DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Food for Animals

Docket No. FDA-2011-N-0922

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy and Planning
Office of the Commissioner

a. The ERG cost model

i. One-time costs

ii. Annual costs

iii. Total food safety plan costs from ERG cost model

b. Additional costs of the proposed animal food safety plan

i. Costs to attest to qualified status and related requirements

aa. Costs to qualified facilities to attest to qualified status

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

ii. Sanitation Controls

aa. Writing procedures for sanitation controls

bb. Additional sanitary control labor cost

cc. Sanitation control monitoring and verification

iii. Validation of the animal food safety plan

iv. Reanalysis of the food safety plan

v. Monitoring preventive controls

vi. Corrective actions

vii. Process controls verification

viii. Requirements for a qualified individual

x. Administrative costs to review the rule and develop a compliance plan.

x. Other costs of proposed rule included in the ERG analysis

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

xii. Total industry costs of the proposed part 507

xiii. Government costs

D. Analysis of Alternatives

1. Customer complaints

2. Finished product testing

3. Performance of environmental monitoring

4. Supplier approval and verification program

a. Written list of approved suppliers

b. Determination, by ingredient, of which regulations the supplier is subject

c. Verification activities for suppliers

i. Audits of suppliers

ii. Supplier Verification Activities other than Audits

iii Verification activities for suppliers that are qualified facilities

iv. Summary of supplier controls costs

5. Review of other records

6. Personnel training

7. Other alternatives

III. Initial Regulatory Flexibility Act

A. Description and Number of Small Entities

B. Impacts on Small Entities

C. Regulatory Relief for Small Entities

I. Introduction and Summary

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

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would impose annualized costs that range from $14,700 to $20,100 on small entities, the Agency has determined that the proposed rule, if finalized, may have a significant economic impact on a substantial number of small entities. Therefore, this analysis of impacts and other sections of the preamble constitute FDA’s initial regulatory flexibility analysis.

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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. This proposed rule may result in 1-year expenditures that would meet or exceed this amount.

In the Food Safety Modernization Act of 2011 (FSMA), Congress amended the FD&C Act by adding section 418 mandating that HHS issue regulations to 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 domestic and foreign facilities that are required to register with FDA under section 415 of the Federal Food, Drug and Cosmetic Act. The proposed rule would implement section 418 provisions for facilities that manufacture, process, pack, or hold food for animals. In addition, the proposed rule includes current good manufacturing practice requirements for the manufacturing, processing, packing, and holding of animal food. The proposed rule would not apply to facilities that also perform any of the above activities for foods for human consumption and choose to follow proposed 21 CFR part 117 (published in the Federal Register January 16, 2013 (78 FR 3646)) with respect to animal food as long as the hazards specific to animal food are addressed.

The major elements of this proposed rule are contained under subparts B and C. Subpart C, titled Hazard Analysis and Risk-Based Preventive Controls, contains the major provisions as outlined in section 418. Under the Hazard Analysis and Risk-Based Preventive Controls, each animal food facility would be required to have a food safety plan for animal food that would include a hazard analysis of facilities, a written preventive control plan (including recall procedures), written procedures for monitoring preventive controls, written corrective action procedures, written verification procedures, and a description of the recordkeeping procedures. Subpart B, titled Current Good Manufacturing Practice, would require current good

manufacturing practices (CGMP) for the following: personnel; plants and grounds; sanitary operations; sanitary facilities and controls; equipment and utensils, processes and controls; and warehousing and distribution.

Small businesses, defined as those with fewer than 500 employees, would not be subject to any final rule until two years after a final rule is published. Very small businesses, co-proposed as those facilities with gross annual sales of animal food of less than 1) $500,000, 2) $1,000,000 and 3) $2,500,000 adjusted for inflation, would not be subject to the hazard analysis and preventive controls requirements of any final rule on the condition that they attest to their qualified status; and would not be subject to the other provisions of any final rule until three years after publication of the final rule.

Certain other on-farm manufacturers that are small and very small businesses and only engage in manufacturing, processing, packing or holding activities that have been determined to be low risk on-farm activities conducted on low-risk animal food, are exempt from the hazard analysis and preventive controls requirements of the proposed rule. Additionally, certain animal food facilities that produce low-acid canned foods are exempt from the microbiological hazard requirements of the hazard analysis and preventive controls requirements, so long as they comply with 21 CFR part 113. Along with the very small businesses, other qualified facilities would also be exempt from the hazard analysis and preventive controls requirements of this rule, but would be subject to the requirements in subpart B (Current Good Manufacturing Practice).

A. Summary of Proposed Regulatory Impacts Analysis

FDA presents costs and benefits of the proposed rule under the assumption that no costs are attributable to baseline activities that were completed prior to the enactment of the Food Safety Modernization Act in 2011. In April, 2011 Eastern Research Group (ERG) delivered its

final report estimating the impacts of a working version of a process controls rule (further referenced in this document as the process controls draft) the Agency had been developing prior to FSMA (Ref. 1). Many of the provisions of this proposed rule are very similar to those in the process controls draft assessed by ERG. FDA therefore relied heavily on the methodology and estimates in the ERG report, including its count of affected facilities and labor and its estimate of capital compliance costs for those provisions contained in both rules. For those provisions in the proposed rule that were not included in the process controls draft, FDA relied on the compliance cost methodology developed for the proposed rule to revise human food CGMPs and implement section 418 of the FD&C Act for human food (based on survey data from facilities producing human foods and expert elicitations) (Refs 2,3), and the expert opinion of FDA personnel with experience in the regulation of animal food production facilities.

1. Costs

Total one-time compliance costs are estimated at $100.74 million for the co-proposal for very small businesses with animal food sales set at less than $500,000. Total annual costs are estimated at $114.418 million. Discounting the one-time costs over 10 years at a 7 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $128.75 million (see Table 1). Discounting the one-time costs over 10 years at a 3 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $126.22 million.

Total one-time compliance costs are estimated at $95.47 million for the co-proposal for very small businesses with animal food sales set at less than $1,000,000. Total annual costs are estimated at $106.30 million. Discounting the one-time costs over 10 years at a 7 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate

of $119.90 million (see Table 1). Discounting the one-time costs over 10 years at a 3 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $117.50 million.

Total one-time compliance costs are estimated at $74.71 million for the co-proposal for very small businesses with animal food sales set at less than $2,500,000. Total annual costs are estimated at $76.28 million. Discounting the one-time costs over 10 years at a 7 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $86.92 million (see Table 1). Discounting the one-time costs over 10 years at a 3 percent discount rate and adding the annual costs results in a total annualized compliance cost estimate of $85.04 million.

2. Benefits

FDA is unable to quantify the benefits of the proposed rule. The proposed rule would result in fewer cases of contaminated animal food ingredients and fewer cases of contaminated finished animal food products for human consumption. The reduction in contaminated ingredients 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 health and the health of companion animals.

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

	1-Time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Total Costs (VSB < $500,000)	$100.74	$114.41	$128.75	$126.22
Total Costs (VSB < $1,000,000)	$95.47	$106.30	$119.90	$117.50
Total Costs (VSB < 2,5000,000)	$74.71	$76.28	$86.92	$85.04
Benefits	Improved food safety systems can reduce the risks of recalls, adverse health effects related to contaminated food, and reduce losses of contaminated food ingredients and animal food products.			

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

In Table 1a, FDA provides the ROCIS accounting information.

Table 1a. Economic Data: Costs and Benefits Statement (VSB < $500,000)

	Category	Primary Estimate	Low Estimate	High Estimate	Units			
					Year Dollars	Discount Rate	Period Covered	Notes
Benefits	Annualized					7%		
	Monetized $millions/year					3%		
	Annualized					7%		
	Quantified					3%		
	Qualitative	Improved food safety systems can reduce the risks of recalls, adverse health effects related to contaminated food, and reduce losses of contaminated feed ingredients and animal food products.						
Costs	Annualized	$128.75			2012	7%	10 years	Primary estimate assumes all foreign costs are passed on to US consumers.
	Monetized $millions/year	$126.22			2012	3%	10 years	
	Annualized					7%		
	Quantified					3%		
	Qualitative							
Transfers	Federal Annualized					7%		
	Monetized $millions/year					3%		
	From/ To	From:			To:			
	Other Annualized					7%		
	Monetized $millions/year					3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No Effect							
	Small Business: The proposed rule may have a significant impact on a substantial number of small entities that manufacture animal foods and animal food ingredients.							
	Wages: No effect							

II. Preliminary Regulatory Impact Analysis

A. Need for Regulation

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

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

In a perfectly competitive market in which consumers and producers both have sufficient information, the optimal level of production of animal foods that are manufactured, processed, packed or held will be provided at an optimal level of safety. In these markets, however, consumers and producers may not have sufficient information on the safety attributes of foods. Although producers do have an incentive to put safety programs into place, the lack of awareness and information about the risk suggests that an inefficiently high demand may exist for animal food products that are produced without using adequate measures to prevent food borne illness, adulteration, or contamination. Because the demand for many manufactured or processed animal foods may not be sufficiently affected by safety considerations, incentives to invest in safety measures from farm to fork is diminished. Consequently, the market may not provide the incentives necessary for optimal food safety.

With sufficient information for consumers and producers, a legal system that awards compensation for harm done due to unsafe foods has the potential to remedy market imperfections by providing producers with incentives to provide the level of safety that is best for society. Currently, the legal system does not ensure the optimum level of safety for animal foods because both the cause and source of a food borne illness may not be known to the

purchaser or consumer of the food. Even in cases where consumers are aware that a pet's illness was contracted from a specific food, it is often difficult to determine who is ultimately responsible for the illness, since the particular source of contamination is not known in many circumstances.

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

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

B. Benefits of the Proposed Rule

The proposed rule would modernize how animal food is manufactured, processed, packed, or held throughout the entire supply chain and minimize potential hazards in animal food. By implementing one of the major requirements of FSMA, the proposed rule would require that facilities develop a food safety plan. The proposed rule also would require facilities to follow current good manufacturing practices (CGMP). Food safety plans would include a hazard analysis, a written preventive control plan (including recall procedures), written procedures for

monitoring preventive controls, written corrective action procedures, written verification procedures and a description of the recordkeeping procedures. Covered facilities would need to implement and follow CGMPs for: personnel; plants and grounds; sanitary operations; sanitary facilities and controls; equipment and utensils, processes and controls; and warehousing and distribution.

The benefits of the proposed rule would result from fewer incidents of adulterated animal food ingredients and adulterated finished animal food products. Better management of hazards in animal food during manufacturing, distribution, storage and handling would reduce the likelihood that adulterated animal food could reach the market. Reducing the adulterated animal food incidents would (1) reduce the risk of serious illness and death to animals, (2) reduce the risk of adverse health effects to humans handling contaminated animal food, and (3) reduce the risk of consuming human food derived from animals that consumed contaminated food.

To achieve these objectives, the proposed rule would require facilities that manufacturer, process, pack, or hold animal food to establish comprehensive animal food safety systems and to follow current good manufacturing practices. Conducting a systematic evaluation of the potential hazards related to their activities with animal food would help facilities identify the potential risks to animal and human health from their current materials management and manufacturing processes. Identifying sources of potential hazards allows manufacturers and other facilities that process, pack or hold animal food to develop prevention-focused food safety systems. More stringent requirements for the entire animal food supply chain would maintain public confidence in the safety of animal foods and protect animal and human health.

1. Potential Hazards Found in Animal Food

Codex defines a food hazard as a biological, chemical, physical or radiological agent that

is capable of causing an adverse health effect (Ref. 4). Who is at risk of an adverse health effect from a hazard and the severity of such an effect depend on the type of hazard and probability that the presence of the hazard in a particular animal food will cause the adverse health effect. For example, *Salmonella*, the most commonly identified biological hazard in animal foods, primarily affects humans that handle contaminated animal food. Chemical contamination of animal food with aflatoxins or melamine creates a risk of adverse health effects for the animals that consume the contaminated food. Humans may be exposed to pesticide residues or aflatoxins when they eat food from animals fed contaminated feed. Formulation or mixing errors can cause nutrient imbalances in animal food that could pose a serious health risk to animals. Foreign substances such as metal, glass or plastic fragments are types of physical hazards found in animal food.

Registered facilities that manufacture, process, pack or hold animal foods are required to submit reports for certain foods to the Reportable Food Registry (RFR) when there is a reasonable probability that use of, or exposure to the food will cause serious adverse health consequences or death to humans or animals. From September 2009 to September 2011, the RFR received 47 primary reports of problems related to animal food. Table 2 presents a summary of reports to the reportable food registry over this period. Based on the potential of a hazard to cause serious adverse health effects, Table 2 also includes the risk ranking for the hazards reported to the RFR. During this two-year period, the largest number of reports identified *Salmonella* as the hazard; no serious adverse health consequences or deaths were reported during this time. In contrast, reports were received of serious adverse health consequences related to nutrient imbalances and physical hazards. During this period, no reports of problems with radiological hazards were submitted.

Table 2. Reports Submitted to the Reportable Food Registry from September, 2009 to September, 2011 by Type of Hazard and Severity of the Health Effect.

Hazard	Number of Reports	Serious Illness or Death Reported?	Hazard Ranking[1]	Species Primarily Affected by Hazard
Biological: (*Salmonella*)	21	No	1	Human
Chemical: contaminants (e.g.,Mycotoxins, Dioxin, Botulism)	5	No	2 (mycotoxin) 3 (dioxin)	All Species
Chemical: nutrient imbalance (e.g., excessive urea, copper; inadequate thiamine, vitamin D)	17	Yes	4 (formulation & mixing errors)	All Species
Physical hazards (e.g., metal, glass, plastic)	4	Yes	6	All Species

[1] Although no reports of melamine contamination (economically motivated chemical hazard) were received during the 2-year period, this hazard has a risk ranking of 5.

2. Effects of Hazards in Animal Food

The proposed rule would decrease the risk that hazards in animal food would occur by requiring animal food manufacturers to institute CGMPs and evaluate and mitigate the hazards of their current food safety systems. Decreasing the risk that adulterated animal food would reach the market reduces adverse health effects attributable to adulterated animal food. Adulterated animal food causes companion animal owners and livestock producers to incur direct costs to treat adulterated food-related illness. When animals die or are destroyed after the consumption of contaminated food or nutrient imbalanced food, owners lose the market value of these animals. In addition to the market value of a companion animal, the economic value of the loss of a companion animal would also include the nonmarket value of companionship.

Adulterated animal food can trigger expensive recalls that may lead to product shortages and higher consumer food costs. Improper storage of animal food ingredients can promote the growth of fungi or bacteria. Fungi release toxins such as aflatoxin, deoxynivalenol (DON), or the

fusarium toxins that can be fatal to animals that consume contaminated food. Products found to contain such toxins or bacterial contamination would likely be recalled. Minimizing hazards that adulterate animal food could reduce some of the recalls of animal food.

Salmonella contaminated animal food can cause illness in humans who handle the food. CDC reported in 2008 that there had been at least 13 recalls involving 135 pet food products for *Salmonella* contamination. One outbreak involved 79 reported cases of *Salmonella* Schwarzengrund infection in 21 states (Ref 5). Another outbreak involved 34 reported cases of *Salmonella* infection in 17 states. Reducing the prevalence of *Salmonella* contamination in animal food products would lower the risk to human health associated with consumers handling animal food.

Physical hazards include metal and glass fragments. One case reported to the RFR described livestock feed contaminated by glass particles. Improper cleaning of the transport truck was likely responsible. The proposed rule would decrease the potential risk from such physical hazards.

Finally, more stringent preventive controls could reduce opportunities, by either domestic or foreign sources, to intentionally contaminate animal food; thus improving the security of the finished animal food supply chain. Because we lack sufficient data to quantify the benefits of reducing hazards in animal food to mitigate the negative effects of those hazards, we illustrate how the proposed regulation would decrease the risk of contaminated animal food products by describing recent recalls and cases of animal food contamination. When possible, we include a discussion of the costs associated with the particular event.

3. Finished Animal Food Recalls

Problems with the quality of animal food ingredients or manufacturing production errors

can cause finished food products to be recalled. When products are recalled, manufacturers incur the costs of the recall, which includes the lost value of the product, and, depending on the severity of the problem, can cause the loss of substantial consumer goodwill. Such market forces apply pressure on manufacturers to adopt manufacturing practices that reduce the risk of recalls. Nevertheless, animal food recalls continue to occur, suggesting that market incentives are not sufficient to motivate manufacturers and others processing and handling animal food to adequately control hazards that can cause recalls. The proposed rule would require specific controls that would help prevent animal food recalls and facilitate the tracking of animal food where recalls are necessary. Table 3 summarizes class I recalls between fiscal years 2006 and 2010 by the type of hazard and animal food. Although chemical contaminants account for the vast majority of class I recalls, the 2007 melamine contamination of pet food alone accounts for 80 percent of recalls for chemical contamination and over 60 percent of all class I recalls.

Table 3. Class I Animal Food Recalls for Fiscal Years 2006-2010

Hazard	Types of Animal Food(s) Recalled	Number of Class I Recalls
Microbiological—All	Pet Food; Livestock Food	339
Salmonella		292
Pseudomonas		1
Prohibited protein*		46
Chemical: contaminants—All	Pet Food; Horse Food; Livestock Food	1,324
Melamine		1,062
All others (e.g., Mycotoxins, Botulinum toxin, Pesticides)		262
Nutrient Imbalance	Pet Food: Livestock Food	39
Physical hazards (e.g., Metal, Glass, Plastic)	Game Bird Food; Horse Food; Livestock Food	32
Total		1,734

a. Pet food

Table 4 shows the number of recalls for pet food by class of recall from 2003 to 2007. As

shown, from 2003 to 2006, there were few recalls of pet foods. However, melamine contaminated pet food recalls caused the spike in class I and class III recalls in 2007.

Table 4. Number of Pet Food Recalls by Class of Recall and Year

Year	I	II	III	Total
2003	1	9	0	10
2004	0	0	0	0
2005	10	0	0	10
2006	0	6	0	6
2007	670	2	231	903
Total	681	17	231	929

Since 2007, 4 incidents have triggered major recalls of pet foods. *Salmonella* contamination caused the 2010 recall of frozen mice used as reptile food, and the 2009 recall of over 100,000 dog treats. An outbreak of *Salmonella* Schwarzengrund infections caused by handling contaminated dry dog and cat food led to a recall of 23,000 tons of dry food and the 2008 closure of the plant where the contamination occurred. In 2011, over 20 million cans of cat food were recalled because they lacked adequate levels of the essential vitamin thiamine.

Two events provide information about the costs of recalls. In 2005, a pet food company recalled 500 tons of pet food contaminated with aflatoxin. The source of the aflatoxin was local corn used to manufacture the dog food. The agency confirmed that 23 dogs died and another 18 dogs became ill from the contaminated food. The firm paid $3.1 million to settle a lawsuit related to this recall event.

The largest modern pet food recall resulted from a case of economically motivated adulteration caused by the intentional addition of melamine to wheat gluten and rice protein concentrate. Wheat gluten and rice protein concentrate are common protein sources for cat and dog foods. Melamine, a nitrogen-rich industrial chemical, was added to animal food ingredients in China and imported by U.S. suppliers to pet food manufacturers. Simple chemical tests for

protein levels failed to detect the melamine. It was later determined that a mix of melamine and cyanuric acid (a contaminant in the melamine) in the pet food likely caused crystals to form in the kidneys, leading to kidney failure in some animals.

Consumers and veterinarians reported many illnesses and deaths potentially associated with a wide variety of pet foods made by a pet food manufacturer and its contract companies. Over 150 brands of pet foods were eventually recalled for melamine contamination. The cost of this recall was approximately $50 million ($55 million in Canadian dollars; Menu Foods Income Fund, 2008). Because these products were also sold by other distributors, the total cost to the pet food industry exceeded the $50 million total. Moreover, this total does not include the extensive resources FDA dedicated to manage this event. For example, more than 400 employees were mobilized to deal with the recall and over 700 samples of pet food were tested in Agency laboratories to identify melamine as the contaminant.

In addition to the direct cost of the recall, the economic impact of this event includes the veterinarian costs to treat the pets that became ill after consuming the contaminated pet food, the value of companion animals that died from the contaminant, and the loss of consumer confidence for the affected pet food products. Immediately following this event, the demand for pet food products not affected by the recall and other niche pet food products (e.g., grain-free pet foods) increased. This demand shift created opportunities for certain manufacturers of pet food products and resulted in a short term distributional impacts within the pet food industry.

Because companion animal ownership is voluntary, owners receive a benefit from the animal that equals or exceeds the cost of owning the animal. According to the pet food industry, as many as half of U.S households own pets, spending about $46 billion on pet food and related products and about $25 billion on veterinary and other pet services. The total willingness to pay

for pets would be larger than this amount by the consumer surplus. (That is, many consumers would have been willing to pay more than the purchase price for their pets.) Pet owners often develop emotional attachments to their pets and often consider the pets as members of the family. For owners who consider pets as family, the consumer surplus could be quite large. Unfortunately, we lack information sufficient to estimate the total value of pets to consumers, and the willingness of households to pay for a reduced risk of contaminated food for pets. The total household spending on pets, however, implies that the willingness to pay for safer pet food could be substantial.

b. Animal feed (food for livestock)

Data are limited on the number of animal deaths caused by recalled adulterated animal feed and on the costs for animal food manufacturers to manage such recalls. The number of animal feed recalls that occurred from 2003 through 2007 is shown in Table 5. Organized by medicated and non-medicated feed, recalls are tallied for each year by class of recall (i.e., classes I, II, and III, with class I being the most severe). Over five years, there were almost 100 Class I recalls of animal feed. There is no obvious trend in recall events, and some years (2003 and 2005) produced very few Class I recalls.

Table 5. Number of Recalls by Class of Recall and Year

Medicated Feeds				
Year	I	II	III	Total
2003	1	146	1	148
2004	16	17	2	35
2005	3	13	61	77
2006	1	15	8	24
2007	0	2	19	21
Total	21	193	91	305
Average	4.2	38.6	18.2	61.0
Non-Medicated Feeds				
Year	I	II	III	Total
2003	2	431	8	441
2004	23	40	0	63
2005	1	4	0	5
2006	35	29	1	65
2007	12	21	59	92
Total	73	525	68	666
Average	14.6	105	13.6	133.2

Source: FDA, 2009.

Table 6 shows the distribution of the amount of material recalled for the medicated and non-medicated feed categories. The amount of material recalled in the animal feed categories is often fairly small, with many recalls of 0 to 5 tons or 5 to 10 tons. However, there were numerous recalls involving more than 25 tons of feed, especially Class II recalls. Among the medicated feeds, the largest recall involved 800,000 tons, followed by a recall involving 23,000 tons. Among the non-medicated feeds, the largest recall reached nearly 25,000 tons. To estimate the cost of animal feed recalls, we calculated an average of 560 tons for the animal feed recalls in which the amount of material is reported, excluding the 800,000-ton recall as an outlier. Using an average value of roughly $300 per ton of feed, the recalls involved direct product losses of $168,000 each. With an average of 194 recalls of animal feed per year, the annual direct product losses total $32.6 million. By reducing the probability of contamination, the proposed rule would avoid some of these recalls, and thus some of the direct losses attributable to livestock feed recalls. However, we are unable to quantify the magnitude of this reduction.

Table 6. Number of Animal Feed Recalls by Quantities and Class of Recall (2003 – 2009)

Medicated Feeds				
Quantity (Tons)	I	II	III	Total
0-5	11	43	46	100
Over 5 to 10	6	26	17	49
Over 10 to 15	1	14	9	24
Over 15 to 20	0	9	1	10
Over 20 to 25	2	7	1	10
Over 25+	0	34	8	42
NA or NR	1	60	9	70
Total	21	193	91	305
Non-Medicated Feeds				
Quantity (Tons)	I	II	III	Total
0-5	23	53	4	80
Over 5 to 10	2	26	3	31
Over 10 to 15	3	10	2	15
Over 15 to 20	3	10	0	13
Over 20 to 25	1	9	3	13
Over 25+	7	106	12	125
NA or NR	34	271	44	349
Total	73	485	68	626
Source: FDA, 2009				

4. Human Illness Associated with Contaminated Animal Food Products

CDC reported a multi-state outbreak of *Salmonella* serotype Schwarzengrund infections that primarily affected children. This outbreak continued over a three-year period from 2006 to 2008 and was eventually traced to a single pet food manufacturing plant in Pennsylvania. This strain of *Salmonella* was found in dry pet food and is a strain of *Salmonella* not commonly found in other food products. Seventy-nine cases of human infections have been linked to handling of the contaminated dry pet food. Of these, 48 percent of the affected patients were children under the age of 3. Results of a case-control study suggest that in most cases, the outbreak resulted from improper handling (hand-to-mouth contact) of contaminated dry pet food.

In 2010, CDC reported that 34 individuals in 17 states had been infected with a *Salmonella* serotype. The *Salmonella* strain in the US outbreak is indistinguishable from the

strain that caused a similar outbreak in 2009 in the United Kingdom. The source of contamination for both outbreaks appeared to be improper handling of frozen mice used as food for reptiles.

According to the CDC, symptoms of *Salmonella* infection occur 12 to 72 hours after infection and include diarrhea, fever, and abdominal cramps. Normally the acute symptoms of *Salmonella* infections last for four to seven days and often do not require treatment. Certain groups, such as the elderly, children and persons with compromised immune systems can be more susceptible to severe illness and need hospitalization. Although rare, death can occur if the *Salmonella* infection spreads to other parts of the body. Although the proposed rule does not affect how consumers handle animal food products, having more robust food safety systems in place would reduce the risk that contaminated products reach consumers. Reducing the risk that consumers handle contaminated animal food would reduce the risk of *Salmonella* and other bacterial infections. The public health benefit of fewer *Salmonella* infections would be the value of avoided illness and deaths. However, we lack information about the severity of human illness attributable to improper handling of contaminated animal food that would allow us to estimate the value of lost health attributable to fewer bacterial infections.

5. Summary of Potential Benefits

We lack sufficient data to quantify the potential benefits of the proposed rule. The causal chain from contaminated animal food to human health and welfare can be identified but not quantified. Because no data exists to quantify the likelihood of hazards that might be found in different animal food products, we are unable to estimate the effectiveness of the requirements of the proposed rule to reduce potential adverse health effects in humans or animals. Nevertheless, we have described how improved animal food safety systems can reduce the number of recalls,

reduce the risk of adverse health effects related to contaminated animal food, and reduce the losses of contaminated animal food ingredients and products. Furthermore, better control over the supply chain could reduce the opportunity for economically motivated adulteration, such as the melamine contamination of pet foods.

C. Costs of the Proposed Rule

This cost analysis will present estimated individual costs of the proposed rule with the $500,000 sales exemption, unless specifically stated otherwise (such as the description of the total facilities subject to the proposed rule under the three co-proposed definitions of a very small business).

1. Information Sources

FDA uses several different sources in the development of its compliance cost estimates. We discuss the major sources in this section.

a. The Eastern Research Group report

Before FSMA, FDA had been developing a process controls rule, referred to in this document as the process controls draft. As part of that effort, FDA contracted with Eastern Research Group (ERG) to conduct an economic analysis of a draft of that proposed rule that would have required process control standards for animal food (both ingredients and finished food) establishments that process animal food for either food-producing animals or non-food-producing animals (i.e. cats, dogs and other pets).

In its 2011 Final Report titled "Economic Analysis of Proposed Animal Feed Regulation – A Cost Analysis for the Livestock Feed and Pet Food Industries"(Ref. 1), ERG analyzed this process controls draft, which contains requirements similar to the proposed rule. Both the

proposed rule and the process controls draft rely on a hazard analysis (or evaluation in the process controls draft) of those facilities subject to the rule as the basis for the written food safety plan each requires. The majority of the similarities between the proposed rule and the process controls draft are included in the preventive control section (§ 507.36) of the proposed rule. Both would require that the facility identify, write, and then implement preventive control procedures (or process control procedures) for hazards that are reasonably likely to occur. For the proposed rule, these include preventive controls, including at critical control points, for the control of hazards that are reasonably likely to occur. The proposed rule also includes process controls for the procedures that address processing parameters for animal foods being processed, manufactured, packed or held by a facility and a recall plan for animal food in which there is a hazard that is reasonably likely to occur. Finally, the proposed rule would require procedures for ensuring that animal food and ingredient labeling correctly identifies these products. Both the proposed rule and the process controls draft also contain requirements for corrective actions if the preventive control procedures fail to significantly minimize or prevent an identified animal food hazard.

We note that one of the differences between the process controls draft and the proposed rule implies differences in the number and types of entities covered. The ERG report concludes that the process controls draft rule would apply to about 18,100 on-farm mixer/feeder facilities that would not be subject to the proposed rule because they are not required to register under section 415 of the FD&C Act. With the removal of these facilities, the ERG report estimates that about 7,700 domestic establishments would be subject to the process controls draft. Further, the methodology developed for the ERG report calculated costs to importers, as the process controls draft rule would have required. This proposed rule, however, would cover foreign facilities that

manufacture, process or store animal foods and not those importing the animal foods. This analysis, therefore, follows the methodology used in the regulatory impact analysis for the January 2013 proposed rule on preventive controls for human foods (78 FR 3646) in which the average cost per facility type is assigned as the estimated cost for the same type of foreign facilities,

The proposed rule would also require activities beyond those that would have been required by the process controls draft (including sections on monitoring and verification). Even though organizational differences between the process controls draft and the proposed rule make a provision-by-provision comparison of the two rules unfeasible, the 2011 ERG final report provides data and other information sufficient to analyze most of the compliance costs of the preventive controls section of the proposed rule (§ 507.36) as well as parts of the corrective action and monitoring sections of the proposed rule.

In order to estimate a significant part of the compliance costs of the proposed rule, FDA utilizes the 2011 ERG report and its model mill, model supplier and model pet food manufacturer cost approach that estimates the compliance costs of the process controls draft rule. We address the parts of the proposed rule not included in the ERG estimates later in this document.

i. The BSE database of facilities

ERG based the number of establishments in its report on the FDA database of the inspection reports concerning the enforcement of two major rules to help prevent the establishment and spread of bovine spongiform encephalopathy (BSE). In January, 2011, FDA published an update on these activities. This report details the number of active domestic firms in total and by segment of industry. It shows that 276 renderers, 1,047 licensed feed mills, 5,210

unlicensed feed mills and 303 protein blenders, or 6,836 in total, were active or in operation. In the category combining renderers, feed mills and protein blenders, the report lists the total number of unique active firms (in actuality these are specific facilities) at 6,606. The difference in totals is caused by some facilities being counted under more than one category.

ii. Facilities Types and Distribution in ERG Report

The ERG report discusses the reasons for the uncertainty in the number of facilities that manufacture animal feeds. Census of Manufactures data appear to omit a substantial number of small feed mills. ERG combined the 2002 Census of Manufactures data on the number of mills by employee size with information from the FDA BSE database, discussion with FDA staff and contacts with several state agricultural agencies to develop its own estimates of the number of commercial feed mills. Using Census data, it assumed that all mills with more than 50 employees were large mills, and that those with 20-49 employees were medium mills. ERG used the number of small facilities in the BSE database, minus the number of integrator facilities and wholesale facilities that perform some feed mixing to reach an estimate of 3,786 small mills, which would be those with fewer than 20 employees. Additional uncertainty surrounds the number of small mills, and it is possible that that some mills considered small have either more than 20 employees, or produce much larger tonnages of feeds than one would consider average for a small mill.

ERG derived its estimate of 750 integrator facilities from the number of facilities in the BSE database and discussions with FDA staff with experience in regulation of integrated operations. Lacking data on integrator size distributions, FDA distributed one-third to each of the following size categories: facilities with fewer than 20 employees, facilities with 20-99 employees, and facilities with 100-499 employees. FDA notes that the total costs would not

significantly change with 50% of the integrators assigned to the category of facilities with 20-99 employees and 50% to those facilities with 100-499 facilities. FDA acknowledges the uncertainty surrounding the number of integrated facilities and their size distribution. FDA requests public comment and data on these issues.

To derive its estimate of 1,216 wholesaler facilities, ERG used Census data for those North American Industrial Classification System (NAICS) codes 4245 (farm product raw material merchant wholesalers) and 4249 (farm supplies merchant wholesalers) that sell prepared poultry and livestock feeds, including silage, that are mixed on location. Additional uncertainty is attached to the total number of these facilities. It is possible that some of these 1,216 facilities under NAICS codes 4245 and 4249 may only distribute animal food (i.e. not actually manufacture the animal food) according to the precise definition of feed manufacturing included in the process control rule, but ERG could not make that determination from the information available. However, since these facilities were not included in the NAICS codes for other (non-dog, non-cat and non-other pet food) animal food manufacturing and were probably included in the count from the FDA BSE database, ERG determined they should be included separately.

FDA used 2007 Census data to estimate the number of cat and dog food manufacturing facilities at 265. FDA separated the 2007 Census numbers into large and small operations based on the number of employees. FDA defined the 207 operations from the 2007 Census data with fewer than 100 employees as the small operations. The 58 operations with 100 or more employees were defined as large operations. This use of more recent data for numbers does not affect the compliance costs per pet food manufacturing facility as estimated in the ERG report, which is based on the 2002 Census.

The process controls draft would not have applied to the suppliers of raw agricultural

commodities, and this is also true of the proposed rule. ERG estimated the number of animal food ingredient suppliers at about 1,200, including an adjustment of 300 additional facilities for those small operations that its estimation method may have omitted. ERG initially searched the Census data to compile the number of producers of processed ingredients that are used in animal food manufacturing. However, its final report relies on the Reference and Buyers Guide Issue of a Feedstuffs Magazine, which offers free listings to suppliers, for its final estimate of the number of facilities that produce processed ingredients used in animal foods. ERG then apportioned those 1,200 ingredient suppliers over small, medium and large facilities based on number of employees per facility, with small ranging from 1 to 19 employees, medium from 20 to 99 employees, and large from 100 or more employees.

Under the proposed rule, however, a facility that also manufactures foods or food ingredients for human consumption may choose to follow the proposed rule for human foods (78 FR 3646) with respect to its animal food as long as the hazards specific to animal food are addressed. We assume that any ingredient manufacturer that produces ingredients for both human and animal foods would opt to follow the human foods proposed rule. In this case, it is likely that a substantial percentage of these 1,200 ingredient manufacturers would not be subject to this proposed rule because they also manufacture ingredients used in foods for human consumption, and their implementation costs would be covered by the human food proposed rule. The final list of types of facilities manufacturing ingredients in the ERG report includes the following (by facility activity): flour milling, wet corn milling, soybean processing, sugar processing, oilseed processing, alfalfa processing, fish processing, fats and oils, and meat processing (rendering). With the exception of those renderers that do not produce any ingredients used in foods for human consumption (independent renderers), the other ingredient

manufacturers listed above would likely be subject to the human food proposed rule. This reduces the number of ingredient manufacturers subject to the proposed rule to about 155 facilities (231 renderer establishments times an estimated two-thirds which are believed to be independent renderers). FDA adjusted the renderer facility figures by subtracting from the number of large renderers and medium renderers until a one-third reduction in total renderers was reached, under the assumption that the packer/renderer facilities, which would not be subject to this rule, would have more employees than the independent renderers, which would likely be subject to this rule. FDA acknowledges some uncertainty surrounding this estimate and requests public comment and data on those facilities that would be subject to this rule, especially those that manufacture ingredients used in animal food production, but that do not manufacture foods or food ingredients for human consumption.

FDA has not accounted for the facilities that produce ethanol from grain crops and distribute the byproducts to animal feed mills or other animal food producers, but expects them to be subject to this proposed rule. FDA request public comment and data on the number of these facilities and their expected compliance actions.

b. The Food Facility Registration database

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires that all domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States be registered with FDA This registration would identify the type of food manufactured (human food, animal food or both) at that facility, among other identifiers. From many years, the FFR database likely contained multiple registrations of individual facilities due to various interpretations of the requirements for registering facilities. Over time, including when ERG was preparing its report,

the FFR database became relatively unreliable for obtaining accurate food facility counts.

Since 2010, both domestic and foreign food facilities have been required to renew their registrations every two years during a 3-month reporting period. This new food facility registration requirement was implemented to ensure an accurate, up-to-date food facility registration count in the database. The most recent reporting period was for three months ending January 31, 2013. The current count of food facility registrations in the database for domestic animal food facilities is 11,652. Of those 11,652 domestic facilities registered as manufacturing, processing, packing or holding animal food, 6,751 also manufacture, process, pack or hold human food. The remaining 4,901domestic facilities only manufacture, process, pack or hold animal food.

The corresponding number of foreign animal food facilities registered in the FFR database is 5,748. Of these foreign facilities registered as manufacturers, processers, packers or holders of animal food, 3,905 also manufacture, process, pack or hold human food. The remaining 1,843 foreign facilities only manufacture, process, pack or hold animal food.

The 2013 FFR count appears to be more accurate than the BSE facility count when compared to data from Dun & Bradstreet, which lists 4,461 animal feed and pet food establishments (Ref. 6). As of 2013, FDA considers the FFR database its most accurate measure of the number of facilities that manufacture, process, pack or hold animal foods. Accordingly, FDA has apportioned the 4,901 domestic facilities across the facility types based on the distribution that ERG estimated in its report. In effect, each affected facility type has had its number of affected facilities reduced by about 27% by using the FFR database for this analysis (the difference between 6,730 domestic facilities in the ERG report and the 4,901 facilities in the FFR divided by the 6,730 domestic facilities in the ERG report).

The number of facilities that are registered in the FFR as handling both some type of animal food or ingredient and human foods or ingredients was subtracted from the count of facilities registered as handling only animal food facilities under the assumption that facilities registered for both animal foods and human foods would be required to comply with the proposed rule for human food in part 117 and would choose not to comply with part 507, based on the contingency that any hazards specific to an animal food are addressed.

2. Number of Affected Facilities in Cost Model

The number and types of facilities that would be subject to any regulation is determined by the scope of the regulation. Tables 7a, 7b and 7c (below) show the estimated numbers covered by type of facility under the three co-proposed definitions of a very small business.

Section 507.5 of the proposed rule would exempt qualified facilities from subpart C, which includes all of the hazard analysis and preventive controls requirements. A qualified facility is defined as a very small business, or a facility to which, when the sales by any parent company, subsidiary, or affiliate are included, both of the following apply: (1) during the three-year period preceding the applicable calendar year, the average annual monetary value of the animal food manufactured, processed, packed, or held at the facility and sold directly to consumers (not businesses), or restaurants or retail food establishments that are located in the same state or not more than 275 miles from the facility and that sold the food directly to consumers, exceeds the value of the animal food sold by the facility to all other purchasers; and (2) the average annual monetary value of the animal food sold during the three-year period preceding the applicable calendar year was less than $500,000 in 2011 or, for subsequent years, $500,000, adjusted for inflation. A very small business, being co-proposed as three options in this proposed rule, is a business that has total annual sales of animal food, adjusted for inflation,

of less than 1) $500,000, 2) $1,000,000, and 3) $2,500,000. In this section of the analysis, we estimate the total facilities subject to the proposed rule under each of the three co-proposals.

The analysis of the human food proposed rule contains a discussion of the calculation of the number of the facilities that would meet the criteria to be considered qualified for that proposed rule, which proposes a lower range of food sales for its three co-proposed definitions of very small businesses for human foods. That calculation relies on facility sales information from the same Dun & Bradstreet global business database that was used as the basis for significant portions of that regulatory impact analysis, as well as raw data from the National Agricultural Statistics Service's (NASS) 2008 Organic Production Survey to generate an estimate of the percentage of facility's that are likely to sell their products directly to end-users within the same state or within 275 miles of their facility. The previously discussed methodology that ERG used to estimate the number and type of facilities that would be affected in its analysis of the animal food process controls draft used a mixture of many different data sources. The resulting facilities estimate in the ERG analysis does not allow for a practical comparison with sales data from the Dun & Bradstreet database. Additionally, since the lowest of the three co-proposed very small business definitions is $500,000, those animal food facilities that meet the definition of a very small business would include all that would meet the criteria for qualified facilities through the other statutory criteria.. FDA estimates the number of firms that would meet the very small business definition for this proposed rule using 2007 Census average sales data for the smallest establishments reported by employee size (0-4 employees) for animal food manufacturers, using 2007 Census average sales data for the smallest establishments for wholesalers that mix animal food by employee size (0-4 employees), and using 2007 average sales data for non-employer establishments. The use of establishment rather than firm data for the smallest animal food

manufacturers may result in an overestimate of the number of firms that would be qualified due to the possibility of multi-establishment firms which would otherwise not be qualified based on total firm sales. This overestimate is likely to be negligible since any manufacturing establishment with sales small enough to qualify is unlikely to be part of a multi-establishment firm, which are usually characterized by higher sales per establishment. FDA notes the uncertainty concerning these figures due to the use of average sales data rather than establishment specific sales data within each size category. Tables 7a, 7b and 7c show the estimated total number of qualified and non-qualified facilities that would be affected under the three different definitions of a very small business.

Table 7a. Number of Facilities Affected by Proposed Rule with VSB<$500,000

Sector	Type	Number of Non-qualified Facilities	Number of Qualified Facilities	Total Facilities
Commercial Livestock Feed Manufacturing	Large Mills	98		98
	Medium Mills	291		291
	Small Mills	2,699	1,155	3,854
Other Livestock Feed Manufacturing	Wholesalers*	845	41	886
	Integrators	546		546
Pet Food Manufacturing	Large Operations	42		42
	Small Operations	147	197	344
Ingredient Suppliers	Large Suppliers	4		4
	Medium Suppliers	49		49
	Small Suppliers	77	95	172
Total Domestic Manufacturers		4799	1,488	6,287
Foreign Manufacturers	Foreign Manufacturers	1,805	38	1,843
Total		6,603	1,526	8,130

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

Table 7b. Number of Facilities Affected by Proposed Rule with VSB<$1,000,000

Sector	Type	Number of Non-qualified Facilities	Number of Qualified Facilities	Total Facilities
Commercial Livestock Feed Manufacturing	Large Mills	98	0	98
	Medium Mills	291	0	291
	Small Mills	2,469	1,386	3,854
Other Livestock Feed Manufacturing	Wholesalers	763	123	886
	Integrators	546	0	546
Pet Food Manufacturing	Large Operations	42	0	42
	Small Operations	115	229	344
Ingredient Suppliers	Large Suppliers	4	0	4
	Medium Suppliers	49	0	49
	Small Suppliers	73	99	172
Total Domestic Manufacturers		4,451	1,836	6,287
Foreign Manufacturers	Foreign Manufacturers	1,674	169	1,843
Total		6,124	2,005	8,130

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

Table 7c. Number of Facilities Affected by Proposed Rule with VSB<$2,500,000

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

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

Section 507.48 of the proposed rule contains modified requirements for facilities engaged solely in the storage of packaged animal food that is not exposed to the environment, specifically concerning the monitoring of temperatures and related activities for refrigerated products. Again, the analysis of the revised human food proposed rule relies on the Dunn & Bradstreet global business database for its estimate of these affected facilities. That analysis based its estimated number of warehouses on those facilities in the farm product warehousing and storage category and in the refrigerated warehousing and storage category. Again, ERG's use of a many different data sources to estimate the number and type of facilities that would be affected in its analysis of the animal food process control precludes a practical comparison with the sales data from the Dun & Bradstreet database, as warehouses were not separately accounted for in the ERG calculation.

The analysis of the human food proposed rule concludes that about 8% of all affected facilities are warehouses. Some subset of this 8% may represent warehouses storing packaged food for both human consumption and animal consumption. These facilities may not be subject to this proposed rule but instead be subject to the proposed rule for human food, and their compliance costs would be included in the regulatory impact analysis for the preventive controls for human food published in January, 2013 (78 FR 3646). FDA does not have the data to estimate the number of facilities that would qualify for the modified requirements for warehouses in this proposed rule. Therefore, FDA does not estimate the reduction in regulatory compliance costs due to the modified requirements for warehouses. The estimated total costs of this proposed rule can therefore be assumed in this respect to overstate compliance costs. FDA requests public comment and data on the number and type of facilities that would qualify as

warehouses storing only packaged animal foods.

3. Individual Cost Elements

a. The ERG cost model

ERG approached its compliance cost estimation for the process controls draft (which, based on its scope, would affect only the non-qualified facilities) by developing the estimated labor and capital requirements for compliance at a model medium-sized feed mill with an average annual tonnage of feed production. It then scaled the model up for larger feed mills, all integrated operations, and larger pet food manufacturers, and scaled it down for smaller mills, wholesalers, and small pet food manufacturers. ERG estimated that the model mill would have 10-19 employees with an estimated feed capacity of 55,000 tons. Ingredient supplier cost estimates were based on the development of a scalable model for suppliers as well. It was estimated to produce about 80,000 tons of ingredients annually.

ERG compared the process controls draft on a provision-by-provision basis with other regulations that contain some of the same elements of the process controls draft. It then attempted to determine the labor hours necessary to accomplish all new or marginal compliance activities for each provision. These determinations were based on discussion with industry personnel, other consultants for this project and literature on CGMPs.

Labor hours were estimated on both a one-time basis and on a recurring or annual basis. Labor hours and wage rates were apportioned over the Standard Occupational Classification (SOC) codes using the Bureau of Labor Statistics (BLS) data for 2007 for NAICS 311100 – Animal Food Manufacturing, based on the expected level of complexity required for the individual or joint compliance efforts. FDA uses the same SOC codes but has updated the model

using May, 2012 BLS hourly compensation rates (see Table 8).

Table 8. Compliance Occupations

SOC Code	Title	Total Hourly Compensation[1]
11-1021	General and operations manager	$72.69
11-3051	Industrial production manager	$58.07
51-0000	Production Occupations	$22.61
51-9061	Inspectors, testers, sorters, samplers, and weighers	$23.03
43-9061	Office Clerks, general	$20.13
43-1011	First line supervisor	$34.26
-------	Food consultant[2]	$100.00

1. Total compensation reflects the mean hourly wage rate plus a 50 percent increase for fringe benefits and other overhead costs.
2. Food Consultant hourly wage estimate was estimated separately by ERG, and defined as feed consultant by ERG although it would apply to a consultant for all animal foods.

Costs for activities other than labor were distributed between capital costs and operating and maintenance costs. Capital costs, composed of one-time costs of about $5,000 for a non-compliant facility, were annualized at a 7% discount rate over seven years. Operating and maintenance costs, composed mostly of laboratory fees for pathogen testing or other types of testing, were assigned as annual costs.

i. One-time costs

This section discusses the development of the one-time costs in ERG's cost model. Using that model and the FFR database of facilities, FDA estimates the one-time cost estimates of the co-proposed rule with a less than $500,000 revenue limit for very small businesses. ERG's estimates of the one-time labor costs for process controls were composed mostly of the efforts by facility management to conduct a hazard evaluation of its operation and to develop written procedures to ensure the safety of the animal food manufacturing process. These procedures are very similar to the proposed rule's reliance on establishing and writing preventive controls in the first year as part of the animal food safety plan. The procedures of the process controls draft would ensure that incoming raw materials are safe, that raw material preparation activities are

safe, that processing and manufacturing activities are safe, that storing and packaging of animal food is safe, that labeling activities ensure the safety of the animal food, that sampling and testing program ensures the safety of ingredients, in-process materials, and finished product, where necessary, that corrective actions are taken in response to the identification of unacceptable animal food risks, and that proper recordkeeping of all the process controls is maintained.[1] The costs from finished product testing in the process controls draft have not been included in the costs of the proposed rule. The production worker totals account for 46% of the estimated needed labor hours for the mills, integrators, wholesalers and pet food facilities, with the industrial production manager and general manager accounting for 30% and 11% of the hours.

ERG estimated that animal food manufacturers would require about eight hours to write each procedure, with personnel at the industrial production manager level providing about 75% of this effort. In total, about 80 hours would be spent creating these written procedures at each facility. These estimates are based on the assumption that industry trade associations or vendors would create draft procedures after the publication of the final rule, which individual facilities could tailor to their own operations.

Based on discussions with industry personnel and consultants, ERG then estimated current compliance levels for each of the provisions of the process controls draft. In an attempt to account for facility practices characterized as sporadically deficient rather than consistently deficient, ERG estimated the frequency of compliance with each of the provisions of the process controls draft. [2] In general, the larger facilities (licensed feed mills and large pet food

---

[1] ERG presents these one-time labor hours for these compliance efforts, assuming no compliance with the regulation, as first-year costs in tables 3-7, 3-8 and 3-9 of its report.

[2] These compliance estimates are available in ERG tables 3-11, 3-12 and 3-13.

manufacturers) are more likely than the smaller facilities to comply with particular provisions, because larger animal food throughputs and revenues per employee result in a greater need for intensive quality control and animal food safety operations.

ERG then applied scale factors (shown in ERG table 3-10) (Ref 1) to account for the different amounts of labor that could be required for facilities of different sizes. These scale factors were not universally applied to each provision for each facility, but were individually applied to each provision based on a determination that the labor for any provision depends on the size of facility as measured by the tonnage of animal feed output. The estimated one-time labor costs (including costs to foreign facilities) amount to $37.24 million.

One-time capital costs are composed of the durable sampling testing equipment necessary to comply with the rule. These include costs for moisture meters, sampling probes and other equipment.[3] Again, ERG expected the larger operations to have higher current compliance. As noted above, one-time capital costs, which are relatively small, are depreciated over 7 years. The estimated one-time capital costs (including costs to foreign facilities) are $11.62 million.

ii. Annual costs

This section discusses the development of the annual costs in ERG's cost model. Using that model and the FFR database of facilities, FDA estimates the annual cost estimates of the proposed rule with a less than $500,000 revenue limit for very small businesses. The ERG model estimated annual costs in a manner similar to that for first-year costs. Labor hours were first estimated assuming complete non-compliance with each provision of the process controls draft. For most facilities, testing costs comprise a large percentage of the annual labor costs. For large and medium mills, integrator operations, and large pet food manufacturers, testing costs account

[3] ERG includes capital item prices in its table 3-3 and compliance estimates for these products in table in tables 3-14.

for more than 50% of total annual costs. The process controls draft did not mandate a precise frequency of testing, or a precise feed hazard to test, at each type of facility. Instead, like the proposed preventive control provision, it relied on the results of a hazard analysis of each facility to determine the exact level of necessary testing for individual animal food hazards.

There is significant uncertainty involved in modeling a provision with flexible requirements, such as the testing requirements implied by the process controls draft. ERG needed to account for the wide range of circumstances, the differences in supplier arrangements, and the irregular distribution of food toxicities across the U.S (Ref. 1). Its model for estimating the marginal costs of testing for animal food hazards therefore focuses on those that are expected to be the most severe and most frequently present, and includes only those that are most commonly recognized (Ref 1). As such, the testing costs in the ERG model and report likely represent the minimal testing requirements for compliance with the process controls draft.

The ERG model estimates the total tonnage of animal food produced for the U.S., the amount of animal food produced by each facility type, and the percent of animal food for each major species by each type of facility. Using these results and discussion with industry contacts and consultants, ERG estimated a plausible program of feed hazard testing for animal food manufacturing facilities that would potentially include tests for any of the following: aflatoxin, vomitoxin, *Salmonella*, fumonisin, heavy metals, moisture, urease and salt. The costs for *Salmonella* testing have been removed from the costs of the proposed rule as they were assumed to be for finished product testing. The model does not require that any facility perform all of these tests, only that these are the seven test types that could be required across the totality of facilities subject to the process controls draft. An individual facility would be expected to perform a subset of these tests, based on the results of its hazard analysis. Section 3.8.1 of the

ERG report contains a detailed explanation of the development of the testing model, including testing frequency assumptions and testing lot sizes.

As with the one-time costs, ERG estimated the annual labor hours across the provisions of the process controls draft. Facility production workers comprise the largest total number of possible labor hours.[4] Assuming no current compliance, worker labor hours are heavily concentrated at the production worker level, at 68 percent of the total estimated labor hours among all facility personnel, due to the sampling needs of the testing requirements.

ERG developed its annual labor cost totals using its estimated levels and frequencies of compliance with the process controls draft (as explained in the first-year cost section), combined with scale factors to account for labor requirements that depend on the size of the facility. (These compliance estimates are available in ERG tables 3-16, 3-18 and 3-20.)(Ref. 1)

Annual capital costs contain the operating and maintenance costs associated with the annual testing regimen at each facility. These include the individual test kits for any of the seven tests as determined by the hazard analysis, as well as any associated lab fees. The unit prices of these tests are included in table 3-4 in the ERG report.

iii. Total food safety plan costs from ERG cost model

The total average annualized costs per sector at a 7 percent discount rate, with per facility costs as estimated in the ERG cost model and affected facilities from the FFR for the proposed rule with a very small business exemption of less than $500,000 in average annual animal food revenues, are shown in Table 9. Total annualized costs for domestic manufacturers are estimated at $56.73 4 million. (At a 3% discount rate, annualized costs are estimated at $55.84 million.) Total annualized costs for foreign manufacturers are estimated at $21.33 million. (At a 3%

---

[4] These estimates are also available in ERG Tables 3-7, 3-8 and 3-9.

discount rate, annualized costs are estimated at $21.00 million.) Assuming that some part of this cost increase is passed on to US consumers, the annualized cost total could be as high as $78.07 million, or $76.84 million at a 3% discount rate. It is important to emphasize that these estimates are based on average costs for each facility type. The estimated current compliance rates and the estimated frequency of the compliance activity strongly influence the size of the estimated compliance cost at an individual facility.

Table 9. Costs per Sector using ERG Cost Model (updated to 2012 wage rates) (VSB<$500,000)

Sector	Type	One Time Costs ($M)		Annual Costs ($M)		Annualized Cost Total[1] ($M)
		Labor	Capital	Labor	Capital	
Commercial Livestock	Large Mills	$0.12	<$0.01	$0.70	$0.30	$1.01
	Medium Mills	$1.02	$0.39	$3.56	$0.53	$4.32
	Small Mills	$16.84	$3.58	$27.73	$2.48	$33.12
Other Livestock	Wholesalers	$6.93	$4.41	$6.84	$0.31	$8.77
	Integrators	$0.65	$0.02	$3.92	$1.68	$5.70
Pet Food	Large Operations	$0.07	<$0.01	$0.42	$0.18	$0.61
	Small Operations	$0.55	<$0.01	$1.62	$0.15	$1.85
Ingredient Suppliers	Large Suppliers	$0.02	<$0.01	$0.03	<$0.01	$0.03
	Medium Suppliers	$0.27	$0.02	$0.38	$0.05	$0.47
	Small Suppliers	$0.60	$0.03	$0.71	$0.05	$0.85
Domestic Manufacturers		$27.06	$8.44	$45.94	$5.74	$56.73
Foreign Manufacturers	Foreign Manufacturing Facilities	$10.18	$3.18	$17.27	$2.16	$21.33
Total		$37.24	$11.62	$63.21	$7.90	$78.07

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

b. Additional costs of the proposed animal food safety plan

As described previously in this analysis, the 2011 ERG report analyzed a process controls draft that contained many provisions that were similar to those of this proposed rule. There are many provisions in the proposed rule, however, that were not included in the process controls draft. Most important, subpart C of the proposed rule includes some requirements for monitoring and verification activities that exceed those in the rule that ERG analyzed in its 2011 report. In this section, we estimate those costs based on the methodology and many of the assumptions

contained in FDA's analysis of the proposed rule for human food. Additionally, other compliance efforts that were not included in the 2011 ERG report and other proposed animal food safety requirements exceeding the current animal food safety requirements for animal food are included in this analysis.

FDA contracted with ERG in 2010 to conduct a survey of the human food industry. While it did not include facilities that specifically manufacture animal food, many of the ingredient manufacturers distribute products to manufacturers of both human foods and animal foods. The primary focus of the survey was the current food safety characteristics of the facility. Among its topics, the survey included questions concerning whether a facility has:

- A written food safety plan;
- Training procedures and practices across employee levels concerning food safety, basic cleaning, sanitation, personal hygiene and other production factors;
- Process controls including supplier control and approval programs; and
- Written procedures for handling incoming raw materials, approving vendors, calibrating equipment, pathogen control, and recordkeeping practices.

FDA also contracted for three expert elicitations of food industry practices to further its understanding of industry norms. The economic analysis of the revised human food proposed rule has a complete explanation of the survey design and results, as well as the three expert elicitations. They are significant because they provide a basis, however imperfect for animal food production, to analyze those requirements of the proposed rule that were not analyzed in the 2011 ERG report on the process controls draft in the animal food industry. While FDA relies on the 2011 ERG report on process controls draft more heavily due to its specific focus on the animal food production sectors, the cost model that FDA presents in its analysis of the revised

human food proposed rule, which is based on the survey and expert elicitations, provides a reasonable foundation for assessing the additional costs to animal food producers beyond the process controls draft of this proposed rule.

i. Costs to attest to qualified status and related requirements

To be exempt from subpart C, qualified facilities would be required to submit certain documents to FDA. These include 1) documentation demonstrating that the facility is a qualified facility, which would likely consist of financial documents that show that the facility's average annual sales are less than the amount necessary to be considered a very small business; and either 2a) documents that show the facility has identified potential hazards and implemented and monitors its own preventive controls, or 2b) documents that show that it follows other State, local, county or other non-Federal food safety laws. If potential qualified facilities decide to provide documentation 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 food in the normal course of business, or in an electronic notice, in the case of internet sales). In FDA's analysis of the human food proposed rule, the Agency estimated that qualified facilities would choose option 2b as the lesser expensive of the two options as the cost of making label changes to affected products is less costly than implementing one preventive control (Ref 7). FDA believes that the qualified facilities subject to this rule would also choose option 2b over option 2a for the same reason.

aa. Costs to qualified facilities to attest to qualified status

FDA estimates that it would take a compliance officer, at about $45 per hour, one-half

hour every two years 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 proposed rule. 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, implemented preventive controls and are monitoring at their facilities instead of attesting that the facility is in compliance with other non-Federal food safety laws. FDA does not estimate the number of these facilities, but expects 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 very small businesses would be in the smallest size category of less than 20 employees. The costs are shown in tables 10a, 10b and 10c.

Table 10a Cost to Qualified Facilities to Attest to Qualified Status (VSB<$500,000)

Number of qualified facilities	1,526
Hours needed to gather and submit financial and compliance documentation	0.5
Wage rate per hour (including overhead)	$46
Total Costs every two years to attest to status	$35,000
Annual cost	$17,500
Cost annually per affected facility	$12

Table 10b. Cost to Qualified Facilities to Attest to Qualified Status (VSB<$1,000,000)

Number of qualified facilities	2,005
Hours needed to gather and submit financial and compliance documentation	0.5
Wage rate per hour (including overhead)	$46
Total Costs every two years to attest to status	$46,000
Annual cost	$23,000
Cost annually per affected facility	$12

Table 10c Cost to Qualified Facilities to Attest to Qualified Status (VSB<$2,500,000)

Number of qualified facilities	3,805
Hours needed to gather and submit financial and compliance documentation	0.5
Wage rate per hour (including overhead)	$46
Total Costs every two years to attest to status	$87,500
Annual cost	$44,000
Cost annually per affected facility	$12

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

FDA assumed 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 of the complete business address of the facility where the animal food was manufactured or processed. This would have to be placed on a conspicuous place on the label itself for food requiring a label. FDA expects that all pet foods manufactured or processed by qualified facilities are required to bear a label. In the case of pet foods and packaged animal foods from feed mills from very small businesses, this would require a minor label change. FDA uses its 2010 Labeling Cost Model (LCM) to estimate the compliance cost of a minor label change to comply with this requirement. The three-year compliance period for this requirement (one year for the proposed rule plus two additional years for very small businesses), would allow for the both brand name and private label pet food products 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 $310, or $44 when annualized over 10 years at a seven percent discount rate. FDA estimates that qualified feed mills and pet food manufacturers would average about 4 products with labels. All facilities are assumed to have less than 20 employees. FDA is uncertain of the percentage of very small animal feed mills that make animal foods requiring labeling, but has included all of them for this analysis in order to not underestimate the cost to

attest to qualified status. FDA requests public comment on the number and types of very small businesses that make animal food products requiring a label, not requiring a label, and the average number of animal food products.

For animal foods that do not require packaging labels, qualified facilities could 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, FDA assumes pet food is required to bear a package label, so FDA does not expect this option to apply to pet food manufacturers. FDA estimates that this would require about one hour for a compliance officer or another employee of equal training to change the address in the sales software that creates the documents that is delivered with animal foods not requiring a label. Tables11a, 11b and11c show the total costs for the three co-proposed very small business exemptions.

Table 11a. Cost of Label Changes (VSB<$500,000)

Cost to Change Label on Products with Labels	
Number of qualified facilities	1,526
Number of SKUs per facility	4
Cost per SKU for 1-time label change	$310
Total cost of 1-time label change	$1,893,000
Annualized total costs of label change	$269,000
Annualized cost per affected facility	$177
Cost to Change Address on Sales Documents	
Number of qualified facilities	1,329
Hours to change address in sales software	1
Wage rate (including overhead)	$45
Total 1-time cost	$61,000
Annualized total costs of labeling change	$9,000
Annualized cost per affected facility	$7
Total annualized cost to change labels/labeling per affected facility	$184

Table 11b Cost of Label Changes (VSB<$1,000,000)

Cost to Change Label on Products with Labels	
Number of qualified facilities	2,005
Number of SKUs per facility	4
Cost per SKU for 1-time label change	$310
Total cost of 1-time label change	$2,487,000
Annualized total costs of label change	$354,000
Annualized cost per affected facility	$177
Cost to Change Address on Sales Documents	
Number of qualified facilities	1,776
Hours to change address in sales software	1
Wage rate (including overhead)	$46
Total 1-time cost	$82,000
Annualized total costs of labeling change	$12,000
Annualized cost per affected facility	$7
Total annualized cost to change labels/labeling per affected facility	$184

Table 11c. Cost of Label Changes (VSB<$2,500,000)

Cost to Change Label on Products with Labels	
Number of qualified facilities	3,805
Number of SKUs per facility	4
Cost per SKU for 1-time label change	$310
Total cost of 1-time label change	$4,718,000
Annualized total costs of label change	$671,000
Annualized cost per affected facility	$177
Cost to Change Address on Sales Documents	
Number of qualified facilities	2,403
Hours to change address in sales software	1
Wage rate (including overhead)	$46
Total 1-time cost	$110,000
Annualized total costs of labeling change	$16,000
Annualized cost per affected facility	$7
Total annualized cost to change labels/labeling per affected facility	$184

The total annualized costs of attesting to qualified status and changing labels/labeling for qualified facilities required in § 507.7 are shown in table 12.

Table 12. Annualized Costs to Comply with Attesting to Qualified Status and Changing Labels

VSB<$500,000	Cost to attest to qualified status	$17,500
	Cost to change labels for products with a label	$269,000
	Cost to change labeling for products not requiring a label	$9,000
	Total Annualized Cost	$295,000
	Average cost per facility	$195
VSB<$1,000,000	Cost to attest to qualified status	$23,000
	Cost to change labels for products with a label	$354,000
	Cost to change labeling for products not requiring a label	$12,000
	Total Annualized Cost	$389,000
	Average cost per facility	$195
VSB<$2,500,000	Cost to attest to qualified status	$44,000
	Cost to change labels for products with a label	$671,000
	Cost to change labeling for products not requiring a label	$16,000
	Total Annualized Cost	$731,000
	Average cost per facility	$195

ii. Sanitation Controls (VSB < $500,000)

Proposed § 507.36(d)(2) would require the owner, operator, or agent in charge of a facility to implement sanitation controls where necessary for hazards that are reasonably likely to occur. Where appropriate, the controls must include written procedures to ensure the cleanliness of animal food contact surfaces, including the animal food contact surfaces of utensils and equipment; and to prevent cross-contamination from insanitary objects 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 environmental pathogens in the animal food processing environment in order to prevent contamination of animal food products. Effective sanitation controls remove undesirable material from the 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 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 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 proposed 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. FDA adds additional compliance cost estimates below to those included in the ERG cost analysis of the process controls draft rule.

aa. Writing procedures for sanitation controls

FDA follows the cost model developed for the proposed rule that would revise 21 CFR part 110 (and re-designated as part 117) (78 FR 3646) for its estimate of the additional effort that each facility would expend to write the procedures for sanitation controls. FDA subject matter experts expected that an additional 5 hours would be required to write the sanitation controls procedures in proposed § 507.36(d)(2) for both animal food-contact surfaces and prevention of cross-contamination from insanitary objects and personnel to animal food. FDA based its

estimate of the percent of facilities that currently have written procedures on the weighted averages of the percents used in the FDA cost model for human foods, which were based on responses to the GMP survey of human food processors. FDA expects the wage rate to be that of a production manager. The one-time cost for writing these procedures is estimated at $646,000, with an annualized value of $92,000 over 10 years at a 7 percent discount rate. FDA assumes that annual updating costs would equal 10 percent of the one-time costs, or about $65,000. Total annualized costs of this provision are estimated at about $156,000. This figure 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. FDA request public comment on the factors used in this analysis.

Table 13. 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	2,922	3,019	662	1	6,603
% Facilities w/o written procedures for sanitation controls	44%	27%	21%	11%	
Total Facilities w/o written procedures for sanitation controls	1,286	800	138	0	2,223
Hours to develop and write procedures	5	5	5	5	
Wage rate (including overhead)	$58	$58	$58	$58	
One-time cost to develop and write procedures	$373,000	$232,000	$40,000	--	$646,000
One-time cost per facility affected	$290	$290	$290	--	
One-time cost annualized over 10 years at 7 percent	$53,000	$33,000	$6,000	--	$92,000
Annual cost to update procedures	$37,000	$23,000	$4,000	--	$65,000
Total annualized cost	$90,000	$56,000	$10,000	--	$156,000

FDA subject matter experts did not expect that these affected facilities would implement a formal training program on the sanitation controls. Rather, they expected that these facilities would use some form of on-the-job training on the sanitation control procedures for production

employees. As a result, FDA has not included any training costs to the cost model here. FDA requests public comment on the need for additional training in sanitation controls for animal food production personnel.

bb. Additional sanitation control labor cost

The section above described the similarity between some of the process controls draft requirements and the proposed 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 sanitary operations and sanitary facilities and controls requirements under proposed part 507 subpart B also will likely result in additional labor required for compliance. Many of the costs would be accounted for under the process controls draft, but the lower level of detail in the process controls draft does not allow FDA 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, FDA subject matter experts made the broad assumption that every facility affected by the sanitation controls would need to expend an additional one hour per week to comply with these controls. FDA assumes that this additional one labor hour per week would also be required at those facilities that are exempt from subpart C but are still subject to the CGMP provisions in subpart B sections 507.19 – Sanitary Operations, and 507.20 – Sanitary Facilities and Controls. This adds 1,386 facilities that are very small businesses to the number of facilities affected by this requirement, plus another 141 facilities from the original 6,744 facilities from the FFR database that are likely to have revenues of less than $500,000. The one labor hour would be assigned to a production employee at the wage rate, including overhead, of about $23 per hour. Total industry costs for this requirement are estimated at about $9.56 million

annually. FDA requests public comment on the need for additional labor to comply with the sanitary operations and sanitary facilities and controls sections of the proposed rule.

Table 14. Additional Costs to Implement Sanitation Controls

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number of Facilities	4,359	3,107	661	1	8,130
Hours to implement additional sanitation controls annually	52	52	52	52	
Wage rate	$23	$23	$23	$23	
Annual labor cost to implement sanitation controls	$5,124,000	$3,652,000	$778,000	$2,000	$9,556,000
Annual cost per facility	$1,175	$1,175	$1,175	$1,175	

cc. Sanitation control monitoring and verification

Proposed § 507.39 requires that the owner, operator, or agency 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. Proposed § 507.45(b) requires that the owner, operator, or agent in charge of a facility verify that the preventive controls are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur and that monitoring is being conducted in accordance with § 507.39. FDA uses the cost model developed for the proposed rule for human foods, which is based on the GMP survey of human food processors, to estimate these compliance costs. FDA expects that the facilities that lack written procedures for their sanitation controls will also lack written procedures to monitor and verify that their sanitation procedures meet the proposed requirements. To estimate the sanitation control monitoring and verification costs, FDA estimates that it will take four hours for a facility with 19 or fewer employees to prepare the written procedures, which will likely be a comprehensive checklist of all the things that supervisors should monitor. FDA estimates that it will take seven hours for larger facilities and

up to 14 hours for the largest facilities. FDA estimates 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 correctly, FDA subject matter experts judged that a trained line supervisor would take 52 hours 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 will typically 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. FDA requests public comment on all of the factors used in this analysis. Total annualized cost of sanitation control and monitoring is estimated at $9.44 million annually (see Table 15).

Table 15. Estimated Costs to Develop and Implement Monitoring and Verification Sanitation Controls by Facility Size

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total number of Facilities	2,922	3,019	662	1	6,603
% without Monitoring and Verification Procedures for Sanitation Controls	48%	15%	4%	0%	
Total Facilities without Monitoring and Verification Sanitation Procedures	1,402	453	26	0	1,882
Hourly Wage Rate for Qualified Individuals	$58	$58	$58	$58	
Labor Hrs to Develop Sanitation Monitoring Procedures	4	7	7	14	
Subtotal Cost to Develop Monitoring Procedures for Sanitation Controls (one-time cost)	$326,000	$184,000	$11,000	0	$521,000
Labor Hrs to Annually Update Monitoring Procedures	1	2	2	4	
Subtotal Cost to Annually Update Monitoring procedures for Sanitation Controls (annual cost)	$81,000	$53,000	$3,000	0	$137,000
Number of Employees that Require Annual Training in Monitoring Procedures for	2	2	3	3	

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Sanitation Controls per Facility					
Hours of Annual Training per Employee	2	2	2	2	
Hourly Wage Rate for first-line supervisor	$34	$34	$34	$34	
Subtotal Costs to Train Supervisors in Monitoring Sanitation Controls (annual cost)	$192,000	$62,000	$5,000	$0	$260,000
Percent facilities that do not maintain monitoring records	40%	17%	10%	0%	
Total number of Non-Qualified Manufacturing and Wholesale Facilities that do not monitor	1,169	513	66	0	1,748
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	52	78	104	104	
Subtotal Recordkeeping Costs for Training in Monitoring and Verification Sanitation Procedures	$2,082,000	$1,371,000	$236,000	$0	$3,689,000
Total hours per year for verification	52	52	52	52	
Sanitation Control Verification – Visual Observation and Records Review (Annual)	$3,529,000	$1,549,000	$199,000	$0	$5,278,000
Total One-Time Costs to prepare monitoring and verification procedures Annualized (7%, 10 Years)	$326,000	$184,000	$11,000	$0	$521,000
One-time costs annualized (7%, 10 years)	$46,000	$26,000	$2,000	$0	$74,000
Total On-going Monitoring and Verification Sanitation Control Costs	$5,884,000	$3,035,000	$444,000	$0	$9,363,000

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Costs Annualized (One-Time annualized + On-Going)	$5,931,000	$3,062,000	$446,000	$0	$9,438,000

iii. Validation of the animal food safety plan (VSB < $500,000)

Section 507.45(a) of the proposed rule would require that the preventive controls be validated prior to the implementation of the food safety plan, or, when necessary during the first six weeks of production. This validation would include collecting and evaluating scientific and technical information, or, if this information were not available or were insufficient, conducting studies to demonstrate whether the preventive controls, when properly implemented, would be effective in controlling the hazards that are reasonably likely to occur. 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 potential hazard at each facility, they can vary significantly. Based on the judgment of FDA subject matter experts, FDA estimates that these initial validation costs range from $1,000 to 2,000 per facility, and uses an average of $1,500. FDA uses 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 and validated a food safety plan. These non-compliance estimates range from 10% at large mills and large pet food manufacturing facilities to 90% non-compliance at wholesale operations that perform some feed mixing. The average annual costs per facility also vary from about $150 at large feed mills and large pet food manufacturing facilities to about $1,350 at wholesalers that perform some animal food mixing. Total one-time validation

costs total about $5.16 million, which is annualized over 10 years at a 7 percent discount rate at $734,000.

Section 507.45(a) of the proposed rule would also require that the preventive controls be validated when a reanalysis of the food safety plan reveals the need to do so. FDA estimates that revalidations 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. FDA again uses the estimated 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 and validated a food safety plan. Moreover, FDA assumes that those facilities that currently perform hazard analyses would also be validating any changes to its food safety plan. Because FDA expects animal foods processors to re-validate only once each year, we estimate revalidation costs at $1.72 million annually. Although the revalidation 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 do some feed mixing, and small ingredient suppliers.

iv. Reanalysis of the food safety plan (VSB < $500,000)

Proposed §§ 507.45(e)(1) would require that the food safety plan be reassessed 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. Proposed § 507.45(e)(3) would also require a revision of the food safety plan, or documentation that no additional or revised preventive controls are needed, if any significant changes are made. In estimating reanalysis costs for proposed rule for human food facilities, FDA estimates that the reassessment of a hazard analysis by an employee who is

familiar with it can be performed in 12 to 24 hours. FDA expects the employee to be a food safety professional. FDA assumes 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 requirements 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 2011 report, ERG estimated the time necessary to perform the hazard analysis activities to be 24 hours, 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 requirement for an annual review of the process controls and modification of the plan following an investigation exceed the reanalysis requirements of this proposed 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 analysis of the proposed revisions to the human foods facilities) would require only 12 to 24 (with a midpoint at 18) hours. FDA subject matter experts, however, expect the re-analysis of the food safety plan for animal food facilities to occur only once every two years. FDA acknowledges uncertainty concerning the level of equivalence between the requirements for the proposed rule and the process controls draft, but judges them to be roughly equivalent. The labor costs of compliance with these two provisions of the process controls draft were included in the total compliance costs outlined in the section on the 2011 ERG model. However, since FDA believes that many of

these manufacturers would not be adding new products frequently and that the most manufacturers do not have the same level of microbiological concern as human food manufacturers, FDA expects the re-analysis to occur every other year. FDA uses one-half of the annual costs from the ERG cost model for the reanalysis of the food safety plan and has not made any further cost adjustments for compliance with the reanalysis requirements of the proposed rule.

v. Monitoring preventive controls (VSB < $500,000)

The proposed rule would require the owner, operator, or agency in charge of a facility to implement process controls, as appropriate, during manufacturing/processing. Process controls include those procedures, practices, and processes performed on a food during manufacturing/processing that are employed to significantly minimize or prevent hazards that are reasonably likely to occur. Process controls can include the steps that are applied in the production process to prevent, reduce or eliminate select physical, biological, radiological or chemical 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 foods 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 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 foods, and is checked on a regular basis. Since the process controls draft already included estimates of these costs, FDA has not included any additional costs for the initial writing of process controls, or the initial implementation of process controls.

FDA has added compliance costs to account for the monitoring efforts required by the proposed rule in § 507.39. The cost model developed for the proposed rule for human food is used, along with the estimates developed by FDA subject matter experts, to account for process control monitoring costs. FDA accounts for the effort to write the monitoring procedures for process controls (which would exceed the writing effort for just the processing and manufacturing section in the process control rule) 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 subject matter experts estimated that animal food processors would have from 2 to 6 processes, and that each would require an additional 3 to 7 hours to write the monitoring procedures for each process. At a production manager's wage of about $58 per hour, this would add $617,000 in one-time labor cost to prepare monitoring procedures, which equals $88,000 when annualized over 10 years at 7 percent (see Table 16). Those facilities without written process controls would incur from $50 to $250 in annualized costs above those contained in the process controls draft report.

These same facilities would be expected to incur some annual costs to update these written procedures. FDA estimates that those facilities without written process controls would require an additional 2 to 4 hours per year per process to update monitoring procedures. At the

same production manager wage rate of $58 per hour, this would impose about $414,000 in annual costs to those facilities without written process controls (see Table 17).

FDA calculated labor costs of the actual monitoring of the process controls based on estimates of FDA subject matter experts. FDA assumed 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 $23 per hour, this results in a total process monitoring cost of about $3.58 million.

FDA calculated the cost to document monitoring based on the assumptions that it would take five minutes to create the recordkeeping document for each days' 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 wage rate of about $20 per hour, FDA estimates the cost to document monitoring of process controls at about $1.80 million.

Table 16. Estimated Initial Costs to Monitor Process Controls

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Total Non-Qualified Manufacturing and Wholesale Facilities	2,922	3,019	662	1	6,603
Percent without Process Controls	47%	11%	2%	0%	
Total Non-Qualified Facilities that require Process Controls	1,373	332	13	0	1,718
Number of Processes per Facility	2	2	6	6	
Hourly Wage Rate for Production Manager	$58	$58	$58	$58	
Average Labor Hrs to Prepare Written Procedures per Production Process	3	3	5	7	
Total One-time Costs to Develop Initial Written Procedures	$478,000	$116,000	$23,000	0	$617,000
One-Time Costs Annualized	$68,000	$16,000	$3,000	$0	$88,000

Table 17. 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	2,922	3,019	662	1	6,603
Percent without Process Controls	47%	11%	2%	0%	
Total Facilities that require Process Controls	1,373	332	13	0	1,718
Number of Processes per Facility	2	2	6	6	
Hourly Wage Rate for Production Manager	$58	$58	$58	$58	
Labor Hrs to Update Written Procedures per Production Process	2	2	4	4	
Subtotal Costs to Annually Update Written Procedures	$319,000	$77,000	$18,000	$0	$414,000
Hourly Wage Rate Process Control Monitoring	$23	$23	$23	$23	
Minutes per day monitoring each process	8	8	24	24	
Hours per year monitoring	42	42	208	208	

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
each process					
Subtotal Monitoring Costs	$2,580,000	$624,000	$373,000	$0	$3,580,000
Records to Document Monitoring of Process Controls (Minutes per Record)	5	5	10	10	
Monitoring Records per Process per Year	300	300	300	300	
Subtotal Costs to Document Monitoring	$1,382,000	$334,000	$80,000	$0	$1,796,000
Total On-going Process Control Costs	$4,284,000	$1,036,000	$471,000	$0	$5,791,000
Total Costs Annualized (One-Time annualized + On-Going)	$4,352,000	$1,052,000	$475,000	$0	$5,879,000

vi. Corrective actions (VSB < $500,000)

Section 507.42 of the proposed rule would require that a facility establish written procedures for taking corrective action if the preventive controls fail due to improper implementation or were not effective. It would require that the affected animal food be evaluated for safety and prevented from entering into commerce if the owner, operator, or agent in charge cannot ensure 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 2012 dollars, the ERG cost model estimates that these 5 provisions concerning corrective actions would cost the 6,603 facilities from the FFR about $6.85 million annually, or an average of about $1,040 per facility. Since the ERG report includes the corrective action compliance cost estimates for a similar corrective action requirement, FDA has not added any additional costs beyond those in the ERG report. FDA has not adjusted the corrective action costs above to account for those related solely to finished product testing in the process controls draft, which is not a requirement of this proposed rule. The $6.85 million can therefore be viewed as an overestimate of the corrective action costs.

FDA does not account for the cost of holding a quarantined product until a determination is made concerning its acceptability for distribution, or for the value of the products that would need to be destroyed. FDA requests public comment and data on the value of holding a quarantined product until it can be destroyed or the value of destroyed product.

vii. Process controls verification (VSB < $500,000)

In the proposed rule, process controls would be required to be verified under § 507.45(b). The process controls verification activities are expected to track the process controls monitoring activities, whose costs have been estimated in a separate section above. The verification activity for process controls would include a review of the monitoring records. Following the cost

analysis of the proposed rule for human foods, FDA assumes that all the facilities would need to undertake some additional process control review procedures to verify that these activities are consistently implemented. This model assigns the verification activity to a production manager with a wage rate of about $58 per hour. FDA relied on the expert elicitation report on the human food processing industry in its estimate that, on average, about 3 minutes per day would be necessary for a 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 $1,800 per year for those facilities that do not currently have written process controls. FDA estimates the total annual costs for process control verification at $3.16 million (Table 18).

Table 18. Cost of Verification of Process Controls

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	2,922	3,019	662	1
Percent without process controls	47%	11%	2%	0%
Hours per day verifying process controls record	0.05	0.05	0.05	0.05
No. of processes per facility	2	2	6	6
Wage rate – hourly	$58	$58	$58	$58
Total annual cost by size	$2,488,000	$602,000	$72,000	$0
Total annual cost	$3,161,000			

viii. Requirements for a qualified individual (VSB < $500,000)

Section 507.45(c) is one of several sections that lists activities that would be required to be carried out by someone who meets the criteria for a “qualified individual.” This person, by definition, 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. FDA subject matter experts believe that some

facilities may already have some personnel that would meet these criteria, but believe that most of these facilities probably do not.

Since there is significant uncertainty about the number of facilities that have at least one employee who would meet the criteria to be considered a qualified individual, FDA assumes that every facility will need at least one person to undertake training to become a qualified individual. FDA subject matter experts 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. FDA expects the training to require about 8 hours for an employee at the production manager level. The one-time cost for this training is estimated at $3.38 million, which equates to $481,000 over 10 years at a 7% discount rate. FDA adds another $500 per person to account for the one-time of training materials or a trainer's fee, which adds another $470,000 on an annualized basis. Additionally, FDA assumes that the annual cost of training is equal to 50% 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 $1.69 million. Total annualized costs of this requirement are estimated at $2.64 million per year.

ix. Administrative costs to review the rule and develop a compliance plan (VSB < $500,000)

FDA expects that all animal food manufacturers would take time to review the rule and their production records to determine what regulatory actions would be necessary to comply with the requirements. FDA estimates that the complexity of the proposed 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 19, FDA estimates 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, FDA estimates that an additional 40 hours may be needed from other levels of upper management. FDA assigns this time to personnel at a legal analyst level. On average manufacturers would pay from about $73-$93 per hour including benefits for personnel to review production processes and to develop a compliance plan. Table 19 shows that the estimated one-time cost per establishment would range from about $2,900 to $6,600. For the entire animal food manufacturing industry subject to the proposed rule, the estimated one-time administrative costs would amount to $26.11 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 those very small firms may not require 40 hours to review the rule once they determine that they are qualified facilities.

Table 19. Estimated Administrative Review Effort

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	4,359	3,107	662	1
Hours to review rule by GM,	40	40	40	40
Hourly wage – general manager	$73	$73	$73	$73
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	$2,900	$2,900	$6,600	$6,600
Annualized review cost per facility	$410	$410	$940	$940
One-time industry review cost by size	$12,675,000	$9,035,000	$4,388,000	$9,000
Annualized industry review cost by size	$1,805,000	$1,286,000	$625,000	$1,000
Total one-time cost to industry	$26,106,000			
Total annualized cost to industry[1]	$3,717,000			

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

x. Other costs of proposed rule included in the ERG analysis (VSB < $500,000)

The analysis above detailed the exclusion of certain food safety plan requirements from the FDA cost model used for the analysis of both the proposed rule for human food in part 117 and proposed rule part 507. These cost of these requirements, which included the reanalysis of the food safety plan and the requirement for corrective actions, were not separately included in the FDA cost model since FDA determined that each of these significant parts of the food safety system was included in the ERG analysis of the process controls draft. Similarly, FDA did not separately account for the costs of several other provisions of the proposed rule in the FDA cost model because they were also included in the 2011 ERG report.

Section 507.25(a)(2) and (a)(3) of the proposed rule would require labeling controls similar to those included in the process controls draft. Although ERG did not individually account for the cost of preparing the written procedures for labeling in its 2011 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. FDA judges that the requirements for labeling controls in the proposed rule and in the process controls draft are similar, and therefore already accounted for in the ERG model. Thus, FDA has not added additional costs for complying with the labeling requirements of the proposed rule.

Section 507.36(d)(3) of the proposed rule would require that each facility develop and write a recall plan for products for which there is a hazard that is reasonably likely to occur. 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, (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 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. The one-time labor costs, updated to 2012 dollars and distributed across the 6,603 facilities from the FFR, were estimated at $8.75 million. The

adjusted annual labor costs were estimated at $2.91 million.

While the recall provisions in the proposed rule are more specific than the more general requirements concerning animal food product recalls in the process controls draft, FDA concludes 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. FDA would not expect the level of activity required for an actual recall to change, and would expect the annual number of recalls to decrease. Notification of those listed in the consignees and of the public would already occur, and the effectiveness checks are already a part of the codified recall strategy. Accordingly, FDA has not included any additional costs beyond those listed above in the 2011 ERG report.

In the proposed rule, both § 507.17, concerning plants and grounds, and § 507.19 concerning sanitary operations, contain measures that would be required to prevent the contamination of animal food from pest infestation. 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, FDA has not added any additional costs specifically for pest infestation activities for the proposed rule. FDA requests public comment and data on the expected compliance efforts.

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. FDA has not estimated any additional costs for compliance with these activities beyond those referring to the prevention of pest infestation that could be connected to the labor efforts described above in the ERG report. Though unable to quantify any additional costs, FDA believes the costs would be low as the proposed requirements are such that a high percentage of animal food facilities likely already comply. FDA requests public comment and data on the current level of compliance with these proposed requirements and the costs necessary to bring all facilities into compliance.

Proposed § 507.22 includes a requirement that equipment and utensils used in manufacturing, processing, packing, and holding must be designed as to be adequately cleanable and must be properly maintained to protect against the contamination of food. Section 507.25 in this proposed rule, related to processing and controls, contains requirements for adequate sanitation of manufacturing, processing, packing, and holding operations, from incoming raw materials, containers, equipment and utensils, to packing and storage facilities. 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. FDA judges 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 proposed rule.

In addition, proposed § 507.25 also contains requirements for incoming raw materials and

ingredients storage conditions and other contamination prevention activities. The process controls draft contained a requirement that raw materials are 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 processed 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, FDA has not added any additional costs specifically for proposed §507.25 beyond those totals in the ERG report.

Proposed § 507.25 also contains a requirement for proper disposal of contaminated animal food, raw materials or ingredients, or their reconditioning under the proper conditions. 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 B, in which § 507.25 resides. As such, FDA has already accounted for this provision and has not included any additional compliance costs for these provisions. The proposed rule also would require proper packaging and storing of animal food to prevent or minimize contamination and deterioration. This mirrors the process controls draft provision for which ERG estimated 13 hours of annual labor at the industrial production manager level at those facilities that do not currently properly dispose of or recondition contaminated animal food.

Section 507.28 of the proposed rule, concerning warehousing and distribution, would require that storage and transportation of animal food must be under conditions that will protect

against biological, chemical, physical and radiological contamination and deterioration of the animal food and container. The process controls draft contains a requirement 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. FDA has not added any further compliance costs to those in the ERG report.

xi. Cost to facilities covered by both part 117 and part 507 (VSB < $500,000)

Proposed § 507.1(d) would allow 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 B 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 all hazards that are reasonably likely to occur in the animal food, including nutrient imbalances. FDA assumes that since the proposed rule on part 117 published prior to this proposed rule, any final rule that may be published on part 117 would be published prior to or at the same time as any final rule on part 507, and would also become effective earlier or on the same date. Based on this, FDA assumes that any facility that would need to comply with either subpart B or subpart C of both part 117 and part 507, and those that would need to comply with subpart B and subpart C of both part 117 and part 507, would choose to comply with the relevant parts of part 117.

FDA does not have the data to make a confident estimate of the percent of the food

handling procedures and processes occurring at facilities subject to both part 117 and part 507 that are due solely to animal food handling. With that in mind, FDA subject matter experts have initially estimated that only about 5% to 10% 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. Accordingly, FDA has increased the estimated total costs of this proposed rule by assigning 7.5% of the cost at the average facility for all those additional facilities handling both animal and human food. This adds an additional $13.384 million in total annualized costs to this proposed rule. FDA notes the significant uncertainty in this estimate and request comment and data on both the number and types of facilities that would be subject to both part 117 and part 507, and the extent to which the processes in these facilities are related solely to animal food.

xii. Total industry costs of the proposed part 507 (VSB < $500,000)

The additional annualized costs to domestic animal food-only manufacturers for the parts of the proposed part 507 (including the Hazard Analysis And Risk-Based Preventive Controls in subpart C and the Current Good Manufacturing Practices in subpart B) that were not included in the compliance costs of the 2011 ERG report sum to $28.45 million. Along with the $56.73 million in applicable annualized costs from the ERG report and $9.88 million in applicable annualized costs from facilities that are subject to both part 117 and part 507, FDA estimates that the sum total of the annualized costs to domestic animal food-only manufacturers of the proposed rule is $95.07 million at a 7 percent discount rate (see table 20). At a 3 percent discount rate, the annualized cost is $93.16 million.

FDA estimates that the total annualized costs for foreign manufacturers (including both

those based on the compliance cost model in the 2011 ERG report, those estimated under the additional compliance costs of the proposed animal food safety plan and those subject to both part 117 and part 507) are $33.68 million at a 7 percent discount rate. With a 3 percent discount rate, these annualized costs total $33.051 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 be as high as $128.75 million at a 7 percent discount rate, or $126.22 million at a 3 percent discount rate.

Table 20. Industry Compliance Costs of Proposed Rule (VSB < $500,000) ($ million)

Rule Provision	1-Time Cost	Annual Cost	Total Annualized Cost at 7%[1]	Total Annualized Cost at 3%[1]
Validation of food safety plan	$4.27	$1.42	$2.03	$1.92
Process control monitoring	$0.45	$4.21	$4.27	$4.26
Process control monitoring – verification		$2.30	$2.30	$2.30
Sanitation Controls – writing procedures for food contact surfaces and cross-contamination	$0.47	$0.05	$0.11	$0.10
Sanitation controls – monitoring and verification	$0.38	$6.82	$6.87	$6.86
Subpart B – additional sanitation labor		$7.39	$7.39	$7.39
Training for qualified individuals	$4.85	$1.23	$1.92	$1.80
Attesting to qualified status and changing product labels	$1.95	$0.02	$.30	$0.25
Administrative review of rule	$20.07		$2.86	$2.35
Subtotal	$32.45	$23.83	$28.45	$27.63
ERG Analysis of process controls draft (Includes food safety plan reanalysis and corrective actions)	$35.51	$51.68	$56.73	$55.84
	`			
Facilities subject to both part 117 and part 507	$7.53	$8.81	$9.88	$9.69
Domestic Manufacturers	$75.49	$84.32	$95.07	$93.16
Foreign Manufacturers	$25.26	$30.09	$33.68	$33.05
Total	$100.75	$114.41	$128.75	$126.22

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

The average annualized costs per facility type are shown in Table 21 (does not include facilities that are subject to both part 117 and part 507).

Table 21. Annualized Cost per Facility (VSB < $500,000)

Sector	Type	Labor Cost[1]	Capital Cost[2]	Cost Total
Commercial Livestock	Large Mills	$12,600	$3,000	$15,600
	Medium Mills	$18,100	$2,000	$20,100
	Small Mills	$16,200	$1,100	$17,300
Other Livestock	Wholesalers	$14,100	$1,100	$15,200
	Integrators	$12,600	$3,100	$15,700
Pet Food	Large Operations	$15,400	$4,300	$19,700
	Small Operations	$16,800	$1,000	$17,900
Ingredient Suppliers	Large Suppliers	$14,400	$300	$14,700
	Medium Suppliers	$13,800	$1,200	$15,000
	Small Suppliers	$15,600	$700	$16,300

1. Labor cost column contains one-time labor costs annualized 7% over 10 years plus annual labor costs.
2. Capital cost column contains one-time capital costs annualized 7% over 7 years (see ERG report) plus annual capital costs.

xiii. Government costs

FDA estimates that it will require 10 full-time equivalent positions (FTEs) in the first year for development and implementation of the final rule and guidance, development and delivery of training, and other outreach activities. Based on the FY 2010 appropriation for the Center for Veterinary Medicine at FDA, the average cost of one of these employees is $213,000, including the cost of all overhead support of that FTE. The total cost of these ten employees in the first year would be $2.13 million. Additionally, FDA estimates that it would require $1.5 million in up front overhead costs. The total government cost in the first year for this rule would be $3.63 million.

In the second year, FDA estimates that an additional 3 FTEs would be required to manage the additional activities of the proposed rule. The 13 FTEs (the original 10 FTEs in FY 2012 plus the additional 3 FTEs in FY 2013) would cost $2.77 million in the second year.

Given the estimated number of affected facilities, the number of high risk facilities, and the required inspection frequencies defined in FSMA for both domestic and foreign facilities,

FDA estimates that, at a minimum, about 40 FTEs would be required in the second year for inspection-related purposes of this rule. Based on the FY 2011 budget request for CVM inspection activities, the cost of an inspection-related FTE is about $194,000, including all overhead support of that FTE. Thus, FDA estimates that the cost of these 40 inspection-related FTEs would be about $7.76 million in the second year. In sum, FDA projects that total costs to FDA of this rule in the second year would be about $10.53 million.

Inspection-related costs are for foreign inspections for an additional 5 years. At that time, FDA expects that about 52 FTEs would be required for all inspection activities related to this rule. FDA estimates that these 52 FTEs would cost $10.09 million by the fifth additional year. Along with the original 13 FTEs for CVM implementation and management of the rule, FDA concludes that the proposed rule would add $12.86 million to agency costs in the fifth additional year.

The annualized cost over 10 years at a 7 percent discount rate for FDA enforcement activities is equal to $10.36 million ($10.59 million at a 3 percent discount rate).

D. Analysis of Alternatives

FDA considered other provisions for the proposed rule, many of which would require that each facility add more verification procedures to insure that its preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur. The following sections contain the incremental compliance costs associated with additional verification activities and other alternatives that were considered but not included in the proposed rule.

1. Customer complaints (VSB < $500,000)

This provision would require review of customer, consumer or other complaints to

determine whether a complaint relates to the effectiveness of the animal food safety plan. The process controls draft did not include any provision containing this or a similar requirement. Lacking any data on complaint review activities at animal food production facilities, FDA uses the data on human food production facilities. Both the 2010 ERG survey and the expert elicitations show that the larger the facility, the more likely it will have a formal system for complaint review. Most facilities, even in the smallest size category, keep records of consumer and other complaints. Based on survey questions, FDA estimates that the number of facilities that do not keep records of complaints ranges from about 20% of those with fewer than 20 employees to about 1% of those with 20 to 99 employees. All larger facilities are expected to have these systems. Although the amount of time spent in review can vary greatly, FDA estimates an average of 4 hours per month to review complaints and, if necessary, modify the safety plan. This analysis assigns this review effort to the facility manager, and uses the production manager wage rate of $58 per hour. For those 634 affected facilities, this would result in an additional $2,800 per facility in annual compliance costs. In the Table 22 total, this sums to $1.767 million annually.

Table 22. Cost to Review Customer Complaints

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	2,922	3,019	662	1
% not reviewing complaints	20%	1%	0%	0%
Facilities needing to implement complaint review system	594	40	0	0
Hours per month reviewing complaints	4	4	4	4
Wage rate – hourly	$58	$58	$58	$58
Annual cost per facility	$2,800	$2,800	-	-
Total annual cost by size of facility	$1,655,000	$111,000	-	-
Total annual cost	$1,767,000			

2. Finished product testing (VSB < $500,000)

FDA considered requiring verification by scientifically valid finished product testing,

where appropriate. The 2011 ERG report includes a testing model that contains *Salmonella* testing for some small pet food manufacturers and small ingredient manufacturers that are not expected to currently undergo *Salmonella* testing. It also includes salt testing for those medium and small feed mills and wholesale facilities that do some mixing, but do not currently have a procedure for testing. FDA, however, assumes that no salt testing would be required by this alternative, as it is used to determine the uniformity of a mixed feed, rather than to identify feed hazards. The testing model also includes moisture testing for some medium and small ingredient manufacturers that do not currently have a procedure for moisture testing, and urease testing for some ingredient manufacturers of all sizes that do not currently have a procedure for urease testing (see the testing cost section in the 2011 ERG, and Appendix A of the report, for a full explanation of the testing program) (Ref 1.). In total, the ERG testing cost model with the 6,603 facilities distributed across the various facility types (excluding the salt testing costs) for finished products would project to about $2.88 million in annual testing costs.

3. Performance of environmental monitoring (VSB < $500,000)

FDA considered requiring that facilities perform environmental monitoring for microorganisms of animal or human health significance, as appropriate to the facility. Not all facilities would need to conduct environmental monitoring; only those facilities where pathogens are reasonably likely to occur would be expected to conduct such testing. These facilities would be expected to conduct such testing on a monthly basis as a minimum frequency.

Effective environmental pathogen controls will be product, process, and plant specific. Effective environmental pathogen control does not target all pathogens that could potentially come from the environment, but rather those that are reasonably likely to be a problem based on product and production procedures. FDA subject matter experts expect that *Salmonella* to be the

organism of concern for certain dry animal food products.

FDA uses the sampling time, testing time and capital cost estimates that ERG developed for the raw material testing and finished product testing regimen in the process controls draft report to estimate the testing costs for environmental monitoring. These factors sum to about $19.20 per sample tested using a quick time test that is performed at the facility. FDA uses the estimate of 15 samples per month estimated for the proposed rule for human food. The result of these two factors is about $290 per month per facility for environmental testing for *Salmonella*. FDA subject matter experts expect that pet food manufacturing facilities would be required to perform this testing. Assuming that foreign pet food manufacturers represent the same percent of all importer facilities as domestic pet food manufacturers represent of all affected domestic facilities, FDA estimates that about 261 facilities would be subject to this requirement. Based on the current compliance estimates from the human foods manufacturer survey, FDA estimates that 184 facilities (or 70%) of the 261would need to begin environmental monitoring. Total annual testing costs for this alternative are estimated at about $636,000, or about $3,000 per facility that needs to begin environmental monitoring (see table 23).

Table 23- Annual Cost of Environmental Monitoring

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
No. of facilities subject to part 507	141	61	57	1	261
Percent that currently test	21%	28%	50%	62%	
No. of facilities that need to begin testing	111	44	28	1	184
Cost per facility for annual testing	$3,457	$3,457	$3,457	$3,457	
Total testing costs for environmental monitoring	$384,000	$152,000	$99,000	$2,000	$636,000

4. Supplier approval and verification program (VSB < $500,000)

Another option would be to require that the owner, operator, or agent in charge of each

facility establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur. Such an alternative would include: a written list of approved suppliers and verification activities, a written list of which hazards are reasonably likely to occur in each raw material and ingredient, and various verification activities.

For this alternative, a receiving facility would not be required to comply for raw materials and ingredients for which the preventive controls at its facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur, or where there are no hazards identified as reasonably likely to occur for any raw materials or ingredients. Further, receiving facilities relying on annual written assurances from its customers that each customer has established and is following procedures that will significantly minimize or prevent the hazard, would also not be required to comply with the supplier verification and approval program. This option would likely be less costly to implement than those verification activities whose costs are estimated later in this section of this analysis. FDA does not have any data with which to estimate the percent of facilities that could choose this option, and does not include it in its cost estimation. As such, the cost totals for this section will likely represent the high end of the range of true compliance costs.

FDA also cannot say which individual facilities or industries will have process controls in place that would reduce or eliminate all possible hazards. The likelihood of all hazards being reduced or eliminated by the receiving facility will be depend greatly on the products produced at each facility and how those products are produced. For this analysis we assume that under the baseline no specific industry facility has a complete supplier approval and verification program in place, which results in an overestimate of actual compliance costs for this provision. FDA

requests comment on both the likelihood of specific facilities or industries not needing a supplier approval and verification program because all hazards are reduced or eliminated at the manufacturing (receiving) facilities, and the number or percent of receiving facilities whose customers could provide a written assurance that each has established and is following procedures that will significantly minimize or prevent these hazards.

a. Written list of approved suppliers

Creating a written list of approved suppliers is not expected to be a time consuming task. For this alternative, there would be no requirements specified as to how the list would need to be constructed (e.g. no requirement that the supplier be vetted or evaluated before being added to the list), so it likely that if manufacturers are satisfied with their current raw material and ingredient suppliers, they can compile the approved supplier list rather quickly. FDA estimates that it will take facilities one to two hours to develop a written approved supplier list once the necessary information has been developed and collected. FDA expects the approved supplier list to be developed by an Industrial Production manager with a wage per hour of about $58, including overhead. FDA uses information from the GMP survey of human food processors to determine the percentage of facilities that use potentially hazardous raw materials or ingredients and that do not currently have a written approved list of suppliers. These percentages range from about 6% or the largest facilities to about 64% of the smallest facilities. FDA estimates the first year cost to be about $212,000, which equals about $30,000 when annualized over 10 years at a 7% discount rate (see Table 24).

Table 24- Supplier Approval and Verification Program - Written Approved Supplier Lists

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Number of facilities possibly needing supplier approval and verification program	2,922	3,019	662	1	6,603
Percent Of Facilities That Use Potentially Hazardous Raw Materials or Ingredients and Do Not Have Written Approved Supplier Lists	64.43%	44.63%	31.78%	6.49%	
Number Of Facilities That Need New Written Approved Supplier Lists	1,882	1,347	210	0	3,440
Number of hours to Write Approved Suppliers List	1	1	2	2	
Cost per hour	$58	$58	$58	$58	
Cost In Year 1	$109,000	$78,000	$24,000	--	$212,000
First year costs annualized over 10 years	$16,000	$11,000	$3,000	--	$30,000
Annualized Costs per Affected Facility	$8	$8	$17	--	

FDA expects the costs to update the written supplier approval list to be negligible and has not included them in this analysis. Further, we do not estimate the costs of developing an approved supplier list for those facilities that do not currently use potentially hazardous raw materials but may do so in the future. FDA requests comment on this number of these facilities each year that would need to develop approved supplier lists.

b. Determination, by raw material or ingredient, of hazards that are reasonably likely to occur

Each receiving facility would create a written list of the hazards that are reasonably likely to occur in each of its raw materials and ingredients. Given that receiving facilities will spend some time completing the hazard analyses required by proposed § 507.33, including considering the effect of raw materials and ingredients on the safety of the finished animal food, it should not take facilities long to create a written list of hazards that are reasonably likely to occur in the raw materials and ingredients.

FDA estimates that it would take facilities with fewer than 100 employees one hour and facilities with 100 or more employees two hours to create a written list of hazards to its raw

materials and ingredients. Using the wage of a production manager for this one to two hour writing effort, FDA estimates the first year costs to be about $422,000, which equates to about $60,000 when annualized over 10 years at a 7 percent discount rate (see Table 25).

This hazards list may need to be updated if the facility begins to use a new ingredient. FDA does not have information on how often ingredients in products are changed or new products are added to the facility's output. FDA requests comment on the initial burden estimate and the likelihood of having to update this determination based on new ingredients or products.

Table 25- Supplier Approval and Verification Program - Written Determination for Ingredients

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
No. of facilities needing a supplier approval and verification program	2,922	3,019	662	1	6,603
Number of hours to Write Determination	1	1	2	2	
Cost per hour	$58	$58	$58	$58	
Cost In Year 1	$170,000	$175,000	$77,000	--	$422,000
First year costs annualized over 10 years	$24,000	$25,000	$11,000	--	$60,000
Cost per affected facility	$8	$8	$17	$17	

c. Verification activities for suppliers

Facilities would need to have verification activities for their ingredient suppliers. Verification activities would be required unless all hazards that are reasonably likely to occur in the ingredients are controlled for or eliminated by the receiving facility, the ingredient does not contain a hazard that is reasonably likely to occur, or the customer of the receiving facility provides a written assurance that it has established and is following procedures to significantly minimize or prevent the hazard. As noted above, this analysis assumes that none of these three conditions will be met at any receiving facility and each will undergo some verification activity, resulting in the high end of the range of costs.

The owner, operator, or agent in charge of a receiving facility would be required to

conduct, or obtain documentation of, an initial onsite audit of a supplier before using a raw material or ingredient from that supplier and periodic onsite audits, when the hazard is one for which there is a reasonable probability that exposure to the hazard would result in serious adverse health consequences or death to humans or animals. If a supplying facility is not controlling hazards reasonably likely to occur, the receiving facility would need to take prompt action, which may include discontinuing the use of the supplier, to ensure the hazards associated with the ingredient have been significantly minimized or prevented. Based on the experience of FDA subject matter experts, FDA estimates that the ingredient suppliers subject to proposed part 507 comprise all ingredient supplier facilities supplying all those other facilities subject to proposed part 507. A proportionate number of foreign manufacturing facilities have been added to this total. This estimate also assumes that the remaining supplier facilities also supply food manufacturing, processing, packing, and holding facilities that would be subject to a similar alternative to the proposed rule for human food and would therefore be subject its supplier approval and verification program. Their supplier approval compliance costs are not included in this analysis.

i. Audits of suppliers

We estimate that supplying facilities would undergo one audit annually to satisfy an alternative requirement that receiving animal food facilities verify their suppliers of raw materials and food ingredients. The estimate of one audit per year will overstate auditing frequency in cases where the ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals. In those cases the audit would be required every other year, in which case the compliance cost estimated below would only be one-half as large.

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

Table 26- Annual Cost of Raw Material and Ingredient Supplier Audits

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
No. of facilities subject to part 507	95	83	0	0	178
Percent of facilities that do not currently conduct audits	43%	21%	14%	0%	
No. of facilities that will need to conduct audits	41	17	0	0	59
Cost per audit	$2,625	$3,750	$4,375	$5,000	
Travel and incidental expenses per audit	$625	$625	$625	$625	
Total cost of audit annually	$135,000	$75,000	$0	$0	$210,000
Annual cost per affected facility	$3,250	$4,375	N/A	N/A	

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

As another alternative to an audit, a receiving facility could be allowed to rely on the results of an inspection of the supplier by FDA or, for a foreign supplier, by FDA or the food safety authority of a country whose food safety system FDA has determined to be comparable or equivalent to that of the United States when certain other conditions are met. FDA does not

know the percent of suppliers that would be able to use this alternative approach. For those that could, however, compliance costs would be reduced as the audit costs would not be incurred.

ii. Supplier Verification Activities other than Audits

If the hazard to a raw material and ingredient is not one for which there is a reasonable probability that exposure to the hazard would result in a serious adverse health consequence or death to humans or animals, then, under this alternative, the receiving facility would have the choice of the following as a supplier verification activity: 1) auditing the supplying facility periodically, 2) sampling and testing the raw materials or ingredients before use, 3) periodically reviewing the suppliers food safety records (e.g., audits of their suppliers), or 4) other appropriate supplier control verification measures based on the risk associated with the hazard. The cost analysis for the analogous alternative to the proposed rule for human foods assumed that this requirement would likely be addressed by the testing ingredients from suppliers. FDA assumes the same would be done to comply with this requirement for manufacturers of animal foods. The ERG analysis of the process controls draft for animal foods included a raw material testing regimen for those hazards that were identified in the hazard analysis as being likely to occur (see Appendix A of the ERG report for a full description of the animal feed testing model). Using that cost model on the 6,603 facilities from the FFR that are subject to the rule would result in ingredient testing costs of about $18.6 million. Since that analysis already accounts for raw material and ingredient testing costs, where appropriate, and those costs are already included in this analysis, no additional testing costs are added here for the supplier approval and verification program. Additionally, the cost estimate for supplier audits assumed that all ingredient supplier facilities would undergo the annual audit, negating the need to estimate costs of these four alternatives.

iii. Verification activities for suppliers that are qualified facilities

This alternative would provide an optional set of verification activities for suppliers that are qualified facilities. Receiving facilities with suppliers that satisfy the criteria to be considered a "qualified" facility would have the option of submitting documentation at the end of each calendar year that their supplier meets the definition of a qualified facility, and obtaining written assurance at least every 2 years that the supplier is producing raw material or ingredients in compliance with section 402 of the FDC Act pertaining to animal food adulteration. A brief description of the processes and procedures that the supplier is following to ensure the safety of the animal food would be required.

FDA estimates that there may be a small number of affected suppliers that would be qualified under the very small business definition of having less than $500,000 in total annual sales of animal food. Following the FDA cost estimate of the human food proposed rule, however, FDA assumes that for those few receiving facilities that might have qualified suppliers, the alternative would require about two hours per year to review records, determine whether any of their suppliers are subject to an FDA warning letter and to prepare the documentation to meet the requirements of this provision. Under the alternative in which covered entities must have a supplier approval and verification program, this optional verification program would likely reduce the total compliance costs for those receiving facilities with qualified facilities as suppliers.

iv. Summary of supplier controls costs

The total costs of the supplier approval and verification alternative would be the sum of the costs of the written procedures and the verification activities. Total annualized costs are estimated at $300,000 per year.

Table 27. Supplier Controls Costs Summary

	<20 employees	20 to 99 employees	100 to 499 employees	≥500 employees	Total
Annualized Costs of Written Approved Supplier Lists	$16,000	$11,000	$3,000	--	$30,000
Annualized Costs of Written Determination	$24,000	$25,000	$11,000	--	$60,000
Annual Costs of Auditing Suppliers	$134,000	$75,000	--	--	$210,000
Total Supplier Approval and Verification Program Costs	$174,000	$111,000	$14,000	--	$300,000

5. Review of other records (VSB < $500,000)

Another alternative would require that records be reviewed to ensure that they are complete, that the activities occurred in accordance with the food safety plan, and that the preventive controls are effective. The cost of reviewing sanitation control and process control verification records has been included earlier in the cost analysis of the proposed rule. The review of records cost presented here represent review time for complaint records, records of finished product testing and environmental testing and supplier verification activity records. According to the expert elicitation for human food production facilities, the number of verification records kept and the time spent in review of these records depends on the size of the facility. Based on responses to the 2010 ERG survey of human food production facilities, FDA estimates that the percentage of facilities without these verification records varies from about 39% of those with fewer than 20 employees to less than 1 percent for those with 100 or more employees. This equates to about 3,000 facilities, two-thirds of which have fewer than 20 employees that would be out of compliance with the record review verification requirements. Although the review time would likely vary among facilities, FDA uses the estimates from the analysis of the alternative to the proposed rule for human foods that range from 0.25 to 1 hour per month reviewing these records. FDA expects this review to be performed by a production

manager with an hourly wage rate of $58 per hour. Total annual industry costs for review of records would equal about $415,000 (Table 28). Although the 2011 ERG report contains over $6 million in annual recordkeeping costs, it does not appear that these costs include a review of the records as required by this alternative.

Table 28. Cost of Record Review

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	2,922	3,019	662	1
% without verification records	39%	20%	<1%	0%
Facilities needing to begin reviewing records	1,53	613	3	0
Hours per month reviewing records	0.25	0.50	0.75	1.00
Wage rate – hourly	$58	$58	$58	$58
Annual cost per facility	$174	$348	$397	$697
Total annual cost by size of facility	$201,000	$213,000	$1,000	--
Total annual cost	$415,000			

6. Personnel training (VSB < $500,000)

FDA considered requiring mandatory education and training requirements for facility personnel in § 507.14(b). In that alternative, plant management would need to provide education and training to ensure that personnel engaged in manufacturing, processing, packing or holding of animal food have the education or experience needed to perform these duties. Also, personnel involved in animal food manufacturing, processing, packing, or holding would need to receive appropriate training on the principles of food hygiene and food, including the importance of employee health and personal hygiene. All training must be received upon hiring with periodic updates as needed.

Lacking data on the education and training programs offered by animal food production facilities, FDA uses responses to the 2010 ERG survey of human food production facilities to gauge training needs necessary to comply with this alternative. The 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. This alternative would impose compliance costs at those facilities that provide little or no training and education to their employees. Based on the survey, FDA estimates that the number of facilities that offer no training on the principles of food safety to employees ranges from 10% of facilities with fewer than 20 employees to 0% of facilities with 500 or more employees. Further, it estimates that about 32% of facilities with fewer than 20 employees, 60% of facilities with 20-99 employees, 48% of facilities with 100-499 employees and 60% of facilities with more than 500 employees provide one hour or less of training in safe food production.

The survey also inquired about training practices concerning personal hygiene practices at food production facilities, including the 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 alternative to the proposed rule for human food, FDA uses the responses to these survey questions to estimate the compliance costs of more stringent alternative personnel training requirements that could have been included in § 507.14(b). These compliance costs would be incurred by those facilities that do not provide any training in either the principles of food safety or food hygiene (including personal hygiene), and those facilities that provide less training than would be necessary.

Training and education materials for human food production, food hygiene and personal hygiene are readily available in book and pamphlet form, on-line and in video format. FDA assumes similar materials are available for animal food production facilities on-line for free, and has not included any materials cost in the analysis of this alternative.

FDA estimates that each food production employee would need to take two hours of training in the principles of food safety each year, and another two hours in food hygiene including personal hygiene. Those facilities that currently provide one hour or less would incur the cost of an additional hour of training in both areas. FDA estimates that facilities with fewer than 20 employees would need to provide the additional hours of training to 10 production employees at the production worker wage rates. Similarly, facilities with 20-99 employees would need to provide the additional training to 50 production employees, facilities with 100 to 499 employees would need to provide the additional training to 200 employees, and facilities with 500 or more employees would need to provide the additional training to 550 employees at the production worker's wage rate. FDA estimates that a qualified individual or trainer at a production manager's wage of $58 per hour would provide the training to the necessary floor employees. The total cost of lost work time would be about $560 per facility ((10 employees x $23/hr. x 2 hr.) + (1 qualified individual x $58/hr. x 2 hr.)) for small facilities that do not provide any training and about $280 ((10 employees x $23/hr. x 1 hr.) + (1 qualified individual x $58/hr. x 1 hr.)) for small facilities that provide at least one hour of training.

Recordkeeping costs are based on 5 minutes per record per training class at a clerk's total wage rate, including overhead, of about $20 per hour. FDA requests public comment and data on all the factors used in the training cost section of the analysis.

The total annual compliance costs for facilities are shown in Table 29. In sum, the total annual cost of both the principles of food safety and the food hygiene, including personal hygiene, is estimated to be $11.50 million.

Table 29. Education and Training Costs

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Total number of facilities	4,359	3,107	662	1
% requiring 2 hours of training in principles of animal food safety	10%	2%	5%	0%
Number of facilities requiring 2 hours of training	440	67	33	0
Number of production workers requiring training	10	50	200	550
Production worker wage	$23	$23	$23	$23
Trainer/manager wage	$58	$58	$58	$58
Subtotal – 2 hours training for principles of food safety	$250,000	$160,000	$299,000	$0
% of facilities requiring an additional 1 hour in training in principles of animal food safety	32%	60%	48%	60%
Number of facilities affected	1,376	1,869	315	1
Number of production workers requiring training	10	50	200	550
Production worker wage	$23	$23	$23	$23
Trainer/manager wage	$58	$58	$58	$58
Subtotal – 1 hour training for principles of food safety	$391,000	$2,221,000	$1,443,000	$10,000
Recordkeeping cost	$30,000	$162,000	$117,000	$1,000
Subtotal – principles of food safety training	$672,000	$2,543,000	$1,859,000	$11,000
% requiring 2 hours of training in food and personal hygiene	10%	2%	5%	0%
Number of facilities affected	415	74	33	0
Number of production workers requiring training	10	50	200	550
Production worker wage	$23	$23	$23	$23
Trainer/manager wage	$58	$58	$58	$58
Subtotal – 2 hours training for food and personal hygiene	$236,000	$177,000	$303,000	$0
% of facilities requiring 1 hour in training in food hygiene	41%	74%	54%	45%
Number of facilities affected	1,792	2,285	359	1

	Facilities with			
	< 20 employees	20-99 employees	100-499 employees	> 500 employees
Number of production workers requiring training	10	50	200	550
Production worker wage	$23	$23	$23	$23
Trainer/manager wage	$58	$58	$58	$58
Subtotal – 1 hour training for food and personal hygiene	$509,000	$2,716,000	$1,644,000	$8,000
Recordkeeping cost	$37,000	$198,000	$132,000	$1,000
Subtotal – food and personal hygiene training	$781,000	$3,090,000	$2,079,000	$8,000
Total annual training costs for food safety and food and personal hygiene by size	$1,453,000	$5,633,000	$3,938,000	$19,000
Total annual training costs for food safety and food and personal hygiene	$11,043,000			

7. Other alternatives

FSMA does not apply to on-farm mixer/feeder facilities because farms are not required to register with FDA under section 415 of the FD&C Act. The process controls draft, however, would have applied to some on-farm mixer/feeder facilities. The process controls draft used facility size, defined by the number of animals by species produced annually at each facility, to limit the number of facilities mixing feed that would be subject to the rule. Even with these size restrictions, the process controls draft would still have covered an additional 18,100 facilities. The ERG report contains cost estimates for these facilities, along with the cost estimates for those facilities that are also subject to this proposed rule. Had these additional 18,100 on-farm mixer/feeder facilities been subject to the proposed rule, it would have imposed $186 million in annualized costs (including one-time costs annualized at 7 percent over 10 years plus annual costs). This equates to over $10,000 annually for each of these facilities. Furthermore, additional costs would be incurred by each of these facilities for the validation, verification and monitoring requirements of the proposed rule. FDA has not estimated the cost of

each of the additional requirements of the proposed rule for the on-farm mixer/feeders, but it would add tens of millions more dollars in annual costs.

Other alternatives FDA identified would be to exclude any of the requirements of the proposed rule that were not specifically required by section 418 of the FD&C Act, which are those listed in subpart B of the proposed rule. One of these is the requirements in proposed § 507.17 that the facility take action to minimize or eliminate pest infestation from raw materials and processing areas and equipment. As mentioned previously, the ERG report estimated labor hours for compliance with this rule, which would amount to annualized costs of about $207,000. Preventing pest infestation plays a part in the success of any food safety system, and the estimated compliance rates show that most facilities already address pest infestation. The removal of this or other requirements in proposed subpart B would not significantly reduce the total costs of the proposed rule.

FDA also considered subjecting facilities that hold and distribute raw agricultural commodities, or grain elevators, to part proposed part 507. Grain elevators can be included under several NAICS categories, but FDA has initially included them under NAICS 424510 –Grain and field bean merchant wholesalers. FDA relies on an estimate from the National Grain and Feed Association that there are from 10,000 to 12,000 grain elevators in the U.S. FDA subject matter experts estimate that, at most, only 5% of these could be expected to hold and distribute products only to human foods manufacturers, which would not be subject to the rule. The remaining 95% of the midpoint of the range of grain elevators, or 11,000, could have been subject to the rule since they are expected to hold grains for distribution to animal food processors. The total number of these grain elevators is estimated at 10,450.

FDA distributed these 10,450 facilities across the employment size categories from the

2007 Census to determine that 80% would have fewer than 20 employees, 17% would have 20 to 99 employees and 3% would have more than 100 employees. These facilities were then included in the cost model outlined previously in this analysis that attempts to capture all costs not included in the ERG report on the process controls draft rule. Additionally, FDA assigned to the grain elevators the lowest per facility cost from domestic manufacturers in the ERG report under the assumption that these facilities would not conduct any processing activities beyond minimal activities such as cleaning and drying the product. The result showed that if grain elevators were subject to proposed part 507, total annualized compliance costs would increase by an estimated $153million, more than doubling total compliance costs. FDA has not included grain elevators in the proposed rule, but has requested comment on whether grain elevators should be covered in the final rule. FDA requests public comment on the estimates included here and the need to include grain elevators in the proposed rule.

III. Initial 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 constitute the initial regulatory flexibility analysis.

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

a primary objective of this proposed rule.

A. Description and Number of Small Entities

The Regulatory Flexibility Act also requires a description of the small entities that would be affected by the rule and an estimate of the number of small entities to which the rule would apply. The Small Business Administration 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, including the alfalfa meal suppliers. SBA has also set the limit for qualification as a small entity for NAICS 311119 at 500 or fewer employees. For the dog and cat food companies, all but one facility would qualify as small businesses 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% of the market (Ref. 1). 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 BSE database described previously adds thousands more facilities that would be subject to the rule. The Census data show that all facilities would qualify as small if they were single facility companies. While this is not the case, 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. FDA expects only independent renderers to be subject to this rule, as the packer/renderer facilities would be subject to the human foods GMP revised rule. Although some independent renderers have multiple facilities that would disqualify them from the small entity classification, numerous independent renderers would still qualify as small entities.

The wholesale facilities that mix some animal feeds 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% of facilities in the NAICS 4245 classification have more than 100 employees, and only about 2% 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, FDA expects that a substantial number of these facilities would qualify as small entities.

B. Impacts on Small Entities

The 2007 Census data report that the average value of 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 $17,900 per facility represents 2.72% of the average value of shipments for the small dog and cat food manufacturing facilities, 1.270% of the average value of shipments for all facilities with fewer than 20 employees, and 0.07% or less for the larger facilities. 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. FDA concludes that there could be significant impacts on a substantial number of dog and cat food companies with fewer than 20

employees.

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 for these facilities equates to 1.46% of the average value of shipments for facilities with fewer than 5 employees and 0.26% or less for all larger facilities. With more than 400 facilities reporting fewer than 5 employees, FDA concludes that it is likely that some of these could be significantly impacted by the proposed rule. Although the regulatory cost to value of shipments ratio of 0.26% appears to show that costs would constitute a reasonably low percentage of revenues for all larger facilities, there would likely be some facilities that would 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 range from 1.02% of the average value of shipments for those facilities with fewer than 5 employees, to 0.44% or less of value of shipments for all larger facilities. There would likely be some facilities with less than 20 employees whose compliance costs represent more than 1% of revenues due to low current compliance rates with provisions of the rule. Impacts on these facilities could also 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 would represent 0.41% of revenues at the smallest of these facilities, and less than 0.12% at the largest of these facilities. FDA concludes it is unlikely that a substantial number of these companies will

be significantly impacted by the proposed rule. However, FDA does not have data for this NAICS category to show how facility size relates to the probability of manufacturing or processing animal food, and requests public comment and data on this issue.

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 would average 3.51% of sales for the smallest of these facilities, and less than 0.52% for facilities with five or more employees. FDA concludes that the smallest of these facilities could be significantly impacted by the proposed rule if they manufacture or process animal food, but notes the considerable uncertainty surrounding whether any small firms in this NAICS actually perform any animal food manufacturing or processing, packing or holding of animal food. FDA requests public comment and data on this issue.

C. Regulatory Relief for Small Entities

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

The proposed rule would also allow small businesses, defined by the proposed rule as employing fewer than 100 persons, two years after publication of any final rule issued to comply with the requirements of the rule. And very small businesses, defined under the three co-proposals as those facilities with gross annual sales of animal food of less than 1) $500,000, 2) $1,000,000 and 3) $2,500,000 (adjusted for inflation), would have an additional three years after publication of the final rule to comply with the requirements of the final rule. For the $500,000 co-proposal, this would give the three year transition period to 1,526 facilities, including the 1,386 non-employer facilities. For the $1,000,000 co-proposal, it would give the three year transition period to 2,005 facilities, including the 1,386 non-employer facilities. And for the $2,500,000 co-proposal, it would give the three year transition period to 3,805 facilities, including the 1,386 non-employer facilities.

IV. Unfunded Mandates Reform Act Analysis

FDA has determined that this proposed rule would be significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections. The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; regions, communities, or industrial sectors; national productivity; economic growth; full employment; job creation; and exports. The additional effects not covered in detail in the cost-benefit and regulatory flexibility analyses of the preceding sections are likely to be small or non-existent.

V. References

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

2. 2010 Nationwide Survey of Food Industry Safety Practices, Draft Final, ERG, January 10, 2011, contract number 223-01-2461, task order 7, ERG task number 0152.00.007.001.

3. Memorandum on Economic Analysis of New FDA Food cGMP Regulations and Related Legislative Initiatives – Subtask 2: Expert Opinions on Current Food Manufacturing Practices, ERG, June 30, 2010.

4. Food and Agriculture Organization of the United Nations (FAO), Animal Feed Impact on Food Safety – Report of the FAO-WHO Expert Meeting, October 8-12, 2007, Rome, Italy.

5. CDC. May 16, 2008. *Multistate outbreak of human salmonella infections caused by contaminated dry dog food---United States, 2006-2007*. MMWR, 57(19): 521-524.

6. Food Processing Sector Study Final Report, Contract HHSF22301010745G, Task Order 13, RTI International, November 2011.

7. Federal Register Vol 78, No. 11, pp. 3646 – 3824; http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334117.pdf