DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Part 117

FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

Docket No. FDA-2011-N-0920

Preliminary Regulatory Impact Analysis

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A. Preliminary Regulatory Impact Analysis

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

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because facilities with less than 20 employees (both qualified and non-qualified facilities) will bear a large portion of the costs, the agency tentatively concludes that the proposed rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2013) 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. Summary of Proposed Changes

Our proposed Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation (Preventive Controls Rule) as analyzed in our original Proposed Regulatory Impact Analysis (PRIA Ref. 1) would include requirements for facilities subject to subpart C to maintain a food safety plan, perform a hazard analysis, and to institute preventive controls for the mitigation of those hazards. Our proposed revisions to the regulation include potential additional requirements for facilities subject to subpart C to institute risk-based environmental monitoring, product testing and a supplier program as appropriate to the food, the facility and the nature of the preventive controls, as well as a requirement to institute controls to help prevent hazards associated with economically motivated adulteration (EMA). If these provisions were adopted, facilities would be required to monitor their controls, verify that they were effective, take any appropriate corrective actions, and maintain records that document these actions. In this document we describe our estimate of the costs for each of our potential additional requirements.

Using the same data, and similar assumptions used to do the proposed rule analysis, we estimate that with a very small business (VSB) definition of $1,000,000, the total costs to domestic facilities in the first year, including both set up costs to implement the rule and the initial recurring monitoring costs, will be approximately $700 million; annually recurring costs, after completion of the staggered compliance dates based on facility size, will be approximately $320 million. At a discount rate of 7 percent and discounted over 7 years, the annualized costs to domestic facilities, after completion of the staggered compliance dates based on facility size, will be approximately $371 million per year; the total annualized cost to foreign facilities will be approximately $100 million. The total annualized domestic and foreign cost will be approximately $471 million per year. We estimate the total annualized cost using a discount rate of 7 percent and discounted over 7 years for each potential requirement is:

a. Environmental Monitoring: $8 million

b. Product Testing: $13 million

c. Supplier Program: $12 million

d. Economically Motivated Adulteration: $18 million

e. Review of Records for these Provisions: Significantly less than $1 million

We estimate the total additional annualized costs for the new subpart C provisions are approximately $52 million. We estimate that with a very small business (VSB) definition of $1,000,000, the total costs to domestic facilities in the first year, if all potential provisions were included and including both set up costs to implement the rule and the initial recurring monitoring costs, will be approximately $700 million; annually recurring costs, after completion of the staggered compliance dates based on facility size, would be approximately $320 million. At a discount rate of 3 percent and discounted over 7 years, the annualized costs to domestic facilities, after completion of the staggered compliance dates based on facility size, would be approximately $359 million per year; the total annualized cost to foreign facilities would be approximately $100 million. The total annualized domestic and foreign cost would be approximately $459 million per year. In section H we describe the likely analytic changes that will impact the cost estimates, to be presented at the time the rule is finalized.

As in our original proposal, we lack sufficient information to fully estimate the proposed rule's likely benefits. Instead we attempt to estimate the total economic burden of the domestic illnesses[1] that

[1] We are not able to estimate the commensurate health benefits that would accrue to foreign citizens that consume safer foods that are produced within their countries because of this rule or that consume safer exported U.S. foods.

could potentially be prevented by this rule. We do not expect that all of these illnesses will be prevented; rather, we expect that the rule would prevent some portion from occurring. We estimate that there are close to 1,000,000 illnesses each year that are attributable to FDA-regulated food products that would fall under the scope of this proposed rule. The monetized cost of these illnesses is estimated to be nearly $2 billion.

For the proposed rule to break even, by which we mean for the proposed rule to reduce the health burden to consumers by approximately the same amount as the compliance costs to industry using our analysis of 7 percent over 7 years, and if we include the costs to foreign firms but ignore the benefits to foreign consumers, the rule would have to reduce the annual social cost of the illnesses by approximately $471 million. We estimate that the average cost per illness is $2,063, so reducing the cost of illness by $471 million requires reducing the number of illnesses by at least 228,000 each year.

The effectiveness of this regulation and the corresponding reduction in food contamination and foodborne illness will depend on how successfully preventive controls are implemented and how effective the proposed provisions are at reducing contamination that leads to illness. Table 1 summarizes the annualized domestic costs of our supplemental notice of proposed rulemaking using a discount rate of both 7 percent and 3 percent discounted over a 7 year period.

Table 1 - Original and Revised Proposed Estimated Total Costs Based on Potential Provisions using Very Small Business Threshold of $1 million

	20 or fewer employees	**20 to 99 employees**	**100 to 499 employees**	**500 or more employees**	**Total**
Original Total Annualized Costs at 7% without additional provisions	$208 million	$67 million	$43 million	$1 million	**$319 million***
Original Total Annualized Costs at 3% without additional provisions	$200 million	$65 million	$42 million	$1 million	**$307 million***

Additional cost of new provisions annualized at 7% [2]	$19 million	$20 million	$10 million	$2 million	**$52 million***
Additional cost of new provisions annualized at 3%	$19 million	$20 million	$10 million	$2 million	**$52 million***
Revised Proposed Total Costs annualized at 7%	$ 227 million	$87 million	$53 million	$3 million	**$371 million***
Revised Proposed Total Costs annualized at 3%	$219 million	$85 million	$52 million	$3 million	**$359 million***
Total Costs to Foreign Facilities (most likely cost) annualized at 7%					**$100 million**
Total Costs to Foreign Facilities (most likely cost) annualized at 3%					**$100 million**
Benefits					**Unquantified**

*Totals may not perfectly match due to rounding errors

C. Need for Regulation

The supplemental notice of proposed rulemaking includes potential new requirements to institute risk-based environmental monitoring, product testing and a supplier approval and verification program as appropriate to the food, the facility and the nature of the preventive controls, as well as a requirement to institute controls to help prevent hazards associated with EMA. As we described in our original PRIA (Ref 1), we must establish, through rulemaking, science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. As a potential part of such standards, in the supplemental

[2] The costs for environmental monitoring, finished product testing and supplier verification were shown in our original PRIA based on a definition for a VSB of $250k. We did not present our estimate for VSB of $1 million. A definition of VSB that exempts more facilities causes the total costs of compliance to decline, consequently, our estimated total costs for VSB of $1 million are less than our estimate for $250k that was presented in our original PRIA (Ref. 1). Our full analysis for the potential provisions is shown below.

notice of proposed rulemaking we are providing an opportunity for public comment on potential requirements for product testing programs, environmental monitoring programs, supplier programs, and hazards that may be intentionally introduced for purposes of economic gain. As we described more fully in our original PRIA (Ref. 1), lack of full information diminishes incentives to invest in such safety measures across the supply chain from the farm through production and distribution to retailers. Consequently, the market, when driven by consumer demand, may not provide the necessary incentives for optimal investment in environmental monitoring, product testing, supplier approval and verification programs, or EMA. Imperfect information about the microbial, chemical and physical risks associated with food covered by the regulation being largely hidden to consumers, means that neither the legal system nor the marketplace may be able to provide adequate economic incentives for the production of safe food. The Government may therefore be able to improve social welfare through targeted regulation.

D. Regulatory Options

The feasible regulatory options have not changed in this supplemental notice of proposed rulemaking. For a detailed discussion of the regulatory options of the proposed rule, please see the PRIA (Ref.1).

E. Potential New Requirements at the Baseline

Below we show our more detailed estimates for the costs of the potential new provisions, as proposed. We estimate the costs to facilities using a definition for a very small business (VSB) as one which has average annual sales of less than $1 million dollars. Previously, we had presented in the proposed PRIA (See Docket FDA-2011-N-0920, Ref. 1) the costs for the following provisions when the VSB definition was estimated to be less than $250,000 annually. The potential provisions in the

supplemental notice of proposed rulemaking also differ from what was shown, but not proposed, in the previous PRIA as our thinking has evolved on what the potential verification activities could be. As examples, instead of requiring lists of approved suppliers, we are proposing that facilities in need of a supplier program have written procedures for their program. We are also not proposing that facilities review consumer complaints as a verification activity, although it was shown as a possibility, but not proposed, in the previous PRIA. FDA's guidance on the application of these verification activities is still being developed, as noted in section H. Thus, we use assumptions about the number of covered facilities, wage rates, the use of the FDA Survey, record keeping and training costs, among others, from the proposed rule PRIA as the basis for this analysis.

1. Environmental Monitoring

Environmental monitoring programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. Effective environmental pathogen controls, if utilized, will be product, process, and plant specific. Generally, *Salmonella* is the organism of concern for certain dry food products,[3] where *Salmonella* would be introduced with a raw product or ingredient, and *Listeria monocytogenes* (Lm) the organism of concern for certain ready-to-eat foods produced in wet processing environments. If a facility adopts an environmental monitoring program as a verification tool, it must identify the organism(s) of concern,

[3]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. (Ref 11)

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, and use a scientifically valid method for the monitoring.

To assess the base case costs of potential environmental monitoring provisions, we assume that, if a facility adopts a monitoring program, testing for *Salmonella* or *Listeria* would occur on a monthly basis. For additional details on the base case assumptions, please see the PRIA (Ref. 1).

Table 2 below shows our primary estimate of the annual cost of environmental monitoring for *Salmonella* to be about $3.6 million. Table 3 below shows our primary estimate of the annual cost of environmental monitoring for *Listeria* to be about $3.7 million.

Table 2 – Potential Environmental Monitoring Provision (Salmonella)

Number of Facilities by Industry and Size	**SIC Code**	**<20 employees**	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	Total
Dry, condensed and evaporated dairy products[a]	20230000	29	28	8	1	66
Dried and powdered milk and milk products	20230300	22	12	1	0	35
Dried milk	20230303	9	9	2	1	21
Dried nonfat milk	20230304	1	3	1	0	5
Dried whey	20230306	6	7	0	0	13
Milk preparations, dried	20230307	5	3	0	0	8
Powdered buttermilk	20230308	1	0	0	0	1
Powdered milk	20230310	20	14	7	1	42
Powdered skim milk	20230311	0	4	1	0	5
Powdered whey	20230312	3	5	1	0	9
Dried and dehydrated fruits, vegetables and soup mixes[a]	20340000	20	8	3	0	31
Dried and dehydrated vegetables	20340300	17	8	3	0	28
Vegetables, dried or dehydrated (except freeze-dried)	20340303	24	9	7	1	41
Cereal Breakfast Foods	2043	321	69	46	8	444
Flour, Blended & Prepared	2045	325	92	38	0	455
Chocolate & Cocoa Products	2066	1,129	90	40	8	1,267
Salted & Roasted Nuts & Seeds	2068	242	79	28	5	354
Food preparations, nec[a]	20990000	516	149	67	7	739
Seasonings and spices	20990400	426	52	9	3	490
Chili pepper or powder	20990402	35	5	2	0	42
Seasonings: dry mixes	20990403	132	19	7	6	164
Spices, including grinding	20990404	42	9	13	6	70
Sauces: dry mixes	20990504	13	3	0	0	16

Almond pastes	20999901	11	1	0	0	12
Bouillon cubes	20999902	0	2	1	1	4
Carob processing	20999905	3	1	0	0	4
Peanut butter	20999912	92	19	7	4	122
Tea blending	20999917	156	32	18	4	210
Total number of manufacturing facilities that may monitor for Salmonella		3,600	732	310	56	4,698
Facilities excluded by Very Small Business Definition		2,714	36	10	1	2,762
Facilities remaining after exclusion		886	696	300	55	1,936
Percent that already test (survey result)						
Facilities that may begin testing		696	500	150	21	1,367
[4]Average number begin testing		435	312	94	13	855
Total testing costs per facility annually		$2,976	$5,239	$5,881	$5,881	
Training materials cost per facility (annualized over 7 yrs.)		$42	$42	$42	$42	
Labor training cost per employee		$23.34	$23.34	$23.34	$23.34	
Annual environmental monitoring costs for Salmonella		$1,323,124	$1,656,617	$559,075	$77,785	$3,616,601
Annual cost per affected Facility		**$3,041**	**$5,304**	**$5,946**	**$5,946**	

[a] Partial category used.[5],[6]

Table 3 – Potential Environmental Monitoring Provision (Listeria)						
	SIC Code	**<20 employees**	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**

[4] Here, the average number of facilities that begin testing is the midpoint of 50 percent of all identified facilities testing and 75 percent of all the identified facilities testing.

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

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

Butter	2021	139	36	12	0	187
Cheese; natural and processed[a]	20220000	96	40	19	1	156
Natural cheese[a]	20229902	41	22	9	1	73
Ice Cream	2024	3,251	271	97	8	3,627
Milk	2026	975	365	287	18	1,645
Frozen fruits and vegetables	2037	384	124	91	22	621
Cole slaw, in bulk	20990702	11	3	0	0	14
Salads, fresh or refrigerated	20990705	155	50	24	10	239
Sandwiches, assembled and packaged: for wholesale market	20990706	147	39	8	4	198
Tofu, except frozen desserts	20999918	79	13	3	0	95
Vegetables, peeled for the trade	20999920	28	12	8	1	49
Fresh-Cut Fruits & Vegetables[a]	5148	323	34	5	0	362
Total number of facilities that may test for Listeria		5,629	1,009	563	65	7,266
Facilities excluded by Very Small Business Definition		4,243	50	19	2	4,313
Facilities remaining after the exclusion		1,386	959	544	63	2,953
Percent that already test (survey result)		23%	54%	84%	77%	
Facilities that may begin testing		1,073	444	87	15	1,619
[7]Average number begin testing		671	278	55	9	1,012
Total testing costs per facility annually		$2,826	$4,939	$5,521	$5,521	
Training materials cost per facility (annualized over 7 yrs.)		$42	$42	$42	$42	
Labor training cost per employee		$23.34	$23.34	$23.34	$23.34	
Annual environmental monitoring costs for Listeria		$1,939,014	$1,389,033	$305,104	$51,002	$3,684,154
Annual cost per affected facility		**$2,891**	**$5,004**	**$5,586**	**$5,586**	

[a] Partial category used.[8]

Table 4 summarizes our primary estimates for the annual total cost of potential environmental testing provisions ($7 million total).

[7] Here, the average number of facilities that begin testing is the midpoint of 50 percent of all identified facilities testing and 75 percent of all the identified facilities testing.

[8] 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 Food GMP survey to estimate the percentage of the facilities under 2022 that would be producing these two cheese types.

Table 4- Total Annual Costs of Potential Environmental Testing Provisions					
Pathogen	**<20 employees**	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Salmonella	$1,323,124	$1,656,617	$559,075	$77,785	$3,616,601
Listeria	$1,939,014	$1,389,033	$305,104	$51,002	$3,684,154
Total Annual Costs of Environmental Testing	**$3,262,138**	**$3,045,650**	**$864,180**	**$128,787**	**$7,300,755**

Should the potential environmental monitoring provision be included in a final rule, any facility undertaking an environmental pathogen monitoring program as a verification activity in its food safety plan would be required to have written procedures regarding the program. The written procedures should establish an environmental monitoring scheme that is scientifically valid and identify the locations from which samples would be collected and the number of sites to be tested during routine environmental monitoring. The written procedures should also identify or include the analytical methods used to test the environmental samples and the timing and frequency of collecting the samples. Our estimates for the cost to prepare written environmental monitoring procedures are shown in Table 5. We assume that facilities identified as starting an environmental monitoring program are the same ones that would need to write-up their environmental monitoring procedures.

Table 5 - Cost to Write-up Potential Environmental Monitoring Procedures					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Number of facilities	1,106	590	149	22	1,867
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	$1,400,168	$746,965	$188,217	$28,126	$2,363,476
First Year cost of write-up annualized over 7 years	$259,806	$138,602	$34,924	$5,219	$438,551
Annualized Cost per Affected Facility	$235	$235	$235	$235	

2. Product Testing

Product testing programs, including ingredient, in-process, or finished product testing, could be used to verify that preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards, when implemented appropriately based on the facility, the food, and the nature of the preventive control. We estimate that on a monthly basis facilities would conduct product testing to verify that the food being produced is not contaminated. For additional details on the base case assumptions regarding product testing, please see the PRIA (Ref. 1). Table 6 shows primary estimates of the potential product testing provision costs, where the costs of testing and holding product are about $13 million.

Table 6 – Potential Product Testing Provision Costs

Number of manufacturing facilities that may conduct product testing

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	136	60	32	7	235

	refrigerated					
20990706	Sandwiches, assembled and packaged: for wholesale market	142	44	12	0	198
20999901	Almond pastes	10	1	1	0	12
20999902	Bouillon cubes	3	1	0	0	4
20999905	Carob processing	3	1	0	0	4
20999907	Coconut, desiccated and shredded	13	4	0	0	17
20999912	Peanut butter	76	28	14	2	120
20999918	Tofu, except frozen desserts	79	14	2	0	95
20999920	Vegetables, peeled for the trade	27	13	9	0	49
Number of manufacturing facilities that may conduct product testing		4,443	946	427	79	5,895
Facilities excluded by Very Small Business Definition		3,349	47	14	2	3,412
Number of facilities remaining after exclusion of qualified facilities		1,094	899	413	77	2,483
Percent that already test (survey result)		69%	76%	83%	94%	
Number of facilities that may begin testing		345	219	69	5	637
[9]Average number begin testing		172	109	35	3	319
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 product annually		$12,276	$28,644	$43,056	$59,616	
Total Cost of Testing Product Annually		$2,114,738	$3,129,943	$1,492,614	$149,372	$6,886,667
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	

[9] Here, the average number of facilities that begin testing is estimated to be the midpoint of 25 percent to 75 percent of all facilities identified.

Percent needing to be held	100%	63%	17%	17%	
Inventory Holding Cost	25%	25%	25%	25%	
Number of days held	4	4	4	4	
Cost of holding product pending test results	$1,334	$1,632	$1,922	$22,185	
Number of times held annually	12	12	12	12	
Per Facility Cost of Holding Product Annually Awaiting Test Results	$16,005	$19,584	$23,062	$266,222	
Total Cost of Holding Product Annually Awaiting Test Results	$2,757,040	$2,139,933	$799,474	$667,037	$6,363,484
Total Costs of Testing and Holding Product Annually	$4,871,778	$5,269,876	$2,292,088	$816,409	$13,250,151
Annual Cost per Affected Facility	**$28,281**	**$48,228**	**$66,118**	**$325,838**	

Should the potential product testing provision be included in a final rule, any facility conducting product testing as a verification activity in its food safety plan would be required to create written procedures regarding such testing. If required, the written procedures should show that a facility's testing scheme is scientifically valid, the procedures for sampling, and the sampling frequency. The written procedures also should identify or include the analytical methods used to test product. Our estimates for the costs to write the product testing procedures are shown in Table 7 and assume that those facilities that we have identified as starting a testing program as the ones who will also write-up testing procedures.

Table 7 - Cost to Write-up Potential Product Testing Procedures

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Number of facilities	172	109	35	3	319
Time needed to write-up testing 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	$218,130	$138,363	$43,897	$3,173	$403,562
Total Costs Annualized	$40,475	$25,674	$8,145	$589	$74,882
Annualized Cost per Affected Facility	$235	$235	$235	$235	

3. Supplier Program

Supplier controls, when implemented appropriately, are an important preventive control that can ensure that significant hazards will be significantly minimized or prevented for those raw materials and ingredients for which the receiving facility has identified a significant hazard when the hazard is controlled before receipt of the raw material or ingredient. If the potential requirement for a supplier program is finalized, the receiving facility would not be required to establish and implement a supplier program for raw materials and ingredients for which there are no significant hazards, the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the significant hazards, or the receiving facility relies on its customer to control the hazard and annually obtains from its customer written assurance that the customer has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard. The verification activities of such a supplier program may include onsite audits, sampling and testing of the raw materials or ingredients, reviewing supplier food safety records or other supplier verification activities as appropriate based on the risk associated with the ingredient and the supplier; when a hazard controlled by the supplier is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans, if finalized, the receiving facility must have documentation of an annual onsite audit of the supplier (unless the facility documents that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance that the hazards are controlled).

If the potential supplier program provision is finalized, receiving facilities that determine they need a supplier program must have the program in writing. Such a written program, in determining the appropriate verification activities, must consider the severity of the hazards applicable to the raw material and ingredients; where the preventive controls for those hazards are applied for the raw material and ingredients; the supplier's procedures, processes, and practices related to the safety of the raw

material and ingredients; any applicable FDA food safety regulations and information relevant to the supplier's regulatory compliance with those regulations; the supplier's food safety performance history; results of testing raw materials and ingredients; responsiveness of supplier in correcting problems; and any other factors as appropriate. If finalized, we estimate that it will take a production manager 16 hours to write such a program. We ask for comment on the time it would take to develop the written procedures for a supplier program. We estimate this cost for facilities that manufacture food in the product categories that we have identified as potentially wanting their suppliers to complete an audit or test ingredients. Table 8 shows the cost of writing a program for these facilities.

Table 8- Potential Supplier Program Provision - Written Procedures

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Total Number Of Domestic Manufacturing Facilities	1,339	793	282	3	2,417
Number of hours to write program	16	16	16	16	
Cost per hour	$61.44	$61.44	$61.44	$61.44	
Cost In Year 1	$1,316,104	$779,353	$277,346	$2,738	$2,375,541
First year costs annualized over 7 years 7%	$244,207	$144,611	$51,462	$508	$440,789
Cost per affected facility	$182	$182	$182	$182	

a. Audits of Suppliers

Table 9 shows the pared down list of facilities by SIC code that we have identified as potential ingredient suppliers;[10] the customers of these facilities may want verification activities to be conducted.

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

For purposes of this analysis, CFSAN experts have identified these facilities as those that manufacture ingredients where an audit would likely be the best verification activity for the receiving facility to demand of the ingredient supplier. Given that the receiving facility is the customer, they will demand of their suppliers the most appropriate verification activity. For additional details on the baseline assumptions regarding the burden of audits, please see the discussion in the PRIA (Ref. 1).

Table 9 - Annual Costs of Audits to Ingredient Suppliers for a Potential Supplier Program Provision

SIC Code	SIC Description	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
2021	Butter	139	36	12	0	187
2022	Cheese	842	350	146	11	1,349
2023	Milk, Condensed & Evaporated	436	138	51	9	634
2026	Milk	975	365	287	18	1,645
2034	Dried Fruits, Vegetables & Soup	594	106	59	5	764
2037	Frozen Fruits & Vegetables	384	124	91	22	621
2041	Flour, Grain Milling	886	295	77	1	1,259
2045	Flour, Blended & Prepared	325	92	38	0	455
2052	Cookies & Crackers	2,118	253	131	32	2,534
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2098	Macaroni, Spaghetti & Noodles	766	83	39	4	892
2099	Food Preparations, NEC[a]	3694	667	247	7	4,616
Total		11,401	2,588	1,206	114	15,310
Facilities excluded by Very Small Business Definition		8,594	128	40	3	8,765
Facilities remaining after the exclusion		2,807	2,461	1,166	112	6,545
Percent of facilities that do not already conduct audits (survey result)		43%	21%	14%	0%	
Number of facilities that may begin having audits conducted		1,220	509	159	0	1,888
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		$3,966,094	$2,227,449	$792,577	$0	$6,986,119
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.

b. Potential Supplier Verification Activities other than Audits

For purposes of this analysis we assume the costs of testing raw materials and ingredients here as the option for verification activities other than (or in addition to) audits.[11] Table 10 presents estimated annual costs of testing raw materials and ingredients. For additional details on the assumptions associated with testing of raw materials please see the PRIA (Ref. 1).

Table 10 - Annual Costs of Testing of Raw Materials and Ingredients for a Potential Supplier Program Provision

SIC Code	SIC Description	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
2022	Cheese	842	350	146	11	1,349
2034	Dried Fruits, Vegetables & Soup	594	106	59	5	764
2037	Frozen Fruits & Vegetables	575	165	121	28	889
2041	Flour, Grain Milling	886	295	77	1	1,259
2045	Flour, Blended & Prepared	325	92	38	0	455
2046	Wet Corn Milling	288	46	24	8	366
2066	Chocolate & Cocoa Products	1,129	90	40	8	1,267
2068	Salted & Roasted Nuts & Seeds	242	79	28	5	354
2099	Food Preparations, NEC[a]	2196	495	223	20	2,934
Total		7,077	1,718	756	86	9,637
Facilities excluded by Very Small Business Definition		5,335	85	25	2	5,447
Facilities remaining after the exclusion		1,742	1,633	731	84	4,190
Facilities w/at least 1 potentially hazardous raw material that do not conduct periodic testing (survey result)		7%	17%	17%	3%	
Number of facilities that may begin periodic testing		118	284	124	3	529
Cost per testing (4 times per year)		$1,362	$1,362	$1,362	$1,362	

[11] To the extent that other food safety records are less costly than another verification activity, then we have overstated the costs of supplier verification activity costs.

Total Costs of New Testing	$161,362	$386,355	$168,364	$3,794	$719,875
[12]Value of a single production line per day	$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	$5,328	$6,480	$7,680	$88,736	
Number of facilities that may begin holding	118	284	124	3	529
Total Costs of Holding	$631,230	$1,838,165	$949,366	$247,168	$3,665,929
Total Annual Costs of Periodic Testing, Holding, Records	$792,591	$2,224,520	$1,117,731	$250,962	$4,385,804
Annual Costs per Affected Facility	$6,690	$7,842	$9,042	$90,098	

c. Potential Verification Activities for Suppliers that are Qualified Facilities

If the potential supplier program provision is finalized and a supplier meets the requirements to be a "qualified facility" as defined under the proposed rule, a receiving facility can document that their supplier meets the definition of a qualified facility and obtain written assurance at least every 2 years that the supplier is producing raw material or ingredients in compliance with applicable FDA food safety regulations and that the raw material or ingredient is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act. The written assurance should include a brief description of the processes and procedures that the supplier is following to ensure the safety of the food.

[12] We estimate cost of segregating and holding product as a percentage of a facility's single line production value. To calculate a single day's value of production we utilize information from the Annual Survey of Manufacturers (2009) provided by the U.S. Census Bureau and facility information from Dun &Bradstreet. 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. For additional details on the assumptions associated with the costs of holding please see the PRIA (Ref. 1).

We previously calculated (in the section of the PRIA on qualified facilities) the costs for all qualified facilities to document that they meet the definition of a qualified facility. We present here the cost estimates for qualified supplying facilities to create a written assurance (to be given to their receiving facility customers) to describe the processes and procedures that the supplier is following to ensure the safety of the food. Our estimates for the costs of the supplier approval and verification program for qualified facilities are shown in Table 11.

Table 11 – Potential Supplier Approval and Verification Program for Qualified Facilities					
	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Qualified Suppliers	13,930	212	66	5	14,212
Number of hours to Prepare Documentation	2	2	2	2	2
Cost per hour	$61.44	$61.44	$61.44	$61.44	$61.44
Total Costs	$1,711,663	$26,096	$8,073	$593	$1,746,426
Total costs annualized 7%	$317,605	$4,842	$1,498	$110	$324,055
Avg Cost per Facility	$23	$23	$23	$23	

The total costs of the potential supplier program provision are presented in Table 12.

Table 12- Potential Supplier Controls Provision Costs Summary					
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥500 employees**	**Total**
Annualized Costs of Written Program	$244,207	$144,611	$51,462	$508	$440,789
Annual costs of Auditing Suppliers	$3,966,094	$2,227,449	$792,577	$0	$6,986,119
Annual Costs of Testing Suppliers	$792,591	$2,224,520	$1,117,731	$250,962	$4,385,804
Annualized Costs for Qualified Facilities who are Suppliers	$317,605	$4,842	$1,498	$110	$324,055
Summation of Potential Supplier Control Provision Costs	$5,320,497	$4,601,423	$1,963,268	$251,580	$12,136,768

4. Review of Records for Potential Requirements for Product Testing, Environmental Monitoring, and Supplier Verification Activities

The proposed regulatory text for the potential provisions on product testing, environmental monitoring and supplier verification activities includes language that would direct facilities to review

records of product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made and establish that the review should be conducted by, or with the oversight of, a qualified individual. Facilities may or may not have records of all the types listed. Some facilities would not keep all the aforementioned records if they do not handle raw materials and ingredients or do not have product testing, for example. Table 13 shows the annual costs of the potential provisions to review product testing, environmental monitoring, and supplier verification activities records. We request comments on the amount of time spent per month on review of records.

Table 13 – Review of Records for Potential Provisions on Product Testing, Environmental Monitoring, and Supplier Verification Activities

	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**≥ 500 employees**	**Total**
Number of Manufacturing Facilities	1,339	793	282	3	2,417
Percent of facilities without verification records	39%	20%	0%	0%	
Facilities needing to begin reviewing records	528	161	-	-	689
Time per month spent on verification records (minutes)	15.00	30.00	45.00	60.00	
Wage including overhead	$61.44	$61.44	$61.44	$61.44	
Cost of Verification Records Review per Month	$15.36	$30.72	$46.08	$61.44	
Total Monthly Cost of Verification Records Review	$8,115	$4,944	$0	$0	$13,059
Number of Reviews per Year	12	12	12	12	
Annual Cost of Reviewing Records	$97,375	$59,328	$0	$0	$156,703
Annual Cost per Affected Facility	$184	$369	$0	$0	

5. Economically Motivated Adulteration

Our supplemental notice of proposed rulemaking adds the requirement that the hazard analysis consider hazards that may be intentionally introduced for purposes of economic gain. In this section, we estimate the additional costs and benefits of this requirement. The additional costs are the time to conduct a more thorough hazard identification, and the actions that are likely to be taken to reduce the hazards that are identified as significant. Potential additional benefits are reduced chances of injury or death to consumers.

We tentatively conclude that the hazard analysis required by this rule will not change the actions of the individuals who are already breaking the law by adulterating their own food for economic gain, and that the costs and benefits of this new requirement will come from food manufacturers considering possible adulteration of ingredients they have purchased from their suppliers.

a. Types of Fraud

In a 2013 *Journal of Food Protection* article (Ref. 2), Everstine et al. describe all unique incidents of Economically Motivated Adulteration (EMA) of food since 1980 that have been reported in scientific journals or the media. We use this article, as well as other sources such as the U.S. Pharmacopeial Convention Food Fraud Database (Ref. 3) and a Congressional Research Service report (Ref. 4) to estimate what kinds of EMA are reasonably foreseeable and would be considered a significant hazard under the proposed rule. As with other hazards, the analysis required by the rule must be based on known or reasonably foreseeable hazards, and must include the possible addition of food allergens. We then estimate the costs of addressing each kind of EMA, and use a database of packaged food ingredients (Ref. 5) to estimate what percentage of facilities will bear these costs.

b. Fraud Types Unlikely to Cause Hazards

Several types of EMA are unlikely to cause most food processors covered by this rule to pay additional costs, because the fraud occurs at places or in foods not covered by the rule, or does not result in a hazard. However, as described in the next section, some types of fraud may be considered a hazard in foods that are marketed to people with food allergies.

Major types of EMA not likely to be addressed by this rule are seafood fraud (e.g., species substitution), the adulteration of fruit juices with sugars and artificial colors and flavorings, and fraud relating to wine. Manufacturers of seafood and fruit juice are not covered by this rule because they are

subject to seafood and juice HACCP regulations, and alcoholic beverages are also not covered by the rule.

Another type of EMA is the adulteration of fats and oils, usually the labeling of inferior grades of olive oil as higher grades. Although there have been cases in other countries where harmful adulterated oils have been sold directly to consumers, there have been no cases where economically adulterated oil sold to a food manufacturer and used as an ingredient caused harm. Therefore, we assume that oil fraud is unlikely to be considered a hazard under this rule.

Honey may be adulterated with sugar and other sweeteners. Because there have been no known adverse health consequences from adulterated honey, we assume that it is unlikely to be considered a hazard under this rule.

There have been incidents of EMA related to infant formula, but most such incidents in the United States have involved counterfeiting or diversion and relabeling (Ref. 2), which are issues that cannot be addressed in a hazard analysis conducted by legitimate manufacturers. Infant formula manufacturers in the United States already follow strict manufacturing standards, so we tentatively conclude that the EMA provisions of this rule will not impose costs on infant formula manufacturers.

We conclude that the types of EMA that are likely to be included in hazard analyses are dairy products (from countries with a history of melamine adulteration), spices and extracts, and allergen-related EMA. We discuss these in more detail, with cost estimates, later in this section.

c. Hazard Analysis to Prevent Intentional Adulteration

We estimate that most facilities conducting a hazard analysis would bear additional costs to determine if there are any incoming ingredients for which it is reasonably foreseeable that the ingredients may contain hazards that were deliberately introduced, and if so, whether they are significant. While some facilities may already conduct such an analysis, we have no data to estimate

how many. To the extent that manufacturers are already conducting such analyses, the actual costs of the rule will be lower than our estimates. We estimate that this will add an average of two hours to the initial hazard analysis of each process. We also estimate that this requirement will add an average of an additional half-hour to the average initial writing time of each hazard analysis. We further estimate that this requirement will add a half-hour to the average time it takes to conduct the updated hazard analysis every year, and 0.1 hours to the time required to write down the updated hazard analysis. We request comments on these estimates.

For each type of facility (small, medium, large, and very large) we estimate the number of processes per facility and find the number of facilities covered from the Dun & Bradstreet Global Business Database. We find that there are about 16,000 food production facilities covered by these additional requirements, and estimate that there are about 42,000 production processes covered by these requirements.

We estimate that the review of these records would be conducted by someone at the level of a production manager making an hourly wage of $61 including overhead.[13] With these wage costs multiplied by the time required and the number of production processes, we estimate that this requirement will add about $2.7 million to the annualized cost of developing and updating the hazard analyses required by this rule. See Table 14.

[13] **Bureau of Labor Statistics**, Occupational Employment Statistics, May 2012, National Industry-Specific Occupational Employment and Wage Estimates, under NAICS 311000 - Food Manufacturing; http://bls.gov/oes/current/naics3_311000.htm

d. Types of Hazards

Allergens

While many of the fraud types that have occurred might not be hazards for most consumers, they could be hazards for consumers with food allergies. A product substitution that is unnoticed by an average consumer could cause a life-threatening adverse reaction in a consumer with a food allergy.

Based on the ingredient listings in the FoodEssentials database (Ref. 5), we estimate that about a third of these processes involve an ingredient for which a reasonably foreseeable substitution could harm an allergic consumer. Based on a report on current allergen control practices (Ref. 6), we estimate that about half of these are already produced with ingredients from trusted and verified suppliers. This leaves about 17 percent of food production processes that are vulnerable to Economically Motivated Adulteration that could cause a hazard due to food allergies.

Allergen testing costs about $100 (Ref. 7) and we estimate that each production process will require an average of about 10 additional diagnostic tests per year on incoming lots of ingredients. This would result in annual costs of $1,000 (10*$100 = $1,000) for each such process. There are about 7,140 (17% x 42,000) production processes affected by this provision, so the additional annual costs of this option due to allergen testing would be about $7 million (See Table 14).

Dairy Products (from countries with a history of melamine adulteration)

A type of EMA that has occurred in the past is the adulteration of non-domestic dairy products with additives such as melamine, urea, and vegetable fats. Some of the additives used can cause serious adverse health consequence or death, so we assume that this type of EMA will be considered a reasonably foreseeable hazard under this rule, and that many facilities that use non-domestic milk and milk powder as ingredients will take action to prevent this hazard from being introduced into their food.

However, as none of this adulterated milk was exported to the United States and no US suppliers have been a source of food safety problems due to milk products adulterated for economic gain, FDA does not expect a facility to consider the potential for melamine to be a significant hazard when using domestic milk products, or milk products from other countries when there is no history of melamine adulteration associated with those countries.

Out of a total of about 234,000 food products listed in the FoodEssentials database (Ref. 5), about 37,000 contain milk in the ingredients list and about 69,000 have a dairy allergen warning.[14] We therefore estimate that between 16 percent and 30 percent of production processes use dairy products as ingredients. We know that most of the industry has taken steps to protect itself from this type of fraud, but we do not have recent data showing exactly how many production processes have such steps in place. We therefore assume that about 70 percent of these processes use dairy products that are already tested for adulterants, are from domestic sources, or are from trusted suppliers that are already tested or verified. To the extent that more processes use tested, domestic, or trusted ingredients, the costs will be lower than our estimates. This means that that about 7 percent of processes ([(16+30)/2]*(1-0.7) = 6.9) use dairy products that are not tested or not from domestic or other trusted suppliers.

We assume that each production process using unverified dairy ingredients would require an average of about 10 additional diagnostic tests per year on incoming lots of ingredients, and that the tests would cost an average of $100, which is the approximate current price of melamine and urea testing (Ref. 7). This would result in annual costs of $1,000 (10*$100 = $1,000) for each such process. There are about 2,850 (=6.9% x 42,000) production processes affected by this provision, so the additional

[14] Products that contain whey or margarine would be in the latter group but not the former.

annual costs of this option due to non-domestic dairy testing would be about $2.9 million (See Table 14).

Spices and Extracts

There have been several documented cases of spices being contaminated with carcinogenic dyes such as Sudan I or lead oxide. We therefore assume that the presence of these chemicals in spice ingredients will be considered a reasonably foreseeable hazard under this rule. We further assume that the spices most likely to be adulterated by dyes are those that are used as a natural coloring, or where coloring us used as an indicator of potency.

According to the FoodEssentials database (Ref. 5), 21% of all food products have an ingredient that is classified as a natural coloring, and these foods have an average of 1.5 natural coloring ingredients each. Most of these are spices that have often been adulterated in the past, such as turmeric, annatto, and paprika. Given that color is the main purpose of the rest, we assume that they would be considered likely suspects for dye adulteration as well. To the extent that these other natural coloring ingredients do not constitute a reasonably foreseeable hazard, the costs of the rule will be less than our estimates.

Testing spices for contamination requires a bundle of High Performance Liquid Chromatography tests. We estimate the average cost of this testing bundle, including sample collection and shipping, to be about $500 per sample. We estimate that testing one sample per ingredient per year is sufficient to detect and deter dye adulteration of these products. This means that the total annual costs of this provision are about $4.4 million. (See Table 14).

Other Products

Ingredients in categories other than the ones listed above may be vulnerable to EMA. Producers will consider whether these hazards are something they need to address in their food safety plans by taking into consideration factors that will differ among facilities. For example, there have been several cases of harmful nitrogen-rich compounds such as urea or melamine being added to grain products to increase its price (Ref. 2.) Some producers may need to test some such ingredients from their suppliers based on factors like a history of adulteration and the source of the ingredients.

We estimate that an additional five to fifteen percent of food production processes, or an average of ten percent, will decide to conduct some additional testing, and that they will conduct about three additional tests per year, at a cost of about $100 per test. The total cost of additional ingredient testing will then be about $1.3 million (See Table 14).

e. Total EMA Costs and Benefits

We estimate that the total annual costs of this requirement for US producers are about $18 million as shown in Table 14. We do not know how many illnesses and deaths are caused by EMA of food ingredients used in food manufacturing, so we are unable to quantify the benefits of this additional requirement.

Table 14 – Summary of Additional Cost to Prevent Intentional Adulteration

Facility Type	Small	Medium	Large	V. Large	Total
Facility Employees	<20	20-99	100-499	>500	
Facilities Covered	6,400	7,600	2,000	190	16,000
Wage Rate	$ 61	$ 61	$ 61	$ 61	
Processes per Facility	2	2	6	10	
Total Processes	13,000	15,000	12,000	1,900	42,000
Conducting the Initial Hazard Analysis					
Labor Hours per Process	2	2	2	2	
Monetized Costs	$ 1,600,000	$ 1,900,000	$ 1,500,000	$ 240,000	$ 5,100,000

Writing the Initial Hazard Analysis					
Labor Hours per Process	0.5	0.5	0.5	0.5	
Monetized Costs	$ 390,000	$ 460,000	$ 370,000	$ 59,000	$ 1,300,000
Total Burden Hours	6,400	7,600	6,000	970	21,000
Analysis Initial Costs	$ 2,000,000	$ 2,300,000	$ 1,800,000	$ 290,000	**$ 6,400,000**
Annualization of Initial Costs (7 year discount period)					
7% Discount Rate	$ 360,000	$ 430,000	$ 340,000	$ 55,000	**$ 1,200,000**
3% Discount Rate	$ 310,000	$ 370,000	$ 290,000	$ 47,000	$ 1,000,000
Hazard Analysis - Annual Updating					
Labor Hours per Process	0.5	0.5	0.5	0.5	
Monetized Costs	$ 390,000	$ 460,000	$ 370,000	$ 59,000	$ 1,300,000
Hazard Analysis - Annual Writing					
Labor Hours per Process	0.1	0.1	0.1	0.1	
Monetized Costs	$ 78,000	$ 93,000	$ 73,000	$ 12,000	$ 260,000
Total Burden Hours	640	760	200	19	1,600
Hazard Analysis - Totals					
Analysis Recurring Costs	$ 470,000	$ 560,000	$ 440,000	$ 71,000	**$ 1,500,000**
Analysis Annualized (7%)	$ 830,000	$ 990,000	$ 780,000	$ 130,000	**$ 2,700,000**
Total Annualized (3%)	$ 780,000	$ 930,000	$ 730,000	$ 120,000	$ 2,600,000
Allergen Testing					
Processes Requiring Testing	17%	17%	17%	17%	
Testing Costs per Process	$ 1,000	$ 1,000	$ 1,000	$ 1,000	
Allergen Testing Costs	$ 2,200,000	$ 2,600,000	$ 2,000,000	$ 330,000	**$ 7,100,000**
Non-Domestic Dairy Product Testing					
Processes Requiring Testing	6.9%	6.9%	6.9%	6.9%	
Testing Costs per Process	$ 1,000	$ 1,000	$ 1,000	$ 1,000	
Non-Domestic Dairy Testing Costs	$ 880,000	$ 1,000,000	$ 830,000	$ 130,000	**$ 2,900,000**
Spice Testing					
Processes Requiring Testing	21%	21%	21%	21%	
Testing Costs per Process	$ 500	$ 500	$ 500	$ 500	
Spice Testing Costs	$ 1,400,000	$ 1,600,000	$ 1,300,000	$ 200,000	**$ 4,400,000**
Other Product Testing					
Processes Requiring Testing	10%	10%	10%	10%	
Testing Costs per Process	$ 300	$ 300	$ 300	$ 300	
Other Testing Costs	$ 380,000	$ 460,000	$ 360,000	$ 58,000	**$ 1,300,000**
Total Annualized Cost of EMA Provisions					
7% Discount Rate	$ 5,600,000	$ 6,700,000	$ 5,300,000	$ 840,000	**$ 18,440,,000**
3% Discount Rate	$5,500,000	$ 6,600,000	$ 5,300,000	$ 840,000	$ 18,200,000
Average per facility (7%)	*$ 670*	*$ 670*	*$ 2,000*	*$ 3,300*	*$ 1,100*

F. Cost Impact for Foreign Facilities

We use a simplified method to estimate the impact to foreign facilities. We assume that the impact to foreign facilities is directly proportional to the impact to domestic facilities. We estimate there are 109,190 foreign facilities that will be covered by the rule and 97,646 domestic facilities that will be covered by the rule (PRIA Ref 1.) We estimate the total domestic cost of the rule with the revised proposed provisions will be $371 million, while the impact to foreign facilities will be $100 million. This analysis probably significantly overstates the true cost to foreign facilities. From our Oasis data, we know that foreign facilities will often only send a small fraction of their total production to the US and therefore our estimate is likely the upper bound estimate. We believe that the most likely total cost to foreign facilities is about 25 percent of the upper bound or about $100 million. If foreign manufacturers already export their better quality or more compliant products and sell their non-compliant or poorer quality products to their domestic markets, then the total cost of compliance will be less. If average foreign wage rates are significantly lower than average US wage rates, if total production costs are lower, or if some foreign facilities simply cease to ship their products to the US because of the proposed regulatory compliance costs, the total costs to foreign facilities might be significantly less. Conversely, if compliance rates are significantly lower, or if average foreign wage rates are higher, then the total costs to foreign facilities could be higher.

G. Comparison of Costs for Original Proposed Rule and New Supplemental Notice of Proposed Rulemaking.

Table 15 shows our estimates for the costs of our original PRIA. Table 16 shows our estimates for the costs of our revised proposed provisions. Both original and revised proposed rule use a definition of $1,000,000 for a very small business.

Table 15 - Original Estimated Total Costs of the Proposed Rule with A VSB cutoff at <$1M					
Original	**20 or fewer employees**	**20 to 99 employees**	**100 to 499 employees**	**500 or more employees**	**Total**
Total Domestic Facilities (Manufacturers, Warehouses and Wholesalers)	80,475	12,283	4,411	477	**97,646**
Total Domestic Manufacturing Facilities	54,206	9,389	3,948	453	**67,996**
Total Qualified Domestic Manufacturing Facilities	47,795	1,798	1,946	260	**51,799**
Total Non-Qualified Domestic Manufacturing Facilities	6,411	7,591	2,002	193	**16,197**
Learn about Rule	$47 million	$7.2 million	$5.7 million	$.62 million	**$61 million**
Total Subpart D Requirements (former Subpart B) Annualized Costs	$24 million	$2.1 million	$3 million	$ .54 million	**$29 million**
Total Subpart C Annualized Costs	$137 million	$58 million	$34 million	$. 29 million	**$230 million**
Total Annualized Costs	$208 million	$67 million	$43 million	$1.4 million	**$318 million**
Average Annualized Cost per Manufacturing Facility exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls					**$1,000**
Average Annualized Cost per Manufacturing Facility subject to Subpart C Hazard Analysis and Risk-based Preventive Controls					**$13,000**
Total Annualized Cost to Foreign Facilities					**$100 million**

Table 16 - Original Estimated Total Costs with Revised Proposed Provisions					
Original (from Table 15)	**20 or fewer employees**	**20 to 99 employees**	**100 to 499 employees**	**500 or more employees**	**Total**
Total Domestic Facilities (Manufacturers, Warehouses and Wholesalers)	80,475	12,283	4,411	477	**97,646**
Total Domestic Manufacturing Facilities	54,206	9,389	3,948	453	**67,996**
Total Qualified Domestic Manufacturing Facilities	47,795	1,798	1,946	260	**51,799**
Total Non-Qualified Domestic Manufacturing Facilities	6,411	7,591	2,002	193	**16,197**
Learn about Rule	$47 million	$7.2 million	$5.7 million	$.62 million	**$61 million**
Total Subpart D Requirements (former Subpart B) Annualized Costs	$24 million	$2.1 million	$3 million	$ .54 million	**$29 million**
Original Total Subpart C Annualized Costs	$137 million	$58 million	$34 million	$. 29 million	**$230 million**
Potential Provisions					
Environmental Monitoring Costs	$3.5 million	$3.1 million	$.9 million	$.1 million	**$8 million**
Product Testing	$4.9 million	$5.3 million	$2.3 million	$.8 million	**$13 million**
Supplier Approval and Verification Program	$5.3 million	$4.6 million	$2 million	$.25 million	**$12 million**
Economically Motivated Adulteration	$5.6 million	$6.7 million	$5.3 million	$.9 million	**$18 million**
Review of Records for Environmental Monitoring, Product testing and Supplier Verification	$.01 million	$0	$0	$0	**$.01 million**
Total Annualized Costs	$227 million	$87 million	$53 million	$3 million	**$371 million***
Average Annualized Cost per Manufacturing Facility exempt from Subpart C Hazard Analysis and Risk-based Preventive Controls					**$1,000**
Average Annualized Cost per Manufacturing Facility subject to Subpart C Hazard Analysis and Risk-based Preventive Controls					**$18,000**
Total Annualized Cost to Foreign Facilities					**$100 million**

*Totals may not perfectly match due to rounding errors

H. Anticipated Modifications to Our Estimate of the Cost of the Final Rule

For the final rule, we anticipate making several modifications to our estimate of the cost of our proposed rule, including provisions in the supplementary proposal. Based on the comments that we received, we anticipate improving our cost estimates to more accurately reflect real world practices. We anticipate that most, although not all, of the adjustments that we will make will increase our estimate of the cost of the regulation. We will revise our estimate of the total number of covered facilities based on the latest Dun & Bradstreet, OASIS data and a revised analysis of mixed use facilities based on our revised definition of a farm. We do not know yet if there will be more or fewer total covered facilities, although we anticipate that there will be significantly more mixed use facilities that will be exempt from subpart C and the most costly provisions of the rule.

1. We will modify our method for determining the number of qualified and non-qualified facilities to be more consistent with the statute. We originally made our estimate for qualified facilities based on the number of *facilities* with less than $1 million in annual sales, rather than the number of *firms* with less than $1 million in annual sales. We will revise our estimate by revising the number of facilities owned by firms with less than $1 million in sales. The facility-to-firm adjustment will combine annual sales from individual facilities at the firm level. We believe our current calculation based on firm sales rather than facility sales is more consistent with section 418(l)(1)(B). The effect of this adjustment will be that more facilities will be required to comply with the proposed rule at any given definition of "very small business" but they are expected to be affiliates of larger firms rather than smaller entities. Once this change has been made, the estimated costs of the rule will increase for any particular cutoff level. Table 17 shows our estimate for the number of qualified and non-qualified facilities using different definitions for a very small business.

Table 17 - Comparison of numbers of qualified and non-qualified facilities under different definitions for a very small business and using our original method and our revised method						
	Original Method			Revised Method		
Cutoff ($)	Qualified Facilities	Non-Qualified	Mkt Share Covered	Qualified Facilities	Non-Qualified	Mkt Share Covered
250k	44,900	52,700	99.5%	35,300	60,400	99.8%
500k	59,700	37,900	99.1%	44,900	50,800	99.7%
1m	74,900	22,700	98.1%	55,700	40,000	99.4%

2. Comments that we already received for our potential provisions indicate that we should increase the assumed frequency of any potential environmental monitoring and product testing provisions to a more statistically valid level. Commenters expect that any facilities subject to environmental monitoring or product testing, should they be included in the final rule, will require significantly higher numbers of samples per facility than we originally estimated. We also are considering increasing our estimate for the frequency of sampling from a monthly basis to a weekly basis for the testing or monitoring for *Listeria monocytogenes.* Comments also suggest that the costs for laboratory analysis of samples and the wage rate for the technician taking the samples should be higher than we estimated in our original PRIA. In addition, our thinking regarding environmental monitoring and product testing continues to evolve based on the comments received and new scientific information. We plan on obtaining updated information for these costs,

along with other improvements to our analysis that we cannot anticipate at this stage. We presented the costs of environmental monitoring in this supplemental notice as costing about $8 million annually for the final rule. We present product testing in this supplemental notice of proposed rulemaking as costing about $13 million annually. We continue to seek comment on these potential costs.

3. We anticipate estimating the additional costs for farms that are suppliers to manufacturing facilities; under this proposed rule, some farms supplying raw ingredients to manufacturing facilities will need to supply information to their customers to allow evaluation of the safety of the raw material by the receiving facility. In addition, our thinking regarding an effective supplier program continues to evolve based on the comments received and new scientific information. We plan on obtaining updated information for these costs, along with other improvements to our analysis that we cannot anticipate at this stage. As with environmental monitoring and product testing, we expect the estimated costs of the supplier program to change, and likely increase in the final regulatory impact analysis. Currently, for this supplemental notice of proposed rulemaking, we have estimated the costs of a supplier program to be about $12 million on an annual basis. We continue to seek comment on these potential costs.
4. We anticipate increasing all the labor costs used in our estimates. The increase will occur due to inflation and also due to a change in our estimate of the costs of overhead and worker fringe benefits. We continue to seek comment on these costs.
5. We are still in the process of coordinating the firm coverage between the multiple regulations required by FSMA. As the provisions of the individual rules are revised and

updated, we will evaluate the coverage to ensure the various components of the rules are consistent and not redundant.

6. Finally, we expect changes to our estimates based on potential new sources of information, such as new studies or industry data.

Regulatory Flexibility Options

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. §§ 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA tentatively concludes that the proposed rules will have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) 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 62 of our proposed PRIA (Ref 1) shows the SBA size classifications for many of the various sectors of food manufacturing.

Small and very small businesses may need additional time to comply with the proposed requirements. The proposed rule allows small businesses two years and very small businesses three years to come into compliance after the effective date of the final rule. If qualified facilities were to incur the same average cost per provision as facilities not subject to subpart C Hazard Analysis and Risk-Based Preventive Controls, then by exempting them, the supplemental notice of proposed

rulemaking will reduce their costs by approximately $440 million (($18,000 per non-qualified facility - $1,000 per qualified facility) x 51,799 qualified manufacturing facilities) x 0.5 for those that already perform the activities.

As described in the proposed PRIA (Ref. 1) one option to reduce the impact on small entities is change the definition for a very small business in order to exempt more or all of them from the proposed rule. Most entities affected by this rule, however, are small. We estimate that about 99.5 percent are small. Exempting too many small establishments might substantially reduce any benefit of the rule. Another option is to allow a longer compliance period. Small and very small businesses are not subject to section 418 of the FD&C Act until two years (small businesses) or three years (very small businesses) after the effective date of FDA's final rule (§ 103(i) of FSMA). This is a period beyond the time given to larger facilities to comply with this rule. For a more detailed description of the full regulatory flexibility options offered for this proposed rule, see the PRIA (Ref.1).

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 $144 million, using the most current (2013) 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 more detail in the cost benefit analysis of the preceding sections and in the PRIA (Ref. 1).

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.

Paperwork Reduction Act of 1995

The information collection provisions are included in the supplemental notice of proposed rulemaking, which can be found in the Federal Register at http://www.federalregister.gov, Docket No. FDA-2011-N-0920 (FSMA Supplemental Notice of Proposed Rulemaking for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food).

Reference List

1. FDA. Proposed Analysis of Economic Impacts - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food available under Docket FDA-2011-N-0920.

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3. Food Fraud Database, U.S. Pharmacopeial Convention, http://www.foodfraud.org/

4. Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients, Congressional Research Service 7-5700, http://www.fas.org/sgp/crs/misc/R43358.pdf

5. ELISA Technologies. Gluten Testing Laboratory. [Online] http://www.elisa-tek.com/gluten-testing-laboratory/

6. Eastern Research Group (2010) Economic Analysis of new FDA Food cGMP Regulations and Related Legislative Initiatives—Subtask 2: Expert Opinions on Current Food Manufacturing Practices—FINAL, Memorandum, June 30, 2010.

7. Arbro Analytical Division. Testing Rates. Melamine Testing. Urea Testing. [Online] 2013. http://www.melaminetesting.in/rates.html