingredients, partitioning of a food product, or cross-contamination.

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These factors affect microbial growth, survival, and inactivation and must be considered when assessing the exposure to a microbial hazard.

Apart from the frequency and levels of contamination, consumer exposure to pathogens would also depend on the frequency of consumption of the food. There is also variability in human response to an exposure to foodborne pathogen, in terms of duration and severity of illness. Factors affecting the variability in the extent of disease include virulence characteristics of the pathogen, the general health and immune status of the consumer, and attributes of the food that may alter microbial or host status.

If we had data that would allow measuring the changes in the prevalence and concentration of pathogens that would occur because of improved food manufacturing practices, then we could potentially estimate changes in the probability of illness. One approach would be if we had dose-response models for specific pathogen-commodity combinations then we could describe the interactions between all these factors, and extrapolate predicted changes in the probability of illness (typically, per serving) that would result from a change in exposure. Multiplying the change in risk per serving by the number of servings per year, if known, would yield the change in annual risk for a particular pathogen-commodity combination.

If data were available on the size of the exposed population, we could estimate the number of foodborne illnesses that would be prevented by multiplying the change in annual risk by the number of potentially exposed people. While this method, with the necessary data and inputs, would allow quantification of prevented cases of foodborne illness, there would still be considerable uncertainty in estimating changes in risk due to confounding factors that could not be accounted for, as discussed.

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There are a number of dose-response models available in the literature, but they are not standardized or generalizable to all the pathogen-commodity combinations affected by this rule. The existing dose-response models all rely on data either from feeding trials or outbreak data. We believe it is not appropriate to extrapolate the findings from these models to the general food-eating public. For certain pathogen-commodity combinations that may not be representative of the FDA-regulated foods under the scope of this rule, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have undertaken microbial risk assessments with the objective of providing tools and data to inform food safety risk management strategies. In the following section, we provide relevant findings about the risk assessments for *Salmonella* and *L.monocytongenes*, which may suggest that decreasing microbiological contamination through changes in food manufacturing practices as result of this rule could reduce the risk of foodborne illness attributable to FDA-regulated foods under the scope of this rule.

Salmonella

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The risk assessment of *Salmonella* in eggs and broiler chickens finds that reduction in the prevalence of *Salmonella*-contaminated chicken was associated with a reduction in the risk of illness, (Ref. 10). They estimate a one-to-one relationship, with a given percentage change in prevalence, assuming everything else remains constant, reducing the expected risk by a similar percentage. For instance, a 50% reduction in the prevalence of contaminated poultry produced a 50% reduction in the expected risk of illness per serving. Similarly, a large reduction in prevalence from 20% to 0.05% would produce a 99.75% reduction in the expected risk of illness.

If management strategies are implemented that affect the level of contamination, i.e. the numbers of *Salmonella* on chickens, the relationship to risk of illness is estimated to be greater than a one-to-one relationship. A shift in the distribution of *Salmonella* cell numbers on broiler

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chickens exiting the chill tank at the end of processing, such that the mean number of cells is reduced by 40% on the non-log scale, reduces the expected risk of illness per serving by approximately 65%.

Listeria

As part of the risk assessment on *L. monocytogenes* in ready-to-eat (RTE) foods, the scope of the study was limited to retail and post-retail factors that could impact the risk to consumers for selected foods: milk, ice cream, smoked fish, and fermented meats, (Ref. 11). Comparing the annual number of illnesses per population across various countries suggests that differences in manufacturing and handling practices may affect the contamination pattern and therefore the risk of illness per serving.

d. Review of Studies on Preventive Control Effectiveness

In the absence of representative data to estimate potential cases of foodborne illness prevented, the experience of implementing food safety management systems in other food sectors that follow much the same approach may provide a general idea of the changes in the risk of foodborne illness to be expected as a result of this rule. While the risk of foodborne illness is the primary outcome of interest, we also provide the available evidence from studies that assess effectiveness in terms of other outcome measures, including rejected lots, recalls, and contamination levels, as intermediate indicators. Although it is uncertain whether these studies can be generalized to predict effectiveness for FDA-regulated foods under the scope of this rule, the studies discussed below suggest that this rule would on average decrease the risk for foodborne illness.

i. Foodborne Illness

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Mumma et al. (2004) evaluated the reduction in the incidence of *S.* Enteritidis from eggs as a result of the Egg Quality Assurance Programs (EQAPS) using regression analysis (Ref. 12). The analysis found that a 1 percent increase in the number of eggs produced under an EQAP was associated with a 0.14 percent decrease in *S.* Enteritidis incidence ($p < 0.05$). However, Mumma et al. (2004) also noted that they assumed that eggs produced in one state are used to meet the consumption needs of that state, and therefore changes in *S.* Enteritidis incidence within the state would reflect the effect of the state's EQAP; however, this assumption might not be accurate.

ii. Rejected Lots

We identified a study that discusses the effects of HACCP in reducing the number of rejected product lots (Ref. 14). Specifically, Cormier et al. (2007) studied the effect that HACCP implementation had on the contamination of ready-to-eat (RTE) lobster and shrimp and found that the implementation of HACCP-based programs minimized the probability of finding *L. monocytogenes* in both products. The non-compliance rate for *L. monocytogenes* in RTE lobster dropped from a variable 5 to 30 percent before 1997 to remain fairly consistent at about 5 percent after HACCP implementation. In shrimp, the non-compliance rate for *L. monocytogenes* dropped from varying between about 5 and 37 percent before 1994 to remain fairly consistent at about 0.1 percent after HACCP implementation.

iii. Contamination Levels

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Numerous studies evaluate contamination and hygienic performance in plants pre- and post-HACCP. Using samples collected pre- and post-HACCP implementation in 1998 and 1999, the Food Safety and Inspection Service (FSIS) analyzed the change in contaminated broilers, swine, steers and heifers, cows and bulls, ground beef, ground turkey, and ground chicken. Results showed reduced contamination as a result of HACCP, with 88 percent of plants with

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complete data sets meeting their respective *Salmonella* performance standards (Ref. 15). Some notable reductions in contamination were:

- *Salmonella*, found on 20 percent of broiler carcasses in pre-HACCP baseline studies, was found on 10.9 percent of broiler carcasses after the first year of HACCP implementation.
- For swine, *Salmonella* was found on 8.7 percent of carcasses in pre-HACCP baseline studies, and 6.5 percent of carcasses after HACCP implementation.
- In ground beef, *Salmonella* was found in 7.5 percent of samples in pre-HACCP baseline studies, and 4.8 percent of samples after HACCP implementation.
- In ground turkey, *Salmonella* was found in 49.9 percent of samples in pre-HACCP baseline studies, and 36.4 percent of samples after HACCP implementation.

Implementing HACCP also significantly improved the hygienic performance at a Korean pork plant (Ref. 16). Measured using Aerobic Plate Counts (APCs), the proportion of samples exceeding the 3 log CFU/cm2 limit dropped from 73.39 to 4.29 percent following HACCP implementation.

Kokkinakis et al. (2008) examined the microbiological quality of the final product and the safety of the production procedures in an ice cream factory, pre and post-implementation of a HACCP system. Post-HACCP introduction, *Staphylococcus aureus* was undetectable in ice cream and *Escherichia coli* was less than 10 CFU/g in most samples. The levels of spoilage markers (total coliforms – TC, aerobic plate counts – APC) in the ice cream and the environment dropped by 20 to 35 percent (Ref. 17).

v.*Food Safety Plans*

The social benefits of food safety plans are that they require facilities to increase their

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focus on food safety by collecting in one place all the procedures that will be implemented to control the hazards in a facility. With the use of food safety plans, facilities can better assess the totality of their food safety activities that are often interconnected, establish facility-wide worker expectations and train their employees in their food safety procedures, all of which in turn will help reduce the health cost to the consuming public. The use of food safety plans will also reduce the time and effort that food safety inspectors and auditors will need to determine whether the facilities' procedures that are in place are sufficient. The time to inspect or audit a facility should be reduced and the completeness of the inspection or audit should improve because the food safety plans, recordkeeping, and other documentation will be more comprehensive and will more readily show whether the facility is in compliance or not with the requirements of Federal food safety rules.

Most of the academic and trade literature that addresses the use and benefit of plans addresses the use of HACCP plans, which can be similar to food safety plans. Both types of plans include at least a hazard analysis and the procedures for the preventive controls or critical control points to address the hazards that are identified as reasonably likely to occur. Food safety plans often include additional elements such as Sanitation Standard Operating Procedures (SSOPs). Food safety management systems (FSMS), especially as required for ISO 22000,[32] are often addressed in the academic and trade literature and can also be similar to food safety plans, although FSMS are often more comprehensive and include product quality requirements.

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[32] ISO 22000 is a Food Safety Management System developed by the International Organization for Standardization (ISO). ISO created the very successful quality management system standard ISO 9001, which was then revised to add a focus on food safety management which includes HACCP principles (ISO 22000).

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Codex notes that the effectiveness of HACCP plans depend on the knowledge and skills of the management and employees, which can be enhanced through training (Ref. 24). The literature shows that the plans are important in part because they are integral to training and educating a HACCP team (Refs. 25, 26, and 27). None of the studies provided quantitative measures for the effectiveness of HACCP plans, the effect that HACCP training has on the effectiveness of HACCP plans, or the effect of the use of and training for FSMS. Codex also notes that a HACCP team, which is assembled to develop the HACCP plan, should have the appropriate product specific knowledge and expertise for the development of an effective HACCP plan and recommends that if no employees have such knowledge, then expert knowledge should be sought on the outside.

vi. Hazard Analysis

Several studies have investigated the effectiveness of HACCP programs, all or almost all of which provide an endorsement for HACCP programs, but none of which systematically quantify the health or other benefits of HACCP programs or the cost-effectiveness of HACCP programs. These studies provide insight into the baseline, practices and assumptions of the food industry and helped us form our assumptions about the impact of HACCP programs. Most of the studies are case studies of short duration of individual facilities or small groups of facilities, so

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we could not generalize from the results. To our knowledge, no studies look at just the effectiveness of a hazard analysis independently of and without the other steps that are required of HACCP programs. Some HACCP studies focused on the implementation of HACCP programs in specific food manufacturing sectors, including seafood, fermented maize, meat lasagna, and turkey. Other studies are more general in their focus, addressing all food sectors. In general, the studies showed that HACCP programs, when conducted in conjunction with other food safety programs, such as GMPs and SSOPs enhance the food manufacturing industry's ability to ensure the microbiological safety of foods (Refs. 25 through 36).

Several studies examined the effectiveness of a HACCP plan on the microbiological safety of final food products. Amoa-Awua et al (2007) found that implementing a HACCP program resulted in no microbiological contamination and lowered aflatoxin levels of fermented maize (Ref. 29). Martins and Germano (2008) showed that HACCP programs enabled a meat lasagna operator to manufacture products that met country-level and company microbiological standards for mesophiles and faecal coliforms (Ref. 30).

Lupin et al (2010) compared three case studies of fish processing plants in Latin American countries to assess the economic feasibility of HACCP programs for the industry. The authors showed that over a three year period following the implementation of HACCP, the facilities reduced their total quality costs by significantly reducing the quantity of rejected finished fish products, while also implicitly improving the safety of their finished fish products (Ref. 31). Zugarramurdi et al (2007) developed a model to estimate the total quality costs of adopting a HACCP program and used it to compare the predicted costs of the model with case study costs using a frozen fish processing plant in Argentina as an experimental control. The authors determined that HACCP is cost effective and socially beneficial because it reduced the

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plant's defective and potentially hazardous fish products (Ref. 32). In a case study of the application of HACCP to a U.S. food processing plant, the authors used ultrasound techniques that can alter the physical and chemical properties of foods to show that HACCP can be used for product safety when traditional quality control methods are inadequate to control hazards (Ref. 33).

A common theme in the HACCP literature is that small food facilities often lack the technical expertise to conduct a hazard analysis and more generally misunderstand the risks from their products, the technical requirements to control the hazards, or they lack the financial means to adopt HACCP programs (Ref 35). Maldonado *et al* (2005) (Ref. 34) looked at the level of HACCP implementation for the Mexican meat industry by surveying a representative sample of manufacturers. The survey asked respondents for their self-assessment of the costs and benefits of implementation of HACCP. The major costs according to the respondents are for investment in new equipment and for retraining production and supervisory staff; while the major benefits are reduced product microbial counts and a better ability to attract new customers that want greater assurance of safe foods. In another survey that looked at the adoption of HACCP in small food facilities, Taylor (2001) asked whether HACCP is a benefit or burden. Taylor noted that surveys conducted in Europe and the UK in the 1990s showed that small food operations are less likely to adopt HACCP than large food operations, a result that is consistent with our Food GMP survey result (Ref 35).

Panisello and Quantick (2001) also investigated the barriers that prevent manufacturers from implementing HACCP programs. They found that smaller manufacturers underestimate the risks of current food safety control systems and their misperception impedes their implementation (Ref. 27). They, like Taylor, found technical or knowledge barriers prevent

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some companies from implementing HACCP programs. Some food manufacturing sectors have specifically designed HACCP plans that facilitate adoption of HACCP, such as the seafood industry, which help overcome technical barriers, whereas other sectors lack such aids. Some types of food products require more critical control points, thereby complicating the implementation of HACCP and making it more costly to adopt HACCP. Companies that implement HACCP as required by their customers will also be more likely to be regularly audited by their customers.

Panisello and Quantick also noted that even after companies have implemented HACCP, difficulties can still present themselves during implementation. Manufacturers may not have the leadership and staff commitment to execute the system properly. Paperwork requirements might be costly for some manufacturers, resulting in inadequate documentation. Others might not have the necessary equipment and plant layout to support HACCP requirements, such as monitoring of critical control points. Ropkins and Beck (2002) found that HACCP is unlikely to be a good approach to controlling chemical hazards because of certain technical barriers. They noted that high analytical monitoring costs and limited understanding of how to control chemical contamination are obstacles to effective implementation for chemical hazards (Ref. 36).

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Moved down [117]: *Food Manufacturing* magazine (Market Update, 2008) also provides an annual update on the state of HACCP in the industry. Their summary published in October 2008, reported that 80.7 percent of the HACCP plans address physical hazards and 72.9 percent address microbiological contaminants

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vii. *Process Controls*

The benefit of process controls, along with the benefit of equipment calibration, and monitoring and verification when performed together, help to ensure the effectiveness of the preventive controls. Their use, as determined by scientific evidenced-based control practices, permits more effective control of hazards over extended periods. The use of just a small number of critical controls helps ensure a safe product yet allow for relatively inexpensive monitoring in food facilities. However, we are not aware of studies about just the effectiveness of process

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Table 29- Estimated Costs to Annually Update the Hazard Analysis by Facility Size ...

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Process controls would be required to include when applicable, the maximum or minimum value or combination of values that are necessary to control the select hazards identified in the hazard analysis. Maximum or minimum values are the range of values or limits in which process controls are ...

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controls in the absence of the other provisions of HACCP.

viii. *Allergen Controls*

The benefits of preventing cross-contact are to help prevent the unintentional spread of allergenic ingredients to products where they are not declared on the food label. Examples of allergen controls include putting raw materials and ingredients for a specific batch on a pallet prior to moving them to the processing area, or "staging," to help reduce the risk of cross-contact and cross-contamination during transit through the facility.

There are practices that have been effectively used by some to prevent cross-contact. Line clearance, such as removing all the raw materials and ingredients from the production area and checking for cleanliness, can help reduce cross-contact and allergenic cross-contamination (Ref. 37). However, there is very little in the literature that demonstrates the efficacy of allergen control "best practices."

ix. *Recall Controls*

Recall procedures that are fast, thorough, predictable, and precise help reduce the social impact of recalls by enabling establishments to quickly pinpoint where in the manufacturing, supply or distribution chain the problem originated to more quickly remedy the situation before injuries occur. There is anecdotal evidence in the literature on recalls that good recall control procedures can limit the economic harm from recalls for adulterated foods.

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In response to a recall of 270 pounds of ground beef in late January of 2002, Montana Quality Foods began keeping specific records to show the origins of meat used in ground beef and holding processed meats in storage until government test results were received. Changes in their recordkeeping procedures helped Montana Quality Foods when they learned of the results of three tests showing *E. coli* contamination and their new records showed that the meat

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originated from another firm. The meat had not yet been distributed so the company was able to avoid a recall. (Refs. 38, 39) Lack of good recall preparedness, on the other hand, can seriously limit the effectiveness of a recall. FDA's search for the source of green onions that caused 950 people to contract hepatitis A in 2003 was impeded by poor procedures by a vegetable middleman (Ref. 40).

x. *Recordkeeping*

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Recordkeeping is an important mechanism for the accurate assessment of the effectiveness of the food safety plan to assure the owners, operators and agents that the safety measures are working in the production facility and throughout the supply and distribution chain. Recordkeeping also supports regulatory compliance and reduces the legal costs from adulterated and unsafe food products (Ref. 41).

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E. Economic Analysis Costs: Overview of Cost Conventions and Facilities Covered

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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, Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates, under NAICS 311000 - Food Manufacturing; http://bls.gov/oes/current/naics3_311000.htm (Ref. 42) Wages are increased by 50 percent to account for overhead.

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a. Qualified Individuals Mean Wage Rate: Qualified individuals are the persons who have completed training in the development and application of food safety systems or are otherwise qualified through job experience to develop or apply a food safety system. We use two estimates of a wage rate for a qualified individual in this analysis depending on the specific task the individual is performing. One wage estimate is that of a General and Operations manager earning a mean hourly wage of $52.76; we add 50 percent for fringe benefits and other overhead costs ($26.38) for a total estimate of $79.14. The second wage estimate is that of an Industrial Production Manager with a mean hourly wage of $40.96; we add 50 percent for fringe benefits and other overhead costs ($20.48) for a total estimate of $61.44.

b. Industrial Production Manager Mean Wage Rate: Our estimate for the mean hourly wage rate for Production Managers is $61.44 including fringe benefits and other overhead. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate for General and Operations Managers working in the food industry as shown in NAICS code 311000, Food Manufacturing in 2010 of $40.96 and we add 50 percent for fringe benefits and other overhead costs ($20.48) for a total estimate of $61.44. We use this wage rate throughout the analysis when a wage rate for a production manager is needed.

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c. Trainers Mean Wage Rate as Qualified Individuals: Our estimate for the hourly wage rate for trainers is based on our estimate for the hourly wage rate for qualified individuals. We use the mean wage rate for qualified individuals because facilities are most likely to either use industrial production managers as

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their trainers or to contract for outside workers with the same necessary skills. We believe the hourly wage rate for qualified individuals is a reasonable approximation for the opportunity cost of hiring trainers to conduct the training tasks. We ask for comment about our estimate.

d. Food Manufacturing Production Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for food manufacturing workers (non-supervisory) is $19.91 including fringe benefits and other overhead. We derive our estimate from the Bureau of Labor Statistics mean hourly wage rate in the food industry as shown in NAICS code 311000, Food Manufacturing in 2010, Team Assemblers 51-2092 of $13.27 and we add 50 percent for fringe benefits and other overhead costs ($6.64) for a total estimate of $19.91.

- Information from the Food GMP survey is used where possible to create estimates of the rates of specific food safety practices currently being undertaken by food manufacturing facilities (Ref. 9). Whenever we summarize our survey results, the results of the survey are for the entire domestic food industry, including those facilities that are exempt from the hazard analysis and risk-based preventive control requirements. We assume that the percentage of respondents that already perform the proposed provision will be the same whether the facility is exempt or not. For instance, if our survey showed that 42 percent of facilities with fewer than 20 employees have HACCP, then we assume that 42 percent of both the exempt and nonexempt facilities will have HACCP. We request that commenters supply data on similar statistics for foreign facilities.
- We use Dun & Bradstreet's (D&B) global business database to derive the estimate of the number of domestic facilities that will be covered by the proposed rule. D&B provides

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information for millions of U.S. and international public and private businesses. Virtually all active businesses in the U.S. register with D&B to obtain a DUNS number because it is required for credit reporting and other business transactions. Company records in the D&B database include company address, type of ownership, primary and secondary Standard Industry Classification (SIC) codes, number of employees, sales volume and other relevant business data. (Ref 6)

- Where necessary we have adjusted facility counts from D&B using the 4 digit SIC codes and 8 digit SIC codes to include or eliminate facilities as needed. For example, for the category Frozen Fruits, Juices & Vegetables, we have examined the facility count at the 8 digit SIC code level to eliminate any juice facilities that would not be subject to this rule. Other industry categories whose facility counts have been adjusted include: Crop Preparation, Except Cotton Ginning and Animal, Marine Fats & Oils. Other partial industry categories have been used in specific areas of the analysis where it is likely not all facilities under a particular 4 digit SIC code may need to implement a particular rule requirement.

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- We use FDA's Operational and Administrative System for Import Support database, U.S. FDA, internal data query, OASIS 2010 (OASIS), (Ref 43) to estimate the number of foreign facilities that will be covered by the proposed rule.

- We annualize any one time costs over 7 years at a 7 percent discount rate and at a 3 percent discount rate consistent with OMB's basic guidance on the discount rate provided in OMB Circular A-94 (http://www.whitehouse.gov/omb/circulars/index.html). (Ref. 44) 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

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years for our horizon for discounting (our time-preference), based on the IRS allowable recovery periods for manufacturers of foods as shown in IRS publication 946 (Ref. How to Depreciate Property, Table B4 Row 20.4 http://www.irs.gov/pub/irs-pdf/p946.pdf .) (Ref. 45) 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 food industry. We ask for comment on the use of 7 years as our time-preference.

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- We use information from three expert elicitations to help estimate costs of the proposed rule:
  a. Foreign Food GMPs – Expert Elicitation Results – September 3, 2009 (Ref. 46)
  b. Economic Analysis of New FDA Food cGMP Regulations and Related Legislative Initiatives – Subtask 2: Expert Opinions on Current Food Manufacturing Practices – June 30, 2010 (Ref. 47)
  c. Economic Analysis of New FDA Food cGMP Regulations and Related Legislative Initiatives – Subtask 3: Expert Opinions on Current Food Manufacturing Practices of Distributors/Consolidators/Wholesalers and Packers of Produce and Processed Foods – September 17, 2010 (Ref. 48)
- We estimate that all facilities operate 50-52 weeks per year.

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- We use Table 3-1:[33] Typical Food Manufacturing Facility Characteristics, from Evaluation of Recordkeeping Benefits for Food Manufacturers, Final Report, March 30, 2007 (Ref. 49) in creating estimations of number of products produced by facility,

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[33] Our contractor, Eastern Research Group (ERG) provided us with extrapolations for extra large facilities.

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number of manufacturing processes, number of raw material and ingredient suppliers, and number of production lines by food industry sector. Estimates in this table are based on expert opinion.

- To estimate the recordkeeping costs, the time to perform the various recordkeeping functions, the frequency of recordkeeping by record type, and the average minutes spent keeping records by record type, we relied upon FDA's Evaluation of Recordkeeping Costs for Food Manufacturers, a recordkeeping cost model that was developed for FDA. The model was used to estimate the costs for a variety of recordkeeping activities that were needed for several previous food safety related rules (Ref. 50). The basic method of the model for estimating the average recordkeeping cost is to multiply an estimate for the average time it takes to prepare a record which is usually the time it takes to document a food safety action, by the average wage rate of the workers that are doing the recordkeeping.

- To estimate the hours necessary to develop written procedures and the hours necessary to update the written procedures annually, we use Tables 2-4 through 2-10 from FDA's Evaluation of Recordkeeping Costs for Food Manufacturers. Estimates in these tables are based on expert opinion (Ref. 50).

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- The main cost analysis focuses solely on the costs of the proposed rule to domestic facilities that manufacture, process, pack, or hold human food. We discuss impacts of this proposed rule on foreign facilities that manufacture, process, pack, or hold human food for consumption in the U.S. in section E.9.

2. Coverage of the Analysis

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a. All Facilities

The coverage of this rule is for all facilities required to register with FDA under section 415 of the FD&C Act with the exception of facilities exempted as dictated in §117.2 of the proposed rule. We estimate that 97,646 domestic and 109,190 foreign facilities will be covered by the rule as shown in Table 6. We consulted several sources to derive our estimate of the number of domestic and foreign facilities used in our analysis. Our estimate of the number of domestic facilities includes all FDA-regulated food establishments, warehouses, and fruit and vegetable wholesalers (which includes fresh-cut processors) operating in the fifty states, the District of Columbia, as well as the U.S. territories. The 109,190 foreign facilities include every facility that would be covered by this proposed rule that has shipped food or raw materials and ingredients to the U.S. in FY2010. Foreign facilities that import to the U.S. must satisfy all the requirements of this rule.

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Included in the total number of domestic facilities covered by the rule are 1,673 farms that are also food processors under the definitions of this rule. Farms that are also processors are referred to as mixed-type facilities. Of those, 736 would be qualified facilities using a definition of very small business of annual revenue of less than $250,000. The total number of mixed-type facilities covered by the food safety requirements of the rule is 937 using a definition of very small business of annual revenue of less than $250,000, 770 using a definition of very small business of annual revenue of less than $500,000, or 446 using a definition of annual revenue of less than $1 million. This rule clarifies and redefines which facilities would need to register with FDA under section 415 of the FD&C Act. A significant number of farms that were previously required to register would no longer need to register. For example, farms would no longer need to register just because they a) apply waxes, oils or resins to the raw agricultural commodities

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that they grow, b) fumigate the nuts that they grow in order to prevent insect infestation and damage, and c) use pesticides when washing the raw agricultural commodities that they grow. However, farms that dry the herbs that they grow would need to register, whereas they did not have to register in the past. We do not have data that would allow us to estimate the change in the number of farms that will register and stop registering. However, given the relative frequency of the application of waxes, oils, and resins; the use of pesticides when washing; and fumigation to prevent insect infestation and damage relative to the frequency of drying herbs, FDA believes that there will be no net change in the number of facilities that would need to register with FDA under section 415 of the FD&C Act. Therefore, we have not estimated any costs for these changes to which farms would need to register. We request comment on this issue.

We use D&B global business database derived estimate of the number of domestic facilities throughout our analysis.[34] The D&B database contains the most frequently updated data available and provides specific information necessary for the analysis, such as per facility number of employees and type of ownership.

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To estimate the number of foreign facilities covered by the rule, we use FDA's OASIS database, which collects information on all importers of FDA-regulated products into the U.S.[35] Our estimate is based on the OASIS data collected from fiscal year 2010.

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[34] We also consulted FDA's internal database of facilities that have registered with the Food Facility Registration Module (FFRM) in accordance with the Bioterrorism Act of 2002. All domestic and foreign facilities that manufacture, process, pack or hold food for consumption in the United States must biennially register with FDA. unless exempted (e.g., restaurants). The FFRM database lacks important facility-specific information including the number of employees that work at each facility and the type of each facility's ownership.

[35] We used the OASIS database rather than the D&B database to estimate the number of foreign facilities, because D&B does not identify where a facility's final products are sold. Although the D&B database is comprehensive, we cannot know from the D&B database whether a foreign facility actually manufactures, processes, packs or holds food that will be exported to the U.S. This leads to a large overestimate of foreign facilities that actually export goods to the United States. To be registered by OASIS, a facility must have physically shipped goods into the U.S.

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Table 6 - Number of Domestic and Foreign Food Facilities Covered by the Proposed Rule

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total	Foreign Facilities
Number of Food Manufacturers	54,206	9,389	3,948	453	67,996	
Number of Warehouses	6,896	880	157	15	7,948	
Number of Wholesalers	19,373	2,014	306	9	21,702	
Total	80,475	12,283	4,411	477	97,646	109,190

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In Table 7 we have broken down the types of domestic facilities to be included in our analysis based on whether their 4 digit SIC code classified them as what we consider a food manufacturer, food warehouse, or food wholesaler. What we considered a food manufacturer by 4 digit SIC code can be seen in further detail in Table 7. We have classified facilities by their primary manufacturing, processing, packing or holding SIC code. We did not attempt to also classify facilities by any secondary, tertiary, etc. SIC code. To do so would have over-counted the total number of facilities that would be subject to this proposed rule. Only counting facilities by their primary manufacturing, processing, packing, or holding SIC code may mean that some costs of this proposed rule-making to the facility as a result of conducting business in multiple product lines (multiple SIC codes) may not be included (e.g. a facility whose primary business is in crackers but they also manufacture bread). However, these costs that are not included are likely trivial compared with the proposed rule costs that would have been associated with over-counting the total number of facilities (e.g. over-counting the number of hazard analyses that needed to be conducted).[36]

[36] If a facility manufactured two products and the hazards were the same in the products produced and the production process was the same for the types of products, then it could be that only one hazard analysis would need to be conducted, and other procedures would be similar. Given that the facilities are divided according to product category (primary product) produced, we assume that economies of scale are present for the facility to complete the

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We classified food warehouses as those facilities who identified themselves under SIC code 4221-Farm Product Warehousing and Storage and SIC code 4222-Refridgerated Warehousing and Storage. For food wholesalers we include SIC code 5148-Fresh Fruits and Vegetables; these are facilities that consolidate and pack fruits and vegetables and sell them wholesale. Many fresh-cut produce facilities identify themselves under the SIC code for Fruit and Vegetables wholesale. We break out these facilities with assistance from the Blue Book Online Services, which has detailed information on fresh-cut produce facilities (Ref. 51)

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It is important for us to distinguish fresh-cut facilities from other fruit and vegetable wholesalers because of the greater manipulation of the produce by a fresh-cut facility rather than a wholesale establishment (e.g., more food contact surfaces due to cutting, chopping, etc. of produce item). A warehouse or wholesale establishment that may not have much, if any, product exposed to the environment will have fewer provisions to comply with or comply in less detail than fresh-cut facilities.

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Table 7- Number of FDA-Regulated Domestic Food Facilities Subject to this Proposed Rulemaking Partitioned by 4 Digit SIC Code

SIC Code	SIC Description	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
723	Crop Preparation, Except Cotton Ginning	3,453	650	210	18	4,331
2015	Small Game Processing	98	13	6	5	122
2021	Butter	139	36	12		187
2022	Cheese	842	350	146	11	1,349
2023	Milk, Condensed & Evaporated	436	138	51	9	634
2024	Ice Cream	3,251	271	97	8	3,627
2026	Milk	975	365	287	18	1,645
2032	Canned Specialties	1,365	198	68	23	1,654
2033	Canned Fruits, Vegetables & Preserves	1,306	322	183	24	1,835
2034	Dried Fruits, Vegetables & Soup	594	106	59	5	764
2035	Pickled Fruits, Vegetables, Sauces & Dressings	1,357	186	85	6	1,634

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2037	Frozen Fruits, Juices & Vegetables	384	124	91	22	621
2038	Frozen Specialties	1,118	343	173	26	1,660
2041	Flour, Grain Milling	886	295	77	1	1,259
2043	Cereal Breakfast Foods	321	69	46	8	444
2044	Rice Milling	222	62	27	1	312
2045	Flour, Blended & Prepared	325	92	38		455
2046	Wet Corn Milling	288	46	24	8	366
2051	Bread, Bakery Products Exc Cookies & Crackers	9,462	1,215	540	45	11,262
2052	Cookies & Crackers	2,118	253	131	32	2,534
2053	Frozen Bakery Products	266	66	56	10	398
2061	Sugar, Cane	73	24	14	2	113
2062	Sugar, Cane Refining	126	15	14	4	159
2063	Sugar, Beet	98	19	25	5	147
2064	Candy & Confectionery Products	3,780	292	125	21	4,218
2066	Chocolate & Cocoa Products	1,129	90	40	8	1,267
2067	Chewing Gum	61	4	15	5	85
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2074	Cottonseed Oil Mills	82	25	7		114
2075	Soybean Oil Mills	192	82	22	3	299
2076	Vegetable Oil Mills	134	22	6		162
2077	Animal, Marine Fats & Oils (Marine Only)	659	134	66	3	862
2086	Soft Drinks	5,207	1,228	522	51	7,008
2087	Flavoring Extracts & Syrups	1,125	250	60	3	1,438
2095	Coffee	1,056	136	49	1	1,242
2096	Potato Chips & Similar Products	852	244	94	24	1,214
2097	Ice	1,278	175	1		1,454
2098	Macaroni, Spaghetti & Noodles	766	83	39	4	892
2099	Food Preparations, NEC	7,921	1,207	380	31	9,539
2869	Industrial Organic Chemicals, NEC (Food Additives)	219	80	34	3	336
4221	Farm Product Warehousing & Storage	3,319	178	23	1	3,521
4222	Refrigerated Warehousing & Storage	3,577	702	134	14	4,427
5148	Fresh-cut Fruits & Vegetables	323	34	5	0	362
5148	Fresh Fruits & Vegetables Whsle	19,050	1,980	301	9	21,340
	Total	80,475	12,283	4,411	477	97,646

The impact of the proposed rule, the change to baseline or existing practices, is likely to vary across the food industry. Our analysis is largely based on the size of the manufacturing facility as the determining factor for the costs of complying with the rule. We recognize that not all facilities of the same size that do not already comply will have the same risks or incur the

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same costs. We believe it is reasonable to assume that those facilities with practices that place them at more risk of microbial hazards will also be more likely to incur the costs of preventing those hazards, when all other determining factors are equal. Because the hazards will vary by food product type and process, the practices to control the hazards will also likely vary; thus we believe the costs will likely vary by product type. We lack data about how those practices will likely vary and likewise, we lack data about how the costs will vary by food product type. Presumably, the rule will impose greater costs on some food product type sectors than on other sectors. We ask for comment about how the costs will likely vary across the food industry by food product type.

Baseline or existing practices are those manufacturing practices that are currently performed by the food industry to comply with current Federal, state and local regulations, international and industry-wide standards and the manufacturer's own private safety and quality standards. It is necessary to know about the industry's current practices because the cost of the rule will be to those facilities that will have to change their current practices in order to comply with the proposed rule. To learn about the domestic food industry's baseline manufacturing practices and to help us estimate the number of facilities that are likely to change practices to comply with the proposed rule, we contracted ERG to conduct a survey of the food industry (Ref. 9).

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Participation in the Food GMP survey was by domestic facilities only and participation was voluntary; respondent identifiers that would permit an association of specific responses to specific respondents were not accessible to FDA to help ensure the confidentiality and anonymity of the respondents. The only survey information that FDA received from ERG was aggregated summary statistical information with no facility identifiers. For more information

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about our survey methodology, see FDA supporting statements A & B, dated August 29, 2008 (Refs. 52 and 53) and the final survey report. We request that commenters supply data on similar statistics for foreign facilities. In the absence of data to the contrary we have assumed that conditions in foreign facilities are equivalent to conditions in domestic facilities.

The survey was sent to respondents in early calendar year 2010 from a statistically representative sample of FDA-registered facilities in the United States that primarily manufacture or process food products. The survey instrument included the following topics: (1) facility profile, the primary operation characteristics conducted at the facility, such as the type of food manufactured or processed for human consumption and whether the facility has a written food safety plan, (2) training procedures and practices for food production managers, production supervisors, quality control personnel, sanitation and cleaning supervisors and production line employees on the topics of food safety, basic cleaning, sanitizing, sanitation, personal hygiene, specific product and equipment training and allergen control; (3) sanitation and personal hygiene procedures and practices for food contact surfaces, non-food contact surfaces, production areas and warehouses; (4) allergen control procedures and practices for soybean or soybean-based ingredients, peanuts or peanut-based ingredients, finfish and crustacea, tree nuts, milk and other dairy products, eggs, and wheat or wheat-based products; (5) process controls, including supplier control and approval programs, written procedures for handling incoming raw materials, approving vendors, the calibration of operating equipment, pathogen control, and a Hazard Analysis and Critical Control Point system; and (6) recordkeeping practices.

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We selected a representative sample of 2,700 food establishments that registered with FDA's Food Facility Registration Module database (FFRM) (Ref 54) by randomly selecting the targeted facilities from the database to ensure an equal chance that any facility of any product

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type and facility size could be drawn.[37] The sampling was drawn from facilities that were registered with FDA as of mid-2009. We classified the target sample facilities by food product categories and by facility size. We used the U.S. Department of Labor, Occupational Safety and Health Administration's SIC codes for food manufacturers to create our food product categories (Ref. 55).

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The Food GMP survey design was based on three size classes, small (<20 employees), medium (20-99 employees) and large (> 100 employees). The survey design did not include a class for the very largest facilities. Despite this shortcoming in the survey design, we were able to generate summary statistics applicable to that size class using the survey data collected. Our estimates for that size class and for each size class are statistically valid, and generalizable to all domestic manufacturers, although we acknowledge the survey results for the largest facilities are likely to have a larger degree of uncertainty associated with our estimate (i.e., the relative margin of error around the values are larger for that size class in comparison to the others.)

Our sampling frame for the study was based on the FFRM supplemented with information on facility size and the 4 digit SIC code industry classification obtained from the D&B business facility database. The FFRM provides a listing of domestic food facilities, including manufacturers and processors, and is continuously updated by facilities as their registration information changes. Because the proposed rule applies to facilities required to register with FDA, the FFRM provides a comprehensive listing of food manufacturing facilities. The FFRM includes contact information and general information about the type of activity conducted at the facility (e.g., "manufacturer/processor"), but it does not contain the facility size (i.e., number of employees) or SIC code information on registered facilities. To establish a

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[37] The primary facilities not accounted for by this survey are warehouses. We assumed these facilities would incur the costs of each provision in subpart B at the same prevalence as manufacturers.

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complete sampling frame with all the contact and category information, FDA added the size and SIC code information for those facilities registered as manufacturer or processor by purchasing the D&B database for all food manufacturers. This purchase included all records for facilities which the listed primary or secondary SIC codes that corresponded to some form of food manufacturing; the purchased D&B data was then matched to facility information in the FFRM.

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We received 704 completed surveys from food manufacturing facilities.(616 submitted and complete in scope + 88 complete (partial) in scope) Table 8 shows the overall disposition of the survey responses.[38]

Table 8- Overall Survey Disposition (Email and Mail Portions Combined)	
Disposition	**Total**
Submitted and Complete - In Scope	616
Submitted and Complete - Out of Scope	149
Submitted and Complete - Out of Scope - Closed	1
Submitted - Problem	2
Complete (partial) - In Scope	88
Complete (partial) - Out of Scope	3
Incomplete	25
Indeterminate	95
Out of Scope – Pre-canvas	246
Out of Scope - Survey	9
Closed	94
Ownership Change	11
Refused – Pre-canvas	17
Refused - Survey	44
Undeliverable (Bounced email and/or returned mail)	364
Unreachable (No contact after 6 attempts)	748
Submitted Pre-canvas ONLY	247
Target Sample (Total number contacted for the survey)	**2,759**

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Table 9 shows the number of completed surveys by food product type and by the size of the facility. We seek common on our survey methodology.

Table 9_- Complete Responses to the Survey, by Size Class and Industry Group		
Industry Group	**Facility Size in Number of Employees**	**Total**

[38] Survey results initially contained responses from juice and seafood facilities because at the time the survey was being administered, these facilities were within the scope of potential new regulations. Since that time, FSMA has excluded these facilities and we have removed their responses from the results used for cost estimations.

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	< 20	20 to 99	100+	Responses
Grain & Oilseed Milling & Sugar Manufacturing	5	16	17	38
Chocolate & Non-chocolate Confectionery Manufacturing	21	11	16	48
Frozen Food Manufacturing	7	11	29	47
Fruit & Vegetable Canning	21	21	25	67
Dairy Product Manufacturing	12	33	71	116
Seafood Product Preparation	14	8	12	34
Bakeries and Tortilla Manufacturing	97	75	71	243
Other Food Manufacturing	16	19	17	52
Perishable Prepared Food Manufacturing	9	9	11	29
Soft Drink and Ice Manufacturing	7	8	15	30
Total	**209**	**211**	**284**	**704**

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b. Qualified Facilities

The proposed rule identifies "qualified" facilities that are not required to comply with proposed Part 117 subpart C- Hazard Analysis and Risk-Based Preventive Controls. A qualified facility as defined by §418(l) of the FD&C Act is a facility that has revenues of less than $500,000 on average annually and sells more than 50 percent of its product to consumers, or to restaurants, and retail food establishments within the same state as the qualified facility or not more than 275 miles from the manufacturing site. Additionally there will be facilities that are qualified as the result of being a very small business as defined by FDA. Section §418(l) states that very small businesses as defined by FDA are qualified facilities for the purpose of this rule-making. FDA is co-proposing to define a very small business as one with less than $250,000 annually in sales, less than $500,000 annually in sales, or less than $1 million annually in sales.

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i. Number of Qualified Facilities

Tables 10a-10c shows the facility breakdown by manufacturers, warehouses, and wholesalers for facilities that are qualified under § 418(l) of the FD&C Act, and facilities that are not qualified under § 418(l) of the FD&C Act.

We were able to employ data from D&B to estimate the number of manufacturers, warehouses, and wholesalers that reported sales of below $1 million annually, below $500,000

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annually, and below $250,000 annually; D&B data was also used to estimate facilities' employee numbers. We were able to use raw data received directly from the National Agricultural Statistics Service's (NASS) 2008 Organic Production Survey to generate an estimate of the percentage of facilities (20 percent) that are likely to sell their products directly to end-users within the same state or within 275 miles of their facility (Ref. 56) .[39]

The first row in Table 10a shows the total food manufacturers count according to D&B data. Row 2 shows the number of these facilities that report less than $500,000 in annual sales. Row 3 adjusts the information from row 2 to estimate the number of facilities that have less than $500,000 annually in sales and that sell more than 50 percent of their products to end-users (consumer of the food, restaurant, or retail food establishment) located within the same state as the facility or within 275 miles of the manufacturing facility. Row 4 shows the additional number of food manufacturers that would be qualified under the very small business definition of less than $250,000 in annual sales. We calculate the number facilities that would be qualified under the very small business definition § 418(l)(1)(B) after those qualified under the other option (§ 418(l)(1)(C)- limited monetary value of sales) of § 418(l) of the FD&C Act are removed. Row 5 lists the total number of qualified food manufacturers and Row 6 then lists the manufacturers that would not qualify under § 418(l) of the FD&C Act. This set-up is repeated in the additional rows of Table 10a for both food warehouses and for food wholesalers. In Tables 10b and 10c we present this same facility information but with the very small business definition

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[39] We do not have any data on the sale of processed food to qualified end users. However, the 2008 Organic Production Survey produced by the National Agricultural Statistics Service of USDA has a large amount of detailed data on the sales of Organic Produce, including the distance between farm and final sale, and the type a facility the produce was sold to. (Ref 56) We were able to match this data with data on non-organic farms to produce estimates of sales to qualified end users for non-organic farms. With no other information to rely on, we use the estimate for average percent of sales to qualified end users by non-organic farms as a proxy for the average percent of sales to qualified end users by processed food facilities.

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of less than $500,000 in sales annually and less than $1 million in sales annually, respectively.

Table 10a- Food Manufacturers, Warehouses, and Wholesalers: Total Number of Facilities and Qualified and Non-Qualified Facilities Breakdown VSB <$250K

	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Food Manufacturers	54,206	9,389	3,948	453	67,996
Food Manufacturers with less than $500K in sales	43,163	241	33	6	43,443
Qualified Food Manufacturers with less than $500K in sales and selling more than 50% to qualified end-users	8,633	48	7	1	8,689
Additional Qualified Food Manufacturers under Very Small Business Definition of <$250K	27,793	90	21	3	27,906
Total Qualified Food Manufacturers	36,425	138	28	4	36,595
Non-Qualified Food Manufacturers	17,781	9,251	3,920	449	31,401
Total Warehouses	6,896	880	157	15	7,948
Warehouses with less than $500K in sales	5,291	8	0	2	5,301
Qualified Warehouses with less than $500K in sales and selling more than 50% to qualified end-users	1,058	2	0	0	1,060
Additional Qualified Warehouses under Very Small Business Definition < $250K	2,816	5	0	2	2,823
Total Qualified Warehouses	3,874	7	0	2	3,883
Non-Qualified Warehouses	3,022	873	157	13	4,065
Total Wholesalers	19,373	2,014	306	9	21,702
Wholesalers with less than $500K in sales	8,642	25	0	0	8,667
Qualified Wholesalers with less than $500K in sales and selling more than 50% to qualified end-users	1,728	5	0	0	1,733
Additional Qualified Wholesalers under Very Small Business Definition <$250K	3,876	10	0	0	3,886
Total Qualified Wholesalers	5,604	15	0	0	5,619
Non-Qualified Wholesalers	13,769	1,999	306	9	16,083
Total of all facilities	80,475	12,283	4,411	477	97,646
Total facilities with less than $500K in sales annually	57,096	274	33	8	57,411
Total Qualified Facilities with less than $500K in sales and selling more than 50% to qualified end-users	11,419	55	7	2	11,482

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Total Qualified Facilities under Very Small Business Definition <$250K	34,485	104	21	5	34,615
Total Qualified Facilities	45,904	159	28	6	46,097
Total Non-Qualified Facilities	34,571	12,124	4,383	471	51,549

Table 10b - Food Manufacturers, Warehouses, and Wholesalers: Total Number of Facilities and Qualified and Non-Qualified Facilities Breakdown VSB <$500K

	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Food Manufacturers	54,206	9,389	3,948	453	67,996
Food Manufacturers with less than $500K in sales	43,163	241	33	6	43,443
Qualified Food Manufacturers with less than $500K in sales and selling more than 50% to qualified end-users	8,633	48	7	1	8,689
Additional Qualified Food Manufacturers under Very Small Business Definition of <$500K	34,530	193	26	5	34,754
Total Qualified Food Manufacturers	43,163	241	33	6	43,443
Non-Qualified Food Manufacturers	11,043	9,148	3,915	447	24,553
Total Warehouses	6,896	880	157	15	7,948
Warehouses with less than $500K in sales	5,291	8	0	2	5,301
Qualified Warehouses with less than $500K in sales and selling more than 50% to qualified end-users	1,058	2	0	0	1,060
Additional Qualified Warehouses under Very Small Business Definition < $500K	4,233	6	0	2	4,241
Total Qualified Warehouses	5,291	8	0	2	5,301
Non-Qualified Warehouses	1,605	872	157	13	2,647
Total Wholesalers	19,373	2,014	306	9	21,702
Wholesalers with less than $500K in sales	8,642	25	0	0	8,667
Qualified Wholesalers with less than $500K in sales and selling more than 50% to qualified end-users	1,728	5	0	0	1,733
Additional Qualified Wholesalers under Very Small Business Definition <$500K	6,914	20	0	0	6,934
Total Qualified Wholesalers	8,642	25	0	0	8,667
Non-Qualified Wholesalers	10,731	1,989	306	9	13,035
Total of all facilities	80,475	12,283	4,411	477	97,646

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Total facilities with less than $500K in sales annually	57,096	274	33	8	57,411
Total Qualified Facilities with less than $500K in sales and selling more than 50% to qualified end-users	11,419	55	7	2	11,482
Total Qualified Facilities under Very Small Business Definition <$500K	45,677	219	26	6	45,929
Total Qualified Facilities	57,096	274	33	8	57,411
Total Non-Qualified Facilities	23,379	12,009	4,378	469	40,235

Table 10c - Food Manufacturers, Warehouses, and Wholesalers: Total Number of Facilities and Qualified and Non-Qualified Facilities Breakdown VSB <$1M

	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Food Manufacturers	54,206	9,389	3,948	453	67,996
Food Manufacturers with less than $500K in sales	43,163	241	33	6	43,443
Qualified Food Manufacturers with less than $500K in sales and selling more than 50% to qualified end-users	8,633	48	7	1	8,689
Additional Qualified Food Manufacturers under Very Small Business Definition of <$1M	39,162	1,750	1,939	259	43,110
Total Qualified Food Manufacturers	47,795	1,798	1,946	260	51,799
Non-Qualified Food Manufacturers	6,411	7,591	2,002	193	16,197
Total Warehouses	6,896	880	157	15	7,948
Warehouses with less than $500K in sales	5,291	8	0	2	5,301
Qualified Warehouses with less than $500K in sales and selling more than 50% to qualified end-users	1,058	2	0	0	1,060
Additional Qualified Warehouses under Very Small Business Definition < $1M	5,290	420	71	7	5,788
Total Qualified Warehouses	6,348	422	71	7	6,848
Non-Qualified Warehouses	548	458	86	8	1,100
Total Wholesalers	19,373	2,014	306	9	21,702
Wholesalers with less than $500K in sales	8,642	25	0	0	8,667
Qualified Wholesalers with less than $500K in sales and selling more than 50% to qualified end-users	1,728	5	0	0	1,733

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Additional Qualified Wholesalers under Very Small Business Definition <$1M	13,960	516	122	7	14,605
Total Qualified Wholesalers	15,688	521	122	7	16,338
Non-Qualified Wholesalers	3,685	1,493	184	2	5,364
Total of all facilities	80,475	12,283	4,411	477	97,646
Total facilities with less than $500K in sales annually	57,096	274	33	8	57,411
Total Qualified Facilities with less than $500K in sales and selling more than 50% to qualified end-users	11,419	55	7	2	11,482
Total Qualified Facilities under Very Small Business Definition <$1M	58,412	2,686	2,132	272	63,503
Total Qualified Facilities	69,831	2,741	2,139	274	74,985
Total Non-Qualified Facilities	10,644	9,542	2,272	203	22,661

Qualified facilities are not required to comply with Part 117 subpart C- Hazard Analysis and Risk-Based Preventive Controls of this proposed rule-making; they will have to submit documentation to FDA showing they are qualified facilities and they may incur a label change for their products. Facilities not defined as qualified will be expected to implement all of the provisions of this proposed rule-making as it applies to their particular facility or food product unless they are subject to a specific exemption (e.g. facilities under Seafood HACCP are exempt from proposed Part 117 subpart C Hazard Analysis and Risk-Based Preventive Controls).[40]

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ii. Choices Available to Qualified Facilities

As previously stated, qualified food facilities do not have to comply with the requirements for Part 117, Subpart C Hazard Analysis and Risk-Based Preventive Controls. These facilities can comply with the requirement that they submit documentation to FDA electronically at an Internet website maintained by FDA. We estimate that it will less burdensome for facilities to attest to their qualified facility status electronically rather than send

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[40] Even some facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls may not have to do certain activities required by the proposed rule depending on facility type, e.g., a facility producing products that do not contain one of the 8 major allergens are unlikely to need to allergen controls.

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information in to FDA by mail. Online, qualified facilities can attest to : 1) their financial information such as by indicating annual sales for the facility on average are less than the amount necessary to be a qualified facility under the 418(l) of the FD&C Act and attest that 2a) they have identified potential hazards associated with the foods being processed at their facility, have implemented preventive controls to address the hazards, and are monitoring the preventive controls to ensure the controls are effective, or attest that 2b) they are in compliance with State, local, county or other applicable non-Federal food safety laws. If potential qualified facilities decide to follow Option 2b instead of 2a they must, in addition to attesting to compliance with State and local food safety requirements, include on the label of their food products the name and business address of the facility where the food was manufactured or processed (or in the case of products without a food label, the notification must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or in an electronic notice, in the case of Internet sales).

We estimate that qualified facilities will choose to take Option 2b rather than Option 2a as the lesser expensive of the options available to qualified facilities. Therefore, the costs of this proposed rule to qualified facilities will be: 1) the cost of attesting to financial information to show that the average annual monetary value of all food sold is less than the necessary amount to qualify, 2) plus the costs of attesting that the facility is compliance with State, local, county, or other applicable non-Federal food safety laws, and 3) the costs of making changes to their food labels to include the name and complete business address, including the street address or P.O. box, city, state, and zip code for domestic facilities, and comparable full address information for foreign facilities, where the food was manufactured or processed.

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iii. Costs to Qualified Facilities to Attest to Qualified Status

We estimate that it will take a compliance officer (BLS 13-1041) earning $40.80 per hour including overhead 30 minutes every two years to update a facility's information with FDA specifically to attest to the facility's status as a qualified facility (attesting to financial information and compliance information). We assume for our cost estimate that domestic and foreign facility financial and compliance information will already be available in the form of tax records, facility accounting records, or some other readily available records, although the proposed rule does not specify what documents would be sufficient. We request comment on the appropriateness of this assumption for foreign facilities. It is possible that some qualified facilities will attest to having completed a hazard analysis, implementing preventive controls, and monitoring at their facilities instead of attesting that the facility is in compliance with State, local, county, or other law. We do not know how many qualified facilities, if any, have completed a hazard analysis, implemented preventive controls and monitoring. We expect the time to attest to having a hazard analysis instead of attesting to compliance with State, local, county or other applicable non-Federal food safety laws to be similar.

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Table 11a - Cost to Qualified Facilities to Attest to Qualified Status Through Online Portal (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	45,904	159	28	7	46,097
Time needed initially to gather and submit financial and compliance information (hrs)	0.5	0.5	0.5	0.5	
Wage rate per hr (including overhead)	$40.80	$40.80	$40.80	$40.80	
Total Costs Every Two Years to Attest to Status	$936,442	$3,244	$571	$143	$940,399
Cost on an Annual Basis	$468,221	$1,622	$286	$71	$470,200
Cost Annually per Affected Facility	$10	$10	$10	$10	

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Table 11b - Cost to Qualified Facilities to Attest to Qualified Status Through Online Portal (VSB <

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$500K)					
	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	57,096	274	33	8	57,411
Time needed initially to gather and submit financial and compliance information (hrs)	0.5	0.5	0.5	0.5	
Wage rate per hr (including overhead)	$40.80	$40.80	$40.80	$40.80	
Total Costs Every Two Years to Attest to Status	$1,164,758	$5,590	$673	$163	$1,171,184
Cost on an Annual Basis	$582,379	$2,795	$337	$82	$585,592
Cost Annually per Affected Facility	$10	$10	$10	$10	

Table 11c- Cost to Qualified Facilities to Attest to Qualified Status Through Online Portal (VSB < $1M)					
	≤20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	69,831	2741	2139	274	74,985
Time needed initially to gather and submit financial and compliance information (hrs)	0.5	0.5	0.5	0.5	
Wage rate per hr (including overhead)	$40.80	$40.80	$40.80	$40.80	
Total Costs Every Two Years to Attest to Status	$1,424,552	$55,916	$43,636	$5,590	$1,529,694
Cost on an Annual Basis	$712,276	$27,958	$21,818	$2,795	$764,847
Cost Annually per Affected Facility	$10	$10	$10	$10	

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iv. Costs of Changing Food Labels for Qualified Facility Products

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Qualified facilities that submit documentation to the FDA to show they are in compliance with State, local, county, or other applicable non-Federal food safety laws instead of showing that they have completed a hazard analysis and implemented preventive controls and monitoring at their facilities will need to include on the label of their food products the name and business address of the facility where the food was manufactured or processed. In the case of products without a food label, the notification must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the

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food in the normal course of business, or in an electronic notice, in the case of Internet sales. In the absence of information regarding the number of qualified processed food product facilities whose products are not packaged in such a way as to be labeled, we estimate here the costs of a label change for all products. We estimate the cost of a coordinated label change, meaning a qualified food facility will have two years to change their food labels to include the name and business address where the food was manufactured. A label change to include facility name and address is considered a minor label change, e.g., only 1 color is needed. We estimate that every qualified facility will be producing between 3 and 18 different products (3 to 18 different Stock Keeping Units (SKUs),) depending on facility size, which will require label changes. We base this estimate on the average number of production lines per facility by facility size as reported in our Recordkeeping Benefits Model Final Report (Ref. 49). We request comment on this estimate.

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The costs of label changes presented here could be an overestimate if some qualified facilities choose to submit documentation showing they have completed a hazard analysis, and implemented preventive controls and monitoring rather than submitting documentation showing they are in compliance with State, local, county or other applicable non-Federal law. The costs of label changes could be an underestimate if on average facilities handle more than 3 to 18 labeled products in their facility. We expect that most qualified facilities will not have completed a hazard analysis and implemented preventive controls and monitoring, and thus will have to change their labels to show the name and business address of the facility where the food was produced. We request comment on this expectation.

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Table 12a - Cost to Add Facility Address to Food Labels (VSB < $250K)

	≤20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	45,904	159	28	7	46,097
Number of SKUs per Facility	3	7	13	18	
Cost per SKU for one-time	$587	$587	$587	$587	

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Total Costs of One-Time Label Change	$80,836,944	$653,331	$213,668	$73,962	$81,777,905
Annualized Total Costs	$14,999,555	$121,228	$39,647	$13,724	$15,172,780
Cost per Affected Facility	$327	$762	$1,416	$1,961	

Table 12b - Cost to Add Facility Address to Food Labels (VSB < $500K)

	≤20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	57,096	274	33	8	57,411
Number of SKUs per Facility	3	7	13	18	
Cost per SKU for one-time change	$587	$587	$587	$587	
Total Costs of One-Time Label Change	$100,546,056	$1,125,866	$251,823	$84,528	$102,008,273
Annualized Total Costs	$18,656,644	$208,908	$46,727	$15,684	$18,927,963
Cost per Affected Facility	$327	$762	$1,416	$1,961	

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Table 12c- Cost to Add Facility Address to Food Labels (VSB < $1M)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	69,831	2741	2139	274	74,985
Number of SKUs per Facility	3	7	13	18	
Cost per SKU for one-time change	$587	$587	$587	$587	
Total Costs of One-Time Label Change	$122,972,391	$11,262,769	$16,322,709	$2,895,084	$153,452,953
Annualized Total Costs	$22,817,923	$2,089,843	$3,028,731	$537,192	$28,473,689
Cost per Affected Facility	$327	$762	$1,416	$1,961	

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v. Total Costs of Proposed Rule to Qualified Facilities

Tables 13a-c shows the total costs of the proposed rule to qualified facilities. These costs include the costs to gather documents attesting that a facility meets the definition of qualified and the costs of a label change for their products.

Table 13a - Total Costs of Proposed Rule to Qualified Food Facilities (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total

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Total Number Of Domestic Qualified Facilities	45,904	159	28	7	46,097
Annual Costs to Attest to Facility Status	$468,221	$1,622	$286	$71	$470,200
Annualized Total Costs for One-Time Label Change	$14,999,555	$121,228	$39,647	$13,724	$15,174,154
Total Annualized Costs	$15,467,776	$122,849	$39,932	$13,795	$15,644,353
Cost Per Affected Facility	$337	$773	$1,426	$1,971	

Table 13b - Total Costs of Proposed Rule to Qualified Food Facilities (VSB < $500K)

	≤20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	57,096	274	33	8	57,411
Annual Costs to Attest to Facility Status	$582,379	$2,795	$337	$82	$585,592
Annualized Total Costs for One-Time Label Change	$18,656,644	$208,908	$46,727	$15,684	$18,927,963
Total Annualized Costs	$19,239,024	$211,703	$47,063	$15,766	$19,513,556
Cost Per Affected Facility	$337	$773	$1,426	$1,971	

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Table 13c - Total Costs of Proposed Rule to Qualified Food Facilities (VSB < $1M)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	69,831	2,741	2,139	274	74,985
Annual Costs to Attest to Facility Status	$712,276	$27,958	$21,818	$2,795	$764,847
Annualized Total Costs for One-Time Label Change	$22,817,923	$2,089,843	$3,028,731	$537,192	$28,473,689
Total Annualized Costs	$23,530,199	$2,117,801	$3,050,549	$539,987	$29,238,536
Cost Per Affected Facility	$337	$773	$1,426	$1,971	

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vi. Label Change Less Expensive Than Implementing One Preventive Control

The costs of making a label change are less expensive for qualified facilities than implementing one preventive control. The average annualized cost of the label change is about $327 to $1,961 per facility, depending on facility size, while the cost of completing a hazard

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analysis is about $3,000 for a facility with less than 20 employees.[41,42] Thus, even if a qualified facility has completed and implemented at least a hazard analysis and some preventive controls and monitoring, it would still be more expensive to implement the additional preventive controls than it would be to attest to compliance with State, local, county or other applicable non-Federal food safety laws and complete the one-time label change. A facility would need to change 28 SKUs before the costs of a label change would be more prohibitive than completing a hazard analysis.

Table 14 - Comparison of Costs: Label Change to Hazard Analysis or One Preventive Control for Facilities with Less Than 20 Employees

Annualized Cost per Affected Facility	**≤20 employees**
One-Time Label Change	$327
Complete Hazard Analysis	$3,011
Implement Process Controls	$13,564
Implement Sanitation Controls	$11,522

F. Costs Associated with Revisions to Subpart B- Current Good Manufacturing Practices (CGMPs)

Proposed § 117 subpart B revises current § 110 subpart B to clarify that references to cross contamination are meant to include cross-contact. Because this provision only clarifies the meaning of the existing rule, we assume that facilities would not incur a cost. We request comment on our assumption.

G. Costs Associated with Subpart C-Hazard Analysis and Risk-Based Preventive Controls

[41] We only address the smallest businesses because they are the ones who will have to improve their baseline practices the most to comply with this rule.

[42] We are not suggesting that facilities do not already follow the GMP requirements as outlined in the current Part 110. Rather, that to effectively try to comply with the preventive controls proposed in Part 110117 subpart C Hazard Analysis and Risk-Based Preventive Controls, the facilities would need to adjust and improve current practices and would incur a cost in doing so.

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1. Food Safety Plan

a. Creating a food safety plan

The owner, operator, or agent in charge of facilities subject to subpart C of the proposed rule must prepare, or have prepared, a written food safety plan that documents and describes their procedures used to comply with subpart C Hazard Analysis and Risk-Based Preventive Controls. The food safety plan must include: 1) a written hazard analysis, 2) written preventive controls, 3) written procedures and the frequency with which they are to be performed for monitoring the implementation of the preventive controls, 4) written procedures for corrective actions, and 5) a written recall plan. The food safety plan must be prepared by a qualified individual.

Facilities that do not already have food safety plans or that lack some of the required elements will incur the cost to develop their plans or the missing elements of their plans. The costs to develop the written hazard analysis are shown in section 2 of our analysis, the costs to develop the other written procedures required for a facility's food safety plan are found in the sections of this PRIA covering the costs of performing those particular procedures, respectively.

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b. Reanalysis of the Food Safety Plan

Section 117.150(f) of the proposed rule requires that each facility reassess its food safety plan at least once every three years; whenever a significant change is made in the activities conducted at a facility that creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard; whenever the facility owner, operator or agent in charge becomes aware of new information about potential hazards associated with the food; whenever a preventive control is not properly implemented and a specific corrective action procedure has not been established; and whenever a preventive control is found to be ineffective.

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The costs to updating the hazard analysis is presented in section 2 of this analysis; the written updates to the hazard analysis can also be used to update the food safety plan for new hazards or new information about current hazards associated with food processed at the facility. This updating of the hazard analysis is assumed to occur on an annual basis. The costs of reanalyzing the food safety plan in light of new corrective action procedures at facilities are addressed in the corrective actions section of this analysis. The practice of updating corrective action procedures is also assumed to occur on an annual basis. In addition, the costs to update preventive controls are also presented in the section of this analysis corresponding to the specific preventive controls. Again, any written updates to these procedures also can be used to update the food safety plan accordingly.

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2. Hazard Analysis

Proposed §117.130 requires the owner or operator, or agent in charge of an affected facility to have a written hazard analysis that includes, as a first step, the identification and description of known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility. As a second step, the analysis requires the evaluation of the likelihood of the occurrence and severity of the illness or injury that can be caused by the foreseeable hazards. The evaluation of the hazards is required to consider biological hazards including microbiological hazards such as environmental pathogens; chemical hazards including substances such as pesticide and drug residues, natural toxins, decomposing food or color additives and food allergens, and radiological and physical hazards.

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The identification of hazards will be performed by qualified food safety professionals in collaboration with a team of personnel that are knowledgeable about the raw materials and ingredients and processes within the facility. In general, the scope of the hazard analysis

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depends on the number of food products that are processed, the production complexity and the storage requirements for each of the food products. The scope of the hazard analysis requires consideration of natural and unintentional hazards that are potentially introduced, both from within and from outside of the facility (Ref. 47). Proposed §117.130 would require that the hazard analysis identify and evaluate all known or reasonably foreseeable hazards for each type of food manufactured, processed, packed or held at the facility. The time necessary to conduct the hazard analysis is not strictly related to the size of the facility; variables such as container size or food flavor also do not influence the time for conducting a hazard analysis (Ref. 47).

To understand the baseline use of hazard analysis in the food manufacturing industry, the FDA Food GMP survey asked respondents whether they have a HACCP System. One hundred percent of facilities with more than 500 employees report having a HACCP system. Over 58 percent of the responding facilities with fewer than 20 employees indicated that they do not have a HACCP system. Among facilities with 20 to 99 employees, 18 percent report not having a HACCP system and 3 percent of facilities with 100 to 499 employees report not having a HACCP system. *Food Manufacturing* magazine (Market Update, 2008) also provides an annual update on the state of HACCP in the industry. Their summary published in October 2008, reported that 80.7 percent of the HACCP plans address physical hazards and 72.9 percent address microbiological contaminants (Ref 57).

ERG experts judged that a hazard analysis, when it is prepared for the first time, may take 24 to 48 hours to conduct. Subsequent written hazard analyses would most likely require 12 to 24 hours to conduct. The time required will vary with the complexity of the product lines (Ref.47). A qualified individual must prepare the written hazard analysis. Larger or more diversified firms might require 6 to 10 hazard analyses per facility (Ref. 47). Table 16

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summarizes our labor hour estimates for preparing a written hazard analysis.

We used our expert's estimate for the total time to conduct and write the hazard analysis of 24 to 48 hours as shown in Table 16 and we assumed that it will take approximately 4 to 8 hours of the 24 to 48 hours to write the analysis. Of the total time to update the hazard analysis, we assume it will take 2 to 4 hours for the writing alone. We ask for comments on our estimate for the time to conduct and write the initial hazard analysis and the time to update it annually.

Table 16 - Written Hazard Analysis Labor Hours

Type	Total Labor Hours for Written Hazard Analysis (per Product Line)
First Hazard Analysis	24 to 48 hours
Subsequent Hazard Analysis	12 to 24 hours

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Facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls will be required to conduct a hazard analysis when they lack such an analysis of their facility. We base our assumption about whether a hazard analyses will need to be conducted on the results of the Food GMP survey. If a covered facility currently operates using HACCP, then we assume that they have conducted a hazard analysis that would comply with the requirements of the proposed rule. Thus, we assume that large facilities will face no additional costs to comply with this provision. If a facility does not currently operate under HACCP, then we assume that they have not conducted a hazard analysis and they will need to do so to comply.

Unless specifically noted, all of the tables in this section provide costs only for the rule that defines very small business as less than $250,000 in annual revenue. Table 17a summarizes our estimate for the initial costs to conduct a written hazard analysis. For the calculations presented in Table 17a, we have estimated costs to food manufacturers and wholesalers for conducting hazard analyses if necessary. We do not estimate that warehouses will conduct hazard analyses as their primary function is mainly to store food that is not exposed to the environment. We ask for comments about each of our costs estimates.

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Table 17a - Estimate for Initial Costs to Conduct Initial Written Hazard Analysis by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	> 500 employees	Total
Total number of Domestic Manufacturing and Wholesale Facilities	31,550	11,250	4,226	458	47,484
Percent of Facilities w/o Hazard Analysis	58%	18%	3%	0%	
Total Facilities that require Hazard Analysis	18,299	2,025	126	0	20,450
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Number of Processes per Facility	1-3	1-3	3-9	8-12	
Average Labor Hrs to Conduct Hazard Analysis per Process	20 to 40	20 to 40	20 to 40	20 to 40	
Total Costs to Conduct Initial Hazard Analysis	$67,251,475	$7,427,970	$1,387,404	$0	$76,066,849
Average Labor Hrs to Write Hazard Analysis per Process	4 to 8	4 to 8	4 to 8	4 to 8	
Total Costs to Write Initial Hazard Analysis	$13,450,295	$1,485,594	$277,481	$0	$15,213,370
Total Costs to Conduct Initial Hazard Analysis	$80,701,770	$8,913,564	$1,664,885	$0	$91,280,219
One-Time Costs Annualized (7%, 7 yrs)	$14,974,473	$1,653,940	$308,925	$0	$16,937,339
One-Time Costs Annualized (3%, 7 yrs)	$12,953,147	$1,430,684	$267,225	$0	$14,651,055

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Table 18a summarizes our estimate for the on-going annual costs to update the written hazard analysis. Again, we have estimated costs to food manufacturers and wholesalers for updating hazard analyses as necessary. We do not estimate that warehouses will need to conduct or update a hazard analysis.

Table 18a - Estimated Costs to Annually Update the Hazard Analysis by Facility Size (VSB < $250K)

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	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of Domestic Manufacturing Wholesale Facilities	31,550	11,250	4,226	458	47,484
% Facilities w/o Hazard Analysis	58%	18%	3%	0%	
Total Facilities that require Hazard Analysis	18,299	2,025	126	0	20,450
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Number of Process per Facility	1-3	1-3	3-9	8-12	
Average Labor Hrs to Update the Hazard Analysis per Process	10 to 20	10 to 20	10 to 20	10 to 20	
Total Costs to Conduct Updated Hazard Analysis	$33,625,738	$3,713,985	$693,702	$0	$38,033,425
Average Labor Hrs to Write Updated Hazard Analysis per Process	2 to 4	2 to 4	2 to 4	2 to 4	
Total Costs to Conduct Updated Hazard Analysis	$6,725,148	$742,797	$138,740	$0	$7,606,685
Annual Costs to Update the Hazard Analysis	$40,350,885	$4,456,782	$832,443	$0	$45,640,110
Total Costs Annualized @ 7% (one-time + on-going)	$55,325,358	$6,110,722	$1,141,367	$0	$62,577,448
Total Costs Annualized @3% (one-time + on-going)	$53,304,032	$5,887,466	$1,099,667	$0	$60,291,165
Total Costs of Hazard Analysis Per Affected Facility	$3,011	$3,010	$9,058	$0	$3,048

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3. Preventive Controls

a. Process Controls

Proposed § 117.135(d)(1) requires facilities subject to subpart C to implement process controls into their manufacturing process. Process controls are the procedures, practices, and processes performed on food during processing to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls can include the critical control points or steps that are applied in the production process to prevent, reduce or eliminate physical, biological,

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radiological or chemical hazards. For example, a metal detector is a common process control for preventing metal fragments, a physical hazard, from adulterating foods. As another example, the application of heat is a common process control to adequately reduce pathogens in foods.

Process controls would be required to include when applicable, the maximum or minimum value or combination of values that are necessary to control the select hazards identified in the hazard analysis. Maximum or minimum values are the range of values or limits in which process controls are effective against the select hazards. A production process with a thermal kill step above 165º F might only be effective if the production temperature is known to actually reach the minimum temperature of 165º F for a sufficient period, such as 15 seconds. Ensuring the effectiveness of a thermal process control might require a correctly functioning thermometer that is installed, calibrated, monitored and its effectiveness verified with a program of on-going records review by qualified individuals, production managers or quality assurance staff.

The regulatory costs of adopting process controls is the cost to purchase and install the new equipment or adopt new procedures to comply with the proposed rule; the time for qualified individuals to develop the written procedures to incorporate the process controls into the production line; the labor hours to train the production personnel in the use of the new procedures; the costs to calibrate any newly installed equipment in order to better ensure the effectiveness of the controls; the labor hours used by manufacturing workers, managers and qualified personal to monitor and record the results of the controls.

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We assume that facilities which currently have process controls will face no additional costs to comply with this provision. To estimate the number of facilities that currently lack process controls, we referred to the Food GMP survey. The survey asks about the use of

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HACCP. While the use of HACCP is not identical to the use of process controls, it is a close approximation. Some facilities will use process controls, such as metal detectors and thermal kill steps, but do not use HACCP, but all facilities that use HACCP, by definition, use critical control points and critical limits, so they necessarily use what we are describing as process controls. The use of HACCP in other words, is a lower bound estimate for the use of process controls. The survey results show that almost 66 percent of all facilities use HACCP, including 42 percent of facilities with fewer than 20 employees and 100 percent of facilities with 500 or more employees.

The survey asks about the use of written procedures for operational control practices to ensure product safety. This is comparable, but not identical to, the proposed requirement to develop a description or written procedures for the use of process controls. The use of written procedures for operational controls practices indicates the use of process controls, although we recognize that facilities might use process controls but not have written procedures, a description for their use, or records that document their use. The survey results for this question show that 64 percent of all facilities have written procedures, including 47 percent of all facilities with fewer than 20 employees and 100 percent of facilities with 500 or more employees.

The survey asks about the use of production and process control records. The use of these records is another indication of the use of process controls. Facilities that use process controls are very likely to keep records of their use, so we estimate that the presence of records indicates the presence of process controls. Likewise, the absence of records indicates the absence of process controls or at least the absence of adequate process controls. However, we also recognize that production process records might be for production processes that are not

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specifically process controls as defined by the proposed rule, so the relationship between the use of production process records and process controls is not exact. The results show that 80 percent of all facilities use production process records, including 64 percent of facilities with fewer than 20 employees and 100 percent of facilities with 500 or more employees. The results reflect an upper bound estimate for the current use process controls. To estimate the mean number of facilities that use process controls we took the average of the responses to our question about the use of HACCP with our estimate for the use of process control records for a total of 47 percent of facilities with 20 employees or fewer.

We assume, based on our experts' judgment that there are generally one to three process controls per product line depending on the type of the food manufactured. (Ref 47) There may be one or several points in a process that should be monitored, depending upon the type of product being manufactured. It is possible that a facility would only have a single process control, especially for a facility that makes only one line of products or groupings of products with similar characteristics, such as a line of jams and jellies of various flavors and sizes. Even a large facility that only produced a single product might have only a single process control. It is likely that there will be more than one process control as the complexity of the manufacturing increases and two to three process controls per product line are more typical. Many manufacturers may also have identified quality control points in their facility that supplement their process controls, however, these are not the same as process controls. The number of process controls that should be monitored and subject to verification and must match the hazard analysis for each process step.

The preamble describes common process controls. Our estimate for the cost of purchasing and installing common process controls such as pH meters and thermometers among

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Our experts judged that there are generally one to three process controls per product line depending on the type of the food manufactured.

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the other common devices described in the preamble to monitor the freezing, dehydrating, heat processing, acidifying and the refrigerating of foods is $1,000 to $5,000 per process for an average cost of $3,000 per process control per process. Our cost estimate is based on the range of published prices for process controls that we identified on-line as common brand name process controls. For instance, we found the cost for common process controls such as pH measurement electrode devices to range from $50 to a high of $420. The cost for electrode calibration devices ranged from a low of $75 to a high of $750. Temperature thermometers ranged from $75 to about $400. Water activity monitors ranged from a low of $250 to over $3,950.

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We recognize that our cost estimates for process controls are highly uncertain. Our estimates are uncertain because there are so many types of process controls; it may be costly for facilities to search for the most cost effective equipment; and in part, the cost of implementing new process controls in existing systems are determined by the costs of the installation and in part on any lost production during the installation. Because we lack data about the costs for searching for cost effective equipment, the cost of installation, and the cost for lost production during the installation, we ask for comment about our estimate.

We estimate the recordkeeping costs from our recordkeeping cost model; Tables 2-4 through 2-10 estimate the costs for developing written procedures and associated records for calibration, monitoring, records review and other activities for the verification of the effectiveness of the process controls (Ref, 50) From our recordkeeping cost model Table 2-4, we determined the total hours needed by a team of qualified individuals to develop the written procedures is an average of a one-time 13 hours per production process and the time needed to annually update the written procedures is an average of 4 hours per process for facilities with

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fewer than 99 employees, 7 hours per process for facilities with 100 to 499 employees and 11 hours per process for facilities with 500 or more employees.

To estimate the cost of training the production staff to use new process controls, we assume that in a facility with fewer than 20 employees, an average of five production line workers with an average hourly wage rate of $21/hr (including overhead) will require training for an average period of two hours, plus the production managers' time to conduct the training at $61/hr (including overhead) for a total training cost of about $330 per process per year rounded (= 5 production workers x $21/hr x 2 hrs + one supervisor x $61/hr x 2 hrs.) Employees will also need to be trained in the use of revised process controls as they are updated. We assume that facilities with fewer than 20 employees would have an average annual recurring cost of training the five employees for one hour per year in the updated procedures. We assume that facilities with more than 20 employees, will also require 2 hours of training per employee in the procedures and we follow a similar calculation for the total costs of training per facility. We ask for comment about our assumptions and estimates.

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To estimate the cost to calibrate the equipment used as process controls, we asked our experts to estimate the time that would generally be needed to perform the calibration of the process control instruments. To estimate the on-going costs to calibrate the process controls instruments, we assume that one quality control worker with a wage rate of $60 per hour will require between 30 minutes and one hour to four hours per year to check and recalibrate each process control as necessary for each instrument. Verification instruments will also have to be calibrated; we assume one to two hours per year for all verification instruments. We estimate that the costs to generate the records for each calibration check or recalibration from Tables 2-9 of the recordkeeping cost model for equipment calibration records are between 7 and 33 minutes

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per record for a total of 24 hours per year.

We assume process control monitoring will require production workers with an average wage rate of $21/hr to monitor the process controls between 15 minutes to 30 minutes per day per process for every day that the process in used throughout the year. We estimate the recordkeeping cost using our recordkeeping cost model Tables 2-9. (Ref 50)

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A review of the process control records by a qualified individual is required to assure the effectiveness of the process controls in accordance with the proposed section 117.135(d)(1). We assume that it will require one to five minutes for a qualified individual to review each record.

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To estimate the costs for recordkeeping for this and for every provision that requires recordkeeping, we relied upon our recordkeeping cost model that was developed in 2003 and which was derived from an expert elicitation. To conduct the expert elicitation, we assembled a 14-member panel comprised of experts in food safety. Each expert included in the panel had significant practical experience working at food manufacturing plants, allowing them to observe the implications and the associated burden of keeping records. We began by sending a questionnaire to each expert on the panel. Informal discussions with select experts were held beforehand to better ensure effective instrument design. Each expert responded independently and once all responses were collected, the next round of questions was sent out, sometimes including feedback from previous rounds. The elicitation consisted of a total of three rounds. Prior to study commencement, we conducted a comprehensive literature review of federal regulations, industry, trade and academic sources to generate a master list of record types based on our analysis of current regulations, guidelines, voluntary standards, as well as discussions with select expert panel members.

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In the first round, we asked experts to describe the type of recordkeeping systems used by typical small, medium, and large food manufacturing facilities in 17 food sectors. The results of Round 1 show that smaller facilities are more likely to have paper-based recordkeeping systems in comparison to medium to large facilities. As facilities increase in size, they tend to move toward electronic recordkeeping. None of the experts, however, indicated that any typical facility uses a purely electronic recordkeeping system. Most are either mostly electronic or an even mix of electronic and paper systems. The cost of keeping records includes not only the cost of maintaining records, but also the cost of writing and updating SOPs and the training associated with ensuring that the procedures are carried out as intended.

In Round 2, we collected data on the hours spent writing and updating procedures. Experts were asked to estimate these hours by sector and by facility size. In Round 3, we asked our expert panel to estimate the annual frequency that records are produced for different types of activities. We defined annual frequency as the number of instances of a record multiplied by the number of times a record is completed per year at a plant. The experts were first asked, for each record type and whether they thought the annual frequency of keeping a given record varied by sector. In the second question they were asked to estimate the annual frequency (by sector if they indicated in question 1 that it varied by sector) and to describe their reasoning behind the estimate. Finally, they were asked to estimate the number of minutes spent producing each record. The recordkeeping cost study that we conducted in 2003 did not anticipate all of the types of recordkeeping activities that are required by this proposed rule. The experts were not asked for their assessment about every type of record that might be required. Consequently, we extrapolated from their estimates to the records that were not contemplated then. The use of electronic record keeping devices is also more common now than it was when the study was

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conducted. The impact of the more widespread use of electronic devices is to reduce the time it takes to document the activities. We based our estimates on the use of manual, not electronic recordkeeping devices; consequently, our cost estimates are probably an upper bound estimate of the true costs. The results for the expert elicitation and their complete estimates can be found at Ref. 50. We ask for comment about all of our recordkeeping cost estimates.

Tables 19a and 20a show our cost estimates to manufacturing facilities to implement process controls. We do not expect that food wholesalers or warehouses will need to implement process controls so we have not included those types of facilities in the estimations in Tables 19a and 20a.

Table 19a - Estimated Initial Costs to Implement Process Controls by Facility Size
(VSB < $250K)

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	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Domestic Manufacturing Facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
Percent without Process Controls	47%	11%	2%	0%	
Total Facilities that require Process Controls that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	8,357	1,018	78	0	9,453
Number of Processes per Facility	1-3	1-3	3-9	8-12	
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Average Labor Hrs to Prepare Written Procedures per Production Process	13	13	21	30	
Subtotal Costs to Develop Initial Written Procedures	$13,254,313	$1,613,929	$602,582	$0	$15,470,825

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Mean Capital Costs to Install Process Controls per Process per Facility	$1,000 to $5,000	$1,000 to $5,000	$1,000 to $5,000	$1,000 to $5,000	
Subtotal Costs to Install Process Controls	$50,142,420	$6,105,660	$1,411,200	$0	$57,659,280
Number of Employees that Require Training per Process per Facility	5	5	5	5	
Hours of Initial Training per Employee	2	2	2	2	
Hourly Wage Rate for Production Line Workers	$21	$21	$21	$21	
Subtotal Costs to Train Production Workers	$5,549,094	$675,693	$156,173	$0	$6,380,960
Minutes per Record to Document Initial Training	2 to 4	2 to 4	2 to 4	2 to 4	
Subtotal Initial Recordkeeping Costs for Training	$43,875	$5,342	$412	$0	$49,629
Total One-Time Process Control Costs	$68,989,707	$8,400,630	$2,170,372	$0	$79,560,714
One-Time Costs Annualized (7%, 7 yrs)	$12,801,262	$1,558,764	$402,719	$0	$14,762,747
One-Time Costs Annualized (3%, 7 yrs)	$11,073,286	$1,348,354	$348,358	$0	$12,770,000

Table 20a - Estimated On-Going Costs to Implement Process Controls by Facility Size (VSB < $250K)

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	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
Percent without Process Controls	47%	11%	2%	0%	
Total Facilities that require Process Controls that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	8,357	1,018	78	0	9,453

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Number of Processes per Facility	1-3	1-3	3-9	8-12	
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Labor Hrs to Update Written Procedures per Production Process	4	4	7	11	
Subtotal Costs to Annually Update Written Procedures	$4,078,250	$496,594	$200,861	$0	$4,775,705
Number of Employees that Require Training in Updated Written Procedures per Process per Facility	5	5	5	5	
Hours of Initial Training per Employee	2	2	2	2	
Hourly Wage Rate for Production Line Workers	$21	$21	$21	$21	
Subtotal Costs to Train Production Workers in Updated Written Procedures	$2,774,547	$337,847	$78,086	$0	$3,190,480
Minutes per Record to Document Training in Updated Written Procedures	2 to 4	2 to 4	2 to 4	2 to 4	
Subtotal Recordkeeping Costs for Training in Updated Written Procedures	$43,875	$5,342	$412	$0	$49,629
Hourly Wage Rate for QC Personnel to Perform Calibration	$61	$61	$61	$61	
Hours to Calibrate Process Controls per Process per Year	1 to 4	1 to 4	1 to 4	1 to 4	
Subtotal Annual Costs to Perform Calibration	$7,009,492	$853,520	$125,538	$0	$7,988,551
Hours to Generate Calibration Records per Process	.12 to .55	.12 to .55	.12 to .55	.12 to .55	
Number of calibration records per process per year	24	24	24	24	
Subtotal Recordkeeping Costs to Document Calibration	$8,022,787	$976,906	$225,792	$0	$9,225,485

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Hourly Wage Rate Process Control Monitoring	$21	$21	$21	$21	
Average Hours Monitoring each Process Annually	274	274	1095	1825	
Subtotal Monitoring Costs	$48,042,706	$5,849,985	$1,802,808	$0	$55,695,500
Records to Document Monitoring of Process Controls (Minutes per Record)	2 to 4	2 to 4	2 to 4	2 to 4	
Monitoring Records per Process per Year	365	365	365	365	
Subtotal Costs to Document Monitoring	$6,405,694	$779,998	$180,281	$0	$7,365,973
Hours to Generate Verification Instrumentation Calibration Records per Process	.12 to .55	.12 to .55	.12 to .55	.12 to .55	
Number of verification instrumentation calibration records per process per year	24	24	24	24	
Subtotal Recordkeeping Costs to Document Verification Instrumentation Calibration	$8,022,787	$976,906	$225,792	$0	$9,225,485
Hourly Wage Rate for Qualified Individual to Perform Records Review	$61	$61	$61	$61	
Hours to Perform Records Review Annually (365 records x .05 hrs/record)	18.25	18.25	18.25	18.25	
Subtotal Annual Visual Observation Verification - Records Review Costs	$9,303,508	$1,132,,854	$87,279	$0	$10,523,641
Total Annual On-going Process Control Costs	$100,554,356	$12,244,138	$3,049,917	$0	$115,848,410
Total Costs Annualized (One-Time annualized + On-Going) (7%, 7 yrs)	$113,355,618	$13,802,902	$3,452,636	$0	$130,611,157
Total Costs Annualized (One-Time annualized + On-Going) (3%, 7 yrs)	$111,627,642	$13,592,492	$3,398,275	$0	$128,618,410

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Avg. Cost of Process Controls Per Affected Facility per year (7%, 7 yrs)	$13,564	$13,564	$44,039	$0	$13,817

b. Food Allergen Controls

The proposed rule requires facilities that work with major food allergens to develop and implement food allergen controls.[43] Food allergen controls must include the procedures for ensuring protection of food from cross-contact, including during storage and use of food allergens. Food allergen controls also must include procedures to address the labeling of the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the act.[44]

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As a result of this rule, facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls may need to develop new labeling controls. The need for a particular facility to develop new labeling controls for the hazards identified in the hazard analysis depends on the type of food, the type of facility, and whether or not that facility already has acceptable labeling controls. Under this proposed rule, if a facility needs labeling controls to address one or more of the hazards that it has identified in its hazard analysis, then we estimate those labeling controls to include, at a minimum, a review of label application that addresses applying the

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[43] The Food Allergen Labeling and Consumer Protection Act (FALCPA) (21 U.S.C. 321(qq)) amended the FD&C Act to prescribe the manner in which food labels must disclose that a food is, or contains an ingredient that bears or contains, a major food allergen. However, FALCPA does not require facilities that handle allergens to implement the allergen controls proposed here.

[44] The most common CGMP related problem we have identified that resulted in a recall, both before and after FALCPA was passed, is labeling problems (i.e., undeclared allergen). In conjunction with the work of the CGMP Working Group, FDA reviewed CGMP-related food recalls during the period 1999-2003 (Ref. 58). Labeling problems accounted for 68 percent of food recalls, including 34 percent of recalls due to undeclared major food allergens. FDA followed up with a similar review of CGMP-related food recalls during the period 2008-2009, with a focus on primary recalls. In that follow-up review, labeling problems accounted for 62 percent of primary food recalls, including 43 percent of recalls due to undeclared major food allergens (Ref. 8). Thus, although FALCPA was passed in 2004, we continue to see problems with undeclared allergens in foods, as evidenced by recalls.

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correct label to a particular product. We expect that label controls will be an important preventive control for facilities whose products contain allergens and whose products are processed in the same facility as products containing allergens.

i. Proper Storage and Use of Food Allergens

Food allergen controls must include the procedures to ensure proper storage and use of raw materials and ingredients and proper storage of raw materials and ingredients and finished products with food allergens to protect foods from cross-contact. Facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls that use any food allergens are subject to this proposed requirement. Results from the Food GMP survey indicate that of those facilities that responded approximately 60 percent of facilities with fewer than 20 employees, 74 percent of facilities with 20 to 99 employees, 68 percent of facilities with 100 to 499 employees, and approximately 79 percent of facilities with over 500 employees do not manufacture or process ingredients that are, or are derived from any of the eight main allergens that currently require labeling. For those facilities that do use at least one of these main food allergens, approximately 96 percent of facilities with fewer than 20 employees, approximately 72 percent of facilities with 20 to 99 employees, approximately 68 percent of facilities with 100 to 499 employees, and approximately 42 percent of facilities with over 500 employees do not appear to have complete written allergen control plans. Further, because only facilities that use more than one allergen or that have at least two processes would need procedures to protect against cross-contact and the other allergen concerns of this provision, and because we lack data about how many facilities there are with allergens and two or more processes, we assume that between 25 to 75 percent of all facilities with allergens will require written procedures.

Based on our expert elicitation, we assume that it will take six to eight hours to develop

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facility-specific procedures. Facilities without procedures will require training in the proper use of the procedures. We assume that it will take approximately one hour to train staff in the correct use of the procedures. The employees that will monitor and verify the correct use of the food allergen controls are likely to be the same employees that will monitor and verify the sanitation controls. Our estimate for the costs to develop the written procedures for monitoring and for verifying that the food allergen controls are included in the costs to develop the written procedures for monitoring and for verifying the sanitation controls. We believe that only one set of written procedures would need to be developed because the monitoring and verification functions are so similar. We have estimated allergen control costs for manufacturing facilities only; we do not expect wholesalers or warehouses to need allergen controls. We ask for comments on our estimations.

Table 21a - Estimated Costs for Food Allergen Controls by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Domestic Manufacturing Facilities subject to Subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
% Facilities that use any of 8 major allergens	60%	74%	68%	79%	
% Facilities w/o written procedures for food allergen controls	96%	72%	68%	42%	
If 50% require allergen control procedures based on a range of 25% to 75%	50%	50%	50%	50%	
Total Facilities w/o written procedures subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	5,121	2,465	906	74	8,5
Cost per Facility to Develop Facility-specific written procedures	$427	$641	$793	$976	
Subtotal Cost to Develop Written Procedures for Food Allergen Controls	$2,177,297	$1,569,064	$722,715	$72,182	$4,541,259
Cost per Facility to Annually Update Facility-specific Written Procedures	$43	$64	$79	$98	

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Subtotal Cost to Update Written Procedures Annually	$217,730	$156,906	$72,272	$7,218	$454,126
Number of Workers that Require Training	5 to 15	10 to 20	20 to 30	40 to 60	
Training Costs per Facility (Hourly Wage for Production Worker x 2 hrs x no of workers x Wage for Manager Trainer)	$542	$752	$1,172	$2,222	
Subtotal Annual Training Costs	$2,763,689	$1,842,211	$1,068,124	$164,333	$5,836,356
One-time Cost for Containers, Partitions and other equipment per facility	$0 to $2,000	$0 to $5,000	$0 to $10,000	$0 to $10,000	
Subtotal Cost for Container/Partition/Design to Prevent Cross-Contact	$5,099,057	$6,124,370	$4,556,843	$739,570	$16,519,841
Total One-time Costs	**$7,276,355**	**$7,693,434**	**$5,279,559**	**$811,752**	**$21,061,100**
One-time costs annualized (7%, 7 yrs)	**$1,350,151**	**$1,427,541**	**$979,639**	**$150,623**	**$3,907,955**
One-time costs annualized (3%, 7 yrs)	**$1,167,901**	**$1,234,845**	**$847,403**	**$130,291**	**$3,380,440**
Total Recurring Costs	**$3,034,959**	**$2,140,590**	**$1,427,477**	**$220,085**	**$6,823,111**
Annualized one-time cost + recurring costs (7%, 7 yrs)	**$4,385,110**	**$3,568,131**	**$2,407,116**	**$370,708**	**$10,731,065**
Annualized one-time cost + recurring costs (3%, 7 yrs)	**$4,202,860**	**$3,375,435**	**$2,274,879**	**$350,376**	**$10,203,551**
Avg Annual Costs per Affected Facility	**$860**	**$1,457**	**$2,641**	**$5,012**	**$1,257**

ii. Label Application Review

Food allergen controls for labels should include checking the labels on finished products to ensure that the correct label is applied. We assume that only facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls that handle food allergens will need to implement food allergen label controls. We assume that food wholesalers, fresh-cut facilities, or packers will not need to check label application either because they do not handle foods with one

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of the major food allergens (as is likely the case with fresh-cut produce) or that they do not label foods but receive foods already labeled.[45]

We estimated the cost of reviewing that labels have been applied to the correct products based on information from the expert elicitation. According to the experts, reviewing the application of labels to finished products involves a production worker checking the production line one to two times per hour to see that the correct labels are applied to the product. Label verification on the production line consists of examining the label to ensure that it matches the product that the label was applied to, and then recording that information on a form; this procedure usually takes 1 to 2 minutes per verification occasion. The expert elicitation noted that a few large facilities may automate label verification on the production line; however, it did not provide estimates for the percentage of large facilities that have such technology or provide time estimates for using it. Therefore, we base our estimates on manual review of label applications. The cost of the required amount of labor time for manual review of label application is based on the BLS 2010 mean hourly wages for SOC 51-9111 Packaging and Filling Machine Operators; this wage is $13.57; we add 50 percent for overhead.

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We estimated the average number of product lines per facility using information from a report on recordkeeping benefits written for FDA. (Ref. 49) We assume that every production line would involve one labeling component. Very small facilities and small facilities (facilities with less than 100 employees) are assumed to operate 8 and 16 hours a day, respectively, and large and very large facilities are assumed to operate on a 24 hour basis. All facilities are

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[45] The label application review provision of the proposed rule is designed to ensure that labeling for ingredients (specifically allergenic ingredients) on individual food packages is correct; we would not expect outer carton labels to have ingredients listed. We expect most packers to be applying labels to outer cartons only. The exception to this expectation is those re-packers that are putting foods into smaller, consumer-size containers that must have ingredient statements. We cannot identify from our data which packers might be engaged in this re-packing activity.

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assumed to be producing products 50 to 52 weeks per year. We request comment on the operational hours per day and weeks per year by facility size.

We based our assumptions about the estimated the percentage of facilities that use allergens and do not review label application using information from the Food GMP survey. In the Food GMP survey, we asked facilities that handle products containing one of the major allergens two questions relating to reviewing label application. First, we asked facilities whether they have allergen control plans that address processes to verify that they use the appropriate labels. Second, we asked facilities whether they have written procedures to verify that labels match their intended products at the beginning or end of every production run or if they have written procedures to reconcile the number of labels issued and the number of labels used. We use this information in Table 22a to establish a baseline describing which facilities handling allergenic raw materials and ingredients and not conducting label application review will need to do so and at what cost.

We include the burden of recordkeeping for label review in Table 22a. We assume that a qualified individual will review label application records once a week for all product lines.

Table 22a - Label Application Review (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Manufacturing Facilities	17,781	9,251	3,920	449	31,401
Percent Of Facilities That Do Not Handle Allergens	59.18%	74.46%	68.17%	75.61%	
Remaining Facilities Estimated to Handle Allergens	7,258	2,363	1,248	109	10,978
Percent Of Facilities That Use Allergens and Do Not Review Label Application	1.5%	3.5%	2.2%	0.0%	
Number Of Facilities That Need To Start Label Application Review	109	83	27	0	219
Frequency of Review Per Hour	1.5	1.5	1.5	1.5	
Hours of Operation per Day	8	16	24	24	
Days of Operation Per Year	357	357	357	357	

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Time per Application Review (Hrs)	0.03	0.03	0.03	0.03	
Total Time Per Year (Hrs) for Application Review Per Facility	107	214	321	321	964
Labor Cost per Hour for Review	$20.36	$20.36	$20.36	$20.36	
Total Cost Per Facility Per Production Line Per Year	$2,181	$4,361	$6,542	$6,542	
Number Of Production Lines Per Facility	3	7	13	18	
Annual Cost Per Facility	$6,542	$30,528	$85,042	$117,750	
Total Costs of Label Application Review	$712,207	$2,524,431	$2,334,649	$0	$5,571,287
Wage rate for review label application records	$61.44	$61.44	$61.44	$61.44	
Hours per record	0.03	0.03	0.03	0.03	
Once per week records review	51	51	51	51	
Average number of production lines per facility	3	7	13	18	
Total Recordkeeping costs per year	$30,703	$54,414	$33,549	$0	$118,666
Total Annual Label Application Review Cost	**$742,910**	**$2,578,845**	**$2,368,197**	**$0**	**$5,689,952**
Annual Costs per Affected Facility	**$6,824**	**$31,186**	**$86,264**	**$0**	

[a] Warehouses, wholesalers, fresh-cut facilities and qualified facilities are excluded from this calculation.

iii. Written Labeling Controls

Food manufacturing facilities that handle at least one of the eight major allergens will need to have written label controls to satisfy the requirements for preventive controls. These written procedures can also then be used to satisfy the requirements of the food safety plan. We use information from the Food GMP survey as a basis for our assumption about the percentage of facilities that handle food allergens and do not have written label controls. We assume that it will take a qualified individual about 2 hours to write-up the label controls procedures.

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Table 23a - Cost to Write-up the Label Controls (VSB < $250K)

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total number of food manufacturing facilities	17,781	9,251	3,920	449	31,401
Percent Of Facilities That Do Not Handle Allergens	59.18%	74.46%	68.17%	75.61%	
Remaining facilities required to write label controls	7,258	2,363	1,248	109	10,978

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Percent without written label controls	7.14%	1.98%	0.44%	0.00%	
Facilities that need to write-up label controls	518	47	5	0	571
Time needed to write-up label controls (hrs)	2	2	2	2	
Wage for Qualified Individual (including overhead)	$79.14	$79.14	$79.14	$79.14	
Total costs of Initial Write-up	$82,026	$7,404	$869	$0	$90,299
Total Costs Annualized	$15,220	$1,374	$161	$0	$16,755
Annualized costs per affected facility	$2.10	$0.58	$0.13	$0.00	

[a] Warehouses, wholesalers, fresh-cut facilities, and qualified facilities are excluded from this calculation.

iv. Summary of Food Allergen Control Costs

The total costs of food allergen controls would be the sum of the costs of the developing procedures for allergen use and storage to prevent cross-contact (including written procedures and training), reviewing that the appropriate label has been applied to the appropriate product, and the costs of writing up label control procedures. We expect these costs to be incurred by food manufacturing facilities handling foods or food ingredients that contain a major food allergen. We do not estimate that any food wholesalers or warehouses will need to implement allergen controls either because they do not handle foods or ingredients with allergenic properties or they are not handling food exposed to the environment (i.e. there is not the possibility of cross-contact between foods).

Table 24a - Summary of Food Allergen Control Costs (VSB < $250K)

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	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Written Procedures, Training, and Records for Proper Use and Storage (Annualized)	$4,385,110	$3,568,131	$2,407,116	$370,708	$10,731,065
Total Label Application Review Costs Annually	$742,910	$2,578,845	$2,368,197	$0	$5,689,952
Cost to write up Label Controls (Annualized)	$15,220	$1,374	$161	$0	$16,755
Total Annual Costs	$5,143,240	$6,148,350	$4,775,474	$370,708	$16,437,772

c. Sanitation Controls

Proposed subpart C §117.135(d)(3) requires facilities to adopt sanitation controls where

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necessary to significantly minimize or prevent hazards that are reasonably likely to occur. The controls must include at a minimum written procedures to ensure the cleanliness of food contact surfaces including the food contact surfaces of utensils and equipment; and the prevention of cross-contact and cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces and from raw product to processed product.

Sanitation controls are the procedures to control sources of environmental pathogens and food allergens in the food processing environment in order to prevent contamination and cross-contact of food products. Effective sanitation controls remove undesirable material from the food contact surfaces and the environment. When sanitation controls are not effective, microorganisms, filth and food product residues remain at concentrations that can affect the quality and safety of the food.

i. Cleanliness of Food Contact Surfaces

Proposed §117.135(d)(3) requires that facilities develop procedures to promote the cleanliness of food contact surfaces. The written procedures should describe the cleaning steps for the pieces of equipment and utensils with food contact surfaces, including what cleaning chemicals, detergents, sanitizers and cleaning tools to use and the methods to prevent contamination. To estimate the cost to comply, we first estimated the number of facilities that lack the procedures. The total universe of facilities that are covered by this provision are all facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls.

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Our section for the proposed revisions to subpart B, Good Manufacturing Practices §117.35 addresses the requirements and the impact of the revisions to sanitation operations.[47]

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[47] The Part C sanitation controls requirements are largely for written procedures to help ensure that the sanitation practices are adequate and are conducted as necessary for the requirements in Part B. Part B does not require written procedures.

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To estimate the impact of adopting sanitation controls to comply with proposed §117.135(d)(3), we used the results of the FDA GMP survey. In response to a question about whether written procedures for cleaning your food-contact surfaces exists, about 29 percent of facilities with fewer than 20 employees, 16 percent of facilities with 20 to 99 employees, and 11 percent of facilities with 100 to 499 employees responded no. All responding facilities with 500 or more employees indicated that they have written procedures for their food contact surfaces.

FDA's used the expert elicitation to help estimate the cost to develop new written procedures for food contact surfaces. From the expert elicitation final report, the experts' summarized their estimate for the low and high costs necessary to develop facility-specific and equipment-specific written procedures. From the expert elicitation, the primary factor that affects the effort, and therefore the cost, is facility size and numbers of pieces of equipment. We assume that it typically takes six to eight hours per piece of equipment to develop the written procedures, which includes the time to review their procedures and equipment requirements, hold internal meetings, develop an initial draft, and then to develop a final draft. As previously mentioned, sanitation workers should be well-trained and receive annual refresher training. Training typically includes chemical safety and job specific training in their specific written procedures (Ref. 47). We assume that facilities will train five employees for two hours per piece of equipment or contact surface each year. We estimate costs to food manufacturing facilities only; we do not estimate costs for food wholesalers or warehouses here as we do not expect these facilities to have food exposed to the environment and therefore they would not have any food contact surfaces. We ask for comments about our assumptions and estimate.

Table 25a- Estimated Costs to Develop Written Procedures to Prevent the Contamination of Food Contact Surfaces by Fac Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total

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Total number of Domestic Manufacturing Facilities	17,781	9,251	3,920	449	
Percent of Facilities w/o written procedures for Food Contact Surfaces	29%	16%	11%	0%	
Total Facilities w/o written procedures for Food Contact Surfaces	5,156	1,480	431	0	
Cost to develop equipment-specific procedures per contact surface	$244	$427	$427	$427	
Number of Pieces of Equipment/Types of Surfaces	1-9	3-9	10-20	30-40	
One-time Total Cost to Develop written procedures for Food Contact Surfaces	$6,379,858	$3,889,344	$2,701,578	$0	$12,9
Cost to annually update equipment-specific procedures per contact surface (10% of initial development cost)	$24	$43	$43	$43	
Total Cost to update written procedures for Food Contact Surfaces	$637,986	$388,934	$270,158	$0	$1,2
Annual training costs (5 workers @ 2 hrs per equipment per year) Training costs per facility/year	$1,606	$1,927	$4,817	$11,239	

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Annual total training costs	$8,680,791	$3,024,033	$2,100,524	$0	$13,8
Annual training records costs (one record (12 minutes/record) per worker per equipment per year)	$27,454	$47,820	$33,216	$0	$12,9
Total one-time costs	$6,379,858	$3,889,344	$2,701,578	$0	$12,9
One-time costs annualized (7%, 7 yrs)	$1,183,803	$721,680	$501,286	$0	$2,4
Total annual costs	$9,346,231	$3,460,780	$2,403,898	$0	$15,2
Annualized one-time cost + recurring costs	$10,530,034	$4,182,468	$2,905,185	$0	$17,6
Total Average Annual Costs per Facility	$2,014	$2,755	$6,888	$0	

ii. Prevention of Cross-Contamination and Protection of Food from Adulteration

Proposed §117.135(d)(3) requires that facilities develop written procedures to prevent the cross-contact and cross-contamination of food, food packaging material and other food contact surfaces from insanitary objects and from raw to finished products. Common practices that can cause cross-contact and cross-contamination include inadequate cleaning of shared processing and packaging equipment, inadequate control of airborne dusts, and inadequate attention to the traffic patterns by equipment and personnel for the movement of raw and processed materials through the facility. Floor drains in production areas can be a source of cross-contamination; drains often have a P-trap filled with stagnant water. The stagnant water can be atomized or splashed becoming a source of microbial cross-contamination to nearby workers, equipment and food.

To estimate the cost to facilities to develop written procedures to prevent cross-contact

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and cross-contamination from insanitary objects, we looked at four FDA Food GMP survey questions to determine current practices. The first was, "Do you have written procedures for cleaning your non food-contact surfaces?" Almost 57 percent of facilities with fewer than 20 employees answered they do not have written procedures. About 37 percent of facilities with 20 to 99 employees answered they do not. The survey also asked "Do you have written procedures for cleaning your production areas?" Almost 39 percent of facilities with fewer than 20 employees answered they do not have written procedures. About 14 percent of facilities with 20 to 99 employees answered they do not. The survey asked, "Do you have written procedures for cleaning your finished storage areas?" Almost 50 percent of facilities with fewer than 20 employees answered they do not have written procedures. About 28 percent of facilities with 20 to 99 employees answered they do not. Finally, the survey asked, "Do you have written procedures for Raw Material Storage Areas?" Every facility with 500 or more employees answered that they have written procedures for each of these questions. If a facility answered "no" to these questions, then we determined that they lack written procedures for that section of their plant and would need to develop written procedures.

From FDA's expert elicitation, we asked about the use of equipment-specific written procedures, to protect against cross-contamination. Based on our expert elicitation, we assume that facilities with fewer than 20 employees will have one to five pieces of equipment or packaging material or other food items that will require written control procedures. Our experts agreed that it typically takes six to eight hours per piece of equipment to develop these procedures, which includes the time to evaluate the problem and write the procedures. We assume that the effort required to develop cleaning and sanitation procedures is primarily a one-time expense, although facilities also need to revise or add new written procedures when they

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add new equipment or replace old equipment. We assume the annual sanitation control procedures updating effort can be roughly estimated as 10 percent of the initial cost, which includes the annual "turnover" in plant or equipment layout or equipment.

We estimate costs to food manufacturing facilities only for Tables 26a-27a. We do not estimate costs for food wholesalers or warehouses here as we do not expect these facilities to have food exposed to the environment; therefore these types of facilities would likely not cross-contact or cross-contamination issues. We request comment on this assumption.

Table 26a - Estimated Costs to Develop Written Procedures to Prevent Cross-Contact and Cross-Contamination in Raw Mat Areas by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number of Domestic Manufacturing Facilities	17,781	9,251	3,920	449	
Percent of Facilities w/o written procedures for Raw Materials Storage Areas	62%	43%	32%	22%	
Total Facilities w/o written procedures for Raw Materials Storage Areas	11,024	3,977	1,254	99	
Cost per Facility to Develop Facility-specific written procedures for Raw Materials Storage Areas	$427	$641	$793	$976	
Total Cost to Develop written procedures for Raw Materials Storage Areas	$4,669,380	$2,518,238	$979,196	$94,218	
Cost per Facility to Annually Update Facility-specific written procedures for Raw Materials Storage Areas	$43	$64	$79	$98	
Annual Cost to Update written procedures for Raw Materials Storage Areas	$466,938	$251,824	$97,920	$9,422	

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Training Costs per Facility (Hourly Wage for Production Worker x2 hrs x 5 workers x Wage for Manager Trainer)	$321	$321	$321	$321	
Annual Training Costs	$3,511,330	$1,262,461	$396,494	$30,997	$5,201,282
One-time Cost for Containers, Partitions and other equipment per facility	$0 to $2,000	$0 to $5,000	$0 to $10,000	$0 to $10,000	
Total Cost for Container/Partition/Design to Prevent Cross-Contamination in Raw Materials Storage Areas	$10,935,315	$9,829,188	$6,174,000	$482,675	$27,421,178
Total One-time Costs	**$15,604,695**	**$12,347,425**	**$7,153,196**	**$576,893**	**$35,682,209**
One-time costs annualized (7%, 7 yrs)	**$2,895,501**	**$2,291,105**	**$1,327,299**	**$107,044**	**$6,620,949**
Total Recurring Costs	**$4,035,678**	**$1,534,926**	**$500,897**	**$40,926**	**$6,112,427**
Annualized one-time cost + recurring costs	**$6,931,179**	**$3,826,030**	**$1,828,195**	**$147,970**	**$12,733,375**
Total Annual Costs per Facility	**$634**	**$973**	**$1,481**	**$1,533**	

Table 27a- Estimated Costs to Develop Written Procedures to Prevent Cross-Contact and Cross-Contamination in Production & In-Process Areas by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Tot
Total number of Domestic Manufacturing Facilities	17,781	9,251	3,920	449	31,401
Percent of Facilities w/o written procedures for Production Areas	52%	27%	27%	22%	
Total Facilities w/o written procedures for	9,246	2,495	1,058	99	12,898

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Production Areas					
Cost per Facility to Develop Facility-specific written procedures for Production Areas	$427	$641	$793	$976	
Total Cost to Develop written procedures for Production Areas	$3,910,131	$1,570,195	$823,768	$94,218	
Cost per Facility to Annually Update Facility-specific written procedures for Production Areas	$43	$64	$79	$98	
Annual Cost to Update written procedures for Production Areas	$391,013	$157,020	$82,377	$9,422	
Training Costs per Facility (Hourly Wage for Production Worker x2 hrs x 5 workers x Wage for Manager Trainer)	$321	$321	$321	$321	
Annual Training Costs	$3,040,195	$813,903	$344,882	$32,050	
One-time Cost for Containers and Partitions per facility	$0 to $2,000	$0 to $5,000	$0 to $10,000	$0 to $10,000	
Total Cost for Container/Partition/Design to Prevent Cross-Contamination in Production Areas	$9,157,215	$6,128,788	$5,194,000	$482,675	
Total one-time Costs	$13,067,346	$7,698,986	$5,194,000	$482,675	
One-time costs annualized (7%, 7 yrs)	$2,424,688	$1,428,572	$1,116,617	$107,045	
Total Recurring Costs	$3,424,688	$1,428,572	$1,116,617	$107,045	
Annualized one-time cost + recurring costs	$5,903,972	$2,412,365	$1,549,329	$149,023	$10,014,689

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Total Annual Costs per Facility	$645	$984	$1,491	$1,544	

iii. Monitoring and Verification of Sanitation Control Procedures

Proposed §117.140 requires the owner or agent in charge of a facility to also establish and implement written procedures for monitoring the sanitation control procedures, and monitoring procedures must include the monitoring frequency. Proposed §117.150 (b) and (d) require facilities to establish and implement written procedures to verify that the preventive controls are adequate for controlling the hazards that are reasonably likely to occur and the procedures must verify that the monitoring is being conducted as required by §117.140. As before, we assume that the facilities that lack written procedures for their sanitation controls will also lack written procedures to monitor and verify that their sanitation procedures meet the proposed requirements. We ask for comments on our baseline assumption. To estimate the sanitation control monitoring costs, we assume that only manufacturing facilities will incur costs to comply with this requirement and that it will take four hours for a facility with 20 or fewer employees to prepare the written procedures, which will likely be a comprehensive check list of all the things that supervisors should monitor with respect to sanitation. We assume that it will take seven hours for larger facilities and up to 14 hours for the largest facilities. We assume that it will take four hours to train two supervisors in the new procedures and it will take between 2 to 4 minutes to record that the managers are trained in the new sanitation control procedures. To determine the time to monitor the sanitation controls to ensure they are performed correctly, our experts agreed that it will take a trained supervisor 2 to 4 minutes to monitor and document their observations when following a checklist for a total of 89 hours per year for a facility with few than 20 employees, 179 hours per year for a facility with 20 to 99 employees, and 1,071 hours per year for all larger facilities (Ref. 47) We assume that verification will typically be performed

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by the visual inspection of the sanitation controls as a check on the sanitation workers and monitors and by careful records review. We assume that it will take 89 hours per year per facility that does not already perform verification. We ask for comments for each of our estimated times.

Table 28a - Estimated Costs to Develop and Implement Monitoring and Verification Sanitation Controls by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of Domestic Manufacturing Facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
Percent without Monitoring and Verification Procedures for Sanitation Controls	48%	15%	4%	0%	
Total Facilities without Monitoring and Verification Sanitation Procedures	8,535	1,388	157	0	10,080
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Labor Hrs to Develop Sanitation Monitoring Procedures	4	7	7	14	
Subtotal Cost to Develop Monitoring Procedures for Sanitation Controls (one-time cost)	$2,082,511	$591,737	$58,584	0	$2,732,832
Labor Hrs to Annually Update Monitoring Procedures	1	2	2	4	
Subtotal Cost to Annually Update Monitoring procedures for Sanitation Controls (annual cost)	$520,628	$169,068	$16,738	0	$706,434
Number of Employees that Require Annual Training in Monitoring Procedures for Sanitation Controls per Facility	2	2	6	8	

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Hours of Annual Training per Employee	4	4	4	4	
Hourly Wage Rate for Production Line Workers	$21	$21	$21	$21	
Subtotal Costs to Train Managers in Monitoring Sanitation Controls (annual cost)	$6,277,575	$1,019,283	$235,786	$0	$7,532,645
Percent facilities that do not maintain monitoring records	40%	17%	10%	0%	
Total number of Non-Qualified Domestic Manufacturing and Wholesale Facilities that do not monitor	14,291	1,971	406	0	16,668
Minutes per Record to Document Monitoring of Sanitation Controls	2 to 4	2 to 10	6 to 17	6 to 17	
Total hours per year for monitoring	89	179	1071	1071	
Subtotal Recordkeeping Costs for Training in Monitoring and Verification Sanitation Procedures	$12,745,931	$5,710,814	$7,982,707	$0	$26,439,451
Total hours per year for verification	89	89	89	89	
Sanitation Control Verification – Visual Observation and Records Review (Annual) – based on 89 hours per year of management time for visual observation and records review	$39,050,818	$8,748,358	$2,038,109	$0	$49,837,286
Total One-Time Costs to prepare monitoring and verification procedures	$2,082,511	$591,737	$58,584	$0	$2,732,832
One-time costs annualized (7%, 7 yrs)	$685,644	$133,524	$11,719	$0	$830,887
One-time costs annualized (3%, 7 yrs)	$685,644	$133,524	$11,719	$0	$830,887
Total Annual Monitoring and Verification Sanitation	$58,639,022	$15,657,396	$10,280,241	$0	$84,576,658

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Control Costs					
Total Costs Annualized (One-Time annualized + On-Going) (7%, 7 yrs)	$59,025,438	$15,767,194	$10,291,112	$0	$85,083,744
Total Costs Annualized (One-Time annualized + On-Going) (3%, 7 yrs)	$58,973,278	$15,752,373	$10,289,644	$0	$85,015,295
Total Annual Costs per Facility	$8,229	$9,812	$27,490	$0	$9,295

Table 29a presents the summary of all costs associated with implementing sanitation controls.

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Table 29a - Summary of Sanitation Annual Costs (VSB < $250K)

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	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Written Procedures, Training, and Recordkeeping for Food Contact Surfaces	$10,530,034	$4,182,468	$2,905,185	$0	$17,617,687
Annual Cost Per Affected Facility (Food Contact Surfaces)	$2,014	$2,755	$6,888	$0	$2,457
Written Procedures and Training for Prevention Cross-Contamination Raw Materials Storage Areas	$6,931,179	$3,826,030	$1,828,195	$147,970	$12,733,375
Annual Cost Per Affected Facility (Raw Materials Storage)	$634	$973	$1,481	$1,533	$786
Written Procedures and Training for Prevention Cross-Contamination In-Process Areas	$5,903,972	$2,412,365	$1,549,329	$149,023	$10,014,689
Annual Cost Per Affected Facility (Cross-Contamination Production Areas)	$645	$984	$1,491	$1,544	$786
Monitoring and Verification for Sanitation Controls (including Training and Recordkeeping)	$59,025,438	$15,767,194	$10,291,112	$0	$85,083,744
Annual Cost Per Affected Facility (Monitoring and Verification)	$8,229	$9,812	$27,490	$0	$9,295
Total Annual Costs of Sanitation Control	**$82,390,623**	**$26,188,057**	**$16,573,821**	**$296,993**	**$125,449,494**

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4. Recall Controls

Recall controls are the written procedures that describe the steps to take to recall food products from the market as required in proposed §117.137 for products with hazards that are

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reasonably likely to occur. The proposed recall procedures must be taken to recall the products and assign responsibility for the recall. The proposed recall procedures must include: a description of how the facility will notify the direct consignees of the products being recalled (including how to return or dispose of affected product); the procedures to notify the public when necessary; the procedures for conducting effectiveness checks to verify that the recall is carried out; and procedures to appropriately dispose of the recalled product. The preamble and our PRIA section on recalls describe the impact of food recalls. A list of FDA-regulated products that have been recalled can be found on FDA's website at http://www.fda.gov/safety/recalls/default.htm.

The proposed recall controls are intended to be the minimum actions that a facility must take to minimize the disruptive effects of a recall. The costs to a facility to develop their recall control plans with the required procedures are their costs to identify the person responsible for the plan, the costs to determine the actions that should be performed, the costs to notify direct consignees, the public and the costs to perform effectiveness checks to verify that the recall is carried when the establishment would not have performed these functions without the requirement of this rule.

To estimate the costs, we first used the FDA Food GMP survey as the basis for our assumptions about the number of facilities that currently have recall procedures in place. FDA survey question 17.8 asks, "Which of the following elements does your food safety plan address? Procedures for tracing the distribution of articles of food." FDA survey question 17.9 asks, "Which of the following elements does your food safety plan address? Procedures to ensure a safe and secure supply chain for the raw materials and ingredients or components used in facility." We recognize that having recall control plans and tracing the distribution of food and ensuring a safe and secure supply chain are not identical but we can assume that they are similar

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Moved up [129]: There is anecdotal evidence in the literature on recalls that good recall control procedures can limit the economic harm from recalls for adulterated foods.

Moved up [130]: Changes in their recordkeeping procedures helped Montana Quality Foods when they learned of the results of three tests showing *E. coli* contamination and their new records showed that the meat originated from another firm. The meat had not yet been distributed so the company was able to avoid a recall.

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Recall procedures that are fast, thorough, predictable and precise help reduce the social impact of recalls by enabling establishments to quickly pinpoint where in the manufacturing, supply or distribution chain the problem originated to more quickly remedy the situation before injuries occur.

Deleted: In response to a recall of 270 pounds of ground beef in late January of 2002, Montana Quality Foods began keeping specific records to show the origins of meat used in ground beef and holding processed meats in storage until government test results come back (Ref. Migoya, 2002).

Deleted: (Ref: Otto, 1998) Lack of good recall preparedness, on the other hand, can seriously limit the effectiveness of a recall. FDA's search for the source of green onion that caused 950 people to contract Hepatitis A was impeded by poor procedures by a vegetable middleman (Ref. Martin, 2004).

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enough to trace the distribution of their foods and their raw materials and ingredients or not. The responses to both questions are very close. About 53 percent of facilities with 20 or fewer employees responded "no." We expect that the facilities that do not trace the distribution of their food articles or that lack procedures for their supply chain will also currently lack recall procedures that meet the proposed requirements. We also assume that 20% of facilities with 20 to 99 employees and 5% of facilities with 100 to 499 employees do not already have recall plans in place and that 100% of facilities with more than 500 employees have such plans. We ask for comments on our baseline assumptions. We used FDA's recordkeeping cost model to estimate the average number of hours to develop recall procedures, for each size facility. The recordkeeping cost model, Table 2-4 for shipment and distribution SOPs, shows that the hours needed to develop the procedures is seven for facility with 20 or fewer employees and two hours for facilities with 20 or fewer employees to update the procedures each year, while it takes 13 hours for facilities with 100 to 499 employees and 19 hours for facilities with over 500 employees. (Ref 50) To estimate the training costs, we assume that a small facility will need to train at least five workers in their recall procedures. We assume that it will take approximately four hours of training per worker by a manager with an average wage rate of $61/hour for a total cost per facility of $644 per facility with 20 or fewer workers per year ($20/hr x 4 hrs x 5 workers + $61/hr x 4 hrs x 1 manager.) We ask for comments on our assumptions. Our estimate for the costs to develop the recall controls are shown in Table 30a.

We estimate costs of implementing recall controls to food manufacturing facilities only. We do not estimate costs for food wholesalers or warehouses as we expect these facilities to be mostly middlemen in the food production chain. These facilities, for the most part, will not be processing food but rather re-selling or storing finished food and thus would not be the parties to

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initiate a recall. We request comment on this assumption.

Table 30a - Estimated Costs to Implement Recall Controls by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number Domestic Manufacturing Facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
% without Recall Procedures	53%	20%	5%	0%	
Total Facilities without Recall Procedures subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	9,424	1,850	196	0	11,470
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Labor Hrs to Develop Initial Recall Procedures	7	7	13	19	
Subtotal Cost to Develop Recall Controls (one-time cost)	$4,049,073	$795,171	$169,106	0	$5,013,350
Labor Hrs to Annually Update Recall Procedures	2	2	4	10	
Subtotal Cost to Annually Update Recall Controls (annual cost)	$1,156,878	$227,192	$52,033	0	$1,436,102
Number of Employees that Require Annual Training in Recall Controls per Facility	5	10	20	40	
Hours of Annual Training per Employee	4	4	4	4	
Hourly Wage Rate for Production Line Workers	$20	$20	$20	$20	
Subtotal Costs to Train Production Workers Annually in Updated Recall Controls	$6,296,451	$1,236,518	$231,161	$0	$7,764,130
Minutes per Record to Document Training in Annually Updated Recall	2 to 4	2 to 4	2 to 4	2 to 4	

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Controls					
Subtotal Recordkeeping Costs for Training in Updated Recall Procedures	$558,336	$109,648	$25,112	$0	$693,096
Total One-Time Costs	$4,049,073	$795,171	$169,106	$0	$5,013,350
Total One-Time Costs Annualized (7%, 7 Years)	$751,319	$147,546	$31,378	$0	$930,243
Total One-Time Costs Annualized (3%, 7 Years)	$649,902	$127,630	$27,143	$0	$804,674
Total Annual Recall Control Costs**	$8,032,144	$1,583,986	$313,267	$0	$9,929,397
Total Costs Annualized (One-Time annualized + On-Going) (7%, 7 Years)	$8,783,463	$1,731,533	$344,645	$0	$10,859,640
Total Costs Annualized (One-Time annualized + On-Going) (3%, 7 Years)	$8,682,046	$1,711,616	$340,409	$0	$10,734,072
Average Annual Costs per Facility	$926	$930	$1,616	$0	$940

** Total on-going costs include the relatively small costs to notify consignees and the public as described in the test but not shown in the table.

5. Monitoring

This proposed rule requires that all facilities have procedures in place to monitor the implementation of preventive controls; monitoring activities should be conducted for sanitation, process, and allergen controls. The costs of monitoring are incorporated into the specific sections of the PRIA where applicable.

6. Corrective Actions

Proposed § 117.145 requires facilities subject to subpart C to establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented to ensure their foods are not adulterated under section 402 of the act or misbranded under section 403(w) of the act; and for appropriate action to be taken, when necessary to identify and correct the cause of the implementation failure. Corrective actions must be taken in

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the event of unanticipated problems to reduce the likelihood that the problems will recur, evaluate all affected food for safety and then take actions, when necessary, to identify and correct the cause of any failure; and perform or obtain a timely reassessment of their food safety plan to determine whether modifications are required to reduce the risk of recurrence, and modify the food safety plan as necessary. In the event of process deviations, which might occur when critical factors do not comply with the requirements specified for the process controls, then corrective actions might be necessary. Corrective actions can include segregating and holding the affected product, at least until all affected food is evaluated to determine their acceptability for distribution.

From FDA's expert elicitation, common corrective actions can involve assessing whether a facility needs more frequent equipment calibration or the use of two thermometers instead of one; or it may involve improvements in a training program, the creation of a training program that was previously lacking; the addition of a process control or monitoring point where control was found lacking – for example, when foreign materials are found, the facility might add a filter, magnet, or metal detector. Changes in raw material or packaging material inspection procedures are a frequent corrective action to help prevent a mislabeling failure, among many other possible corrective actions to ensure that the food safety plan is working (Ref. 47).

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Our estimate for total new corrective action costs by facility size, are shown in Tables 31-36a. To estimate the cost to adopt corrective action procedures, we first determined the baseline use of corrective actions procedures. Every facility involved in food production should have corrective actions procedures as part of their food safety plan. To determine the number of facilities that lack corrective action procedures, FDA survey asked, "Which of the following elements does your written food safety plan address?: Procedures for taking corrective action."

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Among facilities with both fewer than 20 employees and that have a food safety plan, 48 percent responded no, that they lack written procedures for taking corrective action. Of the facilities with 500 or more employees 100 percent of those responding reported having a food safety plan and all of their food safety plans have corrective action procedures.

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We estimate that facilities that answered "no" to this question will incur the cost of developing corrective action procedures, performing the corrective actions, and recording the results. We recognize that some facilities that responded "no" and lack written procedures might still perform "informal" corrective actions or conduct trouble shooting when they discover safety problems. Multiplying the total number of facilities by the percentage of facilities not already performing corrective actions yields an approximate estimate for the number of facilities that will incur a new cost of developing written procedures and implementing formal corrective actions. All other facilities are excluded from estimation as they report that they are already performing the required activities.

Once we estimated the number of facilities that will incur new corrective action using the Food GMP survey, we estimated the actual cost of a complete corrective action by facility size. To properly execute a corrective action, a facility would: 1) segregate, hold, rework or destroy the affected product so that no product enters commerce that is potentially injurious to their consumers' health or otherwise adulterated; 2) identify and correct the cause of the failure to reduce the likelihood or recurrence of the incident; and 3) it might include reassessing their food safety plan.

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We estimate cost of segregating and holding product as a percentage of a facility's single line production value. To calculate a single day's value of production we utilize information from the Annual Survey of Manufacturers (2009) provided by the U.S. Census Bureau and

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facility information from D&B (Refs. 59, 6). According to the expert elicitation about 75 percent of a line's production at a facility will need to be held for any given corrective action. A study published in the Inventory Management Review suggests that the cost of holding product is somewhere between 15 and 35 percent of its total value. We use 25 percent as the average cost of holding product (Ref. 60). When both of these percentages are applied to the value of one line's production, we get the cost of holding product for a single corrective action. These calculations are shown in Table 35a.

Additionally, industry experts suggest that about five percent of production will need to be destroyed, as part of corrective action procedures, to prevent its entrance into commerce. Again, we apply this percentage to the total value of one line's production to estimate the total cost of downtime or lost product to a facility for each corrective action. Adding these two numbers yields the total cost of holding and downtime in production due to a corrective action. Next we estimate the cost to correct the failure and reassess the food safety plan. According to our expert elicitation and FDA food safety experts, identifying the problem and correcting it should take somewhere between one and 9 hours, depending on the complexity of the problem (Ref. 47). We assume that an average corrective action will take around five hours to identify and correct and that the corrective action will likely be performed by a production supervisor in a food manufacturing industry.

Next, we add the cost of holding products during an investigation and the cost of the downtime of production to the cost to correct and reassess to get the total cost of the corrective actions. Our experts estimated the average number of incidents per year that require corrective actions as shown in Table 31.

Table 31 - Expert Estimates of the Number of Incidents Needing Formal Corrective Action Per Year by Facility Size

Facility size	Number of Incidents

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<20 employees	2
20 to 99 employees	4
100 to 499 employees	8
>500 employees	12

We then take the annual cost of corrective actions and multiply it by the number of facilities that do not already have corrective action procedures.

We estimate costs of corrective actions to food manufacturing facilities only in Tables 32a-36a. We do not estimate costs for food wholesalers or warehouses as we expect these facilities to be mostly middlemen in the food production chain. These facilities, for the most part, will not be processing food but rather re-selling or storing finished food. We request comment on this assumption.

Table 32a - Corrective Action SOP Costs by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Domestic Manufacturing Facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
% Facilities w/o written procedures for Corrective Actions	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	8,534	1,943	628	0	11,105
Hours to Develop General Corrective Action Procedures	7	7	11	16	
Wage Rate (Manager)	$61	$61	$61	$61	
Subtotal One-time Total Cost to Develop Written Procedures for Corrective Actions	$3,673,245	$825,192	$421,640	$0	$4,920,077
Hrs to annually update Corrective Action Procedures per facility	0.7	0.7	0.7	0.7	
Subtotal Cost to annually update Written Procedures for Corrective Actions	$367,325	$82,519	$42,164	$0	$492,008
Number of Incidents that require Corrective Action per Facility	2	4	8	12	
Wage Rate or Production Line Workers	$21	$21	$21	$21	
Wage Rate (Manager-Trainers)	$61	$61	$61	$61	

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Number of Workers that Require (Re)Training in Response to Incident that requires Corrective Action	5	5	5	5	
Hrs to Train per Workers in Response to Incident that requires Corrective Action	2	2	2	2	
Total Annual Training Costs	$5,712,025	$2,566,405	$1,668,967	$0	$9,947,397
Total Annual Training Records Costs (one record (12 minutes/record) per worker per incident per year)	$90,326	$40,583	$26,392	$0	$157,301

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Table 33a - Corrective Action Costs to Identify and Correct Failures by Facility Size (VSB < $250K)

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
% Facilities w/o written procedures for Corrective Actions	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	8,602	1,933	628	0	11,163
Average Hours to identify and take CA for each incident	1 to 9	1 to 9	1 to 9	1 to 9	
Wage Rate (Manager)	$61	$61	$61	$61	
Total Annual Costs to Identify and Correct Failures	$5,285,344	$2,374,698	$1,544,297	$0	$9,204,338

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Table 34a - Corrective Action Costs for New Parts and Equipment by Facility Size (VSB < $250K)

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	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401

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% Facilities w/o written procedures for Corrective Actions	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	8,602	1,933	628	0	11,163
Average Annual Costs for new Parts and Equipment	$0 - $1,000	$0 - $5,000	$0 - $10,000	$0 - $10,000	
Total Annual Costs for New Parts and Equipment	$4,301,224	$4,831,335	$3,141,880	$0	$12,274,439

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Our calculation for the value of one day's production is presented in Table 35a. Initially, we get the total value of the entire food manufacturing industry in 2009 from the Annual Survey of Manufacturers provided by the U.S. Census Bureau minus the segment of the food industry not covered by the proposed rule. We attribute a percentage of this total value to each size category by using information on sales provided by D&B. Because D&B collects categorical sales data, rather than strict sales figures, a percentage of total sales are easier to derive than the exact dollar amount. Applying the percentages to the total value gives the breakdown of sales volume that each size category is responsible for in one year. From before, we estimate that the average facility will operate for 357 days of the year, after which we divide this number by the total number of facilities in each size category to get the value of production for a single manufacturer. Then, dividing the annual value of a single manufacturer's production by the number of operational days yields the value of one day's production by facility size. Our expert elicitation determined that the equivalent days per incident is 0.21 from which we determined the average value of lost production per incident. The experts further judged that approximately 75% of the facilities will have to hold their product after each incident. We estimate that facilities that hold their product will also incur the cost of lost profit during the period of the hold. We assume that the profit margin for these products is 10% of their value. We ask for

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comment about all of our assumptions and estimates.

Table 35a - Corrective Action Costs for Product Losses and Down Time of Production by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Domestic Manufacturing Facilities that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	17,781	9,251	3,920	449	31,401
% Facilities w/o written procedures for Corrective Actions	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C Hazard Analysis and Risk-Based Preventive Controls	8,602	1,933	628	0	11,163
Total Value of Domestic Processed Food	$905 Billion				
Percent of Total Value by Facility Size	12%	8%	24%	56%	
Total Sales Volume by Facility Size (Billions of Dollars)	$109	$68	$218	$510	
Average Annual value of Production per Facility (millions of dollars)	$6.1	$7.3	$55.6	$1,135	
Number of days of production per year	357	357	357	357	
Average value of one day's production	$17,222	$20,579	$155,722	$3,180,342	
Equivalent Days per Incident	.21	.21	.21	.21	
Avg value of lost production per incident	$3,588	$4,287	$32,442	$662,571	
Percent facilities that must hold product after incidents	75%	75%	75%	75%	
Foregone/Lost profit of holding and inventory holding costs	10%	10%	10%	10%	
Total Annual Cost of Product Holding and Production Down Time	$4,629,810	$2,485,643	$12,231,519	$0	$19,346,972

Table 36a presents a summary of all corrective actions costs.

Table 36a - Summary of Corrective Actions Costs (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Written Procedures Annual Costs	$367,325	$82,519	$42,164	$0	$492,008
Annual Training Costs	$5,712,025	$2,566,405	$1,668,967	$0	$9,947,397
Annual Training Records Costs	$90,326	$40,583	$26,392	$0	$157,301
Annual Costs to Identify and Correct Failures	$5,285,344	$2,374,698	$1,544,297	$0	$9,204,338
Annual Costs for New Parts and Equipment	$4,301,224	$4,831,335	$3,141,880	$0	$12,274,439
Annual Costs of Product Holding and Production Downtime	$4,629,810	$2,485,643	$12,231,519	$0	$19,346,972
Total Annual Costs of Corrective Actions	**$20,386,054**	**$12,381,183**	**$18,655,218**	**$0**	**$51,422,454**

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Total Costs Annualized (One-Time annualized + On-Going) (7%, 7 yrs)	**$21,067,636**	**$12,534,300**	**$18,733,455**	**$0**	**$52,335,391**
Total Costs Annualized (One-Time annualized + On-Going) (3%, 7 yrs)	**$20,975,633**	**$12,513,631**	**$18,722,894**	**$0**	**$52,212,158**
Avg. Cost of Per Affected Facility per year	**$2,449**	**$6,486**	**$29,812**	**$0**	**$4,698**

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7. Verification

Proposed part 117.150 requires that facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls to conduct verification activities. Verification activities ensure that the preventive controls implemented are functioning as they should to prevent hazards, as identified in the hazard analysis, from occurring during food production. Verification activities also ensure that the facility is monitoring their preventive controls with sufficient frequency, the facility is taking the appropriate corrective actions when needed, and that those corrective actions are working properly. There are many different activities that a facility can undertake to verify that their food safety system is operating correctly. Some such activities include validating the food safety plan, checking the calibration of instruments (such as thermometers) and reviewing records.

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a. Validation of food safety plan

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The costs of validating preventive controls are addressed, where applicable, in the cost section for preventive controls.

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b. Monitoring

The verification of monitoring is addressed in the appropriate sections of the analysis where monitoring is needed. These sections include process controls and sanitation controls.

c. Corrective actions

Verification of appropriate corrective actions and the associated costs are included in the section of the PRIA on corrective actions.

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d. Verification Activities-Implementation and Effectiveness

- Calibration of Process Monitoring Instruments and Verification Instruments

Facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls will be required to verify that their process monitoring instruments and verification instruments have been properly calibrated. The costs of verifying instrument calibration is calculated as part of the costs of process controls.

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Moved down [154]: When both of these percentages are applied to the value of one line's production, times the number of days the product is held, we get the cost of holding product on each testing occasion. ¶

Deleted: We expect facilities making certain types of products to begin finished product testing as a result of this rule-making. Experts within CFSAN have identified those product categories for which we would expect the manufacturing facilities to conduct finished product testing, although this identification is imperfect as previously explained. We use information from the GMP survey to estimate the percentage of facilities that are already conducting such testing; the remainder of the facilities will incur the costs of implementing finished product testing on a monthly basis. The costs of finished product testing and holding finished product awaiting testing results is shown in table [...]

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Moved down [160]: Effective environmental pathogen controls will be product, process, and plant specific.

Deleted: Effective environmental pathogen control does not target all pathogens that could potentially come from the environment, but rather those that are reasonably likely to be a problem based on product and production procedures.

Moved down [161]: Generally, *Salmonella* is the organism of concern for certain dry food products,[48] where *Salmonella* would be introduced with a raw product or ingredient,[49] and *Listeria monocytogenes* (Lm) the organism of concern for wet processing environments. ¶

Deleted: Performance of Environmental Monitoring¶
The proposed rule requires that facilities subject to subpart C perform environmental monitoring for environmental pathogens that are reasonably likely to occur. Not all facilities subject to subpart C will need to conduct environmental monitoring; only ...

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Moved down [162]: assess the potential for pathogens of concern being present in their food ...

Deleted: Once it has been established that there is the potential for pathogens of concern to enter a f ...

Moved down [163]: sampling sponges or swabs¶ neutralizing buffer broth¶ ...

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Moved down [164]: gel packs) for samples ¶ coolers ¶ ...

Deleted: We estimate that it will take 15 minutes to collect each sample; each sample will be collec ...

Moved down [165]: need to take fewer samples per sampling occasion than larger facilities. ¶ ...

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Moved down [166]: For samples where *Salmonella* spp. are the organism of concern we u ...

Deleted: For the environmental testing costs presented here we do not include the costs of ...

Moved down [167]: and even product testing by the facility is likely to be undertaken in an effo ...

Deleted: Samples will be collected using sponges, buffer broth, gloves, and collection bags ($2.33 fo ...

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Deleted: tested for and how many samples are being taken. In addition, Facilities that send a high volume of samples to a laboratory can negotiate lower pricing per sample for testing than can facilities sending a lower volume of samples. We show the difference in these costs by number of samples and by pricing based on sample volume in Table 52. We show annual testing costs based on monthly shipments and per shipment costs in this table.¶

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Moved down [171]: Per Shipment Costs

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Moved down [173]: The information on

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Table 54- Facilities Needing Monthly Environmental Testing for Listeria ...

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¶
v.

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Part of the verification activities required by this proposed rule includes the reviewing of some types of facility records. Facilities should review records of monitoring and corrective actions within a week after the records were made; records should be reviewed by a qualified individual. Facilities should review records of consumer, customer, or other complaints, calibration, finished product testing, ...

Moved down [180]: Review of records for ...

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Moved down [181]: According to one of the ...

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Moved down [182]: Large to very large ...

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Moved down [183]: spend less time reviewi ...

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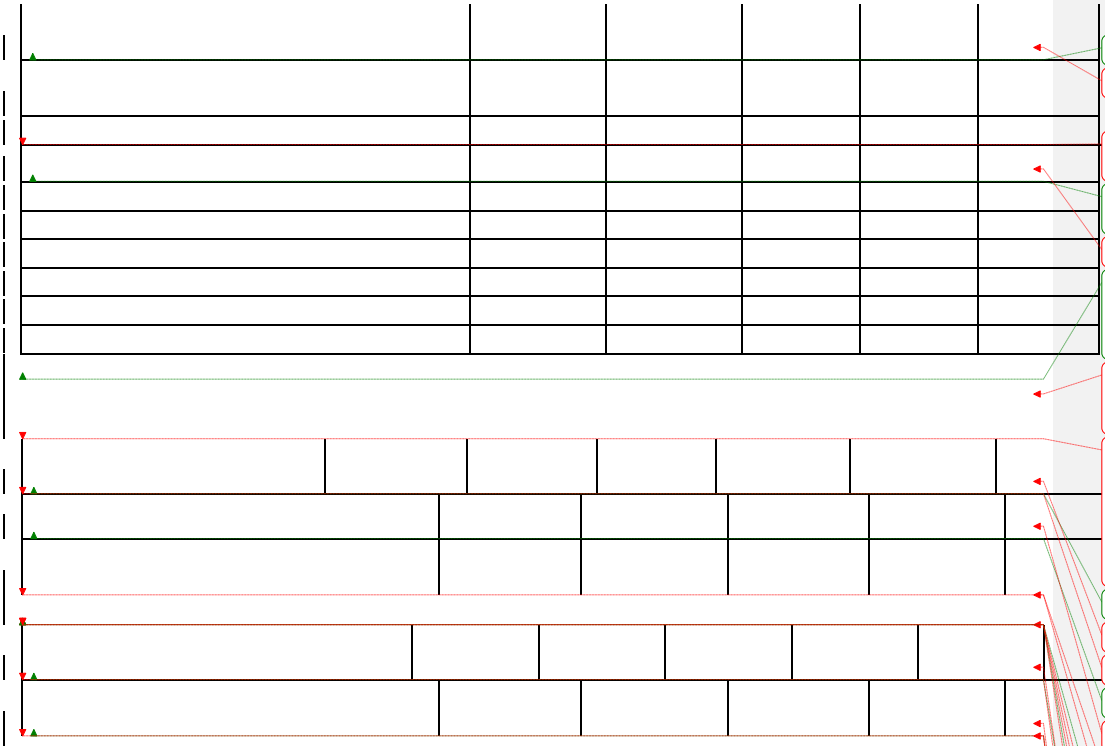

Written procedures for frequency of calibrating process monitoring instruments and verification instruments are also included as part of the costs of written procedures for process controls.

e. Review of Records

Review of records for monitoring, corrective actions, and calibration of instruments are discussed in the process controls, sanitation controls, and corrective actions sections of this analysis.

f. Reanalysis of the Food Safety Plan

The verification requirement of reanalyzing the food safety plan is discussed under the section of the analysis on the food safety plan and costs are calculated in the hazard analysis

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Moved down [187]: Time per month spent on records (minutes)
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Moved down [188]: [a] Warehouses, wholesalers, and qualified facilities are excluded from this calculation.¶ ¶
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Deleted: e. Written Procedures for Verification Activities¶ i. finished product testing¶ The proposed rule would require that any facility conducting finished product testing have written procedures regarding such testing. The written procedures must show that the finished product ...
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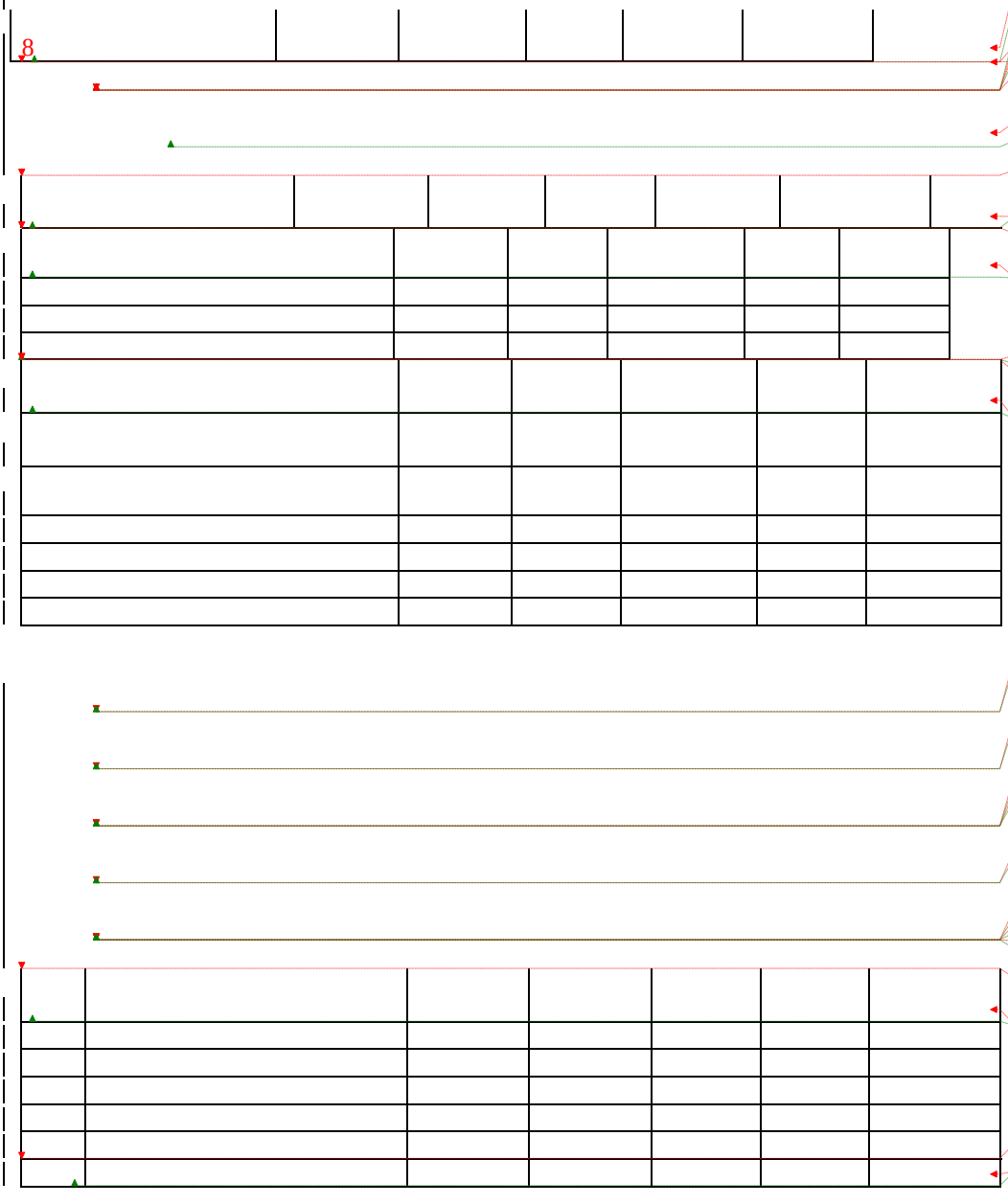
section, preventive controls section, and corrective actions sections of the analysis, respectively. Any changes made in these areas can be used to update the food safety plan as needed.

8



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Deleted: g. Records for verification activities¶
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Moved down [200]: the supplier's food safe
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Moved down [201]: We cannot tell how ma
Deleted: Of the facilities remaining that might
Moved down [202]: packaged final product
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Moved down [205]: We estimate the travel
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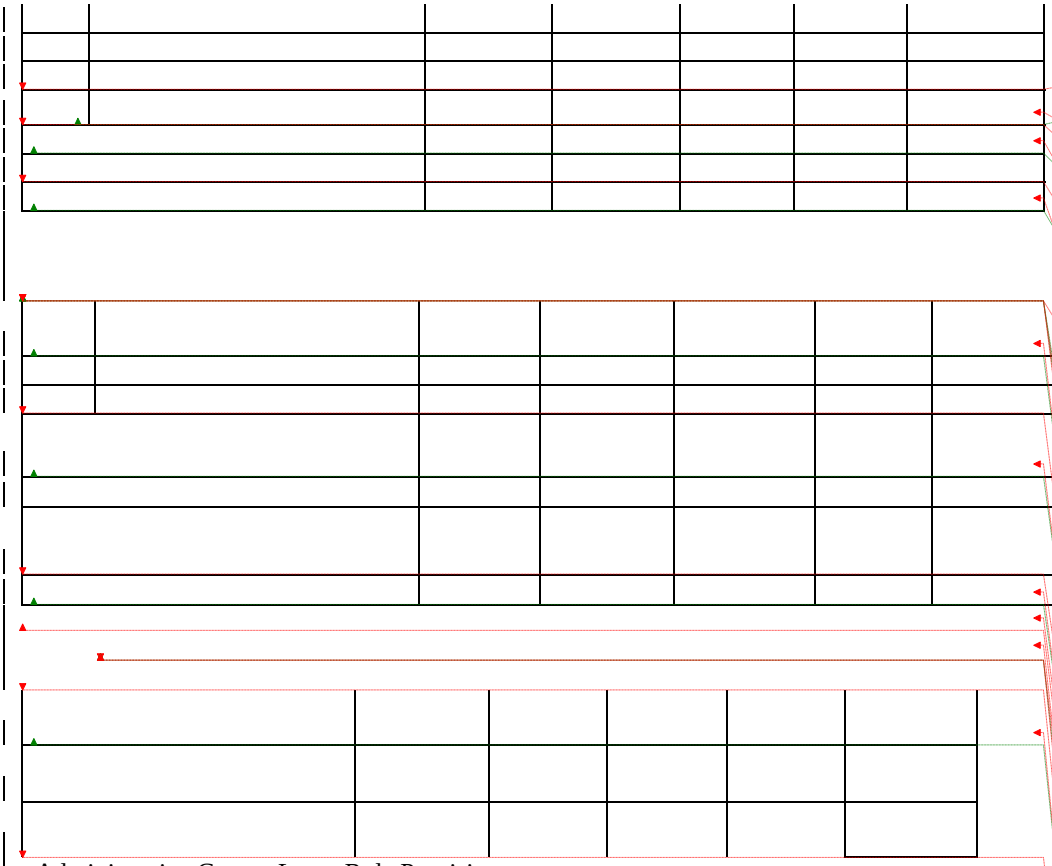

. Administrative Cost to Learn Rule Provisions

Each food manufacturing and processing facility covered under this proposed rule-making will incur administrative costs to learn about the rule requirements in order to comply with the rule provisions. It is likely that an individual at each facility will become aware of this proposed rule-making through normal business activities: reading the trade press, reading industry news, FDA outreach, trade outreach, or conversation with other facility operators who also would be required to comply with the proposed regulation. Once an individual at each covered facility becomes aware of the regulation, he or she will need to learn the requirements of the regulation, which will require finding a copy of the requirements and reading and

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Deleted: v. Supplier Verification Activities other than Audits¶
If the supplier(s) of raw materials and other ingredients has not applied a preventive control during manufacturing or processing at the supplying facility or the supplier is not subject to a designated food safety regulation, then the receiving facility has the choice of requiring the following supplier verification activities: 1) conducting or obtaining documentation of periodic onsite audits of the supplier; 2),periodic or lot-by-lot sampling and testing of the raw material or ingredient (the receiving facility can conduct the testing or have i
Moved down [212]: We use quarterly testing
Deleted: We estimate that when an ingredient is
Moved down [213]: The costs per day of
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Deleted: Summary of Supplier Controls Costs ¶
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understanding them. To become familiar with the requirements for this proposed rule-making, FDA estimates that for facilities with less than 20 employees and facilities with 20 to 99 employees it will take one individual at the level of an operations manager about 40 hours to read and understand the requirements. For larger facilities, those facilities with 100 to 499 employees and facilities with 500 or more employees, FDA estimates that in addition to an operations manager learning about the rule, a legal analyst will also spend about 40 hours reviewing the rule requirements.

Table 37 shows the annualized costs to facilities to learn about the proposed rule requirements based on facility size. Wage rates are from the May 2010 BLS Occupational Employment Statistics for a General and Operations manager (11-1021) and a lawyer (23-1011) and include overhead. We assume that facilities will incur these costs whether they are qualified facilities or non-qualified facilities.

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Table 37 - Reading and Learning about Rule Requirements

	<20 employees	20 to 99 employees	100 to 499 employees	> 500 employees	To
Number of Facilities	80,475	12,283	4,411	477	
General and Operations Manager Wage including overhead ($ per hour)	$79.14	$79.14	$79.14	$79.14	
Time reading and learning rule (hours)	40	40	40	40	
Legal Analyst Wage including overhead ($ per hour)			$95.78	$95.78	
Time reading and learning rule (hours)			40	40	
Per Facility Learning Cost	**$3,166**	**$3,166**	**$6,997**	**$6,997**	
One Time Cost to Learn about the Rule	**$254,751,660**	**$38,883,065**	**$30,862,885**	**$3,337,474**	**$327,8**
One-time costs Annualized over 7 years	**$47,269,991**	**$7,214,878**	**$5,726,708**	**$619,279**	**$60,8**

Moved down [218]: ¶
voluntary adoption of some or all provisions of the proposed regulations, ¶
current or enhanced State and local enforcement activity to bring about a reduction of potential harm from adulterated or mislabeled foods, or ¶
the tort system, with litigation or the threat of litigation serving to bring about the goals of the proposed rule. ¶
We believe that there are several reasons not to rely on these alternatives.¶
The advantage of the current regime is that it is already in place and the food industry generally understands the requirements. The disadvantage is that the regime lacks several of the most important provisions of the proposed regulations that have the potential to prevent

Deleted: G. Other Regulatory Options¶
¶
FDA considered several regulatory options for dealing with current manufacturing, processing, packing and holding practices that might not prevent foods from becoming adulterated or mislabeled. The options that we considered include: (1) no new regulatory action, (2) a definition for very small businesses based on annual earnings of $100,000, (3) a definition for very small businesses based on annual earnings of $500,000, and (4) the proposed rule. ¶
Option (1) No New Regulatory Action¶
Under this option, FDA would rely on: ¶
the current food CGMP regulations (21 CFR part 110),

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Deleted: millions of otherwise avoidable foodborne illnesses.

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By voluntarily introducing preventive controls, establishments that do so demonstrate that their expected private economic benefits of preventive controls will exceed their private costs. Voluntary adoption of any practices will occur when it is profitable to do so. Although many establishments have adopted the proposed practices in order to meet the demand for safer products, FDA's survey shows that many facilities have not adopted

Deleted: safe practices. As mentioned in our section entitled, Need for the Rule, entities will adopt those practices that are economical, not necessarily those practices that are sufficient to ensure the safety of their consumers, so there will often be an under provision of safety practices.

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Public and private health agencies, consumer groups, competitors, trade organizations or other independent parties could publicize the risks from food products not processed or held using sufficient preventive controls and allow consumers to decide for themselves about the risks of adulteration. The weakness of this alternative is that independent organizations cannot easily discover the risks until after consumers are sickened. In the absence of the proposed preventive control regulations, the burden of monitoring manufacturing practices fall more heavily on consumers, despite their difficulties in ...

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¶ ...

Deleted: Current or enhanced State and local regulations could bring about a reduction of potential harm from contaminated foods. This alternative h ...

Deleted: http://www.census.gov/econ/cbp/methodology.htm)¶

Moved down [222]: Because no one is responsible for checking expired records and facilities have no incentive to withdraw registratio ...

Deleted: Table 69 shows the results of these calculations. ¶ ...

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VI. Preliminary Regulatory Flexibility Analysis¶
¶ ...

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Deleted: Table 70- shows the SBA size classifications for many of the various sectors of food manufacturing. (Ref. SBA table from websi ...

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Moved down [226]: as having fewer than 500 employees, consistent with the SBA definition for most food manufacturers. About 99.5 percent of all food manufacturers, warehouses, and wholesalers that are covered by the proposed rule employ fewer than 500 employees and are therefore, considered small businesses under the proposed rule.

Deleted: FDA, for purposes of this proposed rule-making, has defined a small business for CFR part 110

Deleted: FDA defines a very small business for purposes of part 110, as a business that has less than $250,000.00 in total annual sales of food, adjusted for inflation. ¶
The proposed rule reduces the burden on small businesses through the use of modifications and exemptions from the proposed requirements when the small businesses meet the following requirements under section 418 or 421 of the FD&C Act: 1) for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (§ 103(c)(1)(D) of FSMA), 2) small businesses have an additional six months to comply after the effective date of FDA's final rule (§ 103(i) of FSMA) and very small businesses have an additional 18 months, and 3) v ...

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b. Costs to small entities.¶

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The costs to implement the proposed rule after ...

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Moved down [229]: summarizes the annual revenues for facilities by revenue category to sho ...

Deleted: Table 72- Food Manufacturers, Warehouses, and Wholesalers: Annual Revenues ...

Moved down [230]: Annual Revenue per Facility ($1,000's)

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Deleted: Table 73 shows our estimate for the average cost for affected small businesses: 1) with ...

Moved down [231]: . Affected businesses are businesses that do not currently perform the ...

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Moved down [232]: The results show that the average costs to small businesses are potentially ...

Moved down [233]: The regulatory costs of this proposed rule are further likely to discourage ...

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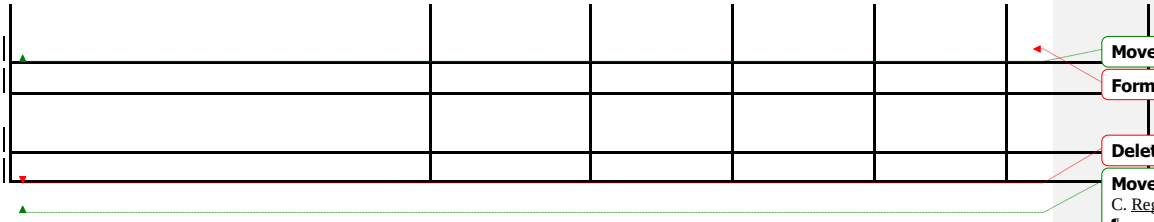

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C. Regulatory Flexibility Options¶
¶
¶
Small and very small businesses may need additional time to comply with the proposed requirements. The proposed rule allows small businesses six months and very small businesses 18 months to come into compliance after the effective date of the final rule.

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¶
1. Exemptions for Small Entities¶

Deleted: If qualified facilities were to incur the same average cost per provision as facilities not subject to subpart C, then by exempting them, the proposed rule will reduce their costs by approximately $455 million ($25,000 per facilities x 36,425 qualified facilities x 0.5 for those that already perform the activities).

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Moved down [237]: One option to reduce the impact on small entities is to exempt all of them from the proposed rule. Most entities affected by this rule, however, are small. We estimate that 97,169 out of a total of 97,646 facilities, or about 99.5 percent, are small. Exempting small establishments would substantially reduce any benefit of the rule. ¶
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 hire or train workers to become qualified individuals to help develop their food safety plan, to conduct their ...

Moved down [238]: VII. Unfunded Mandates¶
¶
Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a writt ...

Deleted: The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product.

Moved down [239]: 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 ...

Deleted: , with the exception of the trade effects of this proposed rule, which we will discuss here.¶

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9. Costs Impact to for Foreign Facilities and Trade Effects

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In this section, we estimate the cost to foreign entities. For Option 1 of the co-proposal, we estimate there are 109,190 foreign facilities that will be covered by the rule and 97,646 domestic facilities (of which, approximately 46,097 facilities are subject to subpart C Hazard Analysis and Risk-based Preventive Controls and therefore, for most of the requirements of the proposed rule and 51,549 facilities that are not subject to subpart C and therefore, would be exempt from most of the proposed rule). Because we lack survey data about baseline foreign facility food safety practices and the likely costs to incorporate all the changes to comply with the proposed rule, we estimate the costs by assuming that the average costs will be the same for foreign and domestic facilities; they will have the same proportion of baseline practices, the same proportion of qualified and non-qualified facilities and the same proportion of manufacturing to total facilities. We ask for comment about these assumptions. Our calculation for the proportion of total foreign manufacturing facilities to total foreign facilities covered is 67,996/97,646 = 70 percent of the total or 76,433 are foreign manufacturing facilities. Our calculation for the number of qualified to non-qualified manufacturing facilities is 36,595/(36,595 +31,401) = 54% qualified or 41,274 foreign manufacturing facilities are qualified and 46% or 35,159 foreign manufacturing facilities are non-qualified. Applying the average cost of the proposed rule for domestic qualified manufacturing facilities of $1,000/facility and for non-qualified manufacturing facilities of $13,000/facililty; yields an estimated total annualized cost to foreign facilities of $500 million (= $1,000/facility x 41,274 + $13, 000 x 35,159).

For Option 2 of the co-proposal, we again estimate there are 109,190 foreign facilities that will be covered by the rule and 97,646 domestic facilities (of which, approximately 40,235 facilities are subject to subpart C Hazard Analysis and Risk-based Preventive Controls and therefore, for most of the requirements of the proposed rule and 57,411 facilities that are not

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subject to subpart C and therefore, would be exempt from most of the proposed rule). Because again, we lack survey data about baseline foreign facility food safety practices and the likely costs to incorporate the changes to comply with the proposed rule, we estimate the costs by assuming that the average costs will be the same for foreign and domestic facilities; they will have the same proportion of baseline practices, the same proportion of qualified and non-qualified facilities and the same proportion of manufacturing to total facilities. Our calculation for the proportion of total foreign manufacturing facilities to total foreign facilities covered is 67,996/97,646 = 70 percent of the total or 76,433 are foreign manufacturing facilities. Our calculation for the number of qualified to non-qualified manufacturing facilities is 43,443/(43,443 +24,553) = 64% qualified or 48,833 foreign manufacturing facilities are qualified and 36% or 27,600 foreign manufacturing facilities are non-qualified. Applying the average cost of the proposed rule for domestic qualified manufacturing facilities of $1,000/facility and for non-qualified manufacturing facilities of $13,000/facility; yields an estimated total annualized cost to foreign facilities of $400 million (= $1,000/facility x 48,833 + $13,000 x 27,600).

For Option 3 of the co-proposal, we again estimate there are 109,190 foreign facilities that will be covered by the rule and 97,646 domestic facilities (of which, approximately 22,661 facilities are subject to subpart C Hazard Analysis and Risk-based Preventive Controls and therefore, for most of the requirements of the proposed rule and 74,985 facilities that are not subject to subpart C and therefore, would be exempt from most of the proposed rule). Because again, we lack survey data about baseline foreign facility food safety practices and the likely costs to incorporate all the changes to comply with the proposed rule, we estimate the costs by assuming that the average costs will be the same for foreign and domestic facilities; they will have the same proportion of baseline practices, the same proportion of qualified and non-

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qualified facilities and the same proportion of manufacturing to total facilities. Our calculation for the proportion of total foreign manufacturing facilities to total foreign facilities covered is 67,996/97,646 = 70 percent of the total or 76,433 are foreign manufacturing facilities. Our calculation for the number of qualified to non-qualified manufacturing facilities is 51,799/(51,799 + 16,197) = 76% qualified or 58,090 foreign manufacturing facilities are qualified and 24% or 18,343 foreign manufacturing facilities are non-qualified. Applying the average cost of the proposed rule for domestic qualified manufacturing facilities of $1,000/facility and for non-qualified manufacturing facilities of $13,000/facility; yields an estimated total annualized cost to foreign facilities of $300 million (= $1,000/facility x 58,090 + $13,000 x 18,343).

We do not attempt an estimate of the potential benefits that would come from applying the rule to foreign facilities. To the extent that the proposed rule encourages best-practices in foreign facilities that sell their products not bound for the U.S. market, they will incur health benefits that we have not attempted to calculate. We anticipate that fewer foreign consumers will be exposed to contaminated foods. We have also not attempted to quantify the rule's potential health benefits attributable to U.S. food products that are bound for export.

The Proposed Rule's Impact on Trade

To assess the proposed rule's impact on foreign entities, this section considers whether the proposed rule would be consistent with widely adopted international food safety regulations based on the Codex Alimentarius Commission (Codex) General Principles of Food Hygiene and the Codex principles of the Hazard Analysis and Critical Control Point (HACCP) system. If the proposed rule is consistent with Codex General Principles of Food Hygiene and HACCP, if most

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Deleted: http://www.fao.org/DOCREP/005/Y1579E/y1579e03.htm ; 2) is consistent with World Trade Organization (WTO) treaty obligations http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact2_e.htm ; and 3) whether the proposed rule could 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.

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manufacturers are generally already performing the food safety practices that are being proposed, and if the costs to comply with the proposed rule are relatively small compared to the total costs of production, then the proposed rule if finalized should not adversely affect the international trade of FDA-regulated food products (Ref. 61)

From our analysis, we believe that at least some foreign food manufacturers from all regions of the world could have to incur the cost to change at least some of their manufacturing, processing, packing and holding practices to comply with the proposed rule. Any potential U.S. price increase that would occur as a result of compliance costs is likely to be passed on to both domestic and foreign customers and would likely be very small relative to the total costs to manufacture, process, pack and hold foods for sale in the United States. Likewise, any foreign price increase that would occur as compliance costs is likely to be very small relative to the total foreign costs to manufacture, process, pack and hold foods.

For Option 1, we estimate that the annualized cost to domestic facilities is approximately $475 million dollars and for foreign facilities approximately $500 million for an annualized total cost of compliance of $975 million. For Option 2, we estimate that the annualized cost to domestic facilities is approximately $395 million dollars and for foreign facilities approximately $400 million, for an annualized total cost of compliance of $795 million. For Option 3, we estimate that the annualized cost to domestic facilities is approximately $320 million dollars and for foreign facilities approximately $300 million, for an annualized total cost of compliance of $620 million. The total manufacturing sales revenue for the domestic food industry in the U.S. is approximately $826 billion. The total compliance cost for both domestic and foreign facilities combined for Option 1, 2 or 3 would be only about one one-hundredth of one percent of the amount that U.S. consumers spend on processed food each year. We estimate that any potential

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Deleted: , including our largest trading partners Canada, Australia, New Zealand, the European Union and other food manufacturers of the industrialized nations, especially their smaller manufacturing facilities

Deleted: Facilities 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. ERG Inc. Memorandum Foreign Food GMPs - Expert Elicitation Results September 3, 2009). Despite this, the proposed rule is not likely to have a significant adverse effect on the total volume of food products traded with the U.S., as described immediately below. The proposed rule is consistent with Codex principles, WTO obligations and it would not act as a non-tariff or technical barrier to trade. Any price increase that would likely occur as compliance costs are

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price increase that might result from the proposed rule will be so small that the demand for either domestic or foreign products will not change enough to impact trade. We request comment on this estimate.

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 food manufacturing sales in the U.S. is valued at about $826 billion (Ref. 62). The long-term trend in international trade between the U.S and its trading partners for food products, including FDA-regulated foods, is toward ever increasing volumes (Ref. 63). For most of the last 10 years, the international trade in food products has grown by at least 10 percent per year and in some years by over 20 percent as measured in their dollar value. Although most categories of food, including FDA-regulated imported and exported foods, experienced a decline of about 11 percent 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.

To determine the ability of foreign manufacturers to meet the proposed requirements, we compared the proposed rule to Codex Principles, which are the basis for our major trading partners' food safety manufacturing laws and regulations, to determine how consistent they are to each other, ensuring that the proposed rule is consistent with Codex Principles, promotes the equal treatment of domestic and foreign producers, and the volume of FDA-regulated food products traded internationally would likely further expand.

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The Codex Recommended International Code of Practice General Principles of Food Hygiene and the Codex Hazard Analysis and Critical Control Point System and Guidelines for its Application promote measures that are consistent with, and in fact, are in part the basis for the proposed preventive control requirements as described in the preamble. Codex principles have been widely adopted as regulatory requirements for many countries around the world and by many other countries as foundational principles for ensuring food safety. Codex principles promote science-based food safety practices that are designed to prevent, reduce or eliminate potential biological, chemical and physical food safety hazards (Ref 64, 65). Codex principles call for training in food hygiene, sanitation programs, hazard analysis, the development of control measures along with critical control points or process controls, effective monitoring procedures for the critical control points, procedures for corrective actions, for effective verification and for recordkeeping and documentation. While not identical, the Codex principles and the proposed rule are consistent in all major principles.

Notwithstanding that the proposed rule is consistent with Codex Principles, the proposed rule might create an adverse impact on trade if a significant number of foreign manufacturers have high costs of compliance because they are not currently performing in accordance with the proposed requirements.

10. Consideration of Other Provisions

a. Education and Training

Better education and training for first time workers, refresher training for all industry employees and better incentives for workers to learn about food safety and why and how to incorporate what they have learned about food safety into their daily work routines could be a

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Deleted: 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 require of member states at least three essential responsibilities; 1) the equal treatment of domestic and foreign manufacturers; 2)

Deleted: 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 Understanding the WTO http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf). If a proposed rule meets these conditions, then it is consistent with WTO obligations. Because the proposed rule does not distinguish between countries or between domestic and foreign manufacturers, create special favors, and was not developed arbitrarily but is rather based on the best available scientific knowledge and in response to a critical public health need, the proposed rule is consistent with WTO obligations. ¶ Even if

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significant factor in reducing the prevalence of contaminated food and consequently foodborne illnesses. FDA could require education and training so that each person engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof, must receive training, as appropriate to the person's duties upon hiring and periodically thereafter in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as applied at the facility.

Numerous studies have shown that poor hygienic practices among employees contribute to the microbial contamination of food (Ref 67). Employee hygiene is necessary for plant sanitation and its absence is one of the leading causes of food contamination (Refs 68, 69). Education and training are contributing factors to better personal hygiene and facility sanitation (Ref 69).

Most studies about the benefits of training pertain to workers in retail food establishments. The studies show that training retail food establishment workers can be effective in increasing both their knowledge of and their use of better food safety behaviors and practices (Refs. 67-69). We believe the benefits of worker food safety training practices in retail food establishments should be similar to the benefits of worker food safety training in other types of food facilities further down the processing chain: ingredient suppliers, manufacturers, processors, packers, and holders. Food workers should be more knowledgeable about the food safety hazards from their practices in order to help prevent the hazards, although we recognize that the link from suppliers, manufacturers through retailers to consumers is less direct than from retailers directly to consumers. Almost all the available studies about the impact of education and training are on retail food service training and are based on short term observations that use a variety of sometimes inconsistent evaluation measures, which make it difficult to make direct

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comparisons between the various study results or to actual food industry practices that would be covered under this proposed rulemaking (Refs. 67-69). We are not aware of any directly relevant studies that measure the effectiveness or benefits of training programs for reducing microbial product contamination or for reducing the cases of consumer illness caused by contaminated processed foods. Most of the available research assesses worker hygiene practices, worker attitudes, work motivation and worker knowledge pre- and post- training. The studies that we are aware of demonstrate that worker training contributes to, along with other factors, better knowledge of personal hygiene as well as better self-reported and observed food safety practices and behaviors. Two studies show that increased levels of training also increased not only workers' knowledge of safe food handling practices, but also the degree to which this knowledge was implemented, as measured by decreases in bacterial counts of mesophilic and coliform bacteria on raw semi-processed rolled beef and lower microbial contamination levels of ready-to-eat salads sold through retail outlets (Ref 70).

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The largest study to identify the impact of training was conducted by the International Association for Food Protection (IAFP) Committee on Control of Foodborne Illnesses (Ref 68). The Committee on Control of Foodborne Illnesses conducted a retrospective study of 816 foodborne illness outbreaks from 1927 to 2006. Although the study lacked data for some outbreak cases, they determined that there were four major contributing factors to these outbreaks that could have been prevented or mitigated by effective training (Ref. 68). The contributing factors were: 1) improper hand washing or failure to wash hands; 2) bare-handed contact by workers of ready-to-eat foods; 3) improper glove use; and 4) handling of foods by pathogen-infected persons who are asymptomatic or believe themselves to be recovered from a recent food-borne illness.

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Green et al (2007) conducted an observational study to determine the factors that would reinforce good hand washing practices. They observed that workers generally practiced proper hygiene at facilities providing formal food safety training (Ref 70) Pragle et al. (2007) determined that insufficient food worker training and education is the most frequent barrier to implementing good personal hygiene practices (Ref 71). In one study, the efficacy of training was shown by demonstrating that different training levels are correlated with the use of other food safety systems (Ref 72).

Refresher courses promote higher levels of awareness of food safety and compliance, and periodic training improves an employee's retention of knowledge, which often decreases over time, regardless of the subject. Reinforcement techniques, such as participatory and interactive training, as well as posters are useful in this respect, but are most effective when augmented by formal periodic refresher training (Ref 73)

To understand baseline education and training practices, we used responses from the Food GMP survey. Our Food GMP survey included questions about types of training, duration of training, types of employees trained, and whether management conducts refresher training. The final survey report provides a complete summary of all the responses to the training questions. About nine percent of responding facilities with less than 20 employees indicated that they do not provide any food safety and sanitation training to newly hired production employees, while all responding facilities with 500 or more employees indicated that they provide training of some type. Of those facilities that indicated that training is provided, about 33 percent of the facilities with fewer than 20 employees indicated that the principles of food safety, foodborne hazards, and the prevention of such hazards are not covered in their employee training or they spend less than one hour for training; about 61 percent of the facilities with 20 to 99 employees

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and the facilities with 100 to 499 employees also responded that they do not cover this topic or spend less than one hour for training. About 60 percent of facilities with 500 or more employees provide less than one hour for training of food safety, foodborne hazards and hazard prevention. In response to a similar question on personal hygiene practices, about 42 percent of facilities with less than 20 employees responded that they do not provide training for the topic or provide less than one hour of training; almost 100 percent of all other facility sizes provide at least some training in personal hygiene practices, although 53 percent provide less than one hour of training. Respondents to the survey were also asked whether production floor employees are trained to notice and report symptoms of illness in coworkers or themselves. About 12 percent of facilities with less than 20 employees, 13 percent of facilities with 20 to 99 employees, and 16 percent of facilities with 100 to 499 employees reported that they do not provide training in this topic. With respect to the frequency of refresher training in food safety and sanitation for production floor employees, over 19 percent of facilities with less than 20 employees responded that they do not provide refresher training at all. About 15 percent of all facilities responded that they do not provide refresher training.

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Facilities will incur training costs regardless of whether or not they are qualified facilities. For purposes of this analysis we assume facilities would not incur an additional cost for new training materials because the results of the Food GMP survey indicate that 90 percent of all facilities already conduct at least some food safety and personnel hygiene training and because adequate training material is readily available on-line for free. The cost to comply with the alternative education and training provisions would be to those facilities that do not currently provide sufficient, if any, education and training to newly hired employees or refresher training to experienced employees. The additional cost to comply would be for the additional labor hours

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used for training by the production workers and the qualified individuals that conduct the training. Using labor hours as the measure of the costs reflects the lost production time that employees must devote to training. We assume an average of two hours is needed to train employees in the principles of food safety per year and another two hours are needed to train employees in personnel hygiene per year. We also assume that facilities that provide one or fewer hours would incur the cost of adding one hour to their training time for each subject.

To estimate the cost of lost worker time while in training, we estimated the average number of workers in a facility with fewer than 20 employees that would require training to be 10 employees, at an average wage rate per employee of $21 per hour (including overhead). We estimate that a qualified individual would provide the training to the necessary floor employees, so the total cost of lost worker time is about $542 per facility ((10 employees x $21/hr x 2 hr) + (1 qualified individual x $61/hr x 2 hr.)) for facilities that do not provide any training and about $271 ((10 employees x $21/hr x 1 hr) + (1 qualified individual x $61/hr x 1 hr)) for facilities that provide one hour of training.

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Table 38 - Estimate for On-Going Food Safety Training Costs by Facility Size

	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of Domestic Manufacturing Wholesale and Warehouse Facilities	80,475	12,283	4,411	477	97,646
Percent of Facilities w/o Any Food Safety Training	10%	2%	5%	0%	
Total Facilities that Require 2 Hrs of Food Safety Training	8,128	265	218	0	8,611
Hourly Wage Rate for Qualified Individuals – Trainers	$61	$61	$61	$61	

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Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Average Labor Hrs to Conduct Training	2	2	2	2	
Subtotal Food Safety Training Costs – Additional 2 Hours	$4,405,362	$645,241	$2,772,167	$0	$7,822,770
Percent of Facilities that require 1 additional hr	32%	60%	48%	60%	
Total Facilities that Require Additional 1 Hr of Food Safety Training	25,398	7,387	2,100	284	35,169
Hourly Wage Rate for Qualified Individuals – Trainers	$61	$61	$61	$61	
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Average Labor Hrs to Conduct Training	2	2	2	2	
Subtotal Food Safety Training Costs – Additional 1 Hours	$6,882,834	$8,982,587	$13,358,590	$3,749,303	$32,973,315
Total Costs to Provide Food Safety Training per Year	$11,288,196	$9,627,828	$16,130,757	$3,749,303	$40,796,085
Total Facilities that Require Food Safety Training Records per Year	33,526	7,652	2,318	284	
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Minutes per Record	2 to 4	2 to 4	2 to 4	2 to 4	
Hours per Record	.03 to .07	.03 to .07	.03 to .07	.03 to .07	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Avg Records per Employee per Year	2	2	2	2	
Total Recordkeeping Costs per Year	$704,044	$883,842	$1,460,328	$373,196	$3,421,410

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Table 39- Estimate for On-Going Personal Hygiene Training Costs by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of Domestic Manufacturing Wholesale and Warehouse Facilities	80,475	12,283	4,411	477	97,646
Percent of Facilities w/o any Personal Hygiene Training	10%	2%	4%	0%	
Total Facilities that Require 2 Hrs of Personal Hygiene Training	7,661	294	183	0	8,138
Hourly Wage Rate for Qualified Individuals – Trainers	$61	$61	$61	$61	
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Average Labor Hrs to Conduct Training	2	2	2	2	
Subtotal Personal Hygiene Training Costs – Additional 2 Hours	$4,152,381	$713,947	$2,328,845	$0	$7,195,173
Percent of Facilities that require 1 additional hr	41%	74%	54%	45%	
Total Facilities that Require Additional 1 Hr of Personal Hygiene Training	33,075	9,035	2,393	215	44,719
Hourly Wage Rate for Qualified Individuals – Trainers	$61	$61	$61	$61	
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Average Labor Hrs to Conduct Training	2	2	2	2	
Subtotal Personal Hygiene Training Costs – Additional 1 Hours	$8,963,386	$10,987,016	$15,221,666	$2,836,036	$38,008,104
Total Costs to Provide Personal Hygiene Training per Year	$13,115,767	$11,700,963	$17,550,511	$2,836,036	$45,203,277

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Total Facilities that Require Personal Hygiene Training Records per Year	40,736	9,329	2,576	215	52,875
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Minutes per Record	2 to 4	2 to 4	2 to 4	2 to 4	
Hours per Record	.03 to .07	.03 to .07	.03 to .07	.03 to .07	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Avg Records per Employee per Year	2	2	2	2	
Total Recordkeeping Costs per Year	$855,465	$1,077,492	$1,622,895	$282,292	$3,818,144

Table 40 presents a summary of all annual training costs.

Table 40 - Annual Training Costs Summary

	<20 employees	20 to 99 employees	100 to 499 employees	> 500 employees	Total
Total number of Domestic Manufacturing Wholesale and Warehouse Facilities	80,475	12,283	4,411	477	97,646
Food Safety Training Costs	$11,288,196	$9,627,828	$16,130,757	$3,749,303	$40,796,085
Personal Hygiene Training Costs	$13,115,767	$11,700,963	$17,550,511	$2,836,036	$45,203,277
Training Records Costs	$1,559,509	$1,961,334	$3,083,223	$655,485	$7,259,551
Total Annual Costs	$25,963,472	$23,290,125	$36,764,491	$7,240,824	$93,258,913

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b. Sanitary Operations and Process and Controls

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Poor sanitation is a contributing factor to foodborne disease outbreaks. Improperly cleaned surfaces promote the build up of waste, dirt, dust, food product residue, and, in the presence of moisture, contribute to the growth of bacterial biofilms, which can contain pathogenic microorganisms (Ref. 18). Effective cleaning alone can remove more than 90 percent of microorganisms (Ref 19).

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The effectiveness of sanitation operations varies in different settings and according to the training of the employees. A recent study found that typical sanitation practices at a small cider

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processing facility were found to be inadequate for removing pathogens once the pathogens were established. Changes in manufacturing conditions, processes, raw materials and ingredients, and technologies require that food facilities continually evaluate the effectiveness of their sanitation operations (Ref 20).

An alternative would be to revise proposed § 117.35 to require that all food-contact surfaces and all non-food contact surfaces of equipment and utensils used in the operation of a food plant must be cleaned, sanitized and stored in a manner and as frequently as necessary to protect against cross-contact of food and of food-contact surfaces; require, rather than recommend, appropriate storage of single-service articles and sanitized portable equipment with food-contact surfaces and utensils to protect food and food-contact surfaces from contamination and cross-contact; and require, rather than recommend, that non-food-contact surfaces of equipment used in the operation of a food plant be cleaned in a manner and as frequently as necessary to protect against contamination of food and food-contact surfaces.

The alternative would revise proposed § 117.40 to require, rather than recommend, that all equipment be installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces; clarify that food-contact surfaces must be maintained to protect food from cross-contact; and require that certain instruments and controls be precise as well as accurate.

The alternative would revise proposed § 117.80 to clarify that requirements directed to controls on processes, raw materials, work-in-progress, rework and finished food must protect against both contamination and cross-contact; require that work-in-process and rework be handled in a manner that protects against cross-contact, contamination, and growth of undesirable microorganisms; require, rather than recommend, certain practices for protection of food from contamination and cross-contact.

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Current part 110 contains requirements that are intended to prevent food from becoming adulterated. Despite the current requirements, poor sanitation continues to be a contributing factor for foodborne illnesses. Poor sanitation continues to be an on-going problem despite existing requirements. This might be due to several factors including poor employee training, poor cleaning procedures or the absence of or poor monitoring and verification of their sanitation practices.

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We believe the costs to comply with this alternative would be to just those qualified manufacturing facilities that would not already comply with subpart C §117.135(d)(3) Sanitation Controls and to the non-qualified facilities that do not already comply with this alternative. Facilities that would have already adopted sanitation controls to comply with subpart C would likely meet the requirements of this alternative unless their sanitation controls did not address the requirements of this alternative or if they lack a hazard that is reasonably likely to occur so would not have adopted sanitation controls in the first place. For those that do not, we assume that their costs would be for training their employees in this alternative requirement. The impact to manufacturing facilities that would be subject to subpart C §117.135(d)(3) Sanitation Controls are addressed in our section for sanitation controls.

We estimate that the cost to facilities would be for training their employees in the alternative sanitation operations, processes and controls as described in the alternative subpart B. To estimate the costs, we first determined the number of facilities that do not already perform these functions. We lack data about how many of these facilities there are, so we assume that between 0 and 10 percent of facilities covered by subpart C Sanitation Controls would also have to revise their operations to comply with this section of Subpart B. We lack data about how many of the qualified manufacturing facilities would already perform these functions. We

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assume that between 25 and 75 percent of all facilities that would already perform these operations.

The Food GMP survey showed that facilities of all sizes reported that they conduct cleaning and sanitation operations. To estimate the costs of this alternative, we assume that the cleaning problems are associated with poor practices, not from the absence of cleaning. Consequently, we assume that facilities would not incur the costs for additional cleaning materials, nor would they require any additional time for cleaning. We assume that workers spend sufficient time cleaning, but do not clean well. So we assume that facilities only added costs would only be for additional training. We estimate that it would take two hours per year for qualified manufacturing facilities to train their employees in the alternative revisions. Table 41a summarizes our cost estimates. We ask for comment about our assumptions and estimates.

As before, to estimate the cost of lost worker time while in training, we estimated the average number of workers in a facility with fewer than 20 employees that would require training to be 10 employees, at an average wage rate per employee of $21 per hour (including overhead). We estimate that a qualified individual would provide the training to the necessary floor employees, so the total cost of lost worker time is about $542 per facility ((10 employees x $21/hr x 2 hr) + (1 qualified individual x $61/hr x 2 hr.)) for facilities that do not provide any training.

Table 41a - Estimate for On-Going Sanitation Operations Training Costs by Facility Size (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Qualified Domestic Manufacturing Facilities	36,425	138	28	4	36,595

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Percent of Qualified Facilities that would require Training	25 to 75%	25 to 75%	25 to 75%	25 to 75%	
Total Qualified Facilities that Require 2 Hrs of Training	18,213	69	14	2	18,298
Total NonQualified Domestic Manufacturing Facilities	17,781	9,251	3,920	449	31,401
Percent of NonQualified Facilities that would require Training	0 to 10%	0 to 10%	0 to 10%	0 to 10%	
Total NonQualified Facilities that Require 2 Hrs of Training	889	463	196	22	1,570
Total Qualified and NonQualified Facilities	19,102	532	210	24	19,868
Hourly Wage Rate for Qualified Individuals – Trainers	$61	$61	$61	$61	
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Average Labor Hrs to Conduct Training	2	2	2	2	
Subtotal Training Costs – Additional 2 Hours	$10,353,040	$1,292,730	$2,671,620	$644,795	$14,962,185
Total Facilities that Require Training Records per Year	18,213	69	14	2	
Hourly Wage Rate for Production line Workers	$21	$21	$21	$21	
Minutes per Record	2 to 4	2 to 4	2 to 4	2 to 4	
Hours per Record	.03 to .07	.03 to .07	.03 to .07	.03 to .07	
Avg Number of Employees that require Training	5 to 15	30 to 80	200 to 400	550 to 700	
Avg Records per Employee per Year	2	2	2	2	
Subtotal Recordkeeping Costs per Year	$401,133	$61,394	$132,300	$32,091	$626,917
Total Costs per Year	$10,754,173	$1,354,124	$2,803,920	$676,886	$15,589,102

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c. Verification and Preventive Controls

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In the proposed rule we have identified several other verification and preventive control provisions (e.g., review of consumer complaints, environmental monitoring, finished produce testing, and a supplier approval and verification program) that facilities may use to implement a preventive controls system and verify that preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. We are not proposing these provisions at this time; however, we have provided our current thinking about these provisions in the preamble and are requesting comment on these topics so that we can address them appropriately in the final rule. Costs for each of these provisions are presented below.

j. Review Consumer Complaints

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Our Food GMP survey asks whether facilities maintain records on consumer complaints. While there are some facilities that may address consumer complaints without keeping a record, it is unlikely that a facility that truly assesses their consumer complaints with the intent of modifying their food safety plan would not keep a record of the complaint and how it was addressed. Response to the Food GMP survey indicates that about 20 percent of facilities with less than 20 employees do not keep records of consumer complaints while only about one percent of facilities with 20 to 99 employees do not keep records of consumer complaints. All facilities with 100 or more employees maintain records on consumer complaints. The information provided by the expert elicitation on facilities' handling of consumer complaints supported our Food GMP survey results.

We lack formal studies or other information that address a facility's likely response to consumer complaints. According to our expert elicitation, legitimate complaints that involve

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illness or foreign objects usually receive a very high priority as opposed to a quality defect in the product or a taste issue. Large and very large companies are quick to institute changes in monitoring and also often in their HACCP programs in response to a legitimate complaint. Large and very large operations also often have dedicated consumer affairs staff that focuses on the complaint and is responsible for triggering the investigative process at the local manufacturing level. It was the opinion of our experts that small and mid-sized operations often do not have any formal review process for consumer complaints. Small and some medium companies initially deal with a complaint but then move on to ongoing business with no trend analysis of complaints or formal review. (Ref. 47)

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We assume, based on opinion from FDA personnel with experience working in the food industry, that facilities would spend 4 to 24 hours, depending on facility size, on a monthly basis to evaluate consumer complaints as they relate to the effectiveness of the food safety plan. If a serious food safety problem is uncovered through a consumer complaint, a corrective action may be necessary. The costs of corrective actions are addressed in another section of this analysis. We request comment on the estimate of the time it takes to review complaints with an emphasis on food safety plan effectiveness on a monthly basis.

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For purposes of this analysis we assume the complaint assessment and the corresponding food safety plan review to be conducted by a manager at the facility, thus we use the wage rate for a production manager of $61.44 per hour including overhead. We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, total annual consumer complaint costs are shown in Table 42a.

Table 42a - Reviewing Consumer Complaints for Relation to Food Safety Plan Effectiveness (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total

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Number of manufacturing and fresh-cut facilities (non-qualified)	18,010	9,285	3,925	449	**31,669**
Percent that do not maintain Consumer Complaint Records	20.33%	1.32%	0.00%	0.00%	
Facilities that begin Reviewing Consumer Complaints to assess food safety plan effectiveness	3,662	123	0	0	**3,784**
Average Time spent per month reviewing complaints (in hours)	4	8	16	24	
Production Manager Wage including overhead ($ per hour)	$61.44	$61.44	$61.44	$61.44	
Per Facility Complaint Review Cost	**$2,949**	**$5,898**	**$11,796**	**$17,695**	
Total Annual Complaint Review Cost	**$10,798,275**	**$722,865**	**$0**	**$0**	**$11,521,140**
Annual Cost per Affected Facility	**$2,949**	**$5,898**	**$0**	**$0**	

[a] Warehouses, wholesalers, and qualified facilities are excluded from this calculation.

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ii. Performance of Environmental Monitoring

In food facilities where a pathogen is reasonably likely to occur, facilities may choose to conduct environmental monitoring as a verification tool to ensure that hazards are being properly controlled. Effective environmental pathogen controls will be product, process, and plant specific. Generally, *Salmonella* is the organism of concern for certain dry food products,[54] where *Salmonella* would be introduced with a raw product or ingredient,[55] and *Listeria monocytogenes* (Lm) the organism of concern for wet processing environments.

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Food manufacturing facilities should assess the potential for pathogens of concern being present in their food processing facility before engaging in an environmental pathogen monitoring program. The likelihood of a particular pathogen being in a particular food processing environment depends on the types of food products manufactured and the methods in

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[54] A number of outbreaks of salmonellosis have been associated with the consumption of ready-to-eat low-moisture products, including chocolate, powdered infant formula, raw almonds, toasted oats breakfast cereals, dry seasonings, paprika-seasoned potato chips, dried coconut, infant cereals and, more recently, peanut butter and children's snacks made of puffed rice and corn with a vegetable seasoning. (GMA Salmonella Guidance)(Ref 74)

[55] These products include those exposed to the processing environment following a final lethality step, products that are not subjected to an inactivation step, or products in which *Salmonella*-sensitive ingredients are added after an inactivation step. (GMA Salmonella guidance(Ref 74)

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which they are processed. If a facility decides that it is necessary to adopt an environmental monitoring program, practices must be put into place to control the introduction or spread of a particular pathogen throughout the processing environment. Each facility, product, and process should be evaluated to determine the appropriate sampling points. Facilities should determine the points to sample and the frequency of sampling based on knowledge of their specific operation and the controls that have been put into place, as well as any microbiological data available (Ref. 47).

For our base case costs of environmental monitoring, we assume that if a facility adopts a monitoring program:

- testing would occur once per month
- the facility would collect 5, 10, or 15 samples per occasion
- the facility would send the samples to an outside laboratory for analysis

To undertake environmental monitoring on a routine basis, we assume that facilities would 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
- sterile tool to scrape debris out of cracks

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For purposes of this analysis we assume that it would take 15 minutes to collect each sample; each sample would be collected by an environmental science and protection technician (May 2010 BLS food manufacturing code 19-4091) earning an hourly wage rate of $23.34 including overhead. The number of samples taken depends on the facility set-up, age of the facility, and type of product processed. We assume that it is likely that smaller facilities would

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need to take fewer samples per sampling occasion than larger facilities.

We obtained information from Silliker, Inc. on the testing costs per swab depending on the pathogen being tested for. (Refs. 75, 76). For samples where *Salmonella* spp. are the organism of concern we use the price of *Salmonella* spp. testing based on the Enzyme Linked Fluorescent Assay (ELFA) method with no confirmation; for *Listeria* genus we use the pricing for the 48 hour ELFA test with no confirmation. For the environmental monitoring 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 monitoring conducted, additional environmental monitoring and even product testing by the facility 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.

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For purposes of this analysis we assume samples would 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. 77)). We also include the cost of disposable sterile sampling spatulas ($1.04 per spatula) (Ref 78). For shipping supplies, we assume 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) (Refs. 79, 80, 81). We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 43 shows the annual costs of environmental monitoring per facility for these pathogens based on 15 samples per month as an example.

Table 43- Annual Costs of Environmental Monitoring for Pathogens for 15 Samples per Month

	Low Volume pricing		High Volume Pricing	
	Salmonella	Listeria	Salmonella	Listeria

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Hourly labor cost (includes overhead)	$23.34	$23.34	$23.34	$23.34
Time to collect each sample (hours)	0.25	0.25	0.25	0.25
Number of samples	15	15	15	15
Total labor cost	$88	$88	$88	$88
Cost of sampling supplies per sample	$3.37	$3.37	$3.37	$3.37
Number of samples	15	15	15	15
Total sampling supplies cost	$51	$51	$51	$51
Cost of shipping supplies	$21.76	$21.76	$21.76	$21.76
FedEx Standard Overnight	$37.75	$37.75	$37.75	$37.75
Total cost of shipping	$60	$60	$60	$60
lab analysis cost per swab	$28.50	$26.00	$19.50	$17.50
Number of samples	15	15	15	15
Total cost of laboratory analysis	$428	$390	$293	$263
Total Cost Per Shipment	$625	$588	$490	$460
Number of shipments annually	12	12	12	12
Annual testing costs per facility	$7,501	$7,051	$5,881	$5,521

The cost of analysis for samples varies depending on the pathogen being monitored and how many samples are being taken. In addition, facilities that send a high volume of samples to a laboratory can negotiate lower pricing per sample for testing than can facilities sending a lower volume of samples. We show the difference in these costs by number of samples and by pricing based on sample volume in Table 44. We show per shipment monitoring costs, annual monitoring costs (monthly), and annual monitoring costs (weekly) in this table. We estimate the costs of monthly monitoring for hazards as appropriate, but for comparison purposes, we also include the costs of monitoring on a weekly basis. Environmental monitoring may be more effective on a weekly basis for some types of processes and products.

Table 44- Environmental Monitoring Costs Per Shipment, Annual Monthly, and Annual Weekly by Pathogen, Sample Size, and Pricing

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Per Shipment Costs		
	Salmonella	Listeria
Low volume pricing		
5 samples costs per pathogen	$248	$236
10 samples costs per pathogen	$347	$327
15 samples costs per pathogen	$625	$588
High volume pricing		
5 samples costs per pathogen	$203	$193
10 samples costs per pathogen	$437	$412
15 samples costs per pathogen	$490	$460
Annual Testing Costs (Monthly testing)		
Low volume pricing	Salmonella	Listeria
5 samples costs per pathogen	$2,976	$2,826
10 samples costs per pathogen	$5,239	$4,939
15 samples costs per pathogen	$7,501	$7,051
High volume pricing		
5 samples costs per pathogen	$2,436	$2,316
10 samples costs per pathogen	$4,159	$3,919
15 samples costs per pathogen	$5,881	$5,521
Annual Testing Costs (Weekly testing)		
	Salmonella	Listeria
Low volume pricing		
5 samples costs per pathogen	$12,896	$12,272
10 samples costs per pathogen	$18,044	$17,004
15 samples costs per pathogen	$32,500	$30,576
High volume pricing		
5 samples costs per pathogen	$10,556	$10,036
10 samples costs per pathogen	$22,724	$21,424
15 samples costs per pathogen	$25,480	$23,920

As part of the Food GMP survey, facilities were asked about environmental monitoring for the specific pathogens, including Salmonella and Listeria. As part of our estimate, we made assumptions about what types of food producers as described by the food product categories shown in Table 7 would be likely to conduct environmental monitoring and combining that information with survey responses from facilities manufacturing in those product sectors, we can estimate the percentage of facilities that already conduct environmental monitoring for *Salmonella* spp. and Listeria, and thus, also identify those facilities that may implement such monitoring. Tables 45.1a, 45.2a, 46.1a and 46.2a show these estimations. The tables on

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monitoring costs also assume a one-time purchase of training materials on how to take environmental samples and the labor cost to train one person to take samples annually.[56]

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It should be noted that the industries in the tables are a representation of the types and numbers of facilities that may undertake an environmental monitoring program. It is possible that some of the facilities in some of the industries would not undertake an environmental monitoring program; the specific industries listed below by SIC is not meant to be an all-inclusive list of the kinds and types of facilities that may undertake an environmental monitoring program, nor does it imply that all facilities in these industries would adopt a program. The information on facilities listed is used to create the best cost estimate attainable given the limitations of the D&B data. We did not include in these estimates any facilities that processed juice or seafood or any other manufactured product that was outside of the scope of this proposed rule-making. Also, because of the uncertainty surrounding how many facilities in a specific product category may use environmental monitoring as a verification tool, we use a range to estimate monitoring costs. We assume that 50 to 75 percent of the facilities in each product category identified as possibly conducting environmental monitoring[57] would actually conduct such monitoring.[58],[59] We also present, for comparison purposes, the costs of environmental monitoring if it is conducted on a weekly basis rather than a monthly basis (Tables 45.2a and 46.2a).

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[56]Training on how to take environmental samples is estimated to be $225 per facility for a training DVD. (Ref(Silliker). 82)

[57]Experts within CFSAN have identified those product categories in which the manufacturing facilities may conduct environmental monitoring. We recognize that our identification is imperfect.

[58]For ease of presentation of the overall cost summary statistics we use the midpoint of the 50 to 75 percent range.

[59] We use a less broad range for environmental monitoring (50 to 75 percent) than we do for finished product testing (25 to 75 percent) because, based on the types of foods included, the decision to conduct environmental monitoring is less uncertain than the decision to conduct finished product testing. It is likely that more of these facilities will identify environmental pathogens as hazards reasonably likely to occur.

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Table 45.1a - Monthly Testing for Salmonella (VSB < $250K)						
	SIC Code	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Dry, condensed and evaporated dairy products[a]	20230000	29	28	8	1	66
Dried and powdered milk and milk products	20230300	22	12	1	0	35
Dried milk	20230303	9	9	2	1	21
Dried nonfat milk	20230304	1	3	1	0	5
Dried whey	20230306	6	7	0	0	13
Milk preparations, dried	20230307	5	3	0	0	8
Powdered buttermilk	20230308	1	0	0	0	1
Powdered milk	20230310	20	14	7	1	42
Powdered skim milk	20230311	0	4	1	0	5
Powdered whey	20230312	3	5	1	0	9
Dried and dehydrated fruits, vegetables and soup mixes[a]	20340000	20	8	3	0	31
Dried and dehydrated vegetables	20340300	17	8	3	0	28
Vegetables, dried or dehydrated (except freeze-dried)	20340303	24	9	7	1	41
Cereal Breakfast Foods	2043	321	69	46	8	444
Flour, Blended & Prepared	2045	325	92	38	0	455
Chocolate & Cocoa Products	2066	1,129	90	40	8	1,267
Salted & Roasted Nuts & Seeds	2068	242	79	28	5	354
Food preparations, nec[a]	20990000	516	149	67	7	739
Seasonings and spices	20990400	426	52	9	3	490
Chili pepper or powder	20990402	35	5	2	0	42
Seasonings: dry mixes	20990403	132	19	7	6	164
Spices, including grinding	20990404	42	9	13	6	70
Sauces: dry mixes	20990504	13	3	0	0	16
Almond pastes	20999901	11	1	0	0	12
Bouillon cubes	20999902	0	2	1	1	4
Carob processing	20999905	3	1	0	0	4
Peanut butter	20999912	92	19	7	4	122
Tea blending	20999917	156	32	18	4	210
Total number of manufacturing facilities that may test for Salmonella		3,600	732	310	56	4,698
Facilities excluded by § 418(l)(1)(C)		599	2	1	0	601
Facilities remaining after Tester § 418(l)(1)(C) exclusion		3,001	730	309	56	4,097
Facilities excluded by Very Small Business Definition (§ 418(l)(1)(B))		1,975	5	1	0	1,982
Facilities remaining after both exclusions		1,026	725	308	56	2,115
Percent that already test (survey result)		21.45%	28.19%	49.79%	61.70%	
Facilities that may begin testing		806	521	155	21	1,326
Assume 50 percent would begin testing		403	260	77	11	663

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Assume 75 percent would begin testing	604	390	116	16	995
cost per facility for annual testing	$2,976	$5,239	$5,881	$5,881	
Training materials cost (annualized over 7 yrs)	$42	$42	$42	$42	
Labor training cost	$23.34	$23.34	$23.34	$23.34	
annual monthly testing costs for Salmonella 50 percent	**$1,225,342**	**$1,380,416**	**$460,030**	**$63,766**	**$3,129,553**
annual monthly testing costs for Salmonella 75 percent	**$1,838,012**	**$2,070,624**	**$690,044**	**$95,649**	**$4,694,329**
annual testing costs for Salmonella average of 50 to 75 percent (Monthly testing)	**$1,531,677**	**$1,725,520**	**$575,037**	**$79,707**	**$3,911,941**
Annual cost per affected Facility	**$3,041**	**$5,304**	**$5,946**	**$5,946**	

[a] Partial category used.[60] [61]

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Table 45.2a - Costs to Undertake Weekly Testing for Salmonella (VSB < $250K)

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	Total
Facilities that may begin testing	806	521	155	21	1,326
Assume 50 percent would begin testing	403	260	77	11	663
Assume 75 percent would begin testing	604	390	116	16	995
cost per facility for annual testing (weekly)	$12,896	$18,044	$25,480	$25,480	
Training materials cost (annualized over 7 yrs)	$42	$42	$42	$42	
Labor training cost	$23	$23	$23	$23	
annual weekly testing costs for Salmonella 50 percent	$5,222,392	$4,712,981	$1,976,340	$273,946	$12,185,659
annual weekly testing costs for Salmonella 75 percent	$7,833,588	$7,069,471	$2,964,510	$410,918	$18,278,488
annual testing costs for Salmonella average of 50 to 75 percent (Weekly testing)	$6,527,990	$5,891,226	$2,470,425	$342,432	$15,232,074
Annual cost per affected Facility	$12,961	$18,109	$25,545	$25,545	

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[60] To include some facilities under these types of eight digit SIC codes, but not all of them, we take a percentage of the categories in question based on the percentage of specific industry categories under, say, 2099xxxx that would undertake environmental monitoring (e.g., 209904000-Seasonings and Spices, 20999912-Peanut Butter). We were also able to use this same technique to estimate the percentage of facilities to include under 20340000-Dried and Dehydrated Fruits, Vegetables, and Soup Mixes (we want to exclude most soup mixes).

[61] Examining the eight digit SIC codes under 2037-Frozen Fruit, Fruit Juices, and Vegetables revealed that no facilities identified themselves under eight digit SIC codes 20370200- Fruit Juices, 20370201-Fruit Juice Concentrates, Frozen, or 20370202-Fruit Juices, Frozen: fruit juices are outside the scope of proposed 117 part C, so we would have eliminated frozen juice manufacturers if any had shown up in the D&B facility data. We note that the data does not necessarily say that there are no facilities that manufacture frozen fruit juice, just that those facilities must manufacture something else in a greater capacity. We only classify facilities by primary manufacturing activity to avoid double counting facilities that manufacture more than one type of food product.

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Table 46.1a - Monthly Environmental Testing for Listeria (VSB < $250K)

	SIC Code	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Butter	2021	139	36	12	0	187
Cheese; natural and processed[a]	20220000	96	40	19	1	156
Natural cheese[a]	20229902	41	22	9	1	73
Ice Cream	2024	3,251	271	97	8	3,627
Milk	2026	975	365	287	18	1,645
Frozen fruits and vegetables	2037	384	124	91	22	621
Cole slaw, in bulk	20990702	11	3	0	0	14
Salads, fresh or refrigerated	20990705	155	50	24	10	239
Sandwiches, assembled and packaged: for wholesale market	20990706	147	39	8	4	198
Tofu, except frozen desserts	20999918	79	13	3	0	95
Vegetables, peeled for the trade	20999920	28	12	8	1	49
Fresh-Cut Fruits & Vegetables[a]	5148	323	34	5	0	362
Total number of facilities that may test for Listeria		5,629	1,009	563	65	7,266
Facilities excluded by § 418(l)(1)(C)		811	8	1	0	820
Facilities remaining after Tester § 418(l)(1)(C) exclusion		4,818	1,001	562	65	6,446
Facilities excluded by Very Small Business Definition (§ 418(l)(1)(B))		2,417	14	3	0	2,434
Facilities remaining after both exclusions		2,401	987	559	65	4,012
Percent that already test (survey result)		22.56%	53.70%	83.94%	76.97%	
Facilities that may begin testing		1,859	457	90	15	2,421
Assume 50 percent would begin testing		930	229	45	7	1,211
Assume 75 percent would begin testing		1,394	343	67	11	1,816
cost per facility for annual testing		$2,826	$4,939	$5,521	$5,521	
Training materials cost (annualized over 7 yrs)		$42	$42	$42	$42	
Labor training cost		$23.34	$23.34	$23.34	$23.34	
annual monthly testing costs for Listeria 50 percent		**$2,687,558**	**$1,143,823**	**$250,868**	**$41,810**	**$4,124,059**
annual monthly testing costs for Listeria 75 percent		**$4,031,337**	**$1,715,734**	**$376,302**	**$62,716**	**$6,186,089**
annual testing costs for Listeria average of 50 to 75 percent (Monthly testing)		**$3,359,448**	**$1,429,778**	**$313,585**	**$52,263**	**$5,155,074**
Annual cost per affected Facility		**$2,891**	**$5,004**	**$5,586**	**$5,586**	

[a] Partial category used.[62]

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[62] In the case of SIC code 2022- Cheese, even the eight digit SIC code breakdown did not get specific enough for

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Table 46.2a - Costs to Undertake Weekly Testing for Listeria (VSB < $250K)					
	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Facilities that may begin testing	1,859	457	90	15	2,421
Assume 50 percent would begin testing	930	229	45	7	1,211
Assume 75 percent would begin testing	1,394	343	67	11	1,816
cost per facility for annual testing (weekly)	$12,272	$17,004	$23,920	$23,920	
Training materials cost (annualized over 7 yrs)	$42	$42	$42	$42	
Labor training cost	$23	$23	$23	$23	
annual weekly testing costs for Listeria 50 percent	$11,468,564	$3,901,611	$1,077,157	$179,522	$16,626,855
annual weekly testing costs for Listeria 75 percent	$17,202,846	$5,852,417	$1,615,735	$269,284	$24,940,282
annual testing costs for Listeria average of 50 to 75 percent (Weekly testing)	$14,335,705	$4,877,014	$1,346,446	$224,403	$20,783,568
Annual cost per affected Facility	$12,337	$17,069	$23,985	$23,985	

Any facility undertaking an environmental pathogen monitoring program should have written procedures regarding the program. The written procedures should establish an environmental monitoring scheme that is scientifically valid; identify the locations from which samples would be collected and the number of sites to be tested during routine environmental monitoring. (The number and location of sampling sites must be sufficient to determine whether preventive controls are effective and must include appropriate food-contact surfaces and non-food-contact surfaces of equipment and other surfaces within the manufacturing, processing, packing and holding environment); and identify the test microorganism(s). The written procedures should also identify or include the analytical methods used to test the environmental samples. For purposes of this analysis we assume that those facilities that may begin conducting

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us to estimate which facilities were producing fresh soft cheese and soft unripened cheese; these are the two cheese categories that we would expect facilities to conduct environmental monitoring. In this case, we used percentage of types of cheese manufacturers who responded to the Food GMP survey to estimate the percentage of the facilities under 2022 that would be producing these two cheese types.

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environmental monitoring would also create written procedures on conducting such monitoring. For purposes of this analysis we assume that it would take a facility 16 hours to develop their environmental procedures.

Table 47a- Cost to Write-up Environmental Monitoring Procedures (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Number of facilities	1,666	611	153	23	2,452
Time needed to write-up procedures (hrs)	16	16	16	16	
Wage for Qualified Individual (including overhead)	$79.14	$79.14	$79.14	$79.14	
Total costs of Initial Write-up	$2,109,127	$773,724	$193,539	$28,821	$3,105,211
Total Costs Annualized	$391,355	$143,567	$35,912	$5,348	$576,182
Annualized Cost per Affected Facility	$235	$235	$235	$235	

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iii. Finished Product Testing

Finished product testing may be used as a verification tool when facilities determine that such testing may be appropriate based on risk. For example, when the production process does not have a step that will eliminate or reduce hazards to an acceptable level finished product testing may be helpful to verify that the final product does not contain a hazard. For purposes of this analysis we estimate the costs of testing finished product following the testing costs method that we set forth in the environmental monitoring section; see that section of this analysis for more detail.

For purposes of this analysis we assume that facilities would take 5 finished product samples per product line on a monthly basis regardless of facility size; we use the costs for testing samples for either *Listeria monocytogenes* or *Salmonella* spp. although facilities may want to test for other hazards based on hazard analyses conducted at the facilities. We assume that the samples would take about 15 minutes to collect per sample and would be sent by express

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delivery to an outside laboratory for analysis.

We obtained information from Silliker, Inc. on the testing costs per food product depending on the pathogen being tested for. (Refs. 75, 76). For samples where *Salmonella* spp. are the organism of concern we use the price of *Salmonella* spp. testing based on the Polymer Chain Reaction (PCR) method with cultural confirmation; for *Listeria monocytogenes* testing we use the pricing for the PCR method with cultural confirmation. If a sample is confirmed positive for contamination with a pathogen, the facility would then do additional product testing, potentially destroy lots with contamination, and find the source of the contamination. The costs of these actions to correct a problem in manufacturing of the food are not included in this section of the analysis; instead those costs are covered under the corrective actions costs as analyzed in the corrective actions section of this analysis. We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 48 shows the costs of sampling food products on a monthly basis (per production line) for both *Salmonella* spp. and *Listeria monocytogenes*.

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Table 48 - Annual Costs of Food Product Testing for 5 Samples per Month Annually

	Low Volume pricing		High Volume Pricing	
	Salmonella	Listeria	Salmonella	Listeria
Hourly labor cost (includes overhead)	$23.34	$23.34	$23.34	$23.34
Time to collect each sample (hours)	0.25	0.25	0.25	0.25
Number of samples	5	5	5	5
Total labor cost	$29	$29	$29	$29
Cost of sampling supplies per sample	$3.37	$3.37	$3.37	$3.37
Number of samples	5	5	5	5
Total sampling supplies cost	$17	$17	$17	$17
Cost of shipping supplies	$21.76	$21.76	$21.76	$21.76
FedEx Standard Overnight	$37.75	$37.75	$37.75	$37.75
Total cost of shipping	$60	$60	$60	$60

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lab analysis cost per sample	$47.00	$47.00	$34.00	$33.00
Number of samples	5	5	5	5
Total cost of laboratory analysis	$235	$235	$170	$165
Total Cost Per Shipment	$341	$341	$276	$271
Number of shipments annually	12	12	12	12
Annual testing costs per facility	$4,086	$4,086	$3,306	$3,246

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Our estimate of the number and types of facilities that may choose to perform finished product testing to meet this risk-based standard is an inexact estimate. We use facility data from D&B to narrow the number of facilities that we estimate may conduct finished product testing, but this data is often not precise enough to parse out specific facilities within an industry sector. For example, for the product category SIC 2096- Potato Chips & Similar Products, potato chip manufacturers that add certain types of seasonings (e.g., those not treated to significantly minimize pathogens) to the chips after the kill-step in the production process may want to use finished product testing to assure that the final product does not contain a pathogen. Manufacturers who make potato chips that are cooked and not added to, or handled, after the cooking kill-step would not likely benefit from choosing to conduct finished product testing on a regular basis.

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We cannot know from our facility data exactly what types of potato chips are produced at each facility nor can we know when and where the potential kill-steps are in the production process. We also cannot know how much, say, environmental monitoring, a specific facility conducts. If a facility conducts extensive environmental monitoring, then it is likely that they may not conduct as much or any finished product testing unless a problem arises from the environmental monitoring results. Because of the uncertainty surrounding how many facilities in a specific product category may choose to use finished product testing as a verification tool, we

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use a range to estimate testing costs. We assume that 25 to 75 percent of the facilities in each product category identified as possibly conducting finished product testing[63] may actually conduct such testing.[64] The list of types of facilities in Table 49a is not meant to be an all-inclusive list of manufacturing operations that may conduct finished product testing nor is it meant to impose the requirement of finished product testing on any facility.

For purposes of this analysis we estimate cost of segregating and holding finished product while awaiting finished testing results as a percentage of a facility's single line daily production value. To calculate a single day's value of production we utilize information from D&B. We estimate that 100 percent of a day's production may be held pending testing results for all facilities. We use this information to help us scale the costs of holding products based on facility size. The literature also suggests that the cost of holding product is somewhere between 15 and 35 percent of its total value (we use 25 percent as the average cost of holding product) (Ref. 60). When both of these percentages are applied to the value of one line's production, times the number of days the product is held, we get the cost of holding product on each testing occasion.

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We use information from the Food GMP survey to estimate the percentage of facilities that are already conducting finished product testing; the remainder of the facilities that may implement finished product testing would incur the costs of testing on a monthly basis. We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, our estimates for the costs of finished product testing and holding finished product awaiting testing results are shown in Table 49a.

[63]Experts within CFSAN have identified those product categories in which the manufacturing facilities may choose to conduct finished product testing as a verification activity. We recognize that our identification is imperfect.
[64]For ease of presentation of the overall cost summary statistics we use the midpoint of the 25 to 75 percent range.

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Table 49a- Finished Product Testing Costs (VSB < $250K)						
SIC Code	SIC Description	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Tot
2037	Frozen Fruits & Vegetables	384	124	91	22	
2043	Cereal Breakfast Foods	321	69	46	8	444
2066	Chocolate & Cocoa Products	1129	90	40	8	1267
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2096	Potato Chips & Similar Products	852	244	94	24	1214
20990400	Seasonings and spices	414	59	10	0	483
20990402	Chili pepper or powder	34	7	1	0	42
20990403	Seasonings: dry mixes	119	30	14	0	163
20990404	Spices, including grinding	37	11	14	0	62
20990500	Sauce, gravy, dressing, and dip mixes	178	17	3	1	199
20990502	Dressings, salad: dry mixes	24	4	1	0	29
20990700	Ready-to-eat meals, salads, and sandwiches	167	39	15	2	223
20990701	Box lunches, for sale off premises	42	4	0	0	46
20990702	Cole slaw, in bulk	11	3	0	0	14
20990705	Salads, fresh or refrigerated	136	60	32	7	235
20990706	Sandwiches, assembled and packaged: for wholesale market	142	44	12	0	198
20999901	Almond pastes	10	1	1	0	12
20999902	Bouillon cubes	3	1	0	0	4
20999905	Carob processing	3	1	0	0	4
20999907	Coconut, desiccated and shredded	13	4	0	0	17
20999912	Peanut butter	76	28	14	2	120
20999918	Tofu, except frozen desserts	79	14	2	0	95
20999920	Vegetables, peeled for the trade	27	13	9	0	49
Number of manufacturing facilities that may conduct finished product testing		4,443	946	427	79	5,895
Number of facilities excluded by § 418(l)(1)(C)		715	5	1	0	720
Number of facilities remaining after § 418(l)(1)(C) exclusion		3,728	941	426	79	5,175
Additional facilities excluded under Very Small Business definition (§ 418(l)(1)(B))		2,324	11	1	0	2,337
Number of facilities remaining after both exclusions		1,404	931	425	79	2,838
Percent that already test (survey result)		68.5%	75.7%	83.2%	93.5%	
Number of facilities that may begin testing		442	226	71	5	
Assume 25 percent would begin testing		111	57	18	1	186
Assume 75 percent would begin testing		332	170	54	4	
Cost per testing per production line		$341	$341	$276	$276	
Number of production lines		3	7	13	18	

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Number of testing times per year	12	12	12	12	
Cost of testing finished product annually	$12,259	$28,605	$42,983	$59,516	
Total Cost of Testing Finished Product Annually 25 percent of identified facilities test	**$1,355,271**	**$1,616,979**	**$767,460**	**$76,403**	**$3,816,113**
Total Cost of Testing Finished Product Annually 75 percent of identified facilities test	**$4,065,813**	**$4,850,938**	**$2,302,380**	**$229,209**	**$11,448,340**
Average Sales Volume by Facility Size	$1,428,406	$6,473,541	$52,465,246	$838,600,000	
Operational days	357	357	357	357	
Average Daily Value of Production	$4,001	$18,133	$146,961	$2,349,020	
Number of production lines	3	7	13	18	
Value of a single production line per day	$1,334	$2,590	$11,305	$130,501	
Percent needing to be held	100%	100%	100%	100%	
Inventory Holding Cost	25%	25%	25%	25%	
Number of days held	4	4	4	4	
Cost of holding product pending test results	$1,334	$2,590	$11,305	$130,501	
Number of times held annually	12	12	12	12	
Per Facility Cost of Holding Product Annually Awaiting Test Results	$16,005	$31,085	$135,657	$1,566,013	
Total Cost of Holding Product Annually Awaiting Test Results 25 percent	**$1,769,316**	**$1,757,196**	**$2,422,121**	**$2,010,369**	**$7,959,002**
Total Cost of Holding Product Annually Awaiting Test Results 75 percent	**$5,307,947**	**$5,271,589**	**$7,266,362**	**$6,031,108**	**$23,877,006**
Total Costs of Testing and Holding Finished Product Annually 25 percent	**$3,124,587**	**$3,374,176**	**$3,189,581**	**$2,086,772**	**$11,775,115**
Total Costs of Testing and Holding Finished Product Annually 75 percent	**$9,373,760**	**$10,122,527**	**$9,568,742**	**$6,260,317**	**$35,325,346**
Total Costs of Testing and Holding Finished Product Annually Average of 25 to 75 percent	**$6,249,174**	**$6,748,351**	**$6,379,161**	**$4,173,545**	**$23,550,231**
Annual Cost per Affected Facility	**$28,264**	**$59,690**	**$178,640**	**$1,625,529**	

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[a] Under the Pasteurized Milk Ordinance (PMO), official regulatory samples are required to be collected and analyzed by individual State Regulatory Agencies at the frequency referenced from each Grade "A" milk plant within their State. Along with these samples, each Grade "A" milk plant conducts their own internal sampling and testing of finished milk and milk products that they produce and sell. Therefore we estimate that all dairy facilities are already conducting finished product testing as appropriate. (Ref. 83)

Any facility conducting finished product testing may create written procedures regarding such testing. The written procedures can show that a facility's testing scheme is scientifically valid, the procedures for sampling, and the sampling frequency. The written procedures also can identify or include the analytical methods used to test finished product. For purposes of this

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analysis we assume that those facilities that begin conducting finished product testing are the same facilities that would also create written procedures on conducting such testing. For purposes of this analysis we assume that it would take a facility 16 hours to develop their finished product testing procedures.

Table 50a- Cost to Write-up Finished Product Testing Procedures (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Number of facilities	221	113	36	3	372
Time needed to write-up verification procedures (hrs)	16	16	16	16	
Wage for Qualified Individual (including overhead)	$79.14	$79.14	$79.14	$79.14	
Total costs of Initial Write-up	$279,968	$143,156	$45,217	$3,251	$471,592
Total Costs Annualized	$51,949	$26,563	$8,390	$603	$87,505
Annualized Cost per Affected Facility	$235	$235	$235	$235	

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iv. Supplier Approval and Verification Program

A manufacturing facility may establish and implement a supplier approval and verification program for raw materials and ingredients for which the facility has identified hazards that are reasonably likely to occur. A supplier approval and verification program could include requiring a written list of approved suppliers, a written list for each raw material or ingredient of which food safety hazards are reasonably likely to occur, and supplier verification activities. Whether a particular facility would develop new, or additional, supplier approval and verification mechanisms would depend on what a facility currently requires of its suppliers, the hazards identified by the hazard analysis for the raw materials and ingredients and the manufacturing process of the receiving facility.

The owner, operator, or agent in charge of a receiving facility would likely not establish and implement a supplier approval and verification program for raw materials and ingredients for which preventive controls at the receiving facility are adequate to significantly minimize or

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prevent each of the hazards the receiving facility has identified as reasonably likely to occur. It also is possible that some facilities would rely on their customers to control the hazard and thus would not necessarily develop a supplier approval and verification program.

a. Written List of Approved Suppliers

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A supplier approval and verification program could include a facility creating and maintaining a written list of approved suppliers. For purposes of this analysis we assume that it would take facilities one to two hours to develop a written approved supplier list; we expect the approved supplier list to be developed by an Industrial Production manager earning a wage per hour of $61.44, including overhead. We use information from the Food GMP survey to determine the percentage of facilities that use potentially hazardous raw materials or ingredients and that do not currently have a written approved list of suppliers.

The number of new ingredient suppliers that could be added to a facility's supplier list is highly dependent upon the new products being introduced by the purchasing facility. According to our expert elicitation, most purchasing facilities do not introduce a new supplier to their existing program unless the current suppliers are not performing, a better price can be obtained from another supplier, or material for a new product line (i.e., new color or flavor) cannot be purchased through current suppliers (Ref. 47). Therefore we assume costs to update the written approval supplier list to be minimal and do not attempt to include them here.

We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 51a shows the costs of maintaining a list of approved suppliers for facilities that had not previously done so based on the total number of domestic manufacturing facilities that are subject to subpart C and that use raw materials and ingredients that have hazards reasonably likely to occur. We assume that there

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would be no recordkeeping burden associated with approved supplier lists; the lists are the record that that activity was completed.

Table 51a - Supplier Approval and Verification Program - Written Approved Supplier Lists (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Manufacturing and Fresh-cut Facilities that are subject to subpart C	18,010	9,285	3,925	449	31,669
Percent Of Facilities That Use Raw Materials and Ingredients where hazards are likely to occur and Do Not Have Written Approved Supplier Lists	64.43%	44.63%	31.78%	6.49%	
Number Of Facilities that may create Written Approved Supplier Lists	11,604	4,144	1,247	29	17,025
Number of hours to Write Approved Suppliers List	1	1	2	2	
Cost per hour	$61.44	$61.44	$61.44	$61.44	
Cost In Year 1	$712,958	$254,595	$153,292	$3,579	$1,124,424
First year costs annualized over 7 years	**$132,292**	**$47,241**	**$28,444**	**$664**	**$208,641**
Avg Annualized Costs per Facility	$11	$11	$23	$23	

[a] Warehouses, wholesalers, and qualified facilities are excluded from this calculation.

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b. Determination, by Raw Material or Ingredient, of Hazards that are Reasonably Likely to Occur

A supplier approval and verification program could include, for each raw material and ingredient used in a facility, a written list of which hazards are reasonably likely to occur in such raw materials or ingredients.

We expect that larger facilities that produce a diverse range of products may have more raw materials and ingredients in those products and might need more time to write their list of the hazards that are reasonably likely to occur than would facilities that make only one or two products. Therefore, we assume that it would take facilities with less than 100 employees one hour to write their list and facilities with more than 100 employees two hours to write their list.

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We use the wage rage of a production manager as the person who would write-up this information. Their list may need to be updated if the facility begins to use a new ingredient. However, we do not have information about how often raw materials and ingredients in products are changed or new products are added to the facility's output.

Table 52a - Supplier Approval and Verification Program - Written List of Raw Materials and Ingredients (VSB < $250K)

	≤20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Number Of Domestic Manufacturing and Fresh-cut Facilities	18,010	9,285	3,925	449	31,669
Number of hours to Write Determination	1	1	2	2	
Cost per hour	$61.44	$61.44	$61.44	$61.44	
Cost In Year 1	$1,106,562	$570,458	$482,353	$55,149	$2,214,522
First year costs annualized over 7 years	**$205,326**	**$105,850**	**$89,502**	**$10,233**	**$410,912**
Cost per affected facility	**$11**	**$11**	**$23**	**$23**	

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c. Verification Activities for Suppliers

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Manufacturers may choose to have verification activities for raw materials and ingredient suppliers as part of a supplier approval and verification program. The supplier verification activities would not likely be used if all hazards that are reasonably likely to occur in the raw materials and ingredients are controlled for or eliminated by the receiving facility or the raw material or ingredient does not contain a hazard that is reasonably likely to occur.

It is up to the owner, operator, or agent in charge of the facilities receiving the raw materials and ingredients to use appropriate supplier verification activities. The owner, operator, or agent in charge of receiving facilities that use suppliers of raw materials or ingredients for which the hazards reasonably likely to occur at the suppliers' facility or for which there is not a reasonable probability that exposure will result in significant adverse health consequences or death may: 1) conduct or obtain documentation of periodic onsite audits of the supplier; 2) conduct periodic or lot-by-lot sampling and testing of the raw material or ingredient (the

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receiving facility may conduct the testing or have it conducted); 3) review the supplier's food safety records (e.g., audits of their supplier for the hazard) or 4) other appropriate supplier control verification measures based on the risk associated with the hazard.

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The owner, operator or agent in charge of the receiving facilities would decide which supplier verification activity or activities to use based on the hazards that are reasonably likely to occur in the raw materials or ingredients. For purposes of this analysis we estimate whether the facility receiving the ingredient from the supplier would request an audit of a facility, testing of the raw material or ingredient, or both, based on likely industry practices.

We have domestic facility data from D&B that we have used throughout this analysis. The facilities represented in the D&B database could be final manufacturers, suppliers of raw materials and ingredients, or both. We cannot tell how many facilities might be suppliers for other facilities although we can, by SIC industry code, identify facilities that are likely to be manufacturers of final products only; we eliminate facilities that are likely only manufacturers of final products. Of the facilities remaining that might be raw material and ingredient suppliers, in consultation with our subject matter experts, we identified which facilities would not have any hazards reasonably likely to occur in their raw materials and ingredients or food products; receiving facilities would not conduct verification activities for raw materials or ingredients from these facilities and we eliminate these facilities from our potential supplier count.

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We previously showed the comprehensive list of the facilities by SIC code in Table 7. Table 54a shows the pared down list of facilities by SIC code that we have identified as potential ingredient suppliers; the customers of these facilities may want verification activities to be conducted. For purposes of this analysis we assume there would be one audit per supplier, although we recognize that receiving manufacturing facilities with a kill step would not require a

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supplier audit. Also, food products made by some suppliers might be both an ingredient and a finished product. For example, some facilities that are classified as butter manufacturers (SIC code 2021) may be suppliers of butter as an ingredient or they might be final manufacturers of butter (e.g., packaged final product sent to retail) or both. We cannot tell from the D&B data which butter manufacturers are suppliers or final manufacturers (or function in both roles). Therefore all facilities identifying themselves as butter facilities are considered potential suppliers for supplier verification cost estimation.

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Also in consultation with our subject matter experts, we identified which of the potential supplying facilities would have preventive controls at their facilities and therefore may be audited; supplying facilities that would likely be audited even without having a preventive control at their facility; and supplying facilities that may require testing of their ingredients, alone or in combination with, an audit.

Audits of Suppliers

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For purposes of this analysis we assume one audit per supplier annually based on the fact that the food industry is moving toward the practice of recognizing an audit done under certain rigors, such as a GFSI-approved audit, and that the results of such an audit can be used to satisfy multiple customers. (Ref. 84) This effort by industry is an attempt to reduce the number of audits that a supplying facility would be subjected to on an annual basis.

An audit of a facility would usually take a day or more depending on the type of audit that is done; some audits can last four days or more. (Ref. 85) The costs of an audit would depend on the auditor and the type of facility being audited. Daily rates for audits range from about $500 to $2,000 per day; a 5 day audit could cost a facility $7,500 to $10,000. (Ref.86) British Retail Consortium (BRC)-sponsored audits take on average about 2.5 days and cost about

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$3750 including reporting time and auditor fees, but not including travel expenses (Ref. 87). GMA-SAFE[65] offers two auditing program, either the GMA-SAFE Express audit (a 2-day audit which requires that the auditor be in the facility for at least 16 hours) or the GMA-SAFE full audit (which usually runs about 3 to 4 days and requires that the auditor be in the facility for at least 32 hours). (Ref. 88) Supplier assessments conducted under the GMA-SAFE requirements are billed at an hourly rate of $160/hr (based on the average cost of assessments performed in 2008). In addition to the auditing fee,[66] the facility bidding on an audit would also be responsible for the auditor's travel and incidental expenses. On average, an audit conducted to meet the GMA-SAFE express audits costs about $3500 and a full audit costs around $5000, plus travel and incidental expenses (Ref. 88). Making use of this auditing cost information, for purposes of this analysis we estimate that audits of facilities with less than 20 employees would cost $1500-$3750 (average $2625); audits of a small facility with 20 to 99 employees would cost about $3750; audits of facilities with 100 to 499 employees would cost about $3750-$5000 (average $4375); and audits of facilities with more than 500 employees would cost $5000. We estimate the travel expenses for the auditor to be $250-$1000 (average $625). We use number of employees as a rough measure for the complexity of the manufacturing operation, although we recognize that other factors might influence audit costs.

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The Food GMP survey asks facilities "Do you or others conduct audits of your food control safety system?" to estimate the percentage of facilities, as suppliers, who may not currently be conducting audits of their facilities. We do not calculate a separate recordkeeping

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[65] The GMA-SAFE Program was created in 2001 by food industry quality assurance professionals and members of the Grocery Manufacturers Association (GMA). It is operated by QMI-SAI Global Assurance Services. GMA-SAFE is another version of a third party assessment with requirements similar to ISO22000, BRC, and SQF to name a few similar programs.

[66] In the case of GMA-SAFE, the auditing fee is split between the GMA and the contracted auditor. (Ref. 88)

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burden for auditing costs. The paperwork containing the results of the audit serves as a record that the auditing has taken place.

It is possible that some supplier facilities may have to undertake corrective actions to fix problems at the facility as a result of problems identified during an audit. After corrective actions have occurred the supplying facility could be re-audited. We do not have information on the number of facilities that would undertake corrective actions and then be re-audited. Supplying facilities that are subject to subpart C of this proposed rule-making would likely have done all that is required to pass an audit; supplying facilities that are qualified facilities and not subject to subpart C may not have in place everything needed to pass an audit, these facilities may incur additional costs if they need to do extra activities to pass an audit. We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 54a presents estimated annual costs of audits.

Table 54a- Annual Costs of Audits to Ingredient Suppliers (VSB < $250K)

SIC Code	SIC Description	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
2021	Butter	139	36	12	0	187
2022	Cheese	842	350	146	11	1,349
2023	Milk, Condensed & Evaporated	436	138	51	9	634
2026	Milk	975	365	287	18	1,645
2034	Dried Fruits, Vegetables & Soup	594	106	59	5	764
2037	Frozen Fruits & Vegetables	384	124	91	22	621
2041	Flour, Grain Milling	886	295	77	1	1,259
2045	Flour, Blended & Prepared	325	92	38	0	455
2052	Cookies & Crackers	2,118	253	131	32	2,534
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2098	Macaroni, Spaghetti & Noodles	766	83	39	4	892
2099	Food Preparations, NEC[a]	3694	667	247	7	4,616
Total		11,401	2,588	1,206	114	15,310
Facilities excluded by § 418(l)(1)(C)		1,826	141	50	1	2,018
Facilities remaining after Tester § 418(l)(1)(C) exclusion		9,575	2,448	1,156	113	13,291
Facilities excluded by Very Small Business Definition (§ 418(l)(1)(B))		3,643	6	2	0	3,652
Facilities remaining after both exclusions		5,932	2,441	1,154	113	9,640

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Percent of facilities that do not already conduct audits	43.48%	20.69%	13.60%	0.00%	
Number of facilities that may begin conducting audits	2,579	505	157	0	3,241
Cost per audit	$2,625	$3,750	$4,375	$5,000	
Travel and incidental expenses per audit	$625	$625	$625	$625	
Total costs of audits annually	$8,382,069	$2,209,812	$784,634	$0	$11,376,515
Annual Costs per Affected Facility	$3,250	$4,375	$5,000	0	

[a] Partial category; finished food facilities, foods without a hazard that was reasonably likely to occur, and foods that were likely to be tested rather than audited were eliminated from this category.

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Supplier Verification Activities other than Audits

If the supplier(s) of raw materials and other ingredients has not applied a preventive control during manufacturing or processing at the supplying facility, or the hazard is not reasonably likely to cause serious adverse health consequence or death to humans or animals, then the receiving facility may choose to conduct one or more of the following supplier verification activities: 1) conduct or obtain documentation of periodic onsite audits of the supplier; 2) periodic or lot-by-lot sampling and testing of the raw material or ingredient (the receiving facility can conduct the testing or have it conducted); 3) periodic review by the owner, operator, or agent in charge of the receiving facility of the supplier's food safety records (e.g., audits of their supplier for the hazard) or 4) other appropriate supplier control verification measures based on the risk associated with the hazard in the raw material or ingredient.

For purposes of this analysis we estimated the costs of audits when control of the hazards that are reasonably likely to occur at a supplier's facility is best evaluated through audits as presented in the previous paragraphs on audit costs. For purposes of this analysis we assume the costs of testing raw materials and ingredients here as the option for verification activities other than (or in addition to) audits.[67] We do not address the option of reviewing food safety records;

[67] To the extent that other food safety records, besides auditing or testing records, such as the results of an FDA

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we believe those records to possibly include testing and/or auditing records and we are accounting for those costs. The facility would have to conduct these activities to have the records available for a review. We base our estimates of the types of raw material and ingredients that are likely to be tested instead of, or in addition to, auditing on the judgments of our industry experts.

For purposes of this analysis we assume that those raw materials and ingredients that are tested would be tested on a quarterly basis (five samples). We use quarterly testing as an average for testing frequency; costs associated with ingredient testing may be higher or lower depending on testing frequency (which would be based on the ingredient and the hazard that is reasonably likely to occur in the ingredient). For purposes of this analysis we assume that when an ingredient is tested it would be held and not used in manufacture until the testing results are available. Thus, we estimate the costs of holding an ingredient pending testing results in addition to the actual costs of testing.

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Using information from the Food GMP survey, we calculate the percentage of facilities that receive at least one potentially hazardous raw material or ingredient and do not already have periodic testing performed on that ingredient. Costs of testing an ingredient are developed in the same manner as costs for testing a finished product developed earlier in this section. We use the average testing cost for *Salmonella* or *Listeria*.

The costs per day of holding lots of materials is based on average sales volume data from D&B distilled into the value of a production line per day multiplied by the percentage of the value of a production that needs to be held. A study published in the Inventory Management

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inspection, would provide adequate assurance of supplier control of hazards in raw materials and ingredients; those records are less costly than another verification activity, then we have overstated the costs of supplier verification activity costs.

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Review suggests that the cost of holding product is somewhere between 15 and 35 percent of its total value. We use 25 percent as the average cost of holding product (Ref. 60). The average number of days the raw materials and ingredients are held pending test results is based on information from our expert elicitation (Ref 47). We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 55a presents estimated annual costs of testing raw materials and ingredients.

Table 55a- Annual Costs of Testing of Raw Materials and Ingredients (VSB < $250K)

SIC Code	SIC Description	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
2022	Cheese	842	350	146	11	1,349
2034	Dried Fruits, Vegetables & Soup	594	106	59	5	764
2037	Frozen Fruits & Vegetables	575	165	121	28	889
2041	Flour, Grain Milling	886	295	77	1	1,259
2045	Flour, Blended & Prepared	325	92	38	0	455
2046	Wet Corn Milling	288	46	24	8	366
2066	Chocolate & Cocoa Products	1,129	90	40	8	1,267
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2099	Food Preparations, NEC[a]	2196	495	223	20	2,934
Total		7,077	1,718	756	86	9,637
Facilities excluded by § 418(l)(1)(C)		1,113	104	45	4	1,266
Facilities remaining after Tester § 418(l)(1)(C) exclusion		5,964	1,614	711	82	8,371
Facilities excluded by Very Small Business Definition (§ 418(l)(1)(B))		2,285	5	2	0	2,292
Facilities remaining after both exclusions		3,679	1,609	709	82	6,079
Facilities w/at least 1 potentially hazardous raw material that do not conduct periodic testing		6.80%	17.37%	16.92%	3.33%	
Number of facilities that may begin periodic testing		250	279	120	3	652
Cost of testing annually (4 times per year)		$1,362	$1,362	$1,362	$1,362	
Total Costs of New Testing		**$340,721**	**$380,670**	**$163,492**	**$3,709**	**$888,592**
Costs per day of holding ingredients pending test results		$333	$405	$480	$5,546	
Number of days held		4	4	4	4	

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Number of times per year	4	4	4	4	
Total Costs of Holding Pending Test Results per facility	$5,335	$6,476	$7,687	$88,741	
Number of facilities that may begin holding	250	279	120	3	652
Total Costs of Holding	**$1,334,580**	**$1,810,038**	**$922,758**	**$241,640**	**$4,309,016**
Total Annual Costs of Periodic Testing, Holding, Records	**$1,675,301**	**$2,190,708**	**$1,086,250**	**$245,349**	**$5,197,608**
Annual Costs per Affected Facility	$6,697	$7,838	$9,049	$90,103	

[a] Partial category; finished food facilities, foods without a hazard that was reasonably likely to occur, and foods from facilities that would undergo auditing instead of testing were eliminated from this category.

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Verification Activities for Suppliers that are Qualified Facilities

If a supplier meets the requirements to be a "qualified facility" as defined under the proposed rule, a receiving facility could just document that their supplier meets the definition of a qualified facility and obtain written assurance at least every 2 years that the supplier is producing raw material or ingredients in compliance with sections 402 and 403(w) of the Federal Food, Drug, and Cosmetic Act. The written assurance could include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

We have previously calculated, in the section of the PRIA on qualified facilities, the costs for all qualified facilities to document that they meet the definition of a qualified facility. We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, here we present the cost estimates for qualified supplying facilities to create a written assurance (to be given to their receiving facility customers) to describe the processes and procedures that the supplier is following to ensure the safety of the food.

Table 56 - Supplier Approval and Verification Program for Qualified Facilities

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total

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Total Number Of Qualified Suppliers with Hazards Reasonably Likely to Occur	7,782	251	99	5	8,137
Number of hours to Prepare Documentation	2	2	2	2	
Cost per hour	$61.44	$61.44	$61.44	$61.44	
Cost In Year 1	$956,261	$30,853	$12,107	$666	$999,887
First year costs annualized over 7 years	$177,437	$5,725	$2,246	$124	$185,532
Avg Cost per Facility	$23	$23	$23	$23	

Summary of Supplier Controls Costs

The total costs of the supplier approval and verification program are the sum of the costs of the written lists and determinations and the verification activities. We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 57a presents estimate totals for supplier approval and verification.

Table 57a- Supplier Approval and Verification Program Costs Summary (VSB < $250K)

	<20 employees	20 to 99 employees	100 to 499 employees	>500 employees	Total
Annualized Costs of Written Approved Supplier Lists	$132,292	$47,241	$28,444	$664	$208,641
Annualized Costs of Written Determination	$205,326	$105,850	$89,502	$10,233	$410,912
Annual Costs of Auditing Suppliers	$8,382,069	$2,209,812	$784,634	$0	$11,376,515
Annual Costs of Testing Suppliers	$1,675,301	$2,190,708	$1,086,250	$245,349	$5,197,608
Annualized Costs for Qualified Facilities who are Suppliers	$177,437	$5,725	$2,246	$124	$185,532
Summation of Supplier Control Costs	$10,572,425	$4,559,337	$1,991,076	$256,369	$17,379,207

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v. Review of Records for Consumer Complaints, Environmental Monitoring, Finished Product Testing, and Supplier Verification Activities

Facilities should review records of consumer, customer, or other complaints, finished product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made; the review should be conducted by a qualified individual. Facilities may or may not have records of all the types listed. Some facilities would

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not keep all the aforementioned records if they do not handle raw materials and ingredients or do not have finished product testing, for example.

According to one of the expert elicitations conducted for FDA, small operations may not have any records to be reviewed or maybe just a single pre-operation record for review while large to very large facilities can have as many as 15 records created daily that need reviewing. The number of records to be reviewed within an industry sector would vary based on the products being made at a facility. The experts noted that the records in a small company may be reviewed by the facility owner or quality control staff. Often in the small companies the shift lead would also serve as quality control and that person would review records, usually daily, if at all. Large to very large companies most likely have a quality control staff and a more comprehensive document review process. Usually there is daily review that might take roughly 30 to 60 minutes, depending upon the amount of documentation. Smaller facilities would spend less time reviewing documents because there are generally fewer records to review and the information is more basic (e.g., a check mark rather than a written response). Larger facilities might spend up to 4 hours reviewing records. Table 58, from our expert elicitation, gives some examples of the estimated number of records that might be kept by facility size and industry sector.

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Table 58- Estimated Number of Records, by Facility Size and Industry Sector

	Number of Records			
Industry	**Small**	**Medium**	**Large**	**Very Large**
Grains & oilseed	1 to 5	1 to 10	5 to 10	5 to 10
Breakfast cereals	1 to 5	1 to 10	5 to 20	5 to 30
Sugar & confectionery products	1 to 5	1 to 10	5 to 10	5 to 10
Frozen foods	1 to 5	1 to 10	5 to 20	5 to 30
Canned foods	1 to 5	1 to 10	5 to 10	5 to 30
Dairy products	1 to 10	1 to 15	5 to 20	10 to 40
Seafood	1 to 5	1 to 15	5 to 20	10 to 40
Bread & bakery goods	1 to 5	1 to 10	5 to 10	5 to 10
Baked goods	1 to 5	1 to 10	5 to 10	5 to 10
Snack foods	1 to 5	1 to 10	5 to 10	5 to 10

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Coffee & tea	1 to 5	1 to 10	5 to 10	5 to 10
Flavoring syrup & concentrates	1 to 5	1 to 10	5 to 10	5 to 30
Dressing & prepared sauces	1 to 5	1 to 10	5 to 10	5 to 30
Spices & extracts	1 to 5	1 to 10	5 to 10	5 to 10
Perishable prepared foods	1 to 5	1 to 15	5 to 20	10 to 40
Beverages	1 to 5	1 to 10	5 to 10	5 to 20

To estimate the number of facilities that may begin reviewing records of complaints, finished product testing, environmental monitoring, and supplier verification activities as part of their verification process, we look to the Food GMP survey. The survey asks respondents, "Do you regularly maintain the following types of QA/QC and laboratory operations records? By QA/QC and laboratory operations records, we mean analytical testing records, verification records, and consumer complaints." The question goes on to clarify that verification records include internal and/or third-party audit records, document review logs, annual product reviews, material and ingredient reviews, and product recall reviews. If facilities do not maintain these types of records, we assume they are not reviewing complaints, finished product testing, environmental monitoring, and supplier verification activities records as part of their verification activities.

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We are not proposing this provision at this time and these costs are not included in the overall total costs for the proposed rule. Nonetheless, Table 59a shows the annual costs of reviewing complaints, finished product testing, environmental monitoring, and supplier verification activities records. We estimate that the review of these records would be conducted by a production manager making an hourly wage of $61.44 including overhead.

Table 59a- Review of Records (VSB < $250K)

	≤20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Number of manufacturers and fresh-cut facilities	18,010	9,285	3,925	449	31,669
Percent of facilities without records	39.46%	20.30%	0.46%	0.00%	
Facilities that may begin reviewing records				-	

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	7,107	1,885	18		9,010
Time per month spent on records (minutes)	15.00	30.00	45.00	60.00	
Wage including overhead	$61.44	$61.44	$61.44	$61.44	
Cost of Records Review per Month	$15.36	$30.72	$46.08	$61.44	
Total Monthly Cost of Records Review	**$109,162**	**$57,900**	**$832**	**$0**	$167,894
Number of Reviews per Year	12	12	12	12	
Annual Cost of Reviewing Records	**$1,309,948**	**$694,800**	**$9,985**	**$0**	**$2,014,732**
Annual Cost per Affected Facility	**$184**	**$369**	**$553**	**$0**	

[a] Warehouses, wholesalers, and qualified facilities are excluded from this calculation.

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H. Other Regulatory Alternatives

FDA considered several regulatory alternatives for dealing with current manufacturing, processing, packing and holding practices that might not prevent foods from becoming adulterated or mislabeled. In addition to the three options for the definition of a very small business that we have co-proposed, the alternatives that we considered include: (a) no new regulatory action, (b) a lower threshold for the definition of a very small business, and (c) more extensive standards than the proposed rule.

Alternative (a) No New Regulatory Action

Under this alternative, FDA would rely on:

- the current food CGMP regulations (21 CFR part 117),
- voluntary adoption of some or all provisions of the proposed regulations,
- current or enhanced State and local enforcement activity to bring about a reduction of potential harm from adulterated or mislabeled foods, or
- the tort system, with litigation or the threat of litigation serving to bring about the goals of the proposed rule.

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We believe that there are several reasons not to rely on these alternatives.

The advantage of the current regime is that it is already in place and the food industry generally understands the requirements. The disadvantage is that the regime lacks several of the

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most important provisions of the proposed regulations that have the potential to prevent an unknown number of avoidable foodborne illnesses.

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By voluntarily introducing preventive controls, establishments that do so demonstrate that their expected private economic benefits of preventive controls will exceed their private costs. Voluntary adoption of any practices will occur when it is profitable to do so. Although many establishments have adopted the proposed practices in order to meet the demand for safer products, FDA's survey shows that many facilities have not adopted the proposed safe practices. As mentioned in our section entitled, Need for the Rule, entities will adopt those practices that are economical, not necessarily the provisions of the proposed rule.

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Public and private health agencies, consumer groups, competitors, trade organizations or other independent parties could publicize the risks from food products not processed or held using sufficient preventive controls and allow consumers to decide for themselves about the risks of adulteration. The weakness of this alternative is that independent organizations cannot easily discover the risks until after consumers are sickened. In the absence of the proposed preventive control regulations, the burden of monitoring manufacturing practices fall more heavily on consumers, despite their difficulties in monitoring.

This rulemaking is required by FSMA. In addition, we believe that failing to adopt new standards would lead to some number of preventable foodborne illnesses and deaths.

Alternative (b) A Lower Threshold for the Definition of a Very Small Business

Under this alternative, we would define very small businesses for purposes of part 117, as a business that has less than $100,000.00 in total annual sales of food, adjusted for inflation. We use the identical criteria for estimating of the number of facilities that would be covered by this option with one difference; to be exempt the annual earnings from the business must be less than

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$100,000. For purposes of our estimate, we just look at the impact to manufacturers, not warehouses and wholesalers.[68] The impact of this alternative would be to require 13,431 more manufacturing facilities to perform the activities required in proposed subpart C Hazard Analysis and Risk-Based Preventive Controls than would be exempt under a very small business definition of facilities that have less than $250,000 in total annual sales of food. We estimate the total annual cost for this option to be approximately $605 million, which is about $ 133 million per year more than the proposed rule; almost 79 percent of which would be incurred by the very smallest facilities (those with fewer than 20 employees).

Alternative (c) More-Extensive Standards

The proposed rule could be broader in scope and have more extensive provisions: (1) explicitly including subpart B requirements for education and training and additional sanitary operation requirements, (2) explicitly including more verification provisions than those in the proposed rule, and (3) explicitly requiring a supplier approval and verification program. Additional verification activities for facilities would include reviewing consumer complaints with respect to the effectiveness of the food safety plan, conducting finished product testing when appropriate based on risk, and conducting environmental monitoring for pathogens identified as reasonably likely to occur in the facility processing environment. A supplier approval and verification program would include a written list of approved suppliers, written determinations of hazards reasonably likely to occur in raw materials and ingredients, and verification of suppliers (auditing, testing ingredients, review supplier's records or other supplier

[68] We assume that warehouses and wholesalers would not very often not have hazards that are reasonably likely to occur so would not be subject to most provisions. When they are subject, as for training, sanitation and other changes to subpart B, then we included them in our analysis.

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verification activity as appropriate). Costs for this alternative (with very small business defined as less than $250,000 in annual sales) are outlined in the table below.

Table 60: Option 5: Preventive Control Rule Including Additional Standards Not Included in the Proposed Rule Annualized Cost Summary at discount rate of 7% (VSB < $250K)

Benefits are Qualitative Estimates: Fewer illnesses and deaths from potential reduction in adulteration

Provision	<20 employees	20 to 99 employees	100 to 499 employees	500 > employees	Total
Approximate Number of Facilities	34,571	12,227	4,404	475	51,677
Learn about Rule	$47,269,991	$7,214,878	$5,726,708	$619,279	$60,830,856
Subpart B Sanitation Operations, Processes and Controls					
Education and Training	$25,963,472	$23,290,125	$36,764,491	$7,240,824	$93,258,912
Sanitation Operations, Processes and Controls "shoulds to shalls"	$10,754,173	$1,354,124	$2,803,920	$676,886	$15,589,102
Attest Qualified Status to FDA	$468,221	$1,622	$286	$71	$470,200
One-time Label Change	$14,999,555	$121,228	$39,647	$13,724	$15,174,154
Subpart C Hazard Analysis and Risk-Based Preventive Controls					
Hazard Analysis	$55,325,358	$6,110,722	$1,141,367	$0	$62,577,447
Process Controls	$113,355,618	$13,802,902	$3,452,636	$0	$130,611,156
Allergen Controls					
Proper Usage	$4,385,110	$3,568,131	$2,407,116	$370,708	$10,731,065
Label Application Review	$758,130	$2,580,219	$2,368,358	$0	$5,706,708
Sanitation Controls					
Food Contact Surfaces	$10,530,034	$4,182,468	$2,905,185	$0	$17,617,687
Prevent Cross Contamination and Cross Contact Raw	$6,931,179	$3,826,030	$1,828,195	$147,970	$12,733,374

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Ingredients					
Prevent Cross Contamination and Cross Contact In Process/Production Areas	$5,903,972	$2,412,365	$1,549,329	$149,023	$10,014,689
Monitoring / Verification	$59,025,438	$15,767,194	$10,291,112	$0	$85,083,744
Corrective Actions	$21,067,636	$12,534,300	$18,733,455	$0	$52,335,391
Recall Plans	$8,783,463	$1,731,533	$344,645	$0	$10,859,641
Supplier Controls	$10,572,425	$4,559,337	$1,991,076	$256,369	$17,379,207
Verification	$23,691,825	$11,491,444	$7,322,070	$4,311,466	$46,816,805
Total Annualized Costs discounted at 7%	$411,869,732	$117,344,686	$100,018,522	$13,772,919	$647,790,139
Avg Annualized Cost per Qualified Facility					$2,000/facility
Avg Annualized Cost per Non-Qualified Facility					$16,000/facility
Total Annualized Cost to Foreign Facilities					$ 645 million

I. Uncertainty Analysis

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Throughout the analysis we have used D&B data to inform us of the number of domestic food manufacturers, wholesalers, and warehouses. We have used D&B data because of the completeness of the data in terms of employees per facility, sales information, and industry sector. D&B data has the added advantage that facility information is continually updated, thus it should be able to more quickly capture business openings or closures within the industry. While we believe this is the best data available, there is a degree of uncertainty in the estimate. Further, the uncertainty stemming from this estimate is the primary driver of the uncertainty in the cost model. There are two alternative sources of data, County Business Patterns (CBP) and FDA'S Food Facility Registration Module (FFRM), that provide alternative estimates of total number of food facilities. While both alternative datasets are less up-to-date and less comprehensive than

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the facility information from D&B, they are useful in providing bounds for the uncertainty in the number of estimated facilities and the cost estimates.

CBP data is primarily focused on companies with over 250 employees because larger businesses tend to have a larger impact on the economy. Since many of the food production facilities operating in the U.S. have significantly fewer employees than this, CBP data under-represents smaller manufacturers. Additionally, CBP only captures the primary business function of a facility. in the case of a multi-operational plant, this would also cause CBP to be somewhat low. (Ref. 89)

Another source of uncertainty is our Food GMP survey. The survey is based on a representative sample of manufacturing facilities. As we mentioned, our survey is based on a representative sample of 2,700 food establishments that registered with FDA's Food Facility Registration Module database (FFRM) by randomly selecting the targeted facilities from the database to ensure an equal chance that any facility of any product type and facility size could be drawn. The sampling was drawn from facilities that were registered with FDA as of mid-2009. Because the survey was completed in 2010, some practices will already have changed by the time the rule is published. Many facilities enter the market and leave the market that would not be captured by the survey. Further, the Food GMP survey design was based on three size classes, small (<20 employees), medium (20-99 employees) and large (> 100 employees). We noted that we lacked a survey class specifically for the largest size class although we also noted that did not mean that we could not generate summary statistics applicable to that large size class using the survey data collected. We noted that our estimates for that size class and for each size class are statistically valid, and generalizable to all domestic manufacturers, although we acknowledged that the survey results for the largest facilities are likely to have a larger degree of

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uncertainty associated with our estimate and that the survey results in general reflect a degree of statistical uncertainty.

Our cost estimates rely on our assumptions and often the assumptions or judgment of industry experts. Expert judgment is often imprecise and only a tool when no data is available. Our frequent reliance on expert opinion is a source of considerable uncertainty in our analysis.

Because no one is responsible for checking expired records and facilities have no incentive to withdraw registration if they go out of business, the number of food facilities in the FFRM database which are no longer operating could be quite large. This could cause the FFRM data to dramatically overstate the actual number of food producing facilities operating in the U.S. today. In addition, FFRM does not require that facilities address in which area of food manufacturing they operate.

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D&B data facility totals indicate there 97,646 domestic manufacturers, wholesalers, and warehouses of food commodities. CBP facility data indicates that there are 57,775 food manufacturers and wholesalers. FFRM facility registrations indicate that currently there are 166,178 facilities that manufacture, process, pack, or hold food and are required to register with FDA. Using an average cost of the proposed rule per facility based on calculations in this analysis that use D&B data, we can then create alternative costs of the rule estimates using the facility counts from CBP and FFRM. Table 61 shows the results of these calculations.

Table 61a - Costs of the Proposed Rule using Different Sources for Facility Data (Very Small Business defined as less than $250,000 Annual Revenue)

Data Source	Total Facilities (domestic)	Annualized Costs (with 7% discount rate and 7 year time preference)
D&B	97,646	$469,946,609
Average Cost per Facility		$4,813
CBP	57,775	$278,071,075
FFRM	166,178	$799,814,714

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Table 61b - Costs of the Proposed Rule using Different Sources for Facility Data (Very Small Business defined as less than $500,000 Annual Revenue)		
Data Source	Total Facilities (domestic)	Annualized Costs (with 7% discount rate and 7 year time preference)
D&B	97,646	$369,552,912
Average Cost per Facility		$3,785
CBP	57,775	$218,678,375
FFRM	166,178	$628,983,730

Table 61c - Costs of the Proposed Rule using Different Sources for Facility Data (Very Small Business defined as less than $1,000,000 Annual Revenue)		
Data Source	Total Facilities (domestic)	Annualized Costs (with 7% discount rate and 7 year time preference)
D&B	97,646	$318,816,400
Average Cost per Facility		$3,265
CBP	57,775	$188,635,375
FFRM	166,178	$542,571,170

Further uncertainty is in our attempt to characterize the potential health benefits. A major source of uncertainty is our estimate of the baseline burden of illnesses attributable to foods that would be covered under this proposed rule-making. Our estimate is based on the overall number of outbreak-related illness that could potentially be due to foods under the scope of this proposed rule-making. Our estimate includes all outbreaks attributable to a processed food item regardless of where the contamination likely occurred. We estimate that there are approximately 154,279 identified illnesses and 806,247 unidentified illnesses, annually that may be attributable to FDA-regulated foods under the scope of this proposed rule-making. We are highly uncertain of the actual number. We are also uncertain about the cost per illness. We assume a weighted cost per illness, of $11,550, for the identified illnesses attributable to food under the scope of this proposed rule-making and $214 for unidentified illnesses. These values range from $2,737 to

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$18,247 for identified illnesses and $135 to $296 for unidentified illnesses, when we assume varying VSLs ($1.2 million to $12.2 million) and QALD values ($293 to $882). If all illnesses, regardless of the point of contamination, were attributed to a processing failure there would be a total preventable burden of $1.96 ($0.5 to $3.1) billion but this estimate is uncertain. Moreover, as we mentioned, not all of these illnesses are likely to be attributable to problems at the processing faculty or their suppliers.

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VI. 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 food manufacturers as "small" according to their number of employees. For the most part, food manufacturers employing 500 or fewer persons are considered small businesses. However, there are some particular food manufacturing

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industry segments where the employee maximum is higher (750 or 1,000 employees). Table 62 shows the SBA size classifications for many of the various sectors of food manufacturing. (Ref. 90)

Table 62 - SBA Size Classification by Number of Employees

NAICS	Subsector 311 – Food Manufacturing	Number of Employees
311119	Other Animal Food Manufacturing	500
311211	Flour Milling	500
311212	Rice Milling	500
311213	Malt Manufacturing	500
311221	Wet Corn Milling	750
311222	Soybean Processing	500
311223	Other Oilseed Processing	1,000
311225	Fats and Oils Refining and Blending	1,000
311230	Breakfast Cereal Manufacturing	1,000
311311	Sugarcane Mills	500
311312	Cane Sugar Refining	750
311313	Beet Sugar Manufacturing	750
311320	Chocolate and Confectionery Manufacturing from Cacao Beans	500
311330	Confectionery Manufacturing from Purchased Chocolate	500
311340	Nonchocolate Confectionery Manufacturing	500
311411	Frozen Fruit, Juice and Vegetable Manufacturing	500
311412	Frozen Specialty Food Manufacturing	500
311421	Fruit and Vegetable Canning	500
311422	Specialty Canning	1,000
311423	Dried and Dehydrated Food Manufacturing	500

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As described in the preamble, section 418(n)(1)(B) of the FD&C Act requires FDA to define the terms "small business" and "very small business." FDA, for purposes of this proposed rule-making, has defined a small business for CFR part 117 as having fewer than 500 employees, consistent with the SBA definition for most food manufacturers. About 99.5 percent of all food manufacturers, warehouses, and wholesalers that are covered by the proposed rule employ fewer than 500 employees and are therefore, considered small businesses under the proposed rule.

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FDA defines a very small business for purposes of part 117, as a business that has less than $250,000 in total annual sales of food, adjusted for inflation.

The proposed rule reduces the burden on small businesses through the use of modifications and exemptions from the proposed requirements when the small businesses meet the following requirements under section 418 or 421 of the FD&C Act: 1) for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (§ 103(c)(1)(D) of FSMA), 2) small businesses have an additional six months to comply after the effective date of FDA's final rule (§ 103(i) of FSMA) and very small businesses have an additional 18 months, and 3) very small businesses are deemed "qualified" and therefore, qualify for the exemptions from many of the provisions of these regulations as discussed in section X.B.1 of the proposed document (§ 418(l)(1)(B) of the FD&C Act).

As described in the preliminary regulatory impact analysis, Table 63 summarizes our estimate of the total domestic food facilities count. For purposes of the small business analysis, columns 2 to 4 of the table identify the facilities that meet our definition of a small business. We estimate that a total of 97,169 domestic facilities are small entities.

Table 63 - Number of Domestic Food Facilities Covered by the Proposed Rule

	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Number of Food Manufacturers	54,206	9,389	3,948	453	67,996
Number of Warehouses	6,896	880	157	15	7,948
Number of Wholesalers	19,373	2,014	306	9	21,702
Total	80,475	12,283	4,411	477	97,646

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b. Costs to small entities.

Using data from D&B, Table 64 summarizes the annual revenues for facilities by revenue

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category to show that only a small percentage of total industry sales are from facilities with the least annual revenue. The rule is a comprehensive food safety system that will significantly decrease the chance of adulterated food reaching consumers. Facilities with revenues of more than $500,000 account for about 99 percent of the total industry sales. Less than one percent of the food sold will be from facilities that are "qualified" under this regulation.

The facilities with least revenue, which are likely very small businesses, are most at risk of shutting down, although consumers are unlikely to experience any significant change in the availability of goods in the food industry as a whole. Small establishments will probably not be able pass along their entire cost of compliance to consumers. The net impact of the proposed rule to the profits of the smallest establishments is likely to be significantly negative.

Table 64 - Food Manufacturers, Warehouses, and Wholesalers: Annual Revenues per Facility as Percentage of Industry Sales

Annual Revenue per Facility ($1,000's)	Total Number of Facilities	Percent of Total Facilities	Percent of Total Industry Sales
under $25	1,323	1.35%	0.002%
$25-$50	4,153	4.25%	0.014%
$50-$100	14,722	15.08%	0.095%
$100-$150	11,178	11.45%	0.120%
$150-$200	7,848	8.04%	0.117%
$200-$250	5,703	5.84%	0.108%
$250-$500	14,824	15.18%	0.453%
over $500	37,895	38.81%	99.091%
Total	97,646	100%	100%

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Tables 65a shows our estimate for the average cost for affected small businesses for Option 1, $250,000: 1) with fewer than 20 employees, 2) with 20 to 99 employees and 3) for establishments with 100 to 499 employees, Table 65b, for Option 2, $500,000 and Table 65c, for Option 2, $1,000,000. Affected businesses are businesses that do not currently perform the

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proposed required tasks. For comparison, we include our estimated average costs for facilities with 500 or more employees. The results show that the average costs to small businesses are potentially large. Small businesses that are not already performing a significant number of the proposed activities will incur a large average cost. We lack information about how many activities will be required for any one facility. We also lack data about the revenues for facilities that would link a facility with their ability to conduct the proposed required activity, their ability to incur the expense based on their profit margin and the number of activities that they are not currently doing.

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We estimated the cost for Option 1 very small business definition of $250,000, Option 2 very small business definition of $500,000 and Option 3 very small business definition of $1,000,000 for both qualified and non-qualified facilities in steps. For Option 1, to estimate the costs, we first assumed that all facilities will incur a cost to learn about the rule. To estimate that, we divided our estimate for the total cost for learning about rule by the total facilities: $60 million/ 97,646 facilities = $623 per facility.

Qualified facilities would also incur the costs to attest to their status: $ 15.6 million/36,595 facilities = $428 per facility. The total for qualified facilities would be the total of these costs: total average cost for qualified manufacturing facility: $623 + $428 = $1,050 per facility or to round down, approximately $1,000 per facility.

We assume that non-qualified facilities would incur the cost to learn about the rule and the cost to comply with subpart C Hazard Analysis and Risk-based Preventive Controls requirements of the proposed rule so we divided the total for subpart C by just total non-qualified manufacturing facilities: $401 million/31,401 = $12,000 per facility. Total average non-qualified manufacturing facility: $830 + $12,000 = $12,800 per facility or to round up to $13,000 per

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facility.

For Option 2, to estimate the costs, we again assumed that all facilities will incur a cost to learn about the rule. To estimate that, we divided our estimate for the total cost for learning about rule by the total facilities: $60 million/ 97,646 facilities = $623 per facility.

Qualified facilities would also incur the cost to attest to their status: $19.5 million / 43,445 = $450 per facility. The total for qualified facilities would be the total of these costs: total average cost for qualified manufacturing facility: $623 + $450 = $ 1,072 per facility or to round down, approximately $1,000 per facility.

We again assume that non-qualified facilities would incur the cost to learn about the rule and the cost to comply with subpart C Hazard Analysis and Risk-based Preventive Controls requirements of the proposed rule so we divided the total for subpart C by just total non-qualified manufacturing facilities: $314 million/24,553 = $12,000 per facility. Total average non-qualified manufacturing facility: $1,070 + $12,000 = $13,070 per facility or to round down to $13,000 per facility.

For Option 3, to estimate the costs, we first assumed that all facilities will incur a cost to learn about the rule. To estimate that, we divided our estimate for the total cost for learning about rule by the total facilities: $60 million/ 97,646 facilities = $623 per facility.

Qualified facilities would also incur the costs to attest to their status: $29 million/36,595 facilities = $792 per facility. The total for qualified facilities would be the total of these costs: total average cost for qualified manufacturing facility: $623 + $792 = $1,400 per facility or to round down, approximately $1,000 per facility.

We assume that non-qualified facilities would incur the cost to learn about the rule and the cost to comply with subpart C Hazard Analysis and Risk-based Preventive Controls

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requirements of the proposed rule so we divided the total for subpart C by just total non-qualified manufacturing facilities: $319 million/31,401 = $12,200 per facility. Total average non-qualified manufacturing facility: $1,000 + $12,200 = $13,200 per facility or to round down to $13,000 per facility.

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The regulatory costs of this proposed rule are further likely to discourage at least some new small businesses from entering the industry. The food industry is characterized by substantial entry of small businesses. Although we cannot quantify how much that will change, we expect that the rate of entry of small businesses will decrease.

Table 65a – Option 1 Average Annualized Small Business Costs Summary with Very Small Business Definition of $250,000 in Annual Sales

	≤20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of domestic manufacturing wholesale and warehouse facilities	80,475	12,283	4,411	477	97,646
Total Annualized Costs	$348,788,485	$73,852,218	$50,787,878	$1,300,775	$474,729,356
Avg Annualized Cost per Domestic Manufacturing Qualified Facility					$1,000/facility
Avg Annualized Cost per Domestic Manufacturing Non-Qualified Facility					$13,000/facility

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Table 65b – Option 2 Average Annualized Small Business Costs Summary with Very Small Business Definition of $500,000 in Annual Sales

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of domestic manufacturing wholesale and warehouse facilities	80,475	12,283	4,411	477	97,646
Total Annualized Costs	$269,348,619	$73,852,218	$50,787,878	$1,300,775	$474,729,356
Avg Annualized Cost per Domestic Manufacturing Qualified Facility					$1,000/facility
Avg Annualized Cost per Domestic Manufacturing Non-Qualified Facility					$13,000/facility

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Table 65c – Option 3 Average Annualized Small Business Costs Summary with Very Small Business Definition of $1,000,000 in Annual Sales					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Total number of domestic manufacturing wholesale and warehouse facilities	80,475	12,283	4,411	477	97,646
Total Annualized Costs	$207,821,654	$66,877,227	$42,671,245	$1,446,274	$318,816,400
Avg Annualized Cost per Domestic Manufacturing Qualified Facility					$1,000/facility
Avg Annualized Cost per Domestic Manufacturing Non-Qualified Facility					$13,000/facility

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C. Regulatory Flexibility Options

Small and very small businesses may need additional time to comply with the proposed requirements. The proposed rule allows small businesses six months and very small businesses 18 months to come into compliance after the effective date of the final rule. If qualified facilities were to incur the same average cost per provision as facilities not subject to subpart C Hazard Analysis and Risk-Based Preventive Controls, then by exempting them, the proposed rule Option 1 will reduce their costs by approximately $220 million (($13,000 per non-qualified facility - $1,000 per qualified facility) x 36,425 qualified manufacturing facilities) x 0.5 for those that already perform the activities). Option 2 will reduce their costs by approximately $260 million (($13,000 per non-qualified facility - $1,000 per qualified facility) x 43,163 qualified manufacturing facilities) x 0.5 for those that already perform the activities. Option 3 will reduce their costs by approximately $ 290 million (($13,000 per non-qualified facility - $1,000 per qualified facility) x 47,795 qualified manufacturing facilities) x 0.5 for those that already perform the activities.

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1. Exemptions for Small Entities

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The costs to implement the proposed rule after adjusting for the modifications and exemptions for small and very small businesses will vary across the affected establishments as their baseline practices vary. Establishments that do not already perform the proposed requirements will bear the costs for compliance. Standard economic theory suggests that a profit-maximizing establishment of any size will shut down when their expected average costs of doing business are greater than their expected average revenues over time. If an establishment's profit margin is significantly reduced after the regulatory costs are subtracted from its pre-regulatory revenues, then the facility will be at risk of halting the production of their food products that are too costly to manufacture. Regulatory cost burdens tend to vary across different-sized establishments. Establishment size is an important determinant of regulatory impacts and for determining the risk of shutting down. Larger facilities tend to already perform more of the proposed required provisions as shown by FDA's survey, so their compliance costs are often smaller in total. Differences in establishment size also often result in differences in relative revenues and earnings. Smaller facilities often have less revenue than larger facilities. Small establishments with above average costs of doing business will be at a competitive disadvantage and might find it difficult to continue to operate. Some small establishments might determine that their new expected costs are likely to exceed their revenues making it too costly to continue and either change product lines or go out of business.

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One option to reduce the impact on small entities is to exempt all of them from the proposed rule. Most entities affected by this rule, however, are small. We estimate that 97,169 out of a total of 97,646 facilities, or about 99.5 percent, are small. Exempting small establishments would substantially reduce any benefit of the rule.

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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 hire or train workers to become qualified individuals to help develop their food safety plan, to conduct their hazard analysis, to develop their written procedures for and implement their preventive controls, to set up record keeping, to make any improvements to their physical plant, to purchase new or replacement equipment, to arrange financing and for any other initial expenditures of time, effort and money. It will also delay the impact of the annual costs of compliance.

Small and very small businesses are not subject to section 418 of the FD&C Act until 6 months (small businesses) or 18 months (very small businesses) after the effective date of FDA's final rule (§ 103(i) of FSMA). This is an additional 6 months or 18 months beyond the time given to larger facilities to comply with this rule.

FDA plans to publish small entity compliance guidance for to help inform and educate small businesses about the requirements of the rule. 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 rule while preserving the public health benefits of the rule.

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

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purposes described in the proposed rule. Discussion of the costs of recordkeeping, record creation, and reporting can be found in corresponding sections of the analysis. The location of these estimates is shown in Table 66.

Table 66- Location of recordkeeping costs in the analysis	
Type of recordkeeping, record creation, reporting burden	Location
Qualified facility status	Tables 11, 12
Written hazard analysis	Tables 17, 18
Written process controls	Tables 19, 20
Process controls calibration, monitoring, verification, review	Table 20
Written allergen controls	Table 21
Allergen controls label review	Table 22
Written label controls	Table 23
Written sanitation controls (subpart C)	Table 25, 26, 27
Sanitation controls monitoring and verification (subpart C)	Table 28
Written recall controls	Table 30
Written corrective action procedures	Table 32

VII. Unfunded Mandates

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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:

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• 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.

VIII. 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.

IX. 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

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Deleted: To better understand the impact on foreign food manufacturing costs, we examined the actual practices of foreign facilities to determine on average how similar current international manufacturing practices are with what would be required under the proposed rule. We examined their actual practices because some manufacturers might already meet our proposed requirements, or despite comparable local requirements and Codex principles, some exporters to the U.S. might be deficient and might not meet our proposed requirements. As in the regulatory impact analysis of domestic manufacturers, the costs of compliance for foreign facilities from a significant regulatory change could exceed the potential benefits. ¶
We lack a survey based on a statistically representative sample of foreign manufacturers to give us reliable evidence of baseline foreign food safety practices. In the absence of a statistical survey, we employed ERG Inc, a research organization, to conduct an expert elicitation to judge the prevalence of specific food safety baseline practices (Ref. ERG Inc. Memorandum Foreign Food GMPs - Expert Elicitation Results September 3, 2009). The experts were asked a series of detailed questions about common food safety practices. Because the expert elicitation was conducted before the proposed rule was drafted, the experts were asked some questions about foreign manufacturing practices that are not provisions called for in the proposed rule. ¶
To begin the study, ERG determined the value of processed foods exported to the US in 2007. Countries totaling over $50 million or more were identified and divided into seven groups based on their geographical location and their level of industrial development. ¶
The countries that export food to the U.S. were divided into the following seven groups:¶
¶
¶
• **Group 1** – South Africa, Spain, Switzerland, Sweden, Poland, New Zealand, United Kingdom, Norway, Canada, Japan, Ireland, Italy, Australia, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Netherlands, Israel.¶
¶
• **Group 2** – Colombia, Brazil, Argentina, Ecuador, Chile, Peru.¶
¶ ...

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Deleted: Ref Total Import/Exports Memo. The data is from the U.S. International Trade Commission (USITC), which maintains a database of U.S. import statistics for all commodities, including food commodities. To estimate just the FDA-regulated foods, we included all categories of foods with NAICS codes starting with 311, excluding 31111, dog and cat foods; 311119, other animal foods; meat products excluding poultry; m ...

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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: Current Good Manufacturing Practice And Hazard Analysis And Risk-Based Preventive Controls For Human Food

Description: The Food and Drug Administration (FDA) is proposing to amend its regulation for Current Good Manufacturing Practice In Manufacturing, Packing, Or Holding Human Food (CGMPs) to modernize it and to add requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. FDA is taking this action as part of its announced initiative to revisit the CGMPs since they were last revised in 1986 and to implement new statutory provisions in section 418 of the FD&C Act.

Description of Respondents: Section 418 of the FD&C Act is applicable to the owner, operator or agent in charge of a food facility required to register under section 415 of the FD&C Act.

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Generally, a facility is required to register if it manufactures, processes, packs, or holds food for consumption in the United States. There are 97,646 such facilities; 46,097 of these facilities are considered "qualified" facilities and have reduced requirements in regards to this rule-making.

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Information Collection Burden Estimate

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FDA estimates the burden for this information collection as follows:

Recordkeeping Burden

We estimate that the recordkeeping burden for training (117.10(c)(3), 117.120(a)) will fall on 43,780 facilities. Plant management must establish and maintain records that document required training of personnel. There are expected to be a different number of respondents for each type of training depending on a facility's qualified status, the type of facility it is (e.g., what is manufactured), and what types of training the facility already has in place. We have estimated the average number of training records (744) that will be generated per facility documenting that an employee was trained regarding a specific matter relating to food safety. We take these estimates from reviewing the Regulatory Impact Analysis and averaging the number of employees trained for specific tasks in specific cost sections. We estimate that on average each record can be created in 3 minutes (0.05 hours). Costs of documenting training employees for all affected facilities are included as operating and maintenance costs of about $34.2 million. These costs were totaled from the appropriate sections of the Regulatory Impact Analysis. Row 1 of Table 67 shows that the total hour burden is 1,629,243 (32,584,851 records x 0.05 hours per record = 1,629,243).

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We estimate that 25,614 food manufacturers and wholesalers subject to subpart C Hazard Analysis and Risk-Based Preventive Controls will need to create a food safety plan (117.175(a)(1)) which is a compilation of many written food safety procedures. We total the

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hour burdens as presented throughout the regulatory impact analysis to then create an average hour burden for each facility to create or complete a food safety plan. We estimate that creation of the food safety plan will require 110 hours. The total hour burden on an annual basis is 25,614 facilities x 110 hours = 2,817,540 hours. The operating and maintenance costs associated with implementing this food safety plan are $122,546,137 for all facilities affected.

The burden for keeping monitoring records (117.175(a)(2)) follows the same pattern as that for the food safety plan. We estimate that there are 16,668 facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls that will need to keep additional records of the monitoring that they do of different activities within their food facilities. Based on estimates of monitoring created, when appropriate, throughout the Regulatory Impact Analysis, we estimate that each of the 16,668 facilities will keep records of 730 of monitoring activities and that each record can be made in about 3 minutes (0.05 hours) for a total hour burden of 2,295,191. The operating and maintenance costs associated with implementing and maintaining this food safety plan are $48,199,001 for all facilities affected.

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For the burden for corrective action records (117.175(a)(3) we estimate that twice per year 18,291 facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls will have corrective actions to document. The documentation of those corrective actions is expected to take one hour for each record for a total hour burden of 36,582. The operating and maintenance costs associated with implementing and maintaining this food safety plan are $912,623 for all facilities affected.

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The burden for keeping verification records (117.175(a)(4)) follows the same pattern as that for monitoring records. We estimate that there are 16,668 facilities subject to subpart C Hazard Analysis and Risk-Based Preventive Controls that will need to keep additional records of

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the verification that they do of different monitoring activities within their food facilities. Based on estimates of verification created, when appropriate, throughout the Regulatory Impact Analysis, we estimate that each of the 16,668 facilities will keep records of 244 of verification events and that each record can be made in about 3 minutes (0.05 hours) for a total hour burden of 2,033,496. The operating and maintenance costs associated with implementing and maintaining this food safety plan are $124,043,256 for all facilities affected.

Records for the supplier approval program (117.175(a)(5)) are accounted for under the food safety plan because they are part of the food safety plan. Records of verification activities associated with the supplier approval program are accounted for under the verification records because they are part of the verification records.

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We estimate that 47,484 food manufacturers and wholesalers subject to subpart C Hazard Analysis and Risk-Based Preventive Controls will need to document the training of their qualified individual (117.175(a)(6)). We estimate that this will require 15 minutes (0.25 hours) per facility total for a total hour burden of 11,871. The operating and maintenance costs are estimated to be $249,291 for all facilities affected.

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Under 117.206(a)(5) facilities subject to subpart C are required to keep records documenting 1) the monitoring of temperature controls for refrigerated packaged food, 2) the corrective actions taken when there is a problem with the control of temperature for refrigerated packaged food, and 3) the verification activities relating to the temperature control of refrigerated packaged food. We believe that the keeping of such records is already common industry practice and will not constitute an additional paperwork burden.

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Table 67a shows the estimated annual recordkeeping burden associated with this proposed rule.

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Table 67a -Estimated Annual Recordkeeping Burden (VSB < $250K)

21 CFR Part 1, Subpart 117	No. Of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours	Total Operating and Maintenance Costs
117.10 (c)(3), 117.120(a) training records	43,780	744	32,584,851	0.05	1,629,243	$34,214,094
117.175(a)(1) food safety plan	25,614	1	25,614	110	2,817,540	$122,546,137
117.175(a)(2) monitoring records	16668	730	12,167,640	0.05	2,295,191	$ 48,199,001
117.175(a)(3) corrective actions records	18,291	2	36,582	1	36,582	$912,623
117.175(a)(4) verification records	16668	244	4066992	0.5	2033496	$124,043,256
117.175(a)(6) Records that document applicable training for the qualified individual.	47,484	1	47,484	.25	11,871	$249,291
Total annual burden hours and costs					8,823,923	$330,164,402

Reporting Burden

Table 68a shows the estimated annual reporting burden associated with this proposed rule.

Qualified facilities must report their status as such a facility every two years; status will likely be reported electronically through a web portal maintained by FDA. This requirement will cause the 36,689 qualified facilities to spend one-half hour every two years reporting to FDA their status as a qualified facility for a total annual hour burden of about 9,172 hours (36,389 facilities x 0.5 responses annually x 0.5 hours per response).

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Table 68a - Estimated Annual Reporting Burden (VSB < $250K)[1]					
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
117.201(a) Qualified facility	36,689	0.5	18,344.50	0.5	9,172
Total burden hours					9,172

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

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Third Party Disclosure Burden

Under 117.201(d) qualified facilities must add the address of the facility where the food is manufactured to their label. The hour burden of this disclosure is zero as this will be a coordinated label change; facilities will likely be updating their labels anyway, so adding the address to the label will not constitute an additional paperwork burden.

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Under §117.152(b) and (c) some supplying manufacturing facilities will need to make the results of an audit, raw material or ingredient testing, and/or food safety records available to their customers (receiving facilities). In the normal course of doing business these facilities will already be submitting back and forth ingredient requirements and qualifications as well as bills of lading, receipts, etc; some receiving facilities already require audit or testing results as part of this business transaction. As with assurance that a supplier is a qualified facility, we expect that audit and testing results will be passed to a customer electronically. Therefore, we expect that the marginal burden of this third party disclosure to be zero.

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Appendix A

1. Total FDA-Regulated Risk of Foodborne Illness

To estimate the burden of illness associated with Section 103, 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 multi-step 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

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To estimate the total number of illnesses attributable to FDA-regulated foods, we utilize a combination of CDC's OutbreakNet: Foodborne Outbreak Online Database[69] (Refs. 1, 2) and

[69] CDC's OutbreakNet covers domestic foodborne illness outbreaks regardless of the location of the cause of the

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FDA's own epidemiological assessment of those outbreaks. Table 1 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.[70]

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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 1. 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
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

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outbreak. Products identified as responsible for outbreaks could be domestic or foreign in origin.

[70] This omission excludes a vast majority of the outbreak illnesses, because most (approximately 60 percent) are linked to retail or home mishandling.

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TOTAL	**157**	**10,440**	**1,413**	**26**

While Table 1 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.

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Table 2 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 3). 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.[71] 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

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[71] "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.

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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 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.

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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

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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 72, 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. 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 U.S. each year due to these 31 pathogens.

However, this does not account for all foodborne illness in the U.S. 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 U.S.. 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

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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 2011 (Ref. 3). These estimates of foodborne illness take into account that foodborne illnesses are likely to be underreported or not diagnosed as foodborne illnesses (Ref. 3). 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.

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We also explored an alternative methodology for estimating the number of illnesses caused by unknown pathogens attributable to FDA-regulated foods. 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 8 of Table 2, 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

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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 2- 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	[illegible]
Norovirus	119	24,570	0.50%	5,461,731	26,4[illegible]
Other chemical	203	506	40.10%	159	[illegible]
Other fungal	31	93	33.30%	19	[illegible]
Other parasitic	18	18	100.00%	4	[illegible]
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.

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In addition to foodborne outbreaks, there are also food allergic reactions associated with

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FDA-regulated food products. Consumers allergic to certain food ingredients will experience an allergic reaction if the protein they are allergic to is ingested. In some cases, food with only trace amounts of an ingredient may cause an allergic reaction in some consumers. These trace amounts could be the result of inadvertent cross-contact during the manufacture or preparation of the food (i.e., a food product is not supposed to contain peanuts but was processed on the same line as a peanut-containing product).

Allergic reactions to food are not considered outbreaks and are not comprehensively captured in the FDA or CDC outbreak databases. Therefore we use information from Ross et al. (2008) and Patel et al. (2011), which allows us to estimate the number of allergic reactions that occur annually due to allergens in foods (Refs. 4, 91). Specifically, Patel et al estimates 700,000 allergic reactions annually (1,400,000 cases / 2 years) and Ross et al estimates 124,926 allergic reactions annually (20,821 cases x six periods). This gives us a range of allergic reactions of 124,926 to 700,000 annually; the average of these two numbers is 412,463 allergy events per year.

The eight major food allergens of milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) are all FDA-regulated products (with the exception of egg products that are primarily regulated by USDA).[72] Regulation by FDA can address allergic reactions due to these

[72] Apart from the limited whole egg processing uses that are regulated by USDA, the majority of other uses of eggs in food products, especially when egg is added to or found in food as ingredients or contaminants are regulated by FDA. These FDA-regulated uses can and have been shown to cause reactions in sensitive consumers. Food allergen experts at CFSAN have recently done an analysis of recall data associated with adverse consumer reactions and found that eggs were the second most common cause of consumer allergic reactions to FDA-regulated food products, after milk. (Ref 92)

FDA is responsible for those egg products not covered by USDA's Egg Product Inspection Act. Products covered under the Egg Product Inspection Act and those specifically exempted by this act are defined in 9 CFR 590.5 as: "Egg product means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under

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foods when the issues involve problems with cross-contact during processing or with labeling. FDA can less easily prevent allergic reactions from food prepared by restaurants or in households or when the allergic reaction is due to a food not considered one of the major allergens. Given these caveats on the types of food allergic reactions which this regulation directly addresses, we adjust our estimate of annual food allergic reactions due to FDA-regulated food products downward from 412,463 to eliminate allergic reactions that occur because of food prepared at a school or restaurant, for example, and for food that is not considered a major allergen.

To adjust our estimate of annual food allergic reactions to just account for major food allergens we again use information from Ross et al. Ross et al report that of the food-allergic events involving anaphylaxis in their data, 83% involved a food or food category containing a major food allergen identified by the Food Allergen Labeling and Consumer Protection Act of 2004. The foods implicated most often included seafood (fish or shellfish) and nuts (peanut or tree nut). Thus, we reduce our annual estimate of food allergic reactions from 412,500 to 342,375 (412,500 x 0.83).

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such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products. For the purposes of this part, the following products, among others, are exempted as not being egg products: Freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, and sandwiches containing eggs or egg products, provided, such products are prepared from inspected egg products or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. Under the law, USDA has jurisdiction over the manufacture of the products listed under their definition of egg product and loses jurisdiction once the products leave the control of the plant. For this reason, FDA normally monitors and classifies recalls of egg products that were manufactured under USDA's jurisdiction. It is likely that a seizure would be handled by FDA as well. Other egg products that are FDA's responsibility and that are not mentioned in the above definition include hard cooked eggs, in-shell pasteurized eggs and shell eggs (except for grading, which is USDA's responsibility).

We cannot tell from the Ross et al paper or the Patel et al paper whether the allergic reactions due to eggs were due to processed egg products, shell eggs, or USDA egg products that are used by retail establishments or institutions (as opposed to going into FDA-regulated processed foods). If the allergic reaction from the eggs is from a restaurant or school setting, which is likely where a still USDA-jurisdictional egg product would be, we have adjusted our annual number of reactions to eliminate reactions due to that possibility.

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Then, to just adjust the reaction total to eliminate reactions due to food prepared at home or in a restaurant we use information from The U.S. Food and Drug Administration's Food Safety Survey as presented in Vierk et al (2007). (Ref. 93) Questions and responses from the survey were analyzed by the authors to determine the prevalence of food allergy and opinions about food labels in the management of food allergy. Vierk et al report that a packaged food caused the last allergic reaction in 28.1 percent of persons with a self-reported food allergy and in 26.6 percent of persons with a self-reported doctor-diagnosed food allergy (27.35 percent average of the two numbers). Vierk et al also report that prepared food (prepared in a restaurant, the person's home or another home) caused the last reaction in 48 percent of those with a self-reported food allergy and 50.7 percent of those with a self-reported doctor-diagnosed food allergy; and that neither prepared nor packaged food (e.g. a piece of fruit) caused the last allergic reaction in 19.9 percent of those with a self-reported food allergy and 17.5 percent in those with a self-reported doctor-diagnosed food allergy.

In the absence of other information we use the information from Vierk et al to estimate that 27.35 percent of food allergic reactions annually are due to processed foods that FDA regulation can have an impact on (as opposed to food prepared by households or restaurants or food that is not prepared.) We request comment on this estimate. Thus, the annual number of food allergic reactions to include in the baseline estimate of foodborne illnesses attributable to FDA-regulated products that FDA can take action to prevent is 93,632 (27.35 percent x 342,345).

Table 3- Estimated Number of Allergic Reactions Attributable to FDA-Regulated Foods

	Percent of cases annually	**Total Cases Annually**	**Average Annually**
Allergic reactions	100%	124,926-700,000	412,463

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Allergic reaction to 8 major allergens	83%	103,689-581,000	342,345
Allergic reactions to packaged food	27.35%	28,359-158,904	93,632

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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.[73] 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. The consequences of foodborne illness

Illnesses that result from consuming food contaminated by a pathogen can be characterized as acute or long-term. Acute illnesses generally include gastrointestinal symptoms which range 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. Furthermore, the severity of a foodborne illness is often dictated by the overall health of the individual (i.e., the elderly, immuno-compromised, and young children often experience

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[73] The general method of plugging in values from other studies is known as benefit transfer.

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more severe symptoms from foodborne illness than those that would be experienced by an otherwise healthy adult). Foodborne illnesses rarely result in death; although, as previously stated, the likelihood of this outcome depends on the type of foodborne illness and the overall health of the affected individual. Nonetheless, there are several types of foodborne illnesses that do carry a significant risk of death, e.g. a case of listeriosis in an elderly person.

Table 4 includes the medical outcomes of foodborne illness, the duration of conditions acquired due to illness, and the probability of occurrence for each condition with a given level of severity (non-hospitalized or hospitalized). The percentage of cases by severity for each illness is based on Scallan et al for most illnesses except for allergic reactions and marine toxin poisonings. The case severity breakdown for allergic reactions comes from Ross et al (2008) and Patel et al (2011)[74]; the case severity breakdowns for marine toxin poisonings come from CDC data found in the CDC NORS database.

To populate Table 4, we determined 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). 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.[75]

[74] From Ross et al, the case breakdown was 87 percent nonhospitalized and 13 percent hospitalized; no deaths. From Patel et al, the case breakdown was 94.09 percent nonhospitalized cases, 5.91 percent hospitalized cases, and deaths were 0.02 percent. We use the means of these ranges in our calculations (as shown in table 5).

[75] See: Some of the Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health

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Table 4 - 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%

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Care Professionals, MMWR, April 16, 2004, Vol. 53, No. RR-4 (Ref 94); FDA Bad Bug Book (2012) Foodborne Pathogenic Microorganisms and Natural Toxins Handbook (Ref 95); and Centers for Disease Control and Prevention (CDC) http://www.cdc.gov/nczved/divisions/dfbmd/diseases/ (Ref 96)for some examples of illness information.

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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%

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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.

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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 75 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. The percentage of cases that result in the secondary complications were also taken from the literature.[76]

Table 5 - 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%

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[76] For Guillain-Barre Syndrome see: Hadden and Hughes (1998) (Ref 97), Hadden and Gregson (2001) (Ref 98), Nachamkin et al (1998) (Ref 99), Rees, Jeremy (1995) (Ref 100), and Smith, James L. (2002) (Ref 101). For Hemolytic Uremic Syndrome see: Bradbury et al (2007) (Ref 102), Siegler and Oakes (2005) (Ref 103), and Thorpe, Cheleste M (2004) (Ref 104). For reactive arthritis see Rees et al (2004) (Ref 105). For ciguatera poisoning see Dickey and Plakas (2009) (Ref 106).

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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. 107, 108) 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. 109) 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 6, 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.

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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

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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. 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 pain or discomfort, and would not be anxious or depressed. This health determination results in a EQ-5D index score of 22221 which equals 0.689 according to Shaw et al (2005).[77] 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 6 - 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

[77] The values for each EQ-5D score are given in Shaw et al (2005) (Ref. 109).

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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 (Refs 110, 111). 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 seek comment on the average daily QALD losses used here.

Table 7 lists the daily QALD loss we have estimated for each illness type and severity by pathogen. Table 7 also 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 conditions 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.[78]

Table 7 - 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

[78]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.

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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
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

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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

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iii. Valuation of foodborne illnesses

Table 8 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 4, 5, and 7 of this document; for Table 8 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) (Refs 112, 113, 114) We use $7.9 million for the VSL, $214,000 for the VSLY ($586 per QALD), and a 3 percent discount rate.

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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. 115, 116) 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. 117) 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.

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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. 118). 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.

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Scallan et al (Ref 3) 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 105) 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.

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Table 8 - Total Costs of Foodborne Illnesses Identified as Associated with FDA Outbreaks

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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

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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

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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

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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 9 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 4. This is multiplied by the expected dollar loss per case, in column 3, to give the annual cost of each pathogen in the U.S. population, presented in column 4. Summing over all pathogens, we estimate a potential annual cost savings of approximately $6.32 billion dollars if all illnesses attributable to FDA-regulated foods were eliminated. [79,80]

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Table 9 - Estimated Dollar Burden Attributable to All FDA-regulated Foods

Agent	Estimated Attributable Illnesses	Expected Dollar Loss per Case	Dollar Burden
Allergen	103,116	$2,347	$242,013,252
C. Botulinum	13	$1,435,899	$18,333,349

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[79] Under the more restrictive illness estimation scheme, we get a value of foodborne illness of $5.03 billion, annually.

[80] Using a discount rate of 7 percent the total value of foodborne illness attributed to FDA-regulated foods is $6.28 billion dollars.

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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	5,297,281	$214	$1,135,535,478
TOTAL	6,090,128		$5,640,433,731

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Recently there have been two publications on the economic impact of foodborne illness in the United States. (Refs. 119, 129) Those papers do not measure what we are measuring in this document. Those papers estimate the economic impact of all foodborne illness associated either with all pathogens (Scharff) or with 14 foodborne pathogens (Hoffmann). FDA's estimate in this appendix estimates the economic impact of foodborne illness caused by all pathogens but only so far as it is related to FDA regulated foods. We are not able at this time to compare our estimates presented here with the estimates in these papers and discern the reasons for any differences in the estimates. FDA seeks comment on the estimates in the two published papers and in this appendix. FDA will address all these estimates in the analysis for the final rule.

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