Department of Health and Human Services

Food and Drug Administration

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

Docket No. FDA-2011-N-0922

Preliminary Regulatory Impact Analysis

Preliminary Regulatory Flexibility Analysis

Preliminary Unfunded Mandates Reform Act Analysis

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Office of Planning
Office of Policy, Planning, Legislation and Analysis
Office of the Commissioner

Submit either electronic or written comments on the preliminary regulatory impact analysis by 75 days after publication of the supplemental notice of proposed rulemaking in the Federal Register.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2011-N-0922 and RIN for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Submit written comments in the following ways:

Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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I. Introduction and Summary

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 a substantial number of small entities. Because the proposed rule would impose annualized costs that range from $13,200 to $18,300 on many small entities, the Agency determined that the proposed rule, if finalized, may 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.

A. Summary of Proposed Changes

The 2013 proposed rule Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (Preventive Controls Rule) as analyzed in our original Proposed Regulatory Impact Analysis (Ref. 1) would include requirements for facilities subject to subpart C to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards. Our original PRIA included a more detailed analysis of each of the provisions, some of which is further detailed in the 2011 Eastern Research Group (ERG) report, "Economic Analysis of Proposed Animal Feed Regulation – A Cost Analysis for the Livestock Feed and Pet Food Industries"(Ref. 2). The supplemental notice of proposed rulemaking includes potential additional requirements for facilities subject to subpart C to institute product testing, environmental monitoring, a risk-based supplier program, and preventive controls to help prevent economically motivated adulteration (EMA). Further, the supplemental notice of proposed rulemaking defines a very small business as one with total annual sales of animal food of less than $2.5 million, adjusted for inflation. If these provisions were adopted, facilities would also be required to monitor their preventive controls, verify that they were effective, take any appropriate corrective actions, and maintain records documenting these actions.

The estimated costs of the supplemental notice of proposed rulemaking equal the sum of the costs of the 2013 proposed rule and the potential additional requirements added by the supplemental notice of proposed rulemaking. Total one-time compliance costs are estimated at

$79.91 million for the supplemental NPRM. Total annual costs are estimated at $82.07 million. Discounting the one-time costs over 10 years at a 7 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $93.45 million (see Table 1). Discounting the one-time costs over 10 years at a 3 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $91.44 million.

FDA estimates the total annualized costs of the potential additional requirements at $5.81 million (over 10 years at a seven percent discount rate) for those animal food manufacturing facilities that would be subject to subpart C. The individual costs and cost total are listed below:

Product Testing costs:	$131,400
Environmental Monitoring:	$368,200
Supplier Program:	$734,300
Economically Motivated Adulteration:	$4,316,700
Review of Records for these Provisions:	$258,400
Total Costs of Potential New Requirements:	$5,809,000

FDA is unable to quantify the benefits of the supplemental NPRM. The supplemental NPRM may result in fewer instances of contaminated animal food. Any such reduction in contaminated animal food would reduce the risk to animals, to humans handling animal food, and to humans consuming food products of animal origin, which in turn would generate social benefits in the form of potential improvements in public (human and animal) health.

Table 1. Industry Compliance Costs and Benefits of Supplemental NPRM ($ million)

	1-Time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Total Costs	$79.91	$82.07	$93.45	$91.44

Benefits	Improved food safety systems can reduce the risks of recalls, adverse health effects related to contaminated food, and reduce losses of contaminated food ingredients and animal food products.

1. Total annualized cost equal to annualized 1-time cost plus annual cost.

In Table 1a, FDA provides the accounting information.

Table 1a. Summary of Benefits, Costs and Distributional Effects of Supplemental NPRM

Category		Primary Estimate	Units			Notes
			Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized		2012	7%	10 years	
	Monetized $millions/year		2012	3%	10 years	
	Annualized Quantified		2012	7%	10 years	
			2012	3%	10 years	
	Qualitative	Improved food safety systems can reduce the risks of recalls, adverse health effects related to contaminated food, and reduce losses of contaminated food ingredients and animal food products.				
Costs	Annualized	$93.45	2012	7%	10 years	Estimates assume all foreign costs are passed on to US consumers.
	Monetized $millions/year	$91.44	2012	3%	10 years	
	Annualized Quantified		2012	7%	10 years	
			2012	3%	10 years	
	Qualitative					
Transfers	Federal Annualized Monetized $millions/year		2012	7%	10 years	
			2012	3%	10 years	
		To:				
	Other Annualized Monetized $millions/year		2012	7%	10 years	
			2012	3%	10 years	
		To:				
Effects	State, Local or Tribal Government: No effect					
	Small Business: The proposed rule may have a significant impact on a substantial number of small entities that manufacture/process, pack, and hold animal food.					
	Wages: No estimated effect					
	Growth: No estimated effect					

B. Summary of October 29, 2013 Proposed Rule

1. Compliance Costs

FDA summarizes its previous estimate of the costs of the October 29, 2013 proposed rule that would cover animal foods under the very small business exemption of less than $2,500,000 in annual sales of animal foods per firm. In the PRIA for the 2013 proposed rule (Ref 1), FDA did not provide the detailed summary of industry compliance costs for the co-proposal in which the very small business definition was set at less than $2.5 million, but rather provided these details only for the co-proposal in which the definition was set at less than $500,000. Table 2 below shows the detailed summary of industry compliance costs for the 2013 proposed rule.

Total one-time compliance costs were estimated at $74.71 million for the co-proposal for very small businesses with animal food sales set at less than $2,500,000. Total annual costs were estimated at $76.28 million. Discounting the one-time costs over 10 years at a 7 percent discount rate and adding the annual costs resulted in a total annualized compliance cost estimate of $86.92 million (see Table 2). Discounting the one-time costs over 10 years at a 3 percent discount rate and adding the annual costs resulted in a total annualized compliance cost estimate of $85.04 million.

Table 2. Industry Compliance Costs of the October 29, 2013 Proposed Rule (VSB < $2,500,000) ($ million)

Rule Provision	1-Time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Validation of food safety plan	$2.50	$0.83	$1.19	$1.20
Process control monitoring	$0.22	$2.13	$2.16	$2.16
Process control monitoring – verification		$1.09	$1.09	$1.09
Sanitation Controls – writing procedures for food contact surfaces and cross-contamination	$0.28	$0.03	$0.07	$0.06
Sanitation controls – monitoring and verification	$0.22	$3.92	$3.95	$3.94
Subpart B – additional sanitation labor		$7.39	$7.39	$7.39
Training for qualified individuals	$3.26	$0.84	$1.31	$1.22
Attesting to qualified status and changing product labels	$4.83	$0.04	$.0.73	$0.61
Administrative review of rule	$20.07		$2.86	$2.35

Subtotal	$31.37	$16.46	$20.93	$20.14
ERG Analysis of process controls draft (Includes food safety plan reanalysis and corrective actions)[2]				
Hazard Analysis		$1.77	$1.77	$1.77
Preventive Controls	$14.03	$22.28	$24.28	$23.92
Recall Plan	$4.10	$1.37	$1.95	$1.85
Monitoring	$0.05	$0.83	$0.83	$0.83
Corrective Action	$2.53	$5.36	$5.72	$5.65
Recordkeeping		$2.71	$2.71	$2.71
ERG Subtotal	$20.72	$34.31	$37.26	$36.74
Facilities subject to both part 117 and part 507	$5.01	$5.65	$6.36	$6.23
Domestic Manufacturers	$57.09	$56.42	$64.55	$63.11
Foreign Manufacturers	$17.62	$19.87	$22.37	$21.94
Total	$74.71	$76.28	$86.92	$85.04

1. Total annualized cost equal to annualized 1-time cost plus annual cost.
2. Based on a working version of a process control draft rule.

2. Benefits

As described in the original PRIA (Ref 1), FDA lacks sufficient data to quantify the potential benefits of the 2013 proposed rule. The causal chain from contaminated animal food to human and animal health and welfare can be identified but not quantified. Because no data exists to quantify the likelihood of hazards that might be found in different animal foods, we are unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals. Nevertheless, the 2013 PRIA described how improved animal food safety systems can reduce the number of recalls, reduce the risk of adverse health effects related to contaminated animal food, and reduce the losses of contaminated animal food. Furthermore, better control over the supply chain could reduce the opportunity for economically motivated adulteration, such as the melamine added to wheat gluten that resulted in contamination of pet foods.

C. Summary of Total Costs and Benefits of Potential New Requirements in Supplemental Notice of Proposed Rulemaking

1. Compliance Costs

Table 3 summarizes the estimated cost of this supplemental NPRM, including the following additional annualized costs for potential new requirements that have been added in the supplemental NPRM.

Product Testing costs: $131,400 (domestic and foreign)

Environmental Monitoring: $368,200 (domestic and foreign)

Supplier Program: $734,300 (domestic and foreign)

Economically Motivated Adulteration: $4,316,700 (domestic and foreign)

Review of Records for these Provisions: $258,400 (domestic and foreign)

Table 3. Industry Compliance Costs of Supplemental Proposed Rule (VSB < $2,500,000) ($ million)

Rule Provision	1-Time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Validation of food safety plan	$2.50	$0.83	$1.19	$1.20
Process control monitoring	$0.22	$2.13	$2.16	$2.16
Process control monitoring – verification		$1.09	$1.09	$1.09
Sanitation Controls – writing procedures for food contact surfaces and cross-contamination	$0.28	$0.03	$0.07	$0.06
Sanitation controls – monitoring and verification	$0.22	$3.92	$3.95	$3.94
Subpart B – additional sanitation labor		$7.39	$7.39	$7.39
Training for qualified individuals	$3.26	$0.84	$1.31	$1.22
Attesting to qualified status and changing product labels	$4.83	$0.04	$.0.73	$0.61
Administrative review of rule	$20.07		$2.86	$2.35
Product Testing		$0.10	$0.10	$0.10
Environmental Monitoring		$0.27	$0.27	$0.27
Supplier Program	$2.92	$0.12	$0.54	$0.46

Economically Motivated Adulteration	$0.46	$3.07	$3.14	$3.13
Review of Records		$0.19	$0.19	$0.19
Subtotal	$34.75	$20.02	$24.96	$24.09
ERG Analysis of process controls draft (Includes food safety plan reanalysis and corrective actions)				
Hazard Analysis		$1.77	$1.77	$1.77
Preventive Controls	$14.03	$22.28	$24.28	$23.92
Recall Plan	$4.10	$1.37	$1.95	$1.85
Monitoring	$0.05	$0.83	$0.83	$0.83
Corrective Action	$2.53	$5.36	$5.72	$5.65
Recordkeeping		$2.71	$2.71	$2.71
ERG Subtotal	$20.72	$34.31	$37.28	$36.75
Facilities subject to both part 117 and part 507	$5.39	$6.08	$6.85	$6.71
Domestic Manufacturers	$60.85	$60.42	$69.09	$67.55
Foreign Manufacturers	$19.06	$21.65	$24.36	$23.90
Total	$79.91	$82.07	$93.45	$91.44

FDA displays summary estimates of the costs of our original PRIA and our supplemental PRIA using a very small business definition of $2,500,000. The difference between our original estimate and the supplemental PRIA estimate is that we included the additional cost estimates for product testing, environmental monitoring, supplier verification and economically motivated adulteration and records review for these provisions.

Original Total Annualized Costs	$86.92 million
Re-proposed Total Annualized Costs	$93.45 million
Difference in Total Annualized Costs	$6.53 million

2. Benefits

The changes in the provisions of the supplemental NPRM do not compel FDA to change

its conclusion that it lacks sufficient data to quantify the potential benefits of the supplemental NPRM. FDA remains unable to estimate the effectiveness of the requirements of the supplemental proposed rule to reduce potential adverse health effects in humans or animals.

II. Preliminary Regulatory Impacts Analysis

A. Need for Regulation

As described in the original PRIA (Ref 1) this regulation is required by the FDA Food Safety Modernization Act, Section 103 of which states that FDA must establish through rulemaking, science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls. As a potential part of such standards, in the supplemental 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.

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

In a perfectly competitive market in which consumers and producers both have sufficient information, the optimal level of production of animal foods that are manufactured, processed, packed or held will be provided at an optimal level of safety. In these markets, however, consumers and producers may not have sufficient information on the safety attributes of foods. Although producers do have an incentive to put safety programs into place, the lack of awareness and information about the risk suggests that an inefficiently high demand may exist

for animal food products that are produced without using adequate measures to prevent food borne illness, adulteration, or contamination. Because the demand for many manufactured or processed animal foods may not be sufficiently affected by safety considerations, incentives to invest in safety measures from farm to fork is diminished. Consequently, the market may not provide the incentives necessary for optimal food safety.

With sufficient information for consumers and producers, a legal system that awards compensation for harm done due to unsafe foods has the potential to remedy market imperfections by providing producers with incentives to provide the level of safety that is best for society. Currently, the legal system does not ensure the optimum level of safety for animal foods because both the cause and source of a foodborne illness may not be known to the purchaser or consumer of the food. Even in cases where consumers are aware that a pet's illness was contracted from a specific food, it is often difficult to determine who is ultimately responsible for the illness, since the particular source of contamination is not known in many circumstances.

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

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

B. Number of Facilities

In Table 4, FDA shows its previous estimate of the number of qualified and non-qualified facilities affected by the 2013 proposed rule, assuming a definition of very small business involving less than $2,500,000 in annual sales of animal foods per firm. This estimate is used in this supplemental PRIA.

Table 4. Number of Facilities Affected by Supplemental Proposed Rule with VSB<$2,500,000

Sector	Type	Number of Non-qualified Facilities	Number of Qualified Facilities	Total Facilities
Commercial Livestock Feed Manufacturing	Large Mills	98	0	98
	Medium Mills	291	0	291
	Small Mills	1,575	2,279	3,854
Other Livestock Feed Manufacturing	Wholesalers	414	471	886
	Integrators	546	0	546
Pet Food Manufacturing	Large Operations	42	0	42
	Small Operations	74	270	344
Ingredient Suppliers	Large Suppliers	4	0	4
	Medium Suppliers	49	0	49
	Small Suppliers	49	123	172
Total Domestic Manufacturers		3,143	3,144	6,287
Foreign Manufacturers	Foreign Manufacturers	1,182	661	1,843
Total		4,325	3,805	8,130

Does not include non-employer establishments for wholesalers - very low average sales indicate low probability that these establishments manufacture or process animal food.

In the original PRIA, FDA calculated the costs of the rule assuming that no qualified facilities were part of a multi-facility firm because it lacked the data to determine the number of those facilities. FDA acknowledged that this would result in an overcount of qualified facilities, and therefore an undercount of those facilities subject to subpart C of the 2013 proposed rule. As shown above in Table 4, FDA retains those estimates for this supplemental NPRM.

As an alternative, FDA considers a scenario that assumes that there are 1.5 facilities per firm (which is likely a high estimate for very small businesses) along with the proposed exemption for very small businesses at less than $2.5 million in annual animal food sales. Under this scenario, total annualized compliance costs would rise by less than ten percent, without considering possible offsetting costs such as lower rule review costs per facility and other efficiencies that may be available to multi-facility firms.

FDA discusses its intention to further address the issue of the number of qualified and non-qualified facilities based on the very small business definition for the final rule later in this document.

C. Cost of Potential New Requirements in Supplemental Notice of Proposed Rulemaking

As mentioned above, the supplemental NPRM includes additional potential requirements for facilities subject to subpart C. These include product testing, environmental monitoring, a risk-based supplier program, a requirement to institute controls to help prevent economically motivated adulteration (EMA), and a review of records for verification.

The CGMPs for animal food in the supplemental NPRM have narrowed their focus and would appear to reduce the burden when compared to the CGMPs contained in the 2013 NPRM. The PRIA for the 2013 proposed rule, however, contained only a broad overview of the compliance efforts that would be required, with a subject matter expert (SME) estimate of an

additional labor hour per facility per week. While the supplemental NPRM contains a narrower, more focused set of CGMPs that in all likelihood would reduce the compliance burden when compared with the 2013 NPRM, the uncertainty surrounding the original compliance cost estimate leads FDA to retain its 2013 compliance cost estimate.

1. Product testing

a. Labor Costs

FDA considered requiring verification by scientifically valid in-process or finished product testing, where appropriate, in its October 29, 2013 proposed rule. In the supplemental NPRM, we offer a potential product testing provision that 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 animal food, and the nature of the preventive control.

The 2011 ERG report (Ref 2) includes a testing model that identifies *Salmonella* as the pathogen for which some facilities would likely test. ERG judges that the only facilities that would need to undertake *Salmonella* testing of either in-process or finished products would be some of the small pet food manufacturers and small ingredient suppliers. ERG also includes salt testing for those medium and small feed mills and wholesale facilities that do some mixing, but do not currently have a procedure for testing. FDA, however, assumes that no salt testing would be required as a preventive control verification activity, as salt testing is used to determine the uniformity of a mixed feed, rather than to identify animal food hazards. The ERG testing model also includes moisture testing for some medium and small ingredient manufacturers that do not currently have a procedure for moisture testing, and urease testing for some ingredient manufacturers of all sizes that do not currently have a procedure for urease testing (see the

testing cost section in the 2011 ERG report, and Appendix A of the report, for a full explanation of the testing program) (Ref 2). FDA, however, would not expect urease and moisture testing to be implemented as an activity for verification of preventive control implementation and effectiveness because urease testing of soybeans and moisture testing of ingredients are typically used to determine ingredient quality rather than to identify the presence of a hazard. Therefore, urease and moisture testing were not included in any compliance costs from the ERG testing model.

As shown in Table 5, FDA estimates that 102 non-qualified small pet food manufacturers and 67 non-qualified small ingredient supplier facilities would be subject to proposed subpart C. ERG reports that only these two types of facilities do not currently test animal food products for *Salmonella* but might decide to do so under proposed section 507.49(a)(2), if finalized. ERG estimates that 20% of both small pet food manufacturers and small ingredient suppliers would have at least a partially insufficient *Salmonella* testing regimen of animal food products (imperfect compliance), resulting in about 20 small pet food manufacturers and about 13 small suppliers that would need to perform additional testing. The ERG report also estimates that of these facilities, the small pet food manufacturers would be 30% out of compliance (or perform about 70% of the necessary testing), while the small supplier facilities would be 100% out of compliance (or perform none of the necessary testing). The ERG report estimates that a pet food manufacturing facility without any current testing would require 667 hours to comply, and an ingredient supplier would require 50 hours to comply. The ERG test model uses a labor scale factor based on the relative sizes of the estimated tonnages of output of facilities within a category (e.g., small and large pet food manufacturers). For small pet food manufacturers, this

labor scale factor is 1, while for small ingredient suppliers it is 0.63.[1] The results of these factors is about 200 hours of labor for *Salmonella* testing at the small pet food manufacturers, and about 31 hours of labor for *Salmonella* testing for small ingredient suppliers (see Table 5).

In total, FDA used the factors from the ERG testing cost model (excluding the salt, urease and moisture testing costs) and the combined 169 small pet food manufacturers and small ingredient manufacturer facilities to project an additional $102,100 in annual labor costs for the potential new requirement of product testing.

Table 5. Potential Product Testing Provision Labor Costs

	Small Pet Food Manufacturers	Small Ingredient Manufacturers
Number of Non-qualified Facilities	102	67
Percent of Facilities out of Perfect Compliance with Supplemental NPRM	20%	20%
Number of Facilities that Would Need Additional Testing	20	10
Total Hours of Testing that Would Be Necessary Per Facility	667	50
Of Those out of Perfect Compliance, Percentage of Non-compliance with Supplemental NPRM	30%	100%

[1] The ERG report estimates that a feed mill of medium size produces 33,000 tons of feed per year, and that an ingredient supplier of medium size produces 60,000 tons of feed ingredients per year. These primary estimates are given a labor scale factor of 1.0. ERG then estimates the animal feed tonnages produced for large mills, small mills, wholesalers and integrated facilities, and assigns them a labor scale factor equal to their estimated animal feed tonnage divided by the tonnage of the primary feed mill. It does the same for large and small ingredient suppliers based on the animal feed tonnage of the primary ingredient supplier. These labor scale factors are then used to increase or decrease the labor hours at each facility, but only for those compliance activities whose costs are judged to be dependent on the size of the facility.

Labor Scale Factor	1.00	0.63
Number of Hours of Labor for Facility to Comply with Supplemental NPRM	200	31
Hourly Labor Cost (Includes Overhead)	$22.61	$22.61
Labor Costs per Facility	$4,500	$700
Total Labor Costs by Facility Type	$92,600	$9,500
Total Labor Costs[1]	$102,100	

1. Total cost may not be exact due to rounding.

Total labor costs for domestic facilities are estimated at $74,200.

b. Capital Costs

FDA uses many of the same cost model factors, along with additional factors, for estimating the capital costs of product testing as it does for the labor costs of product testing. In this case, FDA uses the *Salmonella* test kit cost estimate from the ERG report, adjusted for inflation to 2012 dollars, of $4.34. ERG developed estimates of 1,000 *Salmonella* tests per small pet food manufacturer and 46 *Salmonella* tests per small ingredient manufacturer (Ref 2). The annual capital costs of product testing for *Salmonella* at facilities that would need additional testing is estimated at about $1,300 per small pet food manufacturing facility, and at about $200 per small ingredient supplier facility. The total capital costs of the potential product testing requirements needed to comply with the supplemental NPRM is estimated at about $26,700 for small pet food manufacturers, and at about $2,700 at small ingredient manufacturers, with a combined total of about $29,400 (see Table 6).

Table 6. Potential Product Testing Provision Capital Costs

	Small Pet Food Manufacturers	Small Ingredient Manufacturers
Number of Non-qualified Facilities	102	67
Percent of Facilities out of Perfect Compliance with Supplemental NPRM	20%	20%
Number of Facilities that Would Need Additional Testing	20	13
Total Number of Annual Tests per Facility	1,000	46
Of Those out of Perfect Compliance, Percentage of Non-compliance with Supplemental NPRM	30%	100%
Number of Tests for Facility to Comply with Supplemental NPRM	300	46
Product Test (*Salmonella*) Cost	$4.34	$4.34
Capital Costs for Product Testing per Facility that Would Need Additional Testing	$1,300	$200
Total Capital Costs for Product Testing by Facility Type	$26,700	$2,700
Total Capital Costs[1]	$29,400	

1. Total cost may not be exact due to rounding.

The compliance costs for domestic facilities are estimated to be $21,300.

c. Total Potential Product Testing Provision Costs

The total cost of the potential product testing provision is estimated at about $131,500, with the majority resulting from labor costs of sampling the animal food products and testing those samples. For domestic facilities, the total compliance cost estimate for product testing would be $95,500.

The ERG cost model includes the cost of both writing the procedures for product testing and writing and implementing the procedures for corrective actions that would be taken as a

result of the product testing. As such, FDA has not included additional cost estimates to account for those efforts here.

2. Environmental Monitoring

Environmental monitoring programs, when implemented appropriately based on the facility the food, and the nature of the preventive controls, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards. Not all facilities would need to conduct environmental monitoring if this potential requirement is finalized; only those facilities where pathogens need to be addressed in the food safety plan would be expected to conduct such testing.

Effective environmental pathogen controls would be product, process, and plant specific. Effective environmental pathogen control would not target all pathogens that could potentially come from the environment, but rather those that are significant hazards based on product and production procedures. FDA subject matter experts (SMEs) currently expect that *Salmonella* would be the organism of concern for certain dry animal food products, and estimate that these facilities would conduct such testing on a monthly basis as a minimum frequency.

FDA uses the sampling time, testing time and capital cost estimates that ERG developed for the raw material testing and product testing regimen in the process controls final report to estimate the testing costs of the potential environmental monitoring requirements(Ref. 2). These factors sum to about $19.20 per sample tested using a quick time test that is performed at the facility. FDA bases its estimate of 15 samples per month on information from its SMEs. The result of these two factors is about $290 per month per facility for environmental testing for *Salmonella*. FDA SMEs currently expect that only pet food manufacturing facilities would be required to perform *Salmonella* testing. FDA estimates that about 160 facilities would be subject

to this requirement. Based on the current compliance estimates from an ERG survey of facilities producing human foods (Ref. 3), FDA estimates that 105 facilities (or 66%) of the 160 would need to begin environmental monitoring. Total annual testing costs for this alternative are estimated at about $368,200, or about $3,500 per facility that would need to begin environmental monitoring if these provisions were to be included in the final rule (see table 7).

Table 7. Annual Cost of Potential Environmental Monitoring Provision

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
No. of facilities subject to proposed part 507	41	61	57	1	160
Percent that currently test	21%	28%	50%	62%	
No. of facilities that would need to begin testing	32	44	28	1	105
Cost per facility for annual testing	$3,496	$3,496	$3,496	$3,496	
Total testing costs for environmental monitoring[1]	$113,100	$153,600	$99,600	$1,800	$368,200

1. Total cost may not be exact due to rounding.

The compliance costs for domestic facilities are estimated to be $267,600. FDA seeks comment and data concerning other facility types (for example, manufacturers of (1) milk replacers for dairy calves, and (2) spray dried plasma products) that would also be likely to conduct the potential environmental monitoring activities as preventive control verification.

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, a 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, for which the preventive controls at the receiving facility are adequate to

significantly minimize or prevent each of the significant hazards, or for which 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.

If the potential supplier program provision is finalized, the receiving facility would be required to conduct one or more of the following verification activities, with certain exceptions: 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 or animals, the receiving facility would need to 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).

As noted above, a receiving facility would not be required to establish and implement a supplier program for raw materials and ingredients for which 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. Under this baseline condition, compliance with the proposed supplier program would likely be less costly than when compliance would require those verification activities whose costs are estimated later in this section of this analysis. FDA does not have any data with which to estimate the percent of facilities that would not be required to perform the verifications activities discussed below, and does not include a

percentage in its cost estimation. As such, the cost totals for this section may represent the high end of the range of true compliance costs.

FDA also cannot say which individual facilities or facility types would implement preventive controls to significantly minimize or prevent significant hazards. The likelihood of all significant hazards being significantly minimized or prevented by the receiving facility would depend greatly on the products produced at each facility and how those products are produced. For this analysis we assume as a baseline that no specific industry or facility has a complete written supplier program in place, which may result in an overestimate of actual compliance costs for this provision. FDA requests comment on both the likelihood that specific facilities or industries would not need a supplier program because all hazards are reduced or eliminated at the receiving facilities, and the number or percent of receiving facilities whose customers could provide a written assurance that each has established and is following procedures that would significantly minimize or prevent these hazards.

a. Written Procedures

If the potential supplier program is finalized, receiving facilities that determine they need a supplier program would need to have the program in writing. Such a written program, in determining the appropriate verification activities, would 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, 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 the supplier in correcting problems, and any other factors as

appropriate and necessary. If finalized, FDA estimates that it will take a production manager 16 hours to write such a program. FDA asks for comment on the time it would take to develop the written procedures for a supplier program. FDA estimates this cost for all facilities that manufacture animal food and are registered in the Food Facility Registration (FFR) database. The database likely over-represents the real number of facilities that would need to take action to comply that would incur costs due to the number of receiving facilities that may determine they have no significant hazards or they have preventive controls adequate to significantly minimize or prevent each of the significant hazards. Table 8 shows the cost of writing a program for these facilities.

Table 8. Potential Supplier Program – Written Procedures

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Number Of Domestic Manufacturing Facilities	1,073	2,588	662	1	4,325
Number of hours to write program	16	16	16	16	
Wage rate	$58	$58	$58	$58	
First year cost	$997,200	$2,404,700	$614,900	$1,300	$4,018,000
First year costs annualized over 10 years	$142,000	$342,400	$87,600	$200	$572,100
Annualized cost per affected facility	$132	$132	$132	$132	

FDA estimates one-time compliance costs for domestic facilities at $2,920,000, which equates to an annualized cost of $415,700 over 10 years at a 7% discount rate (and $342,300 at a 3% discount rate).

b. Verification activities for suppliers

If the potential supplier program is finalized, facilities would need to have verification activities for their raw material or ingredient suppliers. Verification activities would be required unless all significant hazards in the raw materials or ingredients are controlled by the receiving

facility, the ingredient does not contain a significant hazard, or the customer of the receiving facility provides a written assurance that it has established and is following procedures to significantly minimize or prevent the hazard. As noted above, this analysis assumes that none of these three conditions would be met at any receiving facility and each will undergo some verification activity, resulting in the high end of the range of costs.

The owner, operator, or agent in charge of a receiving facility would be required to conduct, or obtain documentation of, an initial onsite audit of a supplier before using a raw material or ingredient from that supplier and periodic onsite audits, when the hazard is one for which there is a reasonable probability that exposure to the hazard would result in serious adverse health consequences or death to humans or animals. If a supplying facility is not controlling significant hazards, the receiving facility would need to take prompt action, which may include discontinuing the use of the supplier, to ensure the raw materials or ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated. Based on the experience of FDA SMEs, FDA estimates that the ingredient suppliers subject to proposed part 507 comprise all raw material or ingredient supplier facilities supplying all those other facilities subject to proposed part 507. A proportionate number of foreign manufacturing facilities have been added to this total. This estimate also assumes that the remaining supplier facilities also supply food manufacturing, processing, packing, and holding facilities that would be subject to a similar alternative to the proposed rule for human food and would therefore be subject its supplier approval program. Their supplier program compliance costs are not included in this analysis.

i. Audits of suppliers

FDA estimates that supplying facilities would undergo one audit annually to satisfy an

alternative requirement that receiving animal food facilities verify their suppliers of raw materials and food ingredients. The estimate of one audit per year will overstate auditing frequency in cases where the ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. In those cases, an audit would be required periodically, which would likely be less than once per year, resulting in compliance costs that would be lower than those estimated below.

In developing its cost estimates (see Table 9), FDA uses the assumption developed for the cost analysis of the supplemental notice of proposed rulemaking for human food that a supplier having a single audit done under certain rigors would satisfy multiple customers. Further, FDA uses the responses to the GMP survey of human food processors (Ref. 3) to estimate the percent of facilities that do not currently conduct audits. And last, FDA further bases its costs estimates on the costs per facility developed for the audits of human food processors. FDA requests public comments and data on these assumptions.

Table 9. Annual Cost of Raw Material and Ingredient Supplier Audits for a Potential Supplier Program Provision

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
No. of supplier facilities subject to proposed part 507	56	83	0	0	139
Percent of facilities that do not currently conduct audits	43%	21%	14%	0%	
No. of facilities that would need to conduct audits	24	17	0	0	42
Cost per audit	$2,625	$3,750	$4,375	$5,000	
Travel and incidental expenses per audit	$625	$625	$625	$625	
Total cost of audit annually	$79,100	$75,300	$0	$0	$154,400
Annual cost per affected facility	$3,250	$4,375	N/A	N/A	

FDA estimates compliance costs for domestic facilities at $112,200.

Some supplier facilities may fail audits conducted and would need to take corrective actions to fix problems at the facility, assuming the facility wants to remain a supplier. After corrective actions have occurred, the supplying facility would need to be re-audited. FDA does not have information on the number of facilities that would fail an audit, undertake corrective actions, and then be re-audited. Since supplying facilities will likely have done all that would be required to pass an audit in the course of complying with this requirement, it is unlikely that a significant number would need to be re-audited.

As another alternative to an audit, a receiving facility would be allowed to rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has recognized as comparable or determined to be equivalent to that of the United States when certain other conditions are met. FDA does not know the percent of suppliers that would be able to use this alternative approach. For those that could, however, compliance costs would be reduced as the audit costs would not be incurred.

ii. Potential Supplier Verification Activities other than Audits

If the hazard to a raw material or ingredient is not one for which there is a reasonable probability that exposure to the hazard would result in a serious adverse health consequence or death to humans or animals, then, under this potential alternative, the receiving facility would have the choice of the following as a supplier verification activity: (1) auditing the supplying facility periodically, (2) sampling and testing the raw materials or ingredients before use, (3) periodically reviewing the supplier's food safety records (e.g., audits of their suppliers), or (4) other appropriate supplier control verification measures based on the risk associated with the ingredient and the supplier. The cost analysis for the analogous potential requirement in the

supplemental NPRM for human foods assumed that this potential requirement would likely be addressed by testing ingredients from suppliers. FDA assumes manufacturers of animal food would do the same to comply with this potential requirement. The ERG analysis of the process controls draft for animal foods included a raw material testing regimen for those hazards that were identified in the hazard analysis as being likely to occur (see Appendix A of the ERG report (Ref. 2) for a full description of the animal feed testing model). Using that cost model on the 4,325 facilities from the FFR database (including both domestic and foreign) that would be subject to this proposed rule if finalized results in ingredient testing costs of about $18.3 million. Since that analysis already accounts for raw material and ingredient testing costs, where appropriate, and those costs are already included in this analysis, no additional testing costs are added here for the supplier program.

iii. Potential Verification activities for suppliers that are qualified facilities

This alternative would provide an optional set of verification activities for suppliers that are qualified facilities. If the potential supplier program provision is finalized, receiving facilities with suppliers that satisfy the criteria to be considered a "qualified" facility would have the option of submitting documentation at the end of each calendar year that their suppliers meet the definition of a qualified facility. Additionally, the receiving facility would need to obtain written assurance at least every 2 years that the supplier is producing raw material or ingredients in compliance with the 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. A brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food would be required.

We previously calculated (in the section of the October 29, 2013 PRIA on qualified

facilities) the cost for all qualified facilities to document that they meet the definition of a qualified facility. FDA estimates that there may be a small number of affected suppliers that would be qualified under the very small business definition of having less than $2,500,000 in total annual sales of animal food. Following the FDA cost estimate of the revised PRIA for the human food supplemental notice of proposed rulemaking, FDA presents the cost estimate 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 animal food. FDA estimates that these few qualified supplier facilities would require about two hours to assemble this documentation to be submitted to their receiving facility customers every other year (see Table 10).

Table 10. Annual Cost of Potential Supplier Approval Program for Qualified Facilities

	< 20 employees	20 to 99 employees	100 to 499 employees	>500 employees	Total
No. of Qualified Suppliers	134	0	0	0	134
Hours to Prepare Documentation	2	2	2	2	
Hourly Wage	$58	$58	$58	$58	
Total cost	$15,500	$0	$0	$0	$15,500
Average annual cost	$7,800	$0	$0	$0	$7,800
Average cost per facility per year	$58	$0	$0	$0	

FDA estimates compliance costs for domestic facilities at $7,200 annually.

iv. Total Costs of Potential Supplier Program Provisions

FDA estimates the total costs of the supplier program would be the sum of the costs of the written procedures and the verification activities. Total annualized costs are estimated at $734,300 per year in Table 11.

Table 11. Potential Supplier Program Costs Summary

	< 20 employees	20 to 99 employees	100 to 499 employees	>500 employees	Total
Annualized Costs of Written Program	$142,000	$342,400	$87,600	$200	$572,100
Annual Costs of Auditing Suppliers	$79,100	$75,300	-	-	$154,400
Annual Cost for Qualified Supplier Facilities	$7,800	-	-	-	$7,800
Total Supplier Program Costs	$228,900	$417,700	$687,600	$200	$734,300

FDA does not separately include the $18.3 million in raw ingredient testing costs at receiving facilities for the supplier program because these costs have previously been included as process controls in the cost model.

FDA estimates total compliance costs for the potential supplier program for domestic facilities at $535,100.

4. Economically Motivated Adulteration

The supplemental NPRM adds the proposed 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 of this requirement. The additional costs result from the time to conduct a more thorough hazard identification, and the actions that are likely to be taken to reduce any hazard that is identified as significant. The additional benefits would be reduced chances of injury or death to animal and humans.

FDA SMEs consider that the most likely type of intentional adulteration which many animal food facilities would determine to be a hazard significant enough to include in their food safety plans would be the use of non-protein nitrogen (NPN), e.g., melamine, in some animal food ingredients.

a. Compliance Costs

FDA estimates that all animal food facilities conducting a hazard analysis would incur additional costs to determine if there are any incoming ingredients for which it is known or

reasonably foreseeable that the ingredients may contain hazards that were deliberately introduced for economic gain, and if so, whether they are significant. While some facilities may already conduct such an analysis, FDA has no data to estimate the number of those facilities. To the extent that manufacturers are already conducting such analyses, the actual costs of the rule would be lower than our estimates.

FDA estimates that this would add an average of two hours to the initial hazard analysis of each process. FDA also estimates that this requirement would add an average of an additional half-hour to the average initial writing time of each hazard analysis. Further, FDA estimates that this requirement would add a half-hour to the average time it takes to conduct the updated hazard analysis every other year (as was estimated in the original 2013 PRIA), and 0.1 hours to the time required to write down the updated hazard analysis. FDA bases its labor cost on that of an industrial production manager of $58 (including all benefits and other overhead costs). FDA requests comments on these estimates.

The compliance costs for the additional NPN testing are based on FDA SME's understanding that NPN testing would occur when receiving facilities are establishing a new supplier relationship. FDA estimates that this would affect five to ten new suppliers annually for each facility that would test for NPN. FDA further estimates that the receiving facility would take about 4 samples to test for NPN. A small sample of testing lab prices shows that the average price for NPN testing is $30 (Ref. 4). Total annualized costs over 10 years at a seven percent discount rate are estimated at $4,316,700, as shown in Table 12. Using a 3% discount rate over 10 years, this cost is estimated at $4,300,900.

Table 12. Compliance Costs for Requirements to Address Economically Motivated Adulteration

No. of Employees per Facility	<20	20-99	100-499	>500	Totals
Number of Facilities	1,073	2,588	662	1	4,325
Wage Rate	$58	$58	$58	$58	
Conducting the Initial Hazard Analysis					
Labor Hours per Facility	2	2	2	2	
One-Time Cost	$124,600	$300,600	$76,900	$200	$502,300
Annualized Cost	$17,800	$42,800	$10,900	<$100	$71,500
Writing the Initial Hazard Analysis					
Labor Hours per Facility	0.5	0.5	0.5	0.5	
One-Time Costs	$31,200	$75,100	$19,200	<$100	$125,600
Annualized Costs	$4,400	$10,700	$2,700	<$100	$17,900
Conducting Hazard Analysis Update					
Labor Hours per Facility	0.5	0.5	0.5	0.5	
Annual Frequency	0.5	0.5	0.5	0.5	
Annual Costs	$15,600	$37,600	$9,600	<$100	$62,800
Writing Hazard Analysis Update					
Labor Hours per Facility	0.1	0.1	0.1	0.1	
Annual Frequency	0.5	0.5	0.5	0.5	
Annual Costs	$3,100	$7,500	$1,900	<$100	$12,600
Total Costs - Economically Motivated Adulteration in Hazard Analysis					
Total Annualized Costs (one-time costs annualized plus annual costs	$40,900	$98,600	$25,200	<$100	$164,700
Average Annualized Cost per facility	$38	$38	$38	$38	
Non-Protein Nitrogen Testing (NPN)					
Facilities that Could Require Testing	1,073	2,588	662	1	
Cost per NPN Test	$30	$30	$30	$30	

Annual Number of New Suppliers per Facility	8	8	8	8	
Number of Samples per Facility	4	4	4	4	
Annual Cost	$1,030,400	$2,484,900	$635,400	$1,300	$4,152,000
Average cost per facility	$960	$960	$960	$960	
Total Annualized Costs (one-time costs annualized plus annual costs)	$1,071,300	$2,583,500	$660,600	$1,400	$4,316,700

FDA estimates total annualized costs for domestic facilities at $3,137,000 over 10 years at a seven percent discount rate.

5. Review of Records for Potential New Requirements

Proposed section 507.49(a)(4)(ii) would require that, should these provisions be adopted, records of calibration, product testing, environmental monitoring and supplier verification activities be reviewed to ensure that they are complete, that the activities occurred in accordance with the food safety plan, that the preventive controls are effective, and that appropriate decisions were made about corrective actions. Verification of implementation and effectiveness requires records review for calibration, product testing, environmental monitoring, and supplier verification activities. According to the expert elicitation for human food production facilities, the number of verification records kept and the time spent in review of these records depends on the size of the facility. Based on responses to the ERG survey of human food production facilities, FDA estimates that the percentage of facilities without these verification records varies from about 39% of those with fewer than 20 employees to less than one percent for those with 100 or more employees. This equates to about 950 facilities, all of which would be out of

compliance with the record review verification requirements. Although the review time would likely vary among facilities, FDA uses the estimates from the analysis of the alternative to the proposed rule for human foods that range from 0.25 to 1 hour per month reviewing these records. FDA expects this review to be performed by a production manager with an hourly wage rate of $58 per hour. FDA estimates total annual industry costs for the potential provision to review records would equal about $258,400 (Table 13). Although the 2011 ERG report contains over $6 million in annual recordkeeping costs, it does not appear that these costs include a review of the records as required by the revised proposed rule.

Table 13. Cost of Review of Records of Potential Provisions

	Facilities with				
	< 20 employees	20-99 employees	100-499 employees	> 500 employees	Total
Total number of facilities	1,073	2,588	662	1	4,325
% without verification records	39%	20%	<1%	0%	
Facilities that would need to begin reviewing records	424	525	3	0	952
Hours per month reviewing records	0.25	0.50	0.57	1.00	
Wage rate – hourly	$58	$58	$58	$58	
Annual cost per facility	$174	$348	$397		
Total annual cost by size of facility	$73,800	$183,100	1,600	$0	$258,400

Compliance costs for domestic facilities are estimated at $187,600.

6. Summary of Costs of Potential New Requirements

The sum of the total annualized costs of the five supplemental provisions is estimated at $5.81 million (over 10 years at a seven percent discount rate) for those animal food manufacturing facilities that would be subject to subpart C. The individual costs and cost total are listed below:

Product Testing costs: $131,400

Environmental Monitoring:	$368,200	
Supplier Program:	$734,300	
Economically Motivated Adulteration:		$4,316,700
Review of Records for these Provisions:	$258,400	
Total Costs	$5,809,000	

D. Analysis of Alternatives

1. Food Safety and Food Hygiene Training

FDA considered requiring mandatory education and training requirements for facility personnel in proposed§ 507.14(b) for both the original October, 2013 NPRM and the supplemental NPRM. If it had been required, plant management would need to provide education and training to ensure that personnel engaged in manufacturing, processing, packing or holding of animal food have the education or experience needed to perform these duties. Also, personnel involved in animal food manufacturing, processing, packing, or holding would need to receive appropriate training on the principles of food hygiene and food safety, including the importance of employee health and personal hygiene.

FDA retains its original assumptions and total compliance cost estimate for this alternative (Ref 1). In sum, the total annual cost of both the principles of food safety and the food hygiene, including personal hygiene, is estimated to be $11.05 million.

III. Small Entities Affected

The Regulatory Flexibility Act requires agencies to prepare a regulatory flexibility analysis if a rule is expected to have a significant economic impact on a substantial number of

small entities. The discussion in this section and the previous sections constitutes the initial regulatory flexibility analysis.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. FDA has been directed by Congress in the Food Safety Modernization Act of 2011 (FSMA) to issue regulations that establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls for those facilities that are required to register with FDA under section 415 of the FD&C Act. Satisfying the mandate of Congress is a primary objective of this proposed rule.

A. Description and Number of Small Entities

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the rule and an estimate of the number of small entities to which the rule would apply. Section III (A) of the PRIA of the October 29, 2013 proposed rule discusses the relevant categories of the North American Industrial Classification System (NAICS) in which the facilities subject to the proposed rule are designated, and their corresponding size categories as defined by the Small Business Administration (SBA). For both the 2013 proposed rule and this supplemental NPRM, a substantial number of facilities would be expected to qualify as small businesses under the SBA definitions.

B. Impacts on Small Entities

Section III (B) of the PRIA of the October 29, 2013 proposed rule presents the compliance costs as a percentage of the average value of shipments by the number of employees using 2007 Census data. That assessment concluded that among the various types of industry facilities affected by that proposed rule, there could be significant impacts on a substantial

number of those facilities. While the proposed changes in the supplemental NPRM would result in fewer facilities subject to subpart C than in the original proposed rule, a substantial number of facilities that are considered small entities under the SBA definitions could still incur significant economic impacts.

C. Regulatory Relief for Small Entities

Substantial relief from the compliance costs of this supplemental NPRM would be provided to those firms that meet the criteria for qualified facilities, by exempting them from subpart C – Hazard Analysis and Risk-Based Preventive Controls, as discussed elsewhere in this analysis. Those businesses that meet the requirements of qualified facilities would incur annualized costs of about $1,800, composed of the annualized costs of (1) the initial review of the rule, (2) the additional labor for sanitary efforts under subpart B, and (3) the costs to attest to their qualified status. About $400 of this is the annualized cost of the initial review of the rule, which as stated previously, most likely overstates the cost for qualified firms since they would be exempt from subpart C which contains substantial parts of the rule.

The proposed rule would also allow small businesses, defined by the 2013 proposed rule as employing fewer than 500 persons, two years after publication of any final rule issued to comply with the requirements of the rule if finalized. And very small businesses, defined under the supplemental NPRM as those facilities with gross annual sales of animal food of less $2,500,000 (adjusted for inflation), would have three years after publication of the final rule to comply with the requirements of the rule if finalized. This would give the three year transition period to 3,805 facilities, including the 1,386 non-employer facilities.

IV. Anticipated Modifications to the Estimate of the Cost of the Final Rule

For the final rule, FDA anticipates making several modifications to our estimate of the cost of our proposed rule, including the provisions in the supplementary proposal. Based on comments received from both the 2013 proposed rule and the supplemental NPRM, and other additional information, FDA anticipates improving our cost estimates to more accurately reflect real world practices. FDA anticipates that most, although not all, of the adjustments will increase the estimate of the cost of the final regulation.

FDA will revise its estimate of the total number of covered facilities based on the latest data from the FFR database. We expect the total number of covered facilities to increase at least slightly.

FDA will modify its method for determining the number of qualified and non-qualified facilities. As stated earlier in this document, FDA originally made its estimate for qualified facilities acknowledging it would result in an overcount because it did not have the data to account for the existence of multi-facility firms. FDA intends to revise its estimate by reviewing more recent proprietary data on those subsets of manufacturer categories with significant numbers of facilities that are currently defined as qualified at the $2.5 million sales level for very small businesses. The effect of this adjustment will likely be that more facilities would be required to comply with the proposed rule at any given definition of "very small business." Assuming this change can be made, the costs of the rule would likely increase. If FDA cannot revise its estimates using the proprietary data, it will make an estimate based on the revisions to the human food qualified facilities revisions and its understanding of any relevant differences between the human food industry market structure and the animal food industry market structure that could impact the number of qualified facilities. The scenario assuming 1.5 facilities per firm,

presented previously in this document, showed that the existence of multi-facility firms would increase the total costs of the rule, but likely not significantly. FDA has not been able to make a more precise adjustment for this revised proposed rule.

FDA anticipates increasing all the wage rates used in our estimates. The increase will occur due to inflation and also due to a change in our estimate of the costs of total labor overhead. FDA is still in the process of coordinating the firm coverage among the multiple regulations required by FSMA. As the provisions of the individual rules are revised and updated, FDA will evaluate the coverage to ensure the various components of the rules are consistent and not redundant. Based on public comments or other new information, FDA may adjust its estimate of the additional efforts necessary to comply with this supplemental NPRM at those facilities that manufacture both food for humans and food for animals.

Based on public comments and other information, FDA may revise its estimate of product testing costs to account for the value of holding animal food products while awaiting the results of product testing.

Finally, FDA expects changes to our estimates based on potential new sources of information, such as new studies or industry data, in addition to other information from comments we are still reviewing on the original proposal.

References

1. FDA. Preliminary Regulatory Impact Analysis – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals available under Docket FDA-2011-N-0922.

2. Economic Analysis of Proposed Animal Feed Regulation – A Cost Analysis for the Livestock Feed and Pet Food Industries, Final Report, April 12, 2011, ERG, Lexington, MA. FDA contract HHSF 2232008100171, task order no. 15.

3. 2010 Nationwide Survey of Food Industry Safety Practices, Draft Final, ERG, January 10, 2011, contract number 223-01-2461, task order 7, ERG task number 0152.00.007.001.

4. NPN Pricing Sample Document. Prices of seven commercial laboratories for testing of non-protein nitrogen in June 2014.