Department of Health and Human Services

Food and Drug Administration

FSMA Final Rulemaking for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Docket No. FDA-2011-N-0922

Final Regulatory Impact Analysis

Final Regulatory Flexibility Analysis

Final Unfunded Mandates Reform Act Analysis

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

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I. Introduction and Summaries

We have examined the impacts of the final 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 final rule is a 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 final rule would impose annualized costs that range from $27,000 to $34,000 on many small entities, the Agency determined that the final 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 (2014) Implicit Price Deflator for the Gross Domestic Product. We expect this final rule to result in a 1-year

expenditure that would meet or exceed this amount.

A. Summary of Changes from the Proposed Rule to the Final Rule

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 Preliminary Regulatory Impact Analysis ("2013 PRIA") (Ref. 1) included requirements for facilities subject to subpart C to prepare and implement a written food safety plan, perform a hazard analysis, and identify and implement preventive controls for the mitigation or prevention of those hazards. Our 2013 PRIA included a 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" ("ERG report") (Ref. 2). At FDA's request, ERG estimated the costs to comply with an early, working version for a process control standards rule for animal food ("process controls draft").

The supplemental notice of proposed rulemaking ("supplemental notice") included additional proposed 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 defined a very small business as one with total annual sales of animal food of less than $2.5 million, adjusted for inflation. The estimated costs of the supplemental notice equaled the sum of the costs of the 2013 proposed rule and the potential additional requirements added by the supplemental notice. As analyzed in the PRIA accompanying the supplemental notice ("2014

PRIA"), we estimated the total annualized compliance costs of the supplemental notice at $93.45 million.

The final rule includes a requirement that personnel involved in animal food production receive training in the principles of animal food safety and animal food hygiene, which we estimate at an annualized cost of about $800,000.

We estimate that the final rule will impose annualized compliance costs that range from about $139 million to $171 million, based upon a seven percent discount rate over 10 years (at a three percent rate, the range would be about $136 million to $167 million.)

We were unable to quantify the benefits of both the 2013 proposed rule and the supplemental notice. We tentatively concluded that the provisions in the supplemental notice might result in fewer instances of contaminated animal food. Further, 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. Data gaps persist that prevent us from quantifying all expected benefits of the final rule. For the final RIA, however, we estimate the value of the reduction in human cases of salmonellosis from handling pet food, and the reduced risk of serious illness and death to pets from foodborne hazards. These quantified benefits range from $10.1 million to $138 8million (see Table 1). Additionally, we describe the types of benefits that we would expect to occur, if we had data demonstrating the reduction in risk to public health (human and animal) as a result of the final rule.

Table 1. Industry Compliance Costs and Benefits of Final Rule ($ million)

	One-Time	Annual	Total Annualized	Total Annualized

			Cost at 7%[1]	Cost at 3%[1]
Total Costs	$135.6 to $160.1	$119.7 to $147.8	$139.0 to $170.6	$135.5 to $166.6
Benefits	N/A	10.1 to 138.0	$10.1 to $138.0	$10.1 to $138.0

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

In Table 1a, we provide the accounting information.

Table 1a. Summary of Benefits, Costs and Distributional Effects of Final Rule

Category		Primary Estimate	Units			Notes
			Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized $millions	$10.1 to $138.0	2013	7%	10 years	
	Monetized $millions/year	$10.1 to $138.0	2013	3%	10 years	
	Annualized Quantified		2013	7%	10 years	
			2013	3%	10 years	
	Qualitative	Improved food safety systems can reduce the risk of adverse human health effects from contaminated animal food, reduce the risk of serious illness and death to animals, and reduce losses from safety related recalls of contaminated animal food.				
Costs	Annualized $millions	$139.0 to $170.7	2013	7%	10 years	Estimates assume all foreign costs are passed on to US consumers.
	Monetized $millions/year	$135.6 to $166.7	2013	3%	10 years	
	Annualized Quantified		2013	7%	10 years	
			2013	3%	10 years	
	Qualitative					
Transfers	Federal Annualized Monetized $millions/year		2013	7%	10 years	
			2013	3%	10 years	
		To:				
	Other Annualized Monetized $millions/year		2013	7%	10 years	
			2013	3%	10 years	
		To:				
Effects	State, Local or Tribal Government: No effect					
	Small Business: The final rule will 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 Total Costs and Benefits of Provisions in the Final Rule

1. Compliance Costs

For the final rule, we estimate annualized compliance costs at a range of $139 million to $171 million. Below, in Table 2, we display the detailed cost estimate range by type of provision using a cost model similar to, but revised from, the cost model used in the 2013 and 2014 PRIAs. The largest increase is due to the revision to labor overhead from 50 percent to 100 percent of the wage rate. This results in an additional $27 million in labor costs. Training in animal food safety and hygiene in subpart A adds another $800,000 in annualized labor costs. The increase of over 400 facilities not eligible for the qualified facility exemption ("non-qualified facilities") increases total costs by about $12 million. A significant change to the wage rate of animal food industry consultants results in an additional $9 million in labor costs. Very small businesses (not subject to subparts C or E) will incur total annualized costs estimated at $2,400 per facility.

The present value of total costs for all domestic facilities over ten years at a seven percent discount rate ranges from $0.71 billion to $0.88 billion (at a three percent discount rate, it ranges from $0.87 billion to $1.07 billion). The present value of total costs for all foreign facilities over ten years at a seven percent discount rate ranges from $0.24 billion to $0.29 billion (at a three percent discount rate, it ranges from $0.29 billion to $0.36 billion). The present value of total costs for all facilities over ten years at a seven percent discount rate ranges from $0.97 billion to $1.19 billion (at a three percent discount rate, it ranges from $1.15 billion to $1.42 billion).

Table 2. Compliance Costs of Final Rule
($ million)

Rule Provision	One-time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Validation of preventive controls	$2.57	$0.43	$0.79	$0.73
Monitoring of process controls	$0.28 - $0.69	$2.83 - $6.55	$2.87 - $6.65	$2.86 - $6.63
Verification of monitoring of process controls		$1.43 - $3.54	$1.43 - $3.54	$1.43 - $3.54

Sanitation Controls – documenting procedures for cleanliness of animal food contact surfaces and prevention of cross-contamination	$0.39 - $0.49	$0.04 - $0.05	$0.09 - $0.12	$0.09 - $0.12
Sanitation controls – monitoring and verification	$0.25 - $0.33	$5.10 - $6.48	$5.13 - $6.53	$5.12 - $6.52
Subpart B – additional sanitation labor		$8.93	$8.93	$8.93
Training for preventive controls qualified individuals	$3.65	$1.06	$1.58	$1.49
Attesting to qualified facility status and changing product labels	$5.19	$0.07	$0.80	$0.67
Training in animal food safety/hygiene	$1.02 - $4.39	$0.41 - $4.32	$0.55 - $1.94	$0.53 - $1.83
Product Testing		$0.18	$0.18	$0.18
Environmental monitoring		$0.48	$0.48	$0.48
Hazard analysis for economically motivated adulteration	$0.58	$2.99	$3.08	$3.06
Supply-Chain program	$3.73	$0.50 - $0.61	$1.04 - $1.14	$0.94 - $1.04
Reviewing records to verify implementation and effectiveness of preventive controls		$0.24 - $0.45	$0.24 – 0.45	$0.24 - $0.45
Costs to facilities subject to subpart C that do not identify a hazard requiring a preventive control		$1.35	$1.35	$1.35
Administrative review of rule	$33.73		$4.80	$3.95
Subtotal	$51.40 - $55.36	$26.15 - $34.39	$33.47 - $42.27	$32.17 - $40.88
ERG Analysis of process controls draft (Includes food safety plan reanalysis and corrective actions)				
Hazard Analysis		$4.60	$4.60	$4.60
Preventive Controls	$25.0	$32.23	$35.79	$35.17
Recall Plan	$5.74	$1.91	$2.73	$2.59
Monitoring	$0.07	$1.13	$1.14	$1.14
Corrective Action	$4.43	$7.43	$8.06	$7.95
Recordkeeping		$3.45	$3.45	$3.45
ERG Subtotal	$35.25	$50.75	$55.77	$54.88
Facilities subject to both part 117 and part 507	$14.81 - $29.63	$12.89 – $25.77	$14.99 - $29.99	$14.62 - $29.25
Domestic Manufacturers	$101.47 - $120.24	$89.78 - $110.91	$104.23 - $128.03	$101.68 - $125.00
Foreign Manufacturers	$34.08 - $39.88	$29.92 - $36.99	$34.77 - $42.67	$33.91 - $41.66
Total	$135.55 - $160.12	$119.70 - $147.89	$139.00 - $170.69	$135.59 - $166.66

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

2. Benefits

Data gaps hinder the quantification of the animal food safety problems the final rule will address. Currently animal food companies subject to registration under section 415 of the FD&C Act must report certain food safety incidents to the Agency via the Reportable Food Registry, but no similar requirement exists for veterinarians, livestock producers, or consumers. Although the Agency has some systems in place to track animal food safety problems, no federal agency has a program to track foodborne illness in animals similar to the Centers for Disease Control's (CDC's) surveillance and reporting system for foodborne illness in humans. There are no public registries of animal deaths. The harm caused by some hazards, such as food formulation errors that pose a serious health risk to animals, may not be immediately detectable, leading to underreporting of these types of hazards. Any efforts to track foodborne illness in animals require that observant animal owners recognize when their animals become ill, and realize the cause of the illness may be attributable to a hazard in the animal food. To confirm that a hazard in an animal food caused an adverse health effect requires that a veterinarian conduct diagnostic tests on the affected animal. Even with observant owners, without a national surveillance system to track diagnosed foodborne illness in animals, data gaps will persist.

As discussed in the 2013 PRIA, anecdotal evidence exists that many animal food hazards cause adverse health effects, including death. Lacking data on the baseline occurrence of adverse effects from food safety hazards in animal food, we did not quantify or monetize the benefits of the proposed rule in either the 2013 PRIA or the 2014 PRIA. We still lack sufficient data to quantify the full range of benefits for the FRIA. However, a comment to the supplemental notice included a quantified estimate of some potential benefits of the proposed rule, including an

estimate of the number of humans that suffer from handling contaminated animal food, and an estimate of the willingness to pay to save the life of a pet. We used the information in this comment as the basis to quantify the number of cases of foodborne illness in humans that handle contaminated pet food. We use other information from a national chain of veterinary clinics to develop estimates of the number of dogs and cats that experience foodborne illnesses and are provided medical treatment annually. Additionally, we use the results of an expert elicitation on the potential risk reductions due to the implementation of the final rule to estimate the effectiveness of the final rule. Based upon an effectiveness rate that ranges from 1.8 percent to 24.0 percent, we estimate that at a minimum, the public health benefits of this rule range from $10 million to $138 million. Both the lower bound and upper bound estimates of the quantified benefits are listed below in Table 3. Other non-quantified benefits of the rule include the decreased risk of illness or death of livestock animals, including avoiding the costs to treat illness and avoiding production losses from livestock animals, the decreased risk of illness or death of dogs and cats whose owners do not seek medical treatment, and the decreased risk of illness or death for pets that are not dogs and cats.

Table 3. Value of Certain Types of Public Health Benefits

Type of Benefit	Estimate of cases of foodborne illness seeking medical treatment	Low bound estimate of cases avoided	Upper bound estimate of cases avoided	Expected $ Loss per case	Total Value ($ million)
Assumes a 1.8 percent effectiveness rate					
Reduced risk to humans of salmonellosis from	3,673 to 6,297	66	113	$6,268	$0.4 to $0.7

contaminated pet food					
Reduced risk of illness and death to dogs	143,800	2,600	2,600	$2,434	$6.3 M
Reduced risk of illness and death to cats	76,200	1,400	1,400	$2,434	$3.3
Total value of quantified public health benefits at a 1.8 percent effectiveness rate					$10.1. to $10.3
Assumes a 24.0 percent effectiveness rate					
Reduced risk to humans of salmonellosis from contaminated pet food	3,673 to 6,297	882	1,511	$6,268	$5.5 to $9.5 M.
Reduced risk of illness and death to dogs	143,800	34,500	34,500	$2,434	$84.0
Reduced risk of illness and death to cats	76,200	18,300	18,300	$2,434	$44.5
Total value of quantified public health benefits at a 24.0 percent effectiveness rate					$134.0 to $138.0

3. Comparison of Estimated Costs Between the Proposed Rule Plus Supplemental Notice and the Final Rule

Table 4 presents a side-by-side comparison of the updated estimated costs of the proposed rule plus supplemental notice and the final rule. To present a valid comparison, we have updated the (previously published) estimated costs of the supplemental notice using the latest data and techniques. Estimated total annualized costs to domestic facilities, using a 7 percent discount rate, are $93 million for the proposed rule plus supplemental notice, and $139 million to $171 million for the final rule.

Table 4. Comparison of Updated Estimated Costs of the Proposed Rule Plus Supplemental Notice and the Estimated Costs of the Final Rule

($ million)

Rule Provision	Updated PRIA (Including Supplemental Provisions) – Total Annualized Cost at 7%	FRIA – Total Annualized Cost at 7%
Validation of preventive controls	$0.79	$0.79
Monitoring of process controls	$2.87 - $6.75	$2.87 - $6.65
Verification of monitoring of process controls	$1.43 - $3.54	$1.43 - $3.54
Sanitation Controls – writing procedures for cleanliness of animal food contact surfaces and prevention of cross-contamination	$0.09 - $0.12	$0.09 - $0.12
Sanitation controls – monitoring and verification	$5.13 - $6.53	$5.13 - $6.53
Subpart B – additional sanitation labor	$8.93	$8.93
Training for preventive controls qualified individuals	$1.58	$1.58
Attesting to qualified status and changing product labels	$0.77	$0.80
Training in animal food safety/ hygiene	--	$0.55 - $1.94
Product Testing	$0.18	$0.18
Environmental monitoring	$0.48	$0.48
Hazard analysis for economically motivated adulteration	$3.08	$3.08
Supplier program (Supply-Chain program in final rule)	$1.04 - $1.14	$1.04 - $1.14
Reviewing records to verify implementation and effectiveness of preventive controls	$0.24 - $0.45	$0.24 – 0.45
Costs to facilities subject to subpart C that do not identify a hazard requiring a preventive control	$1.35	$1.35
Administrative review of rule	$6.43	$$6.43
Subtotal	$32.88 – $40.29	$33.47 - $42.27
ERG Analysis of process controls draft (Includes food safety plan reanalysis and corrective actions)		
Hazard Analysis	$4.60	$4.60
Preventive Controls	$35.79	$35.79
Recall Plan	$2.73	$2.73
Monitoring	$1.14	$1.14
Corrective Action	$8.06	$8.06
Recordkeeping	$3.45	$3.45
ERG Subtotal	$55.75	$55.77
Facilities subject to both part 117 and part 507	$14.99 – 29.98	$14.99 - $29.99
Domestic Manufacturers	$103.62 – $126.02	$104.23 - $128.03
Foreign Manufacturers	$34.51 - $42.01	$34.77 - $42.67

Total	$138.13 - $168.03	$139.00 - $170.69

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

The final rule has estimated costs that are one to two percent higher than those in the 2013 proposed rule. Between the publication of the 2013 proposed rule and the final rule, however, we updated the data and techniques used to estimate costs. These updates have led to an increase in estimated nominal costs between the proposed and final rule, an increase that is not related to the one to two percent increase in the actual costs of the final rule. We have updated wage data, updated the way we account for overhead costs in relation to wages, and updated data on the number of facilities affected by the rule. We included the compliance costs to some facilities that are subject to both part 117 and part 507 that had been inadvertently omitted from the 2013 PRIA. We also now account for reduced costs that would be incurred at those facilities that are subject to subpart C but whose hazard analyses are unlikely to identify a hazard requiring a preventive control, based on comments and input from our subject matter experts (SMEs). Our published estimate of the annualized costs of the supplemental notice was $93 million using a 7 percent discount rate (Ref. 3). Our estimate of the annualized costs of the final rule ranges from $139 million to $171 million using a 7 percent discount rate.

One significant cause for the increase in our estimated cost is the change in our estimate of costs of labor hours. Following Department of Health and Human Services (DHHS) guidelines, we corrected our estimate for computing overhead costs to include a 100 percent adjustment relative to the wage, rather than the 50 percent adjustment used in the original estimates. New DHHS guidelines for computing labor costs recommend (based on general industry data) benefits plus other overhead costs equal 100 percent of pre-tax wages (Ref. 4).

This correction results in a roughly 24 percent ($23 million) increase in estimated costs. We also updated the base year for computing wage rates from 2012 to 2013. This update alone results in about a 1 percent (<$1 million) increase in costs. The sum effect of the two updates to the wage estimates results in a roughly 25 percent ($24 million) change in estimated annualized costs.

We obtained more recent data for the facility count. Our estimate of the total facilities covered increased from 18,786 (17,400 registered in 2103 plus 1,386 non-employer facilities) to 21,364 registered in 2015. This resulted in a 14 percent increase in facilities. We excluded the 1,386 non-employer establishments from the count of facilities that would be subject to this rule. Had we not done this, the facility count would have increased by 23 percent. Twenty-two percent of facilities are now estimated to be non-qualified facilities that only produce (manufacture/process, pack, hold) animal food (versus the 24 percent previously estimated). This may be due to an increase in the number of facilities that produce both human food and animal food, rather than an increase in the number of facilities that only produce animal food. By itself, the new facility count results in a 13 percent (roughly $12 million) net increase in costs.

Based on data and information gathered from and in response to public comments, as well as other new sources, we changed the way we modeled the cost estimates of a number of provisions.[1] For example, we did not include any administrative review costs to learn about the rule and prepare a compliance plan for those facilities that are registered as producing both human food and animal food. We include these costs in this analysis, but at a reduced number of hours than for the facilities that only produce animal food. This adds about $6 million in annualized costs. We also included the compliance costs to some of the facilities that produce both human food and animal food that were previously omitted from the PRIAs. This adds an

[1] These changes are described in detail in the full analysis of costs later in this document.

additional 6% in costs, or about $5 million. We also increased the capital costs for on-site rapid testing, which would increase total costs by about $7 million, or 8 percent. We also changed our cost model to incorporate an additional route of compliance that some facilities are likely to adopt, specifically that an estimated 10 to 20 percent of poultry and livestock food producers subject to the preventive controls regulation would not identify any hazards requiring a preventive control. This reduces compliance costs by about $9 million, or about 10 percent.

The net effect of all of these changes ranges from a 48 percent increase to an 80 percent increase (from $45 million to $76 million) in total estimated costs.

The combined effect of updating and correcting our method for estimating overhead costs, using the most recent baseline for calculating wage rates, using the most recent facility count, and making other adjustments to estimates based on public comment and other information, changes the estimate of total domestic costs of the rule from approximately $93 million to a range of $139 million to $171 million.

The additional requirements in the final rule for training for all individuals engaged in manufacturing, processing, packing, or holding animal food at facilities account for the roughly one to two percent difference in costs between the adjusted estimate of the supplemental notice and the estimated cost range of $139 million to $171 million of the final rule.

We use the revised wage rates, most recent base year, the revised facility count, and other adjustments throughout our analysis of the final rule.

II. Final Regulatory Impact Analysis

A. Need for Regulation

This regulation is mandated by statute. Section 103 of the FDA Food Safety Modernization Act of 2011 (FSMA) 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. The rule is needed because of a lack of information about the risks of potentially injurious hazards, which reduces the incentives for producers to invest in the socially optimal level of food safety across the supply chain from the farm through production and distribution to retailers. The people responsible for managing food manufacturers, processors, packers, and holders make many decisions about possible investments to reduce food safety risk to consumers. When doing so, they take into account the probability of their current practices causing a bad event, the probability that they will be found legally responsible for causing the event, and the damage the liability would cause to their firm. If the probability of event, multiplied by the probability of detection, multiplied by the damage to the firm, is equal to or greater than the cost of prevention, then they will invest in prevention.

If the probability of detection is lower than 100 percent, and the private damages are approximately equal to the social damages, then managers will invest less in prevention than the social optimum. Many provisions of this rule, such as recordkeeping requirements, increase the probability of detection. However, it is not feasible to increase the probability of detection to 100 percent, so in many cases, the rule mandates that managers do what they would do if they knew that the probability of detection was 100 percent. Furthermore, the maximum damage that a major contamination event can cause to the owners of a food production company is the value of the company or the owners' wealth. The social damage that a major food outbreak causes, in

many cases, is greater than the private damage done to people who could have invested to stop it. If an outbreak causes more damage than the value of the company, then the probability of an outbreak multiplied by the value of the company may be less than the cost of prevention, while the probability of an outbreak multiplied by the total social damage is greater than the cost of prevention. In this case, it is not rational for profit-maximizing managers to invest in the socially optimal levels of prevention. This rule protects public (human and animal) health by addressing these situations.

Further, consumers are unable to distinguish between firms that have invested in food safety at socially desirable levels and those that have not. Production by brand-name manufacturers does not ensure for consumers that the manufacturers' products were made and distributed safely. Firms that invest in socially desirable levels of food safety might incur higher production costs causing them to compete at a disadvantage with firms that do not. With diminished market incentives, when driven solely by consumer demand, establishments might not voluntarily sufficiently invest in food safety. Establishments might not conduct a hazard analysis, document hazards that require preventive controls, invest in preventive controls, or conduct environmental monitoring, product testing, and supplier approval and verification programs among other controls when needed. When information about the biological, chemical, and physical risks associated with food is imperfect and largely hidden to consumers, 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.

B. Summary of Comments on the 2013 Preliminary Regulatory Impact Analysis and the 2014

Preliminary Regulatory Impact Analysis

We received several comments on the PRIAs, including one comment with an extensive analysis of our preliminary cost estimates, and another comment with an extensive statement on our preliminary benefits estimate. We group our discussion into comments on the benefit estimate and comments on the cost estimates. For those comments with which we agree and have incorporated into our final analysis, we include a comprehensive discussion of the comment in the relevant section of the FRIA.

1. Comments on the Benefits in the PRIAs

We included a section on the qualitative benefits of the 2013 proposed rule as part of our 2013 PRIA. For the supplemental notice, we did not change the underlying qualitative section, or address any comments to the proposed rule. In the supplemental notice we reasserted that we were unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals. We received several comments about both the 2013 PRIA and the 2014 PRIA concerning the benefits of the proposed rule. Most of these comments question why we only presented a qualitative discussion of benefits in the PRIAs, without providing further recommendation or direction. Others take the general view that the benefits would be very small if they could be quantified.

One comment submitted by a regulatory studies program from an academic institution provides a detailed critique of our discussion of the potential benefits and modeled the quantitative benefits that could be expected to result from the proposed rule. Throughout this document, we refer to the quantified estimate of benefits included in this comment as the academic comment or model. Moreover, this comment argues that the 2013 PRIA provides little analysis of the nature, cause and significance of the problem that the proposed rule intends to

address. The comment recommends that FDA take the following actions concerning the benefits of the rule before issuing a final rule:

- "Use empirical evidence to evaluate whether a market failure exists.
- Demonstrate with empirical evidence that any new regulation is likely to produce significant, quantifiable benefits by reducing the risk of hazards below the level that is likely to occur in the absence of regulation."

The comment requests that FDA show that the proposed rule is likely to produce quantifiable benefits by reducing food hazard risks. The comment states that although the PRIA presents market failure as a possibility, our analysis does not show that a market failure exists. Pointing to our use of animal food recall data, which described several recalls linked to a single adulteration incident, the comment argues that we have failed to demonstrate the existence of a widespread animal food adulteration problem. Moreover, the comment suggests that most animal food adulteration problems may be the result of a few bad actors rather than the result of a widespread market failure. The comment identifies *Salmonella* as the largest problem as reported to the Reportable Food Registry (RFR), and requests that FDA consider a less restrictive approach that could be just as effective in reducing *Salmonella*-related illnesses.

We accept many of the assumptions underlying the model described in the academic comment. We have incorporated these assumptions as noted in our benefits estimate in this document.

2. Comments on the Costs in the PRIAs

a. Comments on the Cost Estimate

We received an extensive comment and analysis to both the 2013 proposed rule and the supplemental notice. The original comment included a substantive section on the 2013 PRIA; the comment on the supplemental notice provided detailed critique of the 2014 PRIA. Throughout this document, we refer to cost estimates included in the comment on the 2013 PRIA as the "original association analysis" and refer to cost estimates included in the comment on the 2014 PRIA as the "association analysis." Numerous comments support the cost estimate conclusions in the association analysis.

We address these comments fully in our costs section of this document and note any adjustments we make to our cost model for the final rule in response to comments.

b. Other Comments on the Cost Estimate

We received numerous comments concerning the cost impacts of the proposed rule on animal food industry members, and the PRIAs submitted with both the original and supplemental proposed rules. Those comments concern numerous areas, including but not limited to the following:

- Underestimation of total compliance costs
- Audit costs
- Raw material, ingredient, and finished product testing costs
- Environmental monitoring costs
- Costs to human food producers who supply by-products for use as animal food
- Capital and construction costs
- Animal food industry consultant fees
- Facility closures and job losses (we address these issues later in this document)

We received comments from a pet food association which claims that both large and small pet food producers have already invested significant funds in the last five to seven years into updating production facilities and processes in order to improve animal food safety and in anticipation of the implementation of FSMA. Further, the comment states that these efforts have been successful as the FDA microbial surveillance data of pet food products shows a significant reduction in positive findings for *Salmonella* in pet foods. The comment argues that our cost estimate does not account for this substantial investment in food safety measures.

Because our 2011 report on industry costs was based on both ERG's and its animal food industry consultants' understanding of current practices in the pet food and other animal food industries from 2008 to 2009, it is certainly possible that we did not include some or even most of the pet food industry's investments as costs as mentioned in the comment. To the extent that these investments were directed at animal food safety, they will at least partially offset the need to undertake similar efforts under the requirements of the final rule. We are unable to be more specific about the size of this offset without specific information on the amount and types investments pet food producers made to improve animal food safety.

We received numerous comments that question the need for environmental monitoring, product testing and supplier verification across all types of facilities.

We only assigned product testing costs to the smaller pet food manufacturers (with less than 500 employees) and smaller ingredient suppliers, which is a small subset of total facilities. We agree with the view that many animal food facilities that do not manufacture pet foods will not incur product testing costs or environmental monitoring costs.

c. Testing Costs

Ingredient testing costs for aflatoxin, vomitoxin, fumonisin and moisture at the animal food manufacturer were included in the ERG report that we used as the basis for the PRIAs. These tests were included in both PRIAs and in this FRIA.

We received comments from a rendering consortium (as well as individual renderers) that question many of the cost elements in the 2013 PRIA. Comments take issue with the testing costs included in our cost model, including inaccurately calculating laboratory fees for sampling, and not considering costs for additional personnel and training that would be necessary to collect environmental and product samples. One comment concludes that testing costs would approach $200 per sample for the cost of hiring a preventive controls qualified individual to collect, track and record the collection and sampling process, an amount that far exceeds our estimates taken from both the ERG report and our testing cost model.

We disagree that we did not include the labor necessary to collect the samples required for testing. The ERG report includes production employee labor in its cost model, and we include production employee labor in our finished product testing estimate. It concludes that most of the testing would be composed of on-site rapid tests that do not require laboratory analysis, along with in-laboratory testing three times per year for some hazards for which the facility is testing (a more complete analysis of the testing model is available in Appendix A of the ERG report). For these in-laboratory analyses, our testing cost model also includes shipping fees. We also do not agree with the comment that a preventive controls qualified individual would need to be hired. The rule does not require that a preventive controls qualified individual collect samples or record test results. Personnel already employed in most animal food manufacturing facilities could perform these duties with adequate training. We accounted for this additional training in our cost model. The final rule requires that a preventive controls

qualified individual review testing records to verify that preventive controls are being consistently implemented and are minimizing or preventing hazards. This is included in the costs of the final rule. As for tracking and recording sampling, our cost model includes both one-time and annual process control monitoring and verification (of monitoring and of implementation and effectiveness) costs and sanitation control monitoring and verification costs. Some specific factors in the comment's cost estimate of $200 per test are not fully addressed, such as types of tests and frequency of tests. It appears, though, that one factor is the hiring of a preventive controls qualified individual, which we acknowledge would impose a large marginal cost if an additional full-time equivalent employee is necessary at each facility. Since we do not accept the need for a full-time equivalent employee (2,080 hours per year) just to oversee these activities, we do not accept the $200 estimate as reasonable.

Another comment offers an estimated cost of $25 to $50 for a laboratory to process *Salmonella* tests.

Our estimates for most tests are based on rapid tests that do not require laboratory labor and processing, excluding the three times per year mentioned above. Nonetheless, we have increased the capital cost per sample by 100 percent for the rapid tests for aflatoxin, vomitoxin, fumonisin and *Salmonella* to account for uncertainty surrounding this issue.

This comment also estimates that companies will need to hire and train a preventive controls qualified individual, at an estimated cost of $120,000 per year. However, this comment also states that affected companies did not need to hire additional labor to meet the preventive controls qualified individual requirements. The comment describes current business practices of some members of the rendering industry, including the use of preventive controls (and process control plans for each rendering plant), rodent controls, product testing, employee training,

recordkeeping, third party audits, and maintaining continuing education and training programs that support the Rendering Industry Code of Practice. Once the rule is finalized, the comment anticipates that it will be possible for renderers to make changes to their training programs to comply with FDA requirements for training.

With appropriate changes in firm training programs, employees of the firms can complete the training required to qualify as preventive controls qualified individuals for the purposes of this rule. Consequently, we do not agree that these facilities would need to hire additional preventive controls qualified individuals. The marginal cost of this effort would be the additional training required for an employee(s) to meet the requirements to be a preventive controls qualified individual. We have included additional training cost for preventive controls qualified individuals (based on the assumption that these employees already have significant knowledge of, and experience with, their respective animal food production preventive control plans). We therefore do not agree with the suggestion that annual compliance costs include the cost to hire, train and support an individual who, it implies, does not have any previous knowledge of current animal food safety practices.

We received comments from individual livestock feed mills. Most question the cost of either animal food ingredients as they arrive at the facility, finished product testing, or both. Some comments provide cost estimates without enough information for us to determine the reasonableness of the assumptions underlying the estimates, and some provide enough information for us to respond. One of the latter category provides a methodical calculation of the annual testing costs for five animal food hazards assuming each of the more than 20 daily truck or rail cars making ingredient deliveries (incoming) is tested and each of the more than 60 daily feed deliveries (outgoing) is tested, resulting in annual costs of more than $900,000 per facility.

We do not agree with this comment based on our expectation that finished product testing is not likely to be required by the food safety plans of any animal food manufacturing facility that does not produce pet food because it is not likely any will identify a hazard requiring a preventive control that must be verified through finished product testing. Additionally, we do not agree that the ingredient testing (estimated separately by the comment at more than $100,000 per facility) is a reasonable estimate because it appears to be based on a sampling frequency of 100 percent of shipments (incoming and outgoing). We expect that companies will use the results of their hazard analysis to determine an adequate sampling frequency to verify that preventive controls are effective. In cases where the hazard poses a serious risk of harm, or death, companies may decide to use a 100 percent sampling frequency. In these cases, the benefit of more frequent sampling and testing would justify the additional costs.

Several comments concerned complying with the validation requirements of subpart C. Most comments claim validation would be expensive without providing further information on which to revise our compliance cost estimates. However, one comment describes difficulties obtaining sufficient information for validation.

We maintain that indirect methods (scientific articles, other technical publications) can be used to validate preventive controls. We do not make any revisions to the cost estimate for validation compliance efforts.

d. Supply-Chain Program Costs

Supply-Chain (referred to as the Supplier Program in the 2014 PRIA) controls are an important preventive control that can help ensure that hazards requiring a preventive control will be significantly minimized or prevented for those raw materials and ingredients for which the

receiving facility has identified a hazard that requires a preventive control before receipt of the raw material or ingredient. A receiving facility will not be required to establish and implement a supply-chain program for raw materials and ingredients for which there are no hazards requiring a preventive control, 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.

The receiving facility will 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 supply-chain verification activities as appropriate based on the risk associated with the ingredient and the supplier. Under certain circumstances, the receiving facility will 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).

Receiving facilities that determine they need supply-chain program must have the program in writing. To determine the appropriate verification activities, a written program must consider the nature 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; animal food safety audit results; responsiveness of supplier in correcting problems; and any other factors as appropriate.

We estimated that it would take a production manager 16 hours to write a supplier verification program. We did not receive any comments that lead us to change this estimated burden. For the final rule, this compliance cost has been adjusted due to the change in total compensation rates and the number of facilities. This results in a one-time cost of $4.99 million, which equates to an annualized cost of $710,000 over 10 years at a 7 percent discount rate. We estimate this cost for all non-qualified facilities, as they may potentially want their suppliers to complete an audit or test ingredients.

i. Cost of Audits of Suppliers

We received numerous comments on the supplier program included with the supplemental notice. Many comments claim that the supplier program would cause the audits of up to hundreds of suppliers each year. Others include estimated costs at facilities that would sum to many hundreds of thousands of dollars each.

We maintain that most facilities that supply ingredients to animal food receiving facilities also supply food ingredients to human food receiving facilities. Those human food receiving facilities will be required by part 117 to have a supply-chain program to evaluate supplier performance. For this analysis, we have increased the number of suppliers whose customers may decide to seek an audit to include all rendering facilities. This increases the number from 139 facilities in the 2014 PRIA to 237 facilities for the FRIA and results in a total cost of $257,000. This compliance cost is a small fraction of the cost estimates submitted in comments because we assume that almost all receiving facilities will opt to use verification activities other than audits. We also add an additional cost for the effort of each supplier to share that audit information with

multiple customers. Those additional costs range from $25 to $67 per audit.

We did not include any costs for audits of farms in the 2014 PRIA. Due to changes in the definition of a farm, it may be slightly more likely that a farm could be asked by its customers to undergo an audit as a condition of their purchase agreement. However, our SMEs judge even that possibility to be very rare, and we include no cost estimate for audits of farms for animal food separate from audits of farms that might be conducted under part 117.

ii. Costs of Potential Supply-Chain Verification Activities Other than Audits

We noted above the comments we received concerning testing costs, and the revisions we have made to the cost model to account for some of these comments. The cost analysis for the analogous requirement in the final preventive controls rule for human food assumes that this requirement would likely be addressed by testing ingredients from suppliers. As we did for the 2014 PRIA, we assume manufacturers of animal food would do the same to comply with the part 507 requirement to perform sampling and testing of raw materials and other ingredients, as appropriate. The ERG report 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 4,072 facilities from the food facility registration (FFR) database (including both domestic and foreign facilities) that are subject to the final rule results in ingredient testing costs of about $22.6 million, including the 100 percent increase to the capital costs for the on-site rapid tests for certain hazards. These ingredient testing costs by the animal food producers negates the need for further supply-chain program testing costs. We therefore do not need to account again for the same testing costs.

We do, however, add costs for the burden to facilities from the requirement to share the results of the testing documents with multiple customers. Using the same assumptions that we use for the FRIA for the final preventive controls rule for human food, we calculate that the additional burden of sharing documents among customers and suppliers would amount to about $540,000 annually, or about $100 to $270 per facility.

C. Benefits of the Final Rule

Data gaps hinder the quantification of the animal food safety problems the final rule will address. Currently animal food companies subject to registration under section 415 of the FD&C Act must report certain food safety incidents to the Agency via the Reportable Food Registry, but no similar requirement exists for veterinarians, livestock producers or consumers. Although the Agency has some systems in place to track animal food safety, no federal agency has a program to track foodborne illness in animals similar to CDC's surveillance and reporting system for foodborne illness in humans. There are no public registries of animal deaths. The harm caused by some hazards, such as formulation errors that pose a serious health risk to animals, may not be immediately detectable, leading to underreporting of these types of hazards. Any efforts to track foodborne illness in animals require that observant animal owners recognize when their animals become ill, and recognize the cause of the illness may be attributable to a hazard in the animal food. It is difficult to confirm that a hazard in an animal food caused an adverse health effect, and even with the assistance of a veterinarian or veterinary diagnostic laboratory. Even with observant owners, without a national surveillance system to track diagnosed foodborne illness in animals, data gaps will persist.

As discussed in the 2013 PRIA, anecdotal evidence exists that many animal food hazards cause adverse health effects, including death. Lacking data on the baseline occurrence of adverse

effects from food safety hazards in animal food, we did not quantify or monetize the benefits of the proposed rule in either the 2013 proposed rule or the supplemental notice. We still lack sufficient data to quantify the full range of benefits for the FRIA, although we now provide some benefit estimates based on expert opinion and our estimates of numbers of pets with foodborne illness.

1. Potential benefits

As discussed previously, the academic comment includes a quantitative estimate of potential benefits of the final rule. We accept many of the specific estimates from the academic comment and either incorporate them in whole or in part in our benefits estimate in this FRIA. Using the four potential benefits that we identified in our 2013 PRIA, the comment presents quantified benefits for the reduced risk of adverse health effects to humans handling contaminated animal food, the reduced risk of serious illness and death to animals, the reduced risk of humans consuming food derived from animals that consumed contaminated animal food, and the reduced risk of recalls. Moreover, the analysis describes assumptions made about the potential risk reduction used to estimate the maximum number of illnesses associated with animal food and the value of those illnesses.

a. Reduced Risk of Adverse Health Effects to Humans Handling Contaminated Animal Food

We stated that *Salmonella* is the most commonly identified biological hazard in animal food, and humans can be exposed to *Salmonella* by handling contaminated pet food. To determine the size of the potential health problem from *Salmonella*-contaminated pet food, the

academic comment uses CDC data on the number of human cases of salmonellosis that do not arise from human food consumption. Based on this data, an estimated 65,589 cases of salmonellosis occur annually which do not originate from human food. Next, the analysis uses CDC reports of human non-foodborne *Salmonella* outbreak investigations to estimate that about 8 percent are the result of pet food contamination. These two factors result in an estimated 4,979 cases of human salmonellosis due to handling of contaminated pet food. Further, the academic comment uses the value for the average case of foodborne *Salmonella* of $4,622 from the 2013 FSMA Produce PRIA (see Table 143 on page 386 of the PRIA at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm334171.htm for a full explanation of the derivation of this estimate). Multiplying the 4,979 cases of human salmonellosis due to contaminated pet food times the $4,622 per case results in a value of $23.0 million. This represents the potential value to be gained if the rule prevents all of the estimated 4,979 annual human cases of salmonellosis attributable to handling contaminated pet food.

We accept the basic assumptions used in the academic model, but disagree with the estimate of the number of annual cases of salmonellosis due to handling contaminated pet food. The academic comment acknowledges that the CDC does not include all outbreaks on its web site, but then claims that "it is reasonable to believe that all known [human foodborne illness] outbreaks associated with animal food are reported on the CDC web site," because FDA did not "claim that any other [human foodborne illness] outbreaks related to animal food exist". In our 2013 PRIA analysis, we only discuss the types of potential benefits of the proposed rule. Furthermore, we did not claim that CDC was the only source of data on these outbreaks, whereas

the comment acknowledges that not all outbreaks may be on the CDC web site, but then assumes they are all included on the web site in its calculation.

Relying only on CDC *Salmonella* outbreak investigation reports likely understates the average number of cases of salmonellosis due to the handling of *Salmonella*-contaminated pet food. Because point estimates may obscure data uncertainty, we display a range of estimates for the percentages derived from CDC data. We apply a range of 5.6 percent to 9.6 percent of pet food-confirmed cases to the total number of salmonellosis cases whose origins were not human foods. Applying this distribution, the potential benefits of avoiding human illness caused by handling *Salmonella*-contaminated pet food would range from $17.0 million to $29.1 million annually.

We also adjust the value of a statistical life (VSL) estimate from $7.9 million used in the academic model to $9.1 million, the most recent VSL estimate recommended by DHHS. This represents an increase of approximately 15.2 percent in the VSL. Similarly, we adjust the inpatient hospitalizations costs by about 15.5 percent and the outpatient medical care services by about 15 percent, according to the consumer price indices for these services from 2010 to 2013. In 2010, an inpatient hospitalization for a *Salmonella* infection had an average cost of $26,343, and an outpatient treatment for a *Salmonella* infection had an average cost of $17. Adjusting to 2013 costs, an inpatient hospitalization had an average cost of $30,434 and an outpatient treatment had an average cost of $20. We adjust the value of the health losses from a foodborne *Salmonella* case in Table 143 of the 2013 FSMA Produce PRIA by the 15.2 percent to account for the increase in the VSL figure. We then multiply the sum of the adjusted value of the health losses and the medical costs by the probability of each health outcome as shown in Table 143 of

the FSMA Produce PRIA. Thus, we increase the probability-adjusted average per case cost for *Salmonella* from $4,622 to $5,324. Adjusting for a higher value Quality-Adjusted Life Day (QALD) than the value used as a factor in the $4,622 cost estimate used in the 2013 Produce PRIA, results in a value per case of *Salmonella* at $6,268. The potential benefits of avoiding human illness caused by handling *Salmonella*-contaminated pet food are therefore increased by 35.6 percent, to a range from $23.0 million to $39.5 million annually.

b. Reduced Risk of Serious Illness and Death to Animals

i. Quantitative Benefit Estimates for Foodborne Illness in Pets

The academic comment counts the sum of the average annual number of consumer complaints reported to the FDA district offices regarding animal food, annual reports to the RFR concerning animal food, and annual consumer complaints related to pet food to the FDA Safety Reporting Portal (SRP). Assuming there are no duplicate reports and that the reports are accurate, and that one animal is involved in each report, the academic comment estimates that 1,500 animals are made sick from their food annually. The comment mentions problems with inaccuracy in self-reporting, and that those who report problems often do it in more than one database, while also mentioning that more than one animal could be involved in each incident. Taking all these issues into account, it projects that there could be three times as many animals getting sick from their food as the number of reports on each incident. This increases the number of sick animals to 4,500. Our records show that approximately 99 percent of complaints received by the FDA district offices and submitted to the SRP involve pets, and livestock feed has only recently been added to the SRP. Therefore, we assume that all of the animals in this analysis are pets, although it is possible that a very small minority may be livestock. It should be noted, also,

that a single reported case of food-borne illness in livestock may pertain to many thousands of sick animals.

The academic comment proposes two different methods to value the animal sickness, willingness to pay (WTP) to save a sick pet, and the value to avoid the suffering of a farm animal. Citing a 2010 survey on pet owners' willingness to pay (WTP) for saving a sick pet, the comment calculates a weighted average of pet owners' WTP at $1,530, which equates to $1,608 in 2013 dollars. The academic comment uses its estimated value of an animal's life of $1,608 (for pets) times its estimate of 4,500 animals to arrive at a maximum possible benefit from the proposed rule for saving pets sickened by contaminated animal food of $7.24 million annually. Additionally, we note that although the academic comment uses the survey results to estimate the value of an animal's life, the survey question focuses on WTP to treat a seriously sick pet, not the WTP to save a sick pet's life.

Because the complaints underlying the academic comment estimate concern pets, we only accept the $1,608 figure as near the low end of a range of possible values. However, we make two significant adjustments to the calculation that the academic comment appears to use to reach the $1,608 figure. The first adjustment concerns the number of respondents that can be interpreted to have answered that they would be likely to treat their seriously sick animals at the treatment cost figures supplied in the survey. The survey only include the following 5 choices to the question about how likely would one be to treat their seriously sick animal at the costs of $500, $1,000, $2,000 and $5,000: "extremely likely", "very likely", "somewhat likely", "not too likely", and "not at all likely". The academic comment appears to only have included the

respondents choosing the “extremely likely” and “very likely” respondents for those who would pay the various costs for the treatment. However, significant numbers of respondents chose “somewhat likely” under each of the cost figures. While we do not know what percent of these “somewhat likely” respondents would have chosen the “very likely” or “not too likely” (the choices above and below it in a ranking of WTP) had “somewhat likely” not been one of the choices, we believe it is reasonable that some portion would choose to do so. Since we are unaware of any additional factors that the respondents would have relied upon to make this choice, we conservatively estimate that only 25 percent of the “somewhat likely” respondents would make the choice to treat their pets at each of the cost figures. We add the 25 percent of “somewhat likely’ respondents at each cost figure to the number of those respondents that would treat their pets at each cost figure. This increases the weighted average by 17 percent from $1,608 to $1,884.

The second adjustment is necessary because the survey only offered respondents the four values among which to choose for pet treatments--$500, $1,000, $2,000 and $5,000, and the academic comment appears to have used a calculation in which every respondent in that cost category would only be willing to pay that amount, when in reality the respondents under each cost figure includes those respondents that would pay at least that much, but somewhat less than the next higher cost category. For instance, those who are willing to pay $1,000, but not $2,000 to treat their pets are included in the $1,000 category. The academic comment appears to assume those respondents would only pay $1,000 in its weighting calculation. In reality, though, these respondents would be willing to pay from $1,000 to $1,999 to treat their pets. We do not know the slope of the line at any point in the demand equation, but assume that the median respondent in this category is at a cost point less than the midpoint of the range between $1,000 and $2,000.

We conservatively estimate an additional 40 percent of the difference between the cost category and the next highest cost category for the average WTP in each cost category. In the case of the $1,000 cost category, we add $400, or 40 percent of the difference between $1,000 and $2,000, resulting in an average WTP in this category of $1,400. We also include a WTP of $200 (40 percent of the difference between zero and $500) for the 38% of all respondents that were unwilling to pay $500 to treat their seriously ill pets, a category omitted by the academic comment. The survey does not have a cost figure higher than $5,000 with which to calculate higher average WTP for the $5,000 cost category. In this case we assume that four percent of survey respondents said they would pay $10,000, and one-halfpercent said they would pay $15,000 to save a sick pet. We acknowledge significant uncertainty about these estimates, but believe they are not unreasonable. The result of the adjustments across the cost categories is a 29% increase in the weighted average WTP figure from $1,884 to $2,434.

The academic comment describes a second method to value illness and death of animals by referencing another survey which compares the relative value of farm animal suffering to human suffering. For this method, it uses an estimated value of a statistical human life of $7.9 million to estimate the value of a statistical farm animal life to be $700, which does not include the productive value of the animal. We note that the current accepted VSL for humans is $9.1 million, which would raise the VSL as calculated for farm animals to about $800. However, we do not have a method for calculating the average productive value of a farm animal, which would presumably involve weighting the average or imputed sales price of each animal species

by its average weight at which it would suffer a foodborne illness. Due to these limitations, we do not rely on this method for valuing the avoidance of foodborne disease in animals.

We next present a range of new estimates of the annual number of pets with foodborne illness based on information developed since the publication of the supplemental proposed rule in 2014, as well as information from the academic comment. First, we develop separate estimates of the number of both dogs and cats in the U.S. that suffer from foodborne illness annually. We believe that both dogs and cats with foodborne illnesses are very likely to present at an animal hospital or veterinarian with symptoms of gastroenteritis. Banfield Pet Hospitals reports it treated 2,021,800 dogs in 2011. Table 5 shows the number and ages of the dogs at Banfield Pet Hospitals from 201l.

Table 5. Dogs Visiting Banfield Pet Hospitals for Treatment

Age range	Proportion of dogs in each class[1]	Dogs seen at Banfield in 2011	Proportion of Dogs presenting with gastroenteritis [2]	Dogs seen with Gastroenteritis in age class
Puppies (<1 yr.)	24%	485,200	3.5%	17,000
Young adult (1-3 yrs.)	26%	525,700	3%	15,800
Mature adult (3-10 yrs.)	41%	829,000	.5%[3]	4,100
Geriatric (>10 yrs.)	9%	182,000	.5%[3]	900
Total		2,021,800		37,800

1. [Ref. 5]
2. [Ref. 6]
3. We are unsure of the exact percent, and it could be lower than 0.5 percent. If the figure was as low as 0.05% for both mature adult dogs and geriatric dogs, the total number of cases would decrease by 12 percent.

The 37,800 dogs seen at Banfield Pet Hospitals for gastroenteritis represent 1.87% of all dogs treated at those hospitals. Only 36 percent of dog owners report that they would take their dogs to see a veterinarian to manage an existing condition or disease. [Ref. 6] We therefore increase the number of dogs by a multiplier of 2.78 (or 1/.36) to account for the greater number of dogs that would not be taken to a veterinarian than those that would be taken for gastroenteritis. We note that foodborne illness is not an existing disease and the probability that a dog would be taken to the veterinarian may be greater than 36 percent, resulting in a lower multiplier than 2.78. However, about 20% of dog owners are aware that heart disease may cause vomiting in dogs, and about 33% are aware that kidney disease may cause vomiting in dogs, so some cases of foodborne illness could be mistaken for an existing condition, implying only a small reduction in the 2.78 multiplier.

We further adjust the number of gastroenteritis cases in dogs to account for only those that are due to foodborne illnesses. The percent of gastroenteritis cases in humans that are caused by foodborne illnesses has been reported at 32 percent. [Ref. 7] Veterinarians at FDA believe that the maximum percent of gastroenteritis cases caused by foodborne illness in dogs would be 20 percent, but that 10 percent is the more likely estimate, so we include a multiplier factor of 0.1. In addition, we adjust the multiplier for those cases of foodborne illness that would not present as a case of gastroenteritis, (such as septicemia with salmonellosis in some dogs). FDA estimates these types of cases to appear in about 10 percent of the cases of foodborne illness. Since this adjustment would increase the total number of cases, we include the multiplier of 1.1.[Ref. 8]

We next adjust the baseline amount of illness by the ratio of the population treated nationally to the population of dogs treated at Banfield Pet Hospitals. Dividing the estimated number of dogs nationally, or about 69,350,000, by the number of dogs treated at Banfield Pet Hospitals, or about 2,020,000, results in a multiplier factor of 34.6.[Ref. 9]. We note here that one other source estimates the number of dogs nationally in 2012 at 83,300,000, an increase of about 19 percent from the source we use in our estimate. [Ref. 10].

The multiplier that results from these factors is 10.57 (2.78 times 0.1 times 1.1 times 34.6 equals 10.57). We multiply the 10.57 times the number of dogs with gastroenteritis at Banfield hospitals in table 5, or 37,800 dogs, resulting in an annual estimate of 399,400 dogs with cases of foodborne illnesses. Assuming 36 percent of dogs that would likely be taken for medical treatment, results in about 143,800 cases annually.

We perform the same calculations for cats using the same or similar data sources. Banfield Pet Hospitals reports that it treated about 429,700 cats in 2011. Because, in contrast to the dog data, we do not have the data on the number of cats treated for gastroenteritis at those facilities, we use the same 1.87 percent for cats that we derived for dogs. This results in about 8,000 cats treated for gastroenteritis at these facilities.

Cat owners are even less likely than are dog owners to take their cats to a veterinarian to treat an existing disease. Only 28 percent report that they would do this. [Ref. 6] The resulting multiplier to account for those cats that would not be taken to the vet is therefore 3.57 (or 1/.28). Again we note that foodborne illness is not an existing disease and the probability than a cat would be taken to the veterinarian may be greater than 28 percent, resulting in a lower multiplier than 3.57. However, up to 25% of cat owners are aware that heart disease may cause vomiting in

cats, and up to 40% are aware that kidney disease may cause vomiting in cats, so some cases of foodborne illness could be mistaken for an existing condition, implying only a small reduction in the 3.57 multiplier. We next adjust for the proportion of gastroenteritis cases that are due to foodborne disease. Based on a study showing that cats are only about one-half as likely to carry *Salmonella*, we adjust downward the 10 percent estimate of gastroenteritis cases that are caused by foodborne disease used for dogs to 5 percent for cats.[Ref. 8] The multiplier is then adjusted again for those cases of foodborne illness that would not present as a case of gastroenteritis, (such as septicemia with salmonellosis in some cats). FDA estimates these types of cases to appear in about 10 percent of the cases of foodborne illness, the same percent developed on the basis of the information for dogs [Ref. 7]. Since this would increase the total number of cases, we include the multiplier factor of 1.1.

We then adjust the population of cats treated at Banfield Pet Hospitals to a national estimate. Dividing the estimated number of cats nationally, or about 74,100,000, by the number of cats treated at Banfield Pet Hospitals, or about 429,600, results in a multiplier of 172.4.[Ref. 8]. We note here that one other source estimates the number of cats nationally in 2012 at 95,600,000, an increase of about 29 percent from the source we use in our estimate. [Ref. 9].

The multiplier that results from these factors is 33.86 (3.57 times 0.05 times 1.1 times 172.4 equals 33.86). We multiply the 33.86 times the number of cats with gastroenteritis at Banfield hospitals about 8,000 cats, resulting in an annual estimate of 272,000 cats with cases of foodborne illnesses. Assuming 28 percent of cats that would likely be taken for medical treatment, results in about 76,200 cases annually.

Overall, we estimate more than 670,000 cases of foodborne illness in pets annually, of which about 220,000 would be taken for medical treatment. We anticipate that the final rule will avert a certain percentage of these cases. The magnitude of these benefits depends on the effectiveness of the rule to reduce hazards in pet foods.

ii. Qualitative Discussion of Benefits

Table 3-2 in the expert elicitation report (described in more detail below in section C.2.) includes estimates of baseline hazard rates for chemical hazards (including mycotoxins, nutrient imbalances, and industrial chemical hazards) and physical hazards across various categories of finished animal food and animal food ingredients [Ref. 11]. The experts rank chemical hazards in finished animal feeds (livestock and poultry food) with the highest baseline contamination rates. For animal food ingredients, baseline contamination rates vary by the type of ingredient. For example, the experts rank the baseline contamination rates in grains higher from mycotoxins and physical hazards than from the other chemical hazards.

Table 3-3 in the expert elicitation report presents estimates of the percentage reduction in hazard rates after implementation of the final rule [Ref. 11]. Similar to the baseline estimates, risk reduction estimates vary. For example, the estimated risk reduction rate for nutrient imbalances in finished animal feed ranges from 1 percent to 80 percent (1 percent to 60 percent for dry feed and 1 percent to 80 percent for liquid feed). The data gaps discussed previously prevent us from generating an estimate of the number of animals that may be affected by these hazards. Nonetheless, the results of the expert elicitation suggest a wide range of potential benefits beyond those estimated for dogs and cats from avoiding cases of foodborne illness. In the case of livestock and poultry, potential benefits include the avoidance of reduced weight gain

(or increased animal food cost, or decreased productivity for dairy animals and egg-laying hens) for the sick animals, the value of animals that die as a result of foodborne illness, and the costs of medical treatment.

Potential benefits not quantified here could also include avoiding cases of foodborne illness in pets other than cats and dogs.

c. Reduced Risk of Humans Consuming Food Derived from Animals that Consumed Contaminated Food

The academic comment cites data from the 2011 Pesticide Data Program (PDP) at the U.S. Department of Agriculture (USDA) to show that FDA should not claim any reduction in health risks to humans from consuming food derived from animals that consumed contaminated food. It follows with a 2013 quote from EPA that the PDP data confirm that pesticide residues in food do not pose a safety concern to humans. The comment also addresses human exposure to aflatoxin in meats, noting a study which concludes it is uncommon and rarely found. To support its position the academic comment further claims that there have been no producer recalls or enforcement actions by either the USDA Food Safety and Inspection Service (FSIS) or the FDA in recent years related to aflatoxin in meat, poultry, eggs, seafood or dairy products.

Although we believe there is benefit that will be realized from reducing the likelihood that food-producing animals will consume animal food that will contaminate the food derived from those animals (e.g., meat, milk, eggs), we are unable to quantify those benefits at this time. Therefore, we do not include any benefits to humans based on food-producing animals not eating contaminated animal food.

d. Reduced Risk of Recalls

The academic comment addresses FDA's claim that the proposed rule would help prevent the need for animal food recalls and facilitate the tracking of animal food where recalls are necessary, as well as avoid some of the direct losses attributable to livestock food recalls. The comment states that FDA offered no evidence supporting the claim that the proposed rule would result in fewer recalls. Moreover, the comment cites the opposite effect– that regulation causes more recalls, offering as evidence the FSIS Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule that went into effect between January, 1998 and January, 2000. Presenting USDA data on meat and poultry recalls from 1994 to 2012, the average number of these recalls was less than 36 per year from 1994 to 1997, while it has exceeded an average of 70 per year since 1998. Based on this observed increase in recalls, the comment concludes that an increase in recalls would be a cost, not a benefit, of the rule.

We disagree that we can infer how companies will respond to our final rule from the USDA recall data. Comparing the meat and poultry industry in the late 1990s to the current day animal food industry ignores the globalization of the food supply chain and technological innovation. The final rule requires that companies conduct hazard analyses to identify hazards requiring a preventive control and when identified, to implement control measures to prevent or significantly minimize these hazards. Animal food producers have better technologies available to monitor their ingredients, processes, and finished products to ensure that identified hazards are adequately controlled. We expect companies will choose the most efficient measures to comply with the provisions of the final rule taking into account the risk and magnitude of the potential harm posed by the identified hazards. For example, when the cost of a recall outweighs the

potential harm caused by a hazard, we expect that companies will take necessary measures to reduce the number of recalls and avoid the cost of these recalls. In contrast, companies might increase the number of recalls for hazards that pose a high risk of severe illness or death and that expose the company to legal liability and damages. As noted in the academic comment, companies will weigh the cost of recalls and the potential harm from adulterated animal food. We expect that companies will take actions based on their hazard evaluations that minimize the risks of identified hazards—actions that may increase, decrease, or leave unchanged the number of recalls.

We disagree that an increase in the number of recalls will occur and thus should categorically be a cost of the rule. It is possible that the implementation of a food safety rule combined with an increased frequency of inspections may increase the number of recalls. Although each additional recall has a cost, without knowing the extent of the potential harm avoided by such recalls, it is impossible to judge if additional recalls would generate net benefits or net costs. Thus, in the short-run, we cannot predict the impact of the final rule on recalls. Despite this uncertainty, we expect that in the long-run, companies will identify and prevent potentially harmful hazards from entering the animal food supply.

2. Effectiveness of the Rule

The academic comment questions our assertion that the proposed rule would reduce animal food contamination, stating that we failed to present any scientific evidence. Without evidence, the comment claims that it is impossible to determine if the rule would reduce the risk of animal food contamination, or the amount by which it would reduce it. The comment discusses the recent problem with animal illnesses associated with jerky pet treats as a

representative example of the percent of animal food foodborne illnesses, and asserts that no regulatory program would be able to prevent them. The comment alleges that about 30 percent of all foodborne illnesses in pets since 2007 are related to the jerky pet treats. We have searched for the source of the animal illnesses related to jerky treat consumption, including investigating both facilities and products, and have not been able to determine the cause of the animal illnesses. The comment uses this 30 percent factor as its estimate of the portion of animal food contamination that the proposed rule would not be able to prevent, even if it were able to prevent all of the instances of animal food contamination from known causes.

We disagree with the assertion that the jerky pet treats are representative of animal food safety issues. However, over the 7-year period discussed in the comment, we do not disagree that some causes of animal food safety problems may be difficult to identify. Even though the cause of 30 percent of reported [foodborne] illnesses is unknown at this time, we lack data to estimate the proportion of animal food-related illnesses of unknown causes over longer periods of time, but believe it would be lower than 30 percent.

The academic comment uses our estimate of a 56 percent effectiveness rate from the produce rule as an assumption for the effectiveness rate of the proposed rule, though it notes that the real effectiveness rate could be as low as 0 percent. It multiplies our estimated effectiveness rate from the proposed produce rule PRIA times the sum of the $23 million value of reductions to human illnesses from handling contaminated animal food plus the $7.24 million value of reducing the risk to animals from consuming contaminated animal food, to produce an estimated value of $16.9 million in benefits of the proposed rule.

The literature on foodborne diseases in animals does not provide a reasonable estimate on the risk reduction from the adoption of procedures that are required by the final rule. As an alternative, we use the foodborne disease risk reduction estimates provided in a recent expert elicitation [Ref 10]. The report on the expert elicitation shows the experts' estimates of baseline contamination rates of certain foodborne hazards on a daily ration basis for livestock and poultry food, pet foods, and animal food ingredients (in Table 3-2 of the expert elicitation report) as of 2010, which is the year prior to the enactment of FSMA. These hazards include mycotoxins, nutrient imbalances (deficiencies and toxicities), industrial chemicals, pesticides and heavy metals, physical hazards, biological hazards including *Salmonella*, *Listeria monocytogenes* and *E. coli*. The report shows the experts' minimum, maximum, mode and median estimates for each hazard/animal food combination.

The report also shows the experts' estimates of the percentage reduction in these hazard rates after the final rule is implemented (in table 3-3 of the expert elicitation report). These risk reduction estimates across the hazard and pet food combinations vary considerably, due to the nature of the hazard and the type of food, food ingredient or manufacturing process. For pet food treats, the elicitation yielded an expert estimate of the minimum effectiveness rate of zero. For dry pet foods, the elicitation yielded an expert estimate of a maximum effectiveness rate of 40 percent for *Salmonella*. For nutrient imbalances in dry pet food, the maximum estimated effectiveness rate is 60 percent. If animal food ingredients such as minerals, vitamins, and micro-ingredients are included, the maximum estimated effectiveness rate is 80 percent. Due to the small number of experts used in this expert elicitation as well as the inherent uncertainty in using expert opinion rather than data, we use a range for the effectiveness rate in pet foods. We define the lower bound of the effectiveness range as the average of the minimum effectiveness rates

reported for each of the major categories of hazards, or 1.8 percent. We define the upper bound of the effectiveness range as the average of the maximum effectiveness rates reported for each of the major categories of hazards, or 24.0 percent.

We apply the 1.8 to 24.0 percent effectiveness rate to our calculation of pets suffering from foodborne diseases and the calculation of WTP to treat seriously ill pets of $2,434. . The results, as shown below in table 6, are low bound estimate of $$10.1 to $10.3 million and high bound estimates of $134.0 to $138.0 million..

Table 6. Value of Certain Types of Public Health Benefits

Type of Benefit	Estimate of cases of foodborne illness seeking medical treatment	Low bound estimate of cases avoided	Upper bound estimate of cases avoided	Expected $ Loss per case	Total Value ($ million)
Assumes a 1.8 percent effectiveness rate					
Reduced risk to humans of salmonellosis from contaminated pet food	3,673 to 6,297	66	113	$6,268	$0.4 M to $0.7 M.
Reduced risk of illness and death to dogs	143,800	2,600	2,600	$2,434	$6.3
Reduced risk of illness and death to cats	76,200	1,400	1,400	$2,434	$3.3
Total value of quantified public health benefits at a 1.8 percent effectiveness rate					$10.1 to $10.3.
Assumes a 24.0 percent effectiveness rate					
Reduced risk to humans of salmonellosis from	3,673 to 6,297	882	1,511	$6,268	$5.5 M to $9.5 M.

contaminated pet food					
Reduced risk of illness and death to dogs	143,800	34,500	34,500	$2,434	$84.0
Reduced risk of illness and death to cats	76,200	18,300	18,300	$2,434	$44.5
Total value of quantified public health benefits at a 24.0 percent effectiveness rate					$134.0 to $138.0

We do not estimate any value for the animals not taken for veterinary treatment. With an effectiveness rate ranging from 1.8 percent to 24.0 percent, the final rule would prevent about 8,000 to 108,000 cases of untreated foodborne illness in pets. The benefit of avoiding untreated foodborne illness includes the value to avoid any pain and suffering of these animals, and any value for possible reduced quality of life or duration of life. The benefits to these pets and their owners are not quantified or monetized, but would increase the total benefits of the final rule.

As an alternative to the method which uses the estimated value of an animal's life to estimate potential benefits of the rule for pets suffering from foodborne illness, we replace the value of life estimate with a cost to treat animals that have a foodborne illness. The Banfield report showed that 36 percent of dog owners would take their dog to a veterinarian to treat an existing disease, resulting in about 144,000 dogs that visit the veterinarian, assuming only one examination and treatment is necessary. The corresponding number of cats that would be taken to the veterinarian is 28 percent, resulting in about 76,000 visits to the veterinarian, again assuming only one examination and treatment is necessary. These sum to a total of about 224,000 visits to the veterinarian annually. If 1.8 percent to 24.0 percent of these veterinary visits were avoided, the number of avoided visits would range from about 4,000 to 53,000.

FDA estimates of spending on its Vet-LIRN program, which investigates cases of foodborne illness and details its expenditures for lab work and wages, is an average cost per case of about $4,500. This may be much higher than the average spending per cat or dog with a foodborne illness, but it illustrates the possible high bound of a range of costs. Even if the average total medical costs for outpatient care per animal (which was taken to a veterinarian) per case of foodborne illness was only $300, the benefit of avoiding that cost for 4,000 to 53,000 veterinary visits would range from $1.2 million to $15.9 million. However, these estimates would not include any value of the lives of the animals affected by a foodborne illness that did not receive veterinary care.

D. Costs of the Final Rule

1. Number of Facilities

We received many comments to the 2013 proposed rule about the 2013 PRIA that demonstrate considerable confusion concerning the types of facilities that would be subject to the proposed rule, as well as additional misunderstanding concerning the exact subparts or provisions of the proposed rule. Comments to the supplemental notice about the 2014 PRIA continue to display some misunderstanding concerning the applicability of the proposed rule to various facility types. The preamble to the final rule addresses those comments, clarifying the issue of coverage by facility type. We discuss certain comments here, our responses to those comments and how they have affected the calculations we use for the cost estimates of the FRIA.

a. Facilities handling human food and food for animals

Various facilities that manufacture or process human food, but whose by-product or co-product is distributed to animal producers for use as animal food, submitted comments to the 2013 proposed rule and PRIA. These included comments from individual firms and associations covering various industries, including breweries and distilleries, potato chip manufacturers, almond shellers and hullers, produce processors, citrus processors, and bio-fuel ethanol producers, as well as many others. Most think they should not have to comply with either the current good manufacturing practice (CGMP) or preventive controls (PC) requirements. Some state that their only alternative would be to send these by-products to a landfill, in effect redirecting a valuable animal food into a worthless waste product with significant disposal costs. We agree with the position of certain human food processors whose by-products are currently used as animal food, and included §§ 507.12 and 507.28 in the supplemental notice that would allow these facilities to comply with a much more limited set of requirements. These facilities were included in the 2013 and 2014 PRIAs as facilities registered as processing both human food and food for animals. For the 2013 proposed rule, FDA SMEs estimated the amount of work that the average facility would need to comply with proposed part 507 once each had already complied with proposed part 117. For the supplemental notice, proposed sections 507.12 and 507.28 were included to specifically cover those facilities that processed human food whose by-products were used without further processing as animal food. The 2014 PRIA again included estimates of both the number of facilities and the compliance costs for those facilities that should be registered as both processing food for humans and animals. We did not specifically link the proposed cost estimates to proposed §§ 507.12 and 507.28 in the 2014 PRIA. However, those are the sections to which the compliance costs for facilities registered as both human food and

animal food manufacturers did apply. In this FRIA, we clarify that this was the case for the 2014 PRIA, and retain that part of the compliance cost model for the FRIA.

One exception to this assumption concerns large breweries and distilleries. These handle large volumes of grains, and sell them after further processing as dried distillers grains, an ingredient in the animal food market. They are registered as processing both human and animal food and will be subject to subpart C. Another exception concerns the bio-fuel ethanol producers. They are not required to register in the FFR database as human food manufacturers, but are required to register as animal food producers since they too sell their further processed by-product as animal food. They are therefore also subject to subpart C. They were also included in the count of facilities subject to subpart C in both of the PRIAs, although they were not identified as such. We have not identified either the large brewers or distillers or bio-fuel ethanol producers as separate manufacturer categories in the calculations for this FRIA, but they are included in the count of facilities subject to subpart C.

In both of the PRIAs, we assumed that rendering facilities that would be subject to both proposed part 117 and proposed part 507 would choose to comply with part 117, under the condition that the food safety plan also would address all hazards that require preventive controls in the animal food, and we assigned only a minor proportion of the compliance costs to renderers subject to only part 507. Comments to the PRIAs disagree with this assumption, stating that those parts of integrated packer/rendering facilities that handle inedible (not inspected and passed for use as human food) rendering are completely separate from the rest of the animal processing plant that is subject to USDA regulation.

As a result of these comments, we have decided to include those inedible rendering facilities, which are separate from but may be associated with packing plants, to the list of those facilities subject to both subparts B and C of part 507 because they manufacture, process, pack or hold animal food. We calculate that about 110 rendering facilities had been previously omitted from those subject to subparts B and C. Since we estimated in the PRIAs that just under 22 percent would be qualified facilities, we estimate that just under 22 percent of the additional 110 renderers, or 24 renderers, would be qualified facilities. The remaining 86 would be subject to both subpart B and subpart C.

b. Very Small Businesses

In the 2014 PRIA, we explained our intention to modify the method for determining the number of qualified and non-qualified facilities. We made the 2013 estimates for qualified facilities acknowledging it would likely result in an over-count because we did not have the data to account for the existence of multi-facility businesses. Our intent was to revise the 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 was expected to be that more facilities would be required to comply with the proposed rule at any given definition of very small business. Accordingly, we expected the cost estimates of the final rule to likely increase due to this effect.

We are now able to identify the parent firm for those facilities that are identified in the Standard Industrial Classification (SIC) codes 2047 and 2048, using Dun and Bradstreet (D&B) DUNS data. SIC code 2047 includes those facilities involved in manufacturing dog and cat food.

SIC code 2048 includes those facilities that manufacture prepared foods and food ingredients for animals and fowls, except dogs and cats. We are able to count the total sales of the individual facilities within the parent firm to determine if that firm qualifies for the very small business definition of firms with sales of animal food less than $2.5 million annually. The D&B data reports a total of 3,440 firms and 4,369 facilities within these 2 SIC codes. Of these 4,369 facilities, 2,237 of them represent facilities whose entire firms (including subsidiaries and affiliates) have less than $2.5 million in annual sales of animal food. These qualified facilities, representing about 51 percent of all facilities, would not be subject to subpart C. The other 2,132 facilities, representing about 49 percent of all facilities, are non-qualified facilities that would be subject to subpart C.

Our cost model uses a different method to estimate the count of facilities that are subject to part 507, as explained in the 2013 PRIA. That method estimates that only 37 percent of those facilities identified as subject to part 507 would qualify as very small businesses under the assumption that all facilities are not part of multi-establishment firms. The D&B data appears to show that we may have understated, not overstated, the percent of firms that would qualify as very small businesses, which would imply that our model overstates the number of facilities subject to subpart C, and therefore overstates the costs of the rule. We are uncertain that this is the case as we know that many multi-establishment firms exist in the animal food manufacturing industries, and because differences in the weighting of the pet food facilities and the other animal food facilities between the two methods used to calculate the estimate do not allow for an exact comparison. Due to this uncertainty, we have not made any changes to the cost model to account for any possible over-counting of the number of facilities that would qualify as very small

businesses because they belong to firms with animal food sales less than $2.5 million annually, instead retaining the lower percentage of facilities that are qualified.

c. Updated Food Facility Registration Data

We use updated FFR data as the basis for the facility count for this FRIA. As of February 15, 2015, the FFR database reports 5,598 domestic facilities registered as producing only animal food and 1,871 foreign facilities registered as producing only animal food, summing to a total of 7,469 facilities producing only animal food. An additional 9,536 domestic facilities registered as producing both human food and animal food and an additional 4,470 foreign facilities registered as producing both human food and animal food. This sums to a total of 14,006 facilities registered as both human food and animal food producers. The FFR data shows that the number of facilities registered only as animal food processors, at 7,469, has increased by 11 percent from the number of those facilities used in both the 2013 PRIA and 2014 PRIA. It also shows that the number of facilities registered as processing both animal food and human food, at 14,006 has increased by 31 percent from the number of those facilities used in both the 2013 PRIA and 2014 PRIA. This number, representing facilities that produce both human and animal food, has increased by about 3,300. As noted above, we have moved 86 facilities to the count of facilities subject to both subpart C and subpart B to account for rendering facilities that handle animal food.

d. Integrator Operations

Another modification to the facility count involves integrator operations. Integrators are those food animal production companies composed of multiple operations that own and manage all or almost all aspects of food animal production from animal breeding through final processing

for human food. They can be separated into fully vertically integrated (FVI) operations and non-fully vertically integrated (Non-FVI) operations. FVI operations are those that own and manage all aspects of the food animal production chain, including animal food production and distribution of animal food to farms owned by the same business where its animals are raised. Since these operations are farms where animal food is both manufactured and consumed, they are not required to register with the FFR database. A non-FVI operation is one that may own some separate parts of an animal production chain, but has a contract with at least one separate business, often to raise the non-FVI operation's poultry or livestock at the other business' location (e.g., a farm), to which it may supply animal food, and veterinary and other services. A non-FVI operation's animal food manufacturing facilities are required to register with the FFR database since they manufacture and distribute animal food for consumption in the U.S. and do not meet any exemption to registration. These facilities are subject to the final rule, and therefore are included in that facility count.

We erroneously included FVI operations in our PRIAs, based on the percent distribution of integrators in the ERG report as applied to the number of facilities in the FFR. However, since the facility count in the PRIAs was based on the FFR database, this error did not result in an over-count of total facilities. Instead, it resulted in an underweighting of all other facility types due to the inclusion of the FVI operations.

We do not have a basis for estimating the distribution of non-FVI operations to FVI operations. We assume that it is a 50:50 distribution. We have reduced the number of integrator operations by one-half, which reweights the other facility types for the facility count for the final rule, but does not change the total number of facilities. Additionally, the definition of a very

small business (VSB) has been changed in the final rule to include, for the purpose of the $2.5 million VSB exemption limit, the value of animal food prepared and distributed, but not sold, to separate businesses. Due to this change, none of the animal food manufacturing facilities affiliated with non-FVI operations are expected to meet the requirements necessary to be considered VSBs. These facilities are all included with those subject to subpart C.

e. Non-Employer Establishment Data

We did not receive any comments on the use of non-employer establishment data from Census in our count of facilities for the PRIAs. We note, however, that the 2007 Census data shows that the average revenue of non-employer facilities for animal food manufacturing facilities ranges from about $38,000 to $58,000, which indicates an extremely low amount of revenues for this category. Additionally, any person that produces animal food in their home is not required to register under section 415 of the FD&C Act, which could represent a sizable number of the non-employer establishments. For these reasons, it is unlikely that they would be registered in the FFR database and be subject to this rule. It should be noted that these facilities were all designated to be very small businesses in the PRIAs and therefore would not have been subject to subpart C. We have not included them in the count of facilities subject to the final rule. The total decrease in the estimated number of facilities that only manufacture, process, pack or hold animal food from the 2014 PRIA to the FRIA is (8,130 minus 7,469), or about 8 percent.

f. Other Facilities

We received comments from both grain elevators and seed producers concerning the applicability of proposed part 507. The inclusion of grain elevators alone would have substantially increased the number of facilities subject to the rule, probably by a factor of two or more. Neither of these facility types is subject to the final rule, and no changes are necessary for the facility count or the cost model in this FRIA.

The association analysis estimates compliance costs for animal food facilities only, not including pet food facilities. It uses the 8,130 facility count used in the supplemental notice (from the FFR database). It subtracts both the domestic and foreign pet food facilities from the total number of facilities, resulting in 7,632 non-pet food facilities that would be subject to CGMPs under the rule. For the number of facilities that would be subject to preventive controls, the association analysis again uses our method of the FFR database count of total facilities that would not meet the proposed very small business exemption of less than $2.5 million in total animal sales. After subtracting the estimated number of pet food facilities from this number, the association analysis estimates the number of non-pet food facilities that would be subject to preventive controls at 4,165. It also notes its skepticism that only 4,165 non-pet food facilities would be subject to preventive controls, inferring that many more facilities would, in reality, be subject to preventive controls based on the very small business exemption.

We accept the association analysis count of non-pet food facilities based on the 2014 PRIA.

g. Total Facilities

In Table 7, we show the number of qualified and non-qualified facilities at a definition of very small business as one with less than $2,500,000 in annual sales of animal food per firm. This does not include the facilities that are registered as manufacturing, processing, packing or holding both animal food and human food.

Table 7. Number of Facilities Affected by the Final Rule

Sector	Type	Number of Non-qualified Facilities	Number of Qualified Facilities	Total Facilities
Commercial Livestock Feed Manufacturing	Large Mills	119	0	119
	Medium Mills	352	0	352
	Small Mills	1,905	1,430	3,335
Other Livestock Feed Manufacturing	Wholesalers	501	570	1,071
	Integrators	330	0	330
Pet Food Manufacturing	Large Operations	51	0	51
	Small Operations	90	92	182
Ingredient Suppliers	Large Suppliers	33	0	33
	Medium Suppliers	88	0	88
	Small Suppliers	88	58	146
Total Domestic Manufacturers		3,558	2,150	5,708
Foreign Manufacturers	Foreign Manufacturers	1,200	671	1,871
Total		4,757	2,821	7,579

h. Facilities not identifying a hazard that requires preventive controls

For the final rule, we estimate a separate and much smaller compliance cost for those facilities subject to subpart C that do not identify any hazards through their hazard analyses that need to be controlled with preventive controls. We did not provide for this possibility in the PRIAs, but our SMEs estimate for the FRIA that 10 percent to 20 percent of non-pet food processing facilities will not identify such a hazard. We use the midpoint of 15 percent of these facilities as our estimate. These 685 facilities will still need to comply with subpart B and

complete a food safety plan that includes preparing and conducting a hazard analysis. We anticipate that large brewers and large distillers will likely make the determination through their hazard analyses that they do not have any hazards that need to be addressed with a preventive control. The compliance cost estimates for these facilities are included later in this document.

Table 8 shows the results of 15 percent reduction (not including pet food processors) in non-qualified facilities.

Table 8. Number of Non-Qualified Facilities Affected by Final Rule

Sector	Type	Non-qualified Facilities that ID a hazard	*Non-Qualified Facilities that do NOT ID a hazard*	Total Facilities
Commercial Livestock Feed Manufacturing	Large Mills	101	*18*	119
	Medium Mills	299	*53*	352
	Small Mills	1,620	*285*	1,905
Other Livestock Feed Manufacturing	Wholesalers	426	*75*	501
	Integrators	281	*49*	330
Pet Food Manufacturing	Large Operations	51	*0*	51
	Small Operations	90	*0*	90
Ingredient Suppliers	Large Suppliers	28	*5*	33
	Medium Suppliers	75	*13*	88
	Small Suppliers	74	*13*	88
Total Domestic Manufacturers		3,045	*513*	3,558
Foreign Manufacturers	Foreign Manufacturers	1,027	*173*	1,200
Total		4,072	*685*	4,757

2. Wage Rates

The association analyses state that it used the same wage rate methodology that we used in our analyses, including the 50 percent increase for overhead. However, the original association

analysis was unable to match its use of 2012 Bureau of Labor Statistics (BLS) data to our use of 2012 BLS data, resulting in what it claimed should be higher labor wage costs in the our 2014 analysis.

We had identified our data (for the year 2012) as that for "NAICS 311100 – Animal Food Manufacturing" in the 2013 PRIA, and used the same data in our 2014 PRIA. The correct name of that data from the U.S. Bureau of the Census is "National Industry-Specific Occupational Employment and Wage Estimates", and it focuses solely on those occupation types as they are classified in the animal food manufacturing sector. The association analyses do not state that they used the wage estimates that are specific to the animal food industry, and may have used wage estimates for those same occupations that cover all industry sectors. In any case, we believe our use of the animal food industry-specific data was proper, and retain it for use in this FRIA.

The association analysis also updates its original analysis from 2012 data to 2013 BLS data, but claims that we had used 2007 BLS data in the 2014 PRIA, possibly inferring that we had used wage rates that likely would have been lower than data from more recent years.

In fact, we used 2012 BLS data in both the 2013 and 2014 PRIAs, and suggest that this misunderstanding arose from the original ERG report in which the compliance occupations and wage rates dated from 2007. The 2013 PRIA states that we had updated our cost model using 2012 BLS data. Since the 2014 PRIA did not change the wage estimates from the 2013 PRIA, we did not restate this point, and our continued use of 2012 BLS data was not made clear in the 2014 PRIA.

The association analysis replaces the industrial production manager occupation used in the ERG report with a first-line supervisor position. The first-line supervisor position has a lower wage than the industrial production manager position. The association analysis estimates the food consultant hourly rate at $400 (including all travel, benefits, fees and overhead), based on information from industry contacts who have hired consultants.

For the FRIA, we adjust wages rates as follows. We use 2013 BLS data on animal food industry-specific wages. Our SMEs have considered the food consultant hourly rate estimate, and agree that our previous consultant rate of $100 per hour was substantially low. In response to comments about our original estimate of the wage rate for animal food consultants and input from our SMEs, we revised our estimate of the compensation for animal food consultants to $400 per hour. We accept the industry position that a first-line supervisor, whom we view as a mid-level manager, would undertake the responsibilities of what we previously referred to as an industrial production manager.

We have further adjusted the wage estimates since the publication of the proposed rule to align with current DHHS guidance on RIAs. DHHS currently requires RIAs to include a 100 percent increase in base wage estimates to account for benefits and all other overhead costs. Total labor cost rates, which were estimated at 1.5 times the 2012 BLS wage estimates for both the 2013 and 2014 PRIAs, are estimated at two times the 2013 BLS wage estimates for the FRIA (see Table 9).

Table 9. Compliance Occupations

SOC Code	Title	Total Hourly Cost (2013$)[1]
11-1021	General and operations manager	$96.02

43-1011	First-line supervisor	$49.42
51-0000	Production Occupations	$30.10
51-9061	Inspectors, testers, sorters, samplers, and weighers	$33.24
43-9061	Office Clerks, general	$28.06
-------	Food consultant[2]	$400.00

1. Total hourly costs reflect the mean hourly wage rate plus a DHHS-mandated 100 percent increase for fringe benefits and other overhead costs.
2. Food consultant hourly wage estimate was revised in 2015.

3. Association analysis Cost Model

The association analysis is based on the association's own survey of livestock animal food and pet food facilities, which closely parallels the methodology used by ERG in its report to FDA which was the basis for much of both PRIAs. Its methodology focuses on 24 of the compliance activities that we used as each was identified in the 2011 ERG report. For these compliance activities, "animal feed and pet food facilities were asked to estimate the time spent by each employment position within a facility on each compliance activity."[2] The cost analysis then applies the various wage rates over the occupation types required for each type of activity, in the same manner that we did for our PRIAs, by calculating annualized one-time costs separately from annual costs. It separately includes both capital cost estimates for the CGMP requirements and labor cost estimates for the additional preventive control requirements in the supplemental notice.

The association analysis calculates total compliance costs as the sum of the labor and capital costs of the proposed CGMPs, the preventive control costs (labor only) that were

[2] National Grain and Feed Association comment, March 31, 2014, p. 93

included in the 2013 proposed rule, and the additional preventive control costs (labor only) in the supplemental notice.

a. Current Compliance in Association analyses

Page 93 of the original association analysis includes the following statement, "As part of [our] survey, animal feed and pet food facilities were asked to estimate the amount of time spent by each employment position within a facility on each compliance activity. In addition to including questions on compliance activities that were estimated in the ERG report, the survey also incorporated questions on provisions that FDA estimated in the PRIA. To obtain information on the estimated cost of capital requirements for compliance with the proposed rule, the association queried its members for information." The statement appears to show that the survey asked facilities to estimate how much time is spent on certain activities. It is not phrased in the analysis as if the survey asked how much additional time would need to be spent on compliance activities. However, on page 94 of the original association analysis, the following statement implies otherwise, "[We] attempted to use the PRIA methodology of estimating additional labor hours by employment position in an animal feed facility". This statement appears to show that the analyses focuses solely on marginal efforts to comply with the requirements of the proposed rule. The survey questions were not submitted with the comment, so we are unsure of how the questions were asked.

Additional uncertainty surrounding the original association analysis is due to the lack of description of the survey sample. The association surveyed its membership, but we have no knowledge of the distribution of firm or facility sizes within this survey sample, or whether the association itself fairly represents the size and breadth of animal food facilities (not including pet

food facilities) affected by the rule. And last, the compliance labor estimates were not changed as a result of the publication of the supplemental notice, in which we clarified our intentions, which could have reduced compliance labor efforts. Nonetheless, the 2014 association analysis is based on some sample of affected (non-pet food) industry members, and presents a methodical attempt at cost estimates for the complex set of provisions in the proposed rule.

The ERG report, upon which a significant portion of the PRIA costs were established, is based on interviews with consultants to the animal food industry, a consultant based in agricultural academics, and FDA SMEs. Its cost analysis included non-compliance estimate factors for each of the provisions by facility type. Its calculations included not only percent estimates of non-compliance for different types of facilities as they related to a provision, but also an estimate of the extent of non-compliance for each provision (for example, it may have estimated that 20 percent of animal food mills of medium size are not in perfect compliance with a certain provision, but each of these may only be 30 percent out of compliance, indicating they are in compliance with 70 percent of the requirements of that provision). It also includes a product testing model based on both geographic and seasonal variation in animal food production in the U.S.

Page 60 of the association analysis includes the following statement, which also appears in the original association analysis, "In addition, we estimate that only a fraction of facilities will need to spend labor on various proposed provisions, implying that such facilities already have practices in place to comply with the new proposed requirements. [We] strongly disagree[] with this assumption, and believe[] based on [our] survey results that all types and sizes of facilities would need to devote significant labor hours towards gaining compliance. Therefore, [our] labor

cost estimates represent averages that would be incurred by all facilities, not just a fraction of the industry." The comment disagrees with our assumption that some facilities would incur very low marginal labor hours over various (but not all) proposed provisions, but then asserts that all facilities would need to devote significant labor hours.

We do not, and did not for the proposed rule, intend to imply that any facilities subject to subpart C would not incur at least moderate costs. The association analysis makes a correction to our assumption, but then asserts a conclusion that is not a logical result of that correction. We disagree with the implication that since industry members would likely all devote significant labor to comply with the proposed rule, then the labor hours estimated from the industry survey are a fair representation of average marginal costs. We therefore do not accept the totality of its cost estimates because we cannot be sure that the survey responses were actually based on marginal labor and capital estimates net of current efforts to ensure safe animal food production. We address many of its cost factors in this analysis and make revisions to many of them based on our SMEs' judgments.

Our SMEs agree with the reasonableness of some of the association analysis's cost estimates, but found others to be very unreasonable, based on the intent of the rule and our understanding of current industry practices concerning animal food safety. For instance, the industry survey reports that consultants, whom survey respondents estimate are compensated at a rate of $400 per hour, would need to expend a total of 26 hours every year at every facility that is subject to subpart B (which includes all 7,469 animal food facilities in the FFR database) simply to minimize pest infestation during raw material preparation, processing and manufacturing, and animal food storage. This would result in a total of $10,400 spent on additional pest infestation prevention efforts. Further, the other five employee positions are estimated to require a total of

49 additional hours for compliance with the CGMP pest infestation prevention efforts, at an additional cost of about $1,300. This totals to about $11,700 per facility, and $90 million for the industry. FDA SMEs do not accept these estimates as reasonable, and believe only a very small percent of this effort would be required. This conclusion is based on their understanding that most, if not all, facilities already have pest infestation prevention programs, whether formalized or not, which at a maximum would require small adjustments.

The only other two provisions that the association analysis classifies as required by the CGMPs are to review the new animal food rule and develop a compliance plan, and complete training in the development and application of sanitation controls. The association analysis does not include any annual labor hours for these two provisions, demonstrating that after the first year costs the animal food industry would not incur any labor compliance efforts for the proposed CGMPs beyond those efforts concerned with preventing pest infestation. Therefore, the association analysis estimates annual labor costs for CGMP compliance, not including pest infestation efforts, at $0.

We do not accept the conclusion of no CGMP compliance costs as reasonable either, as it implies no need for any additional sanitation efforts at any animal food manufacturing facilities.

This discrepancy between necessary compliance efforts as intended by us and as apparently understood by industry based on its survey responses (which occurred prior to the supplemental notice) appears to be sizeable. And it results in an even wider range of compliance cost estimates than may be considered usual for such a complex rule. Adding to this discrepancy are the changes that have been made in the supplemental notice and then in this final rule since the publication of the 2013 proposed rule.

Due to the uncertainty surrounding whether or not the association analysis' compliance hours are actually intended to represent marginal compliance efforts for the average feed mill, our SMEs judged the reasonableness of these estimates assuming our intent for the final rule. These revisions serve as the revised alternative (or association) estimate, which as stated above, is still unclear about its current compliance efforts and expected marginal compliance efforts. Our final cost model is determined by the revisions we made to the original cost methodology using the FDA cost model from both the 2013 PRIA and the 2014 PRIA, along with inputs from the association analysis and other public comments.

b. CGMP Labor Costs in Association analysis

The association analysis assigns five of the original 24 compliance activities to fulfill CGMP requirements for all 7,632 facilities. It notes that we underestimated labor hours for most provisions, and provides its own estimates from the survey of its members. Using its own wage rates, which are not specific to the animal food manufacturing industry, the association analysis then presents the result as the average annualized cost per animal food facility at about $16,000, and the total annualized cost for the livestock food industry (7,632 facilities) at about $122.2 million.

As described above, our SMEs reviewed the hourly estimates included in the association analysis in an effort to determine the reasonableness of each. For the effort to review the new animal food rule and develop a compliance plan, the SMEs agreed that it would be unlikely that production workers would have much input, if any at all, in this phase. Additionally, we thought that the two to three hours or more for management was high because all facilities have standard operating procedures from which to begin the additional planning work. Due to these factors, we

have reduced all of the hourly estimates for that provision by fifty percent. Additionally, we have reduced the time for administrative review of the rule for animal food industry consultants by another 80 percent to account for our assumption that the ratio of facilities to consultants will be 5:1.

The second provision in the CGMP section of the association analysis is "complete training in the development and application of sanitation controls." We note that sanitation controls do not need to be developed for CGMPs. Sanitation controls are preventive controls (subpart C), not CGMPs (subpart B). This misplacement results in an unnecessary $2,400 one-time cost added to all facilities not subject to subpart C, or about $6.5 million (annualized at $0.9 million over 10 years at a seven percent discount rate).

The third and largest hourly compliance issue concerns the last three provisions in the association analysis of CGMP costs. These are the efforts, as mentioned above, to ensure that pest infestation is minimized during raw material preparation, during animal food processing and manufacturing, and during animal food storage. The association analysis understandably uses the breakdown into three parts of the animal food production process since that is the way that ERG organized its report on the process controls draft, which itself was mostly organized along the stages of animal food production. The association analysis includes 82 hours across the various labor categories for one-time costs (including 31 hours for the consultant), and an additional 75 hours annually to handle the anti-pest infestation efforts (including 26 hours from a consultant). The one-time costs sum to about $14,400 (which is equivalent to about $2,000 when discounted at seven percent over 10 years). When added to the $12,200 in annual labor costs for anti-pest infestation efforts, this results in an annualized cost of about $14,300.

Our SMEs do not agree that any animal food facility would undertake anything close to that amount of effort, or cost, to comply. Most if not all facilities already incur some type of cost for pest extermination services, so at the very most each one would only need to increase this effort. This could be satisfied by increasing the frequency of the exterminator visits to service the facility, or increasing the number of traps at the facility. Even this may be unlikely to occur due to the final rule, as a facility that develops a pest problem would likely address the issue simply as a matter of good business practice.

The SMEs estimated additional extermination efforts at most at about $2,000 per facility, because of the probability that pest extermination is already being addressed by the facilities. Applying the estimated $2,000 across the 7,269 facilities we estimate will be subject to subpart B results in annual costs of about $14.5 million. This is significantly less than the $103.7 million that results when the association analysis cost is multiplied by our revised number of facilities subject to the CGMP requirements. Additionally, only a small percentage of these 7,269 facilities likely would have an undiagnosed pest infestation problem which is noticed and corrected due to the CGMP requirements, further reducing the $14.5 million cost.

Total CGMP labor costs using the association analysis' hourly estimates over the five provisions described above would result in about $36,300 in one-time costs (which equates to an annualized cost of about $5,200 when discounted at seven percent over 10 years). Total annualized costs would have been $126.4 million. Our adjustments to this reduce the one-time costs to $12,200 (which equates to an annualized $1,700 at a discount rate of seven percent over t0 years), plus $2,000 in annual costs. Total annualized costs would be $27.2 million, a reduction from the association analysis of 78 percent.

c. CGMP Capital Costs in Association analysis

Capital costs were not included in the original association analysis due to what the industry explains as a lack of detail and clarity about our intentions, but were added to the industry cost model in the comment to the supplemental notice.

The association analysis includes a section that estimates the cost of the storage of toxic materials, as it believes this is required under the proposed CGMPs. It estimates that 75 percent of facilities manufacturing or processing livestock food would need to construct new buildings to store toxic materials. Further, it contains a list of construction costs for a 2,400 square foot building, which sums to a total of $67,000 per building. The analysis adds direct costs, indirect costs, a capital recovery factor, and a seven percent interest rate and over a 20-year lifetime to arrive at an annualized cost of $15,300 per facility. This equates to $116.7 million over the 7,632 livestock food producers that would be subject to the proposed rule.

The second capital cost estimate arises from the association's belief that the proposed rule would require other facility and equipment related redesign or reconstruction activities. Included among these are modifying facilities to provide additional space for cleaning warehouses, processing areas and equipment; redesigning or reconstructing facilities, fixtures, ducts and pipes to prevent potential condensation; redesigning hand-washing areas, toilet rooms, and plumbing systems to meet compliance standards and insure against contamination of animal food. The association analysis does not individually estimate costs for these CGMP efforts, but rather assumes a cost of $75,000 per facility for compliance, while noting that some industry members believe the cost could be significantly higher. The capital cost model again adds direct and indirect costs, a capital recovery factor, and a seven percent interest rate over a 20-year

lifetime to arrive at an annualized cost of about $23,700 per facility. Multiplying this cost by the 7,632 livestock food facilities results in a cost to industry of about $181 million. Total capital costs for CGMP compliance in the association analysis sum to about $298 million.

Our SMEs do not agree that the vast majority of both of these capital costs would be incurred due to the final rule. Neither the proposed rule nor the final rule requires the construction of new structures or the substantial retrofitting of current facilities. The final rule has been revised to clarify that toxic materials not required by the facility for animal food manufacture should not be stored where animal food is manufactured, processed, or exposed. However, the rule does not prohibit storage in the same facility. Similarly our SMEs do not accept that the CGMP requirements would result in the need to redesign, reconstruct or significantly modify any facilities, fixtures, ducts, and pipes to prevent potential condensation, or redesign hand-washing areas, toilet rooms or plumbing systems to meet compliance standards and protect against the contamination of animal food.

Due to some uncertainty about the current compliance level of every facility, our SMEs estimate that about ten percent of each of the industry capital cost estimates could be accepted as the average for each facility for minor modifications to facilities.

We recalculate the estimate of toxic material storage costs cost using the association analysis' factors including direct annual costs of $2,170, plus indirect costs of $1,750 in administrative costs, insurance and taxes, plus overhead costs of $1,302. We include the one-time cost of $43,761 in redesign or reconstruction activities (as calculated in the association analysis), which equates to an annualized cost of $6,230 when discounted at seven percent over ten years). The annualized cost plus the direct and indirect costs equals $11,452. We agree that

ten percent of this may be necessary for material separation activities in facilities as needed. This reduces the average per facility cost to $1,145 for CGMP capital costs. When multiplied by the 7,158 animal food facilities (not including pet food facilities), the result is $8.32 million.

We recalculate the facility modification cost using the association analysis' factors including direct annual costs of $2,170, plus indirect annual costs of $3,000 in administrative costs, insurance and taxes, plus annual overhead costs of $1,302, plus the one-time cost of $75,000 in redesign or reconstruction activities. The $75,000 figure annualizes to $10,678 (using a 7 percent discount rate over 10 years). The sum of this annualized cost plus the direct and indirect costs equal $17,150. As noted above, we agree that ten percent of this may be necessary for simple modifications to facilities as needed. This reduces the average per facility cost to $1,715 for CGMP capital costs. When multiplied by the 7,158 animal food facilities (not including pet food facilities), the result is $12.28 million.

The association analysis' total annualized CGMP capital costs are estimated at about $298 million.

Our revisions to their calculations result in annualized CGMP capital costs of about $21 million. We also note that ordinary capital costs are included in the overhead charge on labor rates. This includes the rent on office or work space. The only items that are pertinent to discuss as additional capital costs would be one time reconfigurations or new specialized equipment.

d. CGMP Total Costs in Association analysis

The association analysis concludes that the proposed rule's CGMP requirements would impose an average of $16,000 in annualized labor costs and $39,000 in annualized capital costs

on each facility, for an annualized total of $55,000 per facility. For the entire industry, this would amount to an annualized total of about $420 million.

Our revisions to the association analysis' model result in an average of $3,400 in annualized labor costs and $2,900 in annualized capital costs. This equates to about $45 million in annualized CGMP costs to the industry.

e. Preventive Control Costs in Association analysis

The remaining 19 of the 24 compliance activities comprise the labor activities that would be required by subpart C (preventive controls) of the proposed rule. The industry survey provides the basis for the association analysis' individual hourly estimates for each compliance activity. As mentioned above, the association analysis claims that the 2013 PRIA significantly underestimated the time necessary to complete these tasks. The association analysis assigns a reduction of $182 million when preventive controls are not required.

Using the association analysis wage rates and labor hours, the labor requirements sum to a total of about $46,100 per affected facility, which equates to about $192 million for the industry. For any facility that did not identify a hazard requiring a preventive control in its hazard analysis, the cost of preventive controls requirements would only amount to about $2,500 to conduct and document an annual hazard analysis. In both of the PRIAs and the FRIA, we estimate that the hazard analysis, which has a conditional frequency whose minimum may be once every three years, will be done on average every other year, rather than annually.

Our SMEs again reviewed the reasonableness of the hourly estimates included in the association analysis. The SMEs agreed that it would be unlikely that production workers would

have much input, if any at all, in the development of a food safety plan. We reduced those 14 hours in first-year labor to zero. For the effort to "write monitoring procedures of preventive controls and update annually," we reduced the first-year hours by fifty percent due to the SMEs' view that these hours are likely inflated, and may even be redundant with the time estimated to develop other parts of the food safety plan. For the effort to "maintain procedures on how to conduct a recall," our SMEs again questioned the need for additional hours considering the number of hours already estimated for developing the other parts of the food safety plan. We reduced these first-year hours by fifty percent. The annual hours estimated for cleaning, by production workers, as required under sanitation controls are reduced by fifty percent as well. Our SMEs thought that this should already be performed to some extent, and the 149 annual hours appeared excessive. For the combination of three provisions (as listed in the association analysis), "dispos[ing] of or recondition[ing] unacceptable feed to eliminate feed risks," "ensur[ing] that unacceptable feed risks do not occur in the future," and "modifying operation's preventive controls plan following an investigation," the SMEs believe that a substantial amount of this work is currently performed, at least for those feed mills that also produce medicated feed. These annual hours were reduced by fifty percent.

Since the process controls draft upon which the ERG report is based contained a requirement for the annual reanalysis of its process control plan,[3] the association analysis (which is modeled after ERG's provisions) contains provisions concerning annual reanalysis of the food safety plan.

[3] The ERG report refers to a process control plan, while the final rule refers to a food safety plan.

We further reduced the annual hours for any provisions that appear to be required as part of an annual reanalysis of the food safety plan. In both the 2013 PRIA and 2014 PRIA, we estimated that a reanalysis of the food safety plan would be required, on average, once every two years, based on the occurrence of one of the conditions requiring reanalysis. (The minimum statutory requirement is every three years.) We maintain the estimate of a reanalysis of the food safety plan in this FRIA at once every two years. Therefore, we reduce the annual hours by fifty percent for the following provisions from the association analysis: 1) develop a food safety plan to ensure feed hazards are ensured, 2) validate the food safety plan prior to implementation and update annually, 3) write monitoring procedures of preventive controls and update annually, 4) maintain procedures on how to conduct a recall, 5) conduct a hazard evaluation of one's operation annually and create a written report, 6) modify operation's food safety plan following an investigation, and 7) review the food safety plan annually.

The association analysis does not appear to take into account any type of learning curve for a consultant's time at facilities with similar production lines. Our experience with the seafood HACCP rules demonstrates that the need for specialty labor decreased significantly after the first year as firms became familiar with the new requirements. Our SMEs conclude that a reduction would occur for the animal food industry consultant efforts. Other factors that could result in reduced consultant efforts on a per facility basis are the consultants' own familiarity with similar types of animal food manufacturers, especially for those that are owned or operated by a single business, or for those that operate in the same geographic areas and provide food for animal production facilities with the same species of animals.

Even with the previous revisions, the association analysis would still contain 66 first-year hours for a consultant. This represents over eight days at every facility in the first year. Although it annualizes to only $3,800, it represents a first year cost of over $26,000 per facility.

After the first year, the association analysis estimates total annual consultant costs at more than $15,000 for a consultant's 38 hours. For example, it claims that a consultant would be needed for 17 hours annually to monitor sanitation controls and verify sanitation records to insure compliance, at a cost of $6,800 over two days. However, the association analysis also estimates that management would monitor sanitation controls and verify sanitation records to insure compliance, at an estimated 68 hours and an annual cost of about $3,500.

As stated above, we question whether facilities would readily incur consultant costs once their own employees and management are familiar with preventive controls, including how to monitor them. Once a facility is required to comply with subpart C, it must have a preventive controls qualified individual available to perform or oversee certain activities, such as reviewing records of the implementation and effectiveness of preventive controls. We do not agree that the facility management would incur high consultant costs when it has a preventive controls qualified individual and experienced employees available at a much lower wage rate. Although we are uncertain about the actual rate at which a consultant hours would decline over the years, the number of years over which the decline would occur, or the number of annual hours at which the consultant hours would stabilize, we have revised the total number of annual consultant hours to 12, or a day and a half. This assumption reduces the association analysis' labor cost for the preventive controls by about $42 million.

We have made the same revision to the FDA cost model, along with an increase to upper management and mid-level management hours that is twice as large as the reduction in consultant hours, to account for less input by the consultant in the hazard analysis and food safety plan revisions in subsequent years.

The average annualized cost per animal food facility in the association analysis was about $46,000. We applied this to the 4,165 facilities estimated for the PRIA, resulting in about $192 million. After revisions to that model and the wage rate increase for overhead described earlier, the revised model would impose preventive controls annualized labor costs of about $119 million, or about $26,000 per facility.

f. 2014 Supplemental Notice Provisions in Association Analysis

The association analysis contains a new section in which it accounts for the compliance efforts that would be required by the five new provisions of the supplemental notice. These are the requirements for product testing, environmental monitoring, economically motivated adulteration, a supplier program, and the review of records for these provisions. The analysis estimates that an additional four hours of daily labor would be necessary to address these requirements at each facility, if hazards requiring preventive controls are determined to be present at the facility. This labor would include obtaining test samples, overseeing the testing, monitoring test results, tracking product batches that are on hold until test results are known, as well as supplier verification activities such as onsite audits, sampling and testing of raw materials and ingredients, reviewing supplier food safety records, and performing other supplier verification activities, as appropriate. The labor is expected to be completed by employees in the production occupation, at the overhead-adjusted rate of $22.61 per hour. Four hours at this labor

rate for 4,165 facilities at five days per week results in about $23,700 per facility. The analysis includes a separate cost to review the records of these provisions, which it equates with the effort of writing monitoring procedures for preventive controls and updating them annually, which would require labor across many occupation categories and adds $2,900 per facility. The total labor costs sum to about $26,600 per facility, which equates to about $111 million for the industry.

We recalculate this figure using the production worker wage rate adjusted for the larger overhead rate, the larger number of non-qualified facilities from the 2015 FFR data which is then further adjusted down by 15 percent to account for those facilities that do not have a hazard requiring a preventive control. This recalculation results in a facility cost of about $33,000, which would sum to about $130 million for all facilities that implement preventive controls.

For a variety of reasons, we do not think the association analysis is a reasonable estimate of the labor costs of the provisions included in the supplemental notice. The major problem is that the association analysis lacks any specificity of the effort or activities in its daily four hour labor estimate for all facilities subject to preventive controls, making a detailed breakdown of the costs impractical. It does, however, provide details on the types of effort, including:

1. Obtaining test samples
2. Performing or overseeing the testing
3. Monitoring test results
4. Tracking the product batches that are on hold until the test results are known
5. Remedying any issues that may be associated with test results.

It provides no further information, however, on the amount of time each of these procedures would require. Further, we believe that many of these procedures are already included in the

preventive controls procedures included previously in the association analysis. That section includes provisions for:

1. Conducting testing based on feed hazard analysis results and documenting preventive controls
2. Investigating any testing results indicating feed risks, including those from a regulatory agency
3. Maintaining records of shipments with relevant information for recalls
4. Disposing of or reconditioning unacceptable feed to eliminate feed risks
5. Ensuring that unacceptable feed risks do not occur in the future.

These five activities are effectively the same as or very similar to those included in the association analysis section on the supplemental notice labor hours. In effect, the association analysis includes the vast majority of these costs twice. Additionally, we clarify that we do not expect animal food that has been tested for hazards to be held separately until the test results are known. Therefore, even though we realize that many animal food facilities, particularly those manufacturing animal food for livestock, do not have the capacity to hold animal food under conditions that could insure its safe storage pending laboratory results, we do not expect additional storage to be constructed.

A further concern about the accuracy of these cost estimates is that the FDA cost model, at the direction of our SMEs, does not include any environmental monitoring costs for any facilities except pet food manufacturers. The percentage of the four hours of daily compliance efforts that is composed of environmental monitoring efforts in the association analysis of animal food for livestock is unknown.

The issues presented above show the uncertainty in the $130 million cost estimate. It is difficult to estimate what percent of the $130 million should be included for the upper bound of

the compliance cost range. For the 2014 PRIA, we estimated an additional $5.81 million for the sum of the supplemental provisions. We have increased this estimate to $6.70 million for the final rule. Assuming we are underestimating the total, we increase the upper bound by a factor of five, resulting in an annualized cost estimate of $33.5 million.

The association analysis also estimates the labor cost to a facility that, through its hazard analysis, does not identify a hazard requiring a preventive control. It estimates this at an annual cost of $1,374. Using updated wages, we estimate this cost at an annual rate of $1,481. Our SMEs estimate that 10 percent to 20 percent of those non-pet food manufacturing facilities that conduct a hazard analysis will not identify a hazard requiring a preventive control. Based on the midpoint of 15 percent, we estimate that 698 non-pet food manufacturers will only need to perform the hazard analysis (once every other year), resulting in an annual labor cost of $1.0 million.

g. FDA Revisions to the Association Analysis Compliance Costs

The association analysis concludes that the industry would incur $420 million in costs to comply with the CGMPs, plus another $192 million to comply with the preventive controls requirements in the 2013 proposed rule, plus another $111 million to comply with the additional preventive controls requirements in the supplemental notice. That sums to a total of $723 million in compliance costs, at an average of $95,000 per facility. (For those facilities that must comply with CGMPs and preventive controls, the average cost per facility is estimated at $128,000.)

Based on the adjustments that we describe earlier in this section, our revisions to the association analysis costs sum to about $197 million in compliance costs.

If we account for the pet food facilities with the average annualized cost as calculated for the final rule for pet food facilities that are subject to subpart C, about $32,100 times the 187 domestic and foreign facilities that are subject to subpart C, this results in an annualized cost of about $5.6 million. We also add the average annualized cost as calculated for the final rule for pet food facilities that are subject only to subpart B, about $2,100 times the 122 domestic and foreign facilities that are subject only to subpart B, which results in an annualized cost of about $0.5 million. These costs sum to an annualized cost for pet food manufacturers of $6.1 million. We add this to the $197.6 million from the revised alternative estimate, which sums to about $204 million across all facilities affected by the final rule.

4. New Provisions in the Final Rule

a. Animal Food Safety and Hygiene Training

We discussed requiring mandatory education and training for facility personnel in the preamble to the 2013 proposed rule [78 FR 64736 at 64776] and proposed training requirements in § 507.14(b) in the supplemental notice. Supervisory personnel would have been required to ensure that personnel engaged in handling animal food would receive the appropriate training in proper food handling techniques and food-protection principles, and would be informed on the importance of employee health and personal hygiene.

The cost of that provision was estimated at $11.05 million. For the final rule in § 507.4, we require that individuals manufacturing, processing, packing, and holding animal food have necessary education, training, and experience, including receiving training in the principles of animal food hygiene and animal food safety and records documenting training be established and maintained.

Comments to the proposed rule state that we should not use human food facility cost estimates since those facilities are already subject to, and familiar with, CGMPs.

Lacking data on the training programs offered by animal food production facilities, we again use responses to the 2010 ERG survey of human food production facilities to gauge training necessary to comply with the final rule. We do, however, include adjustments for the training estimates based on SME judgment concerning current compliance with these training requirements. This is included at the end of this section.

The ERG survey contained 22 questions about the types of training, duration of training, types of employees trained, and frequency of refresher training. Types of training included food safety principles, foodborne hazards, and prevention of hazards. The training requirement imposes compliance costs at those facilities that provide little or no training to their employees. Based on the survey, we estimate that the number of facilities that offer no training on the principles of animal food safety to employees ranges from 10 percent of facilities with fewer than 20 employees to 0 percent of facilities with 500 or more employees. Although the ERG survey also provides information on the percentages of human food facilities by size that provide one hour or less of training in safe food production, which may need to expand their training, the judgment of our SMEs is that a facility will either have a sufficient training program or it won't have one at all.

The ERG survey also inquired about training concerning personal hygiene practices at food production facilities, including whether personnel are trained to notice and report symptoms of illness in themselves and coworkers. The survey also asked about the frequency of refresher training in food safety and sanitation for food production personnel. Following the cost model used to estimate training costs for the final preventive controls rule for human food, we use the

responses to these survey questions to estimate the compliance costs of personnel training requirements that are in § 507.4(b). We expect these compliance costs to be incurred by those facilities that do not provide any training on either the principles of animal food safety or animal food hygiene.

Training materials for human food production food hygiene are readily available in book and pamphlet form, on-line and in video format. We assume similar materials are available for animal food production facilities on-line at no cost, and have not included any materials cost in the cost analysis.

We estimate that each animal food production employee would need to take two hours of training in the principles of animal food safety each year, and another two hours in animal food hygiene. We estimate that facilities with fewer than 20 employees would need to provide the training to 10 production employees at the production worker wage rates. Similarly, facilities with 20-99 employees would need to provide the training to 50 production employees, facilities with 100 to 499 employees would need to provide the training to 200 employees, and facilities with 500 or more employees would need to provide the training to 550 employees at the production worker's wage rate. We estimate that a first-line supervisor at a wage of about $49 per hour (including all overhead) would provide the training to the necessary floor employees. The total cost of lost work time would be about $700 per facility ((10 employees x $30 hr. x 2 hr.) + (1 preventive controls qualified individual x $49/hr. x 2 hr.)) for facilities with fewer than 20 employees, that currently do not provide any training.

Production personnel are expected to retake the training periodically, which our SMEs estimate would be once every five years. We account for this cost as an annual cost equal to one-fifth of the first year costs. Additionally, we add in another 10 percent of the first-year costs to

account for employee turnover. These two annual costs are estimated together at 30 percent of first-year costs, or about $260,000.

Recordkeeping costs are based on 5 minutes per record per training class at a clerk's total wage rate, including overhead, of about $28 per hour.

The total annualized compliance costs for facilities are shown in Table 10. In sum, the total annualized cost of training on both the principles of animal food safety and animal food hygiene, and recordkeeping is estimated to be about $750,000.

Table 10. Costs of Employee Training on Animal Food Safety and Animal Food Hygiene

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	3,181	3,664	732	2
% requiring 2 hours of training in principles of animal food safety	10%	2%	5%	0%
Number of facilities requiring 2 hours of training	321	79	36	0
Number of production workers requiring training	10	50	200	550
Production worker wage	$30	$30	$30	$30
First-line Supervisor wage	$49	$49	$49	$49
Subtotal – 2 hours training for principles of food safety in first year	$225,000	$246,000	$439,000	$0
First-year Recordkeeping cost	$5,000	$6,000	$10,000	$0
Annual training for employee turnover	$22,000	$25,000	$44,000	$0
Annual recordkeeping	<$1,000	<$1,000	$1,000	$0
Annual "periodic" training	$45,000	$49,000	$88,000	$0
Annual recordkeeping	$1,000	$1,000	$2,000	$0
Subtotal – Annualized cost of principles of food safety training*	$102,000	$111,000	$199,000	$0

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
% requiring 2 hours of training in animal food hygiene	10%	2%	4%	0%
Number of facilities requiring 2 hours of training	303	88	30	0
Number of production workers requiring training	10	50	200	550
Production worker wage	$30	$30	$30	$30
Trainer/manager wage	$49	$49	$49	$49
Subtotal – 2 hours training for animal food hygiene	$212,000	$272,000	$369,000	$0
First-year recordkeeping cost	$4,000	$6,000	$9,000	<$1,000
Annual training for employee turnover	$21,000	27,000	$37,000	$1,000
Annual recordkeeping	<$1,000	<$1,000	<$1,000	<$1,000
Annual "periodic" training	$42,000	$54,000	$74,000	$0
Annual recordkeeping	$<1,000	$1,000	$2,000	$0
Subtotal – Annualized cost of animal food hygiene training*	$96,000	$123,000	$167,000	$0
Total - Annualized cost of animal food safety and animal food hygiene training*	$197,000	$234,000	$366,000	$0
Total - Annualized cost of animal food safety and animal food hygiene training*	$798,000			

* First year costs are annualized at a 7 percent discount rate over 10 years.

As mentioned above, for Table 10, our SMEs adjusted the expected current non-compliance rates for training programs from those for human food facilities to an estimate for animal food facilities. The estimated training provision non-compliance rates for facilities with fewer than 20 employees was adjusted from 10 percent to 30 percent, and the rate for facilities

with 20 to 99 employees was changed from 2 percent to 15 percent. These adjustments do not affect the cost per facility, but do increase the numbers of facilities affected. The result is an annualized cost estimated at $2.58 million. The final cost estimate for the training provision ranges from $0.80 million to $2.58 million.

5. Other Changes to FDA Cost Model

We have changed the point estimate of the percent of average costs for those facilities that are subject to both part 117 and part 507. For the 2013 PRIA, we had estimated the midpoint of the 5 percent to 10 percent range (or 7.5 percent) of average facility costs that our SMEs estimated for facilities subject to both rules. Due to the significant uncertainty surrounding this estimate, we now use the 5 percent to 10 percent range in our cost estimates. Additionally, we now include a reduced number of hours of compliance costs for the administrative review of the rule and preparation of compliance plans for all of these facilities, exclusive of the 5 percent to 10 percent of the average costs of the facilities subject to subpart C. We also added the compliance costs to that portion of facilities that process both human and animal food that had been inadvertently omitted from the proposed rule. We also include the compliance costs for those facilities that process both human and animal food, but would qualify as VSBs, that had been inadvertently omitted from the proposed rule. These facilities are exempt from subparts C and E due to being VSBs, but still incur costs both to prove they are qualified facilities and to implement CGMPs.

a. Compliance costs for facilities that do not identify a hazard requiring a preventive control

As previously mentioned, we estimate a separate and much smaller compliance cost to 15 percent of non-qualified facilities based on our SMEs' estimate of those facilities subject to

subpart C that will not identify any hazards requiring a preventive control. We did not provide for this possibility in the PRIAs, but our SMEs estimate for the FRIA that 10 percent to 20 percent of non-pet food processing facilities will not identify such a hazard. These 685 facilities will be required to comply with subpart B and prepare and implement a food safety plan that includes conducting a hazard analysis. We base the compliance costs on the hours and labor categories included in the ERG report for the facility to conduct a hazard analysis and prepare a written report. Using our updated wages, the result is an annual cost of almost $2,650 per year per facility. We estimate the total annual cost of this at $1.81 million.

6. Summary of Costs based on ERG cost model

We have described above the changes to the factors used in our cost model, including the number and types of facilities, the individual wage rates to reflect 2013 compensation and a larger percent for labor overhead. We apply these changes to the revised FDA/ERG cost model for all facilities as shown in Table 11.

Table 11. Costs per Sector using FDA/ERG Cost Model

Animal Food Sector	Type	One Time Costs ($M)		Annual Costs ($M)		Annualized Cost Total[1] ($M)
		Labor	Capital	Labor	Capital	
Commercial Livestock	Large Mills	$0.21	<$0.01	$0.98	$0.62	$1.63
	Medium Mills	$1.86	$0.40	$5.15	$1.06	$6.53
	Small Mills	$18.61	$2.18	$24.65	$2.75	$30.36
Other Livestock	Wholesalers	$6.47	$2.26	$5.48	$0.25	$6.70
	Integrators	$0.58	<$.01	$2.75	$1.76	$4.59
Pet Food	Large Operations	$0.14	<$0.01	$0.68	$0.45	$1.15
	Small Operations	$0.59	<$0.01	$1.39	$0.24	$1.71
Ingredient Suppliers	Large Suppliers	$0.17	<$0.01	$0.48	<$0.01	$0.51
	Medium Suppliers	$0.68	$0.03	$.85	$0.08	$1.03
	Small Suppliers	$1.02	$0.03	$1.07	$0.06	$1.28
Domestic Manufacturers		$30.34	$4.91	$43.48	$7.27	$55.77
Foreign Manufacturers	Foreign Manufacturing Facilities	$10.14	$1.64	$14.52	$2.43	$18.63
Total		$40.48	$6.55	$58.00	$9.70	$74.40

1. Annualized cost total is one-time costs annualized at 7% over 10 years plus annual costs.

7. Additional Costs of the Final Rule

We apply the same changes to cost factors as shown directly above to all facilities that are subject to the rule for those requirements for monitoring, verification, and other activities that exceed those in the rule that ERG analyzed in its 2011 report. In this section, we estimate many of those costs based on methodology and assumptions similar to those contained in our analysis of the final preventive controls rule for human food.

a. Cost to attest to Qualified status and Related Requirements

To be exempt from subparts C and E, qualified facilities would be required to submit certain documents to FDA. These include 1) an attestation that the facility is a qualified facility; and either 2a) an attestation that the facility has identified potential hazards associated with the animal food being produced and is implementing and monitoring preventive controls to address the hazards, or 2b) an attestation that the facility is in compliance with State, local, county or other applicable non-Federal food safety laws. If potential qualified facilities decide to provide an attestation under 2b), they must also include on the label of their animal food products the name and business address of the facility where the food was manufactured (or in the case of products that are not required to have a food label, the name and business address must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or on documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of internet sales). In our analysis of the final preventive controls rule for human food, we estimate that qualified facilities would choose option 2b as the less expensive of the two options as the cost of making label changes to affected products is less than implementing one preventive control. We believe that the qualified facilities subject to this

rule would also choose option 2b over option 2a for the same reason.

i. Costs to qualified facilities to attest to qualified status

We estimate that it would take a compliance officer, at about $45 per hour, one-half hour to determine and document the facility's status as a qualified facility each year and to update the facility's information with FDA to attest to its status as a qualified facility through an electronic submission online, as allowed in the final rule, every two years. This assumes that the financial and compliance information is already available as tax records, accounting records, or other readily available records. It is possible that some qualified facilities would attest to having completed a hazard analysis, and implementing and monitoring preventive controls instead of attesting that the facility is in compliance with other non-Federal food safety laws. We increased the frequency of determining status as a qualified facility from every two years to annually in the final rule. We do not estimate the number of these facilities, but expect the time to attest to having a hazard analysis, preventive controls, and monitoring instead of attesting to compliance with other non-Federal food safety laws to be similar. All businesses meeting the final rule definition of very small business would be in the smallest size category of fewer than 20 employees. The costs are shown in Tables 12.

Table 12. Cost to Qualified Facilities to Attest to Qualified Status

Number of qualified facilities	2,822
Hours needed to gather and submit financial and compliance documentation	0.5
Wage rate per hour (including overhead)	$61
Total Costs every year to determine status and every two years to attest to status	$87,000
Cost annually per affected facility	$31

ii. Costs of changing product labels for products at qualified facilities

We assume that all qualified facilities would choose to submit documentation that they

are in compliance with other non-Federal food safety laws, and will therefore also need to include notification to consumers of the complete business address of the facility where the animal food was manufactured or processed. This must be placed on a conspicuous place on the label itself for animal food requiring a label. We expect that all pet foods manufactured or processed by qualified facilities are required to bear a label. A minor label change would be required for pet foods and other packaged animal food. We use our 2014 Labeling Cost Model (LCM) to estimate the compliance cost of a minor label change to comply with this requirement. The four-year compliance period for this requirement (one year for the final rule plus three additional years for very small businesses) would allow for both brand name and private label pet food producers to make a coordinated label change (one that is not made outside the average life of a label). The median cost estimate for that type of label change in the LCM is $595, or $85 when annualized over 10 years at a seven percent discount rate. We estimate that feed mills and pet food manufacturers that are qualified facilities would average about 4 products with labels. All of these facilities are assumed to have fewer than 20 employees. We are uncertain of the percentage of VSB animal feed mills that make animal food requiring labeling, but have included all of them for this analysis in order to not underestimate the cost to attest to qualified facility status.

For animal food that does not require packaging labels, qualified facilities must comply with the requirement to provide notification to consumers as to the complete business address of the facility where the animal food was manufactured or processed by, among several options, adding the address to the sales documents accompanying the animal food product. As stated above, we assume pet food is required to bear a package label, so we do not expect this option to apply to pet food manufacturers. We estimate that this would require about one hour for a

compliance officer or another employee of equal training to add or change the address in the sales software that creates the documents that are delivered with animal food not requiring a label. Table 13 shows the total costs for the label change requirements applicable to qualified facilities.

Table 13. Cost of Label Changes

Cost to Change Label on Products with Labels	
Number of qualified facilities	2,822
Number of SKUs per facility	4
Cost per SKU for one-time label change	$595
Total cost of one-time label change	$6,715,000
Annualized total costs of label change	$956,000
Annualized cost per affected facility	$339
Cost to Change Sales Documents for Products without Labels	
Number of qualified facilities	1,488
Hours to add or change address in sales software	1
Wage rate (including overhead)	$61
Total one-time cost	$91,000
Annualized total costs of labeling change	$13,000
Annualized cost per affected facility	$9
Total annualized cost to change labels/labeling per affected facility	$348

The total annualized costs of attesting to qualified status and changing labels/labeling for qualified facilities are shown in Table 14.

Table 14. Annualized Costs to Comply with Attesting to Qualified Status and Changing Labels/Labeling

Cost to attest to qualified status	$87,000
Cost to change labels for products with a label	$956,000
Cost to change labeling for products not requiring a label	$13,000
Total Annualized Cost	$1,056,000
Average cost per facility	$374

b. Sanitation Controls

The final rule requires the owner, operator, or agent in charge of a facility to implement

sanitation controls to control certain hazards (such as environmental pathogens) requiring a preventive control, as appropriate to the facility and animal food. Sanitation controls must include, as appropriate to the facility and animal food, written procedures for the cleanliness of animal food contact surfaces, including the animal food contact surfaces of utensils and equipment; and for prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food contact surfaces and from raw product to processed product.

These sanitation controls are intended to reduce or eliminate hazards such as environmental pathogens in the animal food processing environment in order to prevent contamination of animal food products. Effective sanitation controls remove undesirable material from animal food-contact surfaces and the environment. When sanitation controls are not effective, microorganisms, filth, and food product residues remain at concentrations that can threaten the safety of the animal food.

The ERG report on the process controls draft contained several individual tasks that would reduce the risk of insanitary conditions at the animal food processing facility. It estimated that each facility complying with that draft would have a production worker expend 12 hours annually to clean containers used for incoming materials and a production worker expend 52 hours annually to ensure that the cleanout of animal food processing equipment occurs on an established schedule, at a marginal cost estimated at about $4.6 million. And it estimated that each facility complying with that draft would have a production worker expend 13 hours annually to ensure that animal food packaging and storage prevent, eliminate, or minimize animal food hazards. Some portion of these 13 hours could be expected to include the sanitary conditions of the animal food storage and processing.

While the process controls draft includes some requirements pertaining to the sanitary conditions of the animal food processing system, it likely does not require the same level of detail as the requirements in the final rule concerning cleanliness of food-contact surfaces including utensils and equipment, and the prevention of cross-contamination from insanitary objects and personnel to animal food and from raw product to processed product. We add additional compliance cost estimates below to those included in the ERG cost analysis of the process controls draft.

i. Writing procedures for sanitation controls

We follow the cost model developed for the final preventive controls rule for human food for our estimate of the additional effort that each facility would expend to write the procedures for sanitation controls. Our SMEs expect that an additional 5 hours will be required to write the sanitation controls procedures for both animal food-contact surfaces and prevention of cross-contamination from insanitary objects and personnel to animal food and from raw product to processed product. We base the first estimate of the percent of facilities that currently have written procedures on the weighted averages of the percentages used in the FDA cost model for the final preventive controls rule for human food, which were based on responses to the CGMP survey (in the ERG report) of human food processors. We base the other end of the non-compliance range on the judgment of our SMEs (our alternate scenario, shown at the bottom of Table 15). We expect the wage rate to be that of a mid-level manager, or first-line supervisor. The one-time cost for writing these procedures is estimated at $553,000, with an annualized value of $74,000 over 10 years at a 7 percent discount rate. We assume that annual updating costs would equal 10 percent of the one-time costs, or about $52,000. Total annualized costs of this provision are estimated at about $126,000. The alternate scenario adds an upper bound to the

cost range of $160,000.This cost range represents the cost of writing the procedures for sanitation controls that exceeds the total amount for writing the process control plan included in the ERG report.

Table 15. Additional Costs to Develop Written Procedures for Sanitation Controls

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number of Facilities	1,064	2,439	567	1	4,072
% Facilities w/o written procedures for sanitation controls	52%	40%	27%	22%	
Total Facilities w/o written procedures for sanitation controls	554	659	153	0	1,366
Hours to develop and write procedures	5	5	5	5	
Wage rate (including overhead)	$76	$76	$76	$76	
One-time cost to develop and write procedures	$212,000	$252,000	$59,000	--	$553,000
One-time cost per facility affected	$383	$383	$383	--	
One-time cost annualized over 10 years at 7 percent	$30,000	$36,000	$8,000	--	$74,000
Annual cost to update procedures	$21,000	$25,000	$6,000	--	$52,000
Total annualized cost	$51,000	$61,000	$14,000	--	$126,000
ALTERNATE SCENARIO					
% Facilities w/o written procedures for sanitation controls based on SME judgment	60%	40%	20%	15%	
Total annualized cost	$59,000	$91,000	$11,000	$0	$160,000

Our SMEs did not expect that these affected facilities would implement a formal training program on the sanitation controls. Rather, they expect that these facilities would use some form of on-the-job training on the sanitation control procedures for production employees. As a result, we have not included any training costs in the cost model.

ii. Additional CGMP sanitation efforts

The section above described the similarity between some of the process controls draft provisions and the part 507, subpart C requirements pertaining to the sanitary conditions of the animal food processing facility, although the requirement to write procedures for sanitation controls required an upward adjustment in the estimated process control cost. Similarly, the greater level of detail in the sanitation requirements under part 507, subpart B than in the process controls draft provisions also will likely result in additional labor required for compliance.

Many of the sanitation CGMP costs would be accounted for under the process controls draft, but the lower level of detail in the process controls draft does not allow us to conclude that all the labor expected to be expended is accounted for in the ERG report on the process controls draft. To adjust for this, our SMEs made the broad assumption that every facility affected by the sanitation CGMPs would need to expend an additional one hour per week to comply with these requirements. We assume that this additional one labor hour per week would also be required at those facilities that are exempt from subparts C and E but are still subject to the CGMP sanitation provisions in subpart B. We received comments that we did not correctly account for CGMP costs, but they do not include any direction on how to estimate these costs any more accurately. We retain the one hour estimate for the final rule. This requirement affects all 7,579 facilities registered in the FFR database as animal food producers. The one labor hour would be assigned to a production employee at the wage rate, including overhead, of about $30 per hour. Total industry costs for this requirement are estimated at about $11.9 million annually.

Table 16. Additional Labor for CGMP Sanitation Efforts

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number of Facilities	3,181	3,664	732	2	7,579
Hours to implement additional sanitation requirements (CGMPs) annually	52	52	52	52	

Wage rate	$23	$30	$30	$30	
Annual labor cost to implement sanitation CGMPs	$4,979,000	$5,735,000	$1,146,000	$3,000	$11,862,000
Annual cost per facility	$1,565	$1,565	$1,565	$1,565	

iii. Sanitation control monitoring and verification

Final § 507.39 states that preventive controls are subject to management components, including monitoring and verification. At a more detailed level, final § 507.40 requires that the owner, operator, or agent in charge of each facility establish and implement written procedures for monitoring preventive controls, which would include the sanitation controls, and addresses the frequency of monitoring. And final § 507.49(a) requires that the owner, operator, or agent in charge of a facility verify that the preventive controls are consistently implemented and effectively and significantly minimizing or preventing the hazards. We use the cost model developed for the proposed preventive controls rule for human food, which is based on the CGMP survey (in the ERG report) of human food processors, to estimate these compliance costs. Again, comments state that we should not use the results from the survey of human food processing facilities because they may overstate current compliance with many of the requirements of this rule, since human food facilities have been required to follow more stringent regulations than have most animal food facilities. Due to these comments, we present an alternative scenario as the upper bound of our cost estimates at the bottom of Table 17, as determined by non-compliance estimates from our SMEs.

We expect that the facilities that lack written procedures for their sanitation controls will also lack written procedures to monitor these controls and verify that monitoring is being conducted. To estimate the sanitation control monitoring and monitoring verification costs, we

estimate that it will take four hours for a facility with fewer than 20 employees to prepare the written procedures, which may be a comprehensive checklist of all the things that supervisors will do to monitor the sanitation controls. We estimate that it will take seven hours for larger facilities and up to 14 hours for the largest facilities. We estimate that it will take two hours to train two line supervisors in the new procedures. To determine the time to monitor the sanitation controls to ensure they are performed consistently, our SMEs judged that a trained line supervisor would take 52 hours per year to monitor and document their observations for a facility with fewer than 20 employees, 78 hours per year for a facility with 20 to 99 employees, and 104 hours per year for all larger facilities. Verification of monitoring may be performed by a careful records review. FDA experts estimate that it will take a production manager 52 hours per year for each facility that does not already perform verification of monitoring. Total annualized cost of sanitation controls monitoring, and verification of monitoring is estimated at $6.9 to $8.7 million annually (see Table 17).

Table 17. Estimated Costs to Develop and Implement Monitoring and Verification of Monitoring of Sanitation Controls by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number of Facilities	1,064	2,439	567	1	4,072
Estimated percent of facilities without Monitoring and Monitoring Verification Procedures for Sanitation Controls	40%	15%	4%	0%	
Total Facilities without Monitoring and Monitoring Verification Procedures for Sanitation Controls	426	366	23	0	814
Hourly Wage Rate for Qualified Individuals	$77	$77	$77	$77	
Labor Hours to Develop Sanitation Controls Monitoring Procedures	4	7	7	14	
Subtotal Cost to Develop Sanitation Controls	$130,000	$196,000	$12,000	0	$339,000

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Monitoring Procedures (one-time cost)					
Labor Hours to Annually Update Sanitation Controls Monitoring Procedures	1	2	2	4	
Subtotal Cost to Annually Update Sanitation Controls Monitoring Procedures (annual cost)	$32,000	056,000	$3,000	0	$92,000
Number of Employees per Facility that Require Annual Training in Sanitation Controls Monitoring Procedures	2	2	3	3	
Hours of Annual Training in Sanitation Controls Monitoring Procedures per Employee	2	2	2	2	
Hourly Wage Rate for first-line supervisor	$49	$49	$49	$49	
Subtotal Costs to Train Supervisors in Monitoring Sanitation Controls (annual cost)	$84,000	$72,000	$7,000	$0	$163,000
Estimated Percent of Non-Qualified facilities that do not maintain monitoring records	40%	17%	10%	0%	
Total number of Non-Qualified Facilities that do not monitor	426	415	57	0	897
Minutes per Record to Document Monitoring of Sanitation Controls	2 to 4	2 to 10	6 to 17	6 to 17	
Total hours per year for monitoring sanitation controls	52	78	104	104	
Subtotal Recordkeeping Costs for Training in Monitoring of Sanitation Controls	$1,094,000	$1,598,000	$291,000	$0	$2,984,000
Total hours per year for verification of sanitation controls monitoring	52	52	52	52	

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Sanitation Controls Monitoring Verification – Observation of Monitoring and Records Review (Annual Cost)	$1,696,000	$1,652,000	$229,000	$0	$3,574,000
Total One-Time Costs to prepare monitoring and monitoring verification procedures	$131,000	$196,000	$12,000	$0	$339,000
One-time costs annualized (7%, 10 years)	$19,000	$28,000	$2,000	$0	$48,000
Total On-going Monitoring and Monitoring Verification for Sanitation Controls Costs	$2,907,000	$3,379,000	527,000	$0	$6,813,000
Total Costs Annualized (One-Time annualized + On-Going)	$2,925,000	$3,407,000	$529,000	$0	$6,861,000
ALTERNATE SCENARIO					
Facilities without Monitoring and Monitoring Verification Procedures for Sanitation Controls based on SME Judgment	50%	20%	4%	0%	
Total Costs Annualized (One-Time annualized + On-Going)	$3,657,000	$4,542,000	$529,000	$0	$8,728,000

c. Validation of the food safety plan

The final rule requires that preventive controls (with some exceptions) be validated prior to the implementation of the food safety plan, or, when necessary to demonstrate the control measures can be implemented as designed, within 90 days after production of the applicable

animal food first begins or within a reasonable timeframe. This validation must include obtaining and evaluating scientific and technical evidence, or, if this evidence is not available or is inadequate, conducting studies, to determine whether the preventive controls, when properly implemented, will be effective in controlling the hazards. It can include referencing up-to-date scientific or technical literature, previous validation studies, or historical knowledge of the performance of the control measure. Because validation costs depend on the number of products, the complexity of the processes, and the hazard, they can vary significantly. Based on the judgment of our SMEs, we estimate that initial validation costs range from $1,000 to 2,000 per facility, and use an average of $1,500. We use the non-compliance rates that ERG estimated to project the number of facilities that already routinely perform hazard analyses, assuming that those facilities that have not performed a hazard analysis would not have created a food safety plan and validated its preventive controls. These non-compliance estimates range from 10 percent at large mills and large pet food manufacturing facilities to 90 percent non-compliance at wholesale operations that perform some animal food mixing (i.e., manufacturing/processing). The average annual costs per facility also vary from about $150 at large feed mills and large pet food manufacturing facilities to about $1,300 at wholesalers that perform some animal food mixing. Total one-time validation costs total about $3.08 million, which is annualized over 10 years at a 7 percent discount rate at $439,000.

The final rule also requires that the preventive controls be validated when a reanalysis of the food safety plan reveals the need to do so. We estimate that re-validations would cost one-third as much as the original validation, or $500; and that the one corrective action would lead to one safety re-validation per year for animal food processors. We again use the non-compliance rates that ERG estimated to project the number of facilities that already routinely perform hazard

analyses, assuming that those that have not performed a hazard analysis would not have created a food safety plan and validated its preventive controls. Moreover, we assume that those facilities that currently perform hazard analyses would also be validating any changes to control measures that could impact their effectiveness. Because we expect animal food processors to re-validate only once each year, we estimate re-validation costs at $513,000 annually. Although the re-validation costs are assumed to be the same for each facility, the ERG model non-compliance rates result in higher probabilities of incurring this new cost for small feed mills, wholesalers that perform some animal food mixing, and small ingredient suppliers.

d. Reanalysis of the food safety plan

The final rule requires that the food safety plan as a whole be reanalyzed at least once every 3 years, and whenever a significant change in the activities at a facility creates a reasonable potential for a new hazard, or there is a significant increase in a previously identified hazard, among other times. It also requires a revision of the written food safety plan, or documentation of the basis for a conclusion that no additional or revised preventive controls are needed, if any significant changes in the activities at a facility create a reasonable potential for a new hazard or a significant increase in a previously identified hazard. In estimating reanalysis costs for the final preventive controls rule for human food facilities, we estimate that the reanalysis of the food safety plan by an employee who is familiar with it can be performed in 12 to 24 hours. (A preventive controls qualified individual must perform or oversee the reanalysis.) We assume this for animal food facilities as well. The process controls draft, however, contained an annual requirement for a hazard analysis and preparation of a written report of the findings. It also contained provisions for a written process control plan, an annual review of that plan, and modifications to that plan due to that review or investigations required as a response to the

identification of an unacceptable animal food risk. In its report, ERG estimated the time necessary to perform the hazard analysis activities to be 24 hours annually, spread across upper and midlevel managers and a consultant. Further, ERG estimated an additional 13 hours annually for process control development, 8 hours for an annual review of the process control plan, and 4 hours to modify the plan following an investigation concerning any element of the plan.

The efforts described by ERG to comply with the provision for an annual review of the process controls and modification of the plan following an investigation exceed the reanalysis requirements of the final rule. The cost estimate for the process controls draft contains 24 hours for the annual hazard analysis, and another 25 hours for annual review, redevelopment and modification to the process control plan. The one reanalysis effort (based on the economic analysis of the 2014 supplemental preventive controls rule for human food) would require only 12 to 24 (with a midpoint at 18) hours annually. Our SMEs, however, expect the reanalysis of the food safety plan for animal food facilities to occur only once every two years. We acknowledge uncertainty concerning the level of equivalence between the requirements for the final rule and the process controls draft, but judge them to be adequately equivalent for the purposes of the analysis. The labor costs of compliance with the annual hazard analysis and the annual review, redevelopment and modification to the process control plan in the process controls draft were included in the total compliance costs included in the 2011 ERG model. However, since we believe that many of these manufacturers would not be adding new products frequently and that most manufacturers do not have the same level of microbiological concern as human food manufacturers, we expect the reanalysis to occur every other year. We use one-half of the annual costs from the ERG cost model for the reanalysis of the food safety plan and have not made any further cost adjustments for compliance with the reanalysis requirements of the final rule. We did

not receive any comments that led us to change the average frequency at which the food safety plan would need to be reanalyzed.

e. Monitoring process controls

The final rule requires the owner, operator, or agent in charge of a facility to implement process controls (except under certain circumstances, as described in the final rule). Process controls include those procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls can include the steps that are applied in the production process to prevent, or significantly minimize select biological, chemical, or physical hazards and include the maximum or minimum values, or combination of values, such as minimum or maximum production temperatures, pH, or processing times to ensure the processed animal food will not be adulterated.

The ERG report on the process controls draft included the preparation of a hazard analysis which was to identify the hazards that are reasonably likely to occur, as well as a section on processing and manufacturing which would require that manufacturers of animal food establish and implement written procedures to ensure animal food safety. Included in this section were requirements for ensuring that scales and metering devices used in the processing and manufacturing of animal food ingredients and finished mixed animal food are appropriate for the range of weights or volumes to be measured and that the devices are tested regularly for accuracy. It would also have required that all processing and manufacturing equipment is installed properly, is operated correctly, and is maintained to produce safe animal food, and is checked on a regular basis. Since the process controls draft already included estimates of these costs, we have not included any additional costs for the initial writing of process controls, or the

initial implementation of process controls.

We add compliance costs to account for the monitoring efforts required by the final rule in § 507.40. The cost model developed for the final preventive controls rule for human food is used, along with the estimates developed by our SMEs, to account for process controls monitoring costs. We account for the effort to write the monitoring procedures for process controls (which would exceed the writing effort estimated by ERG for just the processing and manufacturing section in the process control draft) by using the percentages of human food processors that do not have written process controls. These range from 47 percent of facilities with fewer than 20 employees to about 2 percent of facilities with more than 100 employees. FDA SMEs estimate that animal food processors would have from 2 to 6 process controls, and that each would require an additional 3 to 7 hours to write the monitoring procedures for each process control. At a mid-level manager's wage of about $77 per hour, this would add $379,000 in one-time labor cost to prepare monitoring procedures, which equals $54,000 when annualized over 10 years at 7 percent (see Table 18). Using the alternate scenario in which our SMEs estimated higher non-compliance rates, the annualized cost equals $131,000.

These same facilities would be expected to incur some annual costs to update these written procedures. We estimate that those facilities currently without written process controls would require an additional 2 to 4 hours per year per process control to update monitoring procedures. At the same wage rate of $77 per hour, this would impose about $256,000 in annual costs to those facilities currently without written process controls (see Table 18).

We calculate labor costs of the actual monitoring of the process controls based on estimates of FDA SMEs. We assume that each process control would require 8 minutes per day of monitoring by a production worker for facilities with fewer than 100 employees, and 24

minutes per day of monitoring by a production worker at a facility with more than 100 employees. At the production worker wage rate of about $30 per hour, this results in a total process control monitoring cost of about $2.35 million.

We calculate the cost to document monitoring based on the assumptions that it would take five minutes to create the recordkeeping document for each day's monitoring of each process control for facilities with fewer than 100 employees and 10 minutes for facilities with more than 100 employees. Using a clerk's compensation rate of about $28 per hour, we estimate the cost to document monitoring of process controls at about $1.17 million. We estimate total annual process control costs at $3.78 million. Under our alternate scenario in which our SMEs increased the estimates of non-compliance rates, total annual process control monitoring costs equal $8.76 million.

Table 18. Estimated Initial Costs to Monitor Process Controls

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total Number of Non-Qualified Facilities	1,064	2,439	567	1	6,603
Facilities Currently without Process Controls	47%	11%	2%	0%	
Total Non-Qualified Facilities that require Process Preventive Controls	500	268	11	0	780
Number of Processes Controls per Facility	2	2	6	6	
Hourly Wage Rate for Production Manager	$77	$77	$77	$77	
Average Labor Hours to Prepare Written Procedures per Production Process Control	3	3	5	7	
Total One-time Costs to Develop Initial Written Procedures	$229,000	$123,000	$26,000	0	$379,000
One-Time Costs Annualized	$33,000	$18,000	$4,000	$0	$54,000

ALTERNATE SCENARIO					
Facilities Currently without Process Controls based on SME judgment	80%	45%	2%	0%	
One-Time Costs Annualized	$55,000	$71,000	$4,000	$0	$131,000

Table 19. Estimated Annual Costs to Monitor Process Controls by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥ 500 employees	Total
Total number of Non-Qualified Facilities	1,064	2,439	567	1	4,072
Facilities Currently without Process Controls	47%	11%	2%	0%	
Total Facilities that require Process Controls	500	268	11	0	780
Number of Processes Controls per Facility	2	2	6	6	
Hourly Wage Rate for Production Manager	$77	$77	$	$77	
Labor Hours to Update Written Procedures per Production Process Control	2	2	4	4	
Subtotal Costs to Annually Update Written Procedures	$153,000	$82,000	$21,000	$0	$256,000
Hourly Wage Rate Process Control Monitoring	$30	$30	$30	$30	
Minutes per day monitoring each process control	8	8	24	24	
Hours per year monitoring each process control	42	42	208	208	
Subtotal Monitoring Costs	$1,252,000	$672,000	$426,000	$0	$2,351,000
Records to Document Monitoring of Process Controls (Minutes per Record)	5	5	10	10	
Monitoring Records per Process Control per Year	300	300	300	300	
Subtotal Costs to Document Monitoring	$702,000	$376,000	$95,000	$0	$1,174,000

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total On-going Process Control Costs	$2,108,000	$1,130,000	$542,000	$0	$3,781,000
Total Costs Annualized (One-Time annualized + On-Going)	$2,141,000	$1,148,000	$546,000	$0	$3,835,000
ALTERNATE SCENARIO					
Facilities Currently without Process Controls based on SME judgment	80%	45%	2%	0%	
Total Costs Annualized (One-Time annualized + On-Going)	$3,588,000	$4,625,000	$542,000	$0	$8,756,000

f. Verification of implementation and effectiveness of the process controls

The final rule requires that the implementation and effectiveness of preventive controls be verified under § 507.49. This section of the analysis focuses on the process controls verification activities that are expected to track the process controls monitoring activities, whose costs have been estimated in a separate section above (sanitation controls verification were addressed earlier in this analysis). The verification activity for process controls would include a review of the monitoring records. Following the cost analysis of the final preventive controls rule for human food for process controls, we assume that all the facilities would need to undertake some additional review procedures (e.g., reviewing records of calibration) to verify that process controls are consistently implemented. This model assigns the verification activity to a production manager with a wage rate of about $77 per hour. We rely on an estimate from an expert elicitation report on the human food processing industry that, on average, about 3 minutes per day would be necessary for a preventive controls qualified individual to review each process

control record, even though the frequency of record review may vary. The compliance cost per facility for the verification of process controls by record review is estimated at about $2,400 per year for those facilities that do not currently have written process controls. We estimate the total annual costs for process control verification at $1.92 million (Table 20). Under our alternate scenario, the increase to non-compliance rates estimated by our SMEs results in an upper bound on the total annual costs of $4.74 million.

Table 20. Cost of Verification of Process Controls

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	1,064	2,439	567	1
Facilities without process controls	47%	11%	2%	0%
Hours per day verifying process controls by record review	0.05	0.05	0.05	0.05
No. of processes controls per facility	2	2	6	6
Hourly wage rate	$77	$77	$77	$77
Total annual cost by facility size	$1,196,000	$641,000	$81,000	$0
Total annual cost	$1,918,000			
ALTERNATE SCENARIO				
Facilities without process controls based on SME judgment	80%	45%	2%	0%
Total annual cost	$4,740,000			

g. Requirement for a preventive controls qualified individual

The final rule includes activities that are required to be carried out or overseen by a "preventive controls qualified individual." A preventive controls qualified individual is one who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or is otherwise qualified through job experience to develop and apply a food safety system. Our SMEs believe that some facilities may already have some personnel that

would meet these criteria, but believe that most facilities probably do not.

We received many comments concerning the requirement for a preventive controls qualified individual. The overwhelming position is that it would impose a very high cost on a business to hire, train and support a preventive controls qualified individual.

We do not expect any business to hire an additional person to handle the duties of a preventive controls qualified individual. We expect that all facilities have personnel that are very familiar with animal food production processes who could be further trained to be preventive controls qualified individuals. We do not agree with the comments that state that each facility would need to take on another full-time position to handle the responsibilities of a preventive controls qualified individual.

Since there is significant uncertainty about the number of facilities that have at least one employee who would meet the criteria to be a preventive controls qualified individual without further training, we assume that every facility will need at least one person to undertake training to become a preventive controls qualified individual. Our SMEs estimate that those facilities with fewer than 100 employees would require that one person receive training in the first year, and those facilities with 100 or more employees would require that two persons receive the training in the first year. We expect the training to require about 8 hours for an employee at the first-line supervisor level. The one-time cost for this training is estimated at $2.84 million, which equates to $405,000 over 10 years at a seven percent discount rate. We add another $500 per person to account for the one-time of training materials or a trainer's fee, which adds another $290,000 on an annualized basis. Additionally, we assume that the annual cost of training is equal to 50 percent of the one-time cost. Each facility that needed to train one employee in the first year trains an additional one-half an employee each year (or one employee every other

year), and each facility that needed to train two employees in the first year trains an additional employee each year. This annual cost is estimated at $1.42 million. Total annualized costs of this requirement are estimated at $2.12 million per year.

h. Administrative costs to review the rule

We expect that all establishments manufacturing, processing, packing, and holding animal food for consumption in the U.S. will take time to review the rule to determine what actions are necessary to comply with the requirements.

The association comment, previously discussed, includes 257 hours as the time required to review the rule and prepare a compliance plan.

As we discussed, we do not accept the association's suggested number of hours. In fact, we believe that trade groups will play a significant part in educating those facilities subject to the rule, which could lead us to reduce our estimates. However, because of the uncertainty surrounding the time this review would require, we do not reduce the number of hours for the two smallest size categories of facilities from 40 hours to 10 and 15 hours, unlike the FRIA for the final preventive controls rule for human food.

We estimate that assimilating the complexity of the final rule would require at least one week of additional effort for the smaller firms. As the size of an establishment increases, more organizational levels may become involved in the planning for compliance. We base estimated hours on the assumption that facilities with fewer employees would be more likely to have fewer product lines and would spend less time reviewing existing production records and SOPs than facilities with more employees. As shown in Table 20, we estimate that it would take about 40 hours for personnel at the general and operations manager levels to perform the review and develop a compliance plan. For larger firms, we estimate that an additional 40 hours may be

needed from other levels of upper management. We assign this time to personnel at a legal analyst level. On average manufacturers would pay about $93 hour including benefits for personnel to review production processes and to develop a compliance plan. For those facilities processing only animal food, the estimated one-time administrative costs would amount to $31.84 million. This estimate may overstate total administrative review labor costs because those firms with more than one facility would not require the full administrative review effort at each facility, and some very small firms may not require 40 hours to review the rule once they determine that they are qualified facilities.

For the final rule, we also add review costs for those facilities that are subject to part 117 and part 507. We judged that this would require a more limited effort due to the similarity of the preventive controls requirements and because some human food facilities that have by-product used as food for animals will not be subject to part 507 except for the limited requirements in § 507.28 (§ 117.95). We estimate that this would require ten hours to review. The one-time cost of this effort sums to about $13.34 million, or about $1.90 million when annualized over ten years at a seven percent discount rate. The total one-time cost for all facilities is about $45.18 million, with an annualized cost of about $6.43 million.

Table 21. Estimated Administrative Review Costs

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	3,181	3,644	732	2
Hours to review rule	40	40	40	40
Hourly wage – general manager	$96	$96	$96	$96
Hours to review rule for legal analyst	0	0	40	40
Hourly Wage - legal analyst	N/A	N/A	$93	$93
One-time Review cost per facility	$3,840	$3,840	$7,560	$7,560

Annualized review cost per facility	$550	$550	$1,075	$1,075
One-time industry review cost by size	$12,218,000	$14,072,000	$5,540,000	$12,000
Annualized industry review cost by size	$1,740,000	$2,003,000	$789,000	$2,000
Total number of facilities subject to parts 117 and 507	5,832	6,718	1,343	2
Hours to review rule	10	10	10	10
Hourly wage – general manager	$96	$96	$96	$96
One-time Review cost per facility	$960	$960	$960	$960
Annualized review cost per facility	$137	$137	$137	$137
One-time industry review cost by size	$5,600,000	$6,450,000	$1,289,000	3,000
Annualized industry review cost by size	$797,000	$918,000	$184,000	<$1,000
Total one-time cost to industry	$45,184,000			
Total annualized cost to industry[1]	$6,433,000			

1. One-time costs annualized over 10 years at a 7% discount rate

i. Other costs of final rule included in the ERG report

This section includes discussion from the PRIA that we used to show how the ERG report and cost model included many provisions of the proposed rule. Since we retain that report as the basis for this FRIA, this discussion is still pertinent to the explanation of what compliance costs are covered by the original ERG cost model and what we covered in our cost model. All of the cost calculations for the cost factors in the ERG report are updated into 2013 dollars, use the updated wage compensation rates, and are applied to the updated numbers of facilities.

The analysis above detailed the exclusion of certain food safety plan requirements from our cost model used for the analysis of both the final preventive controls rule for human food and proposed part 507. The costs of these requirements, which included the reanalysis of the food safety plan and the requirement for corrective actions, were not separately included in our cost model since we determined that each of these significant parts of the food safety system was included in the ERG analysis of the process controls draft. Similarly, we did not separately account for the costs of several other provisions of the final rule in our cost model because they

were also included in the ERG report.

The final rule includes labeling requirements similar to those included in the process controls draft. Although ERG did not individually account for the cost of preparing written procedures for labeling in its report, it did include first-year costs for writing the process control procedures. ERG included this cost in the hazard analysis and compliance section of its analysis (see Table 3-7 of the 2011 ERG report). ERG also did not list specific annual costs for compliance with the other labeling requirements, but stated that these costs are usually subsumed into other estimates. We judge that the requirements for labeling in the final rule and in the process controls draft are similar, and therefore already accounted for in the ERG model. Thus, we do not add additional costs for complying with the labeling requirements of the final rule.

The final rule requires that each facility develop and write a recall plan for animal food with a hazard requiring a preventive control. As further described in § 507.38, the recall plan must include procedures for notifying (1) those who received the product, including procedures for how to dispose of or return affected animal food, and (2) the public about any hazards presented by exposure to the recalled animal food. Further, the recall plan must include procedures for conducting effectiveness checks to verify that those receiving the product have been notified and have taken appropriate action.

The final rule requires that a facility establish written procedures for taking corrective action if the preventive controls are not properly implemented. Generally speaking, if a preventive control or the food safety plan as a whole is found to be ineffective, or a review of records shows non-compliance with the food safety plan, the facility must take corrective action. Corrective actions must identify and correct the problem, reduce the likelihood that it will recur, evaluate the affected animal food for safety, and prevent it from entering into commerce if the

owner, operator, or agent in charge cannot ensure the animal food is not adulterated.

The ERG report includes corrective actions under the sampling and testing provisions of the process controls draft. Assuming no baseline compliance with the sampling and testing requirements, it would require 37 hours of effort annually, spread across the upper and mid-level management, production worker and clerk employee levels to investigate results indicating animal food risks, including any results coming from a regulatory agency (this does not include time for actual sampling and testing). Further, the report estimates that 24 hours would be spent each year to quarantine any animal food product whose test results show it poses an unacceptable risk, and to destroy the product if the investigation confirms this risk. It estimates 18 hours to investigate false-positive tests and trace the source of true-positive test results; 16 hours for the disposal or reconditioning of unacceptable animal food to eliminate food risks; and another 4 hours to ensure that unacceptable animal food risks do not occur in the future. After adjusting for estimated baseline compliance rates and a labor scale factor and updating wages, fringe benefits and other overhead to 2013 dollars, we calculate that the ERG cost model estimates that these 5 provisions concerning corrective actions would cost the 4,072 facilities from the FFR database about $4.6 million annually, or an average of about $1,137 per facility. Since the ERG report includes the corrective action compliance cost estimates for corrective action requirements similar to those in the final rule, we do not add any additional costs beyond those in the ERG report.

Comments to the proposed rules state that most animal food facilities, especially in the poultry and livestock food industries, do not have additional storage facilities to hold products while awaiting laboratory test results for hazards. We reassert that the testing protocols that are expected to result from this rule primarily may rely on on-site rapid testing which negates the

need for additional storage facilities. Therefore, we do not account for any cost of holding a quarantined product until a determination is made concerning its acceptability for distribution.

The process controls draft included a provision that required each facility to describe how it would address an occurrence of an unacceptable animal food risk after the product has been released for shipment. In its analysis of the process controls draft, ERG included an estimate of the labor hours that would be required to write and maintain procedures on how to conduct a recall for this provision. For a facility not in compliance with this provision, ERG estimated one-time labor efforts to write these procedures of 12 hours for a general manager, 24 hours for an industrial production manager and 6 hours for an office clerk. Further, ERG estimated annual labor efforts for maintaining and updating the procedures for the same three occupations of 4, 8 and 2 hours. These costs were multiplied by the estimated compliance rates and labor scale factors across the various facility types. We estimate these one-time labor costs, updated to 2013 dollars and distributed across the 4,072 facilities from the FFR database, at $5.18 million. The adjusted annual labor costs were estimated at $1.73 million.

While the recall provisions in the final rule are more specific than the more general requirements concerning animal food product recalls in the process controls draft, we conclude that the labor efforts included in the ERG analysis are a reasonable estimate of the labor that would be required to develop, write, and maintain these recall procedures. We do not expect the level of activity required for an actual recall to change. Notification of consignees and of the public would already occur, and effectiveness checks are already a part of our recall guidance (see 21 CFR part 7). Accordingly, we do not include any additional costs beyond those listed above in the 2011 ERG report.

In the final rule, both § 507.17, concerning plants and grounds, and § 507.19 concerning

sanitation, contain measures that require protection against the contamination of animal food by pests. The ERG report addresses compliance costs for pest infestation prevention in the raw materials preparation section (24 hours expended in the first year and another 4 hours annually for a production worker), the storage and packaging section (an additional 24 hours expended in the first year and another 4 hours annually for a production worker), and the processing and manufacturing section (another 24 hours expended in first year and another 4 hours annually for a production worker) of the process controls draft. Because ERG has accounted for pest infestation prevention activities in its cost estimate of the process controls draft, we do not add any additional costs specifically for pest infestation activities for the final rule.

The remainder of § 507.17, concerning plants and grounds, includes requirements for the general maintenance and suitability of the physical location where animal food production occurs. We do not estimate any additional costs for compliance with these activities (beyond those referring to the prevention of pest infestation), which are covered by the labor efforts described above in the ERG report. Though unable to quantify any additional costs, we believe the costs would be low as the requirements are such that a high percentage of animal food facilities likely already comply.

In the final rule, § 507.22 includes a requirement that equipment and utensils used in manufacturing, processing, packing, and holding animal food must be designed and constructed of such material and workmanship to be adequately cleanable and must be properly maintained. Section 507.19 in this final rule contains requirements for adequate sanitation of the plant and its equipment and utensils. ERG accounted for production equipment cleanout on an established schedule by allotting an additional 52 hours per year for a production worker at each facility that does not currently have adequate sanitation procedures. Additionally, ERG allotted another 12

hours per year to ensure the cleanout of containers used with incoming raw materials at each facility that does not currently have adequate sanitation procedures. We judge that these two estimated labor efforts plus the one additional labor hour per week for sanitation efforts for all facilities that was added elsewhere in this analysis would result in a compliance level roughly comparable with the sanitation requirements of the final rule.

The final rule also contains requirements for incoming raw materials and ingredients storage conditions and other contamination prevention activities. The process controls draft contained a provision that raw materials be used in time to prevent spoilage or other forms of degradation that could result in unacceptable animal food risks. ERG accounted for this in its cost estimate with 2 hours of first year costs and 2 hours of annual costs for those facilities that do not currently have procedures to adequately prevent contamination of incoming raw materials. ERG also accounted for inventory rotation practices for finished animal food in its report. It assigned 25 hours in annual efforts at the industrial production manager level for a facility to comply with this provision of the process controls draft. Consequently, we do not add any additional costs specifically for the final rule beyond those totals in the ERG report.

The final rule also contains a requirement for proper disposal of adulterated animal food, or if appropriate, treatment or processing to eliminate the adulteration (§ 507.25(a)(7)). This requirement would not add to the total compliance costs in this analysis. The ERG compliance cost total for disposing of or reconditioning a product, as explained in the corrective actions section, included costs for both those facilities subject to subparts B and C, and for those facilities only subject to subpart B, which contains § 507.25. As such, we have already accounted for this provision and have not included any additional compliance costs. The final rule also requires proper packaging and storing of animal food to protect against contamination and

minimize deterioration. This mirrors the process controls draft provision for which ERG estimated 13 hours of annual labor at the industrial production manager level to ensure animal food packaging and storage prevent, eliminate, or minimize animal food hazards.

Section 507.27 of the final rule, concerning holding and distribution, requires that animal food be held under conditions that will protect against contamination and minimize deterioration of the animal food. The process controls draft contains a provision for conveyances and transporting vehicles to be inspected for structural soundness and proper cleaning prior to loading and shipment. Additionally, any defect or lack of proper cleaning for these conveyances would need to be corrected and verified prior to loading and shipment. For those facilities that do not currently have procedures for adequate storage and transportation, ERG assigned 75 hours of annual labor for a production worker to inspect conveyances prior to use, and another 9 hours per year to make any necessary corrections to those conveyances that are found to be unsatisfactory. We do not add any further compliance costs to those in the ERG report.

j. Cost to facilities covered by both part 117 and part 507

The final rule, like the proposed rule, allows any facility that is required to comply with subpart B of this rule and also comply with subpart B of part 117, to choose to comply with only the requirements in subpart B of part 117. Likewise, any facility that is required to comply with subpart C of this rule and also comply with subpart C of part 117 may choose to comply with only the requirements in subpart C of part 117, so long as the food safety plan addresses any hazards for the animal food, if applicable, that require a preventive control. We assume that facilities that need to comply with either subpart B or subpart C of both part 117 and part 507, and those that need to comply with subpart B and subpart C of both part 117 and part 507, would choose to comply with the relevant subparts of part 117.

For the 2013 proposed rule, we did not have the data to make a confident estimate of the percentage of the food handling procedures and processes occurring at facilities subject to both part 117 and part 507 that is due solely to animal food handling. With that in mind and based on input from our SMEs, we initially estimated that 7.5 percent of the average costs for each individual facility type would likely need to be added to the previous total costs to account for the additional cost for any animal food-only processes, procedures or food lines that occur in facilities subject to both part 117 and part 507.

Section 507.28 requires both that human food by-products for use as animal food must be held in such a way as to protect against contamination and that labeling that identifies the product must be affixed to or accompany the human food by-products for use as animal food when it is distributed. The intent is to ensure that by-products are properly identified during the time spent at the human food processor before distribution. We believe that using placards, or signage or language on accompanying sales documents is not a costly undertaking for the human food processors, and within the $1,400 average total annualized cost that we estimated for these facilities in the 2014 PRIA. Revisions to other factors in the cost model, from which the above calculation is taken, raise the average annualized cost for these facilities to about $2,000.

8. Summary of Estimated Total Costs of Final Rule

Including the $55.8 million in applicable annualized costs from the ERG report and $15.0 million to $30.0 million in applicable annualized costs for facilities that are subject to both part 117 and part 507, we estimate that the sum total of the annualized costs to domestic animal food producers of the final rule ranges from $104.2 million to $128.0 million at a 7 percent discount rate (see Table 22). At a 3 percent discount rate, the annualized cost ranges from $101.6 million

to $125.0 million.

We estimate the total annualized costs for foreign producers to range from about $34.8 million to $42.7 million at a 7 percent discount rate. With a 3 percent discount rate, these annualized costs range from $33.9 million to $41.7 million. Assuming that some part of this foreign cost increase is passed on to US consumers, the annualized cost total to the US market (including domestic and foreign manufacturers) could range from $138.9 million to $170.6 million at a 7 percent discount rate, or from $135.6 million to $166.7 million at a 3 percent discount rate.

Table 22. Compliance Costs of Final Rule ($ million)

Rule Provision	One-time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Validation of food safety plan	$2.57	$0.43	$0.79	$0.73
Process control monitoring	$0.28 - $0.69	$2.83 - $6.55	$2.87 - $6.65	$2.86 - $6.63
Process control monitoring – verification		$1.43 - $3.54	$1.43 - $3.54	$1.43 - $3.54
Sanitation Controls – writing procedures for food contact surfaces and cross-contamination	$0.39 - $0.49	$0.04 - $0.05	$0.09 - $0.12	$0.09 - $0.12
Sanitation controls – monitoring and verification	$0.25 - $0.33	$5.10 - $6.48	$5.13 - $6.53	$5.12 - $6.52
Subpart B – additional sanitation labor		$8.93	$8.93	$8.93
Training for preventive controls qualified individuals	$3.65	$1.06	$1.58	$1.49
Attesting to qualified status and changing product labels	$5.19	$0.07	$0.80	$0.67
Training in animal food safety/hygiene	$1.02 - $4.39	$0.41 - $4.32	$0.55 - $1.94	$0.53 - $1.83
Product Testing		$0.18	$0.18	$0.18
Environmental monitoring		$0.48	$0.48	$0.48
Economically motivated adulteration	$0.58	$2.99	$3.08	$3.06
Supply-Chain program	$3.73	$0.50 - $0.61	$1.04 - $1.14	$0.94 - $1.04
Review records – verification		$0.24 - $0.45	$0.24 – 0.45	$0.24 - $0.45
Costs to facilities subject to subpart C that do not identify a hazard requiring a preventive control		$1.35	$1.35	$1.35
Administrative review of rule	$33.73		$4.80	$3.95
Subtotal	$51.40 - $55.36	$26.15 - $34.39	$33.47 - $42.27	$32.17 - $40.88
ERG Analysis of process controls draft (Includes food safety plan reanalysis				

and corrective actions)				
Hazard Analysis		$4.60	$4.60	$4.60
Preventive Controls	$25.0	$32.23	$35.79	$35.17
Recall Plan	$5.74	$1.91	$2.73	$2.59
Monitoring	$0.07	$1.13	$1.14	$1.14
Corrective Action	$4.43	$7.43	$8.06	$7.95
Recordkeeping		$3.45	$3.45	$3.45
ERG Subtotal	$35.25	$50.75	$55.77	$54.88
Facilities subject to both part 117 and part 507	$14.81-$29.63	$12.89 – $25.77	$14.99 - $29.99	$14.62 - $29.25
Domestic Manufacturers	$101.547-$120.24	$89.78 - $110.91	$104.23 - $128.03	$101.68 - $125.00
Foreign Manufacturers	$34.08 - $39.88	$29.92 - $36.99	$34.77 - $42.67	$33.91 - $41.66
Total	$135.55 - $160.12	$119.70 - $147.89	$139.00 - $170.69	$135.59 - $166.66

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

9. Secondary Impacts

a. Facility closures and job losses

Comments include requests that we assess the impact on facility closures and job losses. Some comments cite the section in the ERG report on financial impacts of the affected industries (Ref. 2). In that section, ERG used a revised version its Small Business Impacts Model (SBIM) to estimate the financial impacts, including closures, of FDA regulations. The model uses alternative income specifications, such as cash flow, net income, earnings before interest and taxes, and revenues. A full explanation of ERG's SBIM assumptions and parameters are contained in Appendix C of the ERG report. The report states that the SBIM, using changes to a facility's net income due to the process control draft, estimates facility closures ranging from four to thirteen small feed mills, and one pet food manufacturing facility. ERG estimated total annualized costs for the process control draft of about $113 million (once on-farm mixer

facilities are subtracted from the total since they were not included in the 2013 proposed rule or the supplemental notice). This cost estimate is comparable to the $93 million annualized cost estimate of the supplemental notice. We did not acknowledge, but should have acknowledged, that a small number of facilities would likely close due to the proposed rule. Along with these facility closures, the jobs at those facilities would be lost.

While we have not used the SBIM for the analysis of the final rule, we agree with the comments that some small number of facilities that were already financially marginal will likely close due to the costs of the final rule. The annualized cost estimate increases in this analysis average about $29,000 for facilities that are subject to subpart C. We expect the number of facilities that will close as compliance costs increase to be greater than the percentage increase in the range of costs due to our expectation of a normal distribution of facility profits (increasingly larger numbers of facilities will become vulnerable to closure as the cost estimate as a percentage of revenues increases from the rule). Therefore, the increase in facility closures from the original range of four to thirteen small feed mills and one pet food facility would likely be greater than the percentage increase in annualized costs of the final rule. Additional job losses are also expected to occur.

10. Government Costs

We did not receive any comments on our estimates of the costs to government to administer the proposed rule. We retain the same estimates for this final rule.

We estimate that it will require 10 full-time equivalent positions (FTEs) in the first year after the rule becomes effective for development of guidance, development and delivery of training, and other outreach activities. The FDA Budget Office estimates that the average annual

cost of one of these FTEs is $250,000, including the cost of all overhead support. The total cost of these ten employees in the first year will be $2.13 million. Additionally, we estimate that it will require $1.5 million in up front overhead costs. The total government cost in the first year for this rule for development of guidance, development and delivery of training, and other outreach activities is estimated to be $3.63 million.

In the second year, we estimate that an additional 3 FTEs will be required to manage the additional activities of the final rule, for example, as compliance deadlines are reached. The 13 FTEs (the original 10 FTEs in FY 2016 plus the additional 3 FTEs in FY 2017) will cost an estimated $3.25 million in the second year.

Given the estimated number of affected facilities, the number of high risk facilities, and the inspection frequencies required by FSMA for both domestic and foreign facilities, we estimate that, at a minimum, about 40 FTEs will be required in the second year after the rule becomes effective for inspections related to this rule. Based on the FDA Budget Office estimate of $250,000 per FTE, including all overhead support, we estimate that the cost of these 40 inspection-related FTEs will be about $10.00 million in the second year. In sum, we project that total costs to us in the second year will be about $13.25 million.

Inspection-related costs for foreign inspections are expected to increase after the initial five years. At that time, we expect that about 52 FTEs will be required for all (foreign and domestic) inspection activities related to this rule. We estimate that these 52 FTEs will cost $13.00 million by the fifth additional year. Along with the original 13 FTEs for CVM implementation and management of the rule, we conclude that the final rule will add $16.25 million to agency costs in the fifth additional year.

The average annualized cost over 10 years at a 7 percent discount rate for our final rule

administration activities is equal to $12.98 million ($13.29 million at a 3 percent discount rate).

E. Regulatory Alternatives

One comment calculates net benefits for four different options, using the costs from the 2013 PRIA. These options include the 2013 proposed rule, the proposed rule along with the foreshadowed provisions, most of which were included in the supplemental notice, a pet food-only rule, and a pet food-only rule along with the foreshadowed provisions (the latter two of which we understand to include neither preventive controls nor CGMPs for non-pet animal foods). Only the two pet food-only options show positive net benefits, ranging from $5.1 million to $7.1 million per year. The proposed regulation and the proposed regulation with foreshadowed provisions showed negative net benefits, ranging from -$73.5 million to -$128.9 million per year. The comment concludes that the benefits of the rule, as it has calculated them, are significantly exceeded by FDA's analysis of its costs. It also restates that FDA has not provided enough information about the nature or significance of the problem that the rule intends to address, which does not allow for the public to comment intelligently on the rule.

In response to comments, we include cost estimates of the pet food-only option with alternative scenarios. Our cost estimates of the pet-food only scenarios use the revised factors included in the above analysis, including the larger number of pet food facilities.

We include other assumptions as well. Many of the raw materials and other ingredients used in making finished animal food are used by multiple types of animal food manufacturers, not just pet food. We therefore assume that the rendering facilities would be affected by the pet

food-only option. Also, some facilities, including some feed mills, manufacture both pet food and other types of animal food. It may not be feasible to enforce provisions for pet food production but not provisions for the other animal food production in the same facility. We expect that these facilities would incur the costs to comply with the requirements in the facility regardless of the use of the final products, whether they are animal food ingredients or finished animal food. However, we do not have data on the percent of facilities that produce both pet food and other animal food or pet food ingredients and other animal food ingredients, but believe it could be sizable, nor do we have data on how feasible enforcing provisions on only pet food production lines or pet food ingredient production lines would be across the different types of facilities. For these reasons, the cost estimates for this alternative should be viewed with considerable uncertainty.

We present a range of different cost estimates that vary based on the percent of facilities that would be covered by a pet food-only option. At the lower bound of our range of cost estimates, we include only facilities that we identify as pet food manufacturers plus the number of facilities that we identify as rendering facilities, using the same FFR data as used in the full cost model. We assign to these facilities the full cost estimate developed for the final rule. We also include a number of facilities that would be affected that handle both human food and animal food, using the same method used in the cost model for the final rule which imposes only a portion of the average compliance costs on these facilities. Since pet food manufacturing and rendering facilities account for about seven percent of all facilities that would be affected by the final rule, we take seven percent of those facilities that handle both human food and animal food as the estimate for the number of these facilities that would be affected by a pet food-only alternative. We assign to these facilities five to 10 percent (the same rates that we use for the

costs of the final rule) of the approximately $28,000 average annualized cost to all facilities. Under these assumptions, we estimate the lower bound of the range of costs for a pet food-only option at $21.3 million - $23.8 million.

We also include an upper bound of the range of cost estimates under a pet food-only option scenario. In this case, along with the pet food manufacturing and rendering facilities, we include 75 percent of facilities whose principal activity is manufacturing animal foods other than either pet food manufacturing or rendering facilities. These facilities may be included because they produce ingredients that are used in pet foods and foods for other animals, or they produce primarily animal food for non-pets but do produce some pet foods. Under this scenario, we also include 75 percent of the facilities in the FFR database that handle both human food and animal foods. For these facilities, we follow the same method used in the cost model for the final rule, and we impose a range of five percent to ten percent of the $28,000 average facility cost for facilities that only handle animal foods. Under these assumptions, we estimate the upper bound of the range of costs for a pet food-only option at $100.9 - $123.9 million on an annualized basis.

III. Final Regulatory Flexibility Analysis

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 final regulatory flexibility analysis (FRFA).

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. We are directed by Congress in 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 us under section 415 of the FD&C Act. Satisfying the mandate of Congress is a primary objective of this final rule.

This final rule also establishes current good manufacturing practice (CGMP) regulations in order to help ensure the production of safe animal food. CGMPs also serve as a prerequisite program for effective preventive controls.

A. Response to Comments

We received one comment concerning several aspects of the initial Regulatory Flexibility Act analysis included in the 2013 PRIA. One issue raised is the identification of a difference between the annualized costs under the three co-proposals (in which the VSBs are defined differently) in the proposed rule versus the same costs as listed in the 2013 PRIA.

First, the costs the comment refers to are not the annualized costs to VSBs under the three co-proposals of the 2013 proposed rule. The costs it refers to are the cost estimates for the entire rule for the three co-proposals, each of which had a different definition of VSB. Second, the annualized cost estimates in the 2013 PRIA under the three co-proposals ($128.75 million, $119.90 million and $86.92 million) are the correct cost estimates for all industry members, both foreign and domestic. The 2013 proposed rule defines the costs as, and only shows, the annualized cost estimates for domestic manufacturers, not all manufacturers.

The comment also notes the lack of detail about the impact of the rule on small businesses, defined as those businesses with fewer than 500 employees.

Small businesses will have three years from the date of publication of the final rule to come into compliance with the requirements of preventive controls and very small businesses

will have four years to come into compliance with preventive controls. We did not calculate the value to small businesses from this additional year to come into compliance for the proposed rule. For the final rule, at an average per facility cost of about $29,000, the additional value of one year, discounted at seven percent, would be a reduction of about $1,800 (a reduction of about $800 at a three percent discount rate). Additional savings may occur as the facilities can make additional necessary changes to coincide with the normal pace of renovations to their business practices.

The comment asks us to include the SB and VSB estimates in the **R**egulatory Information Service Center and **O**ffice of Information and Regulatory Affairs **C**onsolidated **I**nformation **S**ystem (ROCIS) Tables, which in turn are required in the analysis by OMB. The comment also requests that we be more specific about the firm size category under discussion instead of using the terms "small", "smallest" or "largest" which may be difficult to link to the specific size categories.

The ROCIS Table only includes a summary of the costs and benefits of the rule. We include our detailed estimates of the impacts of the final rule on small entities in this final regulatory flexibility analysis. We change the FRFA to make firm size categories more clear.

The comment also requests that we analyze the impacts of the rule on those facilities that produce human food by-products that are then used in the animal food industry.

The final rule establishes the regulatory framework for these products in §§ 507.12 and 507.28. We clarify in the FRIA that these facilities are, for the most part, included in the FFR count as facilities that are registered as producing both human food and animal food. The impacts on these facilities are identified in the FRIA as those activities necessary to comply with § 507.28 and § 117.95. These sections require the identification of the human food by-products

for use as animal food, and that they be held and distributed under conditions that protect against contamination. We have not separately identified the cost factors for this in our compliance cost model. The cost model developed for the PRIA assigns costs to these facilities which range from 5 to 10 percent of the average annualized costs at those facilities producing only animal food. Our SMEs consider this to still be a reasonable estimate. We use the range of five percent to ten percent, and not just the range midpoint of 7.5 percent, of the average annualized cost to facilities that produce animal food (for the final rule this amounts to about $2,400 per facility) as the average annualized costs for the facilities producing human food by-products for use as animal food.

We do not separately account for all of the human food industry subtypes whose by-products are used as animal food in the FRFA, or the number of these facilities that could meet the requirements to be identified as small businesses or very small businesses for two reasons. First, they are already identified within their industry subtypes and whether they meet the small business and very small business requirements within the FRIA for the final preventive controls rule for human food. And second, each still needs to meet the requirements in §§ 507.12 and 507.28 (found in subparts A and B, respectively), even if they are exempt from subparts C and E because they are a VSB.

B. Description and Number of Small Entities Affected

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. The Small Business Administration (SBA) considers any animal food manufacturing firm with 500 or fewer employees to be small. Dog and cat food manufacturers are classified in the North American Industrial Classification System (NAICS) under industry code 311111 – Dog

and Cat Food Manufacturing. Other pet food manufacturers may be included with data for NAICS 311111 or with NAICS 311119 - Other Animal Food Manufacturing. For the dog and cat food companies, all but one facility would qualify as small entities if none of the firms had more than one establishment. However, the dog and cat food industry is dominated by six large companies, which make up about 86 percent of the market (Ref. 2). Nevertheless, there would still be a sizeable number of independent facilities that would qualify as small entities. The 2007 Census data for NAICS 311119, Other Animal Food Manufacturers, lists 1,502 facilities from 993 companies. The FDA FFR database adds thousands more facilities that are subject to the final rule. Unfortunately, we do not have a count of total employees per firm. The Census data show that all facilities in the Census count would qualify as small entities if they were single facility companies. While some of the facilities that are subject to the rule are part of multi-facility companies that would not qualify as small entities, substantial numbers of the facilities in both the Census and FFR databases would likely qualify as small entities.

Rendering facilities are classified under NAICS 311613 - Rendering and Meat Byproduct Processing. The SBA size limit for small entity classification for renderers is 500 or fewer employees. The 2007 Census data for NAICS 311613 does not list any facilities with more than 500 employees. Renderers that are not regulated by USDA's FSIS and that are making ingredients for animal food are subject to this rule. Although some renderers may be part of multi-facility companies that would disqualify them from the small entity classification, some renderers will still qualify as small entities.

The wholesale facilities that mix some animal food would be classified under either NAICS 4245 – Farm Product Raw Material Merchant Wholesalers, or NAICS 4249 – Miscellaneous Nondurable Goods Merchant Wholesalers. SBA sets the employee limit for small

entities in both of these NAICS codes at 100. The 2007 Census data show that less than 1 percent of facilities in the NAICS 4245 classification have more than 100 employees, and only about 2 percent of facilities in the NAICS 4249 classification have more than 100 employees. As with the other classifications, there may some multi-facility companies that would not qualify as small entities under the SBA definition. However, lacking more definitive data on firm sizes, we expect that a substantial number of these facilities would qualify as small entities.

As shown previously in this analysis, we base the cost model of the final rule on the count of facilities in the FDA Food Facility Registration (FFR) database; this database includes many thousands more facilities subject to the final rule than shown in the Census data for the various industry types. Unfortunately, we do not have a distribution of facilities (or firms) by the number of employees for the facilities included in the FFR database. Without this distribution, we can't derive meaningful estimates of the entities that would be considered small entities using the SBA definition. We think that any table that we would derive from the available information would be more confusing than clarifying, and highly uncertain. We include text in section B to explain why we do not include tables.

C. Impacts on Small Entities

The 2007 Census data report that the average value of animal food shipments ranges from about $660,000 for those dog and cat food facilities with fewer than 10 employees, to over $216 million for those facilities with 100 to 499 employees. The average annualized cost of about $2,000 per facility for the qualified dog and cat food facilities represents about 0.14 percent of the average value of shipments for the dog and cat food manufacturing facilities with fewer than 20 employees. The average annualized cost of about $31,000 per non-qualified facility represents about 0.11 percent or less for facilities with more than 20 employees. The average cost as a

percentage of value of shipments would be greater for those facilities with lower current compliance rates than others in the same size classification.

For facilities in NAICS 311119, Other Animal Food Manufacturing, the average value of shipments for 2007 range from $1.18 million for those facilities with fewer than 5 employees to more than $86 million for those facilities with 100 to 499 employees. The average annualized compliance cost of about $2,000 for qualified facilities equates to 0.17 percent of the average value of shipments for facilities with fewer than 5 employees, and would average even less for those qualified facilities with greater than 5 employees. The average annualized compliance cost at non-qualified animal feed mills of about $30,000 equates to about 0.45 percent of the average value of shipments for those facilities with fewer than 20 employees and 0.1 percent or less for all facilities with more than 20 employees. Although the regulatory cost to value of shipments ratio of 0.45 percent appears to show that costs could constitute a reasonably low percentage of revenues for all larger facilities, some facilities would likely incur substantially higher costs due to lower than average baseline compliance rates.

Rendering facilities report average values of shipments ranging from $1.60 million at those facilities with fewer than 5 employees to $46.62 million at those facilities with 100 to 499 employees. The average annual costs of compliance of about $2,000 for qualified facilities equates to 0.12 percent of the average value of shipments for those facilities with fewer than 5 employees, and less than 0.12 for qualified facilities with less than 20 but greater than 5 employees. The average annual costs of compliance of about $26,000 for non-qualified renderers equates to about 0.76 percent of the average value of shipments for those facilities with fewer than 20 employees but more than $2,500,000 in revenues, and 0.14 percent or less of value of shipments for all facilities with more than 20 employees. We do not know the distribution of

costs around the average cost, but some non-qualified facilities with fewer than 20 employees may have compliance costs that represent more than 1 percent of revenues due to low current compliance rates with provisions of the rule. Impacts on these facilities could be significant.

For facilities in NAICS 4245, Farm Product Raw Material Merchant Wholesalers, the average sales per facility ranged from $4.06 million at those with 2 employees to $560.47 million at those with 100-499 employees. The average annual cost of compliance of about $2,000 for qualified facilities represents about 0.05 percent of revenues at facilities with fewer than 5 employees. The average annual cost of compliance of about $27,000 for non-qualified facilities represents 0.74 percent of revenues at facilities with fewer than 5 employees, 0.21 percent of revenues at facilities with fewer than 20 employees and less than 0.03 percent at those with 20 or more employees. As with the renderers, it is possible that some of the facilities with fewer than 5 employees could incur costs over 1 percent of revenues, but we are unsure if a substantial number of these companies will be significantly impacted by the final rule. We do not have data for this NAICS category to show how facility size relates to the probability of manufacturing or processing animal food, despite requesting public comment and data on this question.

Facilities in NAICS 4249, Miscellaneous Nondurable Goods Merchant Wholesalers, have average sales ranging from $432,000 for those with 1 employee to $221.66 million for those with 100 to 499 employees. The average annual cost of compliance of about $2,000 at qualified facilities would average 0.45 percent of revenues for facilities with only one employee, 0.26 percent of sales for facilities with fewer than 5 employees, and less than 0.07 percent for facilities with fewer than 20 employees. The average annual cost of compliance of about $27,000 at non-qualified facilities would average 0.93 percent of revenues for facilities with less than 20

employees, and 0.10 percent or less for all other facilities. We conclude that the smallest of these non-qualified facilities could incur costs greater than 1 percent of revenues from the final rule if they manufacture or process animal food. Considerable uncertainty remains as to whether any small firms in this NAICS category actually perform any animal food manufacturing, processing, packing, or holding.

D. Regulatory Relief for Small Entities

Substantial relief from the compliance costs of this rule is provided to those firms that are qualified facilities, by exempting them from subpart C – Hazard Analysis and Risk-Based Preventive Controls and subpart E – Requirement to Establish and Implement a Supply-Chain Program, as discussed elsewhere in this analysis. Those businesses that are qualified facilities would incur annualized costs of about $2,200, composed of the annualized costs of 1) the initial review of the rule, 2) the additional labor to comply with subpart B, and 3) the costs to attest to qualified facility status (see section XI, subpart A in the preamble to the final rule for discussion of the requirements that apply to a qualified facility). About $550 of this is the annualized cost of the initial review of the rule, which as stated previously, most likely overstates the cost for qualified facilities since they would be exempt from subparts C and E which contain substantial parts of the rule.

We changed the final rule, in response to comments, to give more time to comply. The final rule will allow small businesses, defined by the proposed rule as employing fewer than 500 persons, three years (not two years as in the proposed rules) after publication of the final rule to comply with the requirements of subpart C of the rule (two years to comply with the requirements of subpart B). And very small businesses, defined under the final rule as those averaging less than $2.5 million per year, adjusted for inflation, during the 3-year period

preceding the applicable calendar year, in both sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale, will have four years (not three years as in the proposed rules) after publication of the final rule to comply with the requirements of subpart C or § 507.7 (three years to comply with the requirements in subpart B). This gives the 2,821 very small facilities (which accounts for all qualified facilities) four years to fully comply with the final rule.

IV. Unfunded Mandates Reform Act Analysis

We have determined that this final rule meets the threshold for requiring a written statement under the Unfunded Mandates Reform Act of 1995. This rule is being promulgated under FSMA section 103 (section 418 of the FD&C Act) and sections 402 and 701 of the FD&C Act, among others, as described in the Legal Authority section of the final rule preamble. We have carried out the cost-benefit analysis of the rulemaking in preceding sections of this FRIA. The other requirements under the Unfunded Mandates Reform Act include assessing the rule's effects on future compliance costs; regions, communities, or industrial sectors; national productivity; economic growth; full employment; job creation; and exports. Effects not covered in detail in the cost-benefit and regulatory flexibility analyses of the preceding sections may be small or non-existent. Comments presented by State, local, and tribal governments and our responses to those comments may be found in the preamble to this final rule.

V. References

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