IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 13563 and12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. FDA has developed a comprehensive preliminary regulatory impact analysis (PRIA); the PRIA is available at http://www.regulations.gov Docket No. 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.

Comment [abl1]: Is this the correct docket number?

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 proposes to certify 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 $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA expects this proposed rule may result in a 1-year expenditure that would meet or exceed this amount.

B. Need for Regulation

The need for the proposed rule is to improve the safety of foods that are manufactured, processed, packed or held to better ensure they do not contain foodborne hazards that are injurious to the public health. Current Federal, state and local regulations are insufficient to reduce the number of injuries from foodborne illnesses. Foodborne hazards are implicated in outbreaks that cause thousands of cases of acute and even chronic illnesses or in some cases, even death (Ref CDC). Establishments that manufacture, process, pack or hold foods (establishments, facilities or owners) might not voluntarily implement sufficient preventive controls to ensure that their ingredients or finished foods are safe and unadulterated.

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: Summary Of Food Recalls, 1999-2003, August 3, 2004).

Food safety problems may also occur because facility owners, operators, or agents in charge might not be aware of need for certain technically complex or minimally sufficient preventive controls; particularly smaller establishments with only a few employees, not all of whom are technically trained in food safety. This suggests that even when economic incentives align to ensure that potential benefits of sufficient preventive controls outweigh the certain costs of controls throughout the supply chain, individual establishments might face considerable technical uncertainty about the efficacy of some or all of the necessary preventive controls. Facility owners, operators, or agents in charge might not be sufficiently informed about the potential microbial, chemical, and physical hazards that are possible in today's complex manufacturing environment. Establishments, even when they have a basic understanding of food safety, might lack the sometimes very technical skills to know how to implement controls effectively to prevent foodborne illnesses. Cleaning, sanitation and process controls, among various other necessary preventive controls, can be technically complex. Workers require adequate on-going training to effectively perform the necessary steps for preventive controls to avert food adulteration.

FDA's survey of food manufacturing establishments in the United States (Ref) shows there is considerable variation in the use of preventive controls in general, and in the use of training in particular, even by facilities that manufacture foods that are similar in product type or by facilities of similar size. Some establishments perform adequate training, while other establishments in the same size class and with seemingly similar

market incentives, do not (Ref. FDA Survey). Furthermore, many of today's food safety issues have just emerged in the past few years. Thus, much of the need for the proposed rule is because of increased knowledge since CFR Part 110 was last revised in 1986. Since the last revisions, the food industry has changed considerably, more is known about foodborne hazards, and more is known about how to control their introduction and growth (Ref. CGMP Working Group Report).

Consumers might be expected to be an effective last line of defense against food contamination and foodborne illness by thoroughly cooking their food or by carefully shopping for name brands thought to be safe. However, many foods have no kill step, or are not cooked or not cooked thoroughly before eating. Brand names do not convey information about the effective use of preventive controls. Consumers can only partially adapt to the risks of foodborne hazards by changing their purchasing behavior. Even well-informed consumers cannot usually detect potential health problems at the point of purchase from the visual inspection of products because most foodborne hazards are not visible to the unaided eye. Rational, well-informed consumers that are aware of the potential harm from foodborne disease will not be able to distinguish foods manufactured and distributed with sufficient preventive controls from those without sufficient controls. In short, the actions by establishments, primarily voluntary preventive controls, do not currently provide sufficiently protective industry-wide minimum safety for manufacturing, processing, packing and holding of foods or food products. In the absence of adequate preventive controls, manufactured or distributed foods are known to cause adulteration and significant injury to the consuming public.

C. Summary of Proposed Rule Costs and Benefits

We summarize the costs and potential benefits of the proposed rule in Table 1. We estimate that the total costs in the first year, which will be period when the industry incurs the largest cost, including both set up costs to implement the rule and annually recurring costs will be approximately $870 million. We estimate that annually recurring costs after the first year will be $545 million. The annualized costs, which include annualized one-time set up costs and annually recurring costs will be approximately $676 million per year using a discount rate of 7 percent for all future years. We discuss our use of the 3 and 7 percent discount rates and our use of a 7 year time preference in accordance with OMB Circular A-4. There are approximately 1.6 million illnesses each year that are attributable to FDA-Regulated processed food products. The total potential benefits of eliminating these foodborne illnesses from FDA-regulated processed foods are approximately $3 billion. We do not expect that we will eliminate all $3 billion dollars worth of foodborne illness. Instead, we expect the proposed food safety regulation 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 are implemented.

Table 1. Summary of Costs and Potential Benefits

Estimated Illnesses Attributable to FDA-Regulated Processed Food Products	**Total Dollar Burden**	**Total First Year Costs (Set up costs + recurring cost in 1st year)**	**Annualized Costs (with 7% discount rate and 7 year time preference)**	**Annualized Costs (with 3% discount rate and 7 year time preference)**
1,608,351	$2,996,126,581	$869,576,575	$676,161,195	$654,672,343

D. 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

a. Measuring total foodborne illness from available outbreak data

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. 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.[1]

In total, there are 10,948 illnesses from 166 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 2. Complete FDA-Regulated Food Outbreaks 2003-2008

Agent	Outbreaks	Cases	Hospitalizations	Deaths
Allergen	1	3	2	0
C. Botulinum	3	13	12	1
Campylobacter jejuni	1	268	7	0
Ciguatera	8	80	1	0
Cryptosporidium	1	144	3	0

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

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
Unidentified	8	505	0	0
TOTAL	**166**	**10948**	**1415**	**26**

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. Additionally, foodborne illnesses can be sporadic in nature; thus, we try and account for the large number of expected sporadic illnesses that do not appear in the outbreak data. Table 2 presents the estimation of the total number of illnesses attributable to FDA foods based on FDA outbreak data combined with CDC outbreak data and adjusted for unidentified pathogens.[2,3] Column one shows agent. Column two

[2]Unidentified, per Scallan et al's definition, means any pathogen known or unknown outside of the 31 pathogens identified in their 2011 paper. Any illnesses attributed to unidentified pathogens do not include undiagnosed cases of Salmonella spp. or E. coli, for example. Cases of undiagnosed illnesses caused by pathogens identified in the Scallan et al paper are accounted for by multipliers.

[3] Scallan, et al. estimates that about 70 percent of all foodborne illnesses are in fact attributable to as yet 'unidentified' pathogens. We estimate that the proportion of identified illnesses holds over the 'unidentified' illnesses. In reality 'unidentified' illnesses could account for more (as Scallan suggests) or less illnesses than the identified illnesses. Without further information, it is impossible to tell.

shows the total number of illnesses attributable to each individual pathogen; this information is taken directly from the raw FDA outbreak data. Column three presents the total illnesses attributable to each individual pathogen in the CDC outbreak data.

Data in column three differs from column two in a few key ways. First, the illnesses in column three can be attributed to any food vehicle; meaning that these illnesses could be from FDA-regulated food, USDA-regulated foods, such as meat, or any unknown vehicle for which we are unable to observe and attribute to a specific food type. This is an important limitation of our initial estimates. Numerous CDC outbreak investigations result in no identifiable vehicle, and with no further information we are implicitly assuming that they cannot be attributable to any foods. This is an extremely restrictive assumption which we attempt to relax in further estimations. Our initial results may therefore be viewed as a lower bound estimation of the illnesses attributable to FDA foods. Second, these illnesses could be due to retail or home mishandling and contamination of food. By design, the illnesses in column two are a subset of the total number of illnesses presented in column three. From these two columns, we are able to 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).[4]

Column four represents the percentage, by pathogen, of outbreak illnesses attributable to FDA-regulated food. To capture not only the illnesses associated with foodborne outbreaks, but also those sporadic cases of foodborne illness, we apply this

[4] We cannot be sure that the CDC data collected is representative of the number of foodborne illnesses caused by unidentified agents. For lack of better information, we therefore estimate that the total number of all reported illnesses is equal to the number of 'unidentified' illnesses, giving them a 50 percent share of the total illnesses.

percentage to the estimated number of annual foodborne illnesses in the U.S. as estimated in Scallan et al 2011(Ref); this total is presented in column five.[5] The estimates of foodborne illness by Scallan et al take into account that foodborne illnesses are likely to be underreported or not diagnosed as foodborne illnesses. 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 3,835,803 foodborne illnesses occur every year due to FDA-regulated foods.

Table 3. Estimated Number of Illnesses Attributable to FDA-Regulated Foods

Agent	FDA Cases (2003-2008)	Total Cases (2003-2008)	Percentage Attributable to FDA Products	Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to FDA-Regulated Products
Allergen	--	--	--	412,463	412,463
C. Botulinum	13	58	22.4%	55	12
Campylobacter jejuni	268	3,851	7.0%	845,024	58,807
Ciguatera	80	353	22.7%	2,100	476
Cryptosporidium	144	229	62.9%	57,616	36,230
Cyclospora	891	990	90.0%	11,407	10,266
E. coli non-0157 STEC	212	624	34.0%	112,752	38,307
E. Coli O157:H7	789	3,283	24.0%	63,153	15,177
E. coli, Enterotoxigenic and other diarrheogenic	15	624	2.4%	11,982	288
Hepatitis A	958	1,190	80.5%	1,566	1,261
Listeria monocytogenes	54	83	65.1%	1,591	1,035
Mycobacterium bovis	35	35	100.0%	60	60
Norovirus	119	62,193	0.2%	5,461,731	10,450
Other chemical	203	794	25.6%	159	41
Other fungal	31	93	33.3%	19	6

[5] Allergic reactions to food are not comprehensively captured in the FDA or CDC outbreak databases. Therefore we use information from Ross et al. (Ref) and Patel et al. (Ref) which allows us to estimate the number of illnesses that occur annually due to foodborne allergens in processed foods. We are able to assume these illnesses are attributable to FDA-regulated products because the eight major pathogens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soybeans) are all non-meat food products that fall under FDA's jurisdiction. Other pathogens not addressed in Scallan et al. (e.g.. Scombroid or ciguatera toxins, and all other categories) are either taken from expert solicitation or the maximum yearly value is derived solely from outbreak data with no multiplier.

Other parasitic	18	18	100.0%	4	4
Plant toxin	8	21	38.1%	4	2
Salmonella	6,113	18,836	32.5%	1,027,561	333,483
Scombroid	154	581	26.5%	20,000	5,301
Seafood poison	5	60	8.3%	360	30
Shigella sonnei	56	2,671	2.1%	131,254	2,752
Vibrio cholerae	5	14	35.7%	84	30
Vibrio parahaemolyticus	269	674	39.9%	34,664	13,835
Unidentified	10,948	145,165	7.5%	38,392,704	2,895,487
Total	**21,391**	**241,816**	**8.8%**		**3,835,803**

As an alternate estimation methodology, we exclude from our data all CDC outbreak illnesses that do not have an identified food vehicle. This changes the proportion of illnesses attributable to FDA-regulated food and the subsequent estimated illnesses. When no food vehicle is identified as a source of contamination, we cannot definitively say anything about the food product that caused the contamination; the resulting illnesses could be due to FDA-regulated food or any other type of food product. Our previous estimates assume that no unidentified outbreaks were due to FDA-regulated foods. Since this is probably not the case, to capture the uncertainty, we omit them from the estimation. 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 more closely represent the true number of illnesses attributable. This method is preferable to the initial estimates for a few reasons. 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 artificially forces that percentage down. This low estimate then carries through the rest of our estimates producing an artificially low estimate of illness burden

attributable to FDA-regulated foods. By excluding these outbreaks altogether, we estimate the percentage based solely on the fully observed data, and then estimate that the unobserved illnesses are distributed accordingly. These estimates provide a much more plausible scenario than the initial numbers. Table 4 presents our alternate baseline estimate of illnesses associated with contamination of FDA-regulated foods. Under this alternative calculation, the total number of foodborne illnesses caused by contamination of FDA foods increases to 6,399,474.

Table 4 Alternative Estimated Number of Illnesses Attributable to FDA-Regulated Foods

Agent	FDA Cases (2003-2008)	Identified Cases (2003-2008)	Percentage Attributable to FDA Products	Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to FDA Products
Allergen	--	--	--	412,463	412,463
C. Botulinum	13	56	23.2%	55	13
Campylobacter jejuni	268	3,448	7.8%	845,024	65,681
Ciguatera	80	353	22.7%	2,100	476
Cryptosporidium	144	149	96.6%	57,616	55,683
Cyclospora	891	919	97.0%	11,407	11,059
E. coli non-0157 STEC	212	481	44.1%	112,752	49,695
E. Coli O157:H7	789	2,452	32.2%	63,153	20,321
E. coli, Enterotoxigenic and other diarrheogenic	15	481	3.1%	11,982	374
Hepatitis A	958	1,086	88.2%	1,566	1,381
Listeria monocytogenes	54	72	75.0%	1,591	1,193
Mycobacterium bovis	35	35	100.0%	60	60
Norovirus	119	24,570	0.5%	5,461,731	26,453
Other chemical	203	506	40.1%	159	64
Other fungal	31	93	33.3%	19	6
Other parasitic	18	18	100.0%	4	4
Plant toxin	8	21	38.1%	4	2
Salmonella	6,113	14,709	41.6%	1,027,561	427,050
Scombroid	154	581	26.5%	20,000	5,301
Seafood poison	5	60	8.3%	360	30
Shigella sonnei	56	667	8.4%	131,254	11,020
Vibrio cholerae	5	14	35.7%	84	30
Vibrio parahaemolyticus	269	674	39.9%	34,664	13,835
Unidentified	10,948	79,347	13.8%	38,392,704	5,297,281
TOTAL	**21,391**	**130,311**			**6,399,474**

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.[6] 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

The acute illness that results from the ingestion of pathogens in food generally causes gastrointestinal symptoms ranging from mild to severe and may include stomach cramping, vomiting, diarrhea, fever, aches, and chills. The exact symptoms of each illness depend on the type of foodborne pathogen involved. The severity of a foodborne illness is often dictated by the overall health of the individual; the elderly, immuno-compromised, and young children often experience more severe symptoms from foodborne illness than those that would be experienced by an otherwise healthy adult. Death as an outcome of a foodborne illness is relatively rare and also depends on foodborne illness type and the overall health of the affected individual. However, there are several types of foodborne illnesses that do carry a significant risk of death, e.g. a case of listeriosis during pregnancy could result in the death of the fetus.

[6] The general method of plugging in values from other studies is known as benefit transfer.

Table 5 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). (Ref Scallan, Illness packet) We only include cost estimates in this section for foodborne illnesses that were identified as having caused outbreaks related to FDA-regulated foods that occurred during the years 2003-2008.

Table 5 - Foodborne Illness: Acute Illness by Cause, Duration and Severity

Gastrointestinal Illness	Duration (days per year)	Percent of Cases
Campylobacter spp.		
nonhospitalized	2 to 10	99.00%
hospitalized	5 to 10	1.00%
death		0.01%
Clostridium botulinum		
nonhospitalized	14 to 90	23.64%
hospitalized	14 to 210	76.36%
death		16.36%
E. coli O157:H7		
nonhospitalized	5 to 10	96.61%
hospitalized	5 to 15	3.39%
death		0.03%
E. coli non-0157 STEC		
nonhospitalized	5 to 10	99.76%
hospitalized	5 to 15	0.24%
Listeria monocytogenes		
nonhospitalized	3 to 7	8.55%
hospitalized	14 to 42	91.45%
death		16.03%
Tuberculosis caused by *M. bovis*		
nonhospitalized	270	48.33%
hospitalized	270	51.67%
death		5.00%
Salmonella spp., Nontyphoidal		
nonhospitalized	4 to 7	98.12%
hospitalized	7 to 14	1.88%
death		0.04%
Shigella, spp.		
nonhospitalized	4 to 10	98.89%
hospitalized	5 to 14	1.11%
death		0.01%
Vibrio cholerae, Toxigenic		
nonhospitalized	3 to 6	97.62%
hospitalized	7 to 14	2.38%
Vibrio vulnificus		

nonhospitalized	2 to 8	3.13%
hospitalized	30 to 60	96.88%
death		37.50%
Vibrio parahaemolyticus		
nonhospitalized	2 to 7	99.71%
hospitalized	15 to 30	0.29%
death		0.01%
Cryptosporidium parvum		
nonhospitalized	1 to 14	99.64%
hospitalized	7 to 60	0.36%
death		0.01%
Cyclospora cayetanensis		
nonhospitalized	5 to 30	99.90%
hospitalized	5 to 60	0.10%
Norovirus		
nonhospitalized	1 to 2	99.73%
hospitalized	1 to 7	0.27%
Hepatitis A		
nonhospitalized	7 to 21	93.68%
hospitalized	1 to 100	6.32%
Ciguatera toxin poisoning		
nonhospitalized	3 to 10	87.36%
hospitalized	10 to 28	12.64%
death		0.14%
Scombroid toxin poisoning		
nonhospitalized	1 to 2	96.10%
hospitalized	2 to 3	3.90%
Food Allergic Reaction		
nonhospitalized	1	90.55%
hospitalized	1 to 2	9.46%
death		0.01%
Foodborne illness, Unknown agent		
nonhospitalized	1 to 2	99.81%
hospitalized	2 to 3	0.19%

We divide our estimates of illness burden into illnesses that are not severe in nature (non-hospitalized illnesses) and those that are severe enough to require hospitalization. We choose this illness severity breakdown for its practicality and usefulness in illustrating where the costs of foodborne illness differentiate. For a mild to moderately severe foodborne illness, the duration of the illness is likely to be similar, and depending on individual's tolerance for discomfort, these persons will likely either treat the symptoms themselves or perhaps visit a family doctor. Hospitalization as a result of a

foodborne illness is rarer and more expensive to treat; the duration of the illness may also be longer than the milder version.

Most acute symptoms of foodborne illness last from a few hours (for some toxins) to a few days to several weeks. However some foodborne illnesses carry a risk of secondary or long-term complications that must be accounted for. For example, a case of foodborne illness caused by *Salmonella* spp. in the short term can cause gastroenteritis; in the long term, the residual effects of the illness may include reactive arthritis. In table 5 we outline the list of secondary complications from foodborne illnesses by pathogen type that we account for in this analysis. We also include estimates of the duration of secondary conditions acquired due to illness, and the probability of occurrence for each secondary condition. (Ref. Illness packet)

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

Gastrointestinal Illness Secondary Complications	Duration	Percent of Cases
Campylobacter spp.		
Guillain-Barre Syndrome (GBS)	30 to 180 days	0.08%
GBS long-term disability	rest of life	0.02%
reactive arthritis	30 to 365 days	1% to 4%
GBS related death		0.00002% to 0.00003%
E. coli O157:H7 and non-O157 STEC		
mild/moderate renal disease	rest of life	0.00089% to 0.00019%
End Stage Renal Disease	1 to 5 years	0.00002% to 0.00008%
Hypertension	rest of life	0.00021% to 0.00210%
Death from ESRD		0.00016% to 0.00144%
Salmonella, Nontyphoidal		
reactive arthritis	30 to 365 (1 year only)	1% to 4%
Shigella, spp		
reactive arthritis	30 to 365 (1 year only)	1% to 4%
Ciguatera toxin poisoning		
post acute illness symptoms	90 to 180	65%

ii. Quality adjusted life years (QALYs)

One approach to estimating health benefits involves the use of QALYs. QALYs can be used to measure the loss of well-being that an individual suffers due to a disease

or condition. QALYs do not include the value of health expenditures caused by the condition in question; we estimate health expenditures separately. QALYs range from 0 to 1, where 0 is equivalent to death and 1 is equivalent to perfect health for one year. Because most foodborne illness last for days or weeks rather than years, the value between 0 and 1 of a QALY (the individual's health state) is more useful if expressed as a daily health state, or quality adjusted life day (QALD). We use a starting QALD value of 0.87 to represent the average health score based on the U.S. population. (Ref. Stewart et al 2007 and Jia et al 2011)

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. Shaw 2005) to calculate QALD value. 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. The EQ-5D scale consists of five domains 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. Total QALDs lost per illness are calculated by estimating the daily health loss from the illness (QALD loss) and then multiplying the daily lost QALD value by the average duration of the illness. Table 7 lists the range QALD values for non-hospitalized and hospitalized cases of foodborne illnesses. We present the possible QALD loss for both acute and secondary

complications of illness. In instances where the residual effects of a foodborne illness last longer than one year; the health loss is discounted at the 3 percent discount rate.[7]

Table 7 - Estimated QALD and QALY loss for Food-related Illnesses by Pathogen Type			
Gastrointestinal Illness	QALD Loss per day	Duration (days per year)	Total Burden per Illness
Campylobacter spp.			
nonhospitalized	0.181	2 to 10	0.362 to 1.81
hospitalized	0.607	5 to 10	3.035 to 6.07
Clostridium botulinum			
nonhospitalized	0.181	14 to 90	0.724 to 16.29
hospitalized rate part 1	0.752	14 to 30	10.528 to 22.56
hospitalized rate part 2	0.181	31 to 180	5.611 to 32.58
E. coli O157:H7 and non-0157 STEC			
nonhospitalized	0.181	5 to 10	0.905 to 1.81
hospitalized	0.607	5 to 15	3.035 to 9.105
E. coli, Enterotoxigenic and other diarrheogenic			
nonhospitalized	0.181	1 to 5	0.181 to 0.905
hospitalized	0.607	5 to 15	3.035 to 9.105
Listeria monocytogenes			
nonhospitalized	0.092	3 to 7	0.276 to 0.644
hospitalized	0.91	14 to 42	12.74 to 38.22
Tuberculosis due to *M. bovis*			
nonhospitalized	0.01	270	2.70
hospitalized rate part 1	0.273	14	3.822
hospitalized rate part 2	0.01	255	2.55
Salmonella, Nontyphoidal			
nonhospitalized	0.181	4 to 7	0.724 to 1.267
hospitalized	0.607	7 to 14	4.249 to 8.498
Shigella, spp			
nonhospitalized	0.181	4 to 10	0.724 to 1.81
hospitalized	0.607	5 to 14	3.035 to 8.498
Vibrio cholerae, Toxigenic			
nonhospitalized	0.181	3 to 6	0.543 to 1.086
hospitalized	0.607	7 to 14	4.249 to 8.498
Vibrio vulnificus			
nonhospitalized	0.181	2 to 8	0.362 to 1.448
hospitalized	0.607	30 to 60	18.21 to 36.42
Vibrio parahaemolyticus			
nonhospitalized	0.181	2 to 7	0.362 to 1.267

[7] Only Campylobacter, Cronobacter, 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.

hospitalized	0.607	15 to 30	9.105 to 18.21
Cryptosporidium parvum			
nonhospitalized	0.181	1 to 14	0.181 to 2.534
hospitalized	0.607	7 to 60	4.249 to 36.42
Cyclospora cayetanensis			
nonhospitalized	0.181	5 to 30	0.905 to 5.43
hospitalized	0.607	5 to 30	3.035 to 18.21
Norovirus			
nonhospitalized	0.181	1 to 2	0.181 to 0.362
hospitalized	0.607	1 to 7	0.607 to 4.249
Hepatitis A			
nonhospitalized	0.181	7 to 21	1.267 to 3.801
hospitalized rate part 1	0.607	1 to 10	0.607 to 6.07
hospitalized rate part 2	0.181	11 to 90	1.991 to 16.29
Ciguatera toxin poisoning			
nonhospitalized	0.192	3 to 10	0.576 to 1.92
hospitalized	0.433	10 to 28	4.33 to 12.124
Scombroid toxin poisoning			
nonhospitalized	0.054	1 to 2	0.054 to 0.108
hospitalized	0.433	2 to 3	0.866 to 1.299
Food Allergic Reaction			
nonhospitalized	0.122	1	0.122
hospitalized	0.654	1 to 2	0.654 to 1.308
Foodborne illness, Unknown agent			
nonhospitalized	0.181	1 to 2	0.181 to 0.362
hospitalized	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)	0.752	30 to 180 days	26.46 to 158.76
GBS long-term disability	0.273	rest of life	1987.00
reactive arthritis	0.092	30 to 365 days	6.66 to 81.03
E. coli O157:H7 and non-0157 STEC			
mild/moderate renal disease	0.162	rest of life	1401.46
End Stage Renal Disease	0.162	1 to 5 years	59.13 to 295.65
Salmonella, Nontyphoidal			
reactive arthritis	0.092	30 to 365 days	2.76 to 33.58
Shigella, spp			
reactive arthritis	0.092	30 to 365 days	2.76 to 33.58
Ciguatera toxin poisoning			
post acute illness symptoms	0.10	90 to 180 days	9.0 to 18.0

The health loss per day for many food-related illnesses is estimated to be identical; this is because many foodborne illnesses include similar symptoms, e.g.,

stomach cramping, vomiting and diarrhea. In these cases where health loss per day is identical, the varying duration of the illness is the factor that makes each illness burden distinct. [8]

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 of table 8 lists the type and severity of ailment. The second and third columns of table 8 are taken from tables 5, 6, 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. For table 7 we use $7.9 million for the VSL[9], $214,000 for the value of a QALY ($586 per QALD), and a 3 percent discount rate. The fifth column of table 7 shows the direct medical costs of each condition. The sixth column of table 8 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

[8]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, (see Sullivan et al 2005 and 2006) but there are no nationally recognized estimates for QALD losses due to foodborne illnesses. The estimates of QALD loss used in this analysis are based on expert judgment of a medical health professional specializing in foodborne illness.

[9] The VSL of $7.9 million is based on EPA National Center for Environmental Economics estimate of $7.4 million in 2006 dollars. This value is within the range of VSLs presented in a meta-analysis by Viscusi and Aldy (2003) and is also reflected in Murphy and Topel (2006). The VSLY is also based on Murphy and Topel and a discussion paper by Aldy and Viscusi (2007) (Ref).

are then summed to calculate the total expected loss associated with each type of food-related illness.

Table 8 - Total Costs of Foodborne Illnesses Identified as Associated with FDA Outbreaks

Gastrointestinal Illness	Case Breakdown	Total QALDs Lost per Illness (based on mean)	Health Loss per Case	Medical Costs per Case	Weighted Dollar Loss per Case
Campylobacter jejuni					
nonhospitalized	99.00%	1.086	$636	$17	$647
hospitalized	1.00%	4.553	$2,668	$22,270	$249
death	0.01%		$7,900,000		$790
Guillain-Barre Syndrome (GBS)	0.08%	78.960	$46,271	$122,132	$135
GBS long-term disability	0.02%	2361.722	$1,383,969	$65,319	$290
GBS-related death	0.00%		$7,900,000		$198
reactive arthritis	2.50%	18.170	$10,648	$486	$278
total expected loss per case					$2,587
Clostridium botulinum					
nonhospitalized	23.64%	9.412	$5,515	$17	$1,308
hospitalized	76.36%	35.640	$20,885	$165,274	$142,151
death	16.36%		$7,900,000		$1,292,440
total expected loss per case					$1,435,899
E. coli O157:H7					
nonhospitalized	96.61%	1.358	$795	$17	$785
hospitalized	3.39%	6.070	$3,557	$56,167	$2,025
death	0.03%		$7,900,000		$2,370
mild/moderate renal disease	0.22%	1401.461	$821,256	$32,611	$1,879
End Stage Renal Disease (ESRD)	0.01%	164.964	$96,669	$750,133	$85
death from ESRD	0.005%		$7,900,000		$395
hypertension	0.12%			$7,479	$9
total expected loss per case					$7,547
E. coli non-0157 STEC					
nonhospitalized	99.76%	1.358	$813	$17	$828
hospitalized	0.24%	6.070	$59,724	$56,167	$278
mild/moderate renal disease	0.02%	1401.461	$821,256	$32,611	$171
End Stage Renal Disease (ESRD)	0.001%	270.798	$96,669	$750,133	$8
death from ESRD	0.0003%		$7,900,000		$24
hypertension	0.12%			$7,479	$9
total expected loss per case					$1,318
E. coli, Enterotoxigenic and other diarrheogenic					
nonhospitalized	99.93%	0.543	$318	$17	$335
hospitalized	0.07%	6.070	$3,557	$22,065	$18
total expected loss per case					$353
Listeria monocytogenes					

nonhospitalized	8.55%	0.460	$270	$17	$25
hospitalized	91.45%	25.480	$14,931	$87,499	$93,672
death	16.03%		$7,900,000		$1,266,370
total expected loss per case					$1,360,067
Mycobacterium bovis					
nonhospitalized	48.33%	2.700	$1,582	$17	$773
hospitalized	51.67%	6.236	$3,654	$76,935	$41,640
death	5.00%		$7,900,000		$395,000
total expected loss per case					$437,413
Salmonella spp. (non-typhoidal)					
nonhospitalized	98.12%	0.996	$583	$17	$589
hospitalized	1.88%	6.374	$3,735	$26,343	$565
death	0.04%		$7,900,000		$3,160
reactive arthritis	2.50%	20.930	$12,265		$307
total expected loss per case					$4,622
Shigella spp.					
nonhospitalized	98.89%	1.267	$742	$17	$751
hospitalized	1.11%	5.767	$3,379	$16,282	$218
death	0.01%		$7,900,000		$790
reactive arthritis	2.50%	20.930	$12,265		$307
total expected loss per case					$2,066
Vibrio cholerae					
nonhospitalized	97.62%	0.815	$477	$17	$483
hospitalized	2.38%	6.374	$3,735	$8,429	$289
total expected loss per case					$772
Vibrio vulnificus					
nonhospitalized	3.13%	0.905	$530	$17	$17
hospitalized	96.88%	27.315	$16,007	$530,317	$529,278
death	37.50%		$7,900,000		$2,962,500
total expected loss per case					$3,491,795
Vibrio parahaemolyticus					
nonhospitalized	99.71%	0.815	$477	$17	$493
hospitalized	0.29%	13.658	$8,003	$21,567	$86
death	0.01%		$7,900,000		$790
total expected loss per case					$1,369
Cryptosporidium parvum					
nonhospitalized	99.64%	1.358	$795	$17	$810
hospitalized	0.36%	20.335	$11,916	$19,885	$114
death	0.01%		$7,900,000		$790
total expected loss per case					$1,714
Cyclospora cayetanensis					
nonhospitalized	99.90%	3.168	$1,856	$17	$1,872
hospitalized	0.10%	10.623	$6,225	$10,900	$17
total expected loss per case					$1,889
Norovirus					
nonhospitalized	99.73%	0.272	$159	$17	$176
hospitalized	0.27%	2.428	$1,423	$26,580	$76
total expected loss per case					$252

Hepatitis A					
nonhospitalized	93.68%	2.534	$1,485	$17	$1,407
hospitalized	6.32%	12.479	$7,313	$28,090	$2,237
total expected loss per case					$3,645
Ciguatera toxin poisoning					
nonhospitalized	87.36%	1.248	$731	$204	$817
hospitalized	12.64%	8.227	$4,821	$15,851	$2,613
death	0.14%		$7,900,000		$11,060
post acute illness symptoms	65%	13.770	$8,069	$391	$5,499
total expected loss per case					$19,989
Scombroid toxin poisoning					
nonhospitalized	96.10%	0.081	$47	$204	$242
hospitalized	3.90%	1.083	$634	$14,526	$591
total expected loss per case					$833
Food Allergic Reaction					
nonhospitalized	90.55%	0.122	$71	$204	$249
hospitalized	9.46%	0.981	$575	$13,256	$1,308
death	0.01%		$7,900,000		$790
total expected loss per case					$2,347
Foodborne illness, Unknown Agent					
nonhospitalized	99.51%	0.272	$159	$17	$176
hospitalized	0.19%	1.518	$889	$19,497	$39
total expected loss per case					$214

iv. The economic impact of illness from FDA-regulated foods

We estimate the total benefits of eliminating foodborne illnesses from FDA-regulated products by multiplying the estimated annual number of illnesses per pathogen by the estimated cost per case. Table 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 US 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. [10,11]

[10] Under the more restrictive illness estimation scheme, we get a value of foodborne illness of $5.03 billion, annually.

Table 9 - Alternative Estimated Dollar Burden Attributable to FDA Foods

Agent	Estimated Attributable Illnesses	Expected Dollar Loss per Case	Dollar Burden
Allergen	412,463	$2,347	$968,052,354
C. Botulinum	13	$1,435,899	$18,333,349
Campylobacter jejuni	65,681	$2,587	$169,918,469
Ciguatera	476	$19,989	$9,513,321
Cryptosporidium	55,683	$1,714	$95,464,676
Cyclospora	11,059	$1,889	$20,889,089
E. coli non-0157 STEC	49,695	$1,318	$65,515,401
E. Coli O157:H7	20,321	$7,547	$153,367,257
E. coli, Enterotoxigenic and other diarrheogenic	374	$353	$132,011
Hepatitis A	1,381	$3,645	$5,035,073
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	**6,399,474**		**$6,317,379,610**

2. Baseline Risk of Foodborne Illness Attributable to Processed Foods

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

[11]Using a discount rate of 7 percent the total value of foodborne illness attributed to FDA-regulated foods is $6.28 billion dollars.

[12] When we refer to illness attributable to processed food, we are referring to illness attributable to food that is manufactured, processed, packed or held; illnesses attributable to products from facilities that are subject to this rule-making.

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

Agent	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Allergen	1	3	2	0
Listeria monocytogenes	7	39	15	1
Mold/Mycotoxins (susp)	2	31	0	0
Mycobacterium bovis	1	35	0	0
Salmonella spp.	8	1,581	210	9
Unidentified	8	505	0	0
TOTAL	27	2,194	227	10

Table 11 presents the estimation of the total number of illnesses attributable to processed foods based on FDA outbreak data combined with CDC outbreak data and adjusted for unidentified pathogens. The methodology is as previously described, accounting for all outbreaks associated with an unidentified food vehicle. Using this calculation methodology, the total number of sporadic and outbreak associated foodborne illnesses caused by contamination of FDA-regulated processed foods is estimated to be

1,608,351.[13]

Table 11- Alternative Estimated Number of Illness Attributable to Processed Food

Agent	FDA Cases (2003-2008)	Total Cases (2003-2008)	Percentage Attributable to FDA Products	Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to FDA Products
Allergen				412,463	412,463
Listeria monocytogenes	39	72	54.17%	1,680	910
Mycobacterium bovis	35	35	100.00%	60	60
Salmonella spp.	1,581	14,709	10.75%	1,072,450	115,272
Unidentified	2,191	79,347	2.76%	39,099,360	1,079,646
TOTAL	**4,382**				**1,608,351**

Note: All illnesses associated with Mold/Mycotoxins (susp) are omitted from this and all subsequent estimations. This is because, although they are attributable to processed foods, we do not have a good estimate of their sporadic or even total outbreak occurrence. As this only represents 31 illnesses, and the health burden associated with these agents is likely very low, we do not expect that this represents a significant omission to the overall human health burden.

b. Economic burden of illnesses attributable to FDA-regulated processed foods

We estimate the total potential benefits of eliminating foodborne illnesses from processed foods by multiplying the annual number of illnesses per pathogen by the estimated cost per case. Table 12 presents the dollar burden of illness attributable to FDA-regulated processed foods. Column 2 contains the total number of illnesses attributable to FDA-regulated processed foods, as previously calculated in table 11. This is multiplied by the expected dollar loss per case, in column 3, to give the annual cost of each pathogen in the US population, presented in column 4. Summing over all pathogens, we estimate an average cost per foodborne illness of $1,862 and a potential annual cost savings of approximately $3 billion dollars if all illnesses attributable to FDA-regulated

[13] Under the more restrictive illness estimation scheme, we get an estimated 1.01 million foodborne illnesses, annually.

processed foods were to be eliminated.[14,15]

Table 12- Alternative Estimated Dollar Burden Attributable to FDA-Regulated Processed Food

Agent	Estimated Illnesses Attributable to FDA-Regulated Processed Food Products	Expected Dollar Loss per Case	Dollar Burden (in Millions)
Allergen	412,463	$2,347	$968,050,661
Listeria monocytogenes	910	$1,360,067	$1,237,660,698
Mycobacterium bovis	60	$437,413	$26,244,795
Salmonella	115,272	$4,622	$532,735,389
Unidentified	1,079,646	$214	$231,435,038
Total	1,608,351	$1,862	$2,996,126,581

We do not expect that this proposed rule will eliminate all $3 billion dollars worth of foodborne illness attributed to FDA-regulated processed foods. Instead, we expect the new, improved food safety regulation as proposed 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 are implemented. However, we believe that this rule, which will effectively create a comprehensive food safety system unlike any previously seen, can be very effective in reducing foodborne illnesses associated with FDA-regulated processed foods. Furthermore, because of the proposed rule's emphasis on monitoring and documenting procedures and results, the effectiveness of the rule is likely to increase over time as facilities learn by doing. Also, the collection of data will enable FDA to perform retrospective reviews to identify changes that would make the rules more effective or less costly.

[14] Under the more restrictive illness estimation scheme, we get a value of foodborne illness of $2.61 billion, annually.

[15] Since none of the foodborne illnesses with chronic complications are attributed to processed foods, the total annual dollar burden remains the same regardless of discount rate used.

c. Potential Underestimation of the Burden of Foodborne Illness

It is important to note that the estimates of the cost burden attributed to processed foods on an annual basis is likely a lower bound estimate of illness burden 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.

Secondly, our starting point, the FDA outbreak database, represents only illnesses where the cause of the food contamination could be directly linked to processed foods. This creates a smaller than possible weighting factor when estimating FDA-regulated foods' share of total foodborne illnesses from the CDC outbreak database. In some instances foodborne illnesses that have been attributed to problems at retail or in the household may have actually had a root cause at the manufacturing level. For example, consumer mishandling of a product that led to the sufficient growth of a bacteria in a food to cause illness could have been ultimately caused by food contamination (and the bacteria's survival) during processing.

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. As evidence, outbreaks associated with FDA regulated processed foods have an average of 81 illnesses while all outbreaks have an average of 20 illnesses. This could indicate that many of the smaller outbreaks, which are associated with no identified food vehicle or pathogen, and thus excluded from our counts, could be attributable to FDA-regulated processed foods.

3. Avoided Recalls

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 zero if this proposed rule is adopted. We estimate that the recalls identified as being preventable by the proposed rule will be reduced, but that mistakes, product quality problems, spoilage, and other product defects will continue to generate food recalls.

The monetary benefits of avoiding recalls are likely very large, although we cannot directly measure them. Past trends of recalled products might not be predictive of

future trends. In some years there have been very large recalls but not in other years. Recalls of adulterated products cause the direct waste of those products that must subsequently be destroyed, reducing their availability to consumers, increasing food prices, and perhaps making consumers more reluctant to purchase certain food products. Consumers might stop eating all or similar foods to the recalled products out of concern that related products are adulterated or hazardous too, especially when the recalls are associated with illnesses. Consumers might stop eating the foods long after the product recall has ended. The demand for fresh-cut spinach was still down by 50 percent one year after the 2006 spinach recall and outbreak had ended (Ref ERS study). The industry can suffer a loss of goodwill and brand names that convey high quality products might be tarnished or ruined. Some studies have estimated the value of lost goodwill because of recalls to be twice the value of the lost product. (Ref Peltzman) Major recalls can lead to the bankruptcy of the establishments that supplied, grew, or distributed the adulterated products, which can lead to the subsequent loss of jobs.

4. Willingness to Pay for Food Safety

In addition to the benefits we have estimated, consumers could also derive a psychological benefit from knowing that their food supply is safer, due to this rule. This effect is much more difficult to isolate and quantify, because it encompasses the overall safer feeling from the general population, rather than traditional market goods that can easily be valued and counted. Despite this difficulty, there is a growing literature on consumer's willingness to pay for non-traditional goods.

The few studies that have attempted to estimate the direct willingness to pay for a reduction in the probability of foodborne illness and increase in safer food (using stated

preference methods) have found much larger values than we have estimated using the cost-of-foodborne-illness avoid method described above (Refs. Haninger, Hammitt (2011), Teisl, Roe (2010), Hayes et al. (1995), and Latouche et al. (1998)). These higher values may incorporate some intangible psychological benefits associated with the existence of safer food.

Primarily, these studies derive their willingness to pay estimates through repeated laboratory experiments using real money and real food. In addition some studies rely on structured surveys. The laboratory research design simulates the consumer's real purchase decisions and allows the researcher to study these habits in a relatively controlled environment. This means that all of the willingness to pay estimates should be a direct result of the consumer's preconceived notions, given information, and rational choices.

While these studies are not directly applicable to this regulation, and the confidence in the actual estimates is not high, they do lend evidence that there may be benefits to the rule beyond the conventional gain in consumer welfare associated with avoiding illnesses. In fact, the magnitude of even the most conservative experimental willingness to pay estimates suggests that our estimated benefits of prevented foodborne illness could be only a portion of the overall willingness to pay.

The results of the experimental studies imply that consumers could place a value on safer processed foods between $19.6 and $130.8 billion, or about 4 to 25 percent of the retail value of processed foods regulated by FDA. Although these values are perhaps implausibly high, they raise the possibility that the benefits estimated in the form of annual foodborne illness costs avoided may be too low.

5. Interpretation of Baseline Illnesses Attributable to Processed Foods

Our baseline estimate of illness costs associated with processed foods may be conservative for a few reasons. First, it does not include the burden of illness associated with food mishandling at retail and at home; such mishandling can amplify bacterial counts in food (for example) and cause illness. If the bacterial counts on food products were eliminated or kept to a lower level at the production stage, mishandling at retail or at home may not have lead to an illness. We are not attempting to regulate at the home or retail level; however, if these foods come into those respective environments with lower levels of bacteria (for example) there may be less chance for cross-contamination or illness from mishandling. Currently, we do not directly estimate the value associated with the cost of reducing these illnesses.

Second, we start with the number of outbreaks that have direct FDA involvement. It is reasonable to assume that some outbreaks, either those with no identified food vehicle (about 40 percent of all foodborne outbreaks result in no identified food vehicle) or those that are never reported to FDA, are due to FDA-regulated processed foods but not attributed as such in the outbreak data. With no direct link to FDA, we are unable to say these illnesses may be preventable under this rule, even though, there are likely such illnesses unaccounted for here. Third, there may be some value to companies from reduced or quicker recalls. This could be realized though less negative press from a recall, less contaminated product loss, or simply fewer labor hours spent on the recall. However, because we cannot verify what will happen to recalls in the immediate future, and because we cannot easily quantify the stated benefits, we do not include these in our baseline estimates of public health benefits. Finally, the budding willingness to pay for

food safety literature indicates that our estimates may understate the value that consumers would place on improved food safety in the processed foods sector. Taken wholly, there are numerous reasons to believe that our $3 billion annual estimate of the baseline illnesses attributable to FDA-regulated processed foods may understate the baseline value of the public health costs from foodborne illnesses associated with processed foods.

Currently we are working on ways to relax our assumptions and quantify a larger portion of the potential human health benefits of this rule. Specifically, pending research may allow us to quantify contamination that occurs at home or retail and outbreaks that FDA was not directly involved in. These two pieces could lead to improved estimates of the illnesses associated with FDA processed foods, and thus the potential direct health benefits from this rule.

6. Effectiveness of Preventive Controls in Manufactured Foods

Because this rule is attempting to create a comprehensive food safety system, unlike anything studied previously, it is nearly impossible to accurately predict the impact that this rule will have on public health. Some small studies have been done to show that individual pieces of this rule (i.e. supplier controls, sanitary conditions, recordkeeping, etc.) will reduce the level of foodborne contaminants and therefore foodborne illness, but a comprehensive study or data on the topic simply does not exist. Additionally, analyzing this very complex system as a whole creates problems that studies which look at only one piece cannot possibly account for, and thus may misrepresent the actual impact on a consumer's well being.

Knowing these limitations, we do not expect that this rule will be able to reduce 100 percent of the foodborne illnesses associated with FDA-regulated processed foods;

however, we do believe that a comprehensive food safety system, such as this, should dramatically reduce the illnesses with its associated industry and improve overall public well-being. Where applicable in the cost-benefit analysis, we have tried to provide qualified evidence that each particular provision is helpful in reducing the prevalence of pathogens. After accounting for exemptions mandated by FSMA, this rule will fully cover more than 99 percent of the processed food sales associated with the burden of illness estimate. 'Qualified' facilities account for only about 1 percent of processed food sales. They will still be responsible for keeping current with good manufacturing practices, informing the public that they are 'qualified' under this rule, and potentially be subject to supplier audits if they do business with a facility subject to subpart C. Considering the vast majority of processed food is covered by this rule, in one way or another, we expect that it should drastically decrease the chance for contamination and illness from nearly all the processed foods consumed in the US.

7. Sensitivity Analysis for Benefits

We estimate a baseline benefit of $3 billion for preventing all illnesses associated with FDA-regulated processed foods. As we explain in the previous section, the number of illnesses likely understates the true total. In this section, we show the effect of a less restrictive assumption about baseline illnesses. Also, we have been estimating benefits using single values per illness prevented. In this section, we show the effects of using a range of potential values per illness, included values from a recent study of consumers' stated preferences.

As stated, our estimate of the baseline burden of illnesses attributable to processed foods is potentially underestimated because it omits home and retail mishandling which

may have been prevented by better manufacturing practices and includes only those outbreaks with direct FDA involvement.[16] To relax both of these assumptions, we estimate the overall number of outbreak related illness that could potentially be due to processed foods. Eliminating all illnesses due to meat, produce, seafood, we estimate that there are approximately 4,983 identified illnesses and 4,414 unidentified illnesses, annually that may be attributable to FDA-regulated processed foods. Since these illnesses are not separable by pathogen we assume a weighted cost per illness, of $5,229, for the identified illnesses attributable to processed food and $214 for unidentified illnesses. These values range from $2,068 to $7,231 for identified illnesses and $135 to $296 for unidentified illnesses, assuming varying VSLs ($1.2 million to $12.2 million) and QALD values ($293 to $882). If all contamination was due to processing there would be a total preventable burden of $6.81 ($2.78 to $9.34) billion. However, not all of these illnesses are likely to be attributable to problems at the processing faculty or its suppliers. Common sources of post-production contamination include improper handling, storage, or preparation methods; therefore, we estimate that approximately 47.4 percent of the contamination occurs at the processing facility or before (Ref Food Handling Practices Model). This yields 2,362 identified and 2,092 unidentified illnesses potentially attributable to FDA-regulated food processing facilities. In total, this gives a potential preventable human health burden of approximately $3.23 ($1.32 to $4.43) billion.

An interesting but limited recent stated preference survey intended to estimate the relationship between the severity and duration of hypothetical foodborne illnesses

[16] Outbreaks associated with FDA-regulated processed foods have an average of 81 illnesses while all outbreaks have an average of 20 illnesses. This could indicate that many of the smaller outbreaks, which are associated with no identified food vehicle or pathogen, and thus excluded from our counts, could be attributable to FDA-regulated processed foods.

generated WTP numbers similar to the WTP numbers in our model. Haninger and Hammitt (2011) use an experimental study, valuing acute foodborne illness, to estimate how WTP varies with severity and duration of illness and other observable characteristics. Their study indicates that the marginal WTP is decreasing over severity of the illness, duration of the illness, respondent's age, wealth, and other characteristics. They find that individuals do not have one stated WTP per QALY, so the uniform application of these is likely incorrect. Their results imply that our estimates of the value of preventing foodborne illness may understate the value of preventing an illness with low severity and duration and overstate the value of preventing an illness that is more severe and drawn out. Future work could address the issue by allowing the WTP for health endpoints to vary separately with illness severity and duration, rather than with the combination of the two. In the meantime we allow the burden of illness estimates to vary over the plausible range of VSL and VSLY values, thus accounting for potential underestimation or overestimation bias.

Table 13 presents the values of the human health burden potentially attributable to FDA-regulated processed foods if we allow VSLs and QALDs to vary. Altogether, this provides a rage of between $1.24 and $4.14 billion, annually.

Table 13. Estimated Dollar Burden Attributable to FDA-Regulated Processed Food

	$293 QALD	$586 QALD	$882 QALD
$1.2 Million VSL	$1.24	$1.69	$2.04
$7.9 Million VSL	$2.52	$2.97	$3.32
$12.2 Million VSL	$3.34	$3.79	$4.14

Additionally, using this alternative WTP measure of foodborne illness from Haninger and Hammitt (2011), we re-estimate the potential health savings generated by this proposed rule. Applying their price a consumer is willing to pay to avoid a foodborne

illness, $5,130 to $7,750 (compared to FDA's estimated range of $2,068 to $7,231, and mean estimate $5,229 per illness attributable to processed food), to the total number of identified illnesses that may be preventable by this rule yields $2.7 to $4.1 billion, annually. We do not apply these illness estimates to unidentified illnesses because the Haninger-Hammitt study design, although it uses generic illness descriptions, attempts to find stated willingness to pay to avert recognizable foodborne illnesses. Indeed, many respondents' estimates were at least partly based on their previous experience with known foodborne illness -- as well as the information provided by the survey. Since most unidentified illnesses we consider are not easily recognized by the public as foodborne, it is highly unlikely that these illnesses were taken into consideration for this survey. Instead, keeping a cost per unidentified foodborne illness of $214, because these illnesses are demonstrated to be much less severe (Ref Scallan et al. 2011), with the Haninger-Hammitt estimates we generate a total potential health saving from this rule of between $2.9 and $4.3 billion, annually. This is in line with the $3.0 ($1.2 to $4.1) billion we estimated previously.

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

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 Wages are increased by 50 percent to account for overhead.

    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

(http://bls.gov/oes/current/naics3_311000.htm) 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.

c. Food Manufacturing Production Worker (Nonsupervisory) Mean Wage Rate: Our estimate for the mean hourly wage rate for food manufacturing workers (nonsupervisory) 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 (http://bls.gov/oes/current/naics3_311000.htm) 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 (baseline practices). (Ref. Food GMP Survey)

- 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 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 SIC codes, number of employees, sales volume and other relevant business data.

- 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, such as finished product testing, where it is likely not all facilities under a particular 4 digit SIC code may need to conduct such testing.

- We use FDA's Operational and Administrative System for Import Support (OASIS) database 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). OMB Circular A-94 further suggests that when discounting, estimates for costs and benefits should be based on credible changes in technology over time. We used seven years for our horizon for discounting (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 .) 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.

- 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
    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
    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
- We estimate that all facilities operate 50-52 weeks per year.
- We use Table 3-1:[17] Typical Food Manufacturing Facility Characteristics, from Evaluation of Recordkeeping Benefits for Food Manufacturers, Final Report, March 30, 2007 in creating estimations of number of products produced by facility, number of manufacturing processes, number of raw material and

[17] Our contractor, Eastern Research Group (ERG) provided us with extrapolations for extra large facilities (see email from Aylin Sertkaya to Angela Lasher dated 7-22-10.)

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

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

- 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. briefly under the section titled "Coverage of the Analysis" and then discuss the effects in a bit more detail in the Unfunded Mandates section of the analysis.

2. Coverage of the Analysis

a. <u>All Facilities</u>

The coverage of this rule is for all FDA-regulated establishments that manufacture, process, pack, or hold foods with the exception of facilities exempted as dictated in §110.2 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 12. 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 US 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 food ingredients to the U.S. in FY2010. Foreign facilities that import to the U.S. must satisfy all the requirements of this rule.

We use D&B global business database derived estimate of the number of domestic facilities throughout our analysis.[18] 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.

To estimate the number of foreign facilities covered by the rule, we use FDA's Operational and Administrative System for Import Support (OASIS) database, which collects information on all importers of FDA-regulated products into the U.S.[19]. Our estimate is based on the OASIS data collected from fiscal year 2010.

Table 14- Number of Domestic and Foreign Food Facilities Covered by the Proposed Rule

[18] 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. 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.

[19] 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.

	<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

In table 14 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 15. 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 (see table 15). 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 (as seen in table 15) with assistance from the Blue Book Online Services, which has detailed information on fresh-cut produce facilities. (Ref Blue Book)

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). Fresh-cut facilities will have more provisions of the proposed rule to comply with, or comply with in greater detail, than would a warehouse or wholesale establishment that may not have much, if any, product exposed to the environment.

Table 15- Number of FDA-Regulated Domestic Food Processing 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
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

b. Qualified Facilities

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 Survey to generate an estimate of the percentage of facilities (20 percent) that are likely to sell their products directly to end-users within 275 miles of their facility. (Ref. Acuna email)

The first row in table 16 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 located within 275 miles of their manufacturing facility. Row 4 shows the additional number of food manufacturers that would be qualified under the very small business definition. 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. Very small businesses are facilities that have less than $250,000 annually in sales. 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 16 for both food warehouses and for food wholesalers.

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

	<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 under § 418(l)(1)(C)	8,633	48	7	1	8,689
Additional Qualified Food Manufacturers under Very Small Business Definition of <$250K	27,793	1	0	0	27,794
Total Qualified Food Manufacturers	36,425	49	7	1	36,482
Non-Qualified Food Manufacturers	17,781	9,340	3,941	452	31,514
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 under § 418(l)(1)(C)	1,058	2	0	0	1,060
Additional Qualified Warehouses under Very Small Business Definition < $250K	2,816	0	0	0	2,816
Total Qualified Warehouses	3,874	2	0	0	3,876
Non-Qualified Warehouses	3,022	878	157	15	4,072
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 under § 418(l)(1)(C)	1,728	5	0	0	1,733
Additional Qualified Wholesalers under Very Small Business Definition <$250K	3,876	0	0	0	3,876
Total Qualified Wholesalers	5,604	5	0	0	5,609
Non-Qualified Wholesalers	17,645	2,009	306	9	19,969
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 under § 418(l)(1)(C)	11,419	55	7	2	11,482
Total Qualified Facilities under Very Small Business Definition <$250K	34,485	1	0	0	34,486
Total Qualified Facilities	45,904	56	7	2	45,968
Total Non-Qualified Facilities	34,571	12,227	4,404	475	51,678

Qualified facilities are not required to comply with Part 110 subpart C of this proposed rule-making; they will have to submit documentation to FDA showing they are qualified facilities, they may incur a label change for their products, they may undergo an audit or have ingredients tested if they are suppliers to other manufacturing facilities. They will also have to comply with any changes that are outlined in the Part 110 subpart B; these are changes to the Current Good Manufacturing Practices. 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

110 subpart C).[20]

ii. Choices Available to Qualified Facilities

As previously stated, qualified food facilities do not have to comply with subpart C of Part 110. 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 information in to FDA by mail. Online, qualified facilities can attest to : 1) their financial information 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).

[20]Even some facilities subject to subpart C may not have to do certain activities required by the proposed rule depending on facility type, e.g. a facility producing products not likely to have a microbiological hazard are unlikely to need to conduct environmental testing.

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.[21]

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 (Ref. BLS) 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). 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

[21]In addition to the costs of attesting and the costs of a label change, some qualified facilities may incur the costs of audits (or raw material or ingredient testing) if they supply other manufacturing facilities who require such verification activities. We address those costs under the section of the analysis devoted to the Supplier Approval and Verification Program.

of attesting to compliance with State, local, county or other applicable non-Federal food safety laws to be similar.

Table 17- Cost to Qualified Facilities to Attest to Qualified Status Through Online Portal					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Number Of Domestic Qualified Facilities	45,904	160	28	7	46,098
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	$936,440	$3,260	$563	$135	$940,398
Cost on an Annual Basis	$468,220	$1,630	$282	$67	$470,199
Cost Annually per Affected Facility	$10	$10	$10	$10	

iv. Costs of Changing Food Labels for Qualified Facility Products

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 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 2 and 4 different products (2 to 4 different Stock Keeping Units (SKUs)) that will require label changes.

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 2 to 4 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.

Table 18- Cost to Add Facility Address to Food Labels

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Number Of Domestic Qualified Facilities	45,904	160	28	7	46,098
Number of SKUs per Facility	3	3	3	3	
Cost per SKU for one-time change	$587	$587	$587	$587	
Total Costs of One-Time Label Change	$80,836,818	$281,408	$48,604	$11,623	$81,178,452
Annualized Total Costs	$14,999,532	$52,216	$9,019	$2,157	$15,062,923
Cost per Affected Facility	$327	$327	$327	$327	

v. Total Costs of Proposed Rule to Qualified Facilities

Table 19 shows the total costs of the proposed rule to qualified facilities. These costs include the costs of attesting that a facility meets the definition of qualified and the costs of a label change for their products.

Table 19 - Total Costs of Proposed Rule to Qualified Food Facilities

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Qualified Facilities	45,904	160	28	7	46,098
Annual Costs to Attest to Facility Status	$468,220	$1,630	$282	$67	$470,199
Annualized Total Costs for One-Time Label Change	$14,999,532	$52,216	$9,019	$2,157	$15,062,923
Total Annualized Costs	$15,467,752	$53,846	$9,300	$2,224	$15,533,122
Cost Per Affected Facility	$337	$337	$337	$337	

vi. Label Change Less Expensive Than Implementing Even One Preventive Control

The costs of making a label change are less expensive for qualified facilities than even just implementing one preventive control. The average annualized cost of the label change is about $327 per facility while the cost of completing a hazard analysis is about $3,000 for a facility with less than 20 employees. The costs of implementing just one preventive control range from about $7,700 to $13,400 per affected facility with less than 20 employees.[22] 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. Even if we double the number of SKUs per facility from a range of 2 to 4 SKUs to 4 to 8 SKUs per facility, the costs of a label change are still significantly lower ($436 per facility annualized) than completing a hazard analysis or implementing just one preventive control.

Table 20 - 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

[22] 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 110 subpart C, the facilities would need to adjust and improve current practices and would incur a cost in doing so.

Complete Hazard Analysis	$3,011
Implement Process Controls	$13,412
Implement Allergen Controls	$7,690
Implement Sanitation Controls	$12,053

3. Baseline Food Manufacturing Practices

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 with Eastern Research Group, Inc (ERG) to conduct a survey of the food industry. 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.

We selected 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. 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 Standard Industrial Classification (SIC) codes for food manufacturers (http://www.osha.gov/pls/imis/sic_manual.html) to create our food product categories. To classify the facility by size, we identified manufacturing facilities as very small when they have fewer than 20 employees, small if they have between 20 and 99 employees, medium if they have between 100 and 499 employees and large when they have 500 employees or more. Some facilities did not report their size. We classified those facilities as unknown.

The Small Business Administration (SBA) classifies companies as "small" based on the size of the entire company, including both parent and subsidiaries. SBA classifies food manufacturers as small when they have fewer than 500 employees. Given that most

food facilities have fewer than 500 employees, most food manufacturers would be considered small in size based on the SBA definition of "small". To better estimate the potential impacts of this proposed rule on facilities by facility size, we have further segmented facility size classes as outlined above.

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 Dun & Bradstreet (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 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.

Participation in the GMP survey was voluntary and the 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 about our survey methodology, see FDA supporting statements A & B, dated August 29, 2008 (Ref. http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=200709-0910-008) and the final survey report (Ref. final Survey report).

We received 704 completed surveys from food manufacturing facilities. Table 21 shows the overall disposition of the survey responses.[23]

Table 21: Overall Survey Disposition (Email and Mail Portions Combined)

Disposition	**Total**
Submitted - In Scope	616
Submitted - Out of Scope	149
Submitted - 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**

Table 22 shows the number of completed surveys by food product type and by the size of the facility.

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

Industry Group	**Facility Size in Number of Employees**			**Total**
	< 20	**20 to 99**	**100+**	
Partition A Responses				
Grain & Oilseed Milling & Sugar Manufacturing	3	16	17	**36**

[23]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.

Chocolate & Non-chocolate Confectionery Manufacturing	18	10	15	**43**
Frozen Food Manufacturing	5	9	27	**41**
Fruit & Vegetable Canning	9	16	22	**47**
Dairy Product Manufacturing	9	30	66	**105**
Seafood Product Preparation	4	6	10	**20**
Bakeries and Tortilla Manufacturing	92	74	66	**232**
Other Food Manufacturing	13	18	17	**48**
Perishable Prepared Food Manufacturing	5	9	9	**23**
Soft Drink and Ice Manufacturing	6	8	15	**29**
Total	**164**	**196**	**264**	**624**
Partition B Responses				
Grain & Oilseed Milling & Sugar Manufacturing	2	0	0	**2**
Chocolate & Non-chocolate Confectionery Manufacturing	3	1	1	**5**
Frozen Food Manufacturing	2	2	2	**6**
Fruit & Vegetable Canning	12	5	3	**20**
Dairy Product Manufacturing	3	3	5	**11**
Seafood Product Preparation	10	2	2	**14**
Bakeries and Tortilla Manufacturing	5	1	5	**11**
Other Food Manufacturing	3	1	0	**4**
Perishable Prepared Food Manufacturing	4	0	2	**6**
Soft Drink and Ice Manufacturing	1	0	0	**1**
Total	**45**	**15**	**20**	**80**
Total 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**

4. Records

The proposed rule requires that certain records subject to specific recordkeeping requirements must be established and maintained. These records must be kept as originals, other accurate reproductions or electronic records. The records must contain the actual values and observations during monitoring, be accurate, be created concurrently with performance of the activity documented, be as detailed as necessary to provide a history of the work performed and include the name and location of the facility; the date and time of the activity documented; the signature or initials of the person

performing the activity; and where appropriate, the identity of the product and the production code, if any.

Recordkeeping is the primary mechanism for accurate assessment of the effectiveness of the food safety plan to assure that safety measures are working in the production facility and throughout the supply and distribution chain. Recordkeeping supports the proposed requirements by documenting the safety characteristics of the food products and ingredients, which in turn help producers make better decisions for consumer safety, especially decisions about corrective actions that might be necessary to help ensure safer products and processes. Recordkeeping also supports regulatory compliance and reduces the legal costs of consumer complaints from adulterated and unsafe food products (Ref Avent, 2003).

Economic theory suggests that a typical food manufacturer will select the records they will keep by equating the private benefits of the record to their private costs. In the absence of a regulatory requirement for recordkeeping, most facilities will maintain most records because they are economically beneficial for the safe and effective operation of their facility. This is shown by the FDA survey results to questions 125 to 140, which show that most facilities of all sizes maintain building and facilities records, equipment records, materials records, personnel records and production and process records among many other records. These records can serve as a tool for facility managers to monitor the food safety effort of their in-plant employees, suppliers and distributors to increase consumer good will, reduce the risk of lawsuits and in other ways enhance their profitability. Unfavorable press can damage a company's reputation that can result in huge dollar losses, sometimes putting them out of business.

There are social benefits for the proposed requirement to maintain records. Records when they are accessible, can serve as a verification tool for regulators and auditors that have the authority to inspect for non-compliance with food safety standards. It may be difficult for a regulator to directly observe the level of food safety achieved at a food manufacturing plant without the recordkeeping requirements. The social benefits of recordkeeping are that they enable facilities to conduct business in a more accountable manner to the public; support and document production safety decision-making; and meet their regulatory requirements including audits, inspections and other oversight activities. The proposed recordkeeping requirements are designed to help both owners and operators of facilities and public health officials to identify potential sources of contamination and contain and mitigate the adverse health effects of contaminated food.

Some records might be more beneficial for the public than the facility owner. Because records can generate social benefits that can exceed their private benefits, facilities might not document all of their food safety activities when their activities are insufficient, or they might not maintain sufficient records or disclose their records to fully protect the public, unless required to maintain the records by regulation. Producers might not choose to disclose their food safety level through records in part to avoid undesirable regulatory outcomes such as penalties, and tightening of standards. We cannot estimate the public benefits of individual records or the impact of records without the activity that the record is documenting. We estimate the costs of recordkeeping in the sections for which the record documents the activity performed.

E. Costs Associated with Revisions to Subpart B- Current Good Manufacturing Practices

The proposed rule revises particular provisions to current part 110. This section addresses the provisions that are revised and that will have a potential cost to food facilities.

1. Education and Training

Part 110.10 (c) Education and Training of the proposed rule requires that personnel involved in food manufacturing, processing, packing, or holding, including temporary and seasonal personnel, must receive appropriate training in the principles of food hygiene and food safety, employee health and personal hygiene. Records must document the training. Numerous studies have shown that poor hygienic practices among employees contribute to the microbial contamination of food (Ref. ERG Lit Review). Employee hygiene is necessary for plant sanitation and its absence is one of the leading causes of food contamination (Ref. CDC http://www.cdc.gov/nceh/ehs/EHSNet/highlights.htm#Food_Workers'_Food_Preparation , Todd 2008, Higgins, 2002.) Education and training are contributing factors to better personal hygiene and facility sanitation (Ref Egan et al 2006).

One of the challenges to better personal hygiene and plant sanitation is how to inform and encourage employees to comply. Workers have difficulty identifying what to do about infections, whether trained managers are present or not, which indicates that in part, food workers are not properly trained in recognizing the symptoms of such illnesses or about the importance of staying away from work when ill with infectious diseases that can be transmitted through the food supply.

To understand baseline education and training practices, we use responses from the GMP survey. Our Food GMP survey included 22 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. Question 18.4 of the survey asked about the type of food safety and sanitation training provided to newly hired production employees. About nine percent of facilities with less than 20 employees responded that they do not provide any training, while all facilities with 500 or more employees responded that they provide training of some type. Question 20a asked of those facilities that do provide training, how much time is devoted to training on the principles of food safety, foodborne hazards, and the prevention of such hazards. About 33 percent of the facilities with fewer than 20 employees responded that the topic is 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 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.

Question 20b asked of those facilities that do provide training, whether personal hygiene practices were taught. 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 question 21 were asked about 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.

Food manufacturers with rapid worker turnover, a high proportion of seasonal or temporary staff, and language and education barriers may have difficulty training their workers. These factors may also apply to, and impact, the effectiveness of their in–house preventive control programs. Poor or no worker training might be due to the recruitment of workers with literacy and language barriers (Lillquist et al, 2005).

Refresher training in food safety principles is important because workers may need to be reminded periodically of what they have been taught. Refresher training also is useful in situations when a process or procedure has been added or changed or when a worker has not been following procedures. As an example, if sanitation practices at a facility change when new equipment is installed then refresher training could provide managers with the ability to periodically reinforce the importance of sanitation practices and to further encourage good worker hygiene. Refresher courses are necessary to maintain the highest level of food safety and compliance with facility procedures. A person's retention of knowledge will decrease 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 (Lillquist et al., 2005, Vaz et al., 2005) Question 26 of the GMP survey asked respondents how often refresher training in food safety and sanitation is provided to 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.

The cost to comply with the proposed education and training provisions are to those facilities that do not currently provide sufficient, if any, education and training to newly hired employees or refresher training to experienced employees. To estimate the costs to adequately educate and train employees, we estimate the cost to procure adequate training materials. Training and educational materials are readily available in book and pamphlet form, on-line, and in the form of videos. FDA and USDA provide general food safety and personal hygiene education and training materials on-line for free that is already used by most facilities that conduct food safety training (Ref FDA GMP survey Q23.1 and 23.2 , FDA http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm124134.htm USDA http://fsrio.nal.usda.gov/nal_web/fsrio/fseddb/fseddbsearch.php .) We believe facilities will not incur an additional cost for new training materials to comply with the proposed provision because over 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 additional cost to comply will be for the additional labor hours 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 believe an average of two hours are 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. Facilities that provide one or fewer hours will 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 will 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.

Table 23- 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	
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	$3,421,4094

Table 24- 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
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 25 presents a summary of all annual training costs to comply with proposed subpart B 110.10 (c).

Table 25- 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	$655,486	$7,259,553
Total Annual Costs	$25,963,472	$23,290,125	$36,764,491	$7,240,826	$93,258,915

The benefits of educating and training food manufacturing employees are that over time, education and training is a contributing factor for reducing product adulteration and cases of consumer illnesses. Most studies about the effectiveness of training pertain to workers in retail food establishments; training retail food establishment workers has been shown to be effective in increasing both their knowledge of and their use of better food safety behaviors and practices (Ref Egan *et al* 2005). It is reasonable to infer that the effectiveness of worker training practices in retail food establishments will also pertain to workers in all types of food facilities: ingredient suppliers, manufacturers, processors, packers, and holders.

Almost all the available studies on retail food service training are based on short term observations that use a variety of evaluation measures, which make it difficult to make direct comparisons between the various study results or to actual food industry practices that would be covered under this proposed rulemaking (Ref. Egan 2005). We are not aware of any directly relevant studies that measure the effectiveness 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 is implemented, as measured by decreases in bacterial counts of mesophilic and coliform bacteria on raw semi-processed rolled beef (Ref Vaz 2005) and lower microbial contamination levels of ready-to-eat salads sold through retail outlets (Ref Sagoo 2003).

The largest study to identify the impact of training was conducted by the IAFP Committee on Control of Foodborne Illnesses (Ref. ERG Lit Review and Todd *et al.* 2008). The Committee on Control of Foodborne Illnesses conducted a retrospective study of 816 foodborne illness outbreaks from 1927 to 2006. Although they 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 (Todd et al.2008). 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. Green and Radke (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. Pragle et al., (2007)

determined that insufficient food worker training and education is the most frequent barrier to implementing good personal hygiene practices. 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. Sagoo et al. 2003.) Hedberg (2006) and Cates (2009) showed that retail food establishments with a certified kitchen manager on the premises typically had lower rates of foodborne illness outbreaks and were less likely to have critical violations during inspections. Certified kitchen managers in retail food facilities undergo more in-depth training than other retail food workers; certified kitchen managers were also more likely to stress on-the-job training of subordinate food handlers in their establishments (Cates 2006). In addition, training of food managers in general is more cost-effective than training other retail food workers because managers typically stay with their employers longer. Manager training also produces intangible benefits such as the ability to positively impact the training and management of food handling staff. Pragle (2007) cited proactive, trained managers who took time to educate their staff properly as a positive factor in promoting good personal hygiene practices. The lower turnover rate of managers also helped ensure that such training programs remained consistent over longer time periods. The presence of on-site, certified kitchen managers is also associated with reduced risk for foodborne illness outbreak (Hedberg et al. 2006).

Lillquist et al., (2004) studied the effects of different training methods on retention of training knowledge. The results indicate that subjects who engaged in participatory demonstrations showed better understanding of proper hand washing and retained this knowledge better over a short period. (Lillquist, et al, 2004)

2. Sanitary Operations and Process and Controls

Proposed § 110.35 would revise current § 110.35 to clarify 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.

Proposed § 110.40 would revise current § 110.40 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.

Proposed § 110.80 would revise current § 110.80 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.

Current part 110 section 402(a)(3) stipulates that a food shall be deemed to be

adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) stipulates that a food shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health (Ref.http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/ucm107527.htm) Despite the current requirements, poor sanitation continues to be a contributing factor for foodborne illnesses. FDA's literature review of food manufacturing processes, expert elicitation on current GMP practices, as well as FDA's own inspection reports show that facilities often lack adequate sanitation and there are frequent violations for insanitary conditions (Ref. ERG Evaluation of Hazard Analysis and Critical Control Point (HACCP) Plans for Food Safety, January 21, 2011, ERG Economic Analysis of New FDA cGMP Regulations and Related Legislative Initiative Review Subtask, February 5, 2010, ERG Memorandum, Literature Review on Problems Typically Encountered in the Food Processing Environment and the Range of Preventive Controls Recommended, May 28, 2003, ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010.) The FDA GMP survey reveals that virtually all respondents report cleaning and sanitizing their facilities, yet the presence of insanitary conditions remains a significant cause for class I and II food recalls; an FDA study of recalls showed that ineffective sanitation might have caused 10 percent of the class I and II recalls between the years 1999 and 2003 (Ref. FDA Food GMP Modernization Working Group: Summary Of Food Recalls, 1999-2003, August 3, 2004). In addition, the manufacturing of insanitary foods

is the cause of large numbers of regulatory violations each year and the lack of sanitation controls contributed to 62 percent of the recalls caused by the presence of Listeria monocytogenes and Salmonella (Ref. summary of recall data 2008-2009).

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. Chmielewski et al., 2003). Effective cleaning alone can remove more than 90 percent of microorganisms. (Ref. Gibson, H. et al 1999.) Cleaning is the use of detergents and soaps to remove undesirable materials, protein and mineral fouling layers that can harbor microorganisms. Cleaning effectiveness is usually determined by its ability to remove the undesirable materials (Ref. Gibson, H. et al 1999.)

An economically efficient food facility will choose the level of sanitation operations where the expected revenue from an additional dollar spent on workers, equipment and training for better sanitation equals the expected facility cost from insanitary products. The costs from insanitary products can include product recalls and rejected products, a loss of consumer goodwill and a loss of public health for which the facility might be legally liable. The private incentive for economic efficiency might not be sufficient to protect the public health if facilities do not assess the entire risk-adjusted cost to society for all the consumer illnesses and foregone public health they might cause from their contaminated foods. These facilities might knowingly or unknowingly underestimate their responsibility for the costs they impose on society for the illnesses (including latent and unreported illnesses) caused by their contaminated foods.

The trend in the food industry is to adopt improved sanitation operations in part by using automated equipment that is designed to facilitate self-draining and exposed surfaces for better cleaning and sanitizing (Ref Higgins, 2006.) According to Higgins (2006), automated cleaning systems are gradually replacing manual cleaning systems because they are more effective for sanitation. The food industry's increasing attention to allergen controls is also increasing their interest in better sanitation operations including the use of automated cleaning systems. To test the impact of allergen controls, Roder et al. (2008) conducted a study in a food processing plant to test a wet cleaning procedure. The authors monitored the cleaning efficiency of various steps by measuring the level of hazelnut protein cross-contact. The automated wet cleaning procedures were found to reduce hazelnut protein cross-contact to a level at which severe hazelnut-related allergic reactions were unlikely to occur.

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 processing facility were found to be inadequate for removing pathogens once the pathogens were established (Ref. Keller et al., 2002). Changes in manufacturing conditions, processes, ingredients, and technologies require that food facilities continually evaluate the effectiveness of their sanitation operations.

The effectiveness of cleaning strategies for allergen control is also highly specific and varies in different settings. Jackson et al. (2008) conducted a review of studies of cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. One key finding of Jackson's review is that processors need to evaluate the efficacy of their cleaning protocols for each type of food soil, food contact

surface, piece of equipment, and processing line. Temperature and concentration of the cleaning solution also need to be considered.

Biofilms occur when bacteria form a matrix that adheres to the surface. The adhesion of pathogenic bacteria to a biofilm is a food safety hazard because bacteria can detach and become a significant source of food contamination. Studies have shown that attached bacteria may survive conventional cleaning methods; sanitation operations that are monitored and verified are necessary to help prevent this problem. (Ref. Austin and Berferon, as cited in Stopforth *et al*, 2002)

Niches or harborage sites are sites within the manufacturing environment where bacteria can get established, multiply, and contaminate the food during processing. These sites may be difficult to reach and clean with normal cleaning and sanitizing procedures or by untrained workers. Examples of manufacturing environments that are difficult to clean include hollow rollers on conveyors, cracked tubular support rods, the space between close-fitting metal-to-metal or metal-to-plastic parts, worn or cracked rubber seals around doors, and on-off valves and switches (Ref. Tompkin, 2002). Tompkin (2002) provides an extensive list of potential harborage sites.

Cleaning agents vary in their ability to remove different soil types, further establishing the need for effective procedures that are monitored and verified and conducted by trained workers that have the judgment to select the correct cleaning products (Ref. Blackburn and McClure, 2002). The correct choice of cleaning agent is essential to ensure effective cleaning in a food processing facility. The efficacy of disinfectants is dependent on microbial species, pH, the presence of biofilms, temperature, concentration, and contact time (Ref. Stopforth et al, 2002; Blackburn and

McClure, 2002). Stopforth et al (2002) found that commonly used disinfectants were not always effective, possibly due to inadequate pre-cleaning procedures. Food manufacturers should monitor and 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 revisions. We lack data about how many of the qualified manufacturing facilities already perform these functions. Our estimate for the total costs for this section is based on an estimate that between 25 and 75 percent of all facilities already perform these operations. Table 26 summarizes our cost estimates. We ask for comment on our 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 will 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 26- Estimate for On-Going Sanitation Operations Training Costs by Facility Size

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Total Qualified Domestic Manufacturing Facilities	36,425	138	28	4	
Percent of Facilities w/o Training	25 to 75%	25 to 75%	25 to 75%	25 to 75%	
Total Facilities that Require 2 Hrs of Training	18,213	69	14	2	
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	$9,871,175	$167,808	$178,108	$52,744	$10,269,835
Total Facilities that Require Personal Hygiene 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	$382,463	$7,970	$8,820	$2,625	$401,877
Total Costs per Year	$10,253,638	$175,778	$186,928	$55,369	$10,671,712

3. Recordkeeping

Proposed § 110.120 would add a new section that would list the records that would be required by provisions in subpart B and require that such records be established and maintained in accordance with general recordkeeping requirements that would be established in proposed subpart F. The listed records would be those that document the training of personnel, as would be required by proposed § 110.10(c)(3). We estimate the costs for establishing records in the various sections where we estimate the costs to comply with the proposed provisions.

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

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. 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, 5) written verification procedures and the frequency with which they are to be performed, 6) a written recall plan, and 7) a written list of approved suppliers and written determination of which designated food safety regulation or regulations raw materials and ingredients from each supplier are subject to, if any. The food safety plan must be prepared by a qualified individual.

The social benefits of food safety plans are that they help facilities increase their 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.

Recognition of the benefits of the industry-wide use of food safety plans is fairly recent. 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 SSOPs. Food safety management systems (FSMS), especially as required for ISO 22000,[24] 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.

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. Codex Code of Practice General Principles of Food Hygiene CAC/RCP1-1969, Rev. 4 – 2003). Our literature review found six published studies that address the importance of HACCP plans. (Refs) The literature shows that the plans are important in part because they are integral to training and educating a HACCP team. 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 (Ref. Peters 1998, Panisello and Quantick, 2001). Codex also notes that a HACCP team, which is assembled to develop the HACCP plan, should have the

[24] ISO 22000 is a Food Safety Management System developed by the International Organization of 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).

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 (Ref Codex CAC/RCP1-1969, Rev. 4 – 2003.)

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.

b. Reanalysis of the Food Safety Plan

Section 110.150(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.

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 estimated 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 expected 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.

2. Hazard Analysis

Proposed §110.130 requires the owner or operator 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 or packed 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.

The severity of the health effects from microbiological hazards can be assessed using epidemiological evidence linked to the pathogens when the pathogens are not properly controlled. If a facility manufactures pre-cut leafy greens, then during the hazard identification stage, some reasonably foreseeable hazards are the pathogens that have been found in pre-cut leafy greens in the past such as the enteric pathogens *E. coli* O157:H7 and Salmonella spp. The current epidemiological evidence for the likelihood of

consumers becoming ill from pathogen contamination of pre-cut leafy greens is low (Ref. FDA's Food Handling Practices Model, RTI 2007). The consequences to consumers can be significant, however. *E. coli* O157:H7 and Salmonella spp. can cause severe health effects including death among children, immuno-compromised individuals, and the elderly

The identification of hazards should be performed by qualified food safety professionals in collaboration with a team of personnel that are knowledgeable about the ingredients and processes within the facility. In general, the scope of the hazard analysis 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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010). Proposed §110.130 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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010).

Several studies have investigated the effectiveness of Hazard Analysis and Critical Control Point (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. Most of the studies are case studies of short duration of individual facilities or small groups of facilities. To our knowledge, no studies look at just the effectiveness of a hazard analysis independently of and without the other steps of 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 Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs) enhance the food manufacturing industry's ability to ensure the microbiological safety of foods (Ref. ERG Evaluation of Hazard Analysis and critical Control Point (HACCP) Plans for Food Safety, January 21, 2011, ERG Economic Analysis of New FDA GMP Regulations and Related Legislative Initiative Review Subtask, February 5, 2010, ERG Memorandum, Literature Review on Problems Typically Encountered in the Food Processing Environment and the Range of Preventive Controls Recommended, May 28, 2003)

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 aflatotoxin levels of fermented maize (Ref. Kofi Amoa-Awua, et al. 2007.) 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 mesophile and faecal coliform (Ref. Martins and Germano, 2008.)

Lupin, Parin and Zugarramurdi (2010) compared three case studies of fish processing plants in Latin American countries to assess the economic feasibility of HACCP programs for the industry (Ref. Lupin *et al*, 2010.) 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. Zugarramurdi (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 plant's defective and potentially hazardous fish products (Ref. Zugarramurdi *et. al.,* 2007.) In a case study of the application of HACCP to a US 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. Chemat and Hoarau, 2004.)

Other areas of interest in the literature regardin HACCP are the types of factors that influence the effective implementation of HACCP programs. A common theme in this 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. Maldonado *et al* (2005) 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 survey result (Ref. Taylor, 2001, FDA GMP Survey Q 103.) Taylor surmises that the major barriers to the implementation of HACCP for small facilities are the lack of technical expertise, inadequate training among employees and the relatively high costs of HACCP in the short-term, while the private benefits to small facilities are uncertain and only likely to be derived in the future.

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 implementation. They, like Taylor, found technical or knowledge barriers prevent 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 (Ref. Panisello and Quantick, 2001.)

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. Ropkins and Beck, 2002)

To understand the baseline use of hazard analysis in the food manufacturing industry, the FDA Food GMP survey asked, "Do you have a Hazard Analysis and Critical Control Point (HACCP) System?" (Ref. Survey Q103). Over 58 percent of facilities with fewer than 20 employees responded that they do not have 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. According to their survey, the major motivation for implementing HACCP is to ensure the safety of their products. *Food Manufacturing* magazine's survey also reports that 90 percent of manufacturers that implement HACCP systems report commitment by top management to HACCP.

Our 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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, Question 1., April 19, 2010).

A qualified individual must prepare the written hazard analysis. Larger or more diversified firms might require 6 to 10 hazard analyses per facility (Ref. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, Question 1., April 19, 2010). Table XXXX summarizes our labor hour estimates for preparing a written hazard analysis.

In a previous economic analysis for a rulemaking, FDA estimated the number of hours to conduct a hazard analysis for a facility, on average, was 20 labor-hours for a facility that employs 20 to 99 employees (Ref. FDA Juice HACCP). We estimate that of our expert's estimate for the total time to conduct and write the hazard analysis, it will take approximately 4 to 8 hours for the writing alone. Of the total time to update the hazard analysis, 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 27- 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

Facilities subject to subpart C will be required to conduct a hazard analysis when

they lack such an analysis of their facility. If a covered facility currently operates using HACCP (answered yes to Q103 of FDA GMP Survey), then by definition they have already conducted a hazard analysis. If a facility does not currently operate under HACCP (answered no to Q103), then they probably have not conducted a hazard analysis and they will need to do so to comply. Table 28 summarizes our estimate for the initial costs to conduct a written hazard analysis.

Table 28- Estimate for Initial Costs to Conduct Initial Written Hazard Analysis by Facility Size

	<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	18,375	2,030	126	0	20,531
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

Table 29 summarizes our estimate for the on-going annual costs to update the written hazard analysis.

Table 29- Estimated Costs to Annually Update the Hazard Analysis 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	31,550	11,250	4,226	458	47,484
% Facilities w/o Hazard Analysis (Ref: Survey Q 103)	58%	18%	3%	0%	
Total Facilities that require Hazard Analysis	18,375	2,030	126	0	20,531
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Number of Process per Facility (Ref. Expert Elicitation)	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

3. Preventive Controls

a. Process Controls

Proposed § 110.135(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, 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. Process control values should be scientifically-based as determined from a variety of sources such as Federal government regulatory standards and guidelines, peer reviewed scientific and industry literature reviews, experimental results, and qualified academic, scientific, and industry experts.

The benefit of process controls, along with the benefit of equipment calibration,

and other forms of 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.

The regulatory costs of adopting process controls is often 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; and the labor hours needed by QA/QC personnel and production managers to perform the on-going verification (including the use of verification instruments) to ensure that the process controls continue to be effective over time.

To estimate the number of facilities that currently lack process controls, we referred to questions 103, 106 and 133a of the GMP survey. Question 103 asks about the use of 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 for question 103

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.

Question 106 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.

Question 133a 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 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 of Q133a 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 of Q 133a likely 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 Q103 and Q133a for a total of 47 percent of facilities with 20 employees or fewer.

To further understand the current use of process controls in the food industry, we consulted our experts (Ref. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010 Verification Q 1.) The experts' belief is that the current industry use of process controls varies among facilities. Some small to medium-sized facilities do not use process controls at all, which is consistent with our Food GMP survey results. Our experts assert that some small and medium-sized facilities: 1) lack staff that are trained in HACCP, 2) may be unqualified to generate a HACCP plan, or 3) are incapable of conducting a hazard analysis. This indicates the importance of training and the use of qualified individuals to develop the written procedures to correctly use the process controls. The number of process controls varies directly with the nature and complexity of the foods being manufactured. We ask for comment on this assessment.

Our experts judged that there are generally one to three process controls per product line depending on the type of the food manufactured. 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 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. We ask for comment on this 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: Recordkeeping Cost model.) 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 procedures is an average of 4 hours per process for facilities with 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 estimate 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 estimate 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 ask for comment about our estimates.

To estimate the cost to calibrate the equipment used as process controls, we asked our experts to estimate the time generally needed to perform this task. Their estimate is shown on expert elicitation table 16. To estimate the on-going costs to calibrate the process controls instruments, we determined 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 use the estimate of 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 table 2-9 of the recordkeeping cost model for equipment calibration records are between 7 and 33 minutes per record for a total of 24 hours per year.

We estimate 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 table 2-9.

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

110.135(d)(1). We estimate that it will require one to five minutes for a qualified individual to review each record.

Table 30- Estimated Initial Costs to Implement Process Controls by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Domestic Manufacturing Facilities that are subject to subpart C	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	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
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 31- Estimated On-Going Costs to Implement Process Controls by Facility Size

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C	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	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	
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	2 to 4	2 to 4	2 to 4	2 to 4	

Updated Written Procedures					
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 (EE Table 16)	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 (EE Table 16)	.12 to .55	.12 to .55	.12 to .55	.12 to .55	
Number of calibration records per process per year (EE Table 16)	24	24	24	24	
Subtotal Recordkeeping Costs to Document Calibration	$8,022,787	$976,906	$225,792	$0	$9,225,485
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 (EE Table 16)	.12 to .55	.12 to .55	.12 to .55	.12 to .55	
Number of verification instrumentation calibration records per process per year (EE Table 16)	24	24	24	24	
Subtotal Recordkeeping Costs to Document Verification	$8,022,787	$976,906	$225,792	$0	$9,225,485

Instrumentation Calibration					
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	$16,597,420	$3,836,554	$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
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. 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. This rule may require facilities subject to subpart C 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 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 that use any food allergens are subject to this proposed requirement. To estimate the number of facilities, FDA survey question 68 asks, "Do you manufacture or process ingredients that are, or are derived from any of the following eight (8) main allergenic foods or food groups?" Approximately 60 percent of facilities with fewer than 20 employees answered no, they do not. Approximately 74 percent of facilities with 20 to 99 employees answered no, they do not. Approximately 68 percent of facilities with 100 to 499 employees answered no, they do not and approximately 79 percent of facilities with over 500 employees answered no, they do not. FDA survey questions 72.5, 72.6, 72.7 and 72.8 asked closely related questions about elements in their use of written allergen control plans. A "no" or "not applicable" when they use food allergens, suggests they lack the necessary written procedures. An average of the responses to these questions is approximately 96 percent of facilities with fewer than 20 employees answered no or not applicable, they do not. Approximately 72 percent of facilities with

20 to 99 employees answered no, they do not or not applicable. Approximately 68 percent of facilities with 100 to 499 employees answered no, they do not or not applicable, and approximately 42 percent of facilities with over 500 employees answered no, they do not or not applicable. We lack data about why these facilities answered "not applicable" to these questions, but if these facilities only manufacture foods with one allergen ingredient, then cross contact or undeclared ingredients are not risks. In that case, we estimate that between 25 to 75 percent of facilities do not require written procedures.

From the expert elicitation, we determined that it will take six to eight hours to develop facility-specific procedures. Facilities without procedures will require training in the proper use of the procedures. We estimate that it will take approximately one hour to train their 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 ask for comments.

Table 32- Estimated Costs for Food Allergen Controls by Facility Size

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities subject to Subpart C	17,781	9,251	3,920	449	31,401
% Facilities that do not use any of 8 major allergens –Q68	60%	74%	68%	79%	
% Facilities w/o written procedures for food allergen controls –Avg. of	96%	72%	68%	42%	

Q72.5,72.6,72.7 & 72.8					
If 25% to 75% do not require allergen control procedures	50%	50%	50%	50%	
Total Facilities w/o written procedures subject to subpart C	5,099	2,450	911	74	8,534
Cost per Facility to Develop Facility-specific written procedures - EE pg 23	$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 – 10% EE pg 23	$43	$64	$79	$98	
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 estimate that only facilities subject to subpart C that handle food allergens will need to implement food allergen label controls. We do not estimate that food wholesalers, fresh-cut facilities, or packers will need to check label application either because they do not handle foods with one 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.[25]

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 by using machine vision[26] or bar code

[25] 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.

[26] Machine vision (MV) is the analysis of images by a computer to extract data for controlling a process or activity. MV processes are targeted at recognizing the actual objects in an image and assigning properties to those objects to understand what they mean. The main categories into which MV applications fall are

scanners; 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.

We estimated the average number of product lines per facility using information from a report on recordkeeping benefits written for FDA. (Ref report) We calculate that every production line would involve one labeling component. Very small facilities and small facilities (facilities with less than 100 employees) are expected to operate 8 and 16 hours a day, respectively, and large and very large facilities are expected to operate on a 24 hour basis. All facilities are estimated 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 estimated the percentage of facilities that use allergens and do not review label application using information from the GMP survey. In the 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

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quality assurance, sorting, material handling, robot guidance, and calibration. (Paraphrased from http://en.wikipedia.org/wiki/Machine_vision)

used. We use this information in table _ to estimate which facilities handling allergenic 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 33. We estimate that a qualified individual will review label application records once a week for all product lines.

Table 33- Label Application Review

	<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	
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 GMP survey to estimate the percentage of facilities that handle food allergens and do not have written label controls. We estimate that it will take a qualified individual about 2 hours to write-up the label controls procedures.

Table 34- Cost to Write-up the Label Controls

	<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
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.

Table 35- Summary of Food Allergen Control Costs					
	<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 §110.135(d)(3) requires facilities to adopt sanitation controls where 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 §110.135(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.

Our section for the proposed revisions to subpart B, Good Manufacturing Practices §110.35 addresses the requirements and the impact of the revisions to sanitation operations. To estimate the impact of adopting sanitation controls to comply with proposed §110.135(d)(3), we determined the number of facilities without written procedures for food contact surfaces from question 41 of the FDA GMP survey. Question 41 asked, "Do you have written procedures for CLEANING your FOOD-CONTACT SURFACES?" About 29 percent of facilities with fewer than 20 employees responded no, they do not have written procedures. About 16 percent of facilities with 20 to 99 employees responded no. All facilities with 500 or more employees responded that they have written procedures for their food contact surfaces.

FDA's expert elicitation was used to help estimate the cost to develop new written procedures for food contact surfaces. From the expert elicitation final report (table 6) we have the experts' estimates summarized in a low and high cost range 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. A small facility will simply have fewer areas and pieces of equipment to clean (Ref. ERG

Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010.) 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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010.) We estimate that facilities will train five employees for two hours per piece of equipment or contact surface each year. We ask for comments about our estimate.

Table 36- Estimated Costs to Develop Written Procedures to Prevent the Contamination of Food Contact Surfaces by Facility Size

	<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 written procedures for Food Contact Surfaces –Q 41	29%	16%	11%	0%	
Total Facilities w/o written procedures for Food Contact Surfaces	9,279	1,846	455	0	11,580
Cost to develop equipment-specific procedures per contact surface - EE pg 23 2 to 6 hrs x $61/hr)	$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	$11,320,203	$4,729,772	$2,912,466	$0	$18,962,442
Cost to annually update equipment-specific procedures per contact surface (10% of initial development cost) - EE pg 23	$24	$42	$43	$42	
Total Cost to update written procedures for Food Contact Surfaces	$1,132,020	$472,977	$291,247	$0	$1,896,244

Annual training costs (5 workers @ 2 hrs per equipment per year) Training costs per facility/year	$1,606	$1,927	$4,817	$11,239	
Annual total training costs	$14,897,202	$3,556,744	$2,190,147	$0	$20,644,093
Annual training records costs (one record (12 minutes/record) per worker per equipment per year)	$177,044	$211,349	$130,143	$0	$518,536
Total one time costs	**$11,320,203**	**$4,729,772**	**$2,912,466**	**$0**	**$18,962,442**
One-time costs annualized (7%, 7 yrs)	**$2,100,500**	**$877,624**	**$540,417**	**$0**	**$3,518,542**
Total annual costs	**$16,206,266**	**$4,241,071**	**$2,611,537**	**$0**	**$23,058,874**
Annualized one-time cost + recurring costs	**$18,306,767**	**$5,118,695**	**$3,151,954**	**$0**	**$26,577,416**
Total Average Annual Costs per Facility	**$1,973**	**$2,773**	**$6,932**	**$0**	

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

The proposed rule 110.135(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 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. At a minimum all facilities should have a thorough drain cleaning program as part of their sanitation control procedures (Ref. ERG Inc. Memorandum Expert Opinions on

Current Food Manufacturing Practices, April 19, 2010.) Putting raw ingredients for a specific batch on a pallet prior to moving them to the processing area, or "staging", can help reduce the risk of cross-contact and cross-contamination during transit through the facility. Further, line clearance, such as removing all the ingredients from the production area and checking for cleanliness, can help reduce cross-contamination (Ref. Floyd, 2000.)

To estimate the cost to facilities to develop written procedures to prevent cross-contact and cross-contamination from insanitary objects, we looked at four FDA GMP survey questions to determine current practices. The first was question 50, which asked, "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. Question 52, 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. Question 54, 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, we looked at question 56, which 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. From our expert elicitation, we determined 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 judged 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. 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 add new equipment or replace old equipment. 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.

Table 37- Estimated Costs to Develop Written Procedures to Prevent Cross-Contact and Cross-Contamination in Raw Materials Storage Areas by Facility Size

	<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 written procedures for Raw Materials Storage Areas –Q 56	62%	43%	32%	22%	
Total Facilities w/o written procedures for Raw Materials Storage Areas	19,403	4,781	1,331	98	25,614
Cost per Facility to Develop Facility-specific written procedures for Raw Materials Storage Areas - EE pg 23	$427	$641	$793	$976	
Total Cost to Develop written procedures for Raw Materials Storage Areas	$8,285,188	$3,062,391	$1,055,634	$96,107	$12,499,319
Cost per Facility to Annually Update Facility-specific written procedures for	$43	$64	$79	$98	

Raw Materials Storage Areas – 10% EE pg 23					
Annual Cost to Update written procedures for Raw Materials Storage Areas	$828,519	$306,239	$105,563	$9,611	$1,249,932
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	$6,230,384	$1,535,259	$427,445	$31,619	$8,224,707
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	$19,403,250	$11,953,125	$6,655,950	$492,350	$38,504,675
Total One-time Costs	**$27,688,438**	**$15,015,516**	**$7,711,584**	**$588,457**	**$51,003,994**
One-time costs annualized (7%, 7 yrs)	**$5,137,679**	**$2,786,177**	**$1,430,909**	**$109,190**	**$9,463,955**
Total Recurring Costs	**$7,429,124**	**$1,932,727**	**$558,408**	**$43,108**	**$9,963,367**
Annualized one-time cost + recurring costs	**$12,566,803**	**$4,718,904**	**$1,989,317**	**$152,298**	**$19,427,323**
Total Annual Costs per Facility	**$648**	**$987**	**$1,494**	**$1,547**	

Table 38- Estimated Costs to Develop Written Procedures to Prevent Cross-Contact and Cross-Contamination in Production & In-Process Areas by Facility Size

	<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 written procedures for Production Areas –Q 52	52%	27%	27%	22%	
Total Facilities w/o written procedures for Production Areas	16,248	2,981	1,120	98	20,448

Cost per Facility to Develop Facility-specific written procedures for Production Areas - EE pg 23	$427	$641	$793	$976	
Total Cost to Develop written procedures for Production Areas	$6,938,003	$1,909,491	$888,073	$96,107	$9,831,673
Cost per Facility to Annually Update Facility-specific written procedures for Production Areas – 10% EE pg 23	$43	$64	$79	$98	
Annual Cost to Update written procedures for Production Areas	$693,800	$190,949	$88,807	$9,611	$983,167
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	$5,217,313	$957,279	$359,597	$31,619	$6,565,808
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	$16,248,250	$7,453,125	$5,599,450	$492,350	$29,793,175
Total one-time Costs	$23,186,253	$9,362,627	$6,487,534	$588,468	$39,624,882
One-time costs annualized (7%, 7 yrs)	$4,302,284	$1,737,266	$1,203,783	$109,192	$7,352,525
Total Recurring Costs	$6,221,137	$1,205,112	$469,772	$43,108	$7,939,129
Annualized one-time cost + recurring costs	$10,523,421	$2,942,378	$1,673,555	$152,300	$15,291,653
Total Annual Costs per Facility	$648	$987	$1,494	$1,547	

iii. Monitoring and Verification of Sanitation Control Procedures

Proposed §110.140 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

§110.150 (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 §110.140. As before, we expect 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 estimate. To estimate the sanitation control monitoring costs, we estimate 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 estimate that it will take seven hours for larger facilities and up to 14 hours for the largest facilities. We estimate 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 judged 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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010.) Verification will typically be performed by the visual inspection of the sanitation controls as a check on the sanitation workers and monitors and by careful records review. We estimate 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 39- Estimated Costs to Develop and Implement Monitoring and Verification Sanitation Controls by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of Domestic Manufacturing Facilities subject to subpart C	17,781	9,251	3,920	449	31,401
Percent without Monitoring and Verification Procedures for Sanitation Controls (Ref: Q17.8/ Q17.9)	48%	15%	4%	0%	
Total Facilities without Monitoring and Verification Sanitation Procedures	8,535	1,386	137	0	10,058
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	
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	$6,277,575	$1,019,283	$235,786	$0	$7,532,645

Sanitation Controls (annual cost)					
Percent facilities that do not maintain monitoring records (Q127b/Q137)	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 (EE)	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 Control Costs	$58,639,022	$15,657,396	$10,280,241	$0	$84,576,658
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 40 presents the summary of all costs associated with implementing sanitation controls.

Table 40- Summary of Sanitation Annual Costs

	<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**

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 §110.137 for products with hazards that are 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.

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. 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). 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. (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).

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 preformed, 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 determined the number of baseline 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 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 they are similar enough that we can reasonably infer the impact to facilities with and without recall control plans based on whether they are currently able to trace the distribution of their foods and their 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 ask for comments on our baseline estimate. 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. To estimate the training costs, a small facility will need to train at least five workers in their recall procedures. We estimate 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 estimates. Our estimate for the costs to develop the recall controls are shown in Table 41.

Table 41- Estimated Costs to Implement Recall Controls by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number Domestic Manufacturing and Wholesale Facilities subject to subpart C	17,781	9,251	3,920	449	31,401
% without Recall Procedures (Ref: Q17.8/ Q17.9)	53%	20%	5%	0%	
Total Facilities without Recall Procedures subject to subpart C	9,483	1,862	213	0	11,558
Hourly Wage Rate for Qualified Individuals	$61	$61	$61	$61	
Labor Hrs to Develop Initial Recall Procedures (Recordkeeping Cost Model Table 2-4)	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 Controls (Recordkeeping Cost Model Table 2-6)	2 to 4	2 to 4	2 to 4	2 to 4	
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 § 110.145 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 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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010.)

Our estimate for total new corrective action costs by facility size, are shown in Table _____. 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 question 17.4 asked, "Which of the following elements does your written food safety plan address?: Procedures for taking corrective action." Among facilities with both fewer than 20 employees and that have a food safety plan, 48 per cent responded no, that they lack written procedures for taking corrective action. Of the facilities with 500 or more employees 100 percent reported having a food safety plan and all of their food safety plans have corrective action procedures.

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 the number of facilities that will incur new corrective action costs is calculated, we estimate the actual cost of a complete corrective action by facility size. To properly execute a corrective action, a facility would: 1) segregate and hold 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.

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 US Census Bureau (Ref) and facility information from D&B. An in-depth explanation of this calculation is provided in Table X. 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. Inventory Management Review, September 15, 2005 http://www.inventorymanagementreview.org/2005/09/inventory_holdi.html) 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.

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. ERG Inc. Memorandum Expert Opinions on Current Food Manufacturing Practices, April 19, 2010.) We estimate 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 42.

Table 42- Expert Estimates of the Number of Incidents Needing Formal Corrective Action Per Year by Facility Size [a]

Facility size	**Number of Incidents**
<20 employees	2
20 to 99 employees	4
100 to 499 employees	8
≥500 employees	12

[a] The estimates are expected to vary ± 50%.

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.

Table 43- Corrective Action SOP Costs by Facility Size

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C	17,781	9,251	3,920	449	31,401

% Facilities w/o written procedures for Corrective Actions –Q 17.4/Q124.2	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C	8,602	1,933	628	0	11,163
Hours to Develop General Corrective Action Procedures (Recordkeeping Cost Model 2-4 Process Deviation SOPs)	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 (10% of initial development cost) - EE pg 23	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	
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

Table 44- Corrective Action Costs to Identify and Correct Failures by Facility Size

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C	17,781	9,251	3,920	449	31,401
% Facilities w/o written procedures for Corrective Actions –Q 17.4/Q124.2	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C	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

Table 45- Corrective Action Costs for New Parts and Equipment by Facility Size

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C	17,781	9,251	3,920	449	31,401
% Facilities w/o written procedures for Corrective Actions –Q 17.4/Q124.2	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C	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

Our calculation for the value of one day's production is presented in Table X. 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. 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. 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.

Table 46- Corrective Action Costs for Product Losses and Down Time of Production by Facility Size					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Domestic Manufacturing Facilities that are subject to subpart C	17,781	9,251	3,920	449	31,401
% Facilities w/o written procedures for Corrective Actions –Q 17.4/Q124.2	48%	21%	16%	0%	
Total Facilities w/o written procedures for Corrective Actions that are subject to subpart C	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	
Number of days of production per year	357	357	357	357	
Avg value of one day's production per facility	$4,162	$16,696	$143,496	$3,090,851	
Avg value of lost production per incident	$780	$3,130	$26,905	$579,535	
Percent facilities that must hold product after incidents (EE Q4 pg 21)	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 47 presents a summary of all corrective actions costs.

Table 47- Summary of Corrective Actions Costs					
	<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**
Total Costs Annualized (One-Time annualized + On-Going) (7%, 7 yrs)	**$21,067,636**	**$12,534,300**	**$18,733,455**	**$0**	**$52,335,331**
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**

7. Verification

Facilities subject to subpart C will be required 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, reviewing consumer complaints, checking the calibration of instruments (such as thermometers), raw materials testing or supplier audits, finished product testing, environmental testing, and reviewing records.

a. validation of food safety plan

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

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.

d. Verification activities-Implementation and Effectiveness

i. Review Consumer Complaints

The proposed rule requires that facility personnel review consumer, customer, or other complaints to determine whether the complaint relates to the effectiveness of the food safety plan. According to our expert elicitation, in large and very large operations consumer complaints are used as an important indicator of the quality systems. Legitimate complaints that involve 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. In contrast, the expert elicitation reports 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 EE)

The information provided by the expert elicitation on facilities' handling of consumer complaints is verified by our GMP survey results. Question 135c in the 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 (as required by the proposed rule) would not keep a record of the complaint and how it was addressed. Response to the GMP survey indicates that about 20 percent of facilities with less than 20 employees do not keep

records of consumer complaints while only about 1 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.

We estimate that facilities will 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.

We expect 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. Total annual consumer complaint costs are shown in table 48.

Table 48- Reviewing Consumer Complaints for Relation to Food Safety Plan Effectiveness

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**> 500 employees**	**Total**
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 need to 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.

ii. Calibration of Process Monitoring Instruments and Verification Instruments

Facilities subject to subpart C 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. See that section of the analysis for the specific costs.

iii. Performance of Finished Product Testing

The proposed rule requires that facilities subject to subpart C conduct finished product testing, when required by regulation or when appropriate based on risk (e.g., when the production process does not have a step that will eliminate or reduce hazards to an acceptable level or when handling of the product after such a step may reintroduce a hazard).

Our estimate of the number and types of facilities that will need to conduct finished product testing is an inexact estimate. Our facility data from D&B is often not precise enough to parse out specific facilities within an industry sector; some of which may need to conduct finished product testing on their products and others of which may not. For example, for the product category SIC 2096- Potato Chips & Similar Products, FDA would expect potato chip manufacturers who add certain types of seasonings (e.g. those not treated to significantly minimize pathogens) to the chips after the kill-step to then test the final product. Manufacturers who make potato chips that are cooked and not added to, or handled, after the cooking kill-step would not need to conduct finished product testing.

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 need not conduct as much or any finished product testing unless a problem arises from the environmental monitoring results.

The example of the potato chip industry that is given is just one of many potential scenarios that would illustrate how the necessity for finished product testing may change depending on the specific facility in question. In addition to the likely overestimate of the number of potato chip manufacturers that would need conduct finished product testing we also note that the industry sectors under SIC codes 2043- Cereal Breakfast Foods and 20990500- Sauce, Gravy, Dressing, and Dip Mixes, represent two other categories where it is likely that not all facilities within the categories will need to conduct finished product testing. To this end, in these industry segments in particular, the costs of finished testing are likely to be overestimated.

Thus, we reiterate that our finish product testing costs presented here represent at best an estimate of the number and types of facilities that will conduct finished product testing as a result of this proposed rule. The list of types of facilities in table __is not meant to be an all-inclusive list of manufacturing operations that need to conduct finished product testing nor is it meant to impose the requirement that all facilities within a listed industry must conduct finished product testing. We note that we did not include any facilities whose primary manufacturing operation was juice products, seafood, or any other processed food product not in the scope of this proposed rule-making.

Also important to note, in some cases, SIC codes by industry sector were not specific enough to tell what a facility actually produced. For example, the four-digit SIC code 2099- Food Preparations, NEC, is not useful in determining if facilities within that four digit code should be conducting finished product testing (or environmental monitoring). By looking at the more specific eight digit SIC codes for 2099: 20990000, 20990100, etc. we can get to more specific food industry classifications; SIC code 2099400 is Seasonings and Spices, for example, a category under SIC code 2099 for which we would expect facilities to conduct finished product testing.

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. We estimate that facilities will take 5 finished product samples 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 need to test for other hazards based on hazard analyses conducted at the facilities. The samples will take about 15 minutes to collect per sample and will be sent by express 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. (Ref. Silliker price lists). 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 will then need to 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. Table 49 shows the costs of sampling food products on a monthly basis (per production line) for both *Salmonella* spp. and *Listeria monocytogenes*.

Table 49- Annual Costs of Food ProductTesting 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
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

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 http://www.inventorymanagementreview.org/2005/09/inventory_holdi.html). 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.

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 50.

Table50- Finished Product Testing Costs

SIC Code	SIC Description	**<20 employees**	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
2037	Frozen Fruits & Vegetables	384	124	91	22	621
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
20999917	Tea blending	145	37	14	3	199
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 should conduct finished product testing		4,588	983	441	82	6,094
Number of facilities excluded by § 418(l)(1)(C)		739	5	1	0	745
Number of facilities remaining after § 418(l)(1)(C) exclusion		3,849	978	440	82	5,349
Additional facilities excluded under Very Small Business definition (§ 418(l)(1)(B))		2,407	11	1	0	2,420
Number of facilities remaining after both exclusions		1,442	967	439	82	2,929
Percent that already test (survey result)		68.5%	75.7%	83.2%	93.5%	
Number of facilities still needing testing		454	235	74	5	768
Cost per testing per production line		$341	$341	$276	$276	
Number of production lines		3	7	13	18	
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		**$5,566,640**	**$6,720,844**	**$3,169,447**	**$317,218**	**$15,774,149**
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	$145,730

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	$1,748,760
Total Cost of Holding Product Annually Awaiting Test Results	**$7,267,288**	**$7,303,645**	**$10,002,845**	**$8,346,850**	**$32,920,627**
Total Costs of Testing and Holding Finished Product Annually	**$12,833,928**	**$14,024,489**	**$13,172,292**	**$8,664,068**	**$48,694,776**
Annual Cost per Affected Facility	**$28,264**	**$59,690**	**$178,640**	**$1,625,529**	

[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. Hennes email)

iv. 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 those facilities where pathogens are reasonably likely to occur in the environment would be expected to conduct such testing.

Effective environmental pathogen controls will be product, process, and plant specific. 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. Generally, *Salmonella* is the organism of concern for certain dry food products,[27] where *Salmonella* would be

[27] 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)

introduced with a raw product or ingredient,[28] and *Listeria monocytogenes* (Lm) the organism of concern for wet processing environments.

Food manufacturing facilities will need to 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 which they are processed. Once it has been established that there is the potential for pathogens of concern to enter a food processing operation, 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 must 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. (Tompkin et al 1999)

For our base case costs of environmental testing, we estimate that:

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

To undertake environmental sampling on a routine basis, we estimate that facilities will need to buy the following supplies:

- sampling sponges or swabs
- neutralizing buffer broth

[28]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)

- sample collection bags
- sterile gloves
- cooling medium (e.g. gel packs) for samples
- coolers
- sterile tool to scrape debris out of cracks

We estimate that it will take 15 minutes to collect each sample; each sample will 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 estimate that it is likely that smaller facilities will 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. (Ref. Silliker price lists). 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 testing costs presented here we do not include the costs of confirmation of a presumptive positive sample. If a presumptive positive swab is found based on the environmental testing conducted, additional environmental testing and even product testing by the 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.

Samples will be collected using sponges, buffer broth, gloves, and collection bags ($2.33 for a sponge pre-moistened with buffer broth, sterile gloves and sample bag.)(Ref. Daigger). We also include the cost of disposable sterile sampling spatulas ($1.04 per

spatula) (ref. coleparmer.com). For shipping supplies, we estimate the costs of an insulated shipping carton and gel packs to keep samples at the appropriate refrigerated temperature until they can be analyzed by the laboratory ($18.86 per carton + $2.90 per gel pack+ $37.75 for overnight delivery). Table 51 shows the annual costs of environmental testing per facility for these pathogens based on 15 samples per month as an example.

Table 51- Annual Costs of Environmental Pathogen Testing for 15 Samples per Month

	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	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 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.

Table 52- Environmental Monitoring Testing Costs Annually and Per Shipment by Pathogen, Sample Size, and Pricing

Annual Testing Costs		
	Salmonella	Listeria
Low volume pricing		
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
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

As part of the GMP survey, facilities were asked about environmental testing for the specific pathogens, including Salmonella and Listeria. Using information on food product categories that FDA would expect to conduct environmental pathogen testing 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 pathogen testing for *Salmonella* spp. and Listeria, and thus, also identify those facilities that will need to implement such testing. Tables 53 and 54 show these

estimations. The tables on testing costs also include 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. [29]

As with finished product testing, it should be noted that the industries in the tables are a representation of the types and numbers of facilities that may need an environmental testing program. It is possible that some of the facilities in some of the industries will not need 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 will need an environmental monitoring program. The information on facilities listed is used to create the best cost estimate attainable given the limitations of the D&B data. As with finished product testing costs, we did not include any facilities that processed juice or seafood or any other manufactured product that was outside of the scope of this proposed rule-making.

Also as with finished product testing, in some cases, four digit SIC codes by industry sector were not specific enough to tell what a facility actually produced for estimating the burden of which facilities should be conducting environmental monitoring. For example, the four-digit SIC code 2099- Food Preparations, NEC, is not useful in determining if facilities within that four digit code should be conducting environmental monitoring. Similarly, the four digit product codes 2022- Cheese, 2023- Milk, Condensed & Evaporated, 2034- Dried Fruits, Vegetables & Soup Mixes, 2037- Frozen Fruits, Fruit Juices, Vegetables, are not specific enough; we want to include some

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

facilities under these product categories and not others when estimating the burden of environmental monitoring.

By looking at the more specific eight digit SIC codes for 2099, 2022, 2023, 2034, and 2037 we can get to more specific food industry classifications; SIC code 2099400 is for facilities that have specifically identified themselves as Seasonings and Spices producers, and SIC code 20230304 is for facilities that have identified themselves specifically as dried nonfat milk producers, for example. However, even under the eight digit SIC codes, some producers are still not listed by what they specifically produce. For example, facilities can list themselves as a primary manufacturer under SIC 20990000; which still just classifies them as manufacturing "Food Preparations, NEC".

In cases like these, we would expect that some facilities under SIC code 20990000 and under SIC code 20230100 (as examples) to be processing food products that would require environmental monitoring, like SIC 20990400- Seasonings and Spices would. 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 need to conduct finished product testing (i.e., 209904000-Seasonings and Spices, 20999912-Peanut Butter, etc). 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).

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 Part 110 subpart C, so we would have eliminated frozen juice manufacturers if any had shown up in the D&B facility data.[30] Even with no frozen juice manufacturing facilities accounted for under SIC code 2037, the number of facilities that need to conduct environmental testing is still likely overestimated because most frozen vegetables (e.g. Brussels sprouts) are cooked before being consumed. A kill-step at the consumer level, such as cooking, would eliminate the necessity of the frozen vegetable manufacturing facility to conduct environmental monitoring.

In the case of SIC code 2022- Cheese, even the eight digit SIC code breakdown did not get specific enough for 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 GMP survey to estimate the percentage of the facilities under 2022 that would be producing these two cheese types.

Table 53- Facilities Needing Monthly Testing for Salmonella

	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

[30] We classify all facilities using D&B data by what they list as their primary manufacturing function. Thus, 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. However, in calculating the facilities this way we may avoid double-counting some costs but we likely under estimate some costs as well.

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 should 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 still need testing		806	521	155	21	1,326
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 testing costs for Salmonella		**$2,450,683**	**$2,760,831**	**$920,059**	**$127,532**	**$6,259,106**
Annual cost per affected Facility		**$3,041**	**$5,304**	**$5,946**	**$5,946**	

[a] Partial category used.

Table 54- Facilities Needing Monthly Environmental Testing for Listeria						
	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 should 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 still need testing		1,859	457	90	15	2,421
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 testing costs		**$5,375,116**	**$2,287,645**	**$501,736**	**$83,621**	**$8,248,119**
Annual cost per affected facility		**$2,891**	**$5,004**	**$5,586**	**$5,586**	

[a] Partial category used.

Table 55- Total Annual Costs of Environmental Testing

Pathogen	**<20 employees**	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Salmonella	$2,450,683	$2,760,831	$920,059	$127,532	$6,259,106
Listeria	$5,375,116	$2,287,645	$501,736	$83,621	$8,248,119
Total Annual Costs of Environmental Testing	**$7,825,800**	**$5,048,477**	**$1,421,795**	**$211,153**	**$14,507,224**

v. Review of Records

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, environmental monitoring, and supplier verification activities within a reasonable time after the records are made; again the review should be conducted by a qualified individual. Facilities may or may not have records of all the types listed. Some facilities will not have to keep all the aforementioned records if they do not handle raw materials and ingredients or do not have finished product testing, for example. We address review of complaints records, finished product testing records, environmental monitoring records, and supplier verification activities records here. 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.

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 will 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 will also serve as quality control and that person will 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 will 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 56, from our expert elicitation, gives some examples of the estimated number of records that might be kept by facility size and industry sector.

Table 56- 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
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 subject to subpart C that need to begin reviewing records of complaints, finished product testing, environmental monitoring, and supplier verification activities as part of their verification process, we look to question 135 of the GMP survey. Question 135 of the GMP 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 estimate they are not reviewing complaints, finished product testing, environmental monitoring, and supplier verification activities records as part of their verification activities.

Table 57 shows the annual costs of reviewing complaints, finished product testing, environmental monitoring, and supplier verification activities records for facilities that would be subject to subpart C that currently do not do so. We estimate that the review of these records will be conducted by a production manager making an hourly wage of $61.44 including overhead.

Table 57- Review of Records

	<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 needing to begin reviewing records	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.

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 testing scheme is scientifically valid; it must include the procedures for sampling and the sampling frequency. The written procedures must also identify or include the analytical methods used to test finished product. We estimate that

those facilities that need to begin conducting finished product testing as a result of this proposed rule-making are the same facilities that will also need to create written procedures on conducting such testing.

Table 58- Cost to Write-up Finished Product Testing Procedures					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Number of facilities	454	235	74	5	768
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	$574,970	$297,508	$93,368	$6,749	$972,595
Total Costs Annualized	$106,687	$55,204	$17,325	$1,252	$180,468
Annualized Cost per Affected Facility	$235	$235	$235	$235	

ii. environmental monitoring

The proposed rule would require that any facility needing an environmental pathogen monitoring program have written procedures regarding the program. The written procedures must show that the environmental monitoring scheme is scientifically valid; identify the locations from which samples will 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 must also identify or include the analytical methods used to test the environmental samples. We estimate that those facilities that need to begin conducting environmental monitoring as a result of this proposed rule-making are the same facilities that will also need to create written procedures on conducting such monitoring.

Table 59- Cost to Write-up Environmental Monitoring Procedures					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Number of facilities	2,665	978	245	36	3,924
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	$3,374,603	$1,237,959	$309,662	$46,113	$4,968,337
Total Costs Annualized	$626,168	$229,707	$57,459	$8,556	$921,891
Annualized Cost per Affected Facility	$235	$235	$235	$235	

iii. frequency of calibration for instruments

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

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 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.

g. Records for verification activities

Records on verification activities are addressed in the appropriate places in the analysis where the discussion of the subject appears (e.g. verification of corrective actions appears in the corrective action section of the analysis). In the case of finished product testing, environmental monitoring, and supplier verification activities, the testing results or the audit results constitute the records.

h. Summary of Verification Costs

The summary of the verification costs include the costs to review consumer complaints, test finished product, monitor the environment for pathogens, and the costs to review the associated records. Only facilities subject to subpart C will be required to conduct these verification activities.

Table 60- Summary of Verification Costs Associated with Complaints, Finished Product Testing, Environmental Monitoring, Review of Records

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Annual Complaint Review Cost	$10,798,275	$722,865	$0	$0	$11,521,140
Total Costs of Testing and Holding Finished Product Annually	$12,833,928	$14,024,489	$13,172,292	$8,664,068	$48,694,776
Written procedures for finished product testing (annualized)	$106,687	$55,204	$17,325	$1,252	$180,468
Total Annual Costs of Environmental Monitoring	$7,825,800	$5,048,477	$1,421,795	$211,153	$14,507,224
Written procedures for environmental monitoring (annualized)	$626,168	$229,707	$57,459	$8,556	$921,891
Annual Cost of Reviewing Records	$1,309,948	$694,800	$9,985	$0	$2,014,732
Total Costs of Verification Activities	**$33,500,806**	**$20,775,541**	**$14,678,856**	**$8,885,029**	**$77,840,232**

8. Supplier Approval and Verification Program

This rule requires some facilities to develop a supplier approval and verification program. Except when the manufacturing (receiving) facility has preventive controls adequate to significantly minimize or prevent a hazard, a receiving facility must establish and implement a supplier approval and verification program for ingredients for which the receiving facility has identified hazards that are reasonably likely to occur. The supplier approval and verification program would require a written list of approved suppliers, for each ingredient a determination of which food safety regulations the supplier is subject to with respect to the ingredient, and supplier verification activities.

The need for a particular facility to develop new, or additional, supplier approval and verification mechanisms will depend on what a facility currently requires of its

suppliers, the hazards identified by a the hazard analysis for the ingredients (if applicable and available) and the manufacturing process of the receiving facility. Only facilities subject to subpart C will need to develop and implement a supplier approval and verification program if they do not already have one in place.

The owner, operator, or agent in charge of a receiving facility is not required to establish and implement a supplier approval and verification program for ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur. We cannot say which individual facilities or industries will have such process controls in place that would reduce or eliminate all possible hazards. The likelihood of all hazards being reduced or eliminated by the receiving facility will be depend greatly on the products produced at each facility and how those products are produced. For this analysis we do not eliminate any specific industry's facilities as not having to have a supplier approval and verification program in place. We request comment on the likelihood of specific facilities or industries not needing a supplier approval and verification program because all hazards are reduced are eliminated at the manufacturing (receiving) facilities.

i. Written List of Approved Suppliers

Creating a written list of approved suppliers is not expected to be a time consuming task. There are no requirements specified in the proposed rule as to how the list is to be constructed (e.g. no requirement that the supplier be vetted or evaluated before being added to the list), so it likely that if manufacturers are satisfied with their current raw material and ingredient suppliers, they can compile the approved supplier list

rather quickly. We estimate that it will 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 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 EE) Therefore we expect any costs to update the written approval supplier list to be minimal and do not attempt to include them here. We request comment on this assertion.

Table _ shows the costs of maintaining a list of approved suppliers for facilities that had not previously done so and who use potentially hazardous raw materials or ingredients in their products. In this table we do not estimate the costs of developing an approved supplier list for those facilities that do not currently use potentially hazardous raw materials but may do so in the future. We request comment on the number of facilities each year that may begin to use potentially hazardous raw materials and ingredients in their products and therefore would need to develop approved supplier lists.

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

Table 61- Supplier Approval and Verification Program - Written Approved Supplier Lists					
	<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
Percent Of Facilities That Use Potentially Hazardous Raw Materials or Ingredients and Do Not Have Written Approved Supplier Lists	64.43%	44.63%	31.78%	6.49%	
Number Of Facilities That Need New 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**
Annualized Costs per Affected Facility	$11	$11	$23	$23	

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

ii. Determination, by Ingredient, of which Regulations the Supplier is Subject

The receiving facilities must create a written determination of which designated food safety regulation or regulations, if any, their ingredient suppliers are subject to.

We expect that larger acilities that produce a diverse range of products may have more ingredients in those products and might need more time to write determinations than do facilities that make only one or two products. Therefore, we estimate that it would take facilities with less than 100 employees one hour to write their determinations and facilities with more than 100 employees two hours to write their determinations. We use the wage rage of a production manager as the person who would write-up this information. This determination may need to be updated if the facility begins to use a new ingredient. However, we do not have information on how often ingredients in products are changed or new products are added to the facility's output. We request comment on the initial burden estimate and the likelihood of having to update this determination based on new ingredients or products.

Table 62- Supplier Approval and Verification Program - Written Determination for Ingredients					
	<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**	

iii. Verification Activities for Suppliers

All manufacturing facilities that are subject to subpart C must have verification activities for their ingredient suppliers. Verification activities are required unless all hazards that are reasonably likely to occur in the ingredients are controlled for or eliminated by the receiving facility or the ingredient does not contain a hazard that is reasonably likely to occur. The type of verification activity required by this proposed rule depends on the type of supplier.

It is up to the owner, operator, or agent in charge of the facilities receiving the raw materials and ingredients to make sure that the appropriate supplier verification activities are conducted. In cases where the supplying facilities are subject to a designated food safety regulation and are controlling the hazard(s) at their facilities (e.g. through a preventive control such as a heating kill-step), the owner, operator, or agent in charge of the receiving facilities must conduct or obtain documentation of an onsite audit of the supplier before using the raw material or ingredient.

The owner, operator, or agent in charge of receiving facilities that use suppliers that are not subject to designated food safety regulations or whose suppliers are not controlling hazards reasonably likely to occur at the suppliers' facilities, have the option

of: 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 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.

The owner, operator or agent in charge of the receiving facilities will decide which supplier verification activity or activities to require of the supplying facilities based on the hazards that are reasonably likely to occur in the raw materials or ingredients. We estimate whether the facility receiving the ingredient from the supplier would request an audit of a facility, testing of the ingredient, or both, based on likely industry practices while also adhering to what is required or optional as outlined in the proposed rule. For example, a flour milling facility does not have a preventive control in place, therefore according to the proposed rule the facility may be audited, the ingredient tested, or both. According to FDA subject matter experts, a flouring milling facility is likely to be audited by their customers to make sure any potential pathogen hazards (*Salmonella* spp.) are under control; the flour itself may also be tested when necessary to make sure it is free from mycotoxins. The flour milling facility would not need to undergo supplier verification activities if its products are only sold to receiving facilities that have a preventive control in their process (e.g. cooking); we cannot know if all buyers of flour from flour milling facilities have a preventive control in place. Therefore we estimate supplier verification activities for all flouring milling facilities.

Facilities that supply cookies and crackers as an ingredient, as another example, would only be required to be audited by their customers (the receiving facilities) because all hazards would be controlled for by the supplier (heating kill step). The proposed rule requires that this type of supplying facility be audited annually and this would be consistent with current industry practices. Again, we cannot say whether the cookies or crackers are only sold to receiving facilities with a preventive control in their own production process. In the case of cookies and crackers, since they already could constitute a final RTE product, it is likely that they may be used by receiving facilities without a preventive control. For example, cookies added to ice cream would be added to the ice cream after the ice cream had been pasteurized; there would be no further kill step. Crackers could be bought and assembled by the receiving facility into cheese and cracker sandwiches, a RTE food with no further kill step in that operation.

In estimating auditing and testing costs according to accepted industry practices regarding different ingredients, we note that a supplying facility's status as "qualified" would not affect a receiving facility's desire that a particular facility undergo an audit or testing to ensure the supplier is adequately controlling hazards. Thus, regardless of a supplying facility's status as a qualified facility, if their customers (the receiving manufacturing facilities) require that the supplier undergo a facility audit because of the type of ingredient they are supplying, we estimate that the supplier will submit to an audit.

We have 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 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 ingredient suppliers, in consultation with our subject matter experts, we identified which facilities would not have any hazards reasonably likely to occur in their ingredients or food products; these facilities would not need auditing or testing. Thus, we were also able to eliminate these facilities from our potential supplier count.

We may still be overestimating the number of ingredient suppliers however. For example, some facilities that are classified as butter manufacturers (SIC code 2021) may be suppliers of butter as an ingredient or they may 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.

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 need be audited; supplying facilities that would likely be audited even without having a preventive control at their facility; and supplying facilities that would require testing of their ingredients, alone or in combination with, an audit.

iv. Audits of Suppliers

We estimate which potential supplying facilities in the D&B data will undergo one audit annually to satisfy the requirement that sellers of food ingredients go through a verification process. The estimate of an audit on an annual basis will be an overestimate

of auditing frequency in cases where the hazard reasonably likely to occur is not likely to cause serious adverse health consequences or death to humans or animals. We have not identified any supplying facilities that would need auditing for a hazard of a less than serious nature; such hazards, e.g. mycotoxins, would involve testing of the ingredient rather than an audit of the facility.

We estimate 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) This effort by industry is an attempt to reduce the number of audits that a supplying facility will need to be subjected to on an annual basis. We request comment on our estimation of one audit per supplying facility annually for this analysis.

An audit of a facility will usually take a day or more depending on the type of audit that is done; some audits can last four days or more. (Ref. BRC) The costs of an audit will 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 email Stier) British Retail Consortium (BRC)-sponsored audits take on average about 2.5 days and cost about $3750 including reporting time and auditor fees, but not including travel expenses. (Ref. email Guenther/ Kukoly) Audits conducted under the GMA-SAFE[31] auditing program can be 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-

[31]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.

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. Coles email) 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) (Ref website). In addition to the auditing fee,[32] the facility bidding on an audit will also be responsible for the auditor's travel and incidental expenses. (Ref. GMA website and Coles) 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. Coles) Making use of this auditing cost information, we estimate that audits of facilities with less than 20 employees will cost $1500-$3750 (average $2625); audits of a small facility with 20 to 99 employees will cost about $3750; audits of facilities with 100 to 499 employees will cost about $3750-$5000 (average $4375); and audits of facilities with more than 500 employees will cost $5000. We estimate the travel expenses for the auditor to be $250-$1000 (average $625).

From the GMP survey we use information from Q117 which 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 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 will need to be re-audited. We do

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

not have information on the number of facilities that would need to undertake corrective actions and then be re-audited. Supplying facilities that are subject to subpart C will likely have done all that is required to pass an audit in the course of complying with this rule. 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.

Table 63- Annual Costs of Audits to Ingredient Suppliers

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, Juices & 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
2052	Cookies & Crackers	2,118	253	131	32	2,534
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2098	Macaroni, Spaghetti, & Noodles	652	1	0	0	653
2099	Food Preparations, NEC[a]	3694	667	247	7	4,616
Total		11,478	2,547	1,197	116	15,152
Percent of facilities that do not have audits conducted		43.48%	20.69%	13.60%	0.00%	
Number of facilities that will need to begin having audits conducted		4,991	527	163	0	5,681
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		$16,219,724	$2,305,888	$813,920	$0	$19,339,531
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.

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 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. We have 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 section on audit costs. We estimate the costs of testing raw materials and ingredients, when necessary, here as the option for verification activities other than (or in addition to) audits. We base our estimates of the types of raw material and ingredients that would need testing instead of, or in addition to, auditing on the judgments of our industry experts.

We estimate that those ingredients that need testing will 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). We estimate that when an ingredient is tested it will need to 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.

Using information from the 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 analysis. 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 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. Inventory Management Review, September 15, 2005 http://www.inventorymanagementreview.org/2005/09/inventory_holdi.html). The average number of days the ingredients are held pending test results is based on information from our expert elicitation.

Table 64- Annual Costs of Testing of Ingredients

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, Juices & 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 w/at least 1 PHRM that do not conduct periodic testing		6.80%	17.37%	16.92%	3.33%	
Number of facilities that will need to begin periodic testing		481	298	128	3	910
Cost of testing annually (4 times per year)		$1,362	$1,362	$1,362	$1,362	
Total Costs of New Testing		**$655,477**	**$406,398**	**$174,198**	**$3,888**	**$1,239,960**

Costs per day of holding ingredients pending test results	$333	$405	$480	$5,546	
Number of days held	4	4	4	4	
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	$108,239
Number of facilities that will need to begin holding	481	298	128	3	910
Total Costs of Holding	**$2,567,453**	**$1,932,368**	**$983,184**	**$253,291**	**$5,736,297**
Total Annual Costs of Periodic Testing, Holding, Records	**$3,222,930**	**$2,338,766**	**$1,157,382**	**$257,179**	**$6,976,257**
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.

vi. Summary of Supplier Controls Costs

The total costs of the supplier approval and verification program would be the sum of the costs of the written lists and determinations and the verification activities.

Table 65- Supplier Controls Costs Summary

	<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	$16,219,724	$2,305,888	$813,920	$0	$19,339,531
Annual Costs of Testing Suppliers	$3,222,930	$2,338,766	$1,157,382	$257,179	$6,976,257
Summation of Supplier Control Costs	$19,780,272	$4,797,745	$2,089,248	$268,076	$26,935,341

9. 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 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 66 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.

Table 66- Reading and Learning about Rule Requirements

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**> 500 employees**	**Total**
Number of Facilities	80,475	12,283	4,411	477	97,646
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**	**$327,835,083**
One time costs Annualized over 7 years	**$47,269,991**	**$7,214,878**	**$5,726,708**	**$619,279**	**$60,830,855**

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),
- 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 millions of otherwise avoidable foodborne illnesses.

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 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.

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.

Current or enhanced State and local regulations could bring about a reduction of potential harm from contaminated foods. This alternative has the advantage that State and local regulations can show more discretion when responding to local manufacturing conditions or consumer health practices than the Federal government. Because most of the industry engages in interstate commerce, however, Federal regulations are appropriate. Also, Federal regulations would apply uniformly across the country, whereas State and local regulations might impose an unequal burden on establishments and unequal protection against contamination to consumers.

If consumers or other plaintiffs who experience harm caused by deficient manufacturing practices could successfully sue manufacturers, the incentives to reduce

the risks from contaminated products would increase. Litigation or the threat of litigation could have the beneficial effect of helping to bring about the goals of the proposed rule. The recovery of damages requires the injured person to prove that the injuries were caused by the establishment's product, which is often costly and difficult. Because legal proceedings are always retrospective, the social cost under the legal system is the actual cost of the injury to the plaintive, including lost time at work, pain and suffering and the cost of the legal proceedings. The link between manufacturing practices, contamination and personal harm is sometimes difficult and costly to establish. The millions of cases of food borne illness each year show that the threat of litigation, which is already in place, has not created sufficient incentive for establishments to implement the practices to ensure that foods are not potentially injurious.

Option (2) A Definition for Very Small Businesses based on Annual Earnings of $100,000

Under this option, we would define very small businesses for purposes of part 110, as a business that has less than $100,000.00 in total annual sales of food, adjusted for inflation. The impact of this option would be to require 13,431 more manufacturing facilities to perform the activities required in proposed subpart C than would be exempt under the proposed rule. We estimate the total annual cost for this option to be approximately $832 million, which is about $175 million per year more than the proposed rule; almost 100 percent of which would be incurred by the very smallest facilities (those with fewer than 20 employees). Table 67 summarizes our estimate of the total number of facilities that would be required to comply with proposed subpart C and

our estimate of the total costs. We discuss additional regulatory options for small businesses in our Regulatory Flexibility Analysis.

Table 67- Small Business Costs Summary for Facilities with Annual Revenues with less than $100,000					
	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Number of Domestic Manufacturing Facilities	54,205	9,389	3,948	453	67,996
Total Domestic Manufacturing Facilities with Annual Revenues less than $100,000 subject to subpart C	31,132	9,314	3,933	452	44,832
Total Annualized Costs	$594,301,523	$118,346,714	$102,044,004	$17,461,576	$832,153,817

Option (3) A Definition for Very Small Businesses based on Annual Earnings of $500,000

Under this option, we would define very small businesses for purposes of part 110, as a business that has less than $500,000.00 in total annual sales of food, adjusted for inflation. The impact of this option would be to require 6,848 fewer manufacturing facilities to perform the activities required in proposed subpart C than would otherwise be exempt under the proposed rule. We estimate the total annual cost for this option to be approximately $565 million, which is about $91 million less than the proposed rule. Table 68 summarizes our estimate of the number of facilities that would be required to comply with proposed subpart C and our estimate of the total annual costs. The primary disadvantage of exempting the additional facilities than what is proposed is that it could substantially reduce the potential benefits of the proposed rule. We discuss additional

regulatory options for small businesses in our Regulatory Flexibility Analysis.

Table 68- Small Business Costs Summary for Facilities with Annual Revenues with less than $500,000					
	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Number of Domestic Manufacturing Facilities	54,205	9,389	3,948	453	67,996
Total Domestic Manufacturing Facilities with Annual Revenues less than $500,000 subject to subpart C	11,043	9,148	3,915	447	24,553
Total Annualized Costs	$328,810,460	$117,211,273	$101,878,728	$17,453,836	$565,354,297

Option (4) The Proposed Rule

The costs and benefits of the proposed rule are discussed at length in preceding sections of this analysis.

H. Uncertainty Analysis

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

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.

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 69 shows the results of these calculations.

Table 69- Costs of the Proposed Rule using Different Sources for Facility Data		
Data Source	Total Facilities (domestic)	Annualized Costs (with 7% discount rate and 7 year time preference)
D&B	97,646	$656,663,107
Average Cost per Facility		$6,725
CBP	57,775	$388,533,181
FFRM	166,178	$1,117,536,425

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 industry segments where the employee maximum is higher (750 or 1,000 employees). Table 70- shows the SBA size classifications for many of the various sectors of food manufacturing. (Ref. SBA table from website)

Table70- 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

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 110 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. 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) 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 71 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 (97,646,477).

Table 71- 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

b. Costs to small entities.

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.

Using data from D&B, Table 72 summarizes the annual revenues for facilities by revenue 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 72- 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%

Table 73 shows our estimate for the average cost for affected small businesses: 1) with fewer then 20 employees, 2) with 20 to 99 employees and for establishments with

100 to 499 employees. Affected businesses are businesses that do not currently perform the 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.

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 very small and small businesses will decrease.

Table 73- 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	$419,366,212	$117,924,962	$101,915,009	$17,456,924	$656,663,107
Avg. no. of affected manufacturing facilities per provision	Between 15,000 and 20,000	Between 1,200 and 9,200	Between 1,100 and 3,900	Between 0 and 400	
Avg. annualized costs per manufacturing facility	**$25,000**	**$23,000**	**$41,000**	**$87,000**	

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, 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).

1. Exemptions for Small Entities

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 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.

VII. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA has determined that this proposed rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on:

• Future costs;

• Particular regions, communities, or industrial sectors;

• National productivity;

• Economic growth;

• Full employment;

• Job creation; and

• Exports.

The issues listed above are covered in detail in the cost benefit analysis of the preceding sections, with the exception of the trade effects of this proposed rule, which we will discuss here.

To assess the proposed rule's impact on foreign trade, this section considers whether the proposed rule: 1) would be in harmony with widely adopted international food safety regulations based on the Codex Alimentarius Commission (Codex) General Principles of Food Hygiene http://www.fao.org/docrep/005/Y1579E/y1579e02.htm#bm2.11 and the Codex principles of the Hazard Analysis and Critical Control Point (HACCP) system 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. If the proposed rule is consistent with Codex General Principles of Food Hygiene and HACCP, WTO obligations, then the

proposed rule does not create a technical barrier to trade, and if most manufacturers are generally already performing the food safety practices that are being proposed, then the proposed rule should facilitate U.S. participation in global markets and not adversely affect the international trade of FDA-regulated food products (Ref http://www.fda.gov/Food/InternationalActivities/ucm103013.htm)

From our analysis, we believe that at least some foreign food manufacturers from all regions of the world, 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 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. 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 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 in the U.S. and internationally and consequently are not anti-competitive.

Current international trade in FDA-regulated foods is extensive. We estimate there are currently 97,646 domestic and 109,190 foreign facilities that will be covered by

the rule as shown in table 14 of the regulatory impact analysis, any of which could engage in the international commerce of FDA-regulated foods. 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. D&B 2011). 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. What Share of U.S. Consumed Food is Imported? Amber Waves USDA Feb 2008 http:www.ers.usda.gov/AmberWaves/Febuary08/DataFeature/) For most of the last 10 years, the international trade in food products has grown by at least 10 per cent per year and in some years by over 20 per cent as measured in their dollar value (Ref. U.S. Census Bureau, Statistical Abstract of the United States: 2011 Table 1311. http://www.census.gov/compendia/statab/2011/tables/11s1311.pdf) 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 (Ref. U.S. Census Bureau, Statistical Abstract of the United States: 2011 Table 1311. http://www.census.gov/compendia/statab/2011/tables/11s1311.pdf)

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.

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, including Canada, our largest trading partner for FDA-regulated food products, the European Union countries, 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 http://www.fao.org/docrep/W8088E/w8088e04.htm#module%202%20%20%20the%20codex%20general%20principles%20of%20food%20hygiene ,http://www.who.int/foodsafety/fs_management/haccp/en/) 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.

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) that trade between WTO members be conducted without discrimination, which precludes granting special favors to some countries or regions but not to other countries or regions, and 3) that domestic regulations, standards, testing and certification procedures not create unnecessary regulatory impediments. Domestic regulations, standards, testing and certification procedures are not to be developed arbitrarily, without a scientific basis or for the purpose of creating a trade barrier (Ref 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 the proposed rule is consistent with Codex Principles and WTO obligations, the proposed rule might create an adverse impact on trade if a significant number of foreign manufacturers are not currently performing in accordance with the proposed requirements and their cost of compliance for would be high. If this were the case, U.S. consumers could face a sharply reduced supply or even be deprived of certain imported food products.

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.

▪ **Group 3** – India, Indonesia, Malaysia, Vietnam, Thailand, Taiwan, Singapore, Korea, Hong Kong, Philippines, Fiji.

▪ **Group 4** – Tunisia, Morocco, Iran, Turkey, Other North African countries.

▪ **Group 5** – Cote d'Ivorie, Other Sub-Saharan countries such as Ghana, Nigeria, Zimbabwe, Rwanda, Swaziland.

▪ **Group 6** – Mexico, Costa Rica, Guatemala, Honduras, El Salvador, Nicaragua, Dominican Republic.

▪ **Group 7** – China.

Ten experts evaluated the country groups based on five categories of manufacturing practices: food safety and sanitation training, sanitation & personal hygiene, allergen controls, process controls, and recordkeeping. Within each category, a detailed list of practices was presented to the experts. Their answers depended on the self-rated familiarity of the expert on a group of countries; the experts participated accordingly in the assessments of any or all categories of manufacturing practices of a country group. For each practice, ERG weighed both the experts' lower and upper bound judgments about the prevalence of the food safety practice as measured as a percentage of

food facilities, while accounting for the experts' self-rating of familiarity with the practices in the country groups. None of the experts was able to estimate the manufacturing practices for the regional group 5 which includes the Sub-Saharan countries of Africa.

The results of the elicitation suggest that the use of various food safety manufacturing practices is highest for manufacturers in Group 1 and the lowest for Group 4. Among Group 1, the group includes European and several non-European industrial countries including Canada, Australia, and Japan that have high rates for using the food safety manufacturing practices that are of interest for assessing the proposed rule. This suggests that in general, the countries of the developed industrial world have good implementation of nearly all the proposed practices. Particular strengths of Group 1 include food safety and sanitation training for all types of employees, pest control programs, written procedures related to cleaning and sanitizing food-contact surfaces and production areas; and for process control practices and calibration of operating equipment and measuring devices, HACCP systems, in-process and finished product testing, and maintaining records (raw material inspection; personnel; QA/QC and laboratory operations records; and warehousing and distribution).

The experts estimate for Group 4, the group that includes the countries of North Africa, Turkey and Iran appear to be some of the lowest for all types of food safety practices. In particular, the countries in Group 4 appear to more likely lack pest control programs; lack validation for written cleaning and sanitizing procedures for food contact-surfaces; lack allergen control plans; lack supplier control programs; and lack written procedures for verification and reconciliation of product labels.

The consequence of the relatively lower use of the proposed food safety practices

in the region of North Africa and presumably other developing countries is that it is likely on average to increase their food manufacturing costs in their export sector to the U.S. However, it is also possible and even likely that food manufacturers that currently export to the US are higher than average for their region and may already adhere to Codex Principles or our proposed practices to ensure their export market is viable, while those manufacturers that do not export are less likely to currently follow the proposed practices. Without more data about current food safety practices among exporters to the U.S., we cannot make a more definite determination about the impact of the proposed rule. Because the volume of exports from the developing world is relatively small, the impact of the proposed rule should not significantly affect the total volume of trade to the U.S.

International Trade References

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; meat products from carcasses; 311613, animal fats, oils and by-products; and 311615, poultry, prepared or preserved.

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 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 food facilities. A food facility is one that is engaged in manufacturing, processing, packing, or holding 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.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

Recordkeeping Burden

We estimate that the recordkeeping burden for training (110.10(c)(3), 110.120(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 the 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 74 shows that the total hour burden is 1,629,243 (32,584,851 records x 0.05 hours per record = 1,629,243).

We estimate that 25,614 food manufacturers and wholesalers subject to subpart C will need to create a food safety plan (110.175(a)(1)) which is a compilation of many written food safety procedures. We total the 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 (110.175(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 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.

For the burden for corrective action records (110.175(a)(3) we estimate that twice per year 18,291 facilities subject to subpart C 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.

The burden for keeping verification records (110.175(a)(4)) follows the same pattern as that for monitoring records. We estimate that there are 16,668 facilities subject to subpart C that will need to keep additional records of 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 (110.175(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.

We estimate that 47,484 food manufacturers and wholesalers subject to subpart C will need to document the training of their qualified individual (110.175(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.

Under 110.206(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.

Table 74 shows the estimated annual recordkeeping burden associated with this proposed rule.

Table 74-Estimated Annual Recordkeeping Burden

21 CFR Part 1, Subpart 110	No. Of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours	Total Operating and Maintenance Costs
110.10 (c)(3), 110.120(a) training records	43,780	744	32,584,851	0.05	1,629,243	$34,214,094
110.175(a)(1) food safety plan	25,614	1	25,614	110	2,817,540	$122,546,137
110.175(a)(2) monitoring records	16668	730	12,167,640	0.05	2,295,191	$ 48,199,001
110.175(a)(3) corrective actions records	18,291	2	36,582	1	36,582	$912,623

110.175(a)(4) verification records	16668	244	4066992	0.5	2033496	$124,043,256
110.175(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 75_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).

Table 75- Estimated Annual Reporting Burden[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
110.201(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.

Third Party Disclosure Burden

Under 110.201(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.

Under 110.152(b) and (c) some supplying manufacturing facilities will need to make the results of an audit or ingredient testing 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.