Preliminary Regulatory Impact Analysis for the proposed rules on Foreign Supplier Verification Programs (Docket No. FDA-2011-N-0143) and Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications (Docket No. FDA-2011-N-0146) under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Unfunded Mandates Reform Act of 1995 (Public Law 104-4), and the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520)

Preliminary Regulatory Impact Analysis

FDA has examined the impacts of two proposed rules relating to food importers' foreign supplier verification programs and accredited third-party audits 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). The proposed rules are:

1. Title: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.
2. Title: Accredited Third-Party Food Safety Audits and Food or Facility Certification.

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 believes that only the proposed rule entitled Foreign Supplier Verification Programs for Importers of Food for Humans and Animals is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because most importers that would be affected by both of the proposed rules are small businesses and will need to begin

performing various types of activities that they currently do not perform, the Agency believes that if these proposals are finalized they will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA expects that only the proposed rule entitled Foreign Supplier Verification Programs for Importers of Food for Humans and Animals would result in a 1-year expenditure that would meet or exceed this amount.

A. Need for Regulation

Section 301 of the FDA Food Safety Modernization Act (FSMA) (codified in section 805 of the Federal Food, Drug, and Cosmetic Act) (FD&C Act) requires FDA to adopt regulations on the content of foreign supplier verification programs (FSVPs) of importers of food. Section 805 requires that importers' FSVPs be adequate to provide assurances that their foreign suppliers are following processes and procedures that provide the same level of public health protection as those required under section 418 (on hazard analysis and risk-based preventive controls) and 419 (on standards for produce safety) of the FD&C Act, as applicable, and that the food they import is not adulterated or misbranded with respect to allergen labeling. The proposed rule entitled

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the FSVP proposed rule) would implement section 805.

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 foods that are manufactured, processed, packed or held by food facilities will be provided at an optimal level of safety. In the current market, however, consumers and producers may not have sufficient information on the safety attributes of foods. Although food facilities do have an incentive to put safety programs into place, the lack of awareness and information about the risks suggests that an inefficiently high demand may exist for food products that are produced without using adequate measures to prevent foodborne illness, adulteration, or contamination. Because the demand for many manufactured or processed 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 foods because consumers who become ill often do not know the reason for, or source of, their illness. Even in cases where consumers are aware that their illness was contracted from a specific food,

it is often difficult to determine who is ultimately responsible for their 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 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 food sector and investments in branding vary substantially. As a result, it is unlikely that the existence of brands in the food sector creates the optimal level of safety for society.

As a result of these considerations, an unregulated market may provide less than a socially optimal level of food safety. This deficiency in safe food practices was the impetus that gave rise to FDA's role in safeguarding food safety in the United States. The proposed rule on FSVP is needed to improve the safety of imported food. As discussed below, we estimate that the annual cost of the illnesses associated with imported foods subject to this rule is approximately $1.18 billion, more than one-fifth of the entire estimated burden of illness related to FDA-regulated foods consumed in the United States. Some portion of this annual illness burden will be eliminated by this proposed rule, in conjunction with other proposed rules that we are developing simultaneously with this rule. One such proposed rule would revise the existing Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (food CGMP) regulations (21 CFR part 110, to be moved to part 117) by establishing Hazard Analysis and Risk-Based Preventive Controls regulations for human food (subpart C of part 117). (Ref. 1 Another proposed rule would establish Hazard Analysis and Risk-Based Preventive Controls regulations for animal food (subpart C of 21 CFR Part 507). In this analysis, these two proposals are referred to collectively as the preventive controls (PC) rules or the PC regulations. When this

analysis refers to the PC rule, it is referring to the PC rule for human food. A third proposed rule addresses produce safety. These two PC rules and the produce safety rule apply to both foreign and domestic firms offering food for sale in the United States, and their implementation is expected to substantially reduce the instance of foodborne illness in this country. The FSVP proposed rule would provide assurances that foreign firms are meeting the requirements of the relevant U.S. food safety standards.

In addition to the FSVP proposed rule, this PRIA analyzes the impact of the proposed rule entitled Accredited Third-Party Food Safety Audits and Food or Facility Certification (the Third Party proposed rule). We are amending our regulations to provide for accreditation of third party auditors/certification bodies to conduct food safety audits of foreign food entities, including foreign food facilities, and to issue food and facility certifications, pursuant to section 307 of FSMA (section 808 of the FD&C Act). Use of accredited third-party auditors/certification bodies and food and facility certifications will help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. FDA expects that these regulations for a third-party accreditation program will increase efficiency by reducing the number of redundant food safety audits. We believe that a trusted program for foreign food safety audits and certifications—with clear requirements, standards, and procedures and operated under government oversight—will be appealing to accreditation bodies, auditors/certification bodies, and foreign food facilities. Widespread participation and broad acceptance of audits and certifications will help increase efficiency and reduce costs by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act.

Economic justifications for regulatory interventions in private markets rely on the presence of some market failure. The undersupply of credible information about the safe food practices of foreign firms stems from the same market failures that gave rise to our role in safeguarding food safety in the United States. However, we do not have the resources to monitor and ensure the safety of foods produced overseas at the same level that we do domestically. FSMA directs us to establish a system for accreditation of third-party auditors/certification bodies to conduct food safety audits and to issue certifications to foreign food facilities. We are creating a program to implement the FSMA requirement. If finalized, the Third Party proposed rule will allow us to supplement our oversight of foreign food facilities with a complementary system of food safety audits by auditors/certification bodies accredited by recognized accreditation bodies and, in limited circumstances, through our direct accreditation of auditors/certification bodies.

A third-party certification system is intended to provide customers with relatively inexpensive assurance that suppliers are maintaining high standards of safety in their goods. A pervasive problem in markets is the presence of "asymmetric information," where sellers know more about the safety of their products than buyers. The problem arises for two reasons. First, the value of the product to an individual buyer is less (usually far less) than the cost to that buyer of directly observing the actions that determine the safety of the food products. Second, because the value of the products increase with the increased safety assurances of the good, the sellers cannot credibly communicate that fact to the buyer – the buyer will correctly believe that the seller will claim high safety independent of the actual level of assurance.

By contracting the reporting of safety with a third-party food safety auditor, one that is paid a fixed fee independent of the safety of the good, the seller can theoretically overcome both

problems. A certification of compliance by a third-party food safety auditor can be distributed widely to all customers, reducing information-based inefficiencies that already exist in private markets through the elimination of the incentives for multiple verification activities per supplier, and potentially reducing the burden of some of the activities required by private purchasers.

For domestic food producers we are much better able to ensure the safety of food through our inspection programs and our ability to directly enforce our food safety requirements more easily than we are for foreign food producers. For example, carrying out the same level of inspectional activities for foreign producers is far more costly. In this context, the use of competent and reliable third-party auditors/certification bodies allows for cost-effective and credible verification of food safety compliance by foreign food facilities.

Finally, the creation of a rigorous and credible program for accredited third-party certification for imported foods will help us address some of the practical issues that make it more difficult for us to efficiently and effectively monitor the compliance of foreign food facilities. Under these proposed requirements, foreign producers who opt to be audited under our program will be assessed for compliance with our food safety requirements.

B. Costs and Benefits of the Proposed Rules

Single Analysis for the Proposed Rules

FDA has prepared a single PRIA for the proposed rules on FSVP and accredited third-party audits because both rules relate to supplier verification and auditing. The implementation of the Third Party rule will create cost savings for the entities subject to the FSVP rule. The cost-saving effects of the Third Party rule are incorporated into the FSVP cost estimates. For example, when estimating the potential number of onsite audits that might be triggered by this

rule we estimated that number based on the situation that would apply if and when we implement the FSVP, PC, and produce safety regulations, not the current situation without the implementation of those regulations. However, we have evaluated the proposed rules on preventive controls for human food and for produce safety in separate regulatory impact analyses.

Summary of Costs of the Proposed Rules on Foreign Supplier Verification and Third Party Accreditation

This analysis, including Appendix B, analyzes the costs and benefits of the combined effects of both the FSVP proposed rule and the Third Party Accreditation proposed rule. We quantify costs of these rules and provide qualitative discussions of the benefits of these rules. The following tables shows the estimated costs of both proposed rules over a 10 year time period discounted at both 3 percent and 7 percent. For convenience in this analysis, we assume that all costs associated with these rules are passed on to U.S. consumers. However, it is possible that some of these costs may not be passed on to U.S. consumers. We request comment on the extent to which all of these costs will be passed on to U.S. consumers.

Summary of Annualized Costs Co-Proposal Option 1

	3 Percent	7 Percent
Foreign Supplier Verification Costs, Co-Proposal Option 1	$472,971,342	$473,380,038
Third Party Accreditation Costs for All Participants Corresponding to FSVP Option 1	$55,548,432	$56,756,016
Third Party Accreditation Costs for FDA Corresponding to FSVP Option 1	$17,063,089	$17,640,083
Total Costs Option 1	$545,582,863	$547,776,137

Summary of Annualized Costs Co-Proposal Option 2

	3 Percent	7 Percent
Foreign Supplier Verification Costs, Co-Proposal Option 2	$461,407,455	$461,821,706
Third Party Accreditation Costs for All Participants Corresponding to FSVP Option 2	$51,409,861	$52,437,701
Third Party Accreditation Costs for FDA Corresponding to FSVP Option 2	$16,431,734	$16,999,246
Total Costs Option 2	$529,249,050	$531,258,653

With respect to the FSVP proposed rule, this analysis reflects that the proposed rule includes a "co-proposal" for two alternative approaches to certain requirements for foreign supplier verification activities. Under Option 1 of the co-proposal, if the foreign supplier controls a hazard in a food at its establishment and there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA), the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier at least annually thereafter (possibly more frequently if necessary to adequately verify control of the hazard). For non-SAHCODHA hazards that the foreign supplier controls, the importer would be required to conduct one of more of the following verification activities before using or distributing the food and periodically thereafter: onsite auditing of the foreign supplier, sampling and testing, review of the supplier's food safety records, or some other procedure that the importer has established as appropriate based on the risk associated with the hazard. This requirement would also apply, under Option 1, when the foreign supplier verifies control of a hazard by its ingredient or component supplier, rather than directly controlling the hazard itself.

Under Option 2 of the co-proposal, for all hazards that the foreign supplier will either control or verify control by its supplier, importers would need to choose a verification procedure from among onsite auditing, sampling and testing, review of supplier food safety records, or some other appropriate procedure. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the foreign supplier's compliance with U.S. food safety regulations.

The proposed rule sets forth a similar co-proposal regarding supplier verification for certain raw agricultural commodities that are fruits or vegetables. Option 1 would require onsite auditing to verify control of microbiological hazards in such produce, while under Option 2 the importer would select a verification activity from the list of possible procedures set forth above.

Affected Entities

Coverage of the Foreign Supplier Verification Proposed Rule and Data Used in Analysis

The Foreign Supplier Verification proposed rule requires importers to verify that their foreign suppliers are in compliance with specified food safety standards. In some cases, we break out the number of importers that deal with dietary supplements (DS) because the proposed requirements that apply to these importers are different from those that apply to other importers. We break out the number of importers that import DS and that manufacture or process DS because in some cases the applicable FSVP requirements differ depending on whether an importer is 1) manufacturing, packaging, or labeling a DS or 2) importing a DS that will not be processed further. Specifically, we are proposing that when the importer of a DS or DS component (or the importer's customer) is subject to and in compliance with certain DS CGMP

provisions requiring the creation of and adherence to specifications (e.g., for DS components, packaging, or labeling), the importer would be exempt from most FSVP requirements (except for maintaining a list of foreign suppliers, providing identification at entry, and maintaining records). This is appropriate because confirming that these specifications have been met constitutes a form of "verification" of supplier compliance. With respect to "finished" DS (i.e., packaged and labeled DS that are not subject to further processing), we are proposing that importers would not be subject to the hazard analysis provisions but would need to verify their suppliers' compliance with the DS CGMP regulations (through auditing, sampling & testing, review of supplier food safety records, or some other appropriate method).

The FSVP rule defines an importer as a person in the U.S. who has purchased an article of food that is being offered for import into the U.S. If the article of food has not been sold to a person in the U.S. at the time of entry, then the importer is the person in the U.S. to whom the article has been consigned at the time of entry. If the article of food has not been sold or consigned to a person in the U.S. at the time of entry, then the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry. This definition corresponds closely to the definition of a "consignee" in FDA's Operational and Administrative System for Import Support (OASIS) database. Therefore, for purposes of this analysis, we treated the term "importer" as identical to the OASIS classification "consignee." Similarly, we treated the term "foreign supplier" as identical to the OASIS classification of "manufacturer" except in the case of raw agricultural commodities that are fruits or vegetables (RACs). In the case of RACs we assumed that the OASIS manufacturer would typically be a distributor and that the "foreign supplier" in such cases would be the foreign farms working with that distributor. For these

entities, we followed the estimation procedure we used in the RIA of the produce safety rule and assumed a range of 1 to 10 foreign farms per distributor.

We used OASIS data on food imported to the U.S. in fiscal year 2010, the last full year for which data was available at the time we performed this analysis, to estimate the number of importers that would be subject to the FSVP rule. We adjusted the numbers in various ways to reflect the exemptions discussed in the proposed FSVP rule and other considerations.

We only included imported food that is regulated by FDA.

We excluded food that arrives in the continental U.S. from Puerto Rico because we do not define that food as imported food. However, we included food that arrives in the U.S. from all other U.S. territories including American Samoa, Virgin Islands, Guam, and the United States Outlying Islands.

We excluded imported juice and seafood because the proposed FSVP rule exempts those products if they are produced in facilities following the relevant regulations, and for purposes of this analysis we assume that the facilities producing these products are following the relevant regulations.

We attempted to exclude food being transshipped or imported for further processing and immediate export, food imported for personal consumption, and food imported for research and evaluation because the proposed FSVP rule exempts those products. We used the following OASIS entry types to identify these products: 1) Temporary Importation Bond (TIB), 2) Trade Fair, 3) Permanent Exhibition, 4) Warehouse - Foreign Trade, 5) Aircraft & Vessel (For Immediate Exportation), 6) Warehouse Withdrawal for Immediate Exportation, 7) Warehouse Withdrawal for Transportation and Exportation, 8) Immediate Transportation, 9) Transportation and Exportation, 10) Baggage, and 11) Mail.

We excluded alcoholic beverages because the proposed FSVP rule exempts imported alcoholic beverages from foreign facilities that meet the following two conditions: 1) Under the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) or chapter 51 of subtitle E of the Internal Revenue Code of 1986 (26 U.S.C. 5001 et seq.), the facility is a foreign facility of a type that, if it were a domestic facility, would require obtaining a permit from, registering with, or obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States; and 2) under section 415 of the FD&C Act, the facility is required to register as a facility because it is engaged in manufacturing/processing one or more alcoholic beverages. We were unable to distinguish alcoholic beverages imported from these types of facilities from alcoholic beverages imported from other facilities.[1]

We were unable to address the proposed exclusion for non-alcohol food (i.e., food other than alcoholic beverages) imported from foreign suppliers that meet the first of the two conditions we just mentioned in connection with alcoholic beverages and that meets the following two additional conditions: 1) it is in prepackaged form that prevents any direct human contact; and 2) it constitutes not more than 5 percent of the overall sales of the facility, as determined by the Secretary of the Treasury.[2]

There is considerable uncertainty associated with the OASIS data because in many cases an importer may appear more than once under slightly different names. For example, when we studied the food facility registrations based on the Bioterrorism Act of 2002, we found that between 20 percent and 25 percent of registrations were duplicates or possible duplicates. However, we have not expressed this source of uncertainty in our cost estimates because in many

[1] The Third-Party proposed rule contains a limited exemption for alcoholic beverages imported from facilities that meet these two conditions.

[2] The Third-Party proposed rule contains a limited exemption for prepackaged foods imported from facilities that meet the first two conditions and the two additional conditions.

cases these estimates are based on combinations of importers and suppliers or combinations of importers, suppliers, and products, and we do not know how the number of such combinations varies with potential duplicates in importer records. In some cases a reduction in the number of importers would be associated with an increase in the cost per importer, leaving total estimated costs unchanged. However, to the extent that we do calculate some of our costs on a per importer basis, our estimated costs are maximum costs with respect to this particular source of uncertainty, although not with respect to other potential sources of uncertainty that we have expressed in the other inputs.

For purposes of identifying the importers associated with different activities, we used very broad definitions of the relevant industries and activities. For food manufacturing and processing, we included importers having North American Industry Classification System (NAICS) codes between 311000 and 311999, which cover food manufacturing and processing (including animal food manufacturing and processing), and between 312110 and 312119, which cover non-alcohol beverage manufacturing and processing. For DS manufacturing and processing, we included importers dealing with imported DS products identified within the OASIS system and having NAICS codes between 310000 and 339999, which cover all manufacturing.

In some cases we used ranges for numbers that we estimated using NAICS codes rather than OASIS codes. In these cases, the low ends of the ranges correspond to importers having the relevant NAICS codes as their only activity in their Dun & Bradstreet (D&B) record. The high ends of the ranges correspond to importers having the relevant NAICS codes under any of the up to six activities listed in their D&B record. We considered the latter to be the high ends of the ranges because in the case of importers that have multiple activities in their D&B records, we do

not know which particular activity is associated with imported food. Thus, for example, even though an importer is involved in retail sales as one of various activities in its D&B record, that importer might not be importing food for retail sale.

FSVP Co-proposal Option 1[3]

We first discuss the costs and benefits of the FSVP proposed rule under Option 1 of the co-proposal on foreign supplier verification activities discussed above.

Costs

This proposed FSVP rule does not require foreign suppliers to comply with U.S. food safety standards; if they are exporting to the United States, they are already required to do so under other rules and proposed rules (for example, FDA's proposed rules on produce safety and preventive controls for human food). Thus, those costs are accounted for in the regulatory impact analyses for those rules. This proposed FSVP rule requires importers that are not exempt from the FSVP rule to develop, maintain, and follow an FSVP that adequately describes the procedures the importers will use to comply with the proposed requirements. The FSVP rule requires the FSVP to contain certain elements. We estimate the cost of developing, maintaining, and following the proposed FSVP by considering the cost of each required element separately.

Personnel Requirements

The proposed FSVP rule requires that a qualified individual perform required activities. "Qualified individual" means a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart. This person may be, but is not required to be, an employee of the importer. A qualified individual includes, but is not limited to, a third-party auditor that has been accredited in accordance with section 808 of the FD&C Act (21 U.S.C. 384d)).

[3] There is no co-proposal associated with the Third-Party proposed rule.

We based our cost estimates of the required activity on qualified personnel performing that activity. Therefore, we did not estimate a separate cost for having qualified personnel perform that activity. However, there may be some costs associated with identifying, evaluating, and hiring qualified individuals in the case of importers who do not already employ qualified individuals. Most importers would not hire a permanent employee that is a qualified individual for the sole purpose of complying with the FSVP rule because it would be less expensive to hire a third party that specializes in foreign supplier verification and that already employs qualified individuals. We believe that competent third parties should not be difficult to find because of the availability of accredited third- party auditors. Therefore, we expect that the costs associated with identifying, evaluating, and hiring third parties will be minimal. To reflect this cost we assume that it would take an importer approximately 4 hours to accomplish this task.

The cost of the required amount of labor time depends on the type of personnel involved. In the analysis of the PC rule, we said that the personnel who would prepare PC hazard analyses of production facilities would probably be similar in pay grade to Production Managers in the food industry. We assume that a similar pay grade of employee would produce the required information and identify and evaluate hazards. To estimate this cost, we used the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent, from $40.96 to $61.44, to account for fringe benefits and overhead.

For many FSVP activities, an importer would need to have access to a qualified individual to perform that task. Therefore, we estimated this cost based on the total number of importers that are subject to these provisions in the FSVP rule. However, we assumed that all importers with more than 500 employees would already employ qualified individuals. For importers with 1 employee to 499 employees, we used a uniform distribution of 0 to 100 percent to represent the number of importers that already employ qualified individuals. Individuals that are accredited third-party auditors under the Third-Party proposed rule, when finalized, would be considered qualified individuals under the proposed FSVP rule. Importers who choose to use accredited third parties when they become available would still need to identify and hire a third party, but the costs associated with evaluating whether the third party is a qualified individual would be reduced. However, to the extent that additional costs are associated with third parties becoming accredited, the cost of the activity performed by the third parties may be somewhat

higher than estimated in the FSVP rule. We analyze the costs and benefits of the Third-Party proposed rule in Appendix B.

Importers that import DS only that are required to establish specifications for those imported DS under the DS CGMP regulations as specified in proposed § 1.511(a) would not need to hire qualified individuals. To identify these importers, we looked at the importers with high confidence D&B matches that imported DS products only and had NAICS codes corresponding to manufacturing and extrapolated the results to all importers.

Importers that import DS only and deal only with customers that are required to establish specifications for those imported DS under the DS CGMP regulations as specified in proposed § 1.511(b) would also not need to hire qualified individuals. We do not know the percentage of importers that import DS only that would meet this condition so we used a uniform distribution running from 0 to 1 to correct for this factor.

Importers importing food from a foreign supplier in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent are not subject to the qualified individual requirement (provided certain conditions and requirements are met) in the FSVP proposed rule. To date, FDA has officially recognized only one country (New Zealand) as having a food safety system comparable to that of the United States. However, we do not have sufficient information to make any corresponding adjustment to our analysis of qualified individual costs.

We assume that importers that hire third parties may want to periodically consider other third parties to perform these tasks. Therefore, we interpret these costs as annual costs.

Table 1: Hiring Qualified Individuals under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Number of Hours to Hire Third Party	4	4	4	4	
Cost per Hour	$61	$61	$61	$61	
Cost to Hire Third Party	$246	$246	$246	$246	
Importers Subject to Requirement to Hire Qualified Individuals	34,144	11,315	6,309	1,523	53,291
Percentage of Importers That Would Need to Hire Third Party	50%	50%	50%	0%	
Importers That Would Need to Hire Third Party	17,072	5,658	3,155	0	25,884
Annual Cost for Hiring Third Parties	$4,195,611	$1,390,406	$775,269	$0	$6,361,287

Review of Food and Supplier Compliance Status

The proposed FSVP rule requires importers to review and document the compliance status of the foreign supplier and the food to determine whether they are in compliance with the relevant U.S. food safety standards. Importers must continue to monitor and document the compliance status as long as they import the food from the foreign supplier. The proposed rule does not specify how frequently this must be done, but we assume that the monitoring will take the form of an annual review comparable in scope to the original review.

Conducting the required supplier compliance status reviews involves importers reviewing readily-available information to consider the compliance status of every foreign supplier and imported food, including whether they are the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the FD&C Act relating to the safety of the food. FDA warning letters and import alerts are available on the Agency's Web site, and we anticipate that any requirements for certification issued under section 801(q) would be made available there. All warning letters and import alerts are available on FDA's website at www.fda.gov.

The importers covered by the compliance status provisions are the same as those covered by the qualified individual provision. However, for these provisions, the number of food and supplier compliance status reviews per year depends on the number of suppliers associated with those importers. However, the number of suppliers is not the same across these importers because some of these importers import DS products that are sold to customers that are required to establish specifications for those imported DS under the DS CGMP regulations as specified in proposed § 1.511, which should be excluded. Therefore, we defined these groups and adjusted the number of suppliers for those groups accordingly. All calculations were based on the OASIS data on importers and combinations of importer and suppliers that we described earlier. Although the requirement is stated in terms of both suppliers and products we calculated costs on the basis of suppliers only because an importer would probably look for relevant documentation relating to a particular foreign supplier and then check to see if the information is relevant to the food they import from that supplier rather than conducting this activity separately for each supplier and each product from each supplier.

We do not know how much time an importer would need to conduct the required compliance status review for a given foreign supplier or imported food. To derive our estimates, we assume that an importer will need, on average, approximately 2 hours to conduct a review of a foreign supplier or imported food. We request comment on this estimate.

The cost of the required amount of labor time depends on the type of personnel involved. In the analysis of the PC rule, we said that the personnel who would prepare PC hazard analyses of production facilities would probably be similar in pay grade to Production Managers in the food industry. We assume that a similar pay grade of employee would produce the required information and identify and evaluate hazards. To estimate this cost, we used the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead such as benefits and other non-salary remuneration.

The cost in every year after the first year will depend on three factors: 1) some importers will exit the industry and others will enter, 2) the proposed FSVP rule requires existing importers to continue to monitor the required food and supplier compliance status review, and 3) existing importers will need to conduct entirely new compliance status reviews if they begin to deal with new foreign suppliers or import new products.

Existing importers will need to either continue to monitor compliance status for each imported product or conduct a new compliance status review if they begin to deal with new foreign suppliers or imported products (i.e., a new product from an existing supplier or a product from a new supplier). We do not know the cost of updating compliance status. However, importers would need to obtain roughly the same information for each update as they require for the initial review. Therefore, we assume that the annual cost of updating compliance status is approximately the same as the cost of conducting the original food and supplier compliance status review. We request comment on this assumption. This assumption obviates the need to estimate new entrants and existing importers using new suppliers for this activity. Instead we have based our cost estimate on all importers performing this activity for all their suppliers on a yearly basis. We have not attempted to estimate the change in the overall number of importers over time because of the considerable uncertainties involved. We present estimated costs for conducting the required food and supplier compliance status reviews in Table 2. In this table, we indicate the size of the importer in terms of employees along the top row and we indicate in the left-most column whether costs occur in the first year after the FSVP regulation comes into effect or every year after the first year. We provide information on significant inputs so that readers can follow our basic estimation calculations. In some cases in which a calculation uses the same inputs and follows the same pattern as a previous calculation, we provide only the results to save space.

Table 2. Estimated Cost for Reviewing Food and Supplier Compliance Status under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Number of Hours to Review Supplier Compliance Status	2	2	2	2	
Cost Per Hour	$61	$61	$61	$61	
Cost to Conduct Review	$123	$123	$123	$123	
Total Number of Reviews of Suppliers	155,051	72,726	38,010	8,962	274,749
Total Cost	$19,052,700	$8,936,617	$4,670,641	$1,101,248	$33,761,206

Information and Hazard Analysis Requirements

The proposed FSVP rule requires importers to determine and document the hazards, if any, that are reasonably likely to occur with any food they import, as well as the severity of the resulting illnesses or injuries if such hazards were to occur. The proposed FSVP rule also requires importers to gather certain types of information for this hazard analysis. Importers may attempt to satisfy this requirement by requesting that suppliers provide them with the required information. The required information is as follows: 1) the ingredients of the food, 2) the condition, function, and design of the foreign supplier's establishment and equipment, 3) transportation practices, 4) harvesting, raising, manufacturing, processing, and packing procedures, 5) packaging and labeling activities, 6) storage and distribution, 7) intended or reasonably foreseen use, 8) sanitation, including employee hygiene, and 9) any other relevant factors.

Producing the required information and evaluating hazards involves importers (or their agents) obtaining the information and evaluating hazards for every imported product, which we define as a unique combination of imported product and foreign supplier. We use this definition of an imported product because the same product from different foreign suppliers may be associated with different hazards, and different imported products from the same foreign supplier may also be associated with different hazards.

The following groups of importers that we have already discussed would not have costs under these provisions: importers that must establish DS specifications under DS CGMPs as specified in proposed § 1.511(a), importers that have only customers that must establish DS specifications under DS CGMPs as specified in proposed § 1.511(b), and importers importing food from only foreign suppliers in countries with officially recognized or equivalent food safety systems. In addition, importers that import DS other than those that we discussed previously (i.e., importers of "finished" DS) would also not need to undertake this activity.

Very small importers are also not subject to this provision. A very small importer is defined in the proposed FSVP rule to be an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. We based our estimate of

the number of very small importers on the number of importers with high confidence D&B matches that had annual sales data with sales in FY10 of $500,000 or less. We then extrapolated to the universe of importers.

Importers that import products only from very small suppliers would not need to conduct hazard analysis. Very small foreign supplier is defined in the proposed FSVP rule to be a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. We do not have information on the size characteristics of foreign suppliers. However, we estimated the number of such suppliers by using the size information on domestic suppliers that we used in the RIA of the PC rule and assuming that foreign suppliers would have similar size characteristics to domestic suppliers. Based on this approach, we estimated that 59 percent of foreign suppliers of non-RAC products and 93 percent of foreign suppliers of RAC products would qualify as very small suppliers.

We do not know how much time an importer would require to gather the required information and evaluate the hazards associated with a given imported product. However, we do not envision that importers would need to travel to foreign facilities to fulfill these requirements[4]. In the analysis of the PC rule, we estimated that it would take food manufacturing or processing facilities 24 to 48 hours to conduct an initial hazard analysis of their operations and of incoming raw materials and ingredients, which also involved gathering information and evaluating hazards. (Ref. 3 We do not know how the time required to produce the required information and evaluate the hazards for a given imported product would compare to the time required to produce a PC hazard analysis. Some considerations suggest that gathering the required information and evaluating hazards for a particular imported product should require less time than producing a PC hazard analysis of an entire production operation and of raw materials and ingredients; however, other considerations suggests that this might not be the case. On the one hand, producing the required information and evaluating the hazards for a particular imported product involves only one product while a hazard analysis for a food production

[4] We do not envision that importers would need to travel to foreign facilities to fulfill these requirements. Importers or suppliers would usually know the hazards associated with raw materials and ingredients. Where such hazards may be associated with the supplier's environment, the importer might request the supplier to fill out a questionnaire on their control programs for the hazard, or they might request a supplier to provide an audit report, as part of supplier approval.

operation and all relevant raw materials and ingredients may involve multiple products. In addition, an importer may obtain multiple products from a given foreign supplier, which suggests that in some cases an importer might be able to use some of the same general information relating to the hazard evaluation of one product for the hazard evaluations of other products from the same supplier. On the other hand, different products from the same foreign supplier may be handled differently or by different entities in earlier stages of the production cycle, which suggests that in some cases an importer might be able to use only a limited amount of the same general information relating to one product for other products from the same supplier. On average, an importer probably needs less time to produce the required information and identify and evaluate hazards for a particular imported product than a production facility requires to produce a hazard analysis of their production operations and of raw materials and ingredients, but it may nonetheless require a substantial amount of time. Based on this information, we estimate that it may take an importer 8 to 16 hours (mean of 12 hours) to produce the required information and evaluate the hazards associated with a given imported product. Products that are RACs would require less time than other products because importers would not need to consider microbiological hazards for RACs. We corrected for this factor by reducing the time estimate for RACs by 25 percent (mean of 9 hours). We request comments on these estimates.

Importers also have the option of identifying the hazards by reviewing and evaluating the hazard analyses conducted by their foreign suppliers, if they have any, and documenting any hazard identification they make based on this review and evaluation. The cost of identifying and evaluating hazards for importers that can utilize this option would be substantially below the cost for importers that cannot utilize this option because much of the required information and hazard evaluation should appear in the foreign supplier's hazard analysis. To reflect this consideration, we assume that the cost for importers that can utilize this option would be 10 percent of the cost for importers that cannot utilize this option, or about 1 to 2 hours (mean of 1.2 hours for non-RACs and 0.9 for RACs). The vast majority of foreign suppliers will have hazard evaluations because they are covered by one of the PC rules or other rules that require hazard evaluations or because they voluntarily conduct hazard evaluations. We assume that in most cases foreign suppliers would be willing to share existing hazard analyses with importers because foreign suppliers that did so would have a competitive advantage relative to foreign suppliers that did

not. Therefore, we assume that importers will be able to utilize this option for 90 percent to 100 percent of required information collections and hazard evaluations (mean of 95 percent).

The average cost of the required information and hazard evaluations per product and supplier combination for products other than RACs is therefore 95 percent x 12 hours times $61.44 per hour plus 5 percent x 1.2 hours x $61.44 per hour, which equals $107. Similarly, the average cost of the required information and hazard evaluations per product and supplier combination for products that are RACs is 95 percent x 0.9 hours x $61.44 per hour plus 5 percent x 9 hours x $61.44 per hour, which equals $80.

In order for importers to review and evaluate hazard analyses conducted by foreign suppliers, foreign suppliers would need to transmit copies of those documents to the importer or their representative. We assume that these documents would be available in electronic format and transmitting copies to importers would require very little time on the part of the foreign supplier. Therefore, we assume that foreign suppliers will need only 0.25 hours to transmit a copy of an existing hazard analysis to an importer.

Importers would need to produce the required information and evaluate hazards for each relevant imported product. The number of imported products varies widely among importers. To illustrate this point, we provide information on the distribution of the number of products per importer in Table 4. Although this table gives data for all importers rather than for each of the different size classes of importers as reported in Table 3, the pattern within each size category of importer is similar to the pattern for all importers. For example, in FY10 approximately 45 percent of importers of food dealt with only one combination of product and supplier (defined as the OASIS manufacturer) and approximately 86 percent dealt with ten or fewer product supplier combinations. However, a small number of importers appear to deal with a large number of product and supplier combinations every year. For example, in FY10 the 1 percent of importers with the highest number of product and supplier combinations dealt with 200 or more combinations in that fiscal year. Obviously, the costs associated with producing hazard evaluations for imported products will vary with the number of such products. We based our cost estimates on the entire distribution of the number of imported products per importer for each size class of importers and then reported the overall costs for each size class of importer. This procedure masks the difference in cost burden faced by different importers within a given size category because most of the importers in each size category will deal with only a few imported

products and will therefore face costs that are lower than the estimated average, while a few importers will deal with many more imported products than the average and will therefore face costs that are much higher than the average. However, this procedure should not affect estimated total costs for each size category unless there are truncation effects related to the maximum cost per importer, such as particular importers becoming no longer economically viable before the full estimated cost is reached. In the presence of these types of truncation effects, using the average number of imported products per importer will overstate the actual costs because some importers will go out of business and will therefore not face the full estimated compliance costs.[5]

The cost of the required amount of labor time depends on the type of personnel involved. In the analysis of the PC rule, we said that the personnel who would prepare PC hazard analyses of production facilities would probably be similar in pay grade to Production Managers in the food industry. We assume that a similar pay grade of employee would produce the required information and identify and evaluate hazards. To estimate this cost, we used the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 The personnel that would send and receive documentation of an onsite audit would probably be secretarial or administrative staff. To estimate this cost, we used the mean hourly wage for SOC 43-6014 Secretaries and Administrative Assistants, Except Legal, Medical, and Executive in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2) We increased wages by 50 percent, from $40.96 to $61.44, to account for overhead such as benefits and other non-salary remuneration. We used domestic wage rates for both domestic and foreign firms because we do not have sufficient information on foreign wage rates and because combining foreign wage rates and domestic wage rates raises valuation issues involving the relative value of wages, differences in costs of living, and so on.

The proposed requirement that importers produce the required information and evaluate hazards of imported products may change current business practices because it would prevent importers from importing products when they do not have access to the required information. Currently, a distributor might offer to supply imported food to an importer but not tell the importer the name or address of the foreign supplier. Under the proposed FSVP rule, the

[5] In order to address the issue of importers with unusually high costs going out of business we would need a more complicated analysis that worked with the distributions of products and suppliers rather than with a handful of defined size groups. Given the other data limitations and uncertainties, we did not feel it would be appropriate to attempt that type of analysis in this case.

importer would need to know the name and address of the foreign supplier for the food. A distributor might choose to provide the necessary information, but if it did not do so, the importer might need to obtain the food from a different distributor or supplier. In addition, if the distributor were a qualified individual whose services the importer had obtained to conduct the hazard analysis, then it would be permitted to produce the required information and evaluate hazards on the importer's behalf rather than providing a name and address to the importer. However, even in that case the importer would still need to know the contact information of the foreign supplier to satisfy the requirements to maintain a list of all of their foreign suppliers and to maintain a record of the compliance status assessment they did of the foreign supplier. We do not have sufficient information to estimate the costs associated with this change in practices. We request comment on these costs.

The cost in every year after the first year will depend on three factors: 1) some importers will exit the industry and others will enter, 2) the proposed FSVP rule requires existing importers to reanalyze the hazards promptly when they become aware of new information about potential hazards with the food or, if there's no such new info, every three years., and 3) existing importers will need to produce entirely new information and hazard evaluations if they begin to import new products.

Existing importers will need to either maintain existing information and hazard evaluations or prepare entirely new information and hazard evaluations if they begin to deal with new imported products (i.e., a new product from an existing supplier or a product from a new supplier). The large number of factors that might change throughout the supply chain of any given product suggests that importers may need to revisit the required information and hazard evaluations multiple times per year. We do not know the cost of maintaining the required information and hazard evaluations. As with the case of maintaining written procedures relating to these tasks, we assume that the annual cost of maintaining existing information and hazard evaluations is approximately 10 percent of the cost of producing the information, evaluations, and lists. We request comment on this assumption.

We estimated the percentage of importers that are new to the industry every year by using the OASIS data to count the number of importers that appeared in FY10 but not FY09 and then comparing that number to the total number of importers in FY10.

We do not have information on the percentage of imported products that were new to particular importers in FY10 or carried over from the previous year. However, we do know that 13 percent of the combinations of importers, suppliers, and a more general grouping of products (products by industry) were new in FY10 for existing importers. Therefore, we estimated costs for existing importers by setting the probability that any given imported product was new for any particular importer at between 13 and 100 percent. We request comments on this assumption.

We present estimated costs for producing the required information and evaluating hazards in Table 3. In Table 4, we then present additional information on one of the inputs to Table 3, the number of combinations of products and foreign suppliers per importer.

Table 3. Estimated Cost for Obtaining Required Information and Conducting Hazard Analyses under the FSVP Proposed Rule[6]

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Mean Number of Hours to Produce the Required Information and Evaluate Hazards From Scratch per Product and Supplier Combination For Products Other Than RACs	12	12	12	12	
Mean Number of Hours to Produce the Required Information and Evaluate Hazards From Scratch per Product and Supplier Combination For RACs	9	9	9	9	
Number of Hours to Transmit Existing Hazard Analysis	0.25	0.25	0.25	0.25	
Number of Hours if Importer Can Review Foreign Supplier's Hazard Analysis as Percentage of Number of Hours To Produce the Required Information and	10%	10%	10%	10%	

[6] These costs are estimated on an average basis across all affected importers.

Evaluate Hazards From Scratch					
Number of Hours to Produce the Required Information and Evaluate Hazards From Review and Evaluation of Foreign Supplier's Hazard Analysis For Products Other Than RACs	1.2	1.2	1.2	1.2	
Number of Hours to Produce the Required Information and Evaluate Hazards From Review and Evaluation of Foreign Supplier's Hazard Analysis For RACs	0.9	0.9	0.9	0.9	
Percentage of Required Information and Hazard Evaluations For Which Importer Can Review and Evaluate Foreign Supplier's Hazard Analysis, Midpoint	95%	95%	95%	95%	
Cost Per Hour – Importer	$61	$61	$61	$61	
Cost Per Hour – Supplier	$23	$23	$23	$23	
Cost to Produce the Required Information and Evaluate Hazards per Product and Supplier Combination For Products Other Than RACs	$107	$107	$107	$107	
Cost to Produce the Required Information and Evaluate Hazards per Product and Supplier Combination For RACs	$80	$80	$80	$80	
Average Cost to Process Documentation of an Onsite Audit For	$5	$5	$5	$5	

Transmission to Importer - Foreign Supplier					
Products That Are Not RACs	43,016	54,229	31,538	7,049	135,832
Products That Are RACs	16,378	22,889	9,844	1,516	50,626
Total Cost All Importers Subject To This Requirement	$5,911,757	$7,632,556	$4,160,925	$875,171	$18,580,408
Total Cost for Suppliers	$127,975	$369,344	$192,632	$43,128	$733,079
Total Cost for Importers and Suppliers	$6,039,731	$8,001,900	$4,353,557	$918,299	$19,313,487
Every Year After Year 1					
Percentage of New Importers Entering the Industry Every Year	54%	54%	54%	54%	
Percentage of Product and Supplier Combinations That Are New For Existing Importers Every Year, Midpoint of Range	57%	57%	57%	57%	
Cost to Maintain Existing Information and Hazard Evaluations as Percentage of Initial Cost to Produce	10%	10%	10%	10%	
Total Cost for Importers	$4,854,446	$6,112,087	$3,326,804	$696,373	$14,989,709
Total Cost for Suppliers	$102,661	$296,287	$154,529	$34,597	$588,074
Total Cost for Importers and Suppliers	$4,957,107	$6,408,374	$3,481,333	$730,970	$15,577,784

Table 4. Number of Combinations of Product and Suppliers Per Importer for All Importers under the FSVP Proposed Rule			
Number of Combinations of Products and Suppliers	**Number of Importers**	**Probability of Having Indicated Number of Combinations of Products and Suppliers**	**Cumulative Probability of Having Indicated Number of Combinations of Products and Suppliers or Fewer**
1	25,625	45.3%	45.3%
2	8,528	15.1%	60.3%
3	4,347	7.7%	68.0%
4	2,701	4.8%	72.8%
5	1,939	3.4%	76.2%
6	1,702	3.0%	79.2%
7	1,149	2.0%	81.2%
8	1,092	1.9%	83.2%
9	775	1.4%	84.5%
10	673	1.2%	85.7%
20	4,057	7.2%	92.9%
30	1,312	2.3%	95.2%
40	676	1.2%	96.4%
50	414	0.7%	97.1%
60	283	0.5%	97.6%
70	221	0.4%	98.0%
80	162	0.3%	98.3%
90	124	0.2%	98.5%
100	102	0.2%	98.7%
200	457	0.8%	99.5%
300	138	0.2%	99.8%
400	56	0.1%	99.9%
500	36	0.1%	99.9%
600	15	0.0%	99.9%
700	7	0.0%	100.0%
800	11	0.0%	100.0%
900	3	0.0%	100.0%
1,000	4	0.0%	100.0%
2,000	6	0.0%	100.0%
3,000	1	0.0%	100.0%
4,000	1	0.0%	100.0%

Verification Activities

In general, the proposed FSVP rule requires importers to conduct foreign supplier verification activities for each hazard associated with each imported product. In some cases, an

importer may be able to use a single verification activity to address multiple hazards in the same product or possibly in different products from the same foreign supplier. In other cases, each hazard in any given imported product may require a different verification activity such that an importer may need to use multiple verification activities to address the hazards associated with the product. For example, there might be two different microbiological hazards associated with a food, one of which is a hazard that is controlled directly by the foreign supplier and is likely to result in serious adverse health consequences or death to humans or animals (SAHCODHA), which would require onsite auditing for verification of control, and another which the foreign supplier verifies has been controlled by its own supplier by conducting sampling and testing. In still other cases, a single hazard in a given imported product may require multiple verification activities. For example, an importer of acidified pepper receiving the product from a foreign supplier that had experienced compliance problems because of inadequate pH controls, but that had instituted corrections to address the problem, should conclude that an annual audit to verify the adequacy of the pH controls would not provide sufficient assurances that the compliance problems did not reoccur, and that periodic pH testing of the pepper would also be appropriate until confidence in the supplier has been restored. An importer must conduct these supplier verification activities before initially importing a food from a foreign supplier and then periodically as specified for the various activities. The proposed verification requirements that pertain to DS importers that are not subject to the DS specification requirements in the DS CGMPs as specified in proposed § 1.511(a), and do not have customers that are subject to those DS specification requirements, would not apply on a per-hazard basis, as with other products, but on a per-product basis, because of how the DS CGMPs are written. Therefore, for these importers, we calculated costs on a per-product basis rather than a per-hazard basis.

If there are no hazards associated with an imported food, then the proposed FSVP rule would not require the importer to conduct any supplier verification activity.

In the case of a SAHCODHA hazard controlled by a foreign supplier at its establishment, the importer must conduct (and document) or obtain documentation of an initial onsite audit before importing the food. SAHCODHA hazards are those which for which a recall of a violative product posing such a hazard is designated as "Class 1" under 21 CFR 7.3(m)(1). Examples of hazards that, in some circumstances, historically have resulted in serious adverse health consequences or death to humans or animals include pathogens or their toxins in ready-to-

eat food. If such hazards are identified by the importer as hazards reasonably likely to occur in foods they receive from a foreign supplier, and the foreign supplier applies preventive controls to address those hazards, then onsite auditing must be conducted to verify that those controls have been properly applied.

If the foreign supplier has any written plans relating to complying with any applicable FDA food safety regulations, then the onsite audit must include a review of those plans and the foreign supplier's implementation of those plans for the hazard being audited. The protocols for audits conducted by accredited third-party auditors/certification bodies include requirements for records review and are described in proposed § 1.651 of the Third-Party proposed rule. An importer must then conduct or obtain documentation of an onsite audit of the foreign supplier at least annually or more frequently if necessary to adequately verify that the hazard is adequately controlled. Under § 1.6100 of the Third-Party proposed rule, an importer may use a regulatory audit report by an accredited third-party auditor/certification body in meeting any FSVP audit requirements.

In the case of SAHCODHA hazards not controlled by the foreign supplier and all non-SAHCODHA hazards, the importer must choose an appropriate verification activity or activities for each hazard from the proposed list of potential verification activities. In this case, the importer must determine and document which of the verification activities it finds to be appropriate for that hazard. The importer must also determine the frequency of the verification activities based on the risk associated with the food and must document that determination. The proposed list of verification activities is as follows:

• Conduct (and document) or obtain documentation of an onsite audit (such as a regulatory audit by an accredited third-party auditor/certification body). If the food at the foreign supplier is subject to one or more designated food safety regulations and the foreign supplier has any written plans relating to complying with these regulations, then the onsite audit must include a review of those plans and the foreign supplier's implementation of those plans for any hazard being audited. Under the Third-Party proposed rule, audits conducted by accredited third-party auditors/certification bodies include records review and onsite assessments of facilities, processes, and food to determine compliance with the FD&C Act.

• Conduct (and document) or obtain documentation (such as certificates of analysis containing the results of testing) from the foreign supplier of lot-by-lot or periodic sampling and testing for the hazard.

• Review (and document) or obtain documentation of a review of the foreign supplier's food safety monitoring records at a frequency based on the risk associated with the food.

• Any other appropriate method.

We were not able to analyze the option of using any other appropriate method. We discuss the costs and estimated frequency of the verification activities in the following sections.

Establishing and Maintaining Procedures

The proposed FSVP rule would require importers to establish and follow adequate written procedures for conducting foreign supplier verification activities. We present estimated costs of writing and maintaining procedures relating to verification activities in Table 5. This table follows a format similar to previous tables. We discuss these issues in more detail following the table.

Table 5. Estimated Cost for Writing and Maintaining Procedures Relating to Verification Requirements under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Year 1					
Procedures on Non-DS Hazards					
Number of Hour to Write Procedures on Non-DS Hazards	2	2	2	2	
Cost to Write Procedures	$123	$123	$123	$123	
Non-DS Products	59,228	77,005	41,318	8,552	186,103
Number of Hazards Per Imported Food Per Year	2	2	2	2	
Total Cost Non-DS Products	$14,555,932	$18,924,734	$10,154,410	$2,101,628	$45,736,704
Procedures on DS Products					

Number of Hours to Write Procedures on DS Products	2	2	2	2	
Cost to Write Procedures	$123	$123	$123	$123	
DS Products That Will Not Be Further Processed	1,223	1,059	508	108	2,898
Total Cost DS Products	$150,292	$130,084	$62,481	$13,223	$356,079
Total Cost of Procedures in Year 1	$14,706,224	$19,054,818	$10,216,891	$2,114,851	$46,092,783
Every Year After Year 1					
Percentage of New Importers Entering the Industry Every Year	54%	54%	54%	54%	
Percentage of New Products Per Existing Importer Per Year	57%	57%	57%	57%	
Procedures on Non-DS Hazards	$11,964,652	$15,555,711	$8,346,699	$1,727,491	$37,594,553
Procedures on DS Products	$123,537	$106,926	$51,358	$10,869	$292,689
Total Costs in Every Year After Year 1	$12,088,189	$15,662,637	$8,398,057	$1,738,360	$37,887,242

Establishing and maintaining the procedures that importers use to verify the hazard control activity of foreign suppliers of imported food involves writing standard operating procedures (SOPs) that give the steps importers intend to follow to accomplish these tasks. It would be prohibitively difficult for an importer to develop a general written document that would provide the verification procedures they would follow for every possible hazard in every food they might import because the verification activity will vary at least with the food and the supplier of that food. Therefore, most importers will probably develop written verification procedures as needed based on the hazards in the particular imported products they are currently importing or intending to import.

The importers that would be required to undertake activity under this provision are the same as those we discussed in the context of the provision dealing with hazard analyses with the addition of DS importers that are not subject to the DS specification requirements in DS CGMP as specified in proposed § 1.511(a) and that do not have customers that are subject to those DS specification requirements.

We estimated the number of products using the OASIS and D&B data that we discussed at the beginning of the analysis. We attempted to correct for various factors such as DS status, VSS, RAC (farms), and so on by estimating the number of such importers and applying modified estimates of the products and suppliers for those subgroups.

The cost of developing written verification procedures per importer would depend largely on the number of imported foods that an importer deals with and the number of hazards associated with each of those imported foods. For purposes of this analysis, we define a hazard as a hazard that is relevant to the proposed FSVP rule, that is, a hazard that is reasonably like to occur, which we propose to define as a hazard for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls. Most imported food will have at least one physical, biological, chemical, or radiological hazard that would require control during some stage of its production and distribution process. Many imported foods will have multiple hazards. However, a number of imported foods will have no hazards. We do not have information on the number of hazards associated with every imported food. However, FDA experts believe the average number of hazards per food is probably in the range of 1 to 3 hazards per food. We estimate the cost of writing and maintaining verification procedures for each hazard in each imported food in the same manner that we estimated costs for writing and maintaining procedures relating to the other elements of the FSVP.

The number of hours that importers require to write procedures relating to the verification activity for a particular hazard would be significantly less than the 6 to 8 hours we estimated that importers would require to write general procedures on gathering the required information and evaluating hazards. In many cases, the verification procedures for one hazard will be very similar to the verification procedures for another hazard. To reflect this consideration, we

assume that importers will require an average of 2 hours to write procedures on the verification activities relating to a particular hazard. We request comment on this assumption.

The type of personnel that would write procedures relating to verification activities for particular non-DS hazards and DS products would probably be the same as the type of personnel that would write procedures on gathering the required information and evaluating hazards for non-DS hazards. Therefore, we use the same per-hour cost that we used previously for writing procedures relating to the information and hazard evaluation requirements.

Following Procedures

Following written procedures relating to verification activities involves following the procedures for these tasks for every hazard in every imported product. In this section, we first discuss the basic cost of the various verification activities that importers may need to conduct or obtain documentation on because of this proposed FSVP rule. We then combine the basic cost estimates with other inputs to estimate the verification costs that would be generated by this proposed FSVP rule.

We have not estimated the cost for an importer to document that it has established and is following procedures that adequately control hazards that it controls itself because most importers that would control hazards themselves would be food manufacturers or processers that would be subject to the PC rule and would incur such costs under that rule.

Cost of Maintaining a List of Foreign Suppliers

The proposed FSVP rule would require importers to maintain a written list of their foreign suppliers. We present costs for maintaining a written list of suppliers in Table 6. We discuss the inputs following the table.

Table 6. Estimated Cost for Maintaining List of Suppliers under the FSVP Proposed Rule	
Hours to Maintain Lists of Suppliers Per Importer, Midpoint	1.5
Cost Per Hour	$61
Cost to Maintain Lists of Suppliers Per Importer, Average	$92

An importer maintaining a list of foreign suppliers would involve an importer keeping an authoritative and up-to-date list of its foreign suppliers.

We do not know how much time an importer would require to maintain a list of foreign suppliers. However, the cost should be minimal because importers would already know their suppliers and would simply need to organize that information in a list and then update the list as necessary, by adding new suppliers and removing suppliers the importer no longer uses. In the regulatory impact analysis of the PC proposed rule, we estimated it would take production facilities 1 to 2 hours to maintain a list of suppliers. (Although the PC proposed rule does not include codified provisions on supplier verification, it requests comment on whether there should be supplier verification requirements and, if so, what these requirements should address. The RIA for the proposed rule includes an analysis of an alternative proposal what would include supplier verification provisions. We are referring to this alternative analysis when we reference parts of the PC analysis that involve supplier verification.) We assume importers would require a similar amount of time to maintain a list of their suppliers.

The cost of this amount of labor time depends on the type of personnel involved. The personnel that would keep a list of suppliers would probably be senior personnel at a pay level similar to that of a manager in the food manufacturing industry. To estimate this cost, we used the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

Cost of Determining and Documenting the Appropriate Risk-Based Supplier Verification Activities

We present the estimated cost of determining and documenting appropriate supplier verification activities for each food in Table 7. We discuss the inputs following the table.

Table 7. Estimated Cost of Determining and Documenting the Appropriate Supplier Verification Activity under the FSVP Proposed Rule	
Non-DS Products	
Hours to Determine and Document Appropriate Supplier Verification Activity Per Hazard, Midpoint	0.75
Cost Per Hour	$61
Cost Per Hazard	$46
DS Products That Will Not Be Processed Further	
Hours to Determine and Document Appropriate Supplier Verification Activity Per Product, Midpoint	2.5
Cost Per Hour	$61
Cost Per Product	$154

In the case of non-DS imported food, an importer determining and documenting the appropriate risk-based supplier verification activities for each food it imports involves an importer using the required information and hazard evaluation first to determine and document which entity adequately controls the hazard or hazards that exist in food they import. If any of those entities is a foreign supplier, the importer must then determine and document whether the foreign supplier controls that hazard at its establishment and whether the hazard is a SAHCODHA hazard. If both apply, then the importer must determine the frequency of the audits that are required to adequately verify control of the hazard. In addition, the importer must determine if onsite audits are sufficient to provide adequate assurances that that hazard is adequately controlled or whether it is necessary for the importer to conduct one or more additional verification activities for that particular hazard. If additional verification activities are required for that hazard, the importer must determine and document the appropriate verification activity. For all other hazards, the importer must determine and document which of the available verification options are appropriate for that hazard and the appropriate frequency of any verification activities based on the risk associated with that hazard.

In the case of imported DS products that will not be processed further, an importer determining and documenting the appropriate risk-based supplier verification activities for each food it imports involves an importer using relevant information to determine and document which of the available verification options are appropriate for that product and the appropriate frequency of any verification activities.

We do not know how much time an importer would require to determine and document the appropriate supplier verification activity for each hazard in each food it imports. However,

in the case of non-DS imported food, the cost should be modest because importers will already have much of the information they need to make this determination in the required information and hazard evaluations. Therefore, we assume that it will take importers of these products an additional 0.5 to 1 hour per hazard to determine the appropriate supplier verification activity or activities for that hazard. In the case of imported DS products that will not be processed further, the cost may be somewhat higher because these products are not subject to the proposed information and hazard evaluation requirements, so importers of these products may need to generate or obtain information on which to make a determination of the appropriate verification activity and the frequency of that activity. Therefore, we assume that it will take importers of these products 2 to 3 hours per product to determine the appropriate supplier verification activity or activities for that product.

The cost of this amount of labor time depends on the type of personnel involved. The personnel that would make and document the determination of the appropriate supplier verification activity would probably be senior personnel at a pay level similar to that of a manager in the food manufacturing industry. To estimate this cost, we used the mean hourly wage for Standard Occupations Classification (SOC) 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

Cost of Conducting (and Documenting) Onsite Audit or Obtaining Documentation of Onsite Audit

We present the estimated cost of conducting (and documenting) onsite audits or obtaining documentation of onsite audits under the FSVP proposed rule in Table 8. In this case, we calculated the cost of an onsite audit and the cost for importers and foreign suppliers if the importer obtains documentation of an onsite audit from a foreign supplier. Again, we have not estimated the incidence of this cost. Depending on market conditions, foreign suppliers may be able to pass the costs of their activity to importers, while importers may be able to pass the costs of their activity to their foreign suppliers or to their customers. To simplify the analysis, one may consider all costs to be ultimately borne by importers. The same consideration holds for the other verification activities. We discuss these issues in more detail after the table.

Some in the food industry already rely on third-party auditors to accomplish verification of food safety controls and we expect that they will continue to do so. However, we also recognize that currently there is considerable variance in the quality of auditing services and the nature of audit criteria. Section 307 of FSMA (adding section 808 of the FD&C Act) requires FDA to establish a third-party accreditation system that will help ensure that these third parties provide high-quality auditing services. FSMA directs FDA to establish this third-party accreditation system and develop model accreditation standards. The Third-Party proposed rule is analyzed in this PRIA. We are publishing the Third-Party proposed rule on the same date we are publishing the proposed FSVP regulations. Although the proposed FSVP regulations would not require use of accredited third-party auditors, we expect that adoption of the FSVP regulations will increase the demand among importers and foreign suppliers for the services of accredited third-party auditors once FDA's accreditation system is in place. Rather than have each importer request individual audits of their suppliers, we anticipate that the system ultimately will evolve into one in which the foreign supplier obtains an audit by an accredited third party that will be acceptable to, and used by, most of its customers. We expect that such a system will be more efficient because it will leverage the resources of importers and suppliers. In Appendix B we show our estimates of the costs of establishing and using the proposed accredited third-party system required by section 307 of FSMA. In Appendix B we have also estimated the number of importers that might choose to use accredited third parties to conduct onsite audits of their foreign suppliers given the potential differences in private costs and benefits. We discuss the impacts of the third-party accreditation proposed rule in Appendix B and in the text of this analysis between tables 12 and 13.

Table 8. Estimated Cost of Conducting (and Documenting) Onsite Audit or Obtaining Documentation of Onsite Audit under the FSVP Proposed Rule	
Cost of Audit by Unaccredited Auditor	$2,700
Cost of Audit by Accredited Auditor	$3,600
Foreign Suppliers Currently Conducting Audits Using Accredited Auditors	13%
Foreign Suppliers Currently Conducting Audits Using Unaccredited Auditors, Estimate	50%
Foreign Suppliers Conducting Audits Using Accredited Auditors, Weight For Purposes Of Estimating Average Current Cost Of Audit	21%
Foreign Supplier Conducting Audits Using Unaccredited Auditors, Weight For Purposes Of Estimating Average Current Cost Of Audit	79%
Cost of Onsite Audit Excluding Travel Expenses, Weighted Average	$2,886
Travel Expenses per Onsite Audit	$625
Cost Per Onsite Audit, Total	$3,511
Hours to Process Documentation of an Onsite Audit From Foreign Supplier – Importer	0.25
Hours to Process Documentation of an Onsite Audit For Transmission to Importer - Foreign Supplier	0.25
Cost Per Hour	$23
Cost to Process Documentation of an Onsite Audit – Importer	$6
Cost to Process Documentation of an Onsite Audit - Foreign Supplier	$6

An importer conducting (and documenting) an onsite audit involves an importer, or a qualified, independent third party hired by the importer, visiting a foreign supplier and investigating its hazard control plans and implementation of those plans as they relate to the hazards identified as reasonably likely to occur. Obtaining documentation of an onsite audit from a foreign supplier if the foreign supplier conducts an onsite audit because of the FSVP rule or has already done an onsite audit involves the foreign supplier preparing the required documentation and sending it to the importer and the importer receiving and processing that documentation. A foreign supplier conducting an onsite audit involves a foreign supplier hiring a qualified, independent third party to conduct an audit on its behalf. A foreign supplier using an accredited third-party auditor/certification body under the Third-Party proposed rule could use a regulatory audit for FSVP purposes. A foreign supplier may not conduct an onsite audit of itself (for purposes of an importer meeting its supplier verification requirements under the FSVP regulations).

In the analysis of the third party accreditation rule (Appendix B) we estimate that the average cost of conducting onsite audits of suppliers is between $2,700 for audits by unaccredited auditors and $3,600 for audits by auditors that are currently accredited under other

programs. That analysis found that 13 percent of foreign suppliers are currently being audited by accredited auditors. We do not have information on the percentage of foreign suppliers that are currently being audited by unaccredited auditors. However, that percentage is probably at least as high as the percentage (13 percent) currently being audited by accredited auditors and may be as high as all of the remaining foreign suppliers (87 percent) after accounting for suppliers currently being audited by accredited auditors, which implies a mean value of 50 percent. We used that information to construct a weighted average cost for audits in general by comparing the percentages estimated above for accredited and non-accredited audits but setting the total percentage to 100 percent so that we are considering the fraction of those importers having audits of some type that have either accredited audits rather than the percentage of all importers. The implied weights are 21 percent and 79 percent. When we applied these weights to the cost of accredited and non-accredited audits we obtained a weighted average cost of $2,886. In addition, in the analysis of the PC rule we estimated an average travel and incidental expenses per audit of between $250 and $1,000. We included the same range of travel costs for onsite audits conducted by importers as by foreign suppliers because importers could hire qualified, independent third parties in the country in which a foreign supplier is located, while a foreign supplier could hire qualified, independent third parties based in other countries.

If the foreign supplier conducts an onsite audit because of this rule or has already conducted an onsite audit, then the importer would have a small cost for receiving and processing the documentation of the onsite audit from the foreign supplier and the foreign supplier would have a small cost for preparing and transmitting the documentation to the importer. We do not know how long it would take to send or receive and process documentation of an onsite audit. However, the cost is probably minimal. We base our cost estimates on a cost of 0.25 hours per transmission for both the importer and the foreign supplier.

The cost of this amount of labor time depends on the type of personnel involved. The personnel that would send and receive documentation of an onsite audit would probably be secretarial or administrative staff. To estimate this cost, we used the mean hourly wage for SOC 43-6014 Secretaries and Administrative Assistants, Except Legal, Medical, and Executive in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

Cost of Conducting (and Documenting) or Obtaining Documentation of Lot-by-Lot or Periodic Sampling and Testing

We present the estimated cost of conducting (and documenting) or obtaining documentation of lot-by-lot or periodic sampling and testing as it relates to a particular hazard in Table 9. In this case, we have calculated the cost for sampling and testing based on whether the importer or the foreign supplier is conducting the sampling and testing and the cost for importers and foreign suppliers if the importer obtains documentation of sampling and testing from a foreign supplier. We present costs on a per product rather than a per hazard basis because we calculate costs based on sampling and testing a product for all relevant hazards in that product. We discuss these issues in more detail after the table.

Table 9. Estimated Cost of Conducting (and Documenting) or Obtaining Documentation of Lot-by-Lot or Periodic Sampling Testing under the FSVP Proposed Rule	
Testing Cost Per Product Per Year	$1,362
Hours to Process Documentation of Sampling and Testing – Importer	0.25
Hours to Process Documentation of Sampling and Testing - Foreign Supplier	0.25
Cost Per Hour	$23
Cost to Process Documentation of Sampling and Testing – Importer	$6
Cost to Process Documentation of Sampling and Testing - Foreign Supplier	$6

An importer conducting (and documenting) lot-by-lot or periodic testing involves an importer sampling and testing imported products for relevant hazards. Obtaining documentation of sampling and testing from a foreign supplier if the foreign supplier conducts sampling and testing because of this rule or already conducts sampling and testing involves the foreign supplier preparing the required documentation and sending it to the importer and the importer receiving and processing that documentation.

Although not required in the proposed PC Rule, in the analysis of the PC rule we estimated that the average cost of sampling and testing per year for incoming potentially hazardous raw materials is $1,362. We assume testing costs for an importer that conducted only this verification activity would be roughly similar.

In the analysis of the PC rule we also included a cost for production facilities to hold potentially hazardous raw materials or ingredients an average of three days pending test results. We have not included a comparable product holding cost for importers because many importers that are required to conduct sampling and testing may import finished products and the cost of holding finished products is probably much less than the cost of holding raw materials and ingredients, which may delay production. The cost for a retailer to hold a finished product pending test results would be a 3-day reduction in the remaining shelf life for that product. In most cases this cost is probably minimal given the overall shelf life of finished products. We do not have sufficient information to incorporate this cost.

As with the case of onsite audits, we estimate costs for both the scenario in which an importer does the sampling and testing itself and the scenario in which an importer chooses this verification activity but the actual sampling and testing is carried out by the foreign supplier rather than the importer. We use the same general cost elements and procedures that we used to estimate the cost of onsite audits to estimate the costs if the foreign supplier carries out the sampling and testing rather than the importer.

Cost of Conducting (and Documenting) or Obtaining Documentation of a Review of the Foreign Supplier's Food Safety Records

We present the estimated cost of conducting (and documenting) or obtaining documentation of a review of a foreign supplier's food safety records as they relate to a particular hazard in Table 10. In this case, we have calculated the cost of a review and the cost for importers and foreign suppliers if the importer obtains documentation of a review from a foreign supplier. We discuss these issues in more detail after the table.

Table 10. Estimated Cost of Conducting (and Documenting) or Obtaining Documentation of Review of Food Safety Records under the FSVP Proposed Rule	
Hours Per Foreign Supplier Per Importer Per Year	8
Cost Per Hour	$61
Cost Per Foreign Supplier Per Importer Per Year	$461
Hours to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year – Importer	0.25
Hours to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year - Foreign Supplier	0.25
Cost Per Hour	$23
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year – Importer	$6
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year - Foreign Supplier	$6

An importer reviewing a foreign supplier's food safety records would involve an importer reviewing various food safety records provided by the foreign supplier that relate to a particular hazard. Obtaining documentation of a review from a foreign supplier if the foreign supplier conducts a review because of this rule or already conducts such reviews involves the foreign supplier preparing the required documentation and sending it to the importer and the importer receiving and processing that documentation.

We do not know how long it would take an importer or foreign supplier to review food safety records relating to a particular hazard. In the analysis of the PC rule, we estimated that a production facility would require 15 to 60 minutes per month to review food safety records for verification purposes, based on the size of the production facility. The time an importer or foreign supplier requires to review food safety records would probably be similar to the time a production facility requires to review food safety records. We do not know the size of foreign supplier, so we estimate this cost using a uniform distribution running from 0.25 to 1 hour per month per supplier. Multiplying this range by 12 months in a year gives a mean value of approximately 8 hours per year.

The cost of this amount of labor time depends on the type of personnel involved. In the analysis of the PC rule, we estimated the cost of reviewing process control verification records using the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead. We assume similar personnel would review foreign supplier food safety records.

Number of Verification Activities

In the previous sections we presented the estimated basic costs of the various potential verification activities. In this section we develop our estimate of the verification costs generated by this rule using the basic costs of the potential verification activities as inputs. Other inputs include the number of importers subject to the various requirements and the probability that an importer would determine that particular verification activities are appropriate

We present the results in a series of tables beginning with Table 11. We discuss the tables in more detail following the tables. Table 11 presents results relating to the requirements that involve maintaining lists of suppliers and determining and documenting the appropriate risk-based supplier verification activities.

Table 11. Estimated Cost of Maintaining Lists of Suppliers and Determining and Documenting Appropriate Hazard-Based Verification Activities under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Requirement to Maintain Lists of Suppliers					
Cost of Maintaining List of Suppliers Per Importer Per Year	$92	$92	$92	$92	
Number of Importers	36,617	11,936	6,634	1,613	56,800
Total Cost	$3,374,607	$1,100,013	$611,388	$148,679	$5,234,688
Requirement to Determine and Document the Appropriate Hazard-Based Supplier Verification Activities					
Non-DS Products					

Cost Per Hazard	$46	$46	$46	$46	
Number of Products	59,228	77,005	41,318	8,552	186,103
Number of Hazards Per Imported Food Per Year	2	2	2	2	
Total Cost Non-DS Products	$5,458,474	$7,096,775	$3,807,904	$788,110	$17,151,264
DS Products That Will Not Be Further Processed					
Cost Per Product	$154	$154	$154	$154	
Number of Products	1,223	1,059	508	108	2,898
Total Cost DS Products That Will Not Be Further Processed	$187,865	$162,605	$78,101	$16,529	$445,099
Total Cost DS and Non-DS Products	$5,646,339	$7,259,380	$3,886,005	$804,639	$17,596,363
Grand Total	$9,020,947	$8,359,393	$4,497,393	$953,318	$22,831,051

The proposed requirements to maintain lists of suppliers and to determine and document the appropriate verification activity or activities among those presented in the FSVP proposed rule applies to those importers that we previously identified as being required to establish and maintain written procedures on those tasks. We calculated the basic cost of maintaining lists of suppliers on a per importer per year basis. Therefore, we multiplied the estimated basic cost by the number of relevant importers. We calculated the basic cost of determining and documenting the appropriate verification activity or activities on a per hazard basis for non-DS products and on a per-product basis for DS products that will not be further processed. Therefore, we multiplied the estimated basic cost for each type of product by either the total number of hazards or the total number of products. In both cases, we adjusted the number of products to remove DS for further processing because most of those products would be not be subject to these verification requirements.

Table 12 presents results relating to the mandatory onsite audit requirement that involves non-DS hazards controlled by an importer's foreign supplier at its establishment and there is a reasonable probability that exposure to the hazards will result in serious adverse health consequences or death to humans or animals, which we refer to in the tables as a SAHCODHA hazard.

Table 12. Estimated Cost of Conducting (And Documenting) Or Obtaining Documentation Of Mandatory Onsite Audits under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Of Onsite Audit If Foreign Supplier Conducts Onsite Audit Because of This Rule - Foreign Supplier	$3,511	$3,511	$3,511	$3,511	
Cost to Process Documentation of an Onsite Audit - Foreign Supplier	$6	$6	$6	$6	
Cost to Process Documentation of an Onsite Audit – Importer	$6	$6	$6	$6	
Cost Of Conducting Onsite Audits					
Total Number of Finished Products	55,246	69,080	37,459	8,090	169,875
Relevant Raw Materials or Ingredients	31,376	43,796	23,573	4,718	103,463
Number of Hazards Per Imported Food Per Year	2	2	2	2	
Percentage of Hazards in Raw Materials or Ingredients Controlled by	33%	33%	33%	33%	

Foreign Supplier					
Total Number of Hazards in Imported Finished Products and Raw Materials Controlled by Supplier	131,006	166,795	90,331	19,264	407,395
Percentage of Relevant Hazards that are SAHCODHA Hazards	25%	25%	25%	25%	
Number of Hazards That Would Trigger This Requirement	32,751	41,699	22,583	4,816	101,849
Percentage of Affected Foreign Suppliers Already Conducting Audits	82%	82%	82%	82%	
Number of Audits, Corrected for Foreign Suppliers Already Performing Audits	6,059	7,714	4,178	891	18,842
Alternate - Number of Foreign Suppliers					
Number of Foreign Suppliers Doing Audits If Triggering Hazards Lumped Together	2,560	3,260	1,765	376	7,962
Number of Foreign Suppliers Doing	11,697	14,892	8,065	1,720	36,375

Audits If Triggering Hazards Spread Out					
Number of Foreign Suppliers Doing Audits, Range	7,129	9,076	4,915	1,048	22,168
Average Number of Importers per Foreign Supplier	2.8	2.8	2.8	2.8	
Probability That An Audit Not Accepted By Other Importers Given Third Party, Preventive Controls, and Produce Regulations	25%	25%	25%	25%	
Percentage of Affected Foreign Suppliers Already Conducting Audits	82%	82%	82%	82%	
Total Number of Audits	1,912	2,435	1,319	281	5,947
Cost of Onsite Audits - Foreign Suppliers (Total number of audits * Cost of conducting onsite audits)	$6,713,362	$8,547,388	$4,628,977	$987,196	$20,876,923
Cost of Transmitting Documentation of Onsite Audits					
Average Number of Importers Per Foreign Supplier	2.8	2.8	2.8	2.8	

Number of Transmissions of Onsite Audits	3,693	4,701	2,546	543	11,483
Cost of Transmitting Documentation of Onsite Audits - Foreign Suppliers	$20,896	$26,604	$14,408	$3,073	$64,980
Cost of Transmitting Documentation of Onsite Audits – Importers	$20,896	$26,604	$14,408	$3,073	$64,980
Total Costs					
Total Cost Foreign Suppliers	$6,734,258	$8,573,992	$4,643,385	$990,269	$20,941,903
Total Cost Importers	$20,896	$26,604	$14,408	$3,073	$64,980
Total Cost Foreign Suppliers and Importers	$6,755,153	$8,600,596	$4,657,793	$993,341	$21,006,883

Very small importers would not be subject to the requirement to conduct onsite auditing when the hazard is a SAHCODHA hazard that is controlled by the foreign supplier. Importers that import products only from very small suppliers would not need to undertake any activity under this provision. Importers that import DS only would not need to undertake any activity under this provision. Importers importing food from a foreign supplier in a country with an officially recognized or equivalent foreign food safety system would not be subject to this provision.

We estimated the number of hazards that would trigger this requirement in finished products by taking the total number of hazards in imported finished products and then adjusting that number to address hazards controlled by the supplier at its establishment and hazards that are SAHCODHA hazards. We assumed that suppliers would be controlling all hazards in finished products and we expressed the probability that such hazards are SAHCODHA hazards using a uniform distribution of 0 to 50 percent.

We estimated the number of hazards that would trigger this requirement in raw materials and ingredients using information on the Standard Industrial Classification (SIC) codes identified in the regulatory impact analysis of the proposed rule on preventive controls for human food as the SIC codes most likely to be associated with the control of hazards at the supplier level rather than the final product manufacturer level. We were unable to use the SIC information directly because we do not have information relating imported goods to SIC codes. However, we do have OASIS Industry Descriptions and a count of the entries, import lines, and value of goods imported under those Industry Descriptions. To construct our estimate we identified the OASIS Industry Descriptions that we thought might involve raw materials and ingredients, cross referenced those industries with the SIC codes for industries where hazards are most likely to be controlled at the supplier level, and then calculated the percentage of entries, lines, and value of goods of the raw materials and ingredients that were associated with those SIC codes. As we did for finished products, we expressed the probability that such hazards are SAHCODHA hazards using a uniform distribution of 0 to 50 percent.

We used the same information on the percentage of foreign suppliers already conducting audits that we mentioned previously. It is possible that the importers subject to this requirement are more likely to already be performing audits than the average importer because of the presence of SAHCODHA hazards. To capture this possibility we estimated the percentage of affected foreign suppliers that are already performing audits using a range with one end set at these importers having the same probability of already performing audits as any other importer and other end set to as much overlap as possible between the importers that would need to perform audits under this requirement and the importers that are already performing audits.

We assume that the foreign supplier would obtain any necessary onsite audits (instead of the importer conducting the audit) in this case because of the potential gains from trade if the foreign supplier obtains the audits. One foreign supplier may deal with multiple importers. Therefore, if a foreign supplier obtains an onsite audit, then it can distribute the documentation of that onsite audit to multiple importers. In contrast, if an importer conducts an onsite audit of a foreign supplier and does not share the documentation of that audit with the foreign supplier, then another importer dealing with that same foreign supplier would need to conduct its own audit. Therefore, many foreign suppliers will be able to defray the costs of an audit across multiple importers, which will give their products a cost advantage relative to those of foreign

suppliers that require importers to conduct their own audits. Based on this consideration, we calculated the number of onsite audits based on the total number of foreign suppliers working with the importers subject to this requirement. However, again, the foreign supplier may or may not be able to pass on the cost of this activity to the importer.

To account for the fact that an onsite audit performed at the request of a foreign supplier may address a number of hazards that would trigger this requirement, we calculated the range of foreign suppliers with products that might be associated with the number of hazards we just calculated. We estimated the range of foreign suppliers with products associated with those hazards by taking a range with the minimum number of suppliers set at the number of food hazards divided by the average number of food hazards per supplier (so that the food hazards are concentrated with certain suppliers) and the maximum number of suppliers set at the number of food hazards divided by the average number of importers per supplier (so that the food hazards are distributed across as many suppliers as possible subject to the assumption that all importers working with a given supplier are importing the same products).

We estimated the number of audits that each supplier would perform based on the following: we began with one audit per supplier and added the average number of importers per supplier. We then subtracted one for the importer associated with the initial audit. We multiplied this total by our estimate of the probability that those other importers will not accept the first audit. We estimated the probability that other importers will not accept the first audit using a range of 0 percent to 50 percent. We expect the probability to fall into this range because the Third-Party proposed rule will provide a voluntary mechanism for accrediting third-party auditors/certification bodies. This is a benefit of the proposed Third-Party rule analyzed in Appendix B.

Table 13 presents results relating to relevant hazards associated with a potential secondary verification activity in which that secondary activity is conducting (and documenting) or obtaining documentation of lot-by-lot or periodic testing.

The FSVP rule also proposes that, for some of these hazards that trigger onsite audits, importers may also need to conduct one or more additional verification activities to provide adequate assurances that the hazard is adequately controlled. For other hazards that trigger onsite audits, we do not know how many additional verification activities beyond the onsite audit would be required for hazards that would trigger the onsite audit requirement. Therefore, we

base our cost estimate on the assumption that these hazards would require at most one additional verification activity from the two other verification activities presented in the proposed rule, which are as follows: 1) Conduct (and document) or obtain documentation (such as certificates of analysis containing the results of testing) from the foreign supplier of lot-by-lot or periodic sampling and testing for the hazard; and 2) review (and document) or obtain documentation of a review of the foreign supplier's food safety records at a frequency based on the risk associated with the food. We are unable to analyze the costs associated with the remaining alternative, which is to conduct any other appropriate verification activity.

We do not know the probability that a relevant hazard would require a second verification activity. However, because this would only be triggered in certain limited circumstances, such as when a firm has had compliance issues, the probability is most likely low, in the range of 5 percent to 20 percent. Therefore, we express the probability that a relevant hazard would require a second verification activity with a uniform distribution running from 5 percent to 20 percent. We also do not know the probability that the additional verification activity required would be any particular verification activity. Therefore, we assume that if a hazard requires an additional verification activity, then it has an equal probability of requiring either of the two listed additional verification activities.

Table 13. Estimated Cost of Conducting Secondary Verification Activity: Conducting (And Documenting) Or Obtaining Documentation Of Lot-by-Lot or Periodic Testing under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost of Sampling and Testing - Foreign Supplier	$1,362	$1,362	$1,362	$1,362	
Cost to Process Documentation of Sampling and Testing Per Product - Foreign Supplier	$6	$6	$6	$6	
Cost to Process Documentation of Sampling and Testing Per Product- Importer	$6	$6	$6	$6	
Cost of Conducting Sampling And Testing					
Hazards That Would					

Trigger Requirement					
Number of Hazards That Would Trigger Onsite Audit Requirements	32,751	41,699	22,583	4,816	101,849
Percentage of Relevant Hazards That Require An Additional Verification Activity, Midpoint	13%	13%	13%	13%	
Number of Hazards That Require Additional Verification Activity	4,094	5,212	2,823	602	12,731
Probability That Appropriate Additional Verification Activity Is Sampling And Testing	50%	50%	50%	50%	
Number of Hazards Requiring Sampling and Testing	2,047	2,606	1,411	301	6,366
Alternate - Number of Products					
Maximum Number of Products Requiring Sampling and Testing Based on One Hazard Per Product	2,047	2,606	1,411	301	6,366
Average Hazards Per Product	2	2	2	2	
Minimum Number of Products Based on Average Hazards Per Product	1,023	1,303	706	151	3,183
Number of Products Requiring Sampling and Testing	1,535	1,955	1,059	226	4,774
Cost of Sampling and Testing - Foreign Supplier	$2,090,972	$2,662,205	$1,441,760	$307,476	$6,502,413
Cost of Transmitting Documentation of Sampling and Testing					
Average Number of Importers Per	2.8	2.8	2.8	2.8	

Supplier					
Implied Number of Suppliers	4,299	5,473	2,964	632	13,368
Cost to Process Documentation of Sampling and Testing - Foreign Supplier	$24,325	$30,970	$16,772	$3,577	$75,644
Cost to Process Documentation of Sampling and Testing – Importer	$24,325	$30,970	$16,772	$3,577	$75,644
Total Costs					
Total Cost Foreign Suppliers	$2,115,297	$2,693,175	$1,458,533	$311,053	$6,578,057
Total Cost Importers	$24,325	$30,970	$16,772	$3,577	$75,644
Total Cost Foreign Suppliers and Importers	$2,139,621	$2,724,145	$1,475,305	$314,630	$6,653,702

The relevant cost is the cost of the foreign supplier to obtain the results of sampling and testing and the cost for both the foreign supplier and the importer to process the documentation of sampling and testing. We assume that the foreign supplier would arrange for any necessary sampling and testing for the same reasons that we assumed the foreign supplier would arrange for any necessary onsite audits.

To account for the fact that sampling and testing on a given product performed by a foreign supplier may address a number of hazards that would trigger this requirement, we estimated the total number of relevant products supplied by unique foreign suppliers. We estimated the number of products using a range with the minimum set at the number of hazards divided by the average number of hazards per product (so that the hazards are concentrated in as few products as possible) and the maximum set at one product per hazard (so that the hazards are distributed among as many hazards as possible).

We estimated transmission costs in the same manner we discussed previously. In this case, each product must come from a supplier, and a given supplier may need to transmit the results of tests on more than one product.

Table 14 presents results relating to relevant hazards associated with a potential secondary verification activity in which that secondary activity is conducting (and documenting) or obtaining documentation of a review of safety records.

Table 14. Estimated Cost of Conducting Secondary Verification Activity: Conducting (And Documenting) Or Obtaining Documentation Of A Review of Safety Records under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Of Reviewing Records Per Foreign Supplier Per Importer Per Year	$461	$461	$461	$461	
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year - Foreign Supplier	$6	$6	$6	$6	
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year – Importer	$6	$6	$6	$6	
Cost of Conducting Review					
Hazards That Would Trigger Requirement					
Number of Hazards Requiring Review of Records	2,047	2,606	1,411	301	6,366
Alternate - Number of Foreign Suppliers					
Maximum Number of Products Requiring Review of Records	2,047	2,606	1,411	301	6,366
Average Hazards Per Product	2	2	2	2	
Minimum Number of Products Based on Average Hazards Per Product	1,023	1,303	706	151	3,183
Number of Products Requiring Review	1,535	1,955	1,059	226	4,774
Maximum Number of Suppliers Doing Review of Records Based on One Supplier Per Relevant Product	548	698	378	81	1,705
Average Number of Products Per Foreign	6	6	6	6	

Supplier					
Minimum Number of Suppliers Based on Average Number of Products Per Supplier	86	109	59	13	267
Number of Foreign Suppliers	317	404	219	47	986
Cost of Reviewing Records Per Year - Foreign Supplier	$146,078	$185,985	$100,723	$21,481	$454,266
Cost of Transmitting Documentation of Review					
Average Number of Importers Per Supplier	2.8	2.8	2.8	2.8	
Expected Transmissions	888	1,130	612	131	2,760
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Year - Foreign Supplier	$5,023	$6,395	$3,463	$739	$15,620
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Year –Importer	$5,023	$6,395	$3,463	$739	$15,620
Total Costs					
Total Cost – Foreign Supplier	$151,100	$192,380	$104,186	$22,219	$469,886
Total Cost – Importer	$5,023	$6,395	$3,463	$739	$15,620
Total Cost – Foreign Supplier and Importer	$156,123	$198,775	$107,650	$22,958	$485,506

The relevant cost is the cost of the foreign supplier to review records and the cost for both the foreign supplier and the importer to process the documentation of such review. We assume that the foreign supplier would conduct any necessary review of records for the same reasons that we assumed the foreign supplier would arrange for any necessary onsite audits and sampling and testing.

To account for the fact that reviewing records by a foreign supplier may address a number of hazards that would trigger this requirement and that a transmission from one foreign supplier to one importer may cover a number of hazards that would trigger this requirement, we estimated the number of suppliers and transmission using an approach similar to that we used in previous calculations.

Tables 15 and 16 present results relating to the requirement that involves hazards other than SAHCODHA hazards controlled by a foreign supplier at its establishment: conducting the appropriate verification activity from a specified list of potential verification activities. These verification activities are to conduct (and document) or obtain documentation, as appropriate, on one or more of the following specified alternatives: 1) onsite audits, 2) lot-by-lot or periodic sampling and testing, and 3) review of food safety records. Again, we are not able to analyze the costs associated with the remaining alternative, which is to conduct any other appropriate verification activity. In these two tables we use a short cut for estimating costs in which we compare the estimated number of hazards that would trigger the various verification activities under this provision to results we discussed above involving those same activities triggered by other provisions. We discuss the method in more detail following the tables.

Table 15 presents results relating to the primary verification activity.

Table 15. Estimated Cost of Conducting (And Documenting) Or Obtaining Documentation Of Appropriate Verification Activity From Specified Alternatives – Primary Activity under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Relevant Hazards in Non-DS Products	98,254	125,096	67,748	14,448	305,547
DS Products That Will Not Be Processed Further	1,223	1,059	508	108	2,898
Onsite Audits					
Percentage of Non-DS Hazards and DS Products That Require Onsite Audits Under This Provision	33%	33%	33%	33%	
Number of Non-DS Hazards and DS Products That Require Onsite Audits Under This Provision	33,159	42,052	22,752	4,852	102,815
Number of Hazards That Triggered Mandatory	32,751	41,699	22,583	4,816	101,849

Onsite Audits					
Number of Hazards and Products That Require Onsite Audits Under This Provision as Multiple of Number of Hazards That Triggered Mandatory Onsite Audit	1.01	1.01	1.01	1.01	
Total Cost Foreign Suppliers	$6,818,086	$8,646,549	$4,678,235	$997,644	$21,140,514
Total Cost Importers	$20,896	$26,604	$14,408	$3,073	$64,980
Total Cost Foreign Suppliers and Importers	$6,838,982	$8,673,153	$4,692,643	$1,000,717	$21,205,495
Sampling and Testing					
Percentage of Non-DS Hazards and DS Products That Require Sampling and Testing Under This Provision	33%	33%	33%	33%	
Number of Non-DS Hazards and DS Products That Require Sampling and Testing Under This Provision	33,159	42,052	22,752	4,852	102,815
Number of Hazards That Triggered Sampling and Testing As Secondary Activity With Mandatory Onsite Audits	2,047	2,606	1,411	301	6,366
Number of Hazards and Products That Require Sampling and	16.20	16.14	16.12	16.12	

Testing Under This Provision as Multiple of Number of Hazards That Triggered Sampling and Testing As Secondary Activity With Mandatory Onsite Audits					
Total Cost Foreign Supplier	$34,266,047	$43,455,455	$23,511,674	$5,013,917	$106,247,093
Total Cost Importers	$394,042	$499,715	$270,372	$57,657	$1,221,787
Total Cost Foreign Suppliers and Importers	$34,660,089	$43,955,170	$23,782,046	$5,071,574	$107,468,880
Review of Records					
Percentage of Non-DS Hazards and DS Products That Require Review of Records Under This Provision	33%	33%	33%	33%	
Number of Non-DS Hazards and DS Products That Require Review of Records Under This Provision	33,159	42,052	22,752	4,852	102,815
Number of Hazards That Triggered Sampling and Testing As Secondary Activity With Mandatory Onsite Audits	2,047	2,606	1,411	301	6,366
Number of Hazards and Products That Require Review of Records Under This Provision As Multiple of	16.20	16.14	16.12	16.12	

Number of Hazards That Triggered Review of Records As Secondary Activity With Mandatory Onsite Audits					
Total Cost Foreign Supplier	$2,447,702	$3,104,123	$1,679,493	$358,156	$7,589,474
Total Cost Importers	$81,366	$103,186	$55,829	$11,906	$252,287
Total Cost Foreign Suppliers and Importers	$2,529,068	$3,207,309	$1,735,322	$370,061	$7,841,761
Total Costs					
Foreign Suppliers	$43,531,836	$55,206,127	$29,869,402	$6,369,717	$134,977,081
Importers	$496,303	$629,506	$340,609	$72,636	$1,539,054
Foreign Suppliers And Importers	$44,028,140	$55,835,632	$30,210,011	$6,442,353	$136,516,136

In the case of hazards in non-DS products under any other conditions than those that trigger the mandatory onsite audit requirement, the importer must choose an appropriate verification activity or more than one appropriate verification activities for each hazard from the proposed list of potential verification activities. We have already estimated the hazards that might trigger this requirement in our discussion of the hazards that would trigger the onsite audit requirement. In particular, in our discussion of the onsite audit requirements, we estimated the number of hazards in raw materials or ingredients and in finished products that are controlled by suppliers, but we specified that only a certain percentage of those hazards would meet the criteria that trigger onsite audits. The remaining hazards would trigger the requirement to select an appropriate verification activity. DS products are not subject to the proposed mandatory audit requirements, and verification activity for DS products that will not be processed further occurs on a product by product rather than a hazard by hazard basis. Therefore, all relevant DS products would trigger this requirement. Because we would use the same procedures to calculate these costs as we used to calculate these costs in the context of secondary verification activity associated with the onsite audit requirement, we simply compared the number of non-DS hazards and DS products that trigger these requirements with the number of hazards that triggered these

requirements in the context of the onsite audit requirements and adjusted the previously estimated costs accordingly.

Table 16 presents results relating to the secondary verification activity, if any.

Table 16. Estimated Cost of Conducting (And Documenting) Or Obtaining Documentation Of Appropriate Verification Activity From Specified Alternatives - Secondary Activity under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Probability That Non-DS Hazard or DS Product That Will Not Be Processed Further Requiring One Verification Activity Will Require A Second Verification Activity, Midpoint	13%	13%	13%	13%	
Probability That Second Verification Activity Will Be Either Of The Two Available Alternatives	50%	50%	50%	50%	
Frequency Of Various Verification Activities					
Number of Hazards and Products That Require Onsite Audits That Would Require a Second Verification Activity	4,145	5,256	2,844	606	12,852
Hazards and Products That Require Sampling and Testing	2,072	2,628	1,422	303	6,426
Hazards and Products That Require Review of Records	2,072	2,628	1,422	303	6,426
Number of Non-DS Hazards and DS Products That Require Sampling and Testing That Would Require a Second Verification	4,145	5,256	2,844	606	12,852

Activity					
Hazards and Products That Require Onsite Audits	2,072	2,628	1,422	303	6,426
Hazards and Products That Require Review of Records	2,072	2,628	1,422	303	6,426
Number of Non-DS Hazards and DS Products That Require Review of Records That Would Require a Second Verification Activity	4,145	5,256	2,844	606	12,852
Hazards and Products That Require Onsite Audits	2,072	2,628	1,422	303	6,426
Hazards and Products That Require Sampling and Testing	2,072	2,628	1,422	303	6,426
Onsite Audits					
Non-DS Hazards and DS Products That Require Onsite Audits As Second Verification Activity	4,145	5,256	2,844	606	12,852
Percentage of Hazards That Require Onsite Audits as Primary Verification Activity	13%	13%	13%	13%	
Total Cost Foreign Suppliers	$852,261	$1,080,819	$584,779	$124,706	$2,642,564
Total Cost Importers	$2,612	$3,326	$1,801	$384	$8,123
Total Cost Foreign Suppliers and Importers	$854,873	$1,084,144	$586,580	$125,090	$2,650,687
Sampling And Testing					
Hazards and Products That Require Sampling and Testing As Second Verification Activity	4,145	5,256	2,844	606	12,852
Percentage of Hazards That Require Sampling and Testing as Primary Verification Activity	13%	13%	13%	13%	

Total Cost Foreign Suppliers	$4,283,256	$5,431,932	$2,938,959	$626,740	$13,280,887
Total Cost Importers	$49,255	$62,464	$33,797	$7,207	$152,723
Total Cost Foreign Suppliers and Importers	$4,332,511	$5,494,396	$2,972,756	$633,947	$13,433,610
Review of Records					
Hazards and Products That Require Review of Records As Second Verification Activity	4,145	5,256	2,844	606	12,852
Percentage of Hazards That Require Review of Records as Primary Verification Activity	13%	13%	13%	13%	
Total Cost Foreign Suppliers	$305,963	$388,015	$209,937	$44,769	$948,684
Total Cost Importers	$10,171	$12,898	$6,979	$1,488	$31,536
Total Cost Foreign Suppliers and Importers	$316,134	$400,914	$216,915	$46,258	$980,220
Total Costs					
Foreign Suppliers	$5,441,480	$6,900,766	$3,733,675	$796,215	$16,872,135
Importers	$62,038	$78,688	$42,576	$9,079	$192,382
Foreign Suppliers And Importers	$5,503,517	$6,979,454	$3,776,251	$805,294	$17,064,517

The FSVP proposed rule specifies that some of the hazards and products that trigger this requirement may require more than one verification activity. We again assume that any non-DS hazard or DS product that will not be processed further would need at most two verification activities. We do not know the probability that a given hazard or product will require a second verification activity or, if it does, which verification activity it would require. Therefore, we express the probability that a relevant hazard or product may require an additional verification activity with a uniform distribution running from 0 percent to 100 percent. For the purposes of this analysis, we assume that if a hazard or product requires an additional verification activity, then it has an equal probability of requiring either of the other two verification activities. For example, in the case of a hazard that requires an onsite audit but that also requires another verification activity, we specified an equal probability that that hazard would require sampling and testing or a review of food safety records. We used a similar procedure for the hazards and products that required the other verification activities. Again, we estimated costs by comparing

the number of hazards and products involved with the number of hazards and products involved in previous estimates, in this case the cost estimates expressed in the material relating to the primary verification activity required under this provision of the FSVP proposed rule.

The FSVP proposed rule also requires importers to review the results of the verification activities they conduct or the documentation of verification activities they obtain. Table 17 presents the estimated cost of this review.

Table 17. Estimated Cost of Reviewing Results of Verification Activity under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Number of Hours to Review Results of Verification Activity	1	1	1	1	
Cost Per Hour	$61	$61	$61	$61	
Cost to Review Results of Verification Activity Per Activity, Average	$61	$61	$61	$61	
Number of Verification Activities	128,770	163,345	88,384	18,848	399,347
Total Cost	$7,911,632	$10,035,937	$5,430,303	$1,158,029	$24,535,900

An importer reviewing the results of verification activity or documentation of verification activity involves an importer reviewing the documentation of verification activity to determine if it indicates the need for corrective actions.

We assume that reviewing the results of one verification activity would take approximately one hour on average.

The review would probably be performed by senior personnel at a pay level similar to that of a manager in the food manufacturing industry. Therefore, we based our estimate on the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

We multiplied the average cost of reviewing one verification activity by the total estimated number of verification activities.

The FSVP proposed rule allows an importer to substitute for an audit the results of an inspection of the foreign supplier conducted by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. In Table 18 we present a correction to the estimated cost of onsite audits to account for this proposed provision, which we represent as estimated cost savings, or negative costs, that we will apply to the total estimated cost of audits. We discuss the inputs to this table in the text following the table.

Table 18. Audit Cost Correction for Substitution of Inspection Results under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Cost of Onsite Audit	$3,511	$3,511	$3,511	$3,511	
Number of Previously Estimated Audits Eliminated	321	405	222	47	995
Cost Savings (Negative Costs)	-$1,128,061	-$1,420,772	-$780,602	-$163,724	-$3,493,161

FDA conducted inspections of 995 foreign facilities in FY11. FDA has officially recognized only one country (New Zealand) as having a food safety system comparable or equivalent to that of the United States. Based on the selection criteria for inspecting foreign facilities, it is likely that most of the facilities that FDA inspected would, absent the provisions on officially recognized or equivalent food safety systems, be subject to the proposed audit requirements under the FSVP proposed rule. We do not have sufficient information on inspections conducted by the New Zealand government to correct for those audits. Therefore, we estimated that these provisions would eliminate the need for 995 of the audits we previously estimated. We do not know the proportion of these audit savings that would accrue to audits generated by importers of different sizes. Therefore, we distribute the cost savings across importer size categories based on the distribution of total mandatory audit costs.

To estimate the cost savings we used the same estimated total cost of an onsite audit that we used previously. The cost of transmitting results of inspections is probably similar to the cost of transmitting results of audits. Therefore, we have not adjusted the previously estimated cost of transmitting audit results.

Table 19 presents a summary of the verification costs.

Table 19. Summary of Verification Costs under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Maintaining List of Suppliers Importers	$3,374,607	$1,100,013	$611,388	$148,679	$5,234,688
Determining and Documenting Appropriate Verification Procedures – Importers	$5,646,339	$7,259,380	$3,886,005	$804,639	$17,596,363
Onsite Audits, Required - Importers	$20,896	$26,604	$14,408	$3,073	$64,980
Onsite Audits, Required - Foreign Suppliers	$6,734,258	$8,573,992	$4,643,385	$990,269	$20,941,903
Onsite Audit Cost Savings from Substitution of Inspection Results	-$1,126,589	-$1,428,716	-$773,010	-$164,846	-$3,493,161
Onsite Audits, Required, Secondary Activity – Importers	$29,348	$37,365	$20,236	$4,316	$91,264
Onsite Audits, Required, Secondary Activity - Foreign Suppliers	$2,266,397	$2,885,555	$1,562,719	$333,272	$7,047,943
Selected Verification Activity - Importers	$496,303	$629,506	$340,609	$72,636	$1,539,054
Selected Verification Activity - Foreign Suppliers	$43,531,836	$55,206,127	$29,869,402	$6,369,717	$134,977,081

Selected Verification Activity, Secondary Activity - Importers	$62,038	$78,688	$42,576	$9,079	$192,382
Selected Verification Activity, Secondary Activity - Foreign Suppliers	$5,441,480	$6,900,766	$3,733,675	$796,215	$16,872,135
Review of Results of Verification Activity - Importers	$7,911,632	$10,035,937	$5,430,303	$1,158,029	$24,535,900
Total – Importers	$17,541,163	$19,167,493	$10,345,525	$2,200,451	$49,254,632
Total - Foreign Suppliers	$56,847,381	$72,137,723	$39,036,171	$8,324,626	$176,345,902
Grand Total - All Entities	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534

We applied the cost savings from substituting inspection results for onsite audits to the mandatory audits even though they could apply to either mandatory audits or to audits importers choose as the most appropriate verification activity. In the totals we applied these cost savings to foreign suppliers because we assumed in the discussion of audit costs that these are the entities that would arrange for the performance of the audits, although as we also discussed in the audit cost section we have not estimated the incidence of that cost.

The costs of verification activity in every year after the first year will depend on entry and exit from the industry and on a number of other elements depending on the verification activity in question. Maintaining lists of suppliers, determining and documenting appropriate verification procedures, sampling and testing, and reviewing records occur on a continuous basis throughout the year, so there is no difference between costs in year 1 and costs in subsequent years. For onsite audits, existing importers that conduct onsite audits or obtain documentation of onsite audits because of SAHCODHA hazards that are controlled by the foreign supplier during processing must conduct audits or obtain documentation of onsite audits at least annually and, as based on the importers' assessment, possibly multiple times per year if those importers determine

it is necessary to adequately verify control of the hazard. For other hazards, importers must determine and document how frequently to conduct any appropriate audits based on the risk associated with the hazard. We do not have sufficient information to estimate how many audits will need to be conducted more than once per year, once per year, or once every so many years under the FSVP proposed rule. We base our cost estimates on an average of one audit per year. Based on this information the cost in every year after year 1 will be the same as the cost in year 1.

Written Assurances

The FSVP proposed rule would require importers to obtain written assurances in certain cases involving modified verification requirements for certain categories of importers, most of which we have discussed in other sections of this analysis. Importers that have customers that adequately control hazards an importer has identified as reasonably likely to occur must obtain written assurances from that customer that it has established and is following procedures (identified in the written assurance) that adequately control the hazard. Importers that import DS that deal with customers required to establish specifications for those DS under the DS CGMP regulations (as specified in proposed § 1.511(b)) must obtain written assurances from those customers that they are in compliance with those DS CGMP regulations every year. Very small importers must obtain written assurances, including brief descriptions of processes and procedures, from their foreign suppliers every two years. Importers that deal with very small foreign suppliers must obtain written assurances, including brief descriptions of processes and procedures, from their foreign suppliers every two years.

A) Importers with customers that control hazards

We present the estimated cost per product of obtaining written assurances from customers in Table 20. For the cost per product of obtaining written assurances, we calculated the cost for an importer to receive the documentation from its customer and for the customer to transmit the documentation to the importer. We discuss the latter cost as a cost for the customer because the customer would perform the activity. However, we have not estimated the incidence of this cost.

Depending on market conditions, the customer may be able to pass these costs back to the importer. By the same token, the importer may be able to pass the costs associated with their activity to their customers. The only entities that would actually be subject to the proposed provisions are importers. Therefore, to simplify the analysis, one may consider all costs to be ultimately borne by importers. We discuss the inputs following the table.

Table 20. Estimated Cost of Obtaining Written Assurances From Customers under the FSVP Proposed Rule	
Hours to Process Written Assurances Per Assurance Per Customer Per Year – Importer	0.25
Hours to Process Written Assurances Per Assurance Per Customer or Supplier Per Year – Customer	0.25
Cost Per Hour	$23
Total Cost Per Assurance Per Customer Per Year – Importer	$6
Total Cost Per Assurance Per Customer Per Year – Customer	$6

An importer obtaining written assurance from a customer that it is compliance with the relevant regulations involves the importer's customer preparing the required documentation and sending it to the importer and the importer processing that documentation. One written assurance from a customer on a particular product could cover all hazards in that product.

Sending a copy of a written assurance to the importer probably requires only a small amount of time, which we have estimated as 0.25 hours. The importer would then need to receive and process this information. However, other than ensure the written assurance states that the customer has established and is following procedures (identified in the written assurance) that adequately control the hazard, the FSVP proposed rule does not require the importer to evaluate or otherwise review this information. Therefore, receiving and processing this information probably also only requires a minimal amount of time, which we have again estimated as 0.25 hours.

This processing of documentation would probably be performed by clerical staff at both the importer and the customer. To estimate this cost, we used the mean hourly wage for SOC 43-6014 Secretaries and Administrative Assistants, Except Legal, Medical, and Executive in NAICS code 311000 Food Manufacturing in 2010. (Ref 1.) We increased wages by 50 percent to account for overhead.

We estimate total costs for obtaining written assurances from customers for this group of importers in Table 21. We discuss the table in more detail in the text following the table.

Table 21. Estimated Cost of Obtaining Written Assurances From An Importer's Customer That Controls Hazards under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Assurance Per Customer – Importer	$6	$6	$6	$6	
Cost Per Assurance Per Customer – Customer	$6	$6	$6	$6	
Number of Raw Materials Or Ingredients Going to Importers That Are Not Food or Beverage Manufacturers	24,566	22,144	10,498	2,554	59,761
Percentage of Raw Materials or Ingredients In Which Hazards Are Controlled by Supplier	33%	33%	33%	33%	
Number of Raw Materials Or Ingredients Triggering Written Assurances from Customer	16,535	14,905	7,066	1,719	40,225
Number of Customers To Which Raw Material Or Ingredient Is Sold	2.8	2.8	2.8	2.8	
Number of Assurances	46,298	41,734	19,784	4,813	112,629
Total Cost – Importers	$261,987	$236,163	$111,955	$27,236	$637,340
Total Cost – Customers	$261,987	$236,163	$111,955	$27,236	$637,340
Total Cost - Importers and Customers	$523,973	$472,326	$223,910	$54,472	$1,274,680

In this case, we based our cost estimate on the estimated number of combinations of products containing hazards controlled by the customer and customers to which those products are sold because one assurance would cover all relevant hazards in a given product sold by a given importer to a given customer. We do not know the number of customers to which an importer sells particular products. Therefore, we assume that the number of customers per importer is similar to the number of importers per supplier. We request comment on this assumption.

We estimated the number of products using an approach similar to that we used for the verification activity table. We excluded importers importing only DS, importers obtaining food from suppliers in countries with comparable food safety systems, very small importers, importers with only very small foreign suppliers, and food and beverage manufacturers. We defined special groups for importers that import some but not only DS. We calculated the number of products based on the relevant products per importer for each group. We estimated the number of customers to which an importer sells a product based on the number of importers to which a foreign supplier sells a product.

B) Importers that have customers that establish specifications under the DS CGMPs as specified in proposed § 1.511(b)

The cost for obtaining written assurances per product from customers for this group of importers would be the same as those for other importers.

We estimate total costs for obtaining written assurances from customers for this group of importers in Table 22. We discuss the table in more detail in the text following the table.

Table 22. Estimated Cost of Obtaining Written Assurances From An Importer's Customer Subject to DS Specifications Requirement under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Cost Per Assurance Per Customer – Importer	$6	$6	$6	$6	
Cost Per Assurance Per Customer – Customer	$6	$6	$6	$6	
Number of DS Products for Further Processing	8,271	2,433	1,110	235	12,049
Number of Customers to Which a Given DS Is Sold for Further Processing	3	3	3	3	
Number of Assurances	23,159	6,813	3,108	658	33,738
Total Cost – Importers	$131,049	$38,555	$17,585	$3,724	$190,913
Total Cost – Customers	$131,049	$38,555	$17,585	$3,724	$190,913
Total Cost - Importers and Customers	$262,098	$77,110	$35,171	$7,447	$381,826

We estimated the number of products using an approach similar to that we used for the verification activity table. In this case we only included importers that are not manufacturers and that could import at least some DS not for further processing. We specified subgroups relating to this information as follows: DS only importers (that are not manufacturers) that deal with only raw materials, DS only importers (that are not manufacturers) that deal with some but not only raw materials, importers that import some but not only DS that import raw materials only, and importers that import some but not only DS and some but not only raw materials. We calculated the number of products based on the relevant products per importer for each group.

C) Very small importers and very small suppliers

We present the estimated cost per product of very small importers of obtaining written assurances from their supplier and importers of any size obtaining written assurances from very small suppliers in Table 23. For the cost per product of obtaining written assurances for importers, we calculated the cost for an importer to receive the documentation from its supplier and to review the brief descriptions of processes and procedures. For the cost of processing written assurances, we calculated the cost of preparing a short description of processes and procedures in the case of the first such transmission per supplier and the cost of transmitting existing documentation for subsequent transmissions. We discuss the inputs following the table.

Table 23. Estimated Cost of Obtaining Written Assurances From Foreign Suppliers under the FSVP Proposed Rule	
Hours to Process Written Assurances Including Review of Processes Per Assurance – Importer	1
Hours to Prepare and Process Written Assurances Including Initial Description of Process - Supplier	1
Hours to Process Written Assurances After Initial Description of Processes – Supplier	0.25
Cost Per Hour – Importer	$61
Cost Per Hour For Initial – Supplier	$61
Cost Per Hour After Initial – Supplier	$23
Cost Per Assurance – Importer	$61
Cost Per Initial Assurance - Supplier	$61
Cost Per Assurance After Initial – Supplier	$6

An importer obtaining written assurance from a supplier involves the importer's suppliers preparing the required documentation and sending it to the importer and the importer processing that documentation. One written assurance from a supplier could cover all products received from that supplier and all hazards in each product.

Preparing a written assurance in this case involves the supplier preparing a brief description of the processes and procedures it uses to ensure the food it supplies to importers is in compliance. We estimate that preparing this documentation would take suppliers about 1 hour. A supplier would only need to prepare a brief description of processes and procedures once, regardless of how many very small importers it deals with. For very small importers after the first very small importer, the supplier could simply transmit existing documentation prepared for the first very small importer. We estimate that sending a copy of existing documentation to the importer would only require 0.25 hours.

Preparing brief descriptions of processes and procedures would probably be performed by senior personnel at a pay level similar to that of a manager in the food manufacturing industry. Therefore, we estimated the cost of preparing these descriptions using the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

Processing of written assurances by importers in this case would involve reviewing the brief descriptions of processes and procedures provided by suppliers. We estimate that reviewing this documentation would take importers about 1 hour.

We assume that the personnel that would review documentation of processes and procedures would be similar to the personnel that would prepare the documentation.

We estimate total costs for obtaining written assurances from suppliers for this group of importers in Table 24. In this case we estimate costs in the first year and every year after the first year because very small importers and importers working with very small suppliers only need to obtain written assurances from existing suppliers every two years. We discuss the table in more detail in the text following the table.

Table 24. Estimated Cost of Very Small Importers Obtaining Written Assurances from Foreign Suppliers and Importers of Any Size Obtaining Written Assurances from Very Small Foreign Suppliers under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Per Unit Costs					
Cost Per Assurance - Importer	$61	$61	$61	$61	
Cost Per Initial Assurance - Supplier	$61	$61	$61	$61	
Cost Per Assurance After Initial Insurance - Supplier	$6	$6	$6	$6	
Very Small Importers					
Number of Very Small Importers	24,973	67	20	9	25,069
Suppliers Working with Very Small Importers (Combinations)	67,388	243	70	29	67,730
Total Number of Assurances	67,388	243	70	29	67,730
Average Number of Importers Per Unique Supplier	2.8	2.8	2.8	2.8	
Number of Initial Assurances	24,097	87	25	10	24,219
Number of Assurances After Initial	43,291	156	45	19	43,510
Total Cost - Importers	$4,140,293	$14,909	$4,304	$1,799	$4,161,304
Total Cost - Suppliers	$1,725,494	$6,213	$1,794	$750	$1,734,251
Total Cost - Importers and Suppliers	$5,865,787	$21,123	$6,097	$2,548	$5,895,555
Very Small Suppliers					
Suppliers Of Importers that Import RAC only	23,945	14,680	4,207	39	42,871
Percentage of RAC Suppliers That Are VSS (Combinations of Importers and Suppliers)	63%	63%	63%	63%	
Suppliers of Importers That Import No RAC	147,013	65,464	37,150	9,582	259,209
Percentage of Non-RAC Suppliers That Are VSS (Combinations of Importers and Suppliers)	40%	40%	40%	40%	

Suppliers of Importers That Import Some But Not Only RACs	35,739	16,158	8,971	2,261	63,128
Percentage of Suppliers of Importers That Import Some But Not Only RACs That Are VSS	52%	52%	52%	52%	
Total VSS	92,446	43,826	22,166	5,030	163,468
Total VSS Corrected for OASIS Totals	72,006	34,136	17,265	3,918	127,326
Total Number of Assurances	72,006	34,136	17,265	3,918	127,326
Number of Initial Assurances	58,242	27,135	14,181	3,348	102,907
Number of Assurances After Initial	13,764	7,001	3,084	570	24,419
Total Cost - Importers	$4,424,071	$2,097,322	$1,060,787	$240,707	$127,326
Total Cost - Suppliers	$3,656,298	$1,706,807	$888,749	$208,931	$6,460,784
Total Cost - Importers and Suppliers	$8,080,369	$3,804,129	$1,949,536	$449,638	$14,283,672
Grand Total Year 1 - Importers and Suppliers	$13,946,155	$3,825,252	$1,955,633	$452,186	$20,179,226
Every Year After Year 1					
New Combinations and Suppliers					
Percentage of Combinations of Importers and Suppliers That Are New Each Year	46%	46%	46%	46%	
Annual Cost of Obtaining Assurances From Existing Suppliers as Percentage of Initial Cost (Because Required Every Two Years)	50%	50%	50%	50%	
Percentage of Suppliers That Are New Per Year	54%	54%	54%	54%	
Percentage of Suppliers Involved in New Combinations That Are New Each Year	77%	77%	77%	77%	
Very Small Importers					
Total Cost - Importers	$3,025,370	$10,894	$3,145	$1,314	$3,040,723
Total Cost - Suppliers	$655,071	$2,359	$681	$285	$658,396

Total Cost - Importers and Suppliers	$3,680,441	$13,253	$3,826	$1,599	$3,699,119
Very Small Suppliers					
Total Cost - Importers	$3,232,730	$1,532,543	$775,132	$175,888	$5,716,293
Total Cost - Suppliers	$699,970	$331,835	$167,836	$328,557	$1,528,199
Total Cost - Importers and Suppliers	$3,932,700	$1,864,378	$942,968	$504,445	$7,244,492
Grand Total Ever Year After Year 1 - Importers and Suppliers	$7,613,141	$1,877,631	$946,794	$506,044	$14,488,984

We based our cost estimate relating to very small importers on the estimated number of combinations of very small importers and suppliers of any size using procedures similar to those we used to address other provisions of the FSVP proposed rule. In this case, we constructed a range of suppliers with the low end of the range set at one foreign supplier per very small importers and the high end set at the overall average number of suppliers per importer. We corrected for foreign suppliers of any size who deal with more than one very small importer using the same procedure we used to correct for foreign suppliers who deal with more than one importer in the case of audits. We based our cost estimate relating to importers of any size working with very small suppliers on the estimated number of combinations of importers of any size and very small suppliers using a similar procedure.

We estimated costs in every year after the first year by reducing the cost we estimated in year one by 50 percent for existing combinations of importers and suppliers. We reduced costs by 50 percent for these combinations of importers and suppliers because importers only need written assurances from existing suppliers every two years. We estimated the percentage of combinations of importers and suppliers that are new each year based on the percentage of combinations of importers and suppliers that were new in FY10 in the OASIS importer data. We used the same estimate for the percentage of suppliers that are new each year that we previously used for the percentage of importers that are new each year.

Documenting Very Small Status

The FSVP proposed rule requires very small importers to document that they meet the definition of a very small importer every year. It also requires importers that deal with very

small suppliers to document that their foreign suppliers meet the definition of a very small supplier every year.

We present the cost of documenting the size of very small importers and very small suppliers in Table 25. The data indicate that 9 importers with more than 500 employees fit the definition of very small importer. We request comment on whether this reveals a problem with the data on importers or whether some importers with many employees handle a very small volume of sales.

Table 25. Estimated Cost of Documenting Very Small Importer or Very Small Supplier Status under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Number of Hours to Process Documentation per Importer	1	1	1	1	
Cost Per Hour	$61	$61	$61	$61	
Cost to Process Documentation	$61	$61	$61	$61	
Number of Very Small Importers	24,973	67	20	9	25,069
Combinations of Importers and Suppliers Involving Very Small Suppliers	72,006	34,136	17,265	3,918	127,326
Total Cost to Process Documentation	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109

Preparing documentation of very small importer or supplier status would involve collecting information and documents establishing the annual food sales of the importer (or the firm of which the importer is a part if the importer belongs to a larger firm) or the foreign supplier and calculating the three year average annual sales. We do not know how much time it would take to assemble this type of documentation. We assume this task may take very small importers one hour per year and importers working with very small suppliers one hour per very small supplier per year.

The significance of this task for purposes of establishing the regulatory requirements relevant to the importers in question suggests that the personnel preparing this documentation would probably be similar in pay grade to production managers in the food industry. To estimate

this cost, we used the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

Modified Requirements Relating to Importers That Import Food from Foreign Suppliers in Countries with Comparable or Equivalent Foreign Food Safety Systems

The FSVP proposed rule would establish requirements for importers that import food from foreign suppliers in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States (when certain requirements are met) that are different from those for other importers. However, we have not estimated these costs because FDA has only officially recognized one country, New Zealand, as having a comparable food safety system, and we do not yet have information on the effect of this recognition.

Investigative and Corrective Actions

The FSVP proposed rule would require an importer to undertake certain investigative and corrective actions when the food it imports is adulterated or misbranded or when an importer's foreign suppliers are not producing food in a manner consistent with applicable U.S. food safety requirements (for the sake of convenience, we refer to this as being not "in compliance with" applicable requirements). There are a total of four proposed investigative and corrective action requirements. Two of the proposed requirements relate specifically to the FSVP. The other two requirements relate to more general investigative and corrective actions and not specifically to the FSVP. The first requirement is that an importer must promptly conduct a review of any customer, consumer, or other complaint that it receives to determine if the complaint relates to the adequacy of its FSVP. The second requirement is that if any importer determines by means other than the proposed verification activities or the proposed regular FSVP reassessment that a foreign supplier does not produce food in compliance with the appropriate regulations, then the importer must promptly investigate to determine whether its FSVP is adequate and, when appropriate, modify its FSVP. The importer must document any investigations, corrective

actions, and changes to its FSVP that it makes in this context. The third requirement is that if an importer becomes aware that food that it imports is not in compliance with the appropriate regulations, then it must promptly investigate the cause or causes of the food being out of compliance and must document any such investigation. The fourth requirement is that an importer must promptly take appropriate corrective actions if it determines that an article of food that it imports is not in compliance with the appropriate regulations and must document any corrective actions it takes in accordance with this requirement.

Importers that are not food manufacturers or distributors have no existing regulatory requirement to conduct the proposed investigative and corrective actions. We suggested earlier that we have no information that these importers already have FSVPs that correspond to the FSVP requirements of this rule, so we assume they would not conduct the investigative and corrective actions involving FSVPs. In addition, most of these importers probably do not investigate the reasons an imported food is out of compliance with existing regulations if they determine that to be the case. However, most importers probably already take some type of corrective actions if they determine that a food they import is not in compliance with appropriate regulations and probably document those corrective actions. Therefore, we estimate costs of conducting only the first three investigative and corrective action requirements. With respect to corrective actions not related specifically to the FSVP (the fourth investigative and corrective action requirement), the verification activity and other requirements of this rule might increase the number of such corrective actions. However, because we assume that most importers already take these types of corrective actions, we have not estimated the cost of additional corrective actions here. Instead, to avoid confusion with the new activity that the FSVP proposed rule would require that differs more substantially from the baseline, we will discuss the cost of any increase in corrective actions in conjunction with the benefits of the other provisions. In other words, we interpret the benefits of the other provisions as catching additional problems and we would estimate that benefit by looking at potential health benefits net of the cost of any additional corrective action required to generate those health benefits.

Importers that must establish DS specifications under the DS CGMPs as specified in proposed § 1.511, or that have customers that must establish such DS specifications under the DS CGMPs, would not be required to conduct these activities for such products.

Tables 26, 27, and 28 present the estimated annual costs of conducting the various investigative and corrective actions. We discuss the inputs to the tables following the tables.

We present estimated annual costs for reviewing complaints to determine if they relate to the adequacy of an FSVP in Table 26.

Table 26. Estimated Cost for Reviewing Complaints for FSVP Per Importer Conducting That Activity under the FSVP Proposed Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Hours Per Month To Review Complaints for Food Safety Plan, Average	4	8	16	24	
Hours Per Month to Review Complaints For Relation to FSVP as Percentage of Time to Review Complaints for Relation to Food Safety Plan	0.25	0.25	0.25	0.25	
Hours Per Month To Review Complaints For Relation to FSVP	1	2	4	6	
Hours Per Year, Average	12	24	48	72	
Cost Per Hour	$61.44	$61.44	$61.44	$61.44	
Cost Per Importer Per Year	$737	$1,475	$2,949	$4,424	
Number of Importers	34,144	11,315	6,309	1,523	53,291
Cost of Reviewing Complaints Per Year	$25,173,669	$16,684,875	$18,606,460	$6,735,057	$67,200,060

Reviewing a complaint probably requires little time because most complaints simply report an issue and would not be very long or technically complex. Similarly, it should be readily apparent to a competent reviewer whether or not a given complaint relates in some way to the adequacy of an FSVP. Note that this requirement does not require importers to investigate the issues raised in complaints or determine whether or not its FSVP is actually adequate. However, another investigative and corrective action requirement does require such an investigation under those conditions. In the analysis of the PC rule, we estimated that it would take production facilities an average of 4, 8, 16, or 24 hours per month depending on the size of the facility to review consumer complaints to see if they are related to the effectiveness of the

food safety plan. Reviewing complaints to see if they are related to the food safety plan will require more time than reviewing complaints to see if they are related to the FSVP. To express this relationship, we based our estimate on importers requiring 25 percent as much time per month to review complaints for relevance to the FSVP as production facilities require to review complaints for relevance to the food safety plan.

The cost of this amount of labor time depends on the type of personnel involved. In the analysis of the PC rule, we said that the personnel that would review consumer complaints to determine if they are related to the effectiveness of the food safety plan would be SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We assume similar personnel would review consumer complaints to determine if they are related to the FSVP. We increased wages by 50 percent to account for overhead.

The number of complaints received per product varies widely among products. Many products probably receive very few or no complaints, while other products may generate multiple complaints. We do not know the average number of complaints received per imported product per year. Therefore, we estimate costs based on an average of 0 to 10 complaints per imported product per year. We request comments on the average number of complaints received per importer per year.

We present in Table 27 the estimated annual cost of an importer investigating whether its FSVP is adequate and, when appropriate, modifying its FSVP whenever that importer determines by means other than the proposed verification activities or the proposed regular FSVP reassessment that a foreign supplier does not produce food in compliance with the appropriate regulations and documenting any investigations, corrective actions, and changes to its FSVP that it makes in this context. We discuss the inputs following the table.

Table 27. Estimated Cost for Reviewing Adequacy of FSVP Per Importer Conducting That Activity under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Hours to Conduct Investigation of Adequacy of FSVP, Midpoint	5	5	5	5	
Cost Per Hour	$61.44	$61.44	$61.44	$61.44	
Probability Per Product Per Year That Information About An Imported Product Will Trigger Investigation, Midpoint	2%	2%	2%	2%	
Number of Products Per Importer Per Year, Weighted Average	11	14	13	12	
Number of Investigations Per Importer Per Year	0.2	0.2	0.2	0.2	
Cost Per Importer Per Year To Conduct Investigations Into Adequacy of FSVP	$49	$63	$61	$54	
Hours to Develop Individual Components of FSVP, Midpoint	7	7	7	7	
Hours to Modify Individual Components of FSVP as Percentage of Time to Develop Individual Components, Midpoint	30%	30%	30%	30%	
Number of Components of FSVP Requiring Modification, Midpoint	1	1	1	1	
Hours to Modify FSVP	2	2	2	2	
Probability That An Investigation Will Trigger a Modification of a FSVP, Midpoint	25%	25%	25%	25%	
Cost Per Importer Per Year to Modify FSVP Due To Investigations Into Adequacy of FSVP	$5	$7	$6	$6	
Total Cost Per Importer Per Year	$54	$70	$67	$60	
Number of Importers	34,144	11,315	6,309	1,523	53,291
Cost of Reviewing Complaints Per Year	$1,849,980	$789,152	$422,634	$90,734	$3,152,500

Conducting an investigation to determine whether a FSVP is adequate is a technically complex activity. In the analysis of the PC rule, we said that production facilities would require 1 to 9 hours to reassess the food safety plan in conjunction with corrective actions, depending on the complexity of the problem. The cost of investigating whether an FSVP is adequate is probably roughly similar. Therefore, we estimate that conducting an investigation to determine whether an FSVP is adequate might take 1 to 9 hours.

The cost of modifying the FSVP when necessary would depend on how many components of the FSVP require modification. In most cases, an investigation would probably uncover a problem with only one particular component of the FSVP. The cost of modifying one component of an FSVP will vary with the complexity of the modification, but it is probably considerably less costly than initially developing that component. We previously estimated the time required to develop a number of individual components of the FSVP as 6 to 8 hours each. The time required to modify a particular element of an FSVP is probably in the range of 10 percent to 50 percent of that time.

We did not estimate a time cost for documenting any investigations, corrective actions, and changes to its FSVP that an importer makes in this context because we consider that an importer would normally document activity of this type and that the cost of this documentation is therefore already included in the cost of the activity.

We did not estimate a cost for any changes in verification activity that would be required for an importer to follow the revised procedures in the modified FSVP. The costs we estimated for following the procedures in the various components of the FSVP were predicated on the activity being adequate for that purpose.

The cost of the specified amount of labor time depends on the type of personnel involved. The personnel responsible for investigating potential problems with the FSVP and modifying the FSVP when necessary would probably be senior personnel at a similar pay level to a production manager in the food manufacturing industry. To estimate this cost, we used the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. (Ref. 2 We increased wages by 50 percent to account for overhead.

The cost of investigations will depend on how many times per year this type of investigation is triggered and how many times such an investigation determines that

modifications to the FSVP are necessary. The FSVP proposed rule requires an importer to conduct an investigation to determine the adequacy of its FSVP whenever it determines by means other than routine verification activities or periodic reassessments of the FSVP that a foreign supplier does not produce food in compliance with the appropriate regulations. These means may include complaints, reports of adverse events, and regulatory actions among others. The likelihood of this event will vary with the number of imported products an importer deals with. We do not know the average number of times per year an importer may learn that a foreign supplier does not produce food in compliance with the appropriate regulations through the relevant means. However, this event is probably unlikely on an annual per product basis. Therefore, we estimate costs based on a 0 percent to 3 percent chance per year that an investigation will be triggered for any given imported product in any given year. We request comments on this estimate.

We also do not know the probability that such an investigation will indicate the need to modify a FSVP. If the foreign supplier is having significant problems such that a high proportion of the food it exports to the United States is not in compliance with relevant regulations, then one might assume that an adequate FSVP would uncover the problem prior to an importer discovering the problem through other means. In this case, the probability that an investigation would suggest modifications to the FSVP would be relatively high. However, if a foreign supplier is having problems that arise only rarely or sporadically such that only a small proportion of the food it exports to the United States in not in compliance with relevant regulations, then the probability that an investigation would suggest modifications to the FSVP would be relatively small. In many cases, foreign suppliers will have problems that arise only rarely or sporadically. Therefore, we estimate costs based on a 0 percent to 50 percent chance that any given investigation will indicate the need to modify the FSVP. We request comments on this estimate.

We present in Table 28 the estimated annual cost of an importer investigating the cause or causes of imported food being out of compliance and documenting any such investigation whenever an importer becomes aware that food that it imports is not in compliance with the appropriate regulations.

Table 28. Estimated Cost of Investigating Problems With Imported Products Per Importer Conducting That Activity under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Investigation	$3,511	$3,511	$3,511	$3,511	
Probability Per Product Per Year That Information About An Imported Product Will Trigger Investigation, Average	3%	3%	3%	3%	
Number of Products Per Importer Per Year, Weighted Average	11	14	13	12	
Cost Per Importer Per Year	$934	$1,202	$1,155	$1,027	
Number of Importers	34,144	11,315	6,309	1,523	53,291
Cost of Investigating Complaints Per Year	$31,888,044	$13,602,576	$7,284,920	$1,563,980	$54,339,520

Investigating the causes or causes of an imported food being out of compliance with relevant regulations is a technically complex activity that may involve issues arising at any stage in the production cycle of a given imported product, including harvesting, storing, transporting, and manufacturing. Thus, this activity may involve gathering and analyzing information from a number of different foreign entities beyond the immediate foreign supplier.

We do not know the cost of this type of investigation but it is probably roughly similar to the cost of performing an onsite audit. An onsite audit covers all sources of potential risks at a particular facility while an investigation of a particular problem may be more limited in scope. On the other hand, an importer conducting an investigation of a problem with a particular imported food may need to investigate multiple facilities to locate the problem. Based on these considerations, we estimate that the cost of an investigation into the cause or causes of an imported food being out of compliance with relevant regulations is the same as the cost that we

previously estimated for an onsite audit. Again, we have not estimated a separate cost for documenting such an investigation because we consider that an importer would normally document activity of this type and that the cost of this documentation is therefore already included in the cost of the activity.

The cost of this activity varies with the number of times per year than an importer becomes aware that a food it imports is not in compliance. We do not know the average number of times per year an importer may learn that a food it imports is not in compliance. This event is unlikely on a per product per year basis. We set the probability that an importer will find a given product not in compliance via any means as one percent more than whatever the probability is that an importer will find a given product not in compliance via particular means excluding routine verification activity and periodic reassessments of the FSVP. (We estimated the probability that an importer will find a given product not in compliance via particular means excluding routine verification activity and periodic reassessments of the FSVP using a uniform distribution running from 0 to 3 percent.) We request comments on this estimate.

These are annual costs, so the cost in every year after the first year will be the same as the cost in the first year because the entry of new importers will be balanced by the exit of existing importers.

Reassessment of FSVP

The FSVP proposed rule requires an importer to reassess the effectiveness of its FSVP whenever it becomes aware of new information about potential hazards associated with food it imports or at least once every 3 years, whichever is earlier. Examples of such information might include information on changes to raw materials or source of raw materials, product ingredients, processing methods or systems, finished product distribution systems, and the intended use or consumers of the food. An importer must document each reassessment it conducts. Finally, an importer must appropriately modify its FSVP and document any change or changes promptly when a reassessment reveals that its FSVP is no longer adequate.

We have not estimated a cost for reassessing an importer's FSVP under this requirement because we have already estimated yearly costs for maintaining the various elements of the FSVP, which were meant to address modifications to those elements for the reasons discussed in

this requirement. We request comments on whether this general reassessment requirement generates additional costs beyond those that we discussed in the context of maintaining particular elements of the FSVP.

Importer Identification

The FSVP proposed rule requires that before an article of food is imported or offered for import into the United States, the foreign owner or consignee of the food (if there is no U.S. owner or consignee) must designate a U.S. agent or representative as the importer of the food. It also requires an importer to obtain a Dun & Bradstreet Data Universal Numbering System (DUNS) number and to ensure that, for each line entry of food product offered for importation into the United States, its name, address, and DUNS number are provided electronically at the time of entry identifying it as the importer of the food.

We present the estimated cost of obtaining and providing DUNS numbers in Table 29. We discuss the table in more detail in the text following the table.

Table 29. Estimated Cost of Obtaining and Providing DUNS Numbers under the FSVP Proposed Rule					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Obtaining DUNS Numbers					
Hours to Obtain DUNS Number	0.25	0.25	0.25	0.25	
Cost Per Hour	$23	$23	$23	$23	
Cost of Obtaining DUNS Number Per Importer Per Year	$6	$6	$6	$6	
Number of Importers Without High Confidence D&B Record Matches	14,351	4,678	2,600	632	22,261
Cost of Obtaining DUNS Numbers	$81,208	$26,471	$14,713	$3,578	$125,969
Providing DUNS Numbers					
Hours to Provide DUNS Number at Entry per Entry	0.02	0.02	0.02	0.02	
Cost to Provide DUNS Number at Entry per Entry	$0.5	$0.5	$0.5	$0.5	
Number of Entries	1,908,708	1,734,312	3,210,101	2,064,479	8,917,600
Cost of Providing DUNS Numbers	$993,683	$902,892	$1,671,195	$1,074,778	$4,642,547
Total Costs	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Every Year After Year 1					
Percentage of New Importers Entering the Industry Every Year	54%	54%	54%	54%	
Cost of Obtaining DUNS Numbers	$44,254	$14,425	$8,018	$1,950	$68,647
Cost of Providing DUNS Numbers at Entry	$993,683	$902,892	$1,671,195	$1,074,778	$4,642,547
Total Costs	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194

We do not know how many importers currently do not have a DUNS number and would need to obtain a DUNS number because of this rule. However, importers for which we were able to obtain a high confidence match between OASIS records and D&B probably already have DUNS numbers. Therefore, we based our cost estimate on the number of importers for which we were unable to obtain high confidence matches.

Obtaining a DUNS number is a simple process that we estimate requires 0.25 hours per importer. This activity would probably be performed by clerical staff. To estimate this cost, we used the mean hourly wage for SOC 43-6014 Secretaries and Administrative Assistants, Except Legal, Medical, and Executive in NAICS code 311000 Food Manufacturing in 2010. (Ref 1.) We increased wages by 50 percent to account for overhead.

Providing a DUNS number at entry involves writing or entering a DUNS number in the appropriate entry document or screen. This is a simple action that can be taken at the same time that other information related to an imported food (e.g., the FDA product code, country of production, manufacturer/shipper, ultimate consignee) is provided when the food is offered for import into the United States. We estimate that providing the importer's DUNS number will require only approximately 1 minute (about 0.023 hours) per entry. We assume this activity would be performed by employees at the level of clerical staff, so we used the same cost per hour that we used for obtaining a DUNS number. We obtained an estimate of the average number of entries per importer from OASIS and applied that number to the total number of importers covered by this provision to estimate a total number of entries. We do not have data on entries by size of importer, so we distributed the total number of entries among the importer size categories using the percentage of product and supplier combinations in those importer size categories.

Summary of Costs

We present a summary of the costs of FSVP Co-proposal Option 1 in Table 30. We provide costs separately for writing and maintaining procedures and for following those procedures. We provide costs for year 1 and for every year after year 1 because the cost estimates of some elements of the FSVP have different costs for year 1 and for every year after year 1.

The three components that generate the highest costs are following procedures relating to producing the required information and hazard evaluations, writing and maintaining procedures relating to verification activities, and following procedures relating to verification activities.

The costs in every year after year 1 are less than the costs in year 1 but still quite high because many of the components deal with ongoing activity that is not significantly different in year 1 and in every year after year 1 and because of the high rate of entry and exit from the importing industry. In some cases there is no difference in cost, such as the cost of following procedures relating to verification activities or investigative and corrective actions.

Table 30. Total Cost Summary for All Elements of the FSVP Proposed Regulation - All Entities

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Reviewing Food and Supplier Compliance Status	$19,052,700	$8,936,617	$4,670,641	$1,101,248	$33,761,206
Conducting Information Collection and Hazard Evaluations	$6,039,731	$8,001,900	$4,353,557	$918,299	$19,313,487
Writing and Maintaining Procedures Relating to Verification Requirements	$14,706,224	$19,054,818	$10,216,891	$2,114,851	$46,092,783
Following Procedures Relating to Verification Requirements	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534
Obtaining Written Assurances	$14,732,226	$4,374,687	$2,214,714	$514,105	$21,835,732
Documenting Very Small Size Status	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109

Conducting Investigative and Corrective Actions	$58,911,693	$31,076,603	$26,314,013	$8,389,771	$124,692,080
Obtaining and Providing DUNS Numbers	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Grand Total Year 1	$199,060,040	$167,171,026	$100,674,722	$24,882,947	$491,788,735
Every Year After Year 1					$0
Hiring Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Reviewing Food and Supplier Compliance Status	$19,052,700	$8,936,617	$4,670,641	$1,101,248	$33,761,206
Conducting Information Collection and Hazard Evaluations	$4,957,107	$6,408,374	$3,481,333	$730,970	$15,577,784
Writing and Maintaining Procedures Relating to Verification Requirements	$12,088,189	$15,662,637	$8,398,057	$1,738,360	$37,887,242
Following Procedures Relating to Verification Requirements	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534
Obtaining Written Assurances	$8,399,212	$2,427,067	$1,205,875	$567,962	$12,600,117
Documenting Very Small Size Status	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109
Conducting Investigative and Corrective Actions	$58,911,693	$31,076,603	$26,314,013	$8,389,771	$124,692,080
Obtaining and Providing DUNS Numbers	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194

Grand Total Every Year After Year 1	$188,989,413	$160,225,652	$96,968,130	$24,371,357	$470,554,552

Sensitivity Analysis

Our cost estimate model includes a number of ranges and distributions to reflect uncertainty on various inputs. In the tables that we have presented thus far we have provided only point estimates from those ranges corresponding to the means or midpoints. The costs we presented in these tables correspond to average or expected costs. However, actual costs could be higher or lower. Therefore, we also estimated costs for the FSVP Co-proposal Option 1 using Monte Carlo analysis, which is a procedure designed to estimate the possible range of outcomes for a model that uses probability distributions to reflect uncertainty about the values of input variables. This procedure estimates the range of possible outcomes by probabilistically choosing a value from within any probability distributions present in a model, calculating the outcome, and then repeating the procedure using different probabilistically chosen input values until additional iterations had little significance for the overall range of outcomes. We present the results of this analysis for the total cost of each of the requirements of the FSVP Co-proposal Option 1 in Table 31. This table provides the mean cost estimates for the various provisions and two cost estimates from the tails of the probability distribution corresponding to a low cost (with only 5 percent probability of lower cost) and high cost (with only 5 percent probability of higher cost). This table indicates considerable uncertainty in the cost estimates of most of the requirements of the FSVP Co-proposal Option 1.

Table 31. Sensitivity Analysis			
	Mean	**Low**	**High**
Year 1			
Hiring Qualified Individuals	$6,368,171	$2,284,938	$10,553,310
Conducting Supplier compliance assessments	$33,795,490	$28,502,380	$40,621,400
Conducting Information Collection and Hazard Evaluations	$19,432,130	$10,376,290	$31,624,230
Writing and Maintaining Procedures Relating to Verification Requirements	$45,850,820	$23,462,960	$71,877,430
Following Procedures Relating to Verification Requirements	$229,873,100	$125,220,300	$387,942,600
Obtaining Written Assurances	$21,809,480	$16,654,040	$27,608,330
Documenting Very Small Size Status	$9,338,832	$6,246,745	$12,638,020
Conducting Investigative and Corrective Actions	$125,358,300	$101,415,700	$152,413,600
Obtaining and Providing DUNS Numbers	$4,768,517	$4,768,517	$4,768,517
Grand Total Year 1	$496,594,800	$354,124,800	$684,693,000
Every Year After Year 1	$0	$0	$0
Hiring Qualified Individuals	$6,368,171	$2,284,938	$10,553,310
Conducting Supplier compliance assessments	$33,795,490	$28,502,380	$40,621,400
Conducting Information Collection and Hazard Evaluations	$15,677,750	$8,160,832	$26,294,210
Writing and Maintaining Procedures Relating to Verification Requirements	$37,803,780	$18,140,950	$64,539,340
Following Procedures Relating to Verification Requirements	$229,873,100	$125,220,300	$387,942,600
Obtaining Written Assurances	$12,568,180	$8,659,716	$17,032,210
Documenting Very Small Size Status	$9,338,832	$6,246,745	$12,638,020
Conducting Investigative and Corrective Actions	$125,358,300	$101,415,700	$152,413,600
Obtaining and Providing DUNS Numbers	$4,711,194	$4,711,194	$4,711,194
Grand Total Every Year After Year 1	$475,494,800	$338,314,200	$659,278,300

Benefits of Co-proposal Option 1

We believe that substantial benefits will be realized by the implementation of the integrated and preventive food safety system envisioned by FSMA, including the FSVP and the Third-Party rule. Among other things, FSMA requires us to promulgate regulations to ensure the safety of produce and processed foods and to set minimum safety standards for both. Those

rules will apply to both domestic and imported foods. In addition, all foods intended for sale in the United States are already subject to the adulteration and misbranding provisions of the FD&C Act. This proposed rule on importers' foreign supplier verification programs is an integral part of the overall system envisioned by FSMA: it is designed to help ensure that foreign suppliers fully comply with the relevant requirements for the safe manufacturing and processing of food, including, importantly, the preventive controls and produce safety regulations.

The FSVP proposed rule thus functions as a part of a suite of FSMA and other food safety rules to help ensure the safety of food consumed in the United States. The FSVP rule establishes a critical mechanism for assuring compliance with the preventive controls, produce safety, and other underlying U.S. food safety standards. We believe that this rule, in conjunction with the other new food safety regulations, will create a comprehensive food safety system that will be effective in reducing foodborne illnesses associated with FDA-regulated imported foods. Because of the FSVP rule's emphasis on monitoring and documenting procedures and results, the effectiveness of the rule is likely to increase over time as food importers learn by doing. Also, the collection of data will enable FDA to perform retrospective reviews to identify changes that would make the FSMA rules more effective or less costly.

Although the FSVP proposed rule would not itself establish safety requirements for food manufacturing and processing, it would benefit the public health by helping to ensure that imported food is produced in compliance with other applicable food safety regulations. The RIAs for the proposed rules on preventive controls and produce safety consider and analyze the number of illnesses and deaths that the proposed regulations are aimed at reducing; the benefits figures for those rules include averted illnesses and deaths from imported, as well as domestically produced, foods. The greater the compliance with those regulations, the greater the expected reduction in illnesses and deaths as well as the costs associated with such illnesses and deaths. The FSVP rule is an important mechanism for improving and ensuring compliance with the food safety rules, with respect to their application to imported food. For this reason, we account for the public health benefits of this proposal in the preventive controls rules, produce safety rule, and other applicable food safety rules instead of in this rule.

The Third-Party proposed rule will help FDA ensure the competence and independence of third-party auditors/certification bodies who conduct food safety audits and the reliability of the certifications that they issue. Having comprehensive oversight of a credible and reliable

program for third-party audits and certifications of foreign food facilities will help FDA prevent potentially harmful food from reaching U.S. consumers and improve the safety of the U.S. food supply. We believe that a trusted program for foreign food safety audits and certifications will be appealing to accreditation bodies, third-party auditors/certification bodies, and foreign food facilities. Widespread participation and broad acceptance of audits and certifications will help increase efficiency and reduce costs by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act. FDA believes that the Third-Party proposed rule, when finalized, will provide a less-burdensome means to verify compliance of the imported food supply, thus reducing the costs of the FSVP proposed rule. We believe that both foreign suppliers and importers will have strong incentives to adopt third-party audits as the primary means of import verification. These benefits are captured in this analysis as a reduction in the costs that would otherwise be estimated for this rule. We cannot explicitly quantify the expected reduction in the number of unnecessarily-duplicative, costly foreign supplier verifications. However, we have estimated the costs of this rule based on a very high likelihood that an accredited audit of a foreign supplier will be acceptable to multiple importers. So the existence of a widely credible and acceptable standard for third-party audits (under the Third-Party proposed rule) dramatically reduces the number of audits that we have estimated in this analysis.

To provide context for the benefits that will be realized by the FSMA-related rules, including the FSVP regulations, with respect to imported food, we first present a discussion of the baseline number of illnesses attributable to imported food. To arrive at this baseline number, we first discuss the total number of illnesses attributed to food regulated by FDA and then consider the number of those illnesses attributable to imported food. Considering that the vast majority of imported food is covered by this and the other FSMA rules, in one way or another, we expect that they should significantly decrease the chance for contamination and illness from nearly all the imported foods consumed in the United States. Again, we have already accounted for the benefits described below as a part of the previously issued Produce Safety and Preventive Controls for Human Foods proposed rules. What follows provides a sense of the scope of foodborne illness that is related to FDA regulated imported food.

1. Baseline Risk of Foodborne Illness Attributable to Imported Foods

This rule will help to provide assurances that foreign suppliers are following processes and procedures that provide the same level of public health protection as those required under section 418 (on hazard analysis and risk-based preventive controls) of the FD&C Act, as applicable, and that the food being imported is not adulterated or misbranded with respect to allergen labeling.

a. Foodborne illness attributable to FDA-regulated imported food

To estimate the number of baseline illnesses attributable to imported foods[7] we begin with those outbreaks we can directly attribute to FDA-regulated imported foods. Table 32 presents all outbreaks, organized by pathogen, which can be linked to imported foods other than juice and seafood (which we are excluding because importation of these products would not be subject to the FSVP regulations) based on illnesses recorded in FDA's outbreak database. In total, there are 143 illnesses from 9 separate outbreaks that are linked to imported foods for the years 2003-2008; these data represent only reported and laboratory confirmed illnesses from outbreaks.

Table 32. Relevant Outbreaks Linked to Imported Food

Agent	**Outbreaks**	**Cases**
Listeria monocytogenes	5	37
Mycobacterium bovis	1	35
Salmonella	3	71
TOTAL	9	143

Table 33 presents the estimation of the total number of illnesses attributable to imported foods other than juice and seafood based on FDA outbreak data combined with CDC outbreak data and applied to Scallan et al.'s estimate of the total number of foodborne illnesses. (Ref. 4). We employ a two step calculation[8]: First, to determine the percent of illness attributable to imports we examine FDA specific outbreak data and the whole universe of identified pathogen illnesses, accounting for all outbreaks associated with an identified food vehicle. Dividing the

[7] This includes any food products that were shipped to the US from a foreign country, be it raw produce, dairy, or any other processed foods.
[8] This methodology is laid out completely in Appendix A of the Ref. 7.

number of observed FDA illnesses by the total, gives us the percentage attributable to FDA-regulated products. This number is then multiplied by Scallan et al.'s estimate of the total annual incidence of each specific foodborne pathogen (Ref. 4). This step corrects for numerous downward biases in the CDC database of illnesses such as under-reporting and under-identification of a foodborne illness. Multiplying the percentage attributable to FDA by the annual incidence yields the annual estimated illnesses attributable to FDA regulated imports.

Additionally we estimated the illnesses caused by unidentified pathogens attributable to FDA regulated imports. To do this, we assumed that the share of unidentified cases attributable to food covered by this rule is the same as the share of all cases attributable to food covered by this rule. We used the ratio of the number of FDA-reported cases attributable to regulated imports to all CDC foodborne cases as a proxy for the percentage of unidentified pathogen illnesses attributable to FDA. We make this assumption because outbreak data on unidentified pathogens, specifically their associated food commodity, is extremely sparse. This estimation presumes that the percentage of identified illnesses, across all pathogens, attributable to FDA products is the same as the percentage of unidentified pathogens attributable to FDA products. "FDA Imports" represents the sum of all illnesses in the FDA database. "Total Identified Cases," however, is larger than the sum of observed illnesses from the seven previously implicated pathogens. This is because we estimate the percentage out of all identified pathogens (31 percent) that are implicated in any foodborne illnesses, produce related or not.

Using this calculation methodology, the total number of relevant foodborne illnesses is estimated to be 75,029.

Table 33 Estimated Number of Illnesses Attributable to Imported Food					
Agent	FDA Imports (2003-2008)	Identified Cases (2003-2008)	Percentage Attributable to Imports	Estimated Annual Foodborne Illnesses	Estimated Illnesses Attributable to Imports
Listeria monocytogenes	37	72	51.39%	1,591	818
Mycobacterium bovis	35	35	100.00%	60	60
Salmonella	71	14,709	0.48%	1,027,561	4,960
Total Identified	143	79,347	0.18%		
Total Unidentified			0.18%	38,392,704	69,192
TOTAL					75,029

We note that using this methodology our estimate of the share of illnesses attributable to unidentified pathogens is about 92.2%, which is larger than the overall share estimated by Scallan, et al. They estimated that illnesses attributable to unidentified pathogens represent roughly 80% of all illnesses. Therefore, we also present an alternative estimate of the number of illnesses attributable to unidentified pathogens that is based on this 80% estimate. Using this alternative methodology we estimate that there are 23,350 illnesses attributable to unidentified pathogens and that there are a total of 29,188 illnesses attributable to food covered by this rule. We seek comment on which methodology of estimating the number of illnesses attributable to unidentified pathogens is more likely to be correct.

b. Economic burden of illnesses attributable to imported foods

We estimate the cost of eliminating foodborne illnesses from imported foods by multiplying the annual number of illnesses per pathogen by the estimated cost per case. Table 34 presents the burden of illness attributable to FDA-regulated imported foods. Column two contains the total number of attributable FDA illnesses, previously calculated in Table 33. This number is multiplied by the expected dollar loss per case (Ref. 3, Appendix A), in column three, to give the annual cost of each pathogen in the U.S. population, presented in column four. Summing over all pathogens, we estimate a potential annual cost savings of approximately $1.18 billion if all illnesses attributable to FDA-regulated imported foods were to be eliminated.

Table 34 - Estimated Dollar Burden Attributable to Imported Foods			
Agent	Estimated Attributable Illnesses	Expected Dollar Loss per Case	Dollar Burden
Listeria monocytogenes	818	$1,360,067	$1,111,987,001
Mycobacterium bovis	60	$437,413	$26,244,780
Salmonella	4,960	$4,622	$22,925,180
Total Identified			
Total Unidentified	69,192	$214	$14,807,031
TOTAL	75,029		$1,175,963,993

FSVP Co-proposal Option 2

As discussed previously in this section, the co-proposal sets forth two alternatives regarding requirements for foreign supplier verification activities; the co-proposal does not directly concern other FSVP requirements. Under Option 2 of the co-proposal, all importers would choose the appropriate verification activity from among specified verification activities. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the foreign supplier's compliance with U.S. food safety regulations.

The costs of complying with the FSVP requirements that include FSVP Option 2 would be identical to the costs under FSVP Option 1 except for the cost of conducting supplier verification activities and the cost of reviewing the results of verification activities, which depends on the estimated total number of verification activities. Estimating these costs requires estimating how many of the importers of products with SAHCODHA hazards controlled by foreign suppliers would choose each of the various verification activities available to them under FSVP Option 2. In this instance we have chosen to capture the uncertainty associated with this estimate through three possible scenarios defined in terms of the percentage of these importers that would choose onsite audits. For convenience of comparison of FSVP Option 2 with FSVP

Option 1 we present these estimates as the percentage of importers of products with SAHCODA hazards controlled by foreign suppliers that would be required to conduct or obtain the results of onsite audits under FSVP Option 1 that would choose audits under FSVP Option 2. The percentages we use in the three scenarios are 63 percent, 82 percent, and 100 percent. We choose 63 percent as the low end scenario because that is the estimated average percentage of all importers that are currently choosing to do voluntary accredited or non-accredited audits. We assume that the percentage of importers with products containing SAHCODHA hazards controlled by suppliers that would choose to do onsite audits under FSVP Option 2 would be at least equal to the average percentage of all importers that already choose to do onsite audits voluntarily because importers with SAHCODHA hazards would presumably be at least as likely to decide that onsite audits are the most appropriate verification activity as an importer of food that may or may not contain SAHCODHA hazards. We chose 100 percent as the high end scenario because it is possible that all importers handling SAHCODHA hazards would decide that onsite audits are the most appropriate verification activity. We chose 82 percent as the middle of the range scenario because it is approximately midway between 63 percent and 100 percent.

Table 35. Total Cost Summary for All Elements of Proposed Regulation - All Entities, FSVP Option 2

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Conducting Supplier Assessments	$18,601,611	$8,786,314	$4,593,175	$1,083,877	$33,064,977
Conducing Information Collection and Hazard Evaluations	$6,055,358	$7,970,251	$4,396,049	$913,668	$19,335,326
Writing and Maintaining Procedures Relating to Verification Requirements	$14,747,992	$18,988,400	$10,324,877	$2,104,995	$46,166,264

Following Procedures Relating to Verification Requirements					
Scenario 1 (63 percent)	$73,363,677	$89,491,284	$49,132,446	$10,300,810	$222,288,218
Scenario 2 (82 percent)	$71,114,272	$86,645,259	$47,567,480	$9,972,563	$215,299,574
Scenario 3 (100 percent)	$68,983,315	$83,949,098	$46,084,921	$9,661,601	$208,678,935
Obtaining Written Assurances	$14,478,196	$4,337,137	$2,200,148	$510,027	$21,525,509
Documenting Very Small Size Status	$5,849,769	$2,064,122	$1,043,541	$237,281	$9,194,713
Conducting Investigative and Corrective Actions	$58,964,310	$31,017,040	$26,402,557	$8,380,538	$124,764,445
Obtaining and Providing DUNS Numbers	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Grand Total Year 1					
Scenario 1	$197,331,416	$164,974,317	$100,553,971	$24,609,552	$487,469,256
Scenario 2	$195,082,011	$162,128,292	$98,989,004	$24,281,306	$480,480,613
Scenario 3	$192,951,054	$159,432,131	$97,506,445	$23,970,343	$473,859,973
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Conducting Supplier Assessments	$18,540,535	$8,548,474	$4,536,813	$1,096,081	$32,721,902
Conducting Information Collection and Hazard Evaluations	$4,969,810	$6,381,205	$3,513,023	$727,176	$15,591,212
Writing and Maintaining Procedures	$12,122,521	$15,608,043	$8,486,819	$1,730,259	$37,947,642

Relating to Verification Requirements					
Following Procedures Relating to Verification Requirements					
Scenario 1	$73,363,677	$89,491,284	$49,132,446	$10,300,810	$222,288,218
Scenario 2	$71,114,272	$86,645,259	$47,567,480	$9,972,563	$215,299,574
Scenario 3	$68,983,315	$83,949,098	$46,084,921	$9,661,601	$208,678,935
Obtaining Written Assurances	$8,220,973	$2,390,955	$1,191,999	$561,920	$12,365,846
Documenting Very Small Size Status	$5,849,769	$2,064,122	$1,043,541	$237,281	$9,194,713
Conducting Investigative and Corrective Actions	$58,964,310	$31,017,040	$26,402,557	$8,380,538	$124,764,445
Obtaining and Providing DUNS Numbers	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194
Grand Total Every Year After Year 1					
Scenario 1	$187,265,143	$157,808,845	$96,761,679	$24,110,793	$465,946,460
Scenario 2	$185,015,738	$154,962,820	$95,196,712	$23,782,546	$458,957,816
Scenario 3	$182,884,781	$152,266,659	$93,714,153	$23,471,584	$452,337,177

Our cost estimate model includes a number of ranges and distributions to reflect uncertainty on various inputs. The costs we presented in Table 35 correspond to average or expected costs. However, actual costs could be higher or lower. Therefore, we also estimated costs for FSVP Co-proposal Option 2 using Monte Carlo analysis, which is a procedure designed to estimate the possible range of outcomes for a model that uses probability distributions to reflect uncertainty about the values of input variables. This procedure estimates the range of possible outcomes by probabilistically choosing a value from within any probability distributions present in a model, calculating the outcome, and then repeating the procedure using different probabilistically chosen input values until additional iterations had little significance for the

overall range of outcomes. We present the results of this analysis for the total cost of each of the requirements of FSVP Co-proposal Option 2 in Table 36. This table provides the mean cost estimates for the various provisions and two cost estimates from the tails of the probability distribution corresponding to a low cost (with only 5 percent probability of lower cost) and high cost (with only 5 percent probability of higher cost). This table indicates considerable uncertainty in the cost estimates of most of the requirements of FSVP Co-proposal Option 2.

Table 36. Sensitivity Analysis, FSVP Option 2			
	Mean	**Low**	**High**
Year 1			
Hiring Third Parties With Qualified Individuals	$6,366,742	$2,228,634	$10,530,590
Conducting Supplier Assessments	$33,419,121	$28,349,900	$97,469,740
Conducing Information Collection and Hazard Evaluations	$19,453,654	$10,342,727	$58,430,000
Writing and Maintaining Procedures Relating to Verification Requirements	$46,060,588	$23,088,495	$72,720,128
Following Procedures Relating to Verification Requirements			
Scenario 1	$233,467,578	$127,331,932	$384,177,838
Scenario 2	$209,608,800	$225,019,916	$368,324,395
Scenario 3	$217,017,123	$118,400,983	$355,127,478
Obtaining Written Assurances	$21,851,188	$16,660,412	$28,141,338
Documenting Very Small Size Status	$9,331,370	$6,279,730	$12,578,353
Conducting Investigative and Corrective Actions	$126,026,547	$101,333,009	$153,193,540
Obtaining and Providing DUNS Numbers	$4,768,517	$4,768,517	$4,768,517
Grand Total Year 1			
Scenario 1	$500,745,304	$320,383,354	$737,129,628
Scenario 2	$492,297,642	$315,691,504	$721,276,185
Scenario 3	$464,841,195	$301,109,679	$677,117,590
Every Year After Year 1			
Hiring Third Parties With Qualified Individuals	$6,366,742	$2,228,634	$10,530,590
Conducting Supplier Assessments	$33,423,868.52	$28,332,130.45	$39,801,419.54
Conducting Information Collection and Hazard Evaluations	$15,737,141.29	$8,138,269.29	$26,056,743.38

Writing and Maintaining Procedures Relating to Verification Requirements	$38,100,827.15	$17,888,873.36	$64,445,232.40
Following Procedures Relating to Verification Requirements			
Scenario 1	$233,467,577.83	$127,331,931.88	$384,177,838.01
Scenario 2	$225,019,916.18	$122,640,081.47	$368,324,395.16
Scenario 3	$217,017,122.55	$118,400,983.34	$355,127,477.77
Obtaining Written Assurances	$12,611,911.36	$8,676,995.02	$17,610,106.75
Documenting Very Small Size Status	$9,331,369.90	$6,279,729.65	$12,578,352.80
Conducting Investigative and Corrective Actions	$126,026,546.71	$101,333,008.51	$153,193,540.10
Obtaining and Providing DUNS Numbers	$4,711,194.00	$4,711,194.00	$4,711,194.00
Grand Total Every Year After Year 1			
Scenario 1	$479,781,025.22	$305,010,644.72	$713,147,154.37
Scenario 2	$471,333,363.57	$300,318,794.30	$697,293,711.52
Scenario 3	$463,330,569.94	$296,079,696.17	$684,096,794.13

C. Regulatory Alternatives in the FSVP Proposed Rule

We considered two regulatory alternatives in the FSVP proposed rule: (1) Require the proposed verification activity only; and (2) Require importers to consider foreign supplier hazard control activity only. We request comments on these alternatives and suggestions for other alternatives. We will address any significant comments or suggestions in the analysis of the FSVP final rule.

1. Alternative One: Require verification activity and importer identification only

There are various ways in which we could reduce the costs of the FSVP proposed rule. One way would be to eliminate the proposed requirements other than (1) the verification activities in FSVP Co-proposal Option 1, including the modified activities for certain categories of importers, and (2) importer identification. In this case, no importer would be responsible for conducting reviews of food and supplier compliance status, gathering information and performing hazard identifications and evaluations on the food it imports, or investigating the

cause or causes of an imported food being out of compliance with applicable regulations. Instead an importer would conduct verification actions based on the foreign supplier's hazard identification, when it has one, and what the importer knows about the control procedures of their foreign supplier, and the proposed investigative and corrective actions would be limited to those involving reviewing consumer complaints to determine if they are relevant to the adequacy of the verification activity and to reviewing the verification activity if the importer learns of problems with imported food via a mechanism other than the verification activity. Obviously, the importer would continue with existing corrective actions involving not importing food that it learns is not in compliance with applicable regulations.

Costs

We present the total costs of this alternative in Table 37 using the information in the previous table and the costs we estimated for the verification requirements of the proposed FSVP rule.

Table 37. Alternative One - Total Cost Summary for All Elements of the FSVP Proposed Regulation - All Entities

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Writing and Maintaining Procedures Relating to Verification Requirements	$14,706,224	$19,054,818	$10,216,891	$2,114,851	$46,092,783
Following Procedures Relating to Verification Requirements	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534
Obtaining Written Assurances	$14,732,226	$4,374,687	$2,214,714	$514,105	$21,835,732
Documenting Very Small Size Status	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109
Conducting	$27,023,649	$17,474,027	$19,029,093	$6,825,791	$70,352,560

Investigative and Corrective Actions					
Grand Total Year 1	$141,004,674	$135,700,570	$82,679,697	$20,221,064	$379,606,006
Every Year After Year 1					
Hiring Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Writing and Maintaining Procedures Relating to Verification Requirements	$12,088,189	$15,662,637	$8,398,057	$1,738,360	$37,887,242
Following Procedures Relating to Verification Requirements	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534
Obtaining Written Assurances	$8,399,212	$2,427,067	$1,205,875	$567,962	$12,600,117
Documenting Very Small Size Status	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109
Conducting Investigative and Corrective Actions	$27,023,649	$17,474,027	$19,029,093	$6,825,791	$70,352,560
Grand Total Every Year After Year 1	$132,053,625	$130,360,769	$79,852,024	$19,898,432	$362,164,849

Benefits

Under this FSVP alternative, we would not require any importers to generate their own hazard identifications and evaluations and they would therefore be unable to confirm that the hazard controls put in place by foreign suppliers are adequate for all the hazards in the imported food. In addition, we would not require importers to investigate the reasons an imported food is not in compliance with applicable regulations and they would therefore be unable to identify the causes or causes of an imported food being out of compliance with applicable regulations. Any

benefits resulting from these would be lost under this alternative. We do not have sufficient information on the benefits generated by these activities to quantify that loss of benefits.

2. FSVP Alternative Two: Require Importers to Consider Foreign Supplier Hazard Control Activity Only

Another potential way we could reduce the costs of the FSVP proposed rule would be to eliminate the requirements that involve entities further back in the production and distribution process than the immediate foreign supplier. The two elements that involve or may involve such entities are the required information and hazard evaluation and the investigative and corrective action involving investigating the cause or causes of an imported food being out of compliance with applicable regulations. Restricting these requirements to immediate foreign suppliers would reduce the cost of these requirements.

We do not have sufficient information to determine the proportion of the costs that we estimated for these requirements in the analysis of the FSVP rule that are related to entities further back in the production and distribution process than the foreign supplier. However, the proportion is probably significant because the costs of these activities would vary with the number of entities that an importer would need to consider and a foreign supplier might deal with a number of other entities involved in various activities. To represent the significant reduction in the cost of this activity that would result from restricting this activity to foreign suppliers, we present in Table 38 the total costs of the FSVP regulation that we estimated in the analysis of FSVP Co-proposal Option 1 but with certain costs reduced by 50 percent. These are the cost of writing, maintaining, and following procedures relating to the required information and hazard evaluations and the cost of conducting the investigative and corrective action involving investigating the causes or causes of an imported food being out of compliance with applicable regulations.

Table 38. Alternative Two - Total Cost Summary for All Elements of the FSVP Proposed Regulation - All Entities

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					

Hiring Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Reviewing Food and Supplier Compliance Status	$19,052,700	$8,936,617	$4,670,641	$1,101,248	$33,761,206
Conducting Information Collection and Hazard Evaluations	$3,019,866	$4,000,950	$2,176,778	$459,150	$9,656,744
Writing and Maintaining Procedures Relating to Verification Requirements	$14,706,224	$19,054,818	$10,216,891	$2,114,851	$46,092,783
Following Procedures Relating to Verification Requirements	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534
Obtaining Written Assurances	$14,732,226	$4,374,687	$2,214,714	$514,105	$21,835,732
Documenting Very Small Size Status	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109
Conducting Investigative and Corrective Actions	$29,455,847	$15,538,301	$13,157,007	$4,194,886	$62,346,040
Obtaining and Providing DUNS Numbers	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Grand Total Year 1	$166,584,327	$147,631,775	$85,340,937	$20,228,912	$419,785,952
Every Year After Year 1					
Hiring Qualified Individuals	$4,195,611	$1,390,406	$775,269	$0	$6,361,287
Reviewing Food and Supplier	$19,052,700	$8,936,617	$4,670,641	$1,101,248	$33,761,206

compliance status					
Conducting Information Collection and Hazard Evaluations	$2,478,554	$3,204,187	$1,740,667	$365,485	$7,788,892
Writing and Maintaining Procedures Relating to Verification Requirements	$12,088,189	$15,662,637	$8,398,057	$1,738,360	$37,887,242
Following Procedures Relating to Verification Requirements	$74,388,544	$91,305,216	$49,381,697	$10,525,077	$225,600,534
Obtaining Written Assurances	$8,399,212	$2,427,067	$1,205,875	$567,962	$12,600,117
Documenting Very Small Size Status	$5,958,419	$2,101,416	$1,062,033	$241,241	$9,363,109
Conducting Investigative and Corrective Actions	$29,455,847	$15,538,301	$13,157,007	$4,194,886	$62,346,040
Obtaining and Providing DUNS Numbers	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194
Grand Total Every Year After Year 1	$157,055,012	$141,483,164	$82,070,457	$19,810,987	$400,419,620

Benefits

Under this FSVP alternative, we would not require importers to consider or investigate the activities of entities further back in the production and distribution process than their immediate foreign suppliers. Thus, importers would be unable to identify problems with these entities that are missed by the importer's foreign supplier. Any benefits resulting from this

capability would be lost under this alternative. We do not have sufficient information on the benefits generated by this capability to quantify that loss of benefits.

Reference List

1. U.S.Food and Drug Administration. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Proposed Rule. 78 FR 3646 January 16, 2013. http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm.

2. Bureau of Labor Statistics. Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates for NAICS 31100 - Food Manufacturing. http://www.bls.gov/oes/2010/may/naics3_311000.htm .

3. U.S.Food and Drug Administration. Preliminary Regulatory Impact Analysis for Proposed Rule on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. http://www.regulations.gov/contentStreamer?objectId=09000064811b427a&disposition=attachment&contentType=pdf or http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

4. Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, and et al. 2011. Foodborne Illness Acquired in the United States - Major Pathogens. Emerg Infect Dis. 2011 Jan; 17(1):7-15. http://wwwnc.cdc.gov/eid/article/17/1/pdfs/p1-1101.pdf

Appendix A

Initial Regulatory Flexibility Analysis for the Proposed Rule on Foreign Supplier Verification Programs (Docket No. FDA-2011-N-0143)

The Regulatory Flexibility Act requires a regulatory flexibility analysis (RFA) unless the Agency can certify that the proposed rule would have no significant impact on a substantial number of small entities. Because of the dynamic nature of food importing, large numbers of importers may enter and exit the market each year. We lack information to predict with certainty whether the proposed rule would have a significant economic impact on a substantial number of small entities. Because the number of small businesses affected is large, we are assessing the effects of this proposed rule on very small businesses. This document constitutes our Initial Regulatory Flexibility Analysis (IRFA). FDA will publish Small Entity Compliance Guides for this rule when it is finalized to address topics of most concern to small businesses that are likely to be affected by this rule.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. With fewer resources to devote to regulatory compliance, small entities may be more affected by regulatory compliance costs than larger entities. Alternatives that accommodate the needs of small entities buffer some of the impacts of regulation and reduce the chance that small entities would be forced to shut down in response to the proposed rule.

A. Need for the Rule

Along with other proposed rules aimed at strengthening the security of the food supply chain, this proposed rule focuses on controlling hazards to U.S. consumers that occur in foods imported into the United States. The analysis of impacts describes the different types of verification activities that importers would be required to conduct to ensure that they identify

hazards reasonably likely to occur in the finished food and food ingredients that they import and to exercise due diligence to ensure that these hazards are adequately controlled. Such verification reduces potential harm from imported foods or food ingredients.

B. Economic Effects on Small Businesses

1. Number of Affected Small Importers

The proposed rule would affect importers of food and food ingredients. We used FDA's OASIS data and Dun and Bradstreet data to estimate the number of importers and the size of these businesses based on the number of employees. The proposed rule requires different actions depending on what is imported, who the importer is, and who is supplying the imported food and food ingredient. The proposed rule sets forth a "standard" set of FSVP requirements and several exceptions to the standard FSVP requirements. For example, very small importers (VSI), and importers that only import from very small suppliers (VSS) would be subject to modified FSVP requirements. For example, we are proposing that for VSI and importers that only import from VSS the importer would not be required to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurance that includes a description of the processes and procedures the suppliers use to ensure the safety of the food.

A VSI is defined in the proposed FSVP rule to be an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. A VSS is defined in the proposed FSVP rule to be a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year

period (on a rolling basis) is no more than $500,000, adjusted for inflation. We based our estimate of the number of VSIs on the number of importers with high confidence D&B matches that had annual sales data with sales in FY10 of $500,000 or less. We then extrapolated to the universe of importers. We do not have information on the size characteristics of foreign suppliers. However, we estimated the number of such suppliers by using the size information on domestic suppliers that we used in the RIA of the PC rule and assuming that foreign suppliers would have similar size characteristics to domestic suppliers. Based on this approach, we estimated that 59 percent of foreign suppliers of products other than raw agricultural commodities and 93 percent of foreign suppliers of raw agricultural commodities would qualify as VSSs.

We use the OASIS data to estimate the probability that an importer would fall into one of the following categories: importers of dietary supplements, VSI, and VSS. Using these probabilities and adjusting to avoid double counting, we distribute the estimated 56,800 importers into categories by type of importer.

Table A1. Estimated Number of Importers by Type and Number of Employees

Type of Importer	< 20 Employees	20-99 Employees	100-499 Employees	500 or more Employees	Total Number of Importers	Share of Total
Dietary Supplement Importers	4,372	922	452	139	5,885	10%
Very Small Importers[1]	21,991	61	19	8	22,080	39%
Importers With Imports Only From Very Small Suppliers	545	263	164	66	1,038	2%
Remaining Food and Food Ingredient Importers	9,709	10,690	5,999	1,400	27,798	49%
Total--All Importers	**36,617**	**11,936**	**6,634**	**1,613**	**56,800**	**100%**

Estimates have been adjusted to avoid double counting and may not sum due to rounding.
[1] Our estimate includes those importers identified in the OASIS data with total sales reported in the Dun and Bradstreet data equal to or less than $500,000.

Dun and Bradstreet report up to six NAICS codes for each importer. This allows us to identify the industry classifications most frequently reported for importers in the OASIS system, but the data do not provide sufficient detail to determine the proportion of sales attributable to each of the industries listed. In many cases, food imports may account for only a small share of an importer's sales. These data show that importers can be classified into several hundred NAICS codes, covering almost every major industry subsector of the economy. However, the majority of importers fall into a few broad industry classes including Food Manufacturing (NAICS 311), Merchant Wholesalers (NAICS 423 and 424), Food and Beverage Stores (NAICS 445), and Administrative and Support Services (NAICS 561). It should be noted that some NAICS classes such as Administrative and Support Services cover companies delivering a mix of services to other businesses and may be intermediaries in the food supply chain. As food importers, however, these firms would be required to comply with the requirements of the proposed rule with respect to the food they import even if food imports represent a small fraction of their activity.

The U.S. Census Bureau classifies business firms into a single NAICS code based on their primary type of business. Depending on the NAICS code, the Small Business Administration defines businesses as "small" according to their number of employees or their annual sales. Firms may have multiple establishments conducting business in industries other than the industry of the parent firm or may receive revenue from activities spanning multiple industries. The Small Business Administration considers as small any Merchant Wholesaler with 100 or fewer employees. For the most part, food manufacturers employing 500 or fewer persons are considered small businesses by the Small Business Administration. However, there are some particular food manufacturing industry segments where the employee maximum is

higher (750 or 1,000 employees), such as NAICS 311821 (Cookie and Cracker Manufacturing) or NAICS 311230 (Breakfast Cereal Manufacturing). In contrast, SBA size standards for retail and service industries are based on annual sales. Table A2 shows the SBA size standards for the primary industry subsectors most frequently listed in the Dun and Bradstreet data for importers.

Table A2. Small Business Administration Size Standards for the Most Frequently Listed NAICS Codes for Food Importers Affected by the Proposed Rule

3-Digit NAICS Code and Description	Size Standard for Number of Employees	Size Standard for Sales (million)[1]
311 – Food Manufacturing	500 750 1000	
423 – Merchant Wholesalers, Durable Goods	100	
424 – Merchant Wholesalers, Nondurable Goods	100	
445 – Food and Beverage Stores		$7 $27 $30
561 – Administrative and Support Services		$7

[1] Based on Dun and Bradstreet data for U.S. sales for all firms meeting the Small Business Administration small size standard.

Dun and Bradstreet monitor the small business status of firms and include a flag in their data that indicates whether a firm meets the size definition for small entity. When publicly available, Dun and Bradstreet also report data on establishment-level employment, firm-level employment, and sales in the United States. We used the small business flag to tally the percentage of importers that might be small. According to Dun and Bradstreet records with a confidence score of 8 or higher and a small business indicator of "Yes" for the importer's primary industry, SBA could consider as small about 61 percent (=20,937 ÷ 34,162) of the importers listed in the OASIS system. We lack sufficient information to determine if the Dun and Bradstreet data underreports the small business status of importers or if non-food manufacturing importers are fundamentally different than food manufacturing importers.

Using the first NAICS code listed in the Dun and Bradstreet record, we calculated the average sales for all importers with the Dun and Bradstreet small business flag of "Y" for the most frequently listed 3-digit NAICS codes shown in Table A2. The percentage of importers in these NAICS codes that meet the Small Business Administration's size standards ranges from 55 percent for Food Manufacturing to 83 percent for Administrative and Support Services as illustrated in Table A3. The average sales of small importers for the 3-digit NAICS codes range from $0.4 million to $7.6 million.

Table A3. Small Importers by Most Frequently Listed NAICS Codes

3-Digit NAICS Code and Description	Average Annual Sales for Small Entities ($ million)[1]	Number Small Importers	Total Number of Importers	Percent Small Importers
311 – Food Manufacturing	$7.6	2,092	3,780	55%
423 – Merchant Wholesalers, Durable Goods	$2.8	719	973	74%
424 – Merchant Wholesalers, Nondurable Goods	$5.0	7,300	10,189	72%
445 – Food and Beverage Stores	$1.1	1,772	2,465	72%
561 – Administrative and Support Services	$0.4	1,243	1,493	83%
All Other Importers	$6.9	9,583	17,727	54%

[1] Based on D&B data for U.S. sales for all facilities with annual sales greater than $0 that met the Small Business Administration's size standard.

It is possible that small entities other than the domestic importers counted in this analysis will be affected by this rule. However, because our count of entities is based on current industry

practices of identifying importers, we believe that our counts reasonably reflect the number of entities that are likely to be importers for the purposes of the rule once the rule is in effect. We request comment on this matter.

2. Costs to Small Businesses

The proposed rule would require that importers have foreign supplier verification programs that provide assurances that imported food is produced using processes and procedures that afford the same level of public health protection as would compliance with the preventive controls or produce safety regulations and that imported food is produced in compliance with section 402 regarding adulteration and 403(w) regarding allergen labeling. The specific activities that an affected importer would need to perform depend on several factors, including whether the foreign supplier is inspected by FDA or a foreign food safety authority of a country with a food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, whether the importer or foreign supplier have annual sales of food that meet the "very small" definition, and whether the imported product is a dietary supplement. In some cases, the activities that the importer would need to perform would also depend upon factors such as the outcome of a hazard analysis and whether the foreign supplier, importer, or importer's customer controls identified hazards. To illustrate the potential impact of the proposed rule on small importers, we use lower and upper bound annualized average costs for the different types of importers presented in Table A1.

In general, the minimum set of requirements that an importer might need to take would include maintaining a list of foreign suppliers, ensuring identification of the importer at the border, and maintaining records in English and making them available to the agency. Importers

of dietary supplements and dietary supplement components who establish and verify compliance with certain specifications (concerning dietary supplement components, labels, packaging, and labeling) would be required to comply with this set of requirements. The same would apply to importers whose customer is required to establish such specifications and verify that they are met, except that the importer would have to obtain written assurance that its customer is complying with those requirements.

In addition to the minimum set of requirements, importers of food from countries whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States would also determine whether their foreign supplier is in good compliance standing with the applicable food safety authority, and conduct certain investigations and corrective actions. Furthermore, the importer must document that the foreign supplier is under the regulatory oversight of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent and that the food is within the scope of the official recognition or equivalence determination. Similarly, importers that meet the definition of very small importer or who import food from a very small supplier (i.e., an importer or supplier having average annual sales of food equaling or less than $500,000) would review the compliance status of the food and the foreign supplier of the food, obtain written assurance of foreign supplier compliance at least every 2 years, and conduct certain investigations and corrective actions. Furthermore, each year these importers would need to document that they or their foreign suppliers have sales of food that do not exceed the threshold for very small importer or very small supplier each year.

Importers of finished dietary supplement would need to conduct most of the standard FSVP requirements, but they would not have to conduct hazard analyses, and their supplier

verification activities would focus on verifying that the supplier is in compliance with the dietary supplement CGMP regulations, rather than verifying that hazards identified as reasonably likely to occur are being adequately controlled.. All other importers of food and food ingredients subject to the proposed rule would be subject to all of the standard FSVP requirements of the proposed rule. Tables A4a and A4b illustrate the potential burden of the two options of the proposed rule based on the estimated lower and upper bound annualized average costs to comply with the requirements of the proposed rule for small establishments with (1) fewer then 20 employees, (2) 20 to 99 employees, and (3) 100 to 499 employees. Table 30 of the Preliminary Regulatory Impact Analysis provides information on the total cost to all small establishments within a size category for each element of the FSVP proposed rule. Under Option 1 of the co-proposal average annualized costs range from about $210 to $13,380 for importers with fewer than 20 employees, and range from about $490 to $17,560 for importers with 100 to 499 employees. Under Option 2 of the co-proposal average annualized costs range from about $210 to $13,210 for importers with fewer than 20 employees, and range from about $480 to $17,270 for importers with 100 to 499 employees.

We aggregate the costs regardless of who performs the required action. As discussed elsewhere, some actions, such as onsite audits, may be conducted by the foreign supplier. However, we expect that the market would adjust and in many cases suppliers would pass on their onsite audit costs to the importers they supply. Small importers might lack market power to refuse such charges from foreign suppliers (although the modified requirements for a VSI do not include an onsite audit). However, importers of food from suppliers dealing with multiple importers would effectively reduce their regulatory costs from onsite audits as long as the supplier shared its costs with all of its customers. This could encourage importers to switch from

small foreign suppliers to larger foreign suppliers (although the modified requirements for food imported from a VSS do not include an onsite audit). Smaller suppliers who lack market power would have an incentive to absorb some or all onsite audit costs, if any, to compete with larger suppliers.

Table A4a. Average First Year and Annual Costs by Type of Importer and Number of Employees, Option 1

<20 Employees	Average First Year Cost	Annual After First Year	Annualized Costs With 7 Percent Discount Rate
Type of Importer			
All Dietary Supplement Importers	$186	$183	$209
Very Small Importer	$2,872	$2,782	$3,191
Importer Subject to Standard FSVP Requirements –Lower Bound	$2,580	$2,576	$2,944
Importer Subject to Standard FSVP Requirements –Upper Bound	$12,546	$11,589	$13,376
20 to 99 Employees	Average First Year Cost	Annual After First Year	Annualized Costs With 7 Percent Discount Rate
Dietary Supplement Importer	$262	$260	$297
Very Small Importer	$4,277	$4,137	$4,746
Importer Subject to Standard FSVP Requirements –Lower Bound	$3,903	$3,879	$4,436
Importer Subject to Standard FSVP Requirements – Upper Bound	$14,652	$13,901	$15,988
100 to 499 Employees	Average First Year Cost	Annual After First Year	Annualized Costs With 7 Percent Discount Rate
Dietary Supplement Importer	$431	$428	$490
Very Small Importer	$5,824	$5,702	$6,532
Importer Subject to Standard FSVP Requirements –Lower Bound	$5,466	$5,455	$6,234
Importer Subject to Standard FSVP Requirements – Upper Bound	$15,986	$15,279	$17,555

Table A4b. Average First Year and Annual Costs by Type of Importer and Number of Employees, Option 2

<20 Employees	Average First Year Cost	Annual After First Year	Annualized Costs With 7 Percent Discount Rate
Type of Importer			
Dietary Supplement Importer	$184	$181	$206
Very Small Importer	$2,839	$2,748	$3,152
Importer Subject to Standard FSVP Requirements –Lower Bound	$2,550	$2,545	$2,908
Importer Subject to Standard FSVP Requirements –Upper Bound	$12,401	$11,447	$13,213
20 to 99 Employees	Average First Year Cost	Annual After First Year	Annualized Costs With 7 Percent Discount Rate
Dietary Supplement Importer	$257	$255	$292
Very Small Importer	$4,202	$4,062	$4,750
Importer Subject to Standard FSVP Requirements –Lower Bound	$3,834	$3,808	$4,355
Importer Subject to Standard FSVP Requirements – Upper Bound	$14,397	$13,648	$15,697
100 to 499 Employees	Average First Year Cost	Annual After First Year	Annualized Costs With 7 Percent Discount Rate
Dietary Supplement Importer	$424	$421	$482
Very Small Importer	$5,824	$5,702	$6,425
Importer Subject to Standard FSVP Requirements –Lower Bound	$5,380	$5,366	$6,132
Importer Subject to Standard FSVP Requirements – Upper Bound	$15,735	$15,030	$17,269

3. Regulatory Flexibility Options

The proposed rule would affect importers of food and food ingredients. We used FDA's OASIS data and Dun and Bradstreet data to estimate the number of importers and the size of these businesses based on the number of employees. The proposed rule requires different actions depending on what is imported, who the importer is, and who is supplying the imported food and

food ingredient. The proposed rule sets forth a "standard" set of FSVP requirements and several exceptions to the standard FSVP requirements. For example, very small importers (VSI), and importers that only import from very small suppliers (VSS) would be subject to modified FSVP requirements. For example, we are proposing that for VSI and importers that only import from VSS the importer would not be required to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurance that includes a description of the processes and procedures the suppliers use to ensure the safety of the food.

A VSI is defined in the proposed FSVP rule to be an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. A VSS is defined in the proposed FSVP rule to be a foreign supplier, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation.

Tables A4a and A4b show the costs to very small importers and very small suppliers with modified requirements.

FDA requests comment on other means of reducing the cost of compliance for small entities, such as giving some small entities more time to comply with the rule, while still accomplishing the public health goals of the rule.

4. Special Skills Required and Recordkeeping

Depending on the type of food and importer, the proposed rule would require that small importers write and maintain procedures, perform certain hazard analysis and supplier

verification actions, and conduct certain investigations and corrective actions when needed. Many provisions would require that a qualified individual perform the action. Because importers generally already perform many of the required tasks, we anticipate that firms have personnel adequately trained to perform many of the required actions. However, we anticipate that many small importers lack this required expertise. For these small importers, we expect that it would be less costly to pay an outside source for such expertise than to train an existing employee or to hire a new employee, and our cost estimates assume that they will hire qualified outside sources to perform these tasks.

Many activities required by the proposed rule include recordkeeping. Importers have a responsibility to maintain records in English and make them available to the agency. In addition to records established and maintained by the importer, records may be provided to importers from suppliers or the importer's customers. Tables 11, 12, 13, 14, 15, 17, 21, 22, 23, 24, and 25 of the Preliminary Regulatory Impact Analysis include estimates related to recordkeeping.

5. Burden of the Proposed Rule on Small Entities

To illustrate the potential burden of the proposed rule, Tables A5a and A5b present annualized average costs as a percentage of the average annual sales for the most frequently listed 3-digit NAICS codes. To calculate the burden, we use the average annual sales from Table A3 and the per-establishment annualized average costs from Tables A4a and A4b. The costs for very small importers and importers of food from very small suppliers, as defined by the proposed rule, and dietary supplement importers that are subject to and in compliance with certain CGMP regulations for establishing and verifying specifications for dietary supplements are substantially lower than the costs for most other importers. Using average annual sales for small importers in

the most frequently listed NAICS codes could overstate the impact on very small importers as defined by the proposed rule, that also meet the SBA definition of a small entity. Because the average annual sales for NAICS 561 (Administrative and Support Services) total about $0.4 million, we use this industry as a proxy to provide a reasonable estimate of the potential burden on small entities that also meet the definition of very small importer. Moreover, as discussed previously, using costs based on the average number of products imported for a certain size of importer may also overstate the impact on entities that import fewer products than the average number of products.

The burden of the proposed rule would exceed one percent of average annual sales, a significant economic effect in this industry, for importers in the retail trade industry and certain very small importers. Although a rough estimate of the potential burden on small importers, this suggests that some small entities could be impacted significantly by this proposed rule. Moreover, using average sales for broad industry groups may understate the burden on the smallest importers. We request detailed comment from industry about our estimate.

Table A5a. Estimated Burden on Importers by Employment Size [1]

Industry 3-Digit NAICS Code	Lower Bound for Importers with <20 Employees	Lower Bound for Importers with 20-99 Employees	Lower Bound for Importers with 100-499 Employees	Upper Bound for Importers with <20 Employees	Upper Bound for Importers with 20-99 Employees	Upper Bound for Importers with 100-499 Employees
423	0.1%	0.2%	N.A.	0.5%	0.6%	N.A.
424	0.1%	0.1%	N.A.	0.3%	0.3%	N.A.
445	0.3%	0.4%	0.6%	1.2%	1.5%	1.6%
Other Importer	0.0%	0.1%	0.1%	0.2%	0.2%	0.3%

[1] Based on the average annual sales from Table A3 and the average annualized costs from Tables A4a and A4b for importers subject to the standard FSVP requirements.

Table A5b. Estimated Burden on Very Small Importers by Employment Size [2]

Industry 3-Digit NAICS Code	Lower Bound for Importers with <20 Employees	Lower Bound for Importers with 20-99 Employees	Lower Bound for Importers with 100-499 Employees	Upper Bound for Importers with <20 Employees	Upper Bound for Importers with 20-99 Employees	Upper Bound for Importers with 100-499 Employees
561	0.1%	0.1%	0.1%	0.8%	1.2%	1.6%

[2] Based on the average annual sales from Table A3 and the average annualized costs from Tables A4a and A4b.

We lack information on the impact that these potential regulatory costs might have on the behavior of importers. Some affected small firms import many other products than food and food ingredients and could exit food importing should the regulatory costs cause negative profits for food imports. Other small importers primarily import food, and it is possible that some small importers would be forced to shut down or look for other importing markets. Moreover, the regulatory costs of this proposed rule are further likely to discourage some small businesses from entering the food importing market. The food industry, including the food importing sector, is characterized by substantial and frequent entry of small businesses. Although we cannot quantify how much that will change, we expect that the rate of entry of small businesses could

decrease. Finally, as previously discussed, the proposed rule may affect the relationship between foreign suppliers and domestic importers. However, we cannot predict how such changes may affect the composition of importers and foreign suppliers. We request comment from affected small importers about the potential burden of the proposed requirements on their businesses.

Initial Regulatory Flexibility Analysis for the Proposed Rule on Accredited Third-Party Audits (Docket No. FDA-2011-N-0146)

The Regulatory Flexibility Act requires a regulatory flexibility analysis (RFA) unless the Agency can certify that the proposed rule would have no significant impact on a substantial number of small entities. Foreign food and feed exporters whose products are subject to a safety determination under §801(q) of the FD&C Act will be required to obtain certification under the Third Party proposed rule to gain admissibility of such products. In addition to the §801(q) entities, other foreign food and feed exporters or importers may voluntarily choose to comply with the Third Party proposed rule. These food and feed exporters and importers are not considered in this RFA.

The Regulatory Flexibility Act also requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. With fewer resources to devote to regulatory compliance, small entities may be more affected by regulatory compliance costs than larger entities. Alternatives that accommodate the needs of small entities would reduce the impacts of regulation and likelihood that small entities would be forced to shut down in response to the proposed rule.

A. Need for the Rule

The Third Party proposed rule, along with other proposed rules authorized by the FDA Food Safety Modernization Act (FSMA), aims at strengthening the security of the food supply chain.

Under this proposed rule, we will recognize accreditation bodies (ABs) to accredit third-party auditors/certification bodies (CBs), except for limited circumstances in which we may directly accredit CBs to participate in the accredited third-party audits and certification program. Having comprehensive oversight of a credible and reliable program for third-party audits and certifications of foreign food facilities will help FDA prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. We believe that a trusted program for foreign food safety audits and food and facility certifications--with clear requirements, standards, and procedures and operated under government oversight--will be appealing to accreditation bodies, auditors/certification bodies, and foreign food facilities. Widespread participation and broad acceptance of audits and certifications under the FDA program will help increase efficiency and reduce costs, by eliminating redundant auditing to assess foreign suppliers' compliance with the FD&C Act.

Specifically, we will use certifications issued by accredited third-party auditors/certification bodies in deciding whether to admit certain imported food into the United States that FDA has determined poses a food safety risk and in deciding whether an importer is eligible to participate in a program for expedited review and entry of food imports. B.

Economic Effects on Small Businesses

1. Number of Affected Small Importers

In Appendix B of the combined PRIA of the FSVP and Third Party proposed rules and for purposes of the analysis, we estimated that approximately 10,035 foreign food and feed firms export food that may be subject to an FDA determination of food safety risk under §801(q) of the FD&C Act. We currently do not have data on the size of these entities. For the purpose of this

analysis, we assume they are distributed in size the same as U.S. food and feed producers. Small Business Administration (SBA) considers a food or feed production facility as small if it employs less than 500 employees. Consequently, by SBA definition, approximately 95% of these entities, or 9,533 foreign food and feed exporters would be considered small.

2. Costs to Small Businesses

Using the data in Tables B3a and B3b in Appendix B, we estimate that the average incremental cost to eligible entities whose food FDA has determined poses a food safety risk and must be certified to be admitted into the U.S. under §801(q) of the FD&C Act and the Third Party proposed rule is approximately $987 per year for FSVP co-proposal Option 1 ($982 per year for FSVP co-proposal Option 2). Therefore, on average, annual cost to all small businesses whose food is subject to an FDA safety determination and must be certified under §801(q) of the FD&C Act is approximately $9,409,071 ($987/entity x 9,533 entities) for FSVP co-proposal Option 1 ($9,361,406 under FSVP co-proposal Option 2).

3. Regulatory Flexibility Options

We have not considered additional regulatory options for small businesses whose food may require certification under §801(q) of the FD&C Act, because, by definition, these entities would be producing food or feed that FDA has determined pose a safety risk and must be certified as a condition of its admission into the U.S. In addition, we could not consider additional regulatory options related to the frequency of recertification, such as requiring recertification every two years rather than annually, because section 808(d) of the FD&C Act requires that eligible entities apply for annual recertification if the entity is required to provide to

FDA a certification under section 801(q) for any food from such entity.[9] We request comments on any regulatory options that would potentially reduce the regulatory burden of small businesses under the Third Party proposed rule.

4. Special Skills Required and Recordkeeping

There are no special skills required by small businesses whose food may be subject to a certification requirement under §801(q) of the FD&C Act. Eligible entities that are required to obtain a certification for food FDA has determined to pose a food safety risk under section 801(q) must apply to be recertified, which includes obtaining food safety audits by third party auditors/CBs, on an annual basis. Third party auditors/CBs and ABs bear the responsibility of improved recordkeeping and reporting procedures under the Third Party proposed rule.

5. Burden of the Proposed Rule on Small Entities

As we discussed for purposes of this analysis, we are estimating that 5% of all foreign food and feed exporters, or 10,035 food and feed exporters, would have food determined by FDA to pose a food safety risk and required to have certification under §801(q) of the FD&C Act and incur an annual total compliance cost of approximately $9,409,071 for FSVP co-proposal Option 1 ($9,361,406 under FSVP co-proposal Option 2). Average compliance cost for an eligible entity whose food was subject to an FDA safety determination and a certification requirement under §801(q) of the FD&C Act is approximately $987 for FSVP co-proposal Option 1 ($982 for FSVP co-proposal Option 2) (see Appendix B of the combined PRIA for the FSVP and Third Party proposed rules).

According to the International Trade Commission, in FY 2011, approximately $82.7 billion of food and feed was exported to the U.S. (see Table D2 in Appendix D of the RIA

[9] Under section 801(q) of the FD&C Act, FDA may require recertification at any time. Recertification at frequency other than annual recertification under section 808 of the FD&C Act is outside the scope of this Third-Party proposed rule and, thus, outside the scope of this RFA.

of the combined analysis). Assuming that foreign food and feed exporters whose food would be subject to an FDA safety determination and a certification requirement under §801(q) of the FD&C Act proportionally export the same value of food and feed to the U.S. as food and feed exporters with foods not subject to an FDA safety determination and certification requirement under §801(q), on average, each eligible entity with food subject to an FDA safety determination and a certification requirement under §801(q) exports food and feed valued at approximately $412,058 (($82.7 billion x 5%) ÷ 10,035 entities) to the U.S. each year. On average, estimated compliance cost of $987 per year for an eligible entity (in the case of FSVP co-proposal Option 1) whose food is subject to an FDA safety determination and a certification requirement under §801(q) of the FD&C Act constitutes approximately 0.24% of its total revenue ($987 ÷ $412,058). On average the compliance burden on foreign food and feed exporter whose food is subject to a certification requirement under §801(q) of the FD&C Act is not a significant percentage of average revenue. However, it is possible that some foreign food and feed exporters on the very small end of the size distribution may be significantly affected. While we believe the number to be small, we do not have data that would allow us to estimate the number of firms might be significantly affected by the compliance burden of being subject to 801(q) of the FD&C Act. We request comments on estimation of burden to the small businesses whose foods FDA would determine to pose a food safety risk and require certification to be admitted under §801(q) of the FD&C Act.

Appendix B

This appendix provides substantial documentation of the estimation of the costs of the Third-Party proposed rule. These costs of the Third-Party proposed rule are included in the summary of costs at the beginning of the combined analysis and the cost saving effects of the Third-Party proposed rule are factored into the analysis of costs of the FSVP proposed rule.

With respect to the FSVP proposed rule, this analysis reflects that the proposed rule includes a "co-proposal" for two alternative approaches to certain requirements for foreign supplier verification activities. Under Option 1 of the co-proposal, if the foreign supplier controls a hazard in a food at its establishment and there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA), the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier at least annually thereafter (possibly more frequently if necessary to adequately verify control of the hazard). For non-SAHCODHA hazards that the foreign supplier controls, the importer would be required to conduct one of more of the following verification activities before using or distributing the food and periodically thereafter: onsite auditing of the foreign supplier, sampling and testing, review of the supplier's food safety records, or some other procedure that the importer has established as appropriate based on the risk associated with the hazard. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard and the food and foreign supplier's compliance status. This requirement would also apply, under Option 1, when the foreign supplier verifies control of a hazard by its ingredient or component supplier, rather than directly controlling the hazard itself.

Under Option 2 of the co-proposal, for all hazards that the foreign supplier will either control or verify control by its supplier, importers would need to choose a verification procedure from among onsite auditing, sampling and testing, review of supplier food safety records, or some other appropriate procedure. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the food and foreign supplier's compliance status.

The proposed rule sets forth a similar co-proposal regarding supplier verification for certain raw agricultural commodities that are fruits or vegetables. Option 1 would require, in addition to the other verification, onsite auditing to verify control of microbiological hazards in such produce, while under Option 2 the importer would select a verification activity from the list of possible procedures set forth above.

The only difference that those two different options have for the analysis of the Third-Party proposed rule is that we estimate that fewer importers will use third party audits, conducted by auditors/certification bodies accredited under the FDA program, in meeting FSVP requirements under Option 2 of the FSVP co-proposal. Throughout this appendix where the different FSVP options have different effects on the calculations for the Third-Party proposed rule we will provide two versions of tables ("a" and "b" versions). Tables labeled "a" (e.g., Table B1a) correspond to FSVP co-proposal, Option 1, and tables labeled "b" (e.g., Table B1b) correspond to FSVP co-proposal Option 2.

Entities Affected by the Third-Party Proposed Rule

The coverage of the Third-Party proposed rule includes eligible entities seeking audits, certification, and/or recertification by accredited auditors/certification bodies (CBs) participating

in our program, accreditation bodies (ABs) voluntarily seeking to comply with the recognition requirements of the Third-Party proposed rule, and auditors/CBs voluntarily seeking to comply with the accreditation requirements of the Third-Party proposed rule (including those accredited by recognized ABs and those directly accredited by us to conduct food safety audits).

Eligible entities

An eligible entity is a foreign entity that offers its food or feed for import to the U.S. and that seeks a food safety audit and possibly certification under the requirements for eligible entities under the Third-Party proposed rule. Eligible entities include foreign suppliers as defined in the FSVP proposed rule, as well as those who are excluded from FSVP, such as those subject to the seafood and juice HACCP regulations. Based on OASIS data, we estimate that there are 200,692 foreign food and feed exporters that offer their food and feed for import into the U.S. These foreign food and feed exporters include 129,757 food and feed production facilities and 70,935 farms.

A proportion of these foreign food and feed exporters may offer food subject to mandatory certification requirements under §801(q) of the FD&C Act. (§ 801(q) entities). In that case, the foreign food and feed exporters must either comply with the Third-Party proposed rule in order to obtain certification from an accredited auditor/CB to gain admission of their food or feed products subject to mandatory certification into the U.S. or lose access to U.S. markets. Where we have designated a foreign government to issue certifications for purposes of section 801(q) of the FD&C Act, the certification alternatively may be secured from a designated government. In our cost estimates, we assume that foreign food and feed exporters offering food subject to §801(q) of the FD&C Act represent 5% of all foreign food and feed exporters, or

10,035 (5% x 200,692) foreign food and feed exporters, and that they will choose to comply with the Third-Party proposed rule and become eligible entities (see Tables B1a and B1b).

Some foreign food and feed exporters currently receive third-party food safety audits from accredited or unaccredited auditors/CBs to satisfy requirements set forth under other government or private programs, prior to implementation of our program. We estimate the number of foreign suppliers that would conduct audits, under Option 1 of the FSVP proposed rule, without consideration of whether they are already conducting audits. In the FSVP analysis, we estimated that the proportion of hazards and products that would induce a foreign supplier to choose audits is 101% (or multiple factor of 1.01; see Table 15) of number of hazards that triggers mandatory onsite audits. Therefore, we believe that 22,390 foreign suppliers (22,168 x 101%) choose audits as a primary verification activity. Finally, we estimate the number of foreign suppliers that would perform audits as a secondary verification activity in conjunction with a primary activity (record review or testing) which they have chosen from the menu of verification activities in the FSVP proposed rule. We believe that number of foreign suppliers who choose record review or testing as primary verification activity and audits as a secondary activity is equal to 13% (see Table 13) of foreign suppliers who choose audits as a primary activity. Therefore, we estimate that approximately 2,911 foreign suppliers (22,390 x 13%) will choose audits as secondary activity. Overall, we estimate that 47,469 foreign suppliers (22,168 + 22,390 + 2,911) will choose to perform annual food safety audits to satisfy verification requirements of the FSVP proposed rule.

Based on the above calculations, we estimate that 47,469 foreign suppliers under FSVP analysis of co-proposal, Option 1 (or 43,364 for FSVP co-proposal, Option 2) will be required to have third-party food safety audits to satisfy onsite audit requirements of the proposed FSVP

rule. We assume that these foreign suppliers will also choose to comply with the requirements of the Third-Party proposed rule, thus meeting the definition of eligible entities.

Table B1a: Option 1 - Foreign Food and Feed Exporters, Eligible Entities, FSVP-Compliant Foreign Suppliers Certified by Certification Bodies (CBs)[10] Under the Third-Party Proposed Rule

Certified by	Foreign Food and Feed Exporters	Eligible Entities	
		801(q) Entities	FSVP Entities
Accredited CBs	26,007	1,305	6,171
Unaccredited CBs or No Audits	174,685	8,730	41,298
Total	**200,692**	**10,035**	**47,469**

Table B1b: Option 2 - Foreign Food and Feed Exporters, Eligible Entities, FSVP-Compliant Foreign Suppliers Certified by CBs Under the Third-Party Proposed Rule

Certified by	Foreign Food and Feed Exporters	Eligible Entities	
		801(q) Entities	FSVP Entities
Accredited CBs	26,007	1,305	5,637
Unaccredited CBs or No Audits	174,685	8,730	37,727
Total	**200,692**	**10,035**	**43,364**

Currently some foreign food and feed exporters receive their audits from unaccredited auditors/CBs. A study by the Research Triangle Institute (RTI) (Ref. 5) estimates that 26,007 foreign food and feed exporters, or about 13% of all foreign food and feed exporters, currently receive third-party food safety audits by accredited auditors/CBs (see Appendix C). The remaining 174,685 (200,692 – 26,007) foreign food and feed exporters either currently receive their audits from unaccredited auditors/CBs or currently do not obtain third-party food safety audits. For the purpose of this analysis we need to estimate the number of foreign food and feed exporters already using accredited auditors/CBs and that will choose to become eligible entities; they will have lower costs of compliance with the Third-Party proposed rule than eligible entities

[10] To make the tables in Appendix B easier to read, we are use the abbreviation "CB" when referring to "auditors/certifications bodies" within the tables.

that either currently receive audits from unaccredited auditors/CBs or currently do not obtain third party food safety audits.

For purposes of this analysis we assume that the percentage of eligible entities that will have foods subject to §801(q) of the FD&C Act is 1% to 5%. Furthermore we assume that within that 1% to 5% of eligible entities the proportion of receiving food safety audits and certification from accredited auditors/CBs is the same as the proportion of all foreign food and feed exporters who are currently obtaining food safety audits/certificates from accredited auditors/CBs. In other words, we estimate the number of eligible entities currently receiving food safety audits/certificates from accredited auditors/CBs at 1,305 (13% x 10,035 eligible entities) and that the remaining 8,730 eligible entities (10,035 – 1,305) obtain third party food safety audits/certificates from unaccredited auditors/CBs.

Based on that estimate, we project that 13% of foreign suppliers, or 6,171 (13% x 47,469 foreign suppliers) foreign suppliers under FSVP co-proposal, Option 1 (or 5,637 foreign suppliers under FSVP co-proposal, Option 2), who will be subject to onsite audit requirements under the proposed FSVP rule, will be audited by auditors/CBs accredited under our program. The remaining foreign suppliers needing onsite audits (41,298 for FSVP co-proposal, Option 1, and 37,727 for FSVP co-proposal, Option 2) would obtain their onsite audits from unaccredited auditors/CBs. Tables B1 include estimates of foreign food and feed exporters, §801(q) entities, FSVP-compliant foreign suppliers and accreditation status of their certifiers.

Accreditation Bodies and Auditors/Certification Bodies

Based on data we reviewed, there are currently 71 ABs operating globally that accredit third-party auditors/CBs for food safety. (Ref. 5) Two of the 71 ABs are represented by two

countries that currently do not have trade relations with the U.S. Hence, we estimate that 69 ABs will apply to be recognized (see Appendix D).[11]

Using the results of a survey of a sample of ABs (Ref. 5), we estimate that there are 568 accredited auditors/CBs specializing in food safety audits. So on average, we estimate that each of these accredited auditors/CBs certifies approximately 46 foreign food facilities per year (see Appendix C).

We expect that the estimated 50,028 (8,730 + 41,298 foreign facilities for FSVP co-proposal, Option 1) (or 46,457 for FSVP co-proposal, Option 2) (see Tables B1) that currently obtain food safety audits/certificates from unaccredited auditors/CBs will seek audits under our program. Therefore, we expect that demand for food safety audits will increase for currently accredited auditors/CBs that become accredited under our program. We anticipate that that this demand will affect the industrial organization aspect of accredited third-party audit market in two ways: 1) it will lead to increased number of clients for currently accredited auditors/CBs who will become accredited under our program, and/or 2) auditors/CBs that are not currently accredited will be induced to become accredited under our program. Below, we consider a scenario where a combination of these two effects would potentially bring about a change in the accredited third-party audit market.

As the demand for accredited third-party audits by accredited auditors/CBs grows, accredited auditors/CBs have an incentive to expand and take on more clients. If for the purposes of this analysis we assume that current auditors'/CBs' client-base increases by 25% once they are accredited under our program, then the number of foreign food and feed exporters for which they provide food safety audits/certificates increases from 26,007 to 32,509 (26,007 x 125%).

[11] In addition, we expect 4 auditors/CBs to potentially apply for direct accreditation.

The average number of clients per accredited auditor/CB increases from 46 (see Appendix C) to approximately 57 (32,509 foreign food and feed exporters ÷ 568 accredited CBs[12]). As a result, 6,502 eligible entities (32,509 – 26,007) that currently obtain their food safety audits from unaccredited auditors/CBs can potentially obtain audit services from auditors/CBs accredited under our program. The remaining 43,526 eligible entities for FSVP co-proposal, Option 1 (50,028 – 6,502) (or 39,955 eligible entities for FSVP co-proposal, Option 2) that currently obtain third party audits from unaccredited auditors/CBs will receive their food safety audits by 764 currently unaccredited auditors/CBs for FSVP co-proposal, Option 1 (43,526 eligible entities ÷ 57 eligible entities/CB) (or 701 currently unaccredited auditors/CBs for FSVP co-proposal, Option 2) that will choose to become accredited by recognized ABs once the program is implemented.

FDA has authority to directly accredit third-party auditors/CBs only in limited circumstances. In those circumstances, auditors/CBs may meet the criteria to become directly accredited by FDA. In this analysis, we assume that circumstances will allow FDA to make the determination necessary to invoke direct accreditation authority and that four auditors/CBs will satisfy the criteria for direct accreditation.

We request comments on how we estimated the number of unaccredited auditors/CBs who choose to become accredited under our program. Tables B2 includes number of ABs and auditors/CBs that would potentially be affected by the Third-Party proposed rule.

[12] To make formulas contained in the narrative easier to read, we use the term "CB" to refer to "auditors/certification bodies" in narrative formulas in Appendix B.

Table B2a: Option 1 - Number of Accreditation Bodies (ABs) and CBs

Status of ABs/CBs	Number of ABs/CBs
ABs seeking recognition under the Third-Party proposed rule	69
ABs not seeking recognition under the Third-Party proposed rule	2
Total – ABs	**71**
Currently accredited CBs choosing to comply with the Third-Party proposed rule	568
Unaccredited CBs choosing to comply with the Third-Party proposed rule	764
CBs eligible for direct accreditation by FDA	4
Total – CBs	**1,336**

Table B2b: Option 2 - Number of ABs and CBs

Status of ABs/CBs	Number of ABs/CBs
ABs seeking recognition under the Third-Party proposed rule	69
ABs not seeking recognition under the Third-Party proposed rule	2
Total – ABs	**71**
Currently accredited CBs choosing to comply with the Third-Party proposed rule	568
Unaccredited CBs choosing to comply with the Third-Party proposed rule	701
CBs eligible for direct accreditation by FDA under the Third-Party proposed rule	4
Total – CBs	**1,273**

Economic Costs of Compliance with the Third-Party Proposed Rule

Mandatory Compliance: Eligible Entities with Food Subject to §801(q) of the FD&C Act

A regulatory audit of an eligible entity is conducted to determine whether the entity is in compliance with the provisions of the FD&C Act, and may be certified per requirements of the Third-Party proposed rule. Section 1.681 of the Third-Party proposed rule requires that eligible entities seeking to maintain certification under subpart M apply for recertification on an annual basis (or sooner, if required by the accredited auditor/CB). As a baseline, we assume that all eligible entities currently being audited are audited on at least an annual basis to comply with other regulations or private market verification requirements. We believe the cost of certification primarily depends on the size and nature of operation of the facility and on whether the auditor/CB is accredited or not. Current costs of certification and recertification by accredited auditors/CBs are estimated at approximately $1,200 per day. According to industry experts, most food safety audits last 3 days at a cost of total $3,600. (Ref. 6)

We currently do not have information on the cost for eligible entities that are currently being audited by unaccredited auditors/CBs. We assume that a food/feed processing facility or farm would—unless its customers required an accredited auditor/CB—typically be audited by an unaccredited auditor/CB because it is cheaper to do so (e.g., the auditor/CB would not pass along the costs associated with accreditation and implementation of measures to satisfy AB requirements). We assume that charges of certification and recertification services by unaccredited auditors/CBs are 25% less or $900 (25% x $3,600) than those charged by accredited auditors/CBs. Therefore, we believe that it would take an additional $900 per year for an eligible entity to switch their food safety audits by an unaccredited auditor/CB to a currently accredited auditor/CB (without accounting for additional costs associated with accreditation under our program). In addition, compliance costs of ABs and currently accredited auditors/CBs with the Third-Party proposed rule would amount to approximately $204 per year per eligible entity for FSVP co-proposal, Option 1 (or $199 per year per eligible entity for FSVP co-proposal, Option 2) (see Appendix E). Under these assumptions, the total cost for an eligible entity to switch from an unaccredited auditor/CB to one accredited under the Third-Party proposed rule is $1,104 ($900 + $204) for FSVP co-proposal, Option 1 (or $1,099 for FSVP co-proposal, Option 2). Unit costs for conformance to the Third-Party proposed rule by eligible entities are included in Tables B3.

Table B3a: Option 1 - Unit Costs of Conformance to the Third-Party Proposed Rule – Eligible Entities

Description	Unit Cost
Additional cost for entity to switch from an unaccredited CB to an accredited CB	$900
Additional compliance costs by ABs and CBs passed on to eligible entities*	$204
Total Cost - Eligible Entity currently audited by unaccredited CB	**$1,104**
Total Cost - Eligible Entity currently audited by accredited CB	**$204**

* Assume 100% cost pass-through.

Table B3b: Option 2 - Unit Costs of Conformance to the Third-Party Proposed Rule – Eligible Entities

Description	Unit Cost
Additional cost for entity to switch from an unaccredited CB to an accredited CB	$900
Additional compliance costs by ABs and CBs passed on to eligible entities*	$199
Total Cost - Eligible Entity currently audited by unaccredited CB	**$1,099**
Total Cost - Eligible Entity currently audited by accredited CB	**$199**

* Assume 100% cost pass-through.

For purposes of this analysis, we assume that the proportion of potential §801(q) entities constitutes 5% of all foreign food and feed exporters, or 10,035 §801(q) entities (5% x 200,692 foreign food and feed exporters). In the Sensitivity Analysis section below, we consider the effect in economic costs under different scenarios where the proportion of the §801(q) entities is at 1% and 10% of all foreign food and feed exporters. We will be making case-by-case determinations to require certification under section 801(q) of the FD&C Act. We currently are considering possible circumstances under which we might use this authority. Though no conclusions have been reached, we anticipate using it only in limited circumstances--well within the range of scenarios considered in the Sensitivity Analysis.

Table B4 includes the annual cost of approximately $10 million (at 7% discount rate) for the estimated 10,035 entities whose food would be subject to a mandatory certification requirement under §801(q) of the FD&C Act. Average annual cost of conforming to the Third-Party proposed rule for an eligible entity whose food is subject to §801(q) of the FD&C Act is

approximately $987 for FSVP co-proposal, Option 1 (($204 * 13%) + ($1,104 * 87%) (or $982 per year per eligible entity for FSVP co-proposal, Option 2).

Voluntary Compliance: Eligible Entities Complying with the FSVP Proposed Rule

Based on our analysis of the FSVP proposed rule we estimate that 47,469 foreign suppliers for FSVP co-proposal, Option 1 (or 43,364 foreign suppliers for FSVP co-proposal, Option 2)– who will use third-party audits to satisfy the onsite verification requirement of the proposed FSVP rule – will voluntarily have their audits conducted by an auditor/CB accredited under our Third-Party program. The annual cost of using third-party auditors who comply with our Third-Party proposed rule (if finalized) for these FSVP-compliant entities is estimated at approximately $47 million for FSVP co-proposal, Option 1 (or $43 million for FSVP co-proposal, Option 2) (at 7% discount rate) (referred to as "TP Compliance Cost" in Tables B4). At 7% discount rate, total annual cost of compliance for §801(q) and FSVP entities that use accredited third-party auditors/CBs in the FDA third-party program are estimated at approximately $57 million for FSVP co-proposal, Option 1 (or $52 million for FSVP co-proposal, Option 2). At 3% discount rate, total TP compliance costs are estimated at approximately $56 million for FSVP co-proposal, Option 1 (or $51 million for FSVP co-proposal, Option 2).

Table B4a: Option 1 - Total Annualized* Cost for Eligible Entities

Eligible Entity	**Audited By**		
	Accredited CBs	**Unaccredited CBs**	**Total**
Number of §801(q) Entities (for this RIA)	1,305	8,730	10,035
TP Compliance Cost	$204	$1,104	
§801(q) Compliance Cost	**$266,220**	**$9,637,920**	**$9,904,140**
Number of FSVP Entities (subject to onsite audit requirements)	6,171	41,298	47,469
TP Compliance Cost	$204	$1,104	
FSVP Compliance Cost	**$1,258,884**	**$45,592,992**	**$46,851,876**
Total TP Compliance Cost			**$56,756,016**

* Annualized costs are calculated at 7% discount rate over a time period of 10 years.

Table B4b: Option 2 - Total Annualized Cost* for Eligible Entities

Eligible Entity	Audited By		
	Accredited CBs	Unaccredited CBs	Total
Number of §801(q) Entities (for this RIA)	1,305	8,730	10,035
TP Compliance Cost	$199	$1,099	
§801(q) Compliance Cost	**$259,695**	**$9,594,270**	**$9,853,965**
Number of FSVP Entities (subject to on-site audit requirements)	5,637	37,727	43,364
TP Compliance Cost	$199	$1,099	
FSVP Compliance Cost	**$1,121,763**	**$41,461,973**	**$42,583,736**
Total TP Compliance Cost			**$52,437,701**

* Annualized costs are calculated at 7% discount rate over a time period of 10 years.

Accreditation Bodies and Certification Bodies, and Eligible Entities ((§801(q) Entities and FSVP-Compliant Foreign Suppliers)

The Third-Party proposed rule does not impose any direct requirements on any ABs or auditors/CBs, unless they elect to become part of our program. Instead, the Third-Party proposed rule will, we expect, create a demand for recognized ABs and for audits and certification by accredited auditors/CBs who voluntarily participate in our program. It is expected that ABs and auditors/CBs will comply at a rate that satisfies the demand for audits from third-party auditors/CBs accredited under our program. The costs that ABs and auditors/CBs incur in complying with the regulation are necessarily less than the private benefits they accrue by becoming recognized or accredited, respectively. Likewise, additional costs accrued by foreign food and feed exporters that voluntarily choose to meet on-site audit requirements using accredited auditors/CBs are outweighed by the private benefits they gain.

Discussion of Current Business Practices

Currently, customary business practices of ABs include ensuring the competency of auditors (known as "audit agents" under the Third-Party proposed rule) of their accredited auditors/CBs, providing a public listing of their accredited auditors/CBs, maintaining records on

their internal reviews (e.g., self-assessments), assessing their accredited auditors/CBs, and making decisions on accreditation (including denial of accreditation), and, where necessary, suspension, withdrawal, or reducing the scope of accreditation. In addition, ABs require impartiality between themselves and their accredited auditors/CBs, which is similar to conflict of interest provisions set forth in the Third-Party proposed rule.

Accredited auditors/CBs follow various international standards and private food safety schemes in conducting audits for food safety. Monitoring activities by ABs include surveillance and reassessment audits of their accredited auditors/CBs, and peer evaluation conducted by other ABs. We have no information suggesting that accredited auditors/CBs currently submit their audit reports to their accrediting ABs.

In addition, auditors/CBs provide training for their auditors and monitor their auditor's competency through review of their audits and/or assigning an experienced auditor to shadow other auditors during their audits (also known as witness audits).

Potential Additional Costs Incurred by Accreditation Bodies and Auditors/Certification Bodies

Costs that are presented in brief in this section are discussed in detail in Appendix E. Although the private gains of an AB or auditor/CB in complying with the Third-Party proposed rule may be greater than their compliance costs, the ABs and auditors/CBs may potentially pass their compliance costs down to the eligible entities seeking audits and possibly certification. In this analysis we assume that all costs to ABs and auditors/CBs are passed on so that we can calculate costs on a per eligible entity basis. The annualized costs of complying with the Third-Party proposed rule (compliance costs) for 69 ABs include application for initial and renewal of recognition ($86,521), additional monitoring activities ($2,641), additional recordkeeping

($78,194), reporting requirements ($10,779 for FSVP co-proposal, Option 1 (or $10,336 for FSVP co-proposal, Option 2)) and contract modification ($37,731 for FSVP co-proposal, Option 1 (or $36,148 for FSVP co-proposal, Option 2)). Total annualized compliance cost for 69 ABs is estimated at approximately $215,866 for FSVP co-proposal, Option 1 (or $214,107 for FSVP co-proposal, Option 2) ($86,521 + $2,641 + $78,194 + $10,779 + $35,972). On average, annualized cost for an AB is approximately $3,128 ($215,866 ÷ 69 ABs) for FSVP co-proposal, Option 1 (or $3,103 for FSVP co-proposal, Option 2). If each recognized AB would pass down its compliance cost to its accredited auditors/CBs; on average, each auditor's/CB's burden from its accrediting AB's compliance cost would be $162.10 ($3,128/AB ÷ 19.30 CBs/AB) for FSVP co-proposal, Option 1 (or $168.64 for FSVP co-proposal, Option 2). In turn, if each accredited auditor/CB would pass down its AB's share of compliance cost to its client entities seeking an audit under our program, on average, each eligible entity would be burdened by approximately $2.84 annually ($162.10/CB ÷ 57 entities/CB) for FSVP co-proposal, Option 1 (or $2.96 for FSVP co-proposal, Option 2).

Annualized accreditation costs for 764 unaccredited auditors/CBs for FSVP co-proposal, Option 1 (or 701 for FSVP co-proposal, Option 2) (see Tables B2) are estimated at approximately $10.4 million: $1.5 million for initial application and assessor fees, $2.7 million for conformance to ABs' requirements, and $6.2 million for annual assessment and royalty fees for FSVP co-proposal, Option 1 (or $9.6 million: $1.4 million for initial application and assessor fees, $2.5 million for conformance to AB's requirements, and $5.7 million for annual assessment and royalty fees for FSVP co-proposal, Option 2). (Royalty fees represent the cost of the work of auditors/CBs to strictly enforce the accreditation standard.) Average cost to an unaccredited auditor/CB to comply with the requirements of the Third-Party proposed rule is estimated at

$13,661 ($10,436,631 ÷ 764 CBs). Spreading the annualized accreditation costs of unaccredited auditors/CBs over all anticipated accredited auditors/CBs, on average, the burden of each accredited auditor/CB will be approximately $7,812 ($10,436,631÷ 1,336 accredited auditors/CBs) for FSVP co-proposal, Option 1 (or $7,522 for FSVP co-proposal, Option 2). If each auditor/CB would pass down its cost to become part of our program to its client entities, on average, each eligible entity seeking an audit would pay approximately $137.05 ($7,812 ÷ 57 entities/CB) for FSVP co-proposal, Option 1 (or $131.96 for FSVP co-proposal, Option 2).

Annualized compliance costs by 1,332 auditors/CBs for FSVP co-proposal, Option 1 (or 1,276 auditors/CBs for FSVP co-proposal, Option 2) accredited by recognized ABs and 4 directly accredited auditors/CBs include $7,134 for application for direct accreditation, $77,602 for monitoring, $1,426,501 for recordkeeping requirements, $1,202,885 for reporting requirements, and $2,157,139 for contract modification for FSVP co-proposal, Option 1 (or $74,020 for monitoring, $1,360,179 for recordkeeping requirements, $1,150,146 for reporting requirements, and $2,056,849 for contract modification for FSVP co-proposal, Option 2). Total annualized compliance costs by 1,332 accredited auditors/CBs for FSVP co-proposal, Option 1 (or 1,269 auditors/CBs for FSVP co-proposal, Option 2) and 4 directly-accredited auditors/CBs is estimated at approximately $4,871,261 ($7,134 + 77,602 + $1, 426,501 + $1, 202,885 + $2, 056,849) for FSVP co-proposal, Option 1 (or $4,648,328 for FSVP co-proposal, Option 2), or $3,646 per auditor/CB ($4, 871,261 ÷ (1,332 CBs + 4 directly-accredited CBs)). If each accredited auditor/CB would pass down its AB's share of compliance cost to its client entities seeking an audit, on average, each eligible entity would be burdened by approximately $63.96 annually ($3,646 ÷ 57 entities/CB). Maximum potential of annualized compliance costs being passed down to each eligible entity by 69 recognized ABs, 4 directly-accredited auditors/CBs,

and 1,333 auditors/CBs accredited by recognized ABs is estimated at $204 ($2.84 + $137.05 + $63.96) for FSVP co-proposal, Option 1 (or 1,269 auditors/CBs accredited by recognized ABs is estimated at $199 for FSVP co-proposal, Option 2).

FDA Costs

Our costs can be categorized into three groups: application review process which includes both initial and renewal activities, monitoring activities, and IT infrastructure and support. These estimated costs are detailed below.

Initial Applications for Recognition of ABs and Direct Accreditation of Auditors/CBs

Sections 1.631 and 1.671 of the Third-Party proposed rule require us to review ABs' applications for recognition and, in the limited circumstances in which direct accreditation of auditors/CBs is an option, auditors/CBs' applications for direct accreditation. In addition to review of such applications for completeness, we will review their submissions against the requirements of the Third-Party regulation and will conduct an onsite performance evaluation (field audit). Our IT system will initially automatically determine if an application is complete. The cost of our IT system is discussed separately below under IT Infrastructure and Support.

The total estimated costs for initial recognition of ABs and initial direct accreditation of auditors/CBs include costs for review of submissions, field audit, field audit report preparation, and related costs. We use the FDA FY 2013 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by section 743 of the FD&C Act (FSMA reinspection and recall fee rate) to estimate costs related to various activities conducted by FDA employees under the Third-Party program. These fee rates include employee wages, benefits, overhead costs, travel expenses (if required), and senior management oversight. The FY 2013 FSMA reinspection and recall fee rate for

employees conducting activities at FDA facilities domestically (e.g., records review) is estimated at $209 per hour while the fee rate for activities that require foreign travel is estimated at $289. (Ref. 7)

Initial application review. We currently anticipate that initial review of an AB's submission, on average, will comprise 21 working days or 168 person-hours (21 days x 8 person-hours/day) by a FDA full-time employee at $209 per hour. Unit cost for initial review of an AB's application is estimated at $35,112 (168 hours x $209/hour). Table B5 includes the unit cost of initial review of an AB's submission during our application review process. We expect to incur similar unit costs for initial review of an auditor's/CB's application for direct accreditation, in the limited circumstances under which we will accept applications for direct accreditation.

Field audit and report. When considering whether to grant an initial application for recognition, we expect to conduct an onsite performance evaluation (field audit) of the applicant AB.[13] We estimate that the field audit would take three full-time FDA employees at fee rate of $289 per hour for duration of 3-5 days (average of 4 days is used in the analysis). Unit cost for our labor cost for the initial field audit of an AB is estimated at $27,744 (3 persons x 4 days/person x 8 hours/day x $289/hour). Subsequent to a field audit, our personnel who participate in the audit will take approximately 40-60 hours (average of 50 hours is used in the analysis) to prepare a written report documenting the field audit. Unit cost for preparation of the written report following the field audit of an AB is estimated at $31,350 (3 persons x 50 hours/person x $209/hour). Table B5 includes the unit cost of the initial field audit, and report preparation following the audit of an AB during the application review process.

Total costs. Adding these costs together yields an average total cost of review and evaluation of an initial application for recognition of an AB or an application for direct

[13] If more evaluations are conducted in house at FDA, the costs in this section are over-estimated.

accreditation of an auditor/CB of $94,206 ($35,112 + $27,744 + $31,350) (see Table B5). Undiscounted and annualized costs for our review and evaluation of initial applications for recognition of ABs (§1.631), and direct accreditation of auditors/CBs (§1.671) are included in Table B6.

Subsequent Application Reviews (Renewals)

Sections 1.630 and 1.632 of the Third-Party proposed rule describe the duration of recognition (not to exceed 5 years) and requirements for renewal of recognition by recognized ABs. Sections 1.661, 1.670, and 1.672 of the Third-Party proposed rule describe the duration of accreditation (not to exceed 4 years) and requirements of the renewal of direct accreditation of an auditor/CB. The review and evaluation of renewal applications by recognized ABs and directly accredited auditors/CBs is expected to be less burdensome than the review and evaluation required for initial applications for recognition and direct accreditation, respectively.

The total estimated costs for reviews of renewal applications include estimations of costs for application review, evaluation (i.e., in-house records reviews or onsite field audits), report preparation, and related costs. We have used the FY 2013 FSMA reinspection and recall fee rates of $209/hour and $289/hour to estimate the costs for activities conducted by FDA personnel at FDA facilities or ABs and auditors/CBs, respectively. (Ref. 7)

Renewal application review. We expect that review of a renewal application from a recognized AB or a directly-accredited auditor/CB would take no more than a week by a full-time FDA employee at $209 per hour. Therefore, the unit cost for renewal application review of a recognized AB or a directly-accredited auditor/CB, as part of §1.631 or §1.671 of the Third-Party proposed rule, is estimated at $8,360 (5 days x 8 hours/day x $209/hour).

Evaluations and reports. For ABs' renewal application for recognition, it is expected that 75% of such evaluations would be conducted in the form of in-house records review with approximately 25% conducted through field audits. Therefore, on average, only 24 hours of FDA personnel (96 hours x 25%) is spent on a field audit of an AB facility as part of its renewal of recognition application process. On average, the cost of a field audit for an AB as part of its renewal of recognition application is estimated at $6,936 (24 hours x $289/hour).

Report preparation for field audits for renewal applications would be similar to the initial field audits (i.e., 50 hours for each of the 3-member FDA team) while the report preparation for in-house records review is expected to utilize 100 hours of 2 full-time FDA employees for the AB evaluation at GS-13, Step 5 pay level. The weighted average of report preparation for the field audits and in-house records review results in 112.5 hours ((150 hours x 25%) + (100 hours x 75%)). The unit cost for report preparation of field audits required as part of renewal of recognition application by recognized ABs is estimated at $23,513 (112.5 hours x $209/hour). Total cost for full-time FDA employees to review and evaluate the renewal of recognition application for a recognized AB is estimated at $38,809 (see Table B5).

For directly-accredited auditors/CBs, we expect to conduct all of the performance evaluations through onsite field audits. As in performance evaluations of initial application reviews, the unit cost for the field audit for renewal applications of a directly-accredited auditor/CB is estimated at $27,744 (3 persons x 4 days/person x 8 hours/day x $289/hour) (see Table 5). Report preparation costs are same as those conducted during the initial field audit or $31,350 (150 hours x $209/hour). Total cost for full-time FDA employees to review the renewal of direct accreditation application of a directly-accredited auditor/CB is estimated at $67,454 (see Table B5).

Table B5 - Unit Costs of Application Review and Evaluation– FDA

Third-Party Proposed Rule Section	Number of Hours	Estimated Hourly Cost	Unit Cost	Frequency
§1.631 Initial AB Recognition				One-time
§1.671 Initial Auditor/CB Direct Accreditation				One-time
Application review	168	$209	$35,112	
Field audit	96	$289	$27,744	
Report preparation	150	$209	$31,350	
Total			**$94,206**	
§1.631 Renewal of AB Recognition [1]				Every 5 years
Application review	40	$209	$8,360	
Evaluation	24	$289	$6,936	
Report preparation	112.5	$209	$23,513	
Total			**$38,809**	
§1.671 Renewal of Auditor/CB Direct Accreditation [2]				Every 4 years
Application review	40	$209	$8,360	
Evaluation	96	$289	$27,744	
Report preparation	150	$209	$31,350	
Total			**$67,454**	

1. As part of renewal of AB recognition application, we expect to conduct 25% of the evaluations through on-site field audits.
2. As part of renewal of auditor/CB direct accreditation application, we will conduct 100% of the evaluations through on-site field audits.

We consider cost of our initial and renewal application review process of 69 ABs that would apply for recognition and 4 auditors/CBs that would apply for direct accreditation in a 10-year period. Our costs of implementing these provisions are approximately $1.3 million when annualized at 7 percent and $1.1 million when annualized at 3 percent (see Table B6).

Table B6: Undiscounted and annualized costs for FDA application review and evaluation process – 10-year period

Third-Party Proposed Rule Section	Number of Units	Unit Cost	Number of ABs/CBs	Undiscounted Cost – 10 years
§1.631 Initial AB Recognition				**$6,500,214**
Application review - AB initial standards review	1	$35,112	69	$2,422,728
Application review - AB initial on-site performance evaluation	1	$27,744	69	$1,914,336
Application review - AB initial on-site performance evaluation report preparation	1	$31,350	69	$2,163,150
§1.671 Initial Auditor/CB Direct Accreditation				**$376,824**
Application review - AB initial standards review	1	$35,112	4	$140,448
Application review - AB initial on-site performance evaluation	1	$27,744	4	$110,976
Application review - AB initial on-site performance evaluation report preparation	1	$31,350	4	$125,400
§1.631 Renewal of AB Recognition				**$2,317,149**
Application review - AB initial standards review	1	$8,360	69	$576,840
Application review - AB initial on-site performance evaluation	1	$6,936	17[1]	$117,912
Application review - AB initial on-site performance evaluation report preparation	1	$23,513	69	$1,622,397
§1.671 Renewal of Auditor/CB Direct Accreditation				**$539,632**
Application review - AB initial standards review	2	$8,360	4	$66,880
Application review - AB initial on-site performance evaluation	2	$27,744	4	$221,952
Application review - AB initial on-site performance evaluation report preparation	2	$31,350	4	$250,800
Total				**$9,733,819**
Total Annualized Cost (7%)	**$1,266,022**			
Total Annualized Cost (3%)	**$1,093,591**			

1. As part of renewal of AB recognition application, we expect to conduct 25% of the evaluations through on-site field audits.

Monitoring of Recognized ABs and Directly-Accredited Auditors/CBs

Section 1.633 of the Third-Party proposed rule requires us to evaluate the performance of each recognized AB at least once every 4 years after the date of recognition. It is expected that

monitoring activities would be an abbreviated form of the evaluations conducted during the application review process of the ABs.

The total estimated costs for monitoring activities of ABs and directly-accredited auditors/CBs include costs for records review, performance evaluation, performance evaluation report preparation, and related costs. We have used the FY 2013 FSMA reinspection and recall fee rates of $209/hour and $289/hour to estimate the costs of activities conducted by FDA personnel at FDA facilities (domestic) or foreign locations, respectively. (Ref. 7)

We assume that 10% of monitoring activities for recognized ABs will be conducted onsite while the remaining monitoring activities will be conducted in-house through review of records and assessment of other information, including reports and notifications submitted by recognized ABs.

Review of records as part of monitoring activities would take about the same amount of effort as in-house records reviews conducted in conjunction with the periodic performance evaluations of ABs and auditors/CBs during the renewal application review process discussed above, $8,360 (40 hours x $209/hour).

Unit costs for our monitoring activities are equivalent to the periodic performance evaluations with the exception of number of hours spent on report preparation. Estimated time for report preparation for on-site monitoring is 150 hours, the same as the estimated time to prepare the on-site report for the initial review. Estimated time for report preparation for in-house monitoring is 100 hours, the same as the estimated time for in-house records review associated with renewal applications. The weighted average of report preparation for the onsite and in-house monitoring activities results in 105 hours ((150 hours x 10%) + (100 hours x 90%)). The unit cost for monitoring activities is estimated at $21,945 (105 hours x $209/hour).

Section 1.662(a) of the Third-Party proposed rule requires us to evaluate the performance of each accredited auditor/CB at least once every three years after the date of accreditation. In addition, section 1.662(a) of the proposed Third Party rule requires us to evaluate annually the performance of the subset of accredited auditors/CBs that we directly accredit. These costs are similar to costs of monitoring activities for the recognized ABs and are included in Table B7.

Table B7: Unit Costs of Monitoring Activities – FDA

Third-Party Proposed Rule Section	Number of Hours	Estimated Hourly Cost	Unit Cost	Frequency
§1.633 FDA monitoring of recognized ABs[1]				Every 4 years
§1.662(a) FDA monitoring of accredited CBs[1]				Every 3 years
§1.662(a) FDA monitoring of directly accredited CBs[2]				Annual
Records review	40	$209	$8,360	
Onsite performance evaluation	96	$289	$27,744	
Monitoring report preparation	105	$209	$21,945	
Total			**$58,049**	

1. We expect to conduct 10% of the monitoring activities of ABs and accredited CBs through on-site field audits.
2. We expect to conduct 100% of the monitoring activities of directly-accredited CBs through on-site field audits.

Estimated annualized cost for our monitoring of 69 recognized ABs, 1,332 auditors/CBs for FSVP co-proposal, Option 1 (or 1,269 auditors/CBs for FSVP, co-proposal, Option 2) accredited by recognized ABs, and 4 directly-accredited auditors/CBs is approximately $14.4 million when annualized at 7 percent and $14.2 million when annualized at 3 percent for FSVP co-proposal, Option 1 (or $13.7 million when annualized at 7 percent and $13.5 million when annualized at 3 percent for FSVP, co-proposal, Option 2).

Table B8a: Option 1 - Undiscounted and annualized costs for FDA Monitoring process – 10-year period

Third-Party Proposed Rule Section	Number of Units	Unit Cost	Number of ABs/CBs	Undiscounted cost – 10 years
§1.633 FDA monitoring of recognized ABs				**$4,570,506**
Records review	2	$8,360	69	$1,153,680
On-site performance evaluation	2	$27,744	7[1]	$388,416
Monitoring report preparation	2	$21,945	69	$3,028,410
§1.662(a) FDA monitoring of accredited CBs				**$132,168,636**
Records review	3	$8,360	1,332	$33,406,560
On-site performance evaluation	3	$27,744	133[1]	$11,069,856
Monitoring report preparation	3	$21,945	1,332	$87,692,220
§1.662(a) FDA monitoring of directly accredited CBs				**$2,321,960**
Records review	10	$8,360	4	$334,400
On-site performance evaluation	10	$27,744	4	$1,109,760
Monitoring report preparation	10	$21,945	4	$877,800
Total				**$139,061,102**
Total Annualized Cost (7%)	**$14,375,263**			
Total Annualized Cost (3%)	**$14,158,853**			

1. We expect to conduct 10% of the monitoring activities through on-site field audits.

Table B8b: Option 2 - Undiscounted and annualized costs for FDA Monitoring process – 10-year period

Third-Party Proposed Rule Section	Number of Units	Unit Cost	Number of ABs/CBs	Undiscounted cost – 10 years
§1.633 FDA monitoring of recognized ABs				**$4,570,506**
Records review	2	$8,360	69	$1,153,680
On-site performance evaluation	2	$27,744	7[1]	$388,416
Monitoring report preparation	2	$21,945	69	$3,028,410
§1.662(a) FDA monitoring of accredited CBs				**$125,941,599**
Records review	3	$8,360	1,276	$31,826,520
On-site performance evaluation	3	$27,744	128[1]	$10,570,464
Monitoring report preparation	3	$21,945	1,276	$83,544,615
§1.662(a) FDA monitoring of directly-accredited CBs				**$2,321,960**
Records review	10	$8,360	4	$334,400
On-site performance evaluation	10	$27,744	4	$1,109,760
Monitoring report preparation	10	$21,945	4	$877,800
Total				**$132,834,065**
Total Annualized Cost (7%)	**$13,734,426**			
Total Annualized Cost (3%)	**$13,527,498**			

1. We expect to conduct 10% of the monitoring activities through on-site field audits.

Information Technology Infrastructure and Support

FDA's information technology (IT) infrastructure and support would need to be improved and expanded to allow for receiving applications, verifying completeness, and processing of applications. In addition, the IT infrastructure must enable us to receive other electronic submissions from ABs and auditors/CBs (such as regulatory audit reports and notifications) and support our monitoring of recognized ABs and accredited auditors/CBs. The IT system also must enable us to disclose the names and contact information of recognized ABs and accredited auditors/CBs, and the scope and duration of their recognition or accreditation, respectively, on a publicly available registry per requirements of the Third-Party proposed rule. It also must allow for the interface between submissions by accredited third-party auditors/CBs

(e.g., certifications) and other programs (e.g., the Voluntary Qualified Importer Program, which requires facility certification as an eligibility requirement) and processes (e.g., admissibility of food subject to a certification requirement under section 801(q) of the FD&C Act.

According to FDA IT experts, the costs of building an IT infrastructure and the support to manage the volume of information that would need to be submitted and processed among the FDA, ABs, and auditors/CBs would include a one-time cost to provide a common web portal for all communication between the applicants and the FDA ($1.4 million), to set up a system to integrate database of credentials and conduct performance metrics ($1.1 million), to coordinate information within and across government agencies ($2 million), and to set up a system for internal performance data collection, monitoring, postings/listings of database information and metric reporting ($1.5 million). Total one-time costs add to $6 million (see Table B9). Annual maintenance costs of the IT infrastructure is expected to be approximately 20% of the one-time cost, or $1.2 million (see Table B9).

Table B9: Unit Costs of IT Infrastructure and Support – FDA

Description	Unit Cost	Frequency
Common web portal	$1,400,000	One-time
Integrated database	$1,100,000	One-time
Interagency systems upgrade	$2,000,000	One-time
Data collection, monitoring	$1,500,000	One-time
Interagency systems upgrade	$1,200,000	Annual
Total First Year Costs	**$6,000,000**	
Total Annual Costs After First year	**$1,200,000**	
Total Annualized Cost (7%)	**$1,998,798**	
Total Annualized Cost (3%)	**$1,810,644**	

Training

Training current FDA employees or new employees to conduct the tasks required by the accredited third-party audits and certification program generally would be expected to occur over

the span of 1.5 and 2 years; however, this duration can be shortened to 1-1.5 years if the amount of time spent in training is increased. Training personnel to conduct evaluations and monitoring of ABs and auditors/CBs will include classroom instruction, on-the-job training usually conducted in domestic facilities, and more specialized training obtained through a combination of classroom and on-the-job instruction. We expect it will typically take, at a minimum, a 3-person FDA team to conduct an onsite field audit or monitoring activity at an AB or auditor/CB.

At this time, it is not certain the number of existing and new personnel we will need to train to conduct field audits and monitoring activities of ABs and auditors/CBs per requirements of the Third-Party proposed rule. We invite comments and relevant data to support training cost estimates for FDA personnel and will provide our analysis of these costs in the final rule.

Cost Summary – FDA

The total annualized cost of the FDA application review process, monitoring activities, and implementation and maintenance of IT infrastructure to conform to the Third-Party proposed rule is approximately $17.6 million annualized at 7 percent and $17.1 million annualized at 3 percent for FSVP co-proposal, Option 1 (or $17 million when annualized at 7 percent and $16.4 million when annualized at 3 percent for FSVP, co-proposal, Option 2). In Tables B10, we illustrate how cost could potentially break down over a 10 year period. It is important to note that these should not be taken as actual costs for any particular year, because the schedule for applications, renewals, and periodic monitoring could vary widely, and would probably appear more staggered in reality.

Table B10a: Option 1 - Illustrative Yearly Costs and Annualized Costs for FDA to Implement the Third-Party Proposed Rule

Year	Initial Recognition and Periodic Renewal	Periodic Monitoring[1]	IT Set-up and Maintenance	Undiscounted Costs
0	$6,877,038	$232,196	$7,200,000	$14,309,234
1	$0	$232,196	$1,200,000	$1,432,196
2	$0	$44,288,408	$1,200,000	$45,488,408
3	$0	$2,517,449	$1,200,000	$3,717,449
4	$269,816	$232,196	$1,200,000	$1,702,012
5	$2,317,149	$44,288,408	$1,200,000	$47,805,557
6	$0	$232,196	$1,200,000	$1,432,196
7	$0	$2,517,449	$1,200,000	$3,717,449
8	$269,816	$44,288,408	$1,200,000	$45,758,224
9	$0	$232,196	$1,200,000	$1,432,196
Total Undiscounted Costs, 10 years		**$166,794,921**		
Total Annualized Costs (7%)		**$17,640,083**		
Total Annualized Costs (3%)		**$17,063,089**		

1. Monitoring activities is based on the assumption that only 10% of recognized AB or accredited auditors/CBs will be monitored by FDA personnel through on-site evaluation. If onsite monitoring percentages are increased, periodic monitoring costs increase significantly.

Table B10b: Option 2 - Illustrative Yearly Costs and Annualized Costs for FDA to Implement the Third-Party Proposed Rule

Year	Initial Recognition and Periodic Renewal	Periodic Monitoring[1]	IT Set-up and Maintenance	Undiscounted Costs
0	$6,877,038	$232,196	$7,200,000	$14,309,234
1	$0	$232,196	$1,200,000	$1,432,196
2	$0	$42,212,729	$1,200,000	$43,412,729
3	$0	$2,517,449	$1,200,000	$3,717,449
4	$269,816	$232,196	$1,200,000	$1,702,012
5	$2,317,149	$42,212,729	$1,200,000	$45,729,878
6	$0	$232,196	$1,200,000	$1,432,196
7	$0	$2,517,449	$1,200,000	$3,717,449
8	$269,816	$42,212,729	$1,200,000	$43,682,545
9	$0	$232,196	$1,200,000	$1,432,196
Total Undiscounted Costs, 10 years		**$160,567,884**		
Total Annualized Costs (7%)		**$16,999,264**		
Total Annualized Costs (3%)		**$16,431,734**		

1. Monitoring activities is based on the assumption that only 10% of recognized AB or accredited auditors/CBs will be monitored by FDA personnel through on-site evaluation. If onsite monitoring percentages are increased, periodic monitoring costs increase significantly.

Sensitivity Analysis

For the purposes of this analysis, we assume that the proportion of foreign food and feed exporters whose foods are subject to §801(q) of the FD&C Act comprise 5% of all foreign food and feed exporters who offer their food or feed for import to the U.S. In this section, we assess the effect of this assumption on the Third-Party proposed rule's estimated costs on the eligible entities. We consider scenarios where the proportion of the §801(q) entities are 1% and 10% of all foreign food and feed exporters. Hence, the number of §801(q) entities is approximately 2,007 (200,692 foreign food and feed exporters x 1%) at 1%, and approximately 20,069 at 10% (see Tables B11). We have also included calculation of cost estimates used in the analysis (at 5%) for comparison.

As we discussed in this analysis and Appendix C, there are 26,007 foreign food and feed exporters who are currently being audited by accredited auditors/CBs while the remaining 174,685 are being audited by unaccredited auditors/CBs or do not obtain audits (see Table 1). Assuming that the proportion of §801(q) entities is the same as the proportion of all foreign food and feed exporters receiving food safety audits, we estimate that the number of §801(q) entities under the 1% scenario is approximately 2,007 facilities (200,692 x 1%) from which approximately 261 facilities (2,007 x 13%) are currently being audited by accredited auditors/CBs and the remaining 1,746 facilities (2,007 x 87%) are currently being audited by unaccredited auditors/CBs. Similarly, we estimate 20,069 §801(q) facilities (200,692 x 10%) receiving food safety audits under the 10% scenario: 2,609 entities (20,069 x 13%) receive audits by currently accredited auditors/CBs while 17,460 (20,069 x 87%) receive audits by currently unaccredited auditors/CBs (see Tables B11).

In this sensitivity analysis, the number of facilities using accredited auditors/CBs to meet the onsite audit requirements of the FSVP proposed rule remains unchanged. Therefore, in order for the accredited auditor/CB market to satisfy the demand of foreign food and feed exporters choosing to obtain accredited third party food safety audits, they need to increase their capacity to account for the demand driven by §801(q) and FSVP requirements among entities that are currently being audited by unaccredited food safety auditors/CBs. For the 1% scenario, there are an additional 1,746 §801(q) entities that would choose to be audited by accredited auditors/CBs in addition to the 41,298 for FSVP co-proposal, Option 1 (or 37,727 for FSVP, co-proposal, Option 2) who would switch to accredited third party auditors/CBs for FSVP compliance. Hence, in addition to the 26,007 foreign food and feed exporters that are being audited by accredited third party auditors/CBs, accredited auditors/CBs would need to raise their capacity to satisfy the demand of an additional 43,044 eligible entities (1,746 + 41,298) for FSVP co-proposal, Option 1 (or 39,473 for FSVP, co-proposal, Option 2). Under the 10% scenario, accredited auditors/CBs would potentially have to conduct food safety audits for an estimated 58,758 foreign food and feed exporters (17,460 + 41,298) for FSVP co-proposal, Option 1 (or 55,187 for FSVP, co-proposal, Option 2) (see Tables B11). In order for these remaining foreign food and feed exporters to obtain accredited third-party food safety audits, we expect that 1) currently accredited third-party auditors/CBs increase their capacity, and 2) some unaccredited third-party auditors/CBs choose to become accredited by recognized ABs.

As we discussed earlier, we estimate the costs under a scenario where accredited third-party auditor/CB market expands by 25%. Therefore, under the 1% scenario, 6,502 additional foreign food and feed exporters (32,509 – 26,007) can obtain accredited third-party food safety audit from existing accredited third-party auditors/CBs. The demand driven by the remaining

36,542 foreign food and feed exporters (43,044 – 6,502) for FSVP co-proposal, Option 1 (or 32,971 for FSVP, co-proposal, Option 2) who will choose to obtain accredited third-party food safety audits would induce a number of unaccredited food safety auditors/CBs to become accredited by recognized ABs. In the analysis, we estimated that after the 25% increase in capacity, each of the existing accredited food safety auditors/CBs would have approximately 57 foreign supplier clients. Therefore, under the 1% scenario, the number of unaccredited food safety auditors/CBs who choose to become accredited by a recognized AB is approximately 641 (36,542 foreign food and feed exporters ÷ 57 foreign food and feed exporters/CB) for FSVP co-proposal, Option 1 (or 578 for FSVP, co-proposal, Option 2). Similarly, we calculate the number of unaccredited food safety auditors/CBs who choose to become accredited by a recognized AB under the 10% scenario at 917 CBs (52,256 foreign food and feed exporters ÷ 57 foreign food and feed exporters/CB) for FSVP co-proposal, Option 1 (or 854 for FSVP, co-proposal, Option 2) (see Tables B11).

As in the analysis, based on the number of eligible entities, ABs and auditors/CBs, we estimate the compliance cost to ABs, accredited auditors/CBs, and unaccredited auditors/CBs who choose to become accredited, to estimate the costs that are potentially passed down to the eligible entities for which they provide food safety audits under our program. We estimate that total costs passed from ABs and auditors/CBs to the eligible entities is approximately $194 for the 1% scenario and approximately $214 under the 10% scenario for FSVP co-proposal, Option 1 (or $188 for the 1% scenario and approximately $210 under the 10% scenario for FSVP, co-proposal, Option 2). In addition, as we discussed earlier, we assume that entities that are currently being audited for food safety by unaccredited auditors/CBs would incur an additional cost of $900.

We estimate the total cost burden of eligible entities by 1) multiplying total cost by the number of foreign food and feed exporters who obtained accredited third-party food safety audits before the implementation of the Third-Party proposed rule, and 2) multiplying total cost plus an additional $900 by the number of foreign food and feed exporters who switched from unaccredited third-party auditor/CB before the implementation of the Third-Party proposed rule to an accredited third-party auditor/CB following the implementation of the Third-Party proposed rule. For example, under the 1% scenario, 6,432 foreign food and feed exporters (261 §801(q) entities + 6,171 entities subject to FSVP onsite audit requirements) for FSVP co-proposal, Option 1 (or 5,898 for FSVP, co-proposal, Option 2) would incur an additional $194 compliance cost for FSVP co-proposal, Option 1 (or $188 for FSVP, co-proposal, Option 2). In addition, 43,044 foreign food and feed exporters (1,746 §801(q) entities + 41,298 entities with FSVP audit requirements) for FSVP co-proposal, Option 1 (or 39,473 foreign food and feed exporters for FSVP, co-proposal, Option 2) would incur an additional cost of $1,094 ($194 compliance cost + $900 accreditation cost) for FSVP co-proposal, Option 1 (or $1,088 for FSVP, co-proposal, Option 2).. Total cost under the 1% scenario is approximately $48.3 million ((6,432 foreign supplier x $194/supplier) + (43,044 foreign food and feed exporters x $1,094/supplier) for FSVP co-proposal, Option 1 (or $44.1 million for FSVP, co-proposal, Option 2). Under the 1% scenario, total costs to eligible entities is approximately 15% lower for FSVP co-proposal, Option 1 (or 16% lower for FSVP, co-proposal, Option 2) than the total entities' cost of approximately $56.8 million for FSVP co-proposal, Option 1 (or $52.4 million for FSVP, co-proposal, Option 2) obtained under the 5% assumption used in the analysis. Similarly, we calculate a total annualized cost of $67.3 million for FSVP co-proposal, Option 1 (or $63.0 million for FSVP, co-proposal, Option 2) under the 10% scenario which is approximately 19%

more for FSVP co-proposal, Option 1 (or 20% more for FSVP, co-proposal, Option 2) than the total entities' cost obtained under the 5% assumption used in the analysis.

Table 11a: Option 1 - Sensitivity Analysis of Annualized Costs for Eligible Entities – Proportion of Eligible Entities

Description	Proportion of §801(q)		
	1%	5%	10%
Subject to 801(q)	2,007	10,035	20,069
Audited by accredited auditor/CB	261	1,305	2,609
Audited by unaccredited auditor/CB	1,746	8,730	17,460
Suppliers subject to FSVP onsite audit requirements	47,469	47,469	47,469
Audited by accredited auditor/CB	6,171	6,171	6,171
Audited by unaccredited auditor/CB	41,298	41,298	41,298
Current accredited auditors'/CBs' capacity	26,007	26,007	26,007
Needed additional capacity	43,044	50,028	58,758
Current capacity + 25%	32,509	32,509	32,509
Remaining eligible entities demanding accredited audit	36,542	43,526	52,256
Number of eligible entities/accredited auditor/CB	57	57	57
Number of unaccredited auditors/CBs choosing to become accredited	641	764	917
AB Cost	$3.07	$2.84	$2.62
Accredited auditor/CB Cost	$63.91	$63.96	$63.91
Unaccredited auditor/CB Cost	$126.65	$137.05	$147.60
TP Compliance Cost	$194	$204	$214
TP Cost - currently audited by accredited auditors/CBs	**$1,247,808**	**$1,525,104**	**$1,878,920**
TP Cost - currently audited by unaccredited auditors/CBs	**$47,090,136**	**$55,230,912**	**$65,456,412**
Total TP Cost	**$48,337,944**	**$56,756,016**	**$67,335,332**
% Change from estimate used in the analysis (5%)	**-14.83%**	**N/A**	**18.64%**

Table B11b: Option 2 - Sensitivity Analysis of Annualized Costs for Eligible Entities – Proportion of Eligible Entities

Description	Proportion of §801(q)		
	1%	5%	10%
Subject to 801(q)	2,007	10,035	20,069
Audited by accredited auditor/CB	261	1,305	2,609
Audited by unaccredited auditor/CB	1,746	8,730	17,460
Suppliers subject to FSVP onsite audit requirements	43,364	43,364	43,364
Audited by accredited auditor/CB	5,637	5,637	5,637
Audited by unaccredited CB	37,727	37,727	37,727
Current accredited auditors'/CBs' capacity	26,007	26,007	26,007
Needed additional capacity	39,473	46,457	55,187
Current capacity + 25%	32,509	32,509	32,509
Remaining eligible entities demanding accredited audit	33,971	39,955	48,685
Number of eligible entities/accredited auditor/CB	57	57	57
Number of unaccredited auditors/CBs choosing to become accredited	578	701	854
AB Cost	$3.21	$2.96	$2.71
Accredited auditor/CB Cost	$64.02	$64.05	$63.98
Unaccredited auditor/CB Cost	$120.46	$131.96	$143.53
TP Compliance Cost	$188	$199	$210
TP Cost - currently audited by accredited auditors/CBs	**$1,108,824**	**$1,381,458**	**$1,731,660**
TP Cost - currently audited by unaccredited auditors/CBs	**$42,946,624**	**$51,056,243**	**$61,257,570**
Total TP Cost	**$44,055,448**	**$52,437,701**	**$62,989,230**
% Change from estimate used in the analysis **(5%)**	**-15.99%**	**N/A**	**20.12%**

Appendix C

Proportion of foreign food and feed exporters certified by accredited auditors/CBs

RTI (Ref. 5) conducted a search on the number of foreign facilities that are currently being audited for food safety by auditors/CBs accredited under existing programs. Currently, most ABs and accredited auditors/CBs do not publicly disclose the number of facilities that they certify for food safety. China National Accreditation Service (CNAS), Japan Accreditation Board (JAB), and National Standards Authority of Ireland (NSAI) which is a CB accredited by the United Kingdom Accreditation Service (UKAS) are a few entities that disclose the facilities that are certified under their auspices.

RTI identified 71 ABs (see Table B2; Appendix D) which include 38 government ABs, 24 private ABs, and 9 ABs with unknown affiliation. We separate CNAS, the Chinese government AB, from the data of the other government ABs since it is proportionally much larger than other ABs. According to RTI, CNAS accredited 30 auditors/CBs. On average, each of CNAS' auditors/CBs certifies 161 facilities. Therefore, number of food producing facilities certified by auditors/CBs accredited by CNAS is estimated at 4,830 (161 facilities/CB x 30 CBs) (see Table C1).

Based on a sample, RTI estimates that, on average, other 37 government ABs have 7.9 auditor/CBs, and each auditor/CB that is accredited by a government AB certifies an average of 44 facilities for food safety. Total number of foreign food and feed facilities certified by government ABs other than CNAS is approximately 12,861 (37 ABs x 7.9 CBs/AB x 44 facilities/CB).

RTI also estimates that 24 private ABs, on average have 8.75 auditors/CBs and each of their accredited auditors/CBs certifies an average of 33 foreign facilities. Total number of

foreign food and feed exporters certified by auditors/CBs accredited by private ABs is estimated at 6,930 (24 ABs x 8.75 CBs/AB x 33 facilities/CB).

RTI reports that there are, on average, 4 auditors/CBs for each of the remaining 9 ABs. We assume that an auditor/CB that is accredited by an AB whose affiliation RTI identified as unknown to be the average of facilities certified by private and government ABs, or 38.5 ((44 + 33)/2). Hence, the total number of foreign food and feed facilities certified by auditors/CBs accredited by ABs, whose affiliation was unidentified by RTI, is estimated at 1,386 (9 ABs x 4 CBs/AB x 38.5 facilities/CB).

In total, we estimate that there are 71 ABs, 568 accredited auditors/CBs, and 26,007 foreign facilities that are being audited for food safety by accredited auditors/CBs. Considering that there are an estimated 200,697 foreign food and feed exporters (processors and farms), approximately 13% of foreign food and feed exporters (26,007 / 200,697) that offer their food for import to the U.S. are audited by accredited auditors/CBs. In addition, there are approximately 46 foreign food and feed exporters per accredited auditor/CB. We request comment on how we calculated this proportion, based on the RTI analysis.

Table C1. Number of ABs, Accredited CBs, and Foreign Food and Feed Exporters Certified by Accredited CBs

AB	# of ABs	# of CBs	# of CBs per AB	# of foreign food and feed per CB	# of foreign food and feed exporters	Weighted food and feed exporters per CB
CNAS	1	30	30	161	4,830	8
Other Government ABs	37	292	7.9	44	12,861	23
Private ABs	24	210	8.75	33	6,930	12
Other ABs	9	36	4	38.5	1,386	2
Total	**71**	**568**			**26,007**	**46**

Appendix D

Number of Accreditation Bodies

The Third-Party proposed rule has implications for accreditation bodies (ABs) that accredit auditors/CBs who conduct conformity assessment activities (audits)[14] to determine whether products and systems conform to the specifications of a relevant standard. We have identified five major AB organizations that currently accredit CBs for conformity assessment operating globally: International Accreditation Forum (IAF), and the regional InterAmerican Accreditation Cooperation (IAAC), Pacific Accreditation Cooperation (PAC), European co-operation for Accreditation (EA), and Southern African Development Community Accreditation (SADCA). Some ABs belong to multiple AB groups. Overall, within the five major AB groups described above, there are 103 ABs from which 71 have food safety audits as a part of the scope of their operations. Sixty-nine (69) of the identified ABs operate outside the U.S. while 2 ABs operate within the U.S. Most countries have only one AB with the exception of the U.S. (2), and Republic of Korea (2). One AB, JAS-ANZ, represents two countries: Australia and New Zealand.

Data on value of U.S. imports, in U.S. dollars, for FDA-regulated food and feed for FY 2011 were obtained through U.S. International Trade Commission website (http://dataweb.usitc.gov/scripts/user_set.asp). Table D1 includes food and feed imports and their respective NAIC code classifications that were used to obtain trade value of imports by country into the U.S.

[14] "Conformity assessment" is the term used in the standards community to describe the type of activity (i.e., food safety audit) that will be conducted by accredited auditors/CBs under the Third-Party proposed rule.

Table D1 – FDA-Regulated Food, Feed and NAIC Classification of Imports to the U.S.

NAIC Code	Food/Feed Classification
1111	Oilseed and Grain Farming
1112	Vegetable and Melon Farming
1113	Fruit and Tree Nut Farming
1114	Greenhouse, Nursery, and Floriculture Production
11193	Sugarcane Farming
11194	Hay Farming
11199	All Other Crop Farming
1125	Animal Aquaculture
3111	Animal Food Manufacturing
3112	Grain and Oilseed Milling
3113	Sugar and Confectionery Product Manufacturing
3114	Fruit and Vegetable Preserving and Specialty Food Manufacturing
3115	Dairy Product Manufacturing
3117	Seafood Product Preparation and Packaging
3118	Bakeries and Tortilla Manufacturing
3119	Other Food Manufacturing
3121	Beverage Manufacturing

Table D2 includes a list of the 69 foreign ABs and 2 U.S.-based ABs, the country in which they are based, and the value of food and feed trade in dollars into the U.S. in FY 2011. Excluding the two ABs representing Cuba and Iran, countries which currently are subject to U.S. trade sanctions, there are potentially 69 ABs that would apply for recognition from the FDA. We believe that the implementation of the Third-Party proposed rule would increase demand for food safety audits by third party auditors/CBs accredited by ABs recognized under our program. Considering the increased demand for accredited-third party food safety audits, we expect that all 69 ABs would have strong incentive to voluntarily apply for recognition from the FDA.

Table D2 – Global List of ABs with the Scope of Food Safety Audits

AB	Country	Volume[1]
SCC	Canada	15,976
EMA	Mexico	15,476
COFRAC	France	3,683
CNAS	China	3,659
ACCREDIA	Italy	3,522
CGCRE	Brazil	3,381
INN	Chile	2,812
ONAC	Colombia	2,460
NABCB	India	2,294
NSC	Thailand	2,272
RvA	Netherlands	2,122
Standards Malaysia	Malaysia	2,066
UKAS	U.K.	1,828
JAS-ANZ	Australia	1,002
	New Zealand	821
KAN	Indonesia	1,524
PAO	Philippine	1,517
DAkkS	Germany	1,505
ECA	Costa Rica	1,415
INDECOPI	Peru	1,326
OAA	Argentina	1,282
BA	Vietnam	1,264
ENAC	Spain	1,252
OAE	Ecuador	1,164
INAB	Ireland	801
SAS	Switzerland	751
JAB	Japan	542
BELAC	Belgium	535
BMWFJ	Austria	525
SWEDAC	Sweden	511
KAB	South Korea	384
KAS	South Korea	
TURKAK	Turkey	371
TAF	Taiwan	283
PCA	Poland	276
DANAK	Denmark	237
ESYD	Greece	216

AB	Country	Volume[1]
NA	Norway	197
SANAS	South Africa	196
STC-IS	Russia	120
LATAK	Latvia	117
IPAC	Portugal	110
SAC	Singapore	108
HKAS	Hong Kong	89
TUNAC	Tunisia	84
PNAC	Pakistan	81
EGAC	Egypt	77
FINAS	Finland	73
ONA	Paraguay	67
SLAB	Sri Lanka	67
OUA	Uruguay	43
CAI	Czech Republic	41
MAURITAS	Mauritius	31
ISAC	Iceland	23
CAS	Croatia	16
LA	Lithuania	16
NAAU	Ukraine	14
NAT	Hungary	14
DA	Albania	8
RENAR	Romania	7
JAS	Jordan	6
CAECP	Moldova	6
SA	Slovenia	4
IARM	Macedonia	4
GAC	Georgia	4
SNAS	Slovakia	3
NCA	Kazakhstan	0.2
OLAS	Luxembourg	0.07
IAS	Iran	0.02
ONARC	Cuba	0
ANAB	U.S.	N/A
ANSI	U.S.	N/A

1. In millions U.S. dollars; ITC Data.

Appendix E

Compliance Costs of ABs and Auditors/CBs

We estimate costs of ABs and CBs that would potentially comply with the Third-Party proposed rule. Considering that the ABs and auditors/CBs would pass down their compliance costs to the eligible entities that they audit, we also estimate the share of the ABs' and auditors'/CBs' costs to each eligible entity.

Accreditation Bodies

Application for Recognition

An AB may apply for recognition from FDA in accordance with §1.630 of the Third-Party proposed rule. We believe that a total of 69 ABs will apply for recognition from the FDA. We expect that it will take 80 person-hours to compile all the relevant information and complete the application for recognition from the FDA. Furthermore, we proxy the private sector average hourly wage rate of person(s) who will be completing the application with the equivalent of a public sector GS-14, Step 1 employee at $60.87 per hour (includes 50% overhead cost). Therefore, we estimate that it will cost approximately $4,870 (80 hours x $60.87/hour) for an AB to apply for recognition from the FDA. Unit cost of application for recognition by ABs is included in Table E1.

Section 1.632 of the Third-Party proposed rule stipulates the term of recognition for an AB not to exceed 5 years. Section 1.630 of the Third-Party proposed rule outlines the requirements of abbreviated application for renewal of recognition by a recognized AB. We expect that applications for renewal of recognition will take significantly less time to prepare. We use 50% of amount of effort to prepare and submit an application for renewal of recognition to the FDA. Hence, we believe that it would cost approximately $2,435 to complete an

application for renewal of recognition every 5 years for recognized ABs. Unit cost of application for renewal of recognition by ABs is included in Table E1.

Some application review activities by the FDA will require the presence of FDA personnel in the facilities of ABs that apply for recognition (§1.631), or in the facilities of recognized ABs as part of renewal of recognition applications (§1.631). During these FDA activities, or field audits, it is expected that the subject AB would assign someone to serve as a liaison with the FDA during the entire time that the FDA team is onsite. We estimate that during each field audit at an AB facility, the FDA team will spend approximately 4 days onsite at the AB headquarters. We also expect that the person employed by the AB that is assigned to the FDA team would have a management position and as a proxy for the firm's private labor costs we proxy that person's salary as equivalent to a public GS-13, Step 5 pay level ($58.38/hour including 50% overhead costs). It is expected that there will be an AB representative present at the AB headquarters for a total of 32 hours (4 days x 8 hours/day). Therefore, the cost of AB staff labor to assist during a FDA performance evaluation is estimated at $1,868 (32 hours x $58.38/hour). Unit cost of AB labor cost to assist the FDA team during performance evaluations as part of §1.631 of the Third-Party proposed rule is included in Table E1.

Monitoring

Current business practices of ABs include monitoring the performance of each of their accredited auditors/CBs on annual basis (similar to §1.621 of the Third-Party proposed rule) and internal audits similar to the self assessments in §1.622 of the Third-Party proposed rule.

Section 1.633 of the Third-Party proposed rule requires that the FDA monitor recognized ABs through performance evaluations at least once every 4 years. We expect that approximately 10% of performance evaluations conducted as part of §1.633 of the Third-Party proposed rule

will be conducted onsite. As in the FDA's field audit during the application review process discussed above, it would cost an AB approximately $1,868 to provide staff labor to act as a liaison for the FDA team during their monitoring activities (see Table E1). We seek comments on the estimates associated with onsite performance evaluations by FDA, including the appropriate percentages of onsite evaluations of recognized ABs, their accredited auditors/CBs, and the eligible entities to which certifications were issued.

Recordkeeping

The Third-Party proposed rule requires, in §1.615, that each AB seeking FDA recognition to demonstrate that it has implemented written procedures to maintain records related to its accreditation program and activities demonstrating its authority, qualifications, conflict of interest measures, internal quality assurance program, performance, and corrective actions. Section 1.625 of the Third-Party proposed rule requires each AB, once recognized, to maintain records that include requests for accreditation, challenges to accreditation decisions, monitoring of auditors/CBs that it has accredited, the AB's self-assessments and corrective actions, and regulatory audit reports.

Currently, the AB industry maintains written records of its accreditation program, qualifications, annual self assessment, annual monitoring of its accredited auditors/CBs, and corrective actions. ABs also have provisions in place to ensure that that financial conflict of interest does not occur between themselves and the auditors/CBs that they accredit, and between accredited auditors/CBs and entities that they audit. However, we believe that an recognized AB incurs new recordkeeping burden by making its records available for inspection by the FDA.

We expect that it will take approximately 2 hours each year for a recognized AB to maintain its records to accommodate inspection by the FDA. The average hourly wage rate of

person(s) who will be completing the application is expected to be equivalent to that of a GS-14, Step 1 employee at $60.87 per hour (includes 50% overhead cost). Therefore, we estimate that it will cost approximately $122 per year for an AB to maintain its records in accordance with §1.615 and §1.625 of the Third-Party proposed rule. Unit cost of improving recordkeeping procedures for ABs is included in Table E1.

Section 1.624(c) of the Third-Party proposed rule requires ABs to maintain on its website an up-to-date list of its accredited auditors/CBs, the duration and scope of the accreditation, and the date on which the auditor/CB paid any fee or reimbursement associated with such accreditation. Currently, some but not all ABs disclose the names of their accredited auditors/CBs and scope of the auditors'/CBs' accreditation on their website. Therefore, we believe that some recognized ABs will incur a new recordkeeping burden by making information required by proposed §1.624(c) publicly available on their websites.

According to IT experts, it would cost approximately $1,000 for relatively minor modifications on an existing webpage. It would take an additional $3,000 for creation of a new webpage. We would expect that an AB would have minor changes on its main webpage by creating a link to a new webpage that would list the required information per §1.624(c) of the Third-Party proposed rule; hence, we estimate that each recognized AB would initially spend approximately $4,000 to update its webpage to conform with this section of the Third-Party proposed rule. In addition, we estimate that each AB would spend 8 hours annually, following the initial year, to update information as required by §1.624(c) of the Third-Party proposed rule. We expect the average hourly wage rate of IT person(s) who will be updating information on the AB's webpage to be equivalent to that of a GS-13, Step 5 employee at $58.38 per hour (includes 50% overhead cost).

Annual unit cost for an AB to update its webpage to conform to disclosure of information per §1.624(c) of the Third-Party proposed rule is estimated at $467 ($58.38/hour x 8 hours). One-time and annual unit costs for publicly disclosing information required per §1.624(c) of the Third-Party proposed rule are included in Table E1.

Reporting

Sections 1.621 and 1.623(a) of the Third-Party proposed rule require that recognized ABs annually conduct comprehensive assessments of the performance of auditors/CBs they have accredited and submit the assessments to the FDA within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to electronically send the assessment of each its accredited auditors/CBs to the FDA. Following the implementation of the Third-Party proposed rule, we expect, on average, each recognized AB would accredit 19.3 auditors/CBs ((568 existing accredited CBs + 764 newly accredited CBs) ÷ 69 ABs). Therefore, submission of performance assessments of 19.3 auditors/CBs would take approximately 4.83 hours/AB (0.25 hours/CB x 19.3 CBs/AB). We use hourly wage of an administrative assistant to estimate each AB's cost of submission of performance assessment of its accredited auditors/CBs to the FDA. The Bureau of Labor Statistics (BLS) reports the median hourly wage rate for administrative assistants as $19.25. The hourly wage rate plus 50% overhead cost for such positions are calculated as $28.78. Therefore, we estimate that it would cost each AB approximately $139 every year (4.83 hours/AB x $28.78/hour) to report findings of its review of operations of its accredited auditors/CBs to the FDA (see Table E1).

Sections 1.622 and 1.623(b) of the Third-Party proposed rule require that recognized ABs annually conduct a self-assessment and submit the assessments to the FDA within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to

electronically send a copy of its self-assessment to the FDA. Unit cost of submission of a self-assessment by an administrative assistant to the FDA is estimated at $7 (0.25 hour/AB x $28.78/hour) (see Table E1).

Contract Modification

We expect that upon the implementation of the rule, recognized ABs would modify the contracts they use with accredited auditors/CBs in order to reflect requirements that are set forth in the Third-Party proposed rule. Minor modifications or addenda to contracts with standard language provided by provisions in the Third-Party proposed rule would consist of no more than one hour by an AB executive and one hour by a legal counsel. BLS data indicates that an executive in management, scientific, and technical consulting services earns approximately $94.03 per hour ($62.69/hour plus 50% overhead), and lawyers in management of companies and enterprises earn approximately $105.12 per hour ($70.08/hour plus 50% overhead). Unit costs for contract modification by ABs are included in Table E1.

Table E1: Unit Costs of Participation Under the Third-Party Proposed Rule **– ABs**

Proposed Rule Section/Description	Number of Hours/Units	Wage Rate/ Cost	Unit Cost	Frequency
Application for Recognition				
§1.630 Application for recognition	80	$60.87	$4,870	One-time
§1.630 Application for renewal of recognition	40	$60.87	$2,435	Every 5 years
§1.631 Support for FDA team during initial onsite AB recognition performance evaluation	32	$58.38	$1,868	One-time
§1.631 Support for FDA team during renewal of onsite AB recognition performance evaluation	32	$58.38	$1,868	Every 5 years
Monitoring				
§1.633 Support for FDA team during onsite monitoring activities of ABs	32	$58.38	$1,868	Every 4 years
Recordkeeping				
§1.615, §1.625 Improving recordkeeping procedures	2	$60.87	$122	Annual
§1.624(c) Public list of certification bodies, scope of accreditation of accredited CBs, and fee payments	1	$4,000	$4,000	One-time
§1.624(c) Public list of certification bodies, scope of accreditation of accredited CBs, and fee payments	8	$58.38	$467	Annual
Reporting				
§1.623(a) Submission of review of CB performance	4.83	$28.87	$139	Annual
§1.623(b) Submission of self assessment	0.25	$28.87	$7	Annual
Contract Modification				
Contract modification between ABs and accredited CBs	1	$94.03	$94	One-time
Contract modification between ABs and accredited CBs (legal counsel)	1	$105.12	$105	One-time

Cost Summary – ABs

Total annualized cost for 69 ABs to conform to the Third-Party proposed rule for a 10-year period at 7% discount rate is estimated at approximately $215,866 (see Table E2). On average, cost of conformance to the Third-Party proposed rule for an AB would be approximately $3,128 per year ($215,866 ÷ 69 ABs). Total annualized cost for 69 ABs for a 10-year period at 3% discount rate is estimated at $189,245 or $2,743 per AB, on average.

Table E2: Undiscounted and Annualized Costs for Participation Under the Third-Party Proposed Rule – ABs

Third-Party Proposed Rule Section	Number of Units	Unit Cost	Number of ABs	Undiscounted cost[1]
Application for Recognition				
§1.630 Application for recognition	1	$4,870	69	$336,030
§1.631 Performance evaluation conducted by FDA during initial application review	1	$1,868	69	$128,892
§1.630 Application for renewal of recognition	1	$2,435	69	$168,015
§1.631Performance evaluation conducted by FDA during renewal application review	1	$1,868	17[2]	$31,756
Monitoring				
§1.633 Support for FDA team during onsite monitoring activities of ABs	2	$1,868	7[3]	$26,152
Recordkeeping				
§1.615, §1.625 Improving recordkeeping procedures	10	$122	69	$84,180
§1.624(c) Public list of certification bodies, scope of accreditation of accredited CBs, and fee payments	1	$4,000	69	$276,000
§1.624(c) Public list of certification bodies, scope of accreditation of accredited CBs, and fee payments	9	$467	69	$290,007
Reporting				
§1.623(a) Submission of review of CB performance	10	$139	69	$95,910
§1.623(b) Submission of self assessment	10	$7	69	$4,830
Contract Modification				
Contract modification between ABs and accredited CBs	19.3	$199	69	$265,008
Total Annualized Cost (7%)[4]	**$215,866**			
Total Annualized Cost (3%)[4]	**$189,245**			

1. Undiscounted cost comprises of summing nominal costs over a 10-year period.
2. Onsite performance evaluation during renewal of application activities is conducted at 25% of facilities (69 ABs).
3. Onsite monitoring activities is conducted at 10% of facilities (69 ABs).
4. Estimated for 10-year period at 7% discount rate

$A = \frac{PV}{\left[(1+i)^{n-1}\left(i*(1+i)^{n}\right)\right]}$, where PV = Present Value, n = 10, and i = 0.07 or 0.03

Accredited Auditors/Certification Bodies

Application for Direct Accreditation from FDA

Section 1.670(a-b) of the Third-Party proposed rule allows for CBs to directly apply for accreditation from the FDA under limited circumstances. We estimate that a CB completing and submitting an application for direct accreditation from FDA will expend the same amount of effort that an AB that applies for recognition from the FDA. Hence, we expect that it will take 80 person-hours to compile all the relevant information and complete the application for direct accreditation from the FDA. Therefore, we estimate that it will cost approximately $4,870 (80

hours x $60.87/hour) for an auditor/CB to apply for direct accreditation from the FDA. Unit cost of application for direct accreditation by auditors/CBs is included in Table E3. We seek comment on whether to base the cost estimate for an application for direct accreditation on the cost estimate for an AB's application for recognition, or whether a different assumption should be used.

Section 1.672 of the Third-Party proposed rule stipulates the term of accreditation for a directly-accredited auditor/CB not to exceed 4 years. Section 1.670 of the Third-Party proposed rule outlines the requirements of abbreviated application for renewal of accreditation by directly-accredited auditors/CBs. As with the application process for renewal of recognition by ABs, we expect that application for renewal of direct accreditation by auditors/CBs to take significantly less effort than the initial application. We use 50% of amount of effort to prepare and submit an application for renewal of direct accreditation to the FDA. Hence, it would cost approximately $2,435 to complete an application for renewal of direct accreditation every 4 years. Unit cost of application for renewal of direct accreditation by auditors/CBs is included in Table E3.

Application review activities by the FDA includes presence of FDA personnel in the facilities of auditors/CBs that apply for direct accreditation (§1.671) or that seek renewal of direct accreditation applications (§1.671). During these FDA activities, or field audits, it is expected that the subject CB would assign someone to serve as a liaison with the FDA during the entire time that the FDA team is onsite. We estimate that during each field audit at a CB facility, the FDA team spends approximately 4 days onsite at the auditor/CB headquarters. We also expect that the person employed by the AB that is assigned to the FDA team would have a management position and a salary equivalent to a GS-13, Step 5 pay level ($58.38/hour including 50% overhead costs). It is expected that there will be an auditor/CB representative present at the

auditor/CB headquarters for a total of 32 hours (4 days x 8 hours/day). Therefore, the cost of auditor/CB staff labor to assist during a FDA performance evaluation is estimated at $1,868 (32 hours x $58.38/hour). Unit cost of auditor/CB labor cost to assist FDA team during field audits as part of §1.671 of the Third-Party proposed rule is included in Table E3.

Monitoring

Section 1.662(a) of the Third-Party proposed rule requires that the FDA monitor auditors/CBs accredited by recognized ABs through performance evaluations at least once every 3 years. We expect that approximately 10% of performance evaluations conducted as part of §1.662(a) of the Third-Party proposed rule will be conducted onsite. As in the FDA's field audit during the application review process discussed above, it would cost an auditor/CB approximately $1,868 to provide staff labor to act as a liaison for the FDA team during their monitoring activities. We seek comments on the estimates associated with onsite performance evaluations by FDA, including the appropriate percentages of onsite evaluations of recognized ABs, their accredited auditors/CBs, and the eligible entities to which certifications were issued.

Similarly, section 1.662(a) of the Third-Party proposed rule stipulates that the FDA monitor directly-accredited auditors/CBs on an annual basis. Unit costs of §1.662(a) and §1.662(a) of the Third-Party proposed rule are included in Table E3.

Recordkeeping

Section 1.658 of the Third-Party proposed rule outlines recordkeeping requirements for accredited auditors/CBs. Based on descriptions by industry experts, we believe current recordkeeping practices by accredited auditors/CBs, for the most part, follow recordkeeping requirements set forth by the Third-Party proposed rule. (Ref 4, 5, 6) We expect that it will take approximately 1 hour each year for an accredited auditor/CB to modify its recordkeeping

practices to match the requirements of the Third-Party proposed rule. The average hourly wage rate of person(s) who will be completing the application is expected to be equivalent to that of a GS-14, Step 1 employee at $60.87 per hour (includes 50% overhead cost). Therefore, we estimate that it will cost approximately $61 per year for an accredited auditor/CB to organize records pertaining to §1.658 of the Third-Party proposed rule. Unit cost of recordkeeping requirements of accredited auditors/CBs included in Table E3.

Section 1.657(d) of the Third-Party proposed rule requires accredited auditors/CBs to maintain on its website an up-to-date list of the eligible entities for which it has issued certifications, duration of scope of certification for each eligible entity, and the date on which an the eligible entity paid any fee with regard to the certification. Currently, it is not customary for accredited auditors/CBs to publish information required per §1.657(d) of the Third-Party proposed rule on their websites. Therefore, we believe that public disclosure of information required per §1.657(d) is a new burden to the auditors/CBs.

We use the same cost estimate of $4,000 used in recordkeeping section of ABs, above, for initial cost of updating an auditor's/CB's webpage to include the information required in §1.624(c) of the Third-Party proposed rule. In addition, we estimate that each auditor/CB would spend 8 hours annually to update information as required by §1.657(d) of the Third-Party proposed rule. We expect the average hourly wage rate of IT person(s) who will be updating information on the auditor's/CB's webpage to be equivalent to that of a GS-13, Step 5 employee at $58.38 per hour (includes 50% overhead cost). Therefore, the annual unit cost for an auditor/CB to update its webpage to conform to disclosure of information per §1.657(d) of the Third-Party proposed rule is estimated at $467 ($58.38/hour x 8 hours). One-time and annual

unit costs for publicly disclosing information required per §1.657(d) of the Third-Party proposed rule are included in Table E3.

Reporting

Section 1.656(a) of the Third-Party proposed rule requires that an accredited auditor/CB must submit reports of the regulatory audits it conducts to FDA and to the AB that granted its accreditation within 45 days after completing such audit. In the analysis, we estimate a total of 1,337 CBs that would potentially comply with the Third-Party proposed rule (see Table 2). Furthermore, we estimated that each accredited auditor/CB will conduct annual regulatory audits and certification for approximately 57 eligible entities. We expect that it would take an accredited auditor/CB no more than 15 minutes to electronically submit a copy of a regulatory audit report to the FDA. Therefore, it would take approximately 14.25 hours (0.25 hours/regulatory report x 57 regulatory reports) per year for an accredited auditor/CB to submit its regulatory reports to the FDA, and an additional 14.25 hours per year to submit these records to its AB. We use hourly wage rate of an administrative assistant, $28.87, to calculate the unit cost of submission regulatory audits of eligible entities by an accredited auditor/CB to FDA and its accrediting AB in a given year. Therefore, the annual unit cost for an auditor/CB to submit copies of its regulatory audit reports to FDA or its AB is estimated at $411 (14.25 hours x $28.87/hour) (see Table E3).

Section 1.656(b) of the Third-Party proposed rule requires that an accredited auditor/CB must submit a copy of its annual self-assessment to its AB, or in the case of direct accreditation to the FDA, within 45 days of the anniversary date of its accreditation. We expect that it would take an accredited auditor/CB no more than 15 minutes to electronically submit a copy of its self assessment to its AB or, in the case of direct accreditation, to the FDA. Therefore, we estimate

that the annual submission of self-assessment by accredited auditors/CBs at approximately $7 (0.25 hours x $28.87/hour (see Table E3).

Section 1.656(c) of the Third-Party proposed rule requires that an accredited auditor/CB report to the FDA any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. Currently, we do not have any information on frequency of reporting serious public health risks by an accredited auditor/CB to its AB. We request comments on existence of such information. We believe that these occurrences are rare and may occur once every 4 years. It is expected that an accredited auditor/CB would take no more than 1 hour to prepare such record (notification). Therefore, we estimate that, on average, it would cost an accredited auditor/CB approximately $58 (1 hour x $58.38/hour) to document a condition that could cause or contribute to a serious risk to public health. In addition, it would take an administrative assistant no more than 15 minutes to electronically send the report documenting the serious risk to public health to the FDA. An accredited auditor's/CB's unit cost for documenting and reporting serious risks to the public health discovered during a regulatory or consultative audit of an eligible entity to the FDA is included in Table E3.

Following reporting of a condition that could cause or contribute a serious risk to the public health to the FDA, an accredited auditor/CB is required under §1.656(e) of the Third-Party proposed rule to immediately notify the eligible entity and its accrediting AB of any conditions identified during the audit which triggered the reporting requirement per §1.656(c) of the Third-Party proposed rule. We are not aware of any formal process currently used by CBs to communicate conditions which are identified as serious public health risks to their clients; hence, this provision is considered as a new burden for accredited auditors/CBs. It is expected

that following reporting of a serious public health risk by an accredited auditor/CB to the FDA per §1.656(c) of the Third-Party proposed rule, it would take the accredited auditor/CB no more than 15 minutes to transmit the same report to the eligible entity where the serious hazard was observed and to its AB (if other than FDA). Unit cost of reporting a condition that could cause or contribute to a serious risk to the public health by an accredited auditor/CB to an eligible entity is included in Table E3.

Contract Modification

We expect that upon the implementation of the rule, accredited auditors/CBs would modify the contracts they use with their clients in order to reflect requirements that are set forth in the rule. Minor modifications or addenda to contracts with standard language provided by provisions in the Third-Party proposed rule would consist of no more than one hour by an AB executive and one hour by a legal counsel. BLS data indicates that an executive in management, scientific, and technical consulting services earns approximately $94.03 per hour ($62.69/hour plus 50% overhead), and lawyers in management of companies and enterprises earn approximately $105.12 per hour ($70.08/hour plus 50% overhead). Unit costs for contract modification by auditors/CBs are included in Table E3.

Table E3: Unit Costs of Participation Under the Third-Party Proposed Rule – Accredited CBs

Third-Party Proposed Rule Section	Number of Hours/Units	Wage Rate/ Cost	Unit Cost	Frequency
Application for Direct Accreditation				
§1.670(a-b) Application for direct accreditation	80	$60.87	$4,870	One-time
§1.670 Application for renewal of direct accreditation	40	$60.87	$2,435	Every 4 years
§1.671) Support for FDA team during initial onsite CB direct accreditation performance evaluation	32	$58.38	$1,868	One-time
§1.671 Support for FDA team during renewal of onsite CB direct accreditation performance evaluation	32	$58.38	$1,868	Every 4 years
Monitoring				
§1.662(a) Support for FDA team during monitoring activities of accredited CBs	32	$58.38	$1,868	Every 3 years
§1.662(a) Support for FDA team during monitoring activities of directly-accredited CBs	32	$58.38	$1,868	Annual
Recordkeeping				
§1.658 Organizing records in accordance with the proposed Third Party rule	1	$60.87	$61	Annual
§1.657(d) Public list of certification bodies, and other info (initial)	1	$4,000	$4,000	One-time
§1.657(d) Public list of certification bodies, and other info (annual)	8	$58.38	$467	Annual
Reporting				
§1.656(a) Submission of regulatory audit reports to FDA and to the ABs	14.25	$28.87	$411	Annual
§1.656(b) Submission of self-assessment	0.25	$28.87	$7	Annual
§1.656(c) Reporting to the FDA of a condition that could cause or contribute to a serious risk to the public health (preparation of report)	1	$58.38	$58	Every 4 years
§1.656(c) Reporting to the FDA of a condition that could cause or contribute to a serious risk to the public health (submission of report)	0.25	$28.87	$7	Every 4 years
§1.656(e) Submission of a report to eligible entity documenting a condition that would cause or contribute to a serious risk to the public health	0.25	$28.87	$7	Every 4 years
Contract Modification				
Contract modification between CBs and eligible entities	1	$94.03	$94	One-time
Contract modification between CBs and eligible entities (legal counsel)	1	$105.12	$105	One-time

Cost Summary – Accredited Auditors/CBs

Total annualized cost for 1,332 accredited auditors/CBs and 4 auditors/CBs directly accredited by the FDA to conform to the Third-Party proposed rule for a 10-year period at 7% discount rate is estimated at approximately $4.9 million (see Table E4). On average, cost of conformance to the Third-Party proposed rule for an accredited auditor/CB would be approximately $3,646 ($4,871,261 ÷ 1,336 CBs). Total annualized cost for 1,332 accredited auditors/CBs and 4 auditors/CBs directly accredited by the FDA for a 10-year period at 3% discount rate is estimated at $4,297,105 or $3,216 per accredited auditor/CB, on average.

Table E4: Undiscounted and Annualized Costs Under the Third-Party Proposed Rule – Third Party Auditors/CBs

Third-Party Proposed Rule Section	Number of Units	Unit Cost	Number of CBs/Entities	Undiscounted cost[1]
Application for Direct Accreditation				
§1.670(a-b) Application for direct accreditation	1	$4,870	4	$19,480
§1.670 Application for renewal of recognition	2	$2,435	4	$19,480
§1.671 Performance evaluation conducted by FDA during review of initial application for direct accreditation	1	$1,868	4	$7,472
§1.671 Performance evaluation conducted by FDA during review of renewal application for direct accreditation	2	$1,868	4	$14,944
Monitoring				
§1.662(a) Support for FDA team during monitoring activities of accredited CBs	3	$1,868	133[2]	$745,332
§1.662(a) Support for FDA team during monitoring activities of directly-accredited CBs	10	$1,868	4	$74,720
Recordkeeping				
§1.658 Organizing records in accordance with the proposed Third Party rule	10	$61	1,336	$814,960
§1.657(d) Public list of certification bodies, and other info (initial)	1	$4,000	1,336	$5,344,000
§1.657(d) Public list of certification bodies, and other info (annual)	9	$467	1,336	$5,615,208
Reporting				
§1.656(a) Submission of regulatory audit reports to FDA	10	$411	1,336	$5,490,960
§1.656(a) Submission of regulatory audit reports to ABs	10	$411	1,332	$5,474,520
§1.656(b) Submission of self-assessment	10	$7	1,336	$93,520
§1.656(c) Reporting to the FDA of a condition that could cause or contribute to a serious risk to the public health (preparation of report)	2	$58	1,336	$154,976
§1.656(c) Reporting to the FDA of a condition that could cause or contribute to a serious risk to the public health (submission of report)	2	$7	1,336	$18,704
§1.656(e) Submission of a report to eligible entity documenting a condition that would cause or contribute to a serious risk to the public health	2	$7	1,336	$18,704
Contract Modification				
Contract modification between CBs and eligible entities	1	$199	57,504	$11,463,793
Total Annualized Cost (7%)[3]	**$4,871,261**			
Total Annualized Cost (3%)[3]	**$4,297,105**			

1. Undiscounted cost comprises of summing nominal costs over a 10-year period.
2. On-site monitoring activities is conducted at 10% of facilities (1,333 CBs).
3. Estimated for 10-year period at 7% discount rate

$A = \frac{PV}{\left[(1+i)^{n-1}\left(i*(1+i)^{n}\right)\right]}$, where PV = Present Value, n = 10, and i = 0.07 or 0.03

Unaccredited Auditors/Certification Bodies

The Third-Party proposed rule potentially will induce some unaccredited auditors/CBs to become accredited in order to provide services for eligible entities. Currently, it takes 6-9

months for an unaccredited auditor/CB to conform the requirements of an AB. The costs for an unaccredited auditor/CB to become accredited include cost of requirements (i.e., requirements and standards for training, recordkeeping, etc.), application fee, initial assessment fee, annual accreditation fee, and annual royalty fee. According to the RTI report, cost associated with changes in an unaccredited auditor's/CB's operations in preparation for obtaining accreditation from an AB is between $20,000 and $30,000. We use an average of $25,000 for the initial cost for an unaccredited auditor/CB to become in compliance with the requirements for accreditation. The RTI report also includes a survey of 6 ABs (ANAB, ANSI, UKAS, CNAS, DANAK, and NABCB) to estimate the initial one-time cost and annual cost of auditors/CBs that choose to become accredited. Survey results of these cost estimates are included in Table E5. The initial one-time cost, estimated at $13,850 (average cost of 6 ABs), is based on application fee and an assessment fee which includes a site assessment and comprehensive records assessment. The annual cost, estimated at $7,597 (average cost of 6 ABs), includes annual assessment fee and royalty fee based on revenues from certifying services. These costs are in addition to those costs described for conformance of accredited auditors/CBs to the Third-Party proposed rule (see Tables E3 and E4). Unit costs for accreditation process of unaccredited auditors/CBs are included in Table E6.

Table E5: Initial and Annual Accreditation Costs – Survey of 6 ABs

Description	Initial Cost	Annual Cost
ANAB	$21,250	$12,250
ANSI	$17,500	$7,000
UKAS	$16,598	$6,134
CNAS	$6,850	$8,806
DANAK	$13,022	$5,878
NABCB	$7,880	$5,516
Average	**$13,850**	**$7,597**

Source: RTI Study (2012)

Table E6: Accreditation Unit Costs – Unaccredited Auditors/CBs

Description	Number of Hrs/ Units	Wage Rate/ Cost	Unit Cost	Frequency
Application and assessor fees	1	$13,850	$13,850	One-time
Conformance to accreditation requirements	1	$25,000	$25,000	One-time
Assessment and royalty fees	1	$7,597	$7,597	Annual

We anticipate that, following the implementation of the rule, under a full compliance scenario, 764 unaccredited auditors/CBs (see Table 2) would be induced to become accredited under the FDA program to satisfy demand of eligible entities currently being audited by unaccredited auditors/CBs. We estimate the annualized cost of 764 unaccredited auditor/CBs to become accredited and conform to the Third-Party proposed rule for a 10-year period at 7% and 3% discount rates. Table E7 includes the line item cost for annualized cost (at 7% discount rate) of approximately $10.5 million for an expected 764 unaccredited auditors/CBs that potentially will be induced to conform to the Third-Party proposed rule. Average annualized cost of conforming to the Third-Party proposed rule for each unaccredited auditor/CB is approximately $13,661 ($10,436,631 ÷ 764). Total annualized cost for 764 unaccredited auditors/CBs for a 10-year period at 3% discount rate is estimated at $9,458,060 or $12,380 per unaccredited auditor/CB, on average.

Table E7: Undiscounted and Annualized Costs Under the Third-Party Proposed Rule – Unaccredited CBs

Third-Party Proposed Rule Section	Number of Units	Unit Cost	Number of CBs	Undiscounted Cost[1]
Application and assessor fee	1	$13,850	764	$10,581,400
Conformance to accreditation requirements	1	$25,000	764	$19,100,000
Assessment and royalty fees	10	$7,597	764	$58,043,627
Total Annualized Cost (7%)[2]	**$10,436,631**			
Total Annualized Cost (3%)[2]	**$9,458,060**			

1. Undiscounted cost comprises of summing nominal costs over a 10-year period.
2. Estimated for 10-year period at 7% discount rate

$A = \frac{PV}{\left[(1+i)^{n-1}\left(i*(1+i)^{n}\right)\right]}$, where PV = Present Value, n = 10, and i = 0.07 or 0.03

Cost of Conformance to the Third-Party Proposed Rule

Undiscounted and annualized compliance costs of ABs, accredited auditors/CBs, and unaccredited auditors/CBs are summarized in Table E8. Considering that on average there are 19.3 accredited auditors/CBs per AB, we divide total annualized cost (at 7% discount rate) of ABs by the total number of auditors/CBs to estimate the cost of AB's compliance cost to each auditor/CB: $162.10 ($215,866 ÷ (69 ABs x 19.3 CBs/AB)). As we explained, following the implementation of the proposed Third Party rule, we expect approximately 57 eligible entities per accredited auditor/CB; hence, the cost share of ABs passed further down to each eligible entity is approximately $2.84 ($162.10/ CB ÷ 57 eligible entities/CB). The cost of accredited auditors/CBs and unaccredited auditors/CBs are calculated by dividing total annualized cost of each category by total number of auditors/CBs (1,336[15]), and then dividing each cost by 57 to obtain the cost of auditors'/CBs' compliance costs that are potentially passed down to their client eligible entities.

Table E8: AB and Auditor/CB Pass-Through Costs to Eligible Entities

Description	Undiscounted Cost	Annualized Cost (7%)	Cost Per CB[1]	Cost per Eligible Entity[2]
ABs	$1,706,780	$215,866	$162	$2.84
Accredited CBs	$35,350,276	$4,871,261	$3,646	$63.96
Unaccredited CBs	$87,725,027	$10,436,631	$7,812	$137.05
Cost to eligible entity				**$204**

1. Under full compliance, there are an estimated 69 ABs and 19.3 accredited CBs per AB.
2. Under full compliance, there are an estimated 57 eligible entities per accredited CB.

References

5. Economic Analysis of Third-Party Food Safety Certification of Imported Food, June, 2012. RTI for FDA under Contract HHSF22320710273G, Task Order 13.

6. Meeting with ANSI (Pirouz Foroutan, FDA Economist), December 7, 2011.

[15] There are a total of 1,332 accredited auditors/CBs under a full compliance scenario (see Table 2 in the analysis) and 4 additional auditors/CBs directly accredited by the FDA.

7. Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2013, DHHS, FDA, Docket No. FDA-2012-N-0799, Federal Register, Vol. 77, No. 148, 45636-38.

Appendix F

Paperwork Reduction Act of 1995

Proposed Rule on Foreign Supplier Verification Programs (FSVPs)

This proposed rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). A description of these provisions is given in the Description section of this document with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals.

Description: FDA is proposing to adopt regulations on foreign supplier verification programs (FSVPs) for food for humans and animals. The proposed regulations are intended to ensure that food imported into the United States is produced in compliance with processes and

procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as the processes and procedures required for production of food in compliance with section 418 or 419 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350g or 350h), if either is applicable, and in compliance with sections 402 and 403(w) of the FD&C Act (21 U.S.C. 342 and 343(w)).

Description of Respondents: Generally, persons who import food into the United States. We estimate that there are approximately 56,800 persons who meet the definition of importer set forth in the proposed rule. However, the proposed rule would exempt from the FSVP requirements the importation of certain foods, including certain juice and seafood products, food for research or evaluation (exempt but subject to a third-party disclosure requirement), food for personal consumption, certain alcoholic beverages, food that is transshipped, and food that is imported for further processing and future export. Certain exceptions to the standard FSVP requirements would apply to food for which the importer or its customer controls the hazard and to raw agricultural commodities (RACs) that are fruits or vegetables. In addition, the proposed rule would establish modified FSVP requirements for importers of dietary supplements, very small food importers, importers of food from very small foreign suppliers, and importers of food from suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

Reporting Burden

A. Exemption for Food for Research or Evaluation

Under proposed § 1.501(c), the FSVP regulations would not apply to food that is imported for research or evaluation purposes, provided that:

- The food is not intended for retail sale and is not sold or distributed to the public.
- The food is labeled with the statement "Food for research or evaluation use."
- When filing entry for the food with U.S. Customs and Border Protection (CBP), the customs broker or filer for the food provides an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

As shown in Table 1 of this document, we estimate that annually there will be 36,360 persons for whom a declaration that a food will be used for research or evaluation purposes will be submitted, and that about 40 declarations will be submitted for each such person annually. We further estimate that submission of this declaration should take approximately 0.083 hours, resulting in a total annual burden of 120,715 hours.

B. Importer Identification at Entry

Proposed § 1.509(c) would require importers to ensure that, for each line entry of food product offered for importation into the United States, its name and Dun & Bradstreet Data Universal Numbering System (DUNS) number is provided electronically when filing entry with CBP. As shown in Table 1, we estimate that each of the estimated 56,800 importers will need to ensure that this information is provided for an average of 157 line entries each year. We further estimate that each such submission will require 0.02 hours, resulting in a total annual burden of 178,352 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Exemption for Food for research 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
DUNS number for filing with CBP 1.509(c), 1.511(c), 1.512(b)(2)	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total					299,067

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping Burden

A. Documentation of Production of LACF in Accordance with Part 113

Proposed § 1.502(b) would require importers of thermally processed low-acid canned foods (LACF) packaged in hermetically sealed containers to verify and document that, with respect to microbiological hazards that are controlled under part 113 (21 CFR part 113), the food was produced in accordance with those regulations, and for all matters not controlled under part 113, to have an FSVP as specified in § 1.502(a). As shown in Table 2, we estimate that there are 2,443 importers of LACF importing an estimated 4 LACF products annually. We further estimate that it will take each LACF importer 1 hour to document that a food was produced in accordance with part 113. This results in a total annual burden of 9,772 hours.

B. Review of Food and Supplier Compliance Status

Proposed § 1.504 would require importers, before importing a food from a foreign supplier, to review the compliance status of the food and the foreign supplier, including whether

they are the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the FD&C Act (21 U.S.C. 381(q)) relating to the safety of the food, to determine whether it would be appropriate to import the food from the foreign supplier. Importers would be required to document this review and to continue to monitor and document the compliance status as long as they continue to import the food from the foreign supplier. As shown in Table 2, we estimate that 53,291 importers will spend 2 hours documenting the compliance status review for each supplier (based on an average of 5 suppliers per importer), resulting in a total annual burden of 532,910 hours.

C. Hazard Analysis

Proposed § 1.505(a) would require importers, for each food they import or offer for import, to determine and document the hazards that are reasonably likely to occur with the food and the severity of the illness or injury if such a hazard were to occur. Proposed § 1.505(d) would permit importers to identify the hazards that are reasonably likely to occur with a food by reviewing and evaluating the hazard analysis conducted by the foreign supplier of the food. We estimate that 27,829 importers will take this approach for about 1 product each annually and will need to spend an average of 3.7 hours each determining and documenting hazard analyses, resulting in an estimated annual burden of 102,967 hours under § 1.505(a). Under § 1.505(d) these importers will often be able to review the hazard analyses done by the suppliers of a number of the foods that they import. When the importers are able to use this approach to hazard analysis (which we expect they will be able to do for most of their products) they must document the determination that they make based on their review and evaluation of the foreign supplier's hazard analysis. As shown in Table 2, we estimate that these 27,829 importers will take this approach to hazard analysis for about 7 products each annually, and that evaluating the supplier's

hazard analysis and documenting each evaluation will require about 1 hour on average. This results in a total annual burden of 194,803 hours.

D. Foreign Supplier Verification and Related Activities

Proposed § 1.506(a) would require each importer to maintain a written list of their foreign suppliers. As shown in Table 2, we estimate that it will take 1.5 hours annually for each of an estimated 56,800 importers to maintain its list of foreign suppliers, resulting in a total annual burden of 85,200 hours.

Under proposed § 1.506(b), importers must establish and follow adequate written procedures for conducting foreign supplier verification activities. As shown in Table 2, we estimate that it will take each of 27,829 importers 2 hours to establish procedures for about 7 hazards/products per importer resulting in a total annual burden of 389,606 hours.

Proposed § 1.506(e) would require importers who are controlling a hazard in a food they import to document, at least annually, that they have established and are following procedures that adequately control the hazard. In the Preliminary Regulatory Impact Analysis (PRIA) for the proposed rule, we did not estimate a cost for an importer to document that it has established and is following procedures that adequately control hazards that it controls itself because most importers that would control hazards themselves would be food manufacturers or processers that would be subject to the proposed rule on preventive controls for human food and would thus incur such costs under that rule. Therefore, we do not calculate a PRA burden associated with § 1.506(e) here.

Proposed § 1.506(f) would require importers whose customer is controlling a hazard in a food they import to document that the customer controls the hazard by obtaining written assurance, at least annually, from the customer that it has established and is following procedures

(identified in the written assurance) that adequately control the hazard. As shown in Table 2, we estimate that 23,715 importers will need to obtain about 5 assurances per year and that obtaining and documenting each assurance will require 1 hour, resulting in a total annual burden of 118,575 hours.

We are proposing two alternative approaches for the requirements for other supplier verification activities under § 1.506(g) and § 1.506(h). Option 1 of the co-proposal would establish different requirements for (a) hazards 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 (SAHCODHA hazards) to be controlled by the foreign supplier and (b) all hazards not addressed elsewhere in proposed § 1.506 (including non-SAHCODHA hazards and SAHCODHA hazards that the foreign supplier verifies have been controlled by its raw material or ingredient supplier). Option 2 of the co-proposal would require the importer to determine the supplier verification activity it would use for all hazards that the foreign supplier controls or verifies control of.

Under Option 1, proposed § 1.506(g)(1) would require importers to conduct (and document) or obtain documentation of initial and periodic onsite audits for SAHCODHA hazards to be controlled by the foreign supplier at its establishment. Under Option 1's proposed 1.506(h), importers of RACs that are fruits or vegetables and that are subject to the proposed regulations on standards for produce safety would be required to conduct (and document) or obtain documentation of an onsite audit of the foreign supplier that examines the control of microbiological hazards associated with the fruit or vegetable. As shown in Table 2, under Option 1, we estimate that 5,947 audits will be conducted each year for SAHCODHA hazards in food (under proposed § 1.506(g)) and microbiological hazards in fruits and vegetables (under

proposed § 1.506(h)) and that conducting and documenting of each audit would require an average of 14 hours each, resulting in a total annual burden of 83,258 hours.

With respect to hazards that are not subject to Option 1's proposed § 1.506(g)(1), proposed § 1.506(g)(2) would require the importer to determine and document which of the verification activities in proposed § 1.506(g)(2)(i) through (g)(2)(iv) are appropriate for verifying that the hazard is adequately controlled. In addition, the importer would be required to determine and document the frequency of the verification activities. In determining the appropriate verification activities and how frequently they must be conducted, the importer would be required to consider the risk presented by the hazard and the food and foreign supplier's compliance status as reviewed under § 1.504. We estimate that this provision will affect 23,742 importers annually and that each importer will need to make and document 8 determinations (regarding both the appropriate verification activity and its frequency) each year, with documentation of each determination requiring, on average, 0.75 hours. This results in a total annual burden of 142,452 hours. Under Option 1's proposed § 1.506(g)(2)(i), an importer may conduct (and document) or obtain documentation of a periodic onsite audit. As shown in Table 2, we estimate that 59 such audits will be conducted or documentation obtained for; with each audit requiring an average of 14 hours each, resulting in a total annual burden of 826 hours.

Under Option 1's proposed § 1.506(g)(2)(ii), an importer may conduct (and document) or obtain documentation from a foreign supplier of lot-by-lot or periodic sampling and testing of a food for a hazard. As shown in Table 2, we estimate that 23,742 importers each year will determine that this approach to verification is appropriate an average of 5 times per year. We

further estimate that each incidence of sampling and testing and corresponding documentation will require 4 hours. This results in a total annual burden of 474,840 hours.

Under Option 1's proposed § 1.506(g)(2)(iii), an importer may conduct (and document) or obtain documentation of a review of its foreign supplier's food safety records to verify control of a hazard. As shown in Table 2, we estimate that 23,742 importers each year will determine that this approach to verification is appropriate an average of 5 times per year. We further estimate that conducting and documenting a food safety record review will require 1.6 hours on average per occasion, resulting in a total annual burden of 189,936 hours.

Under Option 1's proposed § 1.506(g)(2)(iv), an importer may use a different verification procedure that it has established as being appropriate based on the risk associated with the hazard for a food; the importer must document such use. We have not identified any alternative verification procedure nor included such costs in the PRIA; therefore we do not identify any associated burden here for Option 1's proposed § 1.506(g)(2)(iv).

Under Option 1's proposed § 1.506(g)(4), instead of an onsite audit conducted under § 1.506(g) or (h), an importer may rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. We do not estimate a PRA burden associated with this option because FDA has only officially recognized one country's food safety system to date and the Agency inspects only a small percentage of foreign food facilities each year.

Under Option 2 of the co-proposal on supplier verification activities, proposed § 1.506(g)(1) would require, for any hazard that the importer has identified as reasonably likely

to occur with a food that is to be controlled by the foreign supplier or for which the foreign supplier verifies control by its supplier, that the importer conduct one or more of the verification activities listed in § 1.506(g)(1)(i) through (g)(1)(iv) before using or distributing the food and periodically thereafter. Option 2's proposed § 1.506(g)(1) also would require the importer to determine and document which verification activity or activities are appropriate to adequately verify that the hazard is adequately controlled, as well as to determine and document how frequently the verification activities must be conducted. In addition, Option 2's proposed § 1.506(g)(1) would require the importer, in determining the appropriate verification activities and how frequently they should be conducted, to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, and the food and foreign supplier's compliance status as reviewed under § 1.504.

Under Option 2's proposed 1.506(h), for a RAC that is a fruit or vegetable and that is subject to part 112, proposed § 1.506(h) would require the importer, in addition to meeting the other requirements of § 1.506, to conduct one or more of the verification activities listed in § 1.506(g)(1)(i) through (iv), before importing the fruit or vegetable from the foreign supplier and at least annually thereafter, to provide adequate assurances that the foreign supplier was producing the fruit or vegetable in accordance with processes and procedures that provide the same level of public health protection as those required under part 112. As shown in Table 2b, under Option 2, we estimate that proposed § 1.506(g) and (h) combined will affect 23,742 importers annually and that each importer will need to make and document 8 determinations (regarding both the appropriate verification activity and its frequency) each year, with

documentation of each determination requiring, on average, 0.75 hours. This results in a total annual burden of 142,452 hours.

Under Option 2's proposed § 1.506(g)(1)(i) and § 1.506(h), an importer may conduct (and document) or obtain documentation of a periodic onsite audit of the foreign supplier. As shown in Table 2b, we estimate that 4,936 such audits will be conducted or documentation obtained for, with each audit requiring an average of 14 hours each, resulting in a total annual burden of 69,104 hours.

Under Option 2's proposed § 1.506(g)(1)(ii) and § 1.506(h), an importer may conduct (and document) or obtain documentation from a foreign supplier of lot-by-lot or periodic sampling and testing of a food for a hazard. As shown in Table 2b, we estimate that 23,742 importers each year will determine that this approach to verification is appropriate an average of 5 times per year. We further estimate that each incidence of sampling and testing and corresponding documentation will require 4 hours. This results in a total annual burden of 474,840 hours.

Under Option 2's proposed § 1.506(g)(1)(iii) and § 1.506(h), an importer may conduct (and document) or obtain documentation of a review of its foreign supplier's food safety records to verify control of a hazard. As shown in Table 2b, we estimate that 23,742 importers each year will determine that this approach to verification is appropriate an average of 5 times per year. We further estimate that documentation of food safety record review will require 1.6 hours, resulting in a total annual burden of 189,936 hours.

Under Option 2's proposed § 1.506(g)(1)(iv) and § 1.506(h), an importer may use a different verification procedure that it has established as being appropriate based on the risk associated with the hazard for a food; the importer must document such use. We have not

identified any alternative verification procedure nor included such costs in the PRIA; therefore we do not identify any associated burden here for Option 2's proposed § 1.506(g)(1)(iv) and (h).

Option 2's proposed § 1.506(g)(3) would allow an importer, instead of conducting an onsite audit conducted under § 1.506(g) or (h), to rely on the results of an inspection of the foreign supplier by FDA or the food safety authority of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, provided that the inspection was conducted within 1 year of the date that the onsite audit would have been required to be conducted. We do not estimate a PRA burden associated with this option because FDA has only officially recognized one country's food safety system to date and the Agency inspects only a small percentage of foreign food facilities each year.

E. Review of Complaints, Investigations, and Corrective Actions

Proposed § 1.507(b) would require an importer, if it became aware that an article of food that it imported was adulterated or misbranded, to promptly investigate the cause or causes of such adulteration or misbranding and to document any such investigation. As shown in Table 2, we estimate that 10,658 importers will need to conduct 1 such investigation each year, and that conducting and documenting an investigation will require 14 hours. This would result in a total annual burden of 149,212 hours.

Proposed § 1.507(c) would require an importer to take corrective actions if it determines that one of its foreign suppliers of a food does not produce the food in compliance with the requirements of section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act. Such corrective actions will depend on the circumstances but could include discontinuing use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding

have been adequately addressed. In the PRIA we postulated that most importers probably already take some type of corrective actions if they determine that a food they import is not in compliance with appropriate regulations and that they probably document those corrective actions. Therefore, because we assume that most importers already take these types of corrective actions, we did not estimate the cost of additional corrective actions in the PRIA nor calculate a burden associated with corrective actions in the PRA.

Proposed § 1.507(d) would require an importer, if it determines by means other than its verification activities conducted under § 1.506 or § 1.511(c) or its FSVP reassessment conducted under § 1.508, that one of its foreign suppliers does not produce food in compliance with the requirements of section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) of the FD&C Act, to promptly investigate to determine whether the importer's FSVP is adequate and, when appropriate, to modify the FSVP. This provision also would require importers to document any such investigations and FSVP changes. As shown in Table 2, we estimate that, on average, 10,658 importers will need to conduct an investigation once a year to determine the adequacy of their FSVP in accordance with proposed § 1.507(d), and that conducting and documenting the investigation will require 5 hours. This results in a total annual burden of 53,290 hours.

F. FSVP Reassessment

Proposed § 1.508(b) would require an importer to document each reassessment of its FSVP that it conducts under § 1.508 and any resulting changes to the FSVP. Reassessment would be required every 3 years or more frequently if an importer becomes aware of new information about potential hazards associated with a food that it imports. We did not estimate a cost for reassessing an importer's FSVP under this requirement in the PRIA because we have

already incorporated the costs of reassessment into the costs for maintaining the various elements of the FSVP in other provisions. Therefore we do not calculate an associated PRA burden here.

G. Food Subject to Certain Dietary Supplement Current Good Manufacturing Practice (CGMP) Regulations

Proposed § 1.511 sets forth modified FSVP requirements for food that is subject to certain dietary supplement CGMP regulations. Under proposed § 1.511(a), importers who are required to establish specifications under 21 CFR 111.70(b), (d), or (f) with respect to a food, and are in compliance with the requirements of part 111 applicable to determining whether those specifications are met, must comply with the requirements in proposed §§ 1.506(a), 1.509, and 1.510, but are not required to comply with the requirements of proposed §§ 1.502 through 1.508 (except § 1.506(a)). These importers are included in the estimated reporting burden for proposed § 1.509(c) and the estimated recordkeeping burden for proposed § 1.506(a).

Under proposed § 1.511(b), if an importer's customer is required to establish specifications under 21 CFR 111.70(b), (d), or (f) with respect to a food, the customer is in compliance with the requirements of part 111 applicable to determining whether those specifications are met, and the importer annually obtains from its customer written assurance that the customer is in compliance with those requirements, then for that food the importer must comply with the requirements in §§ 1.506(a), 1.509, and 1.510, but is not required to comply with the requirements of §§ 1.502 through 1.508 (except § 1.506(a)). As shown in Table 2, we estimate that 3,509 importers (using the maximum number of importers where either they or their customer is required to establish specifications) will need to obtain written assurance from an average of 6 customers in accordance with § 1.511(b) and that documentation of each assurance will take 2.25 hours, resulting in a total annual burden of 47,372 hours. In addition,

these importers are included in the estimated annual reporting burden for proposed § 1.509(c) and the estimated annual recordkeeping burden for proposed § 1.506(a).

Under proposed § 1.511(c), importers of "finished" dietary supplements (i.e., packaged and labeled dietary supplements that are not subject to further processing) would be subject to different FSVP requirements. Proposed § 1.511(c)(2) would require importers of finished dietary supplements to maintain a written list of foreign suppliers from which they are importing food. This burden to importers of "finished" dietary supplements is captured in the burden calculated for proposed § 1.506(a). Proposed § 1.511(c)(3) would require importers of finished dietary supplements to establish and follow procedures for conducting foreign supplier verification activities. This burden is included in the burden of proposed § 1.506(b).

Proposed § 1.511(c)(5) would require importers of finished dietary supplements to determine and document which appropriate verification activities should be conducted, and the frequency with which they should be conducted. As shown in Table 2, we estimate that this provision will affect 1,822 importers annually and that each importer will need to make and document about 2 determinations (regarding both the appropriate verification activity and its frequency) each year, with making and documenting of each determination requiring 2.5 hours. This results in a total annual burden of 9,110 hours.

For each "finished" dietary supplement imported, the importer would need to conduct one or more of the verification activities listed in proposed § 1.511(c)(5)(i) through (c)(5)(iv) before using or distributing the dietary supplement and periodically thereafter. The estimates associated with these activities are included in the burdens presented in Table 2 and 2b for Option 1's § 1.506(g)(2)(i) through (g)(2)(iv) and Option 2's § 1.506(g)(1)(i) through (g)(1)(iv), respectively.

Proposed § 1.511(c) also would require importers of finished dietary supplements to conduct supplier compliance assessments, conduct investigations and corrective actions, reassess the effectiveness of their FSVP, and ensure that information identifying them as the importer is provided at entry. These importers have been included in the estimated recordkeeping and reporting burdens for these activities under proposed §§ 1.504, 1.507(b), and 1.509(c), respectively. We do not estimate any specific burden associated with corrective actions (§ 1.507(c)) nor with reassessment of the FSVP (§ 1.508(b)) as those burdens are encompassed in other calculations.

H. Food Imported by Very Small Importers and from Very Small Foreign Suppliers

Proposed § 1.512 sets forth modified FSVP requirements for very small importers (i.e., importers with annual food sales of not more than $500,000) and food from very small foreign suppliers (i.e., foreign suppliers with annual food sales of not more than $500,000).

Under proposed § 1.512(b)(1), if a very small importer or an importer of food from a very small foreign supplier chooses to comply with the requirements in § 1.512, the importer would be required to document, at the end of each calendar year, that it meets the definition of very small importer in § 1.500 or that the foreign supplier meets the definition of very small foreign supplier in § 1.500, whichever is applicable. As shown in Table 2, we estimate that 152,395 importers will need to document eligibility each year (either that they are a very small importer or that they are obtaining food from a very small foreign supplier) and that such documentation will require 1 hour, resulting in a total annual burden of 152,395 hours.

Under proposed § 1.512(b)(4), each very small importer or importer of food from a very small foreign supplier would need to obtain written assurance, before importing the food and at least every 2 years thereafter, that its foreign supplier is producing the food in compliance with

processes and procedures that provide at least the same level of public health protection as that required under section 418 or 419 of the FD&C Act, if either is applicable, and is producing the food in compliance with sections 402 and 403(w) of the FD&C Act. As shown in Table 2, we estimate that 56,800 importers will need to obtain an average of 2 such written assurances each year and that documentation of each assurance will require 2.25 hours, resulting in a total annual burden of 255,600 hours.

Proposed § 1.512 also requires very small importers and importers of food from very small foreign suppliers to conduct supplier compliance assessments, list their foreign suppliers, document corrective actions, and ensure that information identifying them as the importer is provided at entry; these importers have been included in the estimated recordkeeping and reporting burdens for these activities under proposed §§ 1.504, 1.506(a), 1.507(c), and 1.509(c), respectively. (As previously stated, we do not estimate any specific burden associated with corrective actions (§ 1.507(c)).)

I. Food Imported from a Country with an Officially Recognized or Equivalent Food Safety System

Proposed § 1.513 would establish modified FSVP requirements for importers of food from foreign suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States. If such importers met certain conditions or requirements, they would not be required to comply with the requirements in proposed §§ 1.502 through 1.508 (except § 1.506(a)), but they would be required to comply with §§ 1.506(a), 1.509, and 1.510.

Proposed § 1.513(b)(1) would require an importer, before importing a food from the foreign supplier and annually thereafter, to document that the foreign supplier is in, and under

the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent and that the food is within the scope of FDA's official recognition or equivalency determination regarding the food safety authority of the country in which the foreign supplier is located.

Proposed § 1.513(b)(2) would require an importer, before importing a food from the foreign supplier, to determine and document whether the foreign supplier of the food is in good compliance standing, as defined in proposed § 1.500, with the food safety authority of the country in which the foreign supplier is located. The importer would be required to continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained. If the information indicated that food safety hazards associated with the food were not being adequately controlled, the importer would be required to take prompt corrective action and to document any such action.

FDA has officially recognized New Zealand as having a food safety system that is comparable to that of the United States; we have not yet determined any food safety systems to be equivalent. Because we have only recently entered into a systems recognition arrangement with New Zealand, we have not been able to assess the effect of the arrangement on the importation of food from that country. Therefore, we have not included estimates for the recordkeeping burdens associated with proposed § 1.513.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	No. of Records per Record-keeper	Total Annual Records	Average Burden per Record-keeping	Total Hours	Total Operating & Maintenance Costs
Controls for LACF 1.502(b)	2,443	4	9,772	1	9,772	

Review compliance status for food and supplier 1.504, 1.511(c)(1), 1.512(b)(2)	53,291	5	266,455	2	532,910	
Determine and document hazards 1.505(a)	27,829	1	27,829	3.7	102,967	
Review hazard analysis 1.505(d)	27,829	7	194,803	1	194,803	
Written list of suppliers 1.506(a), 1.511(c)(2), 1.512(b)(3)	56,800	1	56,800	1.50	85,200	
Written procedures for verification 1.506(b), 1.511(c)(3)	27,829	7	194,803	2	389,606	
Written assurances from suppliers 1.506(f)	23,715	5	118,575	1	118,575	
Conduct/Review audits for SAHCODHA hazards 1.506(g)(1), 1.506(h)	5,947	1	5,947	14	83,258	$3,716,875
Determine and document type of verification activities 1.506(g)(2)	23,742	8	189,936	0.75	142,452	
Conduct/Review audits non-SAHCODHA hazards 1.506(g)(2)(i), 1.511(c)(5)(i)	59	1	59	14	826	$36,875
Conduct periodic sampling/testing	23,742	5	118,710	4	474,840	$158,240,430

1.506(g)(2)(ii), 1.511(c)(5)(ii)						
Review records 1.506(g)(2)(iii), 1.511(c)(5)(iii)	23,742	5	118,710	1.6	189,836	
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	10,658	1	10,658	14	149,212	$6,661,250
Investigate and determine FSVP adequacy 1.507(d), 1.511(c)(1)	10,658	1	10,658	5	53,290	
Written assurances for food produced under dietary supplement (DS) CGMPs 1.511(b)	3,509	6	21,054	2.25	47,372	
Determine and document verification activities for importers of DS 1.511(c)(5)	1,822	2	3,644	2.50	9,110	
Document very small importer/very small supplier status 1.512(b)(1)	152,395	1	152,395	1	152,395	
Written assurances from very small importer/very small supplier 1.512(b)(4)	56,800	2	113,600	2.25	255,600	
Total					2,992,024	$168,655,430

[1] There are no capital costs associated with this collection of information.

TABLE 2b.—Option 2--ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	No. of Records per Record-keeper	Total Annual Records	Average Burden per Record-keeping	Total Hours	Total Operating & Maintenance Costs
Controls for LACF 1.502(b)	2,443	4	9,772	1	9,772	
Review compliance status for food and supplier 1.504, 1.511(c)(1), 1.512(b)(2)	53,291	5	266,455	2	532,910	
Determine and document hazards 1.505(a)	27,829	1	27,829	3.7	102,967	
Review hazard analysis 1.505(d)	27,829	7	194,803	1	194,803	
Written list of suppliers 1.506(a), 1.511(c)(2), 1.512(b)(3)	56,800	1	56,800	1.50	85,200	
Written procedures for verification 1.506(b), 1.511(c)(3)	27,829	7	194,803	2	389,606	
Written assurances from suppliers 1.506(f)	23,715	5	118,575	1	118,575	
Determine and document type of verification activities 1.506(g)(1)	23,742	8	189,936	0.75	142,452	
Conduct/Review audits 1.506(g)(1)(i),	4,936	1	4,936	14	69,104	$3,085,000

1.506(h), 1.511(c)(5)(i)						
Conduct periodic sampling/testing 1.506(g)(1)(ii), 1.506(h), 1.511(c)(5)(ii)	23,742	5	118,710	4	474,840	$158,240,430
Review records 1.506(g)(1)(iii), 1.506(h), 1.511(c)(5)(iii)	23,742	5	118,710	1.6	189,936	
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	10,658	1	10,658	14	149,212	$6,661,250
Investigate and determine FSVP adequacy 1.507(d), 1.511(c)(1)	10,658	1	10,658	5	53,290	
Written assurances for food produced under DS CGMPs 1.511(b)	3,509	6	21,054	2.25	47,372	
Determine and document verification activities for importers of DS 1.511(c)(5)	1,822	2	3,644	2.50	9,110	
Document very small importer/very small supplier status 1.512(b)(1)	152,395	1	152,395	1	152,395	
Written assurances from very small importer/very small supplier 1.512(b)(4)	56,800	2	113,600	2.25	255,600	
Total					2,977,044	$167,986,680

[1] There are no capital costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44. U.S.C. 3407(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by [insert date 30 days after date of publication in the FEDERAL REGISTER] to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the title, "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals."

Proposed Rule on Accreditation of Third Party Certification Bodies

The Third Party proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with estimates of the annual recordkeeping and reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use

of automated collection techniques, when appropriate, and other forms of information technology.

Title: Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications

Description: The Food and Drug Administration (FDA) is amending its regulations to provide for accreditation of third party auditors/certification bodies (CBs) to conduct food safety audits of foreign food entities, including foreign food facilities, and to issue food, facility, and process certifications, pursuant to the FDA Food Safety Modernization Act. Use of accredited third party auditors/CBs and food, process, and facility certifications will help us prevent potentially harmful food from reaching U.S. consumers and thereby improve the safety of the U.S. food supply. We also expect that these regulations will increase efficiency by reducing the number of redundant food safety audits to assess compliance with the Food, Drug, and Cosmetic Act.

Description of respondents: The coverage of the Third Party proposed rule includes eligible entities seeking audits, certification, and/or recertification by accredited auditors/CBs participating in our program, accreditation bodies (ABs) seeking to comply with the recognition requirements of the Third Party proposed rule, and auditors/CBs seeking to comply with the accreditation requirements of the Third Party proposed rule (including those accredited by recognized ABs and those directly-accredited auditors/CBs to conduct food safety audits). An eligible entity is a foreign entity that offers its food or feed for import to the U.S. and that seeks a food safety audit and possibly certification under the requirements for eligible entities under the Third Party proposed rule.

Based on OASIS data, we estimate that there are 200,692 foreign food and feed exporters that offer their food and feed for import into the U.S. These foreign food and feed exporters include 129,757 food and feed production facilities and 70,935 farms. A proportion of these foreign food and feed exporters may offer food subject to mandatory certification requirements under §801(q) of the FD&C Act. In that case, the foreign food and feed exporters must either comply with the Third Party proposed rule in order to obtain certification from an accredited auditor/CB to continue exporting their food and feed products into the U.S. or lose their access to U.S. markets.

In the economic analysis of the Third Party proposed rule, we assume that foreign food and feed exporters subject to §801(q) of the FD&C Act represent 5% of all foreign food and feed exporters, or 10,035 (5% x 200,692). In addition, in the combined economic analysis, we estimate that 47,469 foreign suppliers will use third party food safety audits to satisfy supplier verification requirements of the FSVP proposed rule. The economic analysis of the Third Party proposed rule estimates compliance costs under the assumption that expected efficiency gains, and pre-condition to offer food or feed for import to the U.S. would lead all foreign suppliers subject to §801(q) of the FD&C Act, and foreign suppliers who choose to use third party food safety audits to satisfy supplier verification requirements of the FSVP proposed rule become eligible entities and comply with the Third Party proposed rule.

This PRA reflects that the FSVP proposed rule includes a "co-proposal" for two alternative approaches to certain requirements for foreign supplier verification activities. Under Option 1 of the co-proposal, if the foreign supplier controls a hazard in a food at its establishment and there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA), the importer

would be required to conduct or obtain documentation of onsite auditing of the foreign supplier at least annually thereafter (possibly more frequently if necessary to adequately verify control of the hazard). For non-SAHCODHA hazards that the foreign supplier controls, the importer would be required to conduct one of more of the following verification activities before using or distributing the food and periodically thereafter: onsite auditing of the foreign supplier, sampling and testing, review of the supplier's food safety records, or some other procedure that the importer has established as appropriate based on the risk associated with the hazard. This requirement would also apply, under Option 1, when the foreign supplier verifies control of a hazard by its ingredient or component supplier, rather than directly controlling the hazard itself.

Under Option 2 of the co-proposal, for all hazards that the foreign supplier will either control or verify control by its supplier, importers would need to choose a verification procedure from among onsite auditing, sampling and testing, review of supplier food safety records, or some other appropriate procedure. In determining the appropriate verification activities and how frequently they should be conducted, the importer would need to consider the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm, and the food and foreign supplier's compliance status.

The proposed rule sets forth a similar co-proposal regarding supplier verification for certain raw agricultural commodities that are fruits or vegetables. Option 1 would require, in addition to the other verification, onsite auditing to verify control of microbiological hazards in such produce, while under Option 2 the importer would select a verification activity from the list of possible procedures set forth above.

The only difference that those two different options have for the PRA analysis of the Third Party proposed rule is that we estimate that fewer foreign suppliers (43,364) would use

third party audits, conducted by auditors/certification bodies accredited under the FDA program, in meeting FSVP requirements under Option 2 of the FSVP co-proposal. Throughout this PRA analysis where the different FSVP options have different effects on the calculations for the Third Party proposed rule we will provide two versions of tables ("a" and "b" versions). Tables labeled "a" (e.g., Table 1a) correspond to FSVP co-proposal, Option 1, and tables labeled "b" (e.g., Table 1b) correspond to FSVP co-proposal Option 2.

Considering the demand for accredited food safety audits under the Third Party program by foreign suppliers subject to §801(q) of the FD&C Act and the FSVP proposed rule, we expect that all of the ABs and accredited auditors/CBs operating globally will also have an incentive to comply with the Third Party proposed rule. We have identified 69 ABs worldwide that accredit auditors/CBs which provide certification for food safety audits of foreign food and feed exporters that offer food or feed for import to the U.S. We estimate approximately 568 auditors/CBs are accredited by the potential 69 AB applicants that would conform to the Third Party proposed rule. Under FSVP co-proposal Option 1, we believe that demand driven by eligible entities that are currently not certified by accredited auditors/CBs would induce an additional 764 unaccredited auditors/CBs (701 under FSVP co-proposal Option 2) to become accredited by recognized ABs and ultimately comply with the Third Party proposed rule. In addition, we expect that in lieu of becoming accredited by recognized ABs, four (4) auditors/CBs will choose to become directly accredited by the FDA.

In sum, under FSVP co-proposal Option 1, we expect that 57,504 eligible entities (10,035 §801(q) entities + 47,469 FSVP entities), 1,336 auditors/CBs (568 currently accredited CBs + 764 unaccredited CBs choosing to become accredited by recognized ABs + 4 CBs choosing to

become directly accredited by FDA), and 69 ABs will either comply with the Third Party proposed rule due to statutory requirements (§801(q)) or choose to comply voluntarily.

Under FSVP co-proposal Option 2, we expect that 53,399 eligible entities (10,035 §801(q) entities + 43,364 FSVP entities), 1,273 auditors/CBs (568 currently accredited CBs + 701 unaccredited CBs choosing to become accredited by recognized ABs + 4 CBs choosing to become directly accredited by FDA), and 69 ABs will either comply with the Third Party proposed rule due to statutory requirements (§801(q)) or choose to comply voluntarily.

Information Collection Burden Estimate: We estimate the burden for this information collection as follows:

Recordkeeping Burden

In summary, under FSVP co-proposal Option 1, total one-time recordkeeping burden by 69 ABs and 1,336 accredited auditors/CBs is estimated at 335,796 hours (see Table 1a). Total annual recordkeeping burden by 69 ABs and 1,336 accredited auditors/CBs is estimated at 45,274 hours (see Table 2a).

Under FSVP co-proposal Option 2, total one-time recordkeeping burden by 69 ABs and 1,273 accredited auditors/CBs is estimated at 317,306 hours (see Table 1b). Total annual recordkeeping burden by 69 ABs and 1,273 accredited auditors/CBs is estimated at 42,883 hours (see Table 2b).

Table 1a: Option 1 - Estimated One-Time Recordkeeping Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total One-Time Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.615	69	1	69	2	138
§1.645	1,336	1	1,336	2	2,672
§1.624(c)	69	1	69	68.52	4,728
§1.657(d)	1,336	1	1,336	68.52	91,543
§1.620, §1.621	69	19.3	1,332	2	2,663
§1.651	1,336	57	76,152	2	152,304
Unaccredited CBs	764	1	764	107	81,748
Total One-Time Recordkeeping Burden					**335,796**

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

Table 1b: Option 2 - Estimated One-Time Recordkeeping Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total One-Time Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.615	69	1	69	2	138
§1.645	1,273	1	1,273	2	2,546
§1.624(c)	69	1	69	68.52	4,728
§1.657(d)	1,273	1	1,273	68.52	87,226
§1.620, §1.621	69	18.4	1,270	2	2,539
§1.651	1,273	57	72,561	2	145,122
Unaccredited CBs	701	1	701	107	75,007
Total One-Time Recordkeeping Burden					**317,306**

Note: There are no operations and maintenance costs associated with one-time recordkeeping burden.

Table 2a: Option 1 - Estimated Annual Recordkeeping Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.625	69	1,100	75,900	0.25	18,975
§1.624(c)	69	1	69	8	552
§1.657(d)	1,336	1	1,336	8	10,688
§1.652	1,336	57	76,152	0.083	6,321
§1.656(c)	1,336	0.25	334	1	334
Unaccredited CBs	764	1	764	11	8,404
Total Annual Recordkeeping Burden					**45,274**

Note: There are no operations and maintenance costs associated with annual recordkeeping burden.

Table 2b: Option 2 - Estimated Annual Recordkeeping Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.625	69	1,049	72,381	0.25	18,095
§1.624(c)	69	1	69	8	552
§1.657(d)	1,273	1	1,273	8.00	10,184
§1.652	1,273	57	72,561	0.083	6,023
§1.656(c)	1,273	0.25	318	1	318
Unaccredited CBs	701	1	701	11	7,711
Total Annual Recordkeeping Burden					**42,883**

Note: There are no operations and maintenance costs associated with annual recordkeeping burden.

Sections 1.615 and 1.645 of the Third Party proposed rule require that at the time an AB submits an application for recognition (under §1.630 of the Third Party proposed rule) or an auditor/CB submits an application for accreditation (under §1.660, or where applicable under §1.670), the AB or auditor/CB must demonstrate that it has implemented written procedures to adequately maintain records related to its accreditation program and activities including assessment of its authority, qualification, conflict of interest measures, internal quality assurance program, performance, and corrective actions. Currently, ABs maintain recordkeeping protocols relating to their operations; however, we expect that ABs will review their recordkeeping protocols and, if necessary, modify them to meet the requirements of §1.615 of the Third Party proposed rule before submitting applications for recognition. We believe that the records requirements for ABs in §1.615 and auditors/CBs in §1.645 would constitute a new one-time burden for 69 ABs, and 1,336 auditors/CBs respectively under FSVP co-proposal Option 1 (1,273 under FSVP co-proposal Option 2). We expect that it would take no more than 2 hours for an AB or an accredited auditor/CB to modify its recordkeeping protocol to comply with the written recordkeeping requirements described in §1.615 and §1.645 of the Third Party proposed rule (see Tables 1a and 1b). Therefore, we estimate that it would take 138 hours (2 hours/AB x 69 ABs) for ABs to comply with §1.615. Under FSVP co-proposal Option 1, we estimate 2,672

hours (2 hours/CB x 1,336 CBs) for accredited auditors/CBs to comply with §1.645 of the Third Party proposed rule (see Table 1a) and 2,546 hours (2 hours/CB x 1,273 CBs) for FSVP co-proposal Option 2 (see Table 1b).

Section 1.625 of the Third Party proposed rule requires that a recognized AB maintain records documenting requests by auditors/CBs for accreditation from the AB (per §1.660), challenges to adverse accreditation decisions (§1.620(c)), monitoring activities of its accredited auditors/CBs (§1.621), self-assessments and corrective actions (§1.622), copies of regulatory audit reports submitted by its accredited auditors/CBs (§1.656), and copies of records of reports or notifications made to us, as required by §1.623. A recognized AB's requirement for reporting and notifications per §1.623 of the Third Party proposed rule includes submission of results of its annual performance assessment of each of its accredited auditors/CBs (§1.623(a)) and the results of its self-assessment (§1.623(b)). A recognized AB also must notify us immediately upon granting, withdrawing, suspending, reducing the scope of accreditation of an auditor/CB or upon its determination that an auditor/CB it accredited issued a food or facility certification in violation of subpart M, pursuant to § 1.623(c) of the Third Party proposed rule. Additionally, a recognized AB must notify us within 30 days after making significant changes to its operations that would affect the manner in which it complies with the Third Party proposed rule (§1.623(d)).

Currently, ABs maintain records documenting requests by auditors/CBs for accreditation, monitoring activities of their accredited auditors/CBs, and self-assessments and corrective actions. These current records practices are similar to those required for the reports and notifications requirement of §1.623 of the Third Party proposed rule. However, auditors/CBs do not currently send copies of audit reports of their clients (food facilities) to their ABs. Therefore,

an AB's maintenance of records pertaining to regulatory audit reports submitted by their accredited auditors/CBs is considered as a new recordkeeping burden for recognized ABs. We expect that it would take no more than 15 minutes (0.25 hour) for a recognized AB to file a regulatory audit report submitted by its auditors/CBs. We estimate the burden for 69 recognized ABs to maintain regulatory audit reports that were submitted to them by their accredited auditors/CBs. We estimate that following the implementation of the Third Party proposed rule, under FSVP co-proposal Option 1, each recognized AB will accredit approximately 19.3 auditors/CBs, on average (1,332 accredited CBs ÷ 69 ABs) (18.4 CBs/AB for FSVP co-proposal Option 2; 1,269 accredited CBs ÷ 69 ABs). In addition, we estimate that each accredited auditor/CB, on average, will conduct regulatory audits on approximately 57 foreign suppliers (see Appendix E). To comply with the Third Party proposed rule, each eligible entity must be audited and certified for food safety on an annual basis. Under FSVP co-proposal Option 1, we expect that each recognized AB will receive, on average, 1,100 regulatory audit reports (57 regulatory audit reports/CB x 19.3 CBs/AB) from its auditors/CBs annually resulting in a total of 75,900 records per year (1,100 audit reports/AB x 69 ABs). Under FSVP co-proposal Option 2, we expect that each recognized AB will receive, on average, 1,049 regulatory audit reports (57 regulatory audit reports/CB x 18.4 CBs/AB) from its auditors/CBs annually resulting in a total of 72,381 records per year (1,049 audit reports/AB x 69 ABs). Total annual burden of recordkeeping requirement for recognized AB under §1.625 of the Third Party proposed rule is estimated at 18,975 hours (75,900 records x 0.25hours/record) under FSVP co-proposal Option 1 (18,095 under FSVP co-proposal Option 2) (see Tables 2a and 2b).

Section 1.624(c) of the Third Party proposed rule requires each recognized AB maintain on its website an up-to-date list of auditors/CBs it has accredited under the Third Party proposed

rule and for each auditor/CB identify the duration and scope of accreditation and date(s) on which the auditor/CB paid the AB any fee or reimbursement associated with such accreditation. Our review of AB websites found that none of the ABs reviewed publish all the information that is required by §1.620(c) of the Third Party proposed rule on their websites (Ref. 5). We estimate that each AB, on average, would spend approximately a one-time cost of $4,000 to update its webpage to conform with this section of the Third Party proposed rule. We expect the hourly wage rate of an IT expert responsible for updating the AB's webpage be equivalent to that of a GS-13, Step 5 employee at $58.38 per hour (includes 50% overhead cost). Hence, we expect that a one-time burden of updating an AB's website to conform with the information collection requirement of the Third Party proposed rule to be equivalent to 68.52 hours ($4,000 ÷ $58.38/hour). The one-time burden of conforming to §1.624(c) of the Third Party proposed rule by 69 ABs is estimated at approximately 4,728 hours (69 ABs x 68.52 hours/AB) (see Tables 1a and 1b). In addition, we estimate that each recognized AB would spend 8 hours annually, following the initial year, to update information as required by §1.624(c) of the Third Party proposed rule. The annual hourly burden for 69 recognized ABs to update their webpages to conform to disclosure of information requirement per §1.624(c) of the Third Party proposed rule is estimated at 552 hours (8 hours/AB x 69 ABs) (see Tables 2a and 2b).

Similarly, §1.657(d) of the Third Party proposed rule requires an auditor/CB accredited in compliance with the Third Party proposed rule to maintain on its website an up-to-date list of eligible entities which it has issued certifications under this subpart. For each such eligible entity the website also must identify the duration and scope of the certification and date(s) on which the eligible entity paid the accredited auditor/CB any fee or reimbursement associated with such audit or certification. In the Third Party proposed rule economic analysis, we estimate that

following the implementation of the Third Party and FSVP proposed rules, there will be approximately 1,332 auditors/CBs accredited by recognized ABs and 4 directly accredited auditors/CBs under FSVP co-proposal Option 1 (1,269 CBs and 4 directly accredited CBs under FSVP co-proposal Option 2). For FSVP co-proposal Option 1, the one-time recordkeeping burden of 1,336 accredited auditors/CBs to comply with §1.657(d) of the Third Party proposed rule is estimated at 91,543 hours (68.52 hours/CB x 1,336 CBs; see Table 1a) (87,226 hours under FSVP co-proposal Option 2; see Table 1b). In addition, we estimate that each auditor/CB would spend 8 hours annually, following the initial year, to update information as required by §1.657(d) of the Third Party proposed rule. Under FSVP co-proposal Option 1, annual hourly burden for 1336 auditors/CBs to update their webpages to conform to disclosure of information requirement per §1.624(c) of the Third Party proposed rule is estimated at 10,688 hours (8 hours/CB x 1,336 CBs;see Table 2a) (10,184 hours under FSVP co-proposal Option 2; see Table 2b).

There are certain provisions within the Third Party proposed rule (e.g., §1.620 and §1.621) that would require ABs to modify their contracts with their auditors/CBs in order to comply with the Third Party proposed rule. Therefore, it is expected that recognized ABs will modify their contracts with their accredited auditors/CBs to be able to conduct activities such as conducting unannounced audits of their accredited auditors/CBs. Minor modifications or addenda to contracts with standard language provided by provisions in the Third Party proposed rule would consist of no more than one hour by an AB executive and one hour by a legal counsel representing the AB. As we discussed, following the implementation of the Third Party proposed rule, we expect that each recognized AB will accredit approximately 19.3 auditors/CBs. Therefore, under FSVP co-proposal Option 1, a total of 1,332 contracts (19.3

contracts/AB x 69 ABs) (1,270 contracts under FSVP co-proposal Option 2) are expected to be modified to reflect changes in contractual obligations between each recognized AB and its accredited auditors/CBs under the Third Party proposed rule. The one-time burden of initial modification of 1,332 contracts between 69 ABs and their respective accredited auditors/CBs is approximately 2,663 hours (1,332 contracts x 2 hours/contract; see Table 1a) under FSVP co-proposal Option 1 (2,539 hours under FSVP co-proposal Option 2; see Table 1b).

Similarly, auditors/CBs accredited by recognized ABs would need to modify their contracts with their client eligible entities in order to gain access to any records and any area of the facility, its process(es), and food of the eligible entity relevant to the scope and purpose of audit being performed by the auditor/CB (§1.651). Considering that each of the expected 1,336 accredited auditor/CB, under FSVP co-proposal Option 1, will each have approximately 57 client eligible entities, we expect that approximately 76,152 contracts (57 contracts/CB x 1,336 CBs) between accredited auditors/CBs and eligible entities will be modified (72,561 contract under FSVP co-proposal Option 2) (see Tables 1a and 1b). Under FSVP co-proposal Option 1, the one-time burden of initial modification of 76,152 contracts between 1,336 accredited auditors/CBs and their respective client eligible entities is approximately 152,304 hours (76,152 contracts x 2 hours/contract) (see Table 1a). Under FSVP co-proposal Option 2, the one-time burden of initial modification of 72,561 contracts between 1,273 accredited auditors/CBs and their respective client eligible entities is approximately 145,122 hours (76,152 contracts x 2 hours/contract) (see Table 1b).

Section 1.652 of the Third Party proposed rule requires that accredited CBs include certain information in reports of food safety audits. We believe that some of the required information such as Dun and Bradstreet Data Universal Numbering System (D&B DUNS)

number and Global Positioning System coordinates of the facility subject to audit are currently not included in food safety audits conducted by accredited CBs. We expect that it would take about 5 minutes (0.083 hour), on average, by an accredited CB to include additional information, as required in §1.652, in reports of food safety audits. Therefore, at a minimum, each accredited CB must modify a regulatory audit report for each of its 57 client eligible entities every year. Under FSVP co-proposal Option 1, total annual records of 1,336 accredited CBs modifying regulatory audit reports of their client eligible entities is estimated at 76,152 records (1,336 CBs x 57 eligible entity/CB x 1 record/eligible entity) (72, 561 records under FSVP co-proposal Option 2). Annual recordkeeping burden of accredited CBs, per §1.652 of the Third Party proposed rule, is estimated at 6,321 hours (76,152 records x 0.083 hour/record) under FSVP co-proposal Option 1 (6,023 hours under FSVP co-proposal Option 2) (see Tables 2a and 2b).

Section 1.656(c) of the Third Party proposed rule requires that an accredited auditor/CB report to us any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. We believe that these occurrences are rare and may occur once every 4 years, or 0.25 times per year. Reporting serious hazard conditions would consist of the on-site audit agent of an accredited auditor/CB to document the event as a record and to immediately submit the record to us. Therefore, under FSVP co-proposal Option 1, annual number of records prepared by 1,336 accredited auditors/CBs is estimated at 334 (0.25 records/CB x 1,336 CBs) (318 records under FSVP co-proposal Option 2). It is expected that an accredited auditor/CB would take no more than 1 hour to prepare such record (notification). Under FSVP co-proposal Option 1, annual burden of preparation of records per §1.656(c) of the Third Party proposed rule by 1,336 accredited

auditor/CB is estimated at 334 hours (334 records x 1 hour/record; see Table 2a) (318 hours under FSVP co-proposal Option 2; see Table 2b).

In the Third Party proposed rule economic analysis, we estimate that in order to become accredited, an unaccredited CB would initially spend, on average, $25,000 to conform to an ABs's scheme (see Appendix E, Table E7). We expect that this cost burden includes initial modification of an unaccredited CB's recordkeeping, reporting and training protocols, and increased personnel to maintain its standards to that of its accrediting AB. We also estimated that following the implementation of the Third Party and FSVP proposed rules, 764 unaccredited CBs (see Appendix B) would choose to become accredited under FSVP co-proposal Option 1 (701 unaccredited CBs under FSVP co-proposal Option 2). Using an average wage rate of GS-13 Step 5 pay level ($58.38/hour including benefits and overhead costs), average initial burden of an unaccredited CB—to modify its practices to conform to an AB's scheme—is approximately 428 hours ($25,000 ÷ $58.38/hour). We assume that the initial burden of 428 hours for an unaccredited CB is equally divided between four categories of recordkeeping, reporting, training and increased personnel hours. Therefore, an unaccredited CB would initially incur a burden of approximately 107 hours (428 hours ÷ 4) for its initial recordkeeping procedures. The initial recordkeeping burden for unaccredited CBs that become accredited by an AB is estimated at 81,748 hours (764 unaccredited CBs x 107 hour/unaccredited CB; see Table 1a) under FSVP co-proposal Option 1 (75,007 hours under FSVP co-proposal Optoin 2; see Table 1b).

We also assume that the annual increase in recordkeeping, reporting, training and increase in personnel of an unaccredited CB which chooses to become accredited will amount to 10% of the initial burden, or 11 hours per CB per year (107 hour/unaccredited CB x 10%). The

annual recordkeeping burden for unaccredited CBs that become accredited by a recognized AB is estimated at 8,404 hours (764 unaccredited CBs x 11 hour/unaccredited CB; see Table 2a) under FSVP co-proposal Option 1 (7,711 hours under FSVP co-proposal Option 2; see Table 1b). We request comments on our one-time and annual recordkeeping burden estimates of unaccredited CBs who choose to become accredited.

Reporting Burden

In summary, under FSVP co-proposal Option 1, total one-time reporting burden by 69 ABs and 1,336 accredited auditors/CBs is estimated at 88,924 hours (82,120 hours under FSVP co-proposal Option 2) (see Tables 3a and 3b). Total annual reporting burden by 69 ABs and 1,336 accredited auditors/CBs is estimated 73,309 hours (69,581 hours under FSVP co-proposal Option 2) (see Tables 4a and 4b).

Table 3a: Option 1 - Estimated One-Time Reporting Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total One-Time Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.630	69	1	69	80	5,520
§1.653(b)(2)	1,336	1	1,336	1	1,336
§1.670(a-b)	4	1	4	80	320
Unaccredited CBs	764	1	764	107	81,748
Total One-Time Reporting Burden					**88,924**

Note: There are no operations and maintenance costs associated with one-time reporting burden.

Table 3b: Option 2 - Estimated One-Time Reporting Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total One-Time Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.630	69	1	69	80	5,520
§1.653(b)(2)	1,273	1	1,273	1	1,273
§1.670(a-b)	4	1	4	80	320
Unaccredited CBs	701	1	701	107	75,007
Total One-Time Reporting Burden					**82,120**

Note: There are no operations and maintenance costs associated with one-time reporting burden.

Table 4a: Option 1 - Estimated Annual Reporting Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.634	69	1	69	8	552
§1.673	4	1	4	10	40
§1.623(a)	69	19.3	1,332	0.25	333
§1.623(b)	69	1	69	0.25	17
§1.653(b)(1)	1,336	57	76,152	0.25	19,038
§1.653(b)(2)	1,336	57	76,152	0.083	6,321
§1.656(a)[1]	1,332	57	75,924	0.25	18,981
§1.656(a)[2]	1,332	57	75,924	0.25	18,981
§1.656(a)[3]	4	57	228	0.25	57
§1.656(b)[4]	1,332	1	1,332	0.25	333
§1.656(b)[5]	4	1	4	0.25	1
§1.656(c)	1,336	0.25	334	0.25	84
§1.656(e)[6]	1,336	0.25	334	0.25	84
§1.656(e)[7]	1,332	0.25	333	0.25	83
Unaccredited CBs	764	1	764	11	8,404
Total Annual Reporting Burden					**73,309**

Note: There are no operations and maintenance costs associated with annual reporting burden.

1. Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.
2. Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.
3. Annual reporting of regulatory audit reports by directly accredited CBs to the FDA.
4. Annual reporting of self-assessment by accredited CBs to their ABs.
5. Annual reporting of self-assessment by directly accredited CBs to the FDA.
6. Annual reporting of serious risk to public health by accredited CBs to eligible entities.
7. Annual reporting of serious risk to public health by accredited CBs to their ABs.

Table 4b: Option 2 - Estimated Annual Reporting Burden

21 CFR Part 1, Subpart M	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
§1.634	69	1	69	8	552
§1.673	4	1	4	10	40
§1.623(a)	69	18.4	1,270	0.25	317
§1.623(b)	69	1	69	0.25	17
§1.653(b)(1)	1,273	57	72,561	0.25	18,140
§1.653(b)(2)	1,273	57	72,561	0.083	6,023
§1.656(a)[1]	1,269	57	72,333	0.25	18,083
§1.656(a)[2]	1,269	57	72,333	0.25	18,083
§1.656(a)[3]	4	57	228	0.25	57
§1.656(b)[4]	1,273	1	1,273	0.25	318
§1.656(b)[5]	4	1	4	0.25	1
§1.656(c)	1,273	0.25	318	0.25	80
§1.656(e)[6]	1,273	0.25	318	0.25	80
§1.656(e)[7]	1,269	0.25	317	0.25	79
Unaccredited CBs	701	1	701	11	7,711
Total Annual Reporting Burden					**69,581**

Note: There are no operations and maintenance costs associated with annual reporting burden.

1. Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to their accrediting ABs.
2. Annual reporting of regulatory audit reports by CBs accredited by recognized ABs to the FDA.
3. Annual reporting of regulatory audit reports by directly accredited CBs to the FDA.
4. Annual reporting of self-assessment by accredited CBs to their ABs.
5. Annual reporting of self-assessment by directly accredited CBs to the FDA.
6. Annual reporting of serious risk to public health by accredited CBs to eligible entities.
7. Annual reporting of serious risk to public health by accredited CBs to their ABs.

Section 1.630 of the Third Party proposed rule allows for any AB to apply for recognition. We estimate that approximately 69 ABs would apply for recognition. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for recognition. The initial application for recognition is a one-time burden for each AB that applies. The one-time initial application burden for 69 ABs is estimated at 5,520 hours (69 applications x 80 hours/application) (see Tables 3a and 3b). The duration of recognition for a recognized AB will not exceed 5 years per §1.632 of the Third Party proposed rule. Therefore, it is expected that each of the expected 69 recognized ABs would apply to renew its recognition every 5 years per §1.634 of the Third Party proposed rule. We expect that applications for renewal of recognition will take significantly less time to prepare. We use 50% of the amount of

effort to prepare and submit an application for renewal of recognition. Therefore, it is expected that, on average, each recognized AB will spend 40 hours every 5 years to complete and submit an application for renewal of its recognition, or approximately 8 hours per year (40 hours ÷ 5 years) for each AB. Therefore, the annual burden of completing the renewal of recognition application by 69 ABs is 552 hours (69 applications x 8 hours/application) per year (see Tables 4a and 4b).

Similarly, §1.670(a-b) of the Third Party proposed rule allows for auditors/CBs to apply to us for direct accreditation, when the criteria for direct accreditation are met. We estimate that approximately 4 auditors/CBs would apply for direct accreditation. It is expected that the application for direct accreditation would require the same amount of effort as does an AB's application for recognition. Hence, we estimate that the initial application for direct accreditation would take 80-person hours. The one-time initial application burden for 4 auditors/CBs is estimated at 320 hours (4 applications x 80 hours/application) (see Tables 3a and 3b). The duration of accreditation for a directly-accredited CB will not exceed 4 years, per §1.671 of the Third Party proposed rule. Therefore, it is expected that each of the expected 4 directly-accredited auditors/CBs would apply to renew its accreditation every 4 years, per §1.673 of the Third Party proposed rule. We expect that directly-accredited auditors/CBs use 50% amount of effort, or 40 person-hours, for their initial application for direct accreditation, yielding an average of 10 hours per year. Therefore, the annual burden of completing the application for renewal by 4 directly-accredited auditors/CBs is 40 hours (4 applications x 10 hours/application) per year (see Tables 4a and 4b).

For the purposes of the Third Party proposed rule economic and PRA analyses, we have estimated costs assuming that, during the application process, affected entities will do their

paperwork properly and completely the first time. If we assumed a less consistent outcome, one that would result in recognition denials, the initial burden might increase. Therefore, we have not estimated an additional burden for less than complete applications.

Section 1.623(a) of the Third Party proposed rule requires that recognized ABs annually conduct comprehensive assessments of the performance of auditors/CBs they have accredited and submit the results of the assessments to us within 45 days of their completion. We expect that it would take no more than 15 minutes (0.25 hour) for an AB to electronically submit the assessment of each its accredited auditors/CBs. Following the implementation of the Third Party proposed rule and FSVP co-proposal Option 1, we expect, on average, each recognized AB would accredit approximately 19.3 auditors/CBs (18.4 auditors/CBs under FSVP co-proposal Option 2). Therefore, under FSVP co-proposal Option 1, each recognized AB would submit, on average, approximately 1,332 copies of assessments of performance of their accredited auditors/CBs (19.3 assessments/AB x 69 ABs) (1,270 assessments under FSVP co-proposal Option 2). Under FSVP co-proposal Option 1, annual reporting of 1,332 assessments by 69 recognized ABs is estimated at 333 hours (1,332 submission of assessments x 0.25 hour/submission; see Table 4a) (317 hours under FSVP co-proposal Option 2; see Table 4b).

Section 1.623(b) of the Third Party proposed rule requires that recognized ABs annually conduct a self-assessment and submit the assessments within 45 days of their completion. We expect that it would take no more than 15 minutes for an AB to electronically submit a copy of its self-assessment. Annual reporting of 69 self-assessments by 69 recognized ABs is estimated at 17 hours (69 submission of self-assessments x 0.25 hour/submission) (see Tables 4a and 4b).

Section 1.653(b)(2) requires that certifications issued by accredited CBs contain information such as the DUNS number of the eligible entity to which the certification was

issued. We assume that certifications that are currently issued by accredited CBs need to be modified so that they comply with the requirements of §1.653(b)(2). We expect that it will take no more than 1 hour, on average, to change the design of certifications issued by accredited CBs. Under FSVP co-proposal Option 1, we estimate a one-time reporting burden of modifying the design of the certifications of 1,336 accredited CBs at 1,336 hours (1,336 CBs x 1 hour/CB; see Table 4a) (1,273 hours under FSVP co-proposal Option 2; see Table 4b).

We expect that the burden to fill additional information on a certification that is issued is 5 minutes (0.083 hour). Therefore, under FSVP co-proposal Option 1, the annual burden of §1.653(b)(2) is estimated at 6,321 hours (1,336 CBs x 1 certificate/entity x 57 entities/CB x 0.083 hour/certificate; see Table 4a) (6,023 hours under FSVP co-proposal Option 2; see Table 4b).

Section 1.656(a) of the Third Party proposed rule requires that an accredited auditor/CB must submit the regulatory audit reports it conducts to us and to the AB that granted its accreditation (where applicable) within 45 days after completing such audit. In the Third Party proposed rule economic analysis, we estimated that following the implementation of the Third Party proposed rule, there will be 69 recognized ABs that accredit 1,332 auditors/CBs (1,269 auditors/CBs under FSVP co-proposal Option 2), and we will directly accredit 4 auditors/CBs. In addition, we estimated that each accredited auditor/CB, on average, conducts food safety audits and certifies 57 eligible entities. Therefore, auditors/CBs accredited by recognized ABs will annually submit 75,924 regulatory audit reports (1,332 CBs x 57 reports/CB) to their accrediting ABs and 75,924 reports to us (see Table 4a) (72,333 reports under FSVP co-proposal Option 2; see Table 4b). The directly-accredited auditors/CBs will annually submit 228 regulatory audit reports (4 CBs x 57 reports/CB) (see Table 4a and 4b). We expect that it would

take no more than 15 minutes (0.25 hour) for an accredited auditor/CB to electronically submit a copy of the regulatory report it conducts to us and to its AB (where applicable).

Under FSVP co-proposal Option 1, annual reporting burden for auditors/CBs accredited by recognized ABs is estimated at 18,981 hours (75,924 reports x 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 18,981 hours for submitting the same records to us (see Table 4a). Under FSVP co-proposal Option 2, annual reporting burden for auditors/CBs accredited by recognized ABs is estimated at 18,083 hours (75,333 reports x 0.25 hours/report) for submitting copies of regulatory audit reports they have conducted to their accrediting ABs and 18,083 hours for submitting the same records to us (see Table 4b). Annual burden for submission of regulatory audit reports by directly-accredited auditors/CBs is estimated at 57 hours (228 reports x 0.25 hours/report) (see Tables 4a and 4b).

Section 1.656(b) of the Third Party proposed rule requires accredited auditors/CBs to submit reports of their annual self-assessments electronically to their ABs, or in the case of direct accreditation to us, within 45 days of the anniversary date of their accreditation under subpart M. We expect that it would take no more than 15 minutes (0.25 hour) for an accredited auditor/CB to electronically send a copy of its annual self-assessment to its AB or us (as applicable). Under FSVP co-proposal Option 1, the annual burden for auditors/CBs accredited by recognized ABs is estimated at 333 hours (1,332 self-assessments x 0.25 hour/self-assessment; see Table 4a) (318 hours under FSVP co-proposal Option 2; see Table 4b). Annual burden for submission of self-assessments by directly-accredited auditors/CBs is estimated at 1 hour (4 self-assessments x 0.25 hour/self-assessment; see Tables 4a and 4b).

As we discussed, §1.656(c) of the Third Party proposed rule requires that an accredited auditor/CB report to us any condition, found during a regulatory or consultative audit of an eligible entity, which could cause or contribute to a serious risk to the public health. In the Recordkeeping Burden section above, we estimated that such events are expected to occur once every 4 years, or 0.25 per year. We expect that it would take no more than 15 minutes (0.25 hour) for an accredited auditor/CB to electronically send a copy of its notification documenting serious risk to the public health to us. Therefore, under FSVP co-proposal Option 1, the total number of notifications sent to us on an annual basis per §1.656(c) of the Third Party proposed rule is estimated at 334 (1,336 CBs x 0.25 records/CB) (318 notifications under FSVP co-proposal Option 2). Under FSVP co-proposal Option 1, annual burden for submitting serious risk to the public health notification per §1.656(c) of the Third Party proposed rule to us by accredited auditors/CBs is estimated at 84 hours (334 records x 0.25 hour/record; see Table 4a) (80 hours under FSVP co-proposal Option 2; see Table 4b).

Following reporting of a serious risk to the public health hazard condition to us, an accredited auditor/CB is required under §1.656(e) of the Third Party proposed rule to immediately notify the eligible entity and its accrediting AB of any conditions identified during the audit which triggered the reporting requirement per §1.656(c) of the Third Party proposed rule. Under FSVP co-proposal Option 1, total number of notification sent to eligible entities by 1,336 accredited auditors/CBs is estimated at 334 (1,336 CBs x 0.25 records/CB) (318 notifications under FSVP co-proposal Option 2) while the number of notifications sent to ABs by their accredited auditors/CBs is estimated at 333 (1,332 CBs x 0.25 records/CB) (317 hours under FSVP co-proposal Option 2). Under FSVP co-proposal Option 1, annual burden of submitting serious risk to the public health notification per §1.656(e) of the Third Party proposed

rule to affected eligible entities and ABs by accredited auditors/CBs is estimated at 84 hours and 83 hours, respectively (see Table 4a) (80 hours and 79 hours under FSVP co-proposal Option 2; see Table 4b).

In the Recordkeeping Burden section, we estimated that, initially, the increased reporting burden by an unaccredited CB who chooses to become accredited is approximately 107 hours. Estimated initial (one-time) reporting burden of 764 unaccredited CBs, under FSVP co-proposal Option 1, is estimated at 81,748 hours (764 unaccredited CBs x 107 hour/unaccredited CB; see Table 3a) (75,007 hours under FSVP co-proposal Option 2; see Table 3b). Annual increase in reporting burden of an unaccredited CB is calculated as 10% of initial burden, or 11 hours. Estimated annual reporting burden of 764 unaccredited CBs, under FSVP co-proposal Option 1, is estimated at 8,404 hours (764 unaccredited CBs x 11 hour/unaccredited CB; see Table 4a) (7,711 hours under FSVP co-proposal Option 2; see Table 4b).