REGULATORY IMPACT ANALYSIS FOR FINAL RULE ON FOREIGN SUPPLIER VERIFICATION PROGRAMS (DOCKET NO. FDA-2011-N-0143) 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)

Contents

Analysis of Economic Impacts

FDA has examined the impact of a final rule relating to food importers' foreign supplier verification programs (FSVPs), entitled Foreign Supplier Verification Programs for Importers of Food for Humans and Animals ("FSVP final rule"), under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that the FSVP final rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because most importers that would be affected by the final rule are small businesses and will need to begin performing various types of activities that they currently do not perform, the Agency believes that this final rule will have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits,

before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the FSVP final rule would result in a 1-year expenditure that would meet or exceed this amount.

This final regulatory impact analysis revises the initial regulatory impact analysis set forth in the preliminary regulatory impact analysis (PRIA) for the original proposed rule (78 FR 45730, July 29, 2013) and revised in the supplemental preliminary regulatory impact analysis (SPRIA) for the supplemental proposed rule (79 FR 58574, September 29, 2014). Except for the revisions we indicate below, the analysis of the final rule is the same as the analysis presented in the PRIA or the SPRIA.

I. Revisions to Final Rule

The FSVP proposed rule[1] proposed to establish requirements relating to FSVPs for importers of food for humans and animals. The proposed regulations also would have required

[1] FDA published a proposed rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals on July 29, 2013 (78 FR 45730) (original proposed rule). FDA then published a supplemental notice of proposed rulemaking on September 29, 2014 (79 FR 58574) (supplemental proposed rule), which revised certain aspects of the original proposal. In this document, we use the term "FSVP proposed rule" to refer to the complete proposed regulatory text as modified by the supplemental proposed rule.

importers to conduct activities to verify 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 those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as well as verify that the food they import is not adulterated and is not misbranded with respect to food allergen labeling. The main purpose of the proposed regulations was to help ensure that imported food is produced in a manner consistent with U.S. standards.

This overarching framework remains unchanged in the final rule. However, the final rule contains a number of revisions to the FSVP proposed rule. The substantive revisions that require us to revise our preliminary regulatory impact analysis for the supplemental proposed rule (SPRIA) are as follows:

(1) We excluded raw materials and other ingredients that are imported for use in the manufacturing/processing, packing or holding of alcoholic beverages by importers that are registered food facilities that perform such manufacturing/processing, packing, or holding, and where the importer is exempt from the preventive controls regulations in accordance with § 117.5(i).

(2) We provided that the final rule is inapplicable to food manufactured/processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing or processing in the foreign country.

(3) We deleted the proposed provision that deemed importers in compliance with most of

the FSVP regulations when their customers are required to establish and implement risk-based supplier programs under the regulations on preventive controls (PC) (for human food or animal food) for a food that the importer imports. In addition, we deleted the proposed provision that would have provided that if the preventive controls that the importer and/or the importer's customer implement in accordance with the preventive controls regulations are adequate to significantly minimize or prevent all significant hazards in imported food, the importer would not be required to determine what foreign supplier verification and related activities it must conduct and would not be required to conduct such activities. The provision also proposed that if the importer's customer controls one or more such hazards, the importer would be required to annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.

In place of these provisions, we added a provision deeming in compliance with most of the FSVP requirements those importers that implement preventive controls for hazards in food in accordance with the PC regulations, and we added a series of provisions that relieve an importer from the requirements to conduct an evaluation of the food and foreign supplier and conduct supplier verification activities when the importer's customer or a subsequent entity in the importer's distribution chain is controlling the hazard. We also added a provision deeming in compliance with most of the FSVP requirements those importers that are *not* required to implement a preventive control in accordance with certain PC provisions.

(4) We added flexibility to the requirements relating to hazard analyses to allow importers to use hazard analyses conducted by other entities in addition to the foreign suppliers previously allowed, provided that the hazard analyses are performed using qualified individuals and the importer reviews and assesses such hazard analyses and documents the review and assessment.

(5) We added flexibility to the requirements relating to food and foreign supplier evaluations and reevaluations to allow importers to use evaluations and reevaluations conducted by entities other than the importer (but not the foreign supplier), provided that such evaluation and reevaluation is performed using a qualified individual and that the importer reviews and assesses the evaluation or reevaluation and documents the review and assessment.

(6) We added flexibility to the requirements relating to foreign supplier verification to allow importers to rely on entities other than the importer (but not the foreign supplier) to establish the procedures and perform and document verification activities if the importer reviews and assesses that entity's documentation of the procedures and activities, and the importer documents the review and assessment.

(7) We replaced the provisions relating to food from very small foreign suppliers generally with provisions relating to food from certain small suppliers meeting specified size and other criteria.

(8) We removed the proposed requirement that importers promptly review any customer, consumer, or other complaint that the importer receives to determine whether the complaint relates to the adequacy of the importer's FSVP. We also deleted the proposed requirement to

conduct investigations the cause or causes of adulteration or misbranding under section 403(w) if an importer became aware that an article of food it imported was adulterated or misbranded with respect to section 403(w).

(9) We replaced the proposed requirement that importers obtain a DUNS number and ensure that it is provided when filing entry with a requirement to provide the importer's unique facility identifier recognized as acceptable by FDA.

(10) We revised the definition of "importer" so that the FSVP importer is now the "U.S. owner or consignee" of an article of food that is being offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry. (Previously, we proposed that the "importer" would be the U.S. owner at the time of entry and, if there was no U.S. owner, the U.S. consignee. If there was no U.S. owner or consignee at the time of entry, we proposed to require that the foreign owner or consignee designate a U.S. agent or representative.) We also added a clarification to the definition of "importer" in § 1.500 that explains that in order for the foreign owner or consignee of the article to validly designate a U.S. agent or representative (when there is no U.S. owner or consignee) for the purposes of the definition of "importer," the U.S. agent or representative's role must be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer under the FSVP regulations.

(11) We revised the definition of a very small importer.

(12) We limited the special provisions relating to importing food from a country with an officially recognized or equivalent food safety system to food that is not intended for further manufacturing/processing, including packaged food products and raw agricultural commodities (RACs) that will not be commercially processed further before consumption.

(13) We revised the verification activity requirements such that importers may need to conduct verification activities or obtain documentation of verification activities that address the entity or entities that are controlling the hazards or verifying control of the hazards, including entities that are not foreign suppliers. For example, when an entity other than the grower of produce subject to the produce safety regulations in 21 CFR part 112 harvests or packs the produce and controls the hazard or verifies control of the hazard, or when the foreign supplier's raw material supplier controls a hazard, the verification activities must address the hazards controlled by those entities.

(14) We revised the requirements relating to very small importers and importers obtaining food from certain small foreign suppliers. As a result of these changes, importers of food from the specified small suppliers that are not very small importers as defined in the regulations must review supplier compliance history, approve suppliers, reevaluate foreign supplier compliance history, and establish and follow procedures ensuring the use of approved suppliers (or, when necessary and appropriate, on a temporary basis, unapproved foreign suppliers whose foods the importer subjects to adequate verification activities before using or distributing).

In addition to these changes, the FSVP final rule includes a number of changes that did not cause us to revise our preliminary regulatory impact analysis for the SPRIA because the changes are consistent with that analysis (considering the uncertainty ranges and data limitations that applied to that analysis) and/or are sufficiently minor so as not to affect costs. Those changes are as follows:

- We provided that the final rule is inapplicable with respect to the following: meat food products that at the time of importation are subject to the requirements of the United States Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.); poultry products that at the time of importation are subject to the requirements of the USDA under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.); and egg products that at the time of importation are subject to the requirements of the USDA under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.). In the SPRIA we considered only products subject to FDA regulation; therefore, we did not include these products in our previous analysis.
- We revised the list of chemical hazards required to be considered in hazard analyses to include nutrient deficiencies or toxicities in animal food. The proposed rule featured several types of hazards that that importers would be required to consider in hazard analyses, including various types of chemical hazards as well as biological and physical hazards. In the SPRIA we assumed an overall average across all food types of three to five hazards per food. We did not have sufficient information to separately

estimate the prevalence of each of the various types of hazards. Adding types of hazards to the list of hazards required to be considered in hazard analyses will likely increase the average number of hazards per food. However, the addition of nutrient deficiencies or toxicities in animal food is unlikely to have a significant impact on the overall average.

- We revised the requirements relating to sampling and testing to require that importers retain the date of the report of the testing as well as documentation that a qualified individual conducted the testing. In the SPRIA we based our cost of sampling and testing on qualified individuals conducting that activity and we assumed that the use of qualified individuals would be documented. Therefore, in the RIA we did not revise the analysis to reflect this change.
- We revised the requirements relating to reviewing the foreign supplier's relevant food safety records so that the final rule requires documentation of the conclusions of the review. In the SPRIA we assumed that the review of food safety records would be documented. Therefore, we did not revise the analysis to reflect this change.
- We revised certain provisions related to onsite auditing of foreign suppliers to allow the substitution of certain additional types of inspection reports for audits. In addition to the proposed allowance for inspection reports from FDA and food safety authorities of countries whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States, the final rule also allows importers to rely on the written results of an appropriate inspection of

the foreign supplier performed by representatives of other Federal agencies and State, local, tribal, or territorial agencies. Allowing these additional types of inspection reports will reduce the estimated costs relating to audits. However, we do not have sufficient information on the prevalence of these types of reports that would allow us to account for this expected cost reduction, and so therefore have not adjusted this analysis to account for this flexibility in the final rule. Further, it is unlikely that this change will have a significant effect on costs.

- We revised the requirements relating to records to add a requirement that importers keep records as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. In the SPRIA we included the cost of keeping records with the cost of the activity covered by those records and did not account for the format in which those records were kept. Therefore, we did not revise the analysis to reflect this change.
- We revised the requirements relating to records to require that importers provide FDA within a reasonable time an English translation of records maintained in a language other than English if requested to do so by the Agency. In the proposed rule we required records to be kept in English. However, in the SPRIA we did not include a cost for translating records maintained in languages other than English into English and effectively assumed the records would be in English. Requiring records to be translated into English when requested by FDA would thus represent an additional

cost from that which we assumed in the SPRIA. However, we have not revised the analysis to reflect this revision because we do not have sufficient information on how often FDA may request records in languages maintained in languages other than English, how many records would be involved per request, or the cost of translating those records. We would not expect this requirement to have a significant effect on estimated costs.

- We revised the requirements relating to record keeping to no longer require importers to maintain records at their place of business or at a reasonably accessible location, but are instead providing for offsite storage of records if such records can be retrieved and provided onsite within 24 hours of a request by FDA for official review. We consider electronic records onsite if they are accessible from an onsite location. We have not revised the analysis on this basis because of uncertainty regarding the place of storage or the cost of such storage. Storage costs for required records would have a minimal effect on estimated costs.
- We revised the requirements relating to records to exempt FSVP records from 21 CFR part 11. In the SPRIA we did not include a cost for FSVP records being subject to part 11. Therefore, we did not revise the analysis to reflect this change.
- We revised the requirements relating to records to specify that importers need not duplicate existing records (e.g., records they retain to comply with other Federal, State, or local regulations) if they contain all of the information required by the final rule. This change should reduce record keeping costs. However, we do not have

sufficient information to determine how many records required by this rule would already exist for other purposes. We expect this change would not have a significant effect on estimated costs.

- We revised the requirements relating to records so that if requested in writing by FDA, importers must send records to FDA electronically or through another means that delivers the records promptly, rather than making the records available for review at the importer's place of business. In the proposed rule, we proposed to require importers to send FDA records electronically when requested in writing by FDA. The increased flexibility to use another means of delivering records promptly might reduce the cost of transmitting records for some importers. However, we do not have sufficient information on how often FDA might request records, the likelihood that the requested records will be in electronic format, or the cost differences between scanning records for electronic transmission compared to the cost of delivering the records to FDA by other means to adjust our cost estimates on this basis. We expect this change would not have a significant effect on estimated costs.
- We revised the requirements relating to records to require very small importers to retain for at least 3 years records they rely on during the 3-year period preceding the applicable calendar year to support their status as a very small importer. In the proposed rule we required very small importers to retain all FSVP records for 2 years. We do not have sufficient information on the incremental cost of retaining these

particular records for an additional year to revise estimated costs on this basis. We expect this change would not have a significant effect on estimated costs.

- We revised the modified requirements relating to importers of certain dietary supplements and dietary supplement components that the importer (or its customer) subjects to further processing under the dietary supplement CGMP regulations. The proposed rule would have exempted from most of the FSVP requirements importers who establish specifications for dietary supplements or dietary supplement components under 21 CFR 111.70(b) (regarding components), (d) (regarding packaging), or (f) (regarding product for packaging and/or labeling) and comply with the requirements for verifying that these specifications are met; the same exemption would apply when the importer's customer established such specification and verified that they were met. However, the final rule does not apply the modified requirements to importers who establish specifications for a dietary supplement that they will package or label under § 111.70(f) and verify that those specifications are met (or whose customers establish such specifications and verify they are met). Instead, such importers will need to comply with the FSVP requirements applicable to other importers of dietary supplements. However, because in the SPRIA we estimated the number of importers of dietary supplements or dietary supplement components eligible for the modified requirements based on an estimate of dietary supplement manufacturers, this change to the scope of the modified requirements does not result in a change to overall costs.

- We revised the requirements relating to using qualified individuals to require importers to use qualified individuals for all FSVP activities rather than only certain FSVP activities. We have not revised the estimated cost of hiring third parties to be qualified individuals because importers will most likely already have personnel qualified to perform the tasks we are adding to this requirement.
- We exempted juice and seafood processors that are subject to and in compliance with the HACCP regulations (part 120 for juice and part 123 for seafood) from having to perform any FSVP-related activities for imported raw materials or other ingredients that they use in processing juice and seafood products in compliance with parts 120 and 123. In the PRIA we had excluded imported juice and seafood products from the FSVP regulations, reflecting the proposed exemption for imported juice and seafood products (because such products are already subject to verification by importers under the HACCP regulations). Because we classified the raw materials and other ingredients for seafood processing as seafood, the analysis already excludes seafood raw materials and ingredients. However, we did not exclude raw materials or other ingredients used in juice processing. Because we classified juice processors as manufacturers and assumed that manufacturers would not incur any costs as a result of this rule other than the cost of importer identification at entry, the analysis already treats them as exempt from the FSVP requirements for purposes of estimating costs, other than importer identification at entry. Because of the change in the final rule that now exempts from FSVP the raw materials or other ingredients used in processing

juice in accordance with part 120, the exemption for juice raw materials or other ingredients in the final rule would reduce the estimated overall cost of importer identification. However, we did not revise the analysis to reflect this change because importer identification costs are a very small percentage of total costs and removing the relatively small number of domestic juice processors who import raw materials or other ingredients would not have a significant effect on this cost or on total costs.

- We exempted raw materials or other ingredients imported by manufacturers or processors of low-acid canned foods ("LACF") subject to 21 CFR part 113 with respect to microbiological hazards. With respect to all hazards other than microbiological hazards that are controlled by part 113, importers that are LACF manufacturers or processors are required to comply with FSVP requirements. We have not revised the estimated costs as a result of this change because we don't anticipate that this change will have a significant effect on overall costs, and also because the SPRIA already assumed, for purposes of estimating costs, that all domestic manufacturers, including LACF manufacturers, would not incur costs as a result of this rule other than those associated with importer identification at entry. We did not have sufficient information to distinguish LACF manufacturers from other manufacturers for purposes of estimating costs associated with non-microbiological hazards.

In this RIA we discuss the impact of these changes and present the total costs of the final rule and its component provisions. For a detailed analysis of provisions that are not being

revised, see the PRIA of the original proposed rule (Ref. 1) as revised by the SPRIA of the supplemental proposed rule (Ref. 2).

Table A addresses the total costs of both the FSVP proposed rule and the final rule. As was the case with the summary estimates in the previous PRIA and SPRIA, these summary costs are based on the Scenario 1 assumptions relating to the percentage of importers conducting or obtaining documentation of onsite audits as a verification activity. (In the original PRIA (see pages 101 to 102), we calculated costs under three different scenarios reflecting different percentages of importers who, under proposed Option 2, would choose to conduct onsite audits of their foreign suppliers rather than perform another permitted verification activity; the percentages under Scenarios 1, 2, and 3 were 63 percent, 82 percent, and 100 percent, respectively.) We present Scenario 1 estimates in this RIA to keep the summary table easy to read and to facilitate comparison with the summary tables in the PRIA and SPRIA. We provide the estimates for all three scenarios in Table 35, Total Cost Summary for All Elements of FSVP Regulations, and in summary Table B with the same title.

Table A. Summary of FSVP Proposed Rule and Final Rule

	Annualized Total Costs (Domestic + Foreign)
FSVP Proposed Rule	
Costs discounted at 3%	$396,780,114
Costs discounted at 7%	$397,478,400
Final Rule	
Costs discounted at 3%	$434,737,369

Costs discounted at 7%	$435,382,420
Difference	
Costs discounted at 3%	$37,957,255
Costs discounted at 7%	$37,904,020

In the following sections we discuss how each revision to the final rule will impact the estimated costs and benefits of the rule.

II. Need for Regulation

We have not revised the need for regulation from the PRIA or the SPRIA. For a detailed discussion of the need for regulation, see the PRIA.

III. Regulatory Alternatives

We have not revised the feasible regulatory alternatives from the PRIA or the SPRIA. For a detailed discussion of the feasible regulatory alternatives, see the PRIA. In the tables of this final RIA, we have revised the estimated cost of the feasible regulatory alternatives to incorporate the effect of the analytic changes we discuss in the context of the estimated cost of taking the proposed action.

IV. Revised Cost for Final Rule

In this section we first present a review of comments we received on the cost estimates in the PRIA and SPRIA and a discussion of the revisions we made to our cost estimates based on revisions in the final rule and for other reasons such as corrections and updates. We then present a series of tables that appeared in the PRIA and SPRIA that we have revised to reflect the changes in the final rule, comments we received on the PRIA and SPRIA, and other considerations that impact this final analysis. We do not present revised tables after the discussion of each change because the changes interact with one another and the resulting intermediate tables would vary depending on the order we presented them. We have not presented estimated costs for individual changes or groups of changes in isolation. Such an approach would be cumbersome and unlikely to prove useful given the interrelated nature of the revisions.

A. Revisions Based on Comments

Comments on Cost Estimates in the PRIA

One comment asserts that we overstated the costs of the rule by not fully accounting for the cost reductions associated with the proposed rule's exemptions. In particular, the comment

maintains that in the future FDA is likely to officially recognize additional countries as having food safety systems that are comparable to that of the United States, but that we failed to account for this effect in our cost estimate. The comment also makes this claim regarding future recognitions of comparability in the context of the provision allowing importers to substitute for onsite audits inspection reports from a food safety authority whose food safety system FDA has officially recognized as comparable.

We agree that if we were to officially recognize additional food safety systems as comparable to that of the United States as the comment suggests, then the estimated costs of the final rule for future years would decrease. However, we have insufficient information at this time to quantify this effect. In the absence of more specific information about future conditions, we generally estimate costs based on current conditions because forecasting future conditions involves considerable uncertainty relating to not just this one factor but a number of factors associated with the quantity, origin, and safety of imported food.

One comment addresses the proposed provision allowing importers to substitute the results of an FDA inspection for onsite audits under certain conditions. To estimate the cost of the proposed provision allowing for substitution of the results of an FDA inspection, the PRIA accounted for the fact that FDA conducted inspections of 995 foreign facilities in fiscal year (FY) 2011. Therefore, we estimated that the proposed provision would eliminate the need for 995 of the audits that the PRIA had otherwise assumed would take place. The comment asserts that annual costs would be reduced by an additional $1.2 million if we updated the number of

foreign inspections FDA carried out to the number FDA conducted in more recent fiscal years (e.g., 1,342 in FY 2012).

We revised the analysis to update the analysis with the higher number of foreign facility inspections that FDA conducted in FY 2014, which was 3,027.

One comment states that when estimating the number of foreign suppliers meeting the definition of a very small supplier, we assumed the size distribution of foreign suppliers would be similar to the size distribution of domestic suppliers. The comment maintains that we did not provide evidence to justify this assumption.

We assumed similar size distributions for foreign and domestic suppliers because we do not have relevant size information on foreign suppliers. The comment did not provide information that would allow us to revise the assumption.

One comment maintains that we failed to account for the cost of an importer to gather the information needed to prove it qualifies as a very small supplier.

We calculated and accounted for the cost of documenting the size of very small importers and very small suppliers in Table 25 of the PRIA.

One comment notes various assumptions we used in our analysis and argues that if we did not have the necessary information we should have undertaken various types of activity to obtain that information, such as conducting experiments using FDA personnel, conducting pilot studies, and conducting statistically valid surveys. The comment includes the following among examples of such assumptions from the PRIA:

• 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 producers and thus render the importers of their products exempt from the proposed hazard analysis requirement. The comment asserts that, although we assumed that the foreign size distribution would match the U.S. domestic size distribution, we presented no evidence to justify this assumption.

• We estimated 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 that is not a RAC and 9 hours for a product that is a RAC (p. 23 of the PRIA). The comment asserts that these estimates are not based on any empirical data but instead are derived from an estimate that we used in the PRIA for the proposed rule on preventive controls, which the comment argues was without empirical foundation. The comment maintains that we could have produced an estimate of this key parameter by conducting experiments in hazard analysis using FDA personnel or actual importers in a pilot study.

• We assumed that 95 percent of covered importers would be able to use the option of reviewing a hazard analysis conducted by and provided by the subject foreign supplier in lieu of conducting an independent hazard analysis and that this option would reduce the time requirement for the task to 1.2 hours on average for non-RAC food items and 0.9 hours on average for RAC food items. The comment asserts that we provided no empirical basis for these assumptions and maintains that we could have conducted surveys of actual importers, experiments, or pilot studies to provide a credible basis for these key parameters.

• We assumed 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. The comment asserts that there is no basis for this assumption and maintains that we could conduct surveys or pilot studies to determine this empirically.

• We estimated that an audit of a food production facility by an accredited auditor would cost $3,600, based on an estimate in the proposed rules on FSVP and third-party certification of a 3-day onsite inspection at an average audit fee cost of $1,200 per day. The comment maintains that the estimate of 3 days' average effort is without empirical basis and the estimated $1,200 audit fee is based on an FDA staff interview of a single industry official. The comment also asserts that we also calculated the cost of an audit by an unaccredited auditor as $2,400 based on an unfounded assumption that unaccredited auditors earn 25 percent less than accredited ones. The comment argues that we must conduct statistically valid surveys of auditors who perform these duties internationally to establish a credible basis for fees and fee structures.

We base our analyses of the cost of proposed regulations on the best information available to us at the time we write the analyses, using ranges, distributions, and other devices to express uncertainty relating to the data inputs. For example, not all countries maintain accurate information on the relevant characteristics of firms that produce food for export to the United States, particularly in the case of foreign farms and other entities that operate through third-party distributors or exporters and in the case of entities that sell products both within the country where the food was produced and for export to the United States. In such cases, we believe that the most representative data would be data relating to the corresponding entities in the United

States for which we have such data. More generally, we disagree with the claim that our directive to perform regulatory impact analyses requires us to generate new empirical data through experiments, pilot studies, and surveys. The research suggested by the comment could be useful in generating improved information relating to certain inputs but would be both costly and time consuming. We must weigh the value of such research against the cost of research activity given the overall level and sources of uncertainty in an analysis and the practical significance of such improvements in estimates. In the present case, we believe that the additional activity would be unlikely to justify the cost.

Some comments state that we did not consider the following costs in the PRIA: (1) broker entry processing and/or additional internal trade execution resources, (2) IT system changes to accommodate new data and recordkeeping obligations tied to imports, (3) renegotiation of contracts to accommodate FSVP provisions, and (4) training and education of supply chain staff and foreign suppliers.

The activities listed in these comments would be difficult to distinguish from routine adjustments to current business practices such as periodic enhancements to IT systems, the renegotiation of contracts, and training and education. This rule may generate incremental costs beyond the normal adjustments to business practices that would otherwise take place. However, the comment does not provide sufficient information to estimate any incremental effect.

Comments on the Revised Cost Estimates in the SPRIA

One comment asserts that the requirement to use a DUNS number to identify the FSVP importer will generate costs that we did not capture in our analysis. The comment notes that DUNS numbers are generally not managed by the same corporate department that is responsible for import compliance so most companies do not currently store DUNS numbers in their trade compliance software. Also, large corporations with multiple addresses may have multiple DUNS numbers even though one team handles import compliance. The comment argues that requiring importers to use DUNS numbers will require them to modify their internal systems and relationships with brokers in order to establish a new numbering and indexing system. The comment maintains that this cost would be eliminated if we allowed importers to use either a DUNS number or an importer of record number used with U.S. Customs and Border Protection (CBP).

We revised the final rule and no longer require importers to use DUNS numbers. Instead, the final rule requires the use of a unique facility identifier recognized as acceptable by FDA. Because, however, FDA has not yet recognized any specific facility identifier as acceptable, it is not yet possible to estimate whether these changes in the final rule will affect costs. It is also not yet possible to determine the use of any future unique facility identifier system will reduce costs as contemplated by the comment.

Some comments note that the supplemental proposed rule required the importer to assess risks throughout the supply chain even though the supply chain for fresh produce in particular can be quite complex with many intermediaries. The comments claim that importers may not currently have information on the source of produce beyond the direct supplier because the

identity of a broker's or aggregator's suppliers is often proprietary information and substitution of suppliers is frequently necessary. The comments assert that this proposed requirement would require major changes in the current supply chain for produce and generate costs that we did not consider in the SPRIA. Another comment argues along the same lines that in the case of fresh produce the supplemental proposed rule would require one of the following to occur:

• Importers would need to have an FSVP in place for each of their suppliers' suppliers. The comment maintains that currently many importers do not know their suppliers' suppliers and that a supplier may change suppliers without sufficient notice for an importer to implement a new FSVP.

• The exporter would need to separate each supplier's produce to ensure a given importer only receives products from suppliers covered by an FSVP.

• The importer would need to bypass aggregators and purchase only from individual growers. The comment argues that any of these possibilities would be extremely costly, far more complex than current industry practices, and unlikely to have been considered in the SPRIA.

We noted in the PRIA and SPRIA that importers would need to assess risks and verify compliance with applicable U.S. standards throughout the supply chain, and our cost estimates were based on that consideration. These comments did not provide sufficient information for us to revise our estimates. However, the revisions we made in the final rule to allow importers additional flexibility with respect to assessing risks and verifying compliance throughout the supply chain reduces some of the costs estimated in the SPRIA. We discuss the impact of those changes in the context of revisions we made to the final rule.

B. Revisions Based on Changes to Final Rule

1. Exclusion for Ingredients of Alcoholic Beverages

In the proposed rule, we proposed to exempt from the FSVP regulations alcoholic beverages that are imported from a foreign supplier that is a facility that meets two specified conditions. In the final rule, we are also excluding ingredients that are imported for use in the manufacturing/processing, packing or holding of alcoholic beverages by importers that are registered food facilities that perform such manufacturing/processing, packing or holding, and when the importer is exempt from the preventive controls regulations in accordance with § 117.5(i). We have not revised our estimates of the cost effects of the alcoholic beverage exemption as a result of these changes in the final rule because our analysis of primary NAICS codes suggests that a very small percentage of the total number of importers produce alcoholic beverages and would thus potentially meet the conditions of this exemption. In addition, we cannot distinguish ingredients used by such importers to produce alcoholic beverages from ingredients they ship to customers to use to produce alcoholic beverages or sell for other purposes, and we do not have enough information to quantify the effects of these changes. We expect that any change in estimated costs as a result of these revisions would be minimal.

2. Exclusion for U.S. Food Returned

In the final rule, we are providing that the rule is inapplicable to food that is manufactured or processed, raised, or grown in the United States, exported, and returned to the United States without further manufacturing or processing in the foreign country. We do not have sufficient information about the cost effects of this change, if any, to revise our estimate of the costs of the rule based on this change. We expect that only a very small percentage of additional imported food would be excluded under this provision and any change in estimated costs would be minimal.

3. Deletion of Provision Relating to Importers Whose Customers Are Required to Establish and Implement Risk Based Supplier Programs Under the PC Rules, Deletion of Provision Relating to Situation in Which Importers or Importers' Customers Preventive Controls Implemented in Accordance with the PC Rules Are Adequate to Significantly Minimize or Prevent Hazards in Imported Food, and Special Requirements for Importation of Foods with Hazards Controlled by Customers, Entities Subsequent to Customers, or Importers at Subsequent Steps in the Distribution System.

We proposed to deem importers in compliance with most of the FSVP rule when their customers are required to establish and implement risk-based supplier programs under the PC rules for a food that the importer imports. In addition, we proposed to provide that if the preventive controls that the importer and/or the importer's customer implement in accordance

with the preventive controls regulations are adequate to significantly minimize or prevent all significant hazards in imported food, the importer would not be required to determine what foreign supplier verification and related activities it must conduct and would not be required to conduct such activities. (We also proposed that if the importer's customer controls one or more such hazards, the importer would be required to annually obtain from the customer written assurance that it has established and is following procedures (identified in the written assurance) that will significantly minimize or prevent the hazard.)

In place of these provisions, we have done the following:

• Added a provision deeming in compliance with most of the FSVP requirements those importers that implement preventive controls for hazards in food in accordance with the PC regulations; and

• Added a series of provisions that relieve an importer from the requirements to conduct an evaluation of the food and foreign supplier and conduct supplier verification activities when its customer or a subsequent entity in the importer's distribution chain is controlling the hazard.

In the SPRIA we noted we did not have direct information on importers subject to the potential PC supplier verification provisions or whose customers would be subject to those provisions. Therefore, we assumed that imported food that we had classified as raw materials or ingredients in the previous PRIA would be further processed by either the importer or the importer's customer and that in such cases the importer or its customer would be subject to the PC regulations (because we also proposed to deem importers in compliance with most of the FSVP rule when they are subject to and in compliance with the supplier verification

requirements in the PC regulations for the imported food). We revised the PRIA by adjusting the number of importers for the relevant provisions by removing importers dealing only with raw materials and ingredients and adjusting the cost estimates for the remaining importers to account for importers importing raw materials and ingredients as well as other foods. In the case of verification activity, we did not need to adjust the cost estimates because the importers and customers we estimated would be subject to the PC regulations corresponded approximately to those we had estimated previously would control hazards in the original PRIA.

In the final RIA we are adding back in importers dealing only with raw materials and ingredients who are not themselves food or beverage manufacturers and eliminating the adjustment for importers importing foods in addition to raw materials and ingredients.

The final rule includes provisions that relieve an importer from the requirements to conduct an evaluation of the food and foreign supplier and to conduct supplier verification activities under the following circumstances:

• The importer determines and documents that the type of food (e.g., RACs such as cocoa beans and coffee beans) could not be consumed without application of an appropriate control;

• The importer relies on its customer to ensure that the identified hazard will be significantly minimized or prevented (if the customer is subject to PC) or to provide assurance that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements (if the customer is not subject to PC) ;

• The importer relies on its customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer;

• The importer establishes, documents, and implements a system that ensures adequate control, at a subsequent distribution step, of the hazards in the food product it distributes and the importer documents its implementation of that system.

In the circumstances in which the customer or an entity in the distribution chain subsequent to the customer controls the hazard, there must be disclosure in documentation accompanying the food provided by the importer, the importer's customer, or a subsequent entity that the food is "not processed to control [identified hazard]", as well as written assurances from the importer's customer regarding appropriate procedures to ensure that the food will receive further processing for food safety. In addition, the final rule contains provisions holding the customer and subsequent entities accountable for the written assurances.

In the PRIA we estimated the number of importers whose customers control hazards based on the number of importers that were not themselves manufacturers or processors, but were importing raw materials or ingredients. In the SPRIA we estimated the number of importers whose customers are subject to the supplier verification provisions of the PC regulations using the same approach. We have retained this approach to estimate importers that would qualify for the reduced verification requirements because their customers or entities subsequent to customers control hazards or because the importer has implemented a system that ensures control of hazards at a subsequent distribution step.

In the PRIA and SPRIA we assumed that all firms importing raw materials or ingredients that were not themselves manufacturers or processors would need to obtain written assurances from their customers that the customers establish and follow procedures identified in the written

assurance that will significantly minimize or prevent hazards. We expressed these costs in Table 21, Estimated Cost of Obtaining Written Assurances from an Importer's Customer That Is Subject and in Compliance With the PC Supplier Verification Provisions.

The final rule does not require importers to obtain written assurances with respect to imported food that is the type of food that cannot be consumed without the application of appropriate controls for any hazards in those foods. However, written assurances are required in the case of importers whose customers or entities subsequent to the customer in the distribution chain control hazards. For purposes of estimating the costs of these provisions, we do not have sufficient information to separate out the imports of food that cannot be consumed without application of appropriate controls from foods with hazards that are being controlled by the importer's customer or a subsequent entity in the distribution chain, or to estimate the number of entities beyond the customer that may need to provide assurances. Therefore, we retained the assumption of one written assurance per customer for these importers.

As for the requirements regarding disclosure in documentation that the food is "not processed to control [identified hazard]", we do not have sufficient information to estimate the number of shipments requiring such disclosure documents, the likelihood of such documents already being provided, or the cost of the disclosure documents per shipment based on the variety of disclosure methods (e.g., labeling statements) that may be in accordance with the practice of the trade. We expressed this cost using a uniform probability distribution running from $0 per year to $100 per year and applied it to the estimated number of assurances. We distributed the cost equally between importers and customers. We expressed these costs in Table

21, which we have renamed Estimated Cost of Obtaining Written Assurances from an Importer's Customer or Subsequent Entity That Controls Hazards and Providing Disclosure Documents.

4. Ability to Use Hazard Analyses from Other Entities

In the FSVP proposed rule, we proposed to require that importers conduct hazard analyses, but also proposed to provide that if the foreign supplier has conducted a hazard analysis, the importer may meet its requirement to determine whether there are any significant hazards in a food by reviewing and assessing the hazard analysis conducted by the foreign supplier. We have revised the final rule to allow importers to review and assess analyses conducted by other entities in addition to the foreign suppliers previously allowed, provided that that hazard analyses are performed using qualified individuals and the importer reviews and assesses such hazard analyses and documents the review and assessment.

In the PRIA and SPRIA, we based our cost estimate on importers conducting hazard analyses themselves or reviewing and assessing analyses conducted by foreign suppliers. We did not break out the cost of documenting this review and assessment but considered that activity an integral part of reviewing and assessing hazard analyses for cost purposes. We assumed that in the vast majority of cases, represented by a uniform probability distribution of between ninety and one hundred percent with a mean of ninety-five percent, importers would be able to review and assess hazard analyses from their foreign suppliers. The rationale we expressed in the

original PRIA was that most suppliers will have hazard evaluations because they would be covered by one of the PC rules or other regulations that require hazard analyses or would voluntarily conduct such analyses. We provided these cost estimates in the SPRIA in Table 3, Estimated Cost for Obtaining Required Information and Conducting Risk Evaluations (Other Than Reviewing Supplier Compliance Status), Approving Suppliers Based on Risk Evaluations, and Documenting Supplier Approvals.

In the estimated zero to ten percent of cases in which we assumed the foreign supplier would not have a hazard analysis, another entity may have a hazard analysis. We do not know the probability that another entity would have an applicable hazard analysis. Therefore, to capture the impact of this revision to the final rule we have revised the analysis to specify that in the zero to ten percent of cases in which we assumed the importer would not be able to use a hazard analysis from a foreign supplier, the cost of the importer complying with the hazard evaluation requirements would fall in a range between the cost we previously estimated for the importer to conduct a hazard analysis entirely on its own and the cost we previously estimated for the importer to review and assess an analysis from a foreign supplier.

5. Ability to Use Food and Supplier Evaluations from Entities Other than the Foreign Supplier

In the SPRIA, we assumed importers would be conducting the evaluations to meet proposed requirements to evaluate food and foreign supplier risks. The final rule allows importers to review and assess the evaluations (and reevaluations) of foreign supplier performance and the risk posed by a food that were conducted by entities other than the importer (but not the foreign supplier), provided that such evaluation and reevaluation is performed using a qualified individual and that the importer reviews and assesses the evaluation or reevaluation and documents that review and assessment. (The final rule refers to the evaluation of the risk posed by a food but, instead of the "risk" associated with a foreign supplier, the rule refers to the foreign supplier's performance.)

In the SPRIA we expressed the cost of food and supplier evaluations in two places because of how we had structured the analysis for the original proposal: Table 2, Estimated Cost for Reviewing Food and Supplier Compliance Status (Component of Risk Evaluation) and Table 3, Estimated Cost for Obtaining Required Information and Conducting Risk Evaluations (Other Than Reviewing Supplier Compliance Status), Approving Suppliers Based on Risk Evaluations, and Documenting Supplier Approvals.

To reflect the final rule, we revised the estimated cost for the components of the food and foreign supplier evaluation (including the supplier compliance review) in a manner analogous to how we estimated the cost of reviewing and assessing hazard analyses conducted by foreign suppliers and other entities. However, we assumed that the probability that importers would be able to use evaluations from other entities would be lower than the probability that importers could use hazard analyses from other entities. In previous analyses we based the number of

suppliers on the entities providing food directly to importers except in the case of foreign farms growing RACs that are fruits or vegetables, which we assumed would work with consolidators or distributors rather than sell directly to importers. Therefore, we base the percentage of cases in which importers would be able to use food and supplier evaluations from other entities on a uniform probability distribution running from zero to the percentage of suppliers we estimated previously would be foreign farms growing RACs that are fruits or vegetables. As was the case for the estimated cost of hazard analyses, we assume the cost of reviewing and assessing existing food and supplier evaluations (including supplier compliance reviews) and documenting the review and assessment would be ten percent of what it would cost an importer to do a food and supplier evaluation of its own. We do not add a cost for transmitting and processing the supplier compliance status review component of the food and supplier evaluation separately because we address that cost in the context of the other components of the food and supplier evaluation, and because if an entity could provide information on supplier compliance status review it could probably also provide information on other elements of the food and supplier evaluation.

6. Ability to Use Supplier Approval Programs and Determinations of Appropriate Verification Activity from Entities Other than the Foreign Supplier

In the SPRIA, we assumed importers themselves would establish and follow written procedures to ensure they import food from approved foreign suppliers, and also that they

themselves would determine appropriate foreign supplier verification activities. In the final rule, we are allowing importers to rely on other entities (but not the foreign supplier) to establish the procedures and perform and document the activities related to the use of approved suppliers, as well as to determine appropriate foreign supplier verification activities (provided that importers review and assess the other entity's determination, and documents that review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual).

In the SPRIA we expressed the cost of establishing and following written procedures ensuring that importers import food from approved suppliers and the cost of determining appropriate verification activity in Table 6, Estimated Cost for Establishing and Following Procedures for Ensuring Food Is Obtained From Approved Suppliers; and Table 7, Estimated Cost of Determining and Documenting the Appropriate Supplier Verification Activity. We applied those costs and reported the results in Table 11, Estimated Cost of Establishing and Following Procedures for Approving Suppliers and Ensuring Food Is Obtained from Approved Suppliers and of Determining and Documenting Appropriate Verification Activities (Hazard Based and Facility Based).

To reflect the final rule, we revised the estimated cost for these activities in a manner analogous to how we revised the estimated cost for food and foreign supplier evaluations. We assumed the cost of reviewing, assessing, and documenting the review and assessment of the adoption and use of procedures for ensuring the use of approved suppliers and documentation of appropriate supplier verification activity would be ten percent of the cost of conducting such

activity from scratch. We then calculated a weighted mean cost based on setting the probability that an importer can review and assess an existing program or determination equal to a uniform probability distribution running from zero to the percentage of suppliers we estimated previously would be foreign farms growing RACs that are fruits or vegetables. We did not revise the cost of following written procedures for ensuring the use of approved suppliers because the costs should be the same whether followed by the importer or another entity.

7. Revised Requirements for Certain Types of Suppliers

In the FSVP proposed rule we proposed to provide modified requirements for importers obtaining food from very small foreign suppliers (VSFSs), which we defined in the supplemental proposed rule as foreign suppliers whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $1 million, adjusted for inflation. In the supplemental proposed rule importers importing food from a VSFS would have been subject to the requirements relating to the "scope" of an FSVP and requirements related to the use of qualified individuals, as well as requirements related to identification of the importer at entry. However, food from such suppliers would not have been required to comply with the requirements related to proposed §§ 1.504 through 1.508 or § 1.510. This means that importers bringing in food from very small foreign suppliers would not have been required to meet many of the standard FSVP requirements, including those for hazard analysis, evaluation, and supplier

verification. The importer would have been required to document that the suppliers were VSFSs and obtain written assurances that the suppliers controlled hazards, including brief descriptions of the processes and procedures suppliers used to control those hazards, and to take corrective actions as necessary.

In the supplemental proposed rule we also proposed to reduce requirements relating to verification activities relating to food imported from certain farms not subject to the produce safety rule as well as farms subject to provisions for qualified exemptions.

In the final rule, we replaced the provisions relating to food from very small foreign suppliers generally with provisions relating to food from certain small suppliers meeting specified size and other criteria. This has the effect of changing the scope of the types of foreign suppliers to which modified verification activities will apply. These modified provisions in the final rule apply to importers of food from the following:

• Entities that meet the definition of "qualified facility" as defined by 21 CFR 117.3 or 507.3 in the PC regulations, which are facilities subject to the PC regulations that are very small businesses (as defined in the PC regulations for human and animal food, respectively). For human food, a very small business is a business (including any subsidiaries and affiliates) averaging less than $1 million adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). For animal food, a very small business is a business (including any subsidiaries and affiliates) averaging less than $2.5 million adjusted for inflation, per year, during the 3-year period preceding the applicable

calendar year in both sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale). Alternatively, a qualified facility is a facility to which both of the following apply: (1) during the 3-year period preceding the applicable calendar year, the average value of the food manufactured, processed, packed, or held at the facility sold directly to "qualified end users" exceeds the average value of food to all other purchases, and (2) the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

• Suppliers of shell eggs that are not covered by the shell egg safety rule in 21 CFR part 118 because they have fewer than 3,000 laying hens.

• Farms that grow produce and are not covered farms under the produce safety regulations in accordance with § 112.4(a) (the farm has 3-year average annual produce sales of $25,000 or less), or in accordance with §§ 112.4(b) and 112.5 (the farm satisfies the requirements for a qualified exemption under the produce safety regulations).

Importers importing food from these suppliers are subject only to the requirements relating to having an FSVP, hiring qualified individuals if necessary, approving the small suppliers based on an evaluation of the foreign supplier compliance history, reevaluating foreign supplier compliance history, establishing and following procedures ensuring the use of approved suppliers (or, when necessary and appropriate, on a temporary basis, unapproved foreign suppliers whose foods the importer subjects to adequate verification activities), and importer identification. In addition, the importer must obtain assurances from the foreign supplier

regarding the imported food (the specific assurance required depends on whether the foreign supplier is a qualified facility, a small egg producer, or a produce farm). These modified requirements apply if the importer documents at the end of each year that the supplier meets the criteria for one of the categories of certain small suppliers.

In the SPRIA we discussed the procedures we used to revise the analysis to incorporate the modified requirements relating to certain small farms. We have eliminated the category of VSFS and replaced it with the three categories of small suppliers to whom the modified supplier provisions now apply.

We have limited information on foreign suppliers with respect to the certain small farms to whom the modified supplier verification requirements apply. Therefore, we based our estimate of the percentage of foreign farms that would be subject to these modified requirements on the percentage of domestic farms that are not covered in the produce safety rule and those that satisfy the requirements for qualified exemptions, as expressed in the regulatory impact analysis of that rule, which was 69 percent. The RIAs for the preventive controls regulations contain estimates for the percentage of foreign suppliers that are qualified facilities under the PC regulations. We rely on those estimates and use a uniform probability distribution running between the estimated percentages of domestic facilities that are qualified facilities under the two PC rules as expressed in the regulatory impact analyses of those rules, which was 38 percent for PC for animal food and 55 percent for PC for human food. The RIA does not include any cost estimates for the modified requirements related to imports from shell egg suppliers with fewer

than 3,000 laying hens because we are not aware of many such imports, and any effect that such imports would have on the costs estimates for the final rule are minimal.

8. Deletion of Provisions Relating to Investigations and Reviewing Complaints

In the FSVP proposed rule we proposed to require importers to promptly review any customer, consumer, or other complaint that the importer receives to determine whether the complaint relates to the adequacy of the importer's FSVP. We also proposed to require importers to conduct investigations into the cause or causes of adulteration or misbranding under section 403(w) if an importer became aware that an article of food it imported was adulterated or misbranded with respect to section 403(w). In the final rule we deleted those requirements.

In the SPRIA we expressed these costs in Table 28, Estimated Cost of Investigating Problems with Imported Products per Importer Conducting That Activity and Table 26, Estimated Cost for Reviewing Complaints. We have deleted those tables and costs in this RIA but we have retained the numbering of subsequent tables to facilitate comparison and review.

9. Ability to Use Facility Identifiers Other Than DUNS Numbers

In the FSVP proposed rule we proposed to require importers to obtain and use a DUNS number for identification at entry. We revised these provisions in the final rule to allow

importers the flexibility to use any unique facility identifier recognized as acceptable by FDA, which may include, but may not be limited to, a DUNS number.

In the PRIA and SPRIA we expressed the cost of obtaining and using a DUNS number in Table 29, Estimated Cost of Obtaining and Providing DUNS Numbers under the FSVP Proposed Rule.

We have not revised our cost estimate because we have not yet issued guidance specifying which unique facility identifier or identifiers FDA recognizes as acceptable, and we therefore have no information on other acceptable unique facility identifiers. We have also retained the cost of providing a unique facility identifier at entry.

10. Revised Requirements Relating to Definition of Importers and U.S. Agents or Representatives

In the FSVP proposed rule, we proposed that the "importer" would be the U.S. owner at the time of entry and, if there was no U.S. owner, the U.S. consignee. If there was no U.S. owner or consigner at the time of entry, we proposed to require that the foreign owner or consignee must designate a U.S. agent or representative as the importer of the food for purposes of the FSVP regulations. In the final rule we are modifying the definition of "importer" so that the FSVP importer is now the "U.S. owner or consignee" of an article of food that is being offered for import into the United States. We are defining "U.S. owner or consignee" to mean the

person in the United States who, at the time of entry of a food into the United States, either owns the food, has purchased the food, or has agreed in writing to purchase the food. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent or representative of the foreign owner or consignee at the time of entry. We are also adding a clarification to the definition of "importer" explaining that in order for the foreign owner or consignee of the article to validly designate a U.S. agent or representative (when there is no U.S. owner or consignee) for the purposes of the definition of "importer," the U.S. agent or representative's role must be confirmed in a signed statement of consent. The signed statement of consent must confirm that the U.S. agent or representative agrees to serve as the importer for the purposes of the FSVP regulations.

To estimate the number of persons who would meet the "importer" definition, we have used information about the number of persons designated as "consignees" of food imports in FDA's Operational and Administrative System for Import Support (OASIS) database. The "consignee" information in OASIS is populated based on entry filings submitted to CBP that provide "consignee" information about imported products, and does not necessarily correlate exactly with the FSVP definition of "importer." The "consignee" information in OASIS also includes information about "consignees" for seafood and juice products that are exempt from this final rule (provided that those products are in compliance with the applicable HACCP regulations). To account for the fact that importers of HACCP-compliant seafood and juice products are not subject to the FSVP regulations, we have not included the "consignees" of seafood and juice products subject to the HACCP regulations in estimating the number of

importers under the FSVP final rule. Although we cannot be certain that this information reflects the exact number of persons who will meet the definition of FSVP "importer" and will thus be subject to FSVP requirements, it is our most accurate estimate for that figure. One limitation of this data is that it does not provide any information as to the number of FSVP importers who will be U.S. owners or consignees, or U.S. agents or representatives. That therefore means that we do not have sufficient data to estimate the number of FSVP importers that will be affected by our changes to the definition of "importer," including the clarification we made to the definition of "importer" regarding signed statements of consent for U.S. agents and representatives who serve as FSVP importers. Therefore, we have not estimated a cost for these changes, including the change regarding the signed statements of consent.

11. Change to Definition of Very Small Importer

In the original proposed rule, we proposed to define a very small importer (VSI) as an importer, including any subsidiary, affiliate, or subsidiaries, or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliates, whose average annual monetary value of food sales during the previous 3-year period (on a rolling basis) is no more than $0.5 million. In the supplemental proposed rule, we proposed to increase the sales ceiling to $1 million. In the final rule, we revised the definition to refer to importers (including any subsidiaries and affiliates) averaging less than $1 million per year, adjusted for inflation, during the 3-year period

preceding the applicable calendar year, in sales of human food combined with the U.S. market value of human food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee). With respect to the importation of animal food, we are defining a very small importer as an importer (including any subsidiaries or affiliates) averaging less than $2.5 million per year, adjusted for inflation, during the 3-year period preceding the applicable calendar year, in sales of animal food, combined with the U.S. market value of animal food imported, manufactured, processed, packed, or held without sale (e.g., imported for a fee).

Importers that import both human food and animal food with total annual food sales of $3.5 million and over would not qualify as a VSI for both types of food (though they might qualify as a VSI for either human food or animal food). Importers that import both types of food with total annual food sales between $1 million and $3.5 million might qualify as a VSI for both types of food depending on the portion of sales and market value attributable to human food versus animal food. We do not have information on U.S. market value of human and animal food imported, manufactured, processed, packed, or held without sale. For purposes of this analysis, we assume that the market value of such food would be negligible relative to food sales for importers that both sell food and import, manufacture, process, pack, or hold food without sale. In addition, we assume the proportion of importers that mostly import, manufacture, process, pack, or hold food without sale that meet the definition of VSI based on the U.S. market value of such food is the same as the proportion of importers that sell food and meet the definition of VSI based on food sales.

Although, importers that import both human food and animal food could have any total annual food sales and still qualify as a VSI with respect to one or the other type of food, we do not have sufficient data to estimate the number of these importers that might qualify as a VSI with respect to only one type of food. Therefore, we estimated the number of importers that meet the revised definition of VSI (for either human food or animal food or both) using a uniform distribution running from importers with less than $1 million in food sales to importers with less than $3.5 million in food sales.

We have not introduced a cost for importers to determine the U.S. market value of human and animal food imported, manufactured, processed, packed, or held without sale because we assume in most cases importers would already have an estimate of the market value of such food.

12. Limitation of Reduced Requirements for Food from Countries with Officially Recognized or Equivalent Food Safety Systems

In the FSVP proposed rule, we included reduced requirements for importers importing food from a country with an officially recognized or equivalent food safety system. In the final rule, we limited the application of these special requirements relating to food that is not intended for further processing, including packaged food products and RACs that will not be processed further before consumption.

In the PRIA and SPRIA we noted that FDA has officially recognized only one country, New Zealand, as having a comparable food safety system. As we explained, we did not have sufficient information on importers obtaining food products from this country to estimate the cost reductions associated with reduced FSVP requirements for such products. Because we do not have this information about food products imported from New Zealand, we also are unable to estimate the effect on costs of the change in the types of food products from this country that qualify for the reduced requirements.

13. Extending Verification Activity Requirements to Entities Other Than Foreign Suppliers

In the proposed rule the verification activity requirements relating to audits, testing, and reviewing records applied to importers conducting that activity or obtaining documentation of that activity with respect to foreign suppliers. We revised these provisions in the final rule so that verification activities must address the entity or entities that are controlling the hazards or verifying control of the hazards (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and controls the hazard or verifies control of the hazard, or when the foreign supplier's raw material supplier controls a hazard).

In the PRIA and SPRIA we based our estimate of verification activity costs on foreign suppliers conducting or arranging for that activity to be conducted because we expected that

market forces would lead to that result, rather than importers potentially duplicating the same verification activity for the same suppliers. To account for the fact that these activities may involve entities other than the foreign suppliers, we revised our estimate of the number of such activities, adding an estimate of the number of suppliers associated with the estimated number of triggering hazards, to a uniform distribution with the low end based on the previous estimate based on suppliers and the high end based on triggering hazards.

In the case of audits specifically, we had estimated in the PRIA and SPRIA that approximately 80 percent of foreign suppliers for which importers would need to perform audits were already arranging audits they could share with importers. We have used that same assumption for entities other than foreign suppliers.

In the case of transmission of documents relating to sampling and testing, we did not have sufficient information on the number of importers receiving documentation about entities other than foreign suppliers to directly estimate the potential number of transmissions. We revised our previous estimate, which we based on estimating the number of foreign suppliers providing the estimated number of products, by adding additional transmissions equal to the number of products because we assume that the entity that will deliver this information to the importer will be the entity that is most easily able to do so. In some, but not all, cases, the most cost-effective way for entities other than suppliers to provide this testing information to importers might be to have the foreign supplier provide the test results to the importer.

14. Revised Requirements Relating to Very Small Importers and Importers of Food from Certain Small Foreign Suppliers

We revised the requirements relating to importers obtaining food from certain small foreign suppliers in various ways relating to the type of documentation required in different situations. The most significant change is that we require importers that import food from certain small foreign suppliers to comply with a component of the foreign supplier evaluation requirements. In particular, the final rule requires these importers to evaluate foreign supplier compliance history; however, the final rule permits the importer to rely on an evaluation of foreign supplier compliance history conducted by another entity provided that the importer reviews and assesses that evaluation and documents that review and assessment. The final rule also requires these importers to approve suppliers on the basis of the evaluations and to document those approvals, and to also conduct reevaluations. Finally, the final rule requires these importers to establish and follow written procedures to ensure they import food only from foreign suppliers they have approved and to document their use of those procedures (except that the importer may rely on an entity other than the foreign supplier to establish the procedures and perform and document such activities, provided that the importer reviews and assesses that entity's documentation of the procedures and activities and documents that review and assessment).

In the PRIA and SPRIA we provided estimates of the cost of supplier compliance history review in Table 2, Estimated Cost for Reviewing Food and Supplier Compliance Status

(Component of Foreign Supplier Performance Evaluation), the approval and documentation of approvals in Table 3, Estimated Cost for Obtaining Required Information and Conducting Evaluations of Food and Foreign Suppliers (Other Than Reviewing Supplier Compliance Status), Approving Suppliers Based on Evaluations of Food and Foreign Suppliers, and Documenting Supplier Approvals, and the establishment, following, and documentation of procedures to ensure the use of approved suppliers in Table 11, Estimated Cost of Establishing and Following Procedures for Approving Suppliers and Ensuring Food Is Obtained from Approved Suppliers and of Determining and Documenting Appropriate Verification Activities (Hazard Based and Facility Based). We have revised the RIA to include importers obtaining food from certain small foreign suppliers in the estimated costs for those activities in those tables. In the final rule we also changed the documentation that is required for written assurances in some cases. We deleted the proposed requirement that written assurances from foreign suppliers of VSI include a brief description of the processes and procedures those suppliers are following to ensure the safety of the food. We also deleted the requirement relating to the brief description of processes and procedures from the written assurances importers must obtain from certain small suppliers. We replaced the former approach to assurances with different assurance requirements depending on the type of small supplier involved. For suppliers that are qualified facilities, the final rule requires that importers obtain an assurance of one of the following: either (1) a brief description of the preventive controls that the supplier is implementing to control the applicable hazard or (2) a statement from the supplier that it is in compliance with relevant laws and regulations. For suppliers that are certain small produce or egg farms, the final rule requires that importers obtain

an assurance that the imported produce or shell eggs are not adulterated under section 402 of the FD&C Act. We did not revise the cost of these assurances because we have insufficient information on the incremental cost of these countervailing changes. These changes are unlikely to have a major effect on the estimated cost of obtaining these assurances.

C. Revisions Based on Other Factors

In addition to revising the analysis to reflect comments and changes in the final rule, we also revised the analysis for the following reasons.

1. Revision of Estimated Cost of Hiring Qualified Individuals

In the PRIA and SPRIA we estimated the cost of importers hiring qualified individuals when necessary. We did not estimate the cost of suppliers hiring qualified individuals. However, we estimated the cost of each verification activity based on the assumption that suppliers would arrange for that activity rather than importers because of the associated cost savings. Suppliers would need to hire outside qualified individuals in the case of audits and reviewing records although they could use in-house qualified individuals in the case of sampling and testing. For the final rule, we revised the estimate of the cost of hiring third parties by applying the cost to the estimated number of suppliers arranging for audits or records review.

We maintained the estimated cost for importers to hire qualified individuals because importers may need to hire qualified individuals for reasons other than conducting verification activities. We express the cost of hiring qualified individuals in Table 1, Hiring Qualified Individuals.

2. Update and Revision of Labor Costs

In the PRIA and SPRIA, we based the labor cost for activity conducted by a qualified individual on the mean hourly wage for SOC 11-3051 Production Managers in NAICS code 311000 Food Manufacturing in 2010. We increased wages by 50 percent, from $40.96 to $61.44, to account for fringe benefits and overhead. We based the labor cost for activity conducted by secretarial or administrative staff on the mean hourly wage for SOC 43-6014 Secretaries and Administrative Assistants. We increased wages by 50 percent, from $15.09 to $22.64, to account for fringe benefits and overhead.

In the final RIA we have revised the analysis to base the labor cost for activity conducted by a qualified individual on the national estimate of the mean hourly wage for SOC 11-3051 Industrial Production Managers in 2013 (Ref. 3). Following updated guidelines on the development of RIAs issued by the U.S. Department of Health and Human Services (DHHS) (Ref. 4), we increased wages by 100 percent from $47.78 to $95.56, rather than the 50 percent adjustment used in the PRIA and SPRIA. We base the labor cost for activity conducted by secretarial or administrative staff on the national estimate of the mean hourly wage for SOC 43-

6014 Secretaries and Administrative Assistants, Except Legal, Medical, and Executive in 2013 Ref. 4). Again, following DHHS guidelines, we increased wages by 100 percent from $16.35 to $30.18, rather than the 50 percent adjustment used in the PRIA and SPRIA.

These changes affect all tables referencing wage rates or labor costs.

3. Correction of Estimated Cost of Supplier Compliance Assessment

In the original proposed rule different groups of importers were subject to the supplier compliance status review and hazard analysis provisions. In the supplemental proposed rule, we proposed to delete the previously proposed section on compliance status review but incorporate some of the provisions into the requirements concerning hazard analysis and evaluation of certain risk factors in determining appropriate foreign supplier verification and related activities. However, in the SPRIA we neglected to align the number of foreign supplier performance reviews with the number of food (risk) evaluations. In the RIA we have corrected this error and linked the estimated number of supplier performance reviews to the estimated number of food risk evaluations.

4. Revised Estimate of the Cost of Onsite Audits

We revised the estimated cost of audits so that it aligns with the estimate in the PRIA for the proposed rule on preventive controls for human food, which ranged from a low of $1,500 to a

high of $5,000. The new cost range includes but is somewhat broader than the range we used in the FSVP SPRIA and PRIA of $2,700 to $3,600.

D. Revised Tables

In the SPRIA we revised the following tables from the PRIA to reflect the changes in the supplemental proposed rule: 1 to 3, 5, 6, 11, 17, 21, 22, 24 to 28, and 35 to 38. Also in the SPRIA, we deleted the following tables because they referred to an element of the original proposed rule that did not appear in the supplemental proposed rule: 12 to 16, 19, and 30 to 31. However, we retained the table numbering from the PRIA to aid in comparing tables across documents.

In this final RIA we deleted Tables 26 and 28 and revised all tables that we did not delete at the SPRIA stage.

The PRIA for the original proposed rule included tables reflecting the cost of FSVP in conjunction with the original preventive controls proposals. The SPRIA for the FSVP supplemental proposed rule included tables reflecting the cost of FSVP based on the supplemental notice of proposed rulemaking, which considered the inclusion of potential supplier verification provisions in the revised preventive controls proposals. The RIA for the final rule includes tables reflecting the cost of FSVP, taking into account the supply-chain program provisions in the preventive controls final rules.

The following tables set forth the costs associated with various provision of the FSVP final rule. Following each table, we briefly note certain factors that affect the figures in the table. For a full discussion of those factors, see the preceding sections of this RIA.

Table 1. Hiring Qualified Individuals					
	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	$96	$96	$96	$96	
Cost to Hire Third Party	$382	$382	$382	$382	
Importers Subject to Requirement to Hire Qualified Individuals	31,839	9,371	5,026	1,254	47,489
Percentage of Importers That Would Need to Hire Third Party	50%	50%	50%	0%	
Importers That Would Need to Hire Third Party	15,920	4,685	2,513	0	23,118
Estimated Number of Other Entities That Would Need to Hire Third Party					
Scenario 1	4,793	34,300	21,212	4,561	64,866
Scenario 2	4,652	33,286	20,585	4,427	62,950
Scenario 3	4,518	32,327	19,992	4,299	61,135
Annual Cost for Hiring Third Parties					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632

The initial discussion of Table 1 occurred on pp. 15 to 17 of the PRIA. In the SPRIA Table 1 appears on pp. 23 to 24; however, the main discussion of the substantive changes to the proposed rule that caused FDA to revise the estimates in Table 1 of the SPRIA appears on pages 9-21 of the SPRIA. In this final RIA, we revised Table 1 to account for the inclusion of importers who were formerly deemed in compliance with the FSVP regulations because they sold imported food to customers subject to the potential PC supplier verification provisions, the addition of entities other than the importer who may need to hire third parties to be qualified individuals, the change in requirements relating to importers obtaining food from certain small foreign suppliers, and the updated labor cost calculations.

Much of the explanation for our cost estimates in Table 1 can be found in the PRIA, and readers who have been following the development of the FSVP rule are therefore already familiar with the basis for many of our calculations. To provide an example, however, we estimate in the RIA that the average cost to hire a third party (e.g., to conduct an onsite audit of a foreign supplier) is 4 hours times $96 per hour, which equals $382. If 50 percent of importers would need to hire a third party that would amount to 0.5 times 31,839, which equals 15,920 importers. The number of suppliers that may need to hire third parties is related to the number of suppliers that may arrange or in some cases perform verification activities. Under Scenario 1, we estimate 4,793 other entities might need to hire third parties. Thus for Scenario 1 the total annual cost for hiring third parties would be 15,920 importers plus 4,793 other entities equals 20,713 entities times $382 average cost per entity to hire a third party equals $7,917,234.

Table 2. Estimated Cost for Reviewing Food and Supplier Compliance Status (Component of Risk Evaluation)					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Number of Hours to Review Supplier Compliance Status	2.3	2.3	2.3	2.3	
Percentage of Hours Required if Importer Can Review Another Entity's Foreign Supplier Compliance Status Review as Percentage of Number of Hours To Review Supplier Compliance Status	10%	10%	10%	10%	
Hours Required if Importer Can Review Another Entity's Foreign Supplier Compliance Status Review as Percentage of Number of Hours To Review Supplier Compliance Status	0.3	0.3	0.3	0.3	
Cost Per Hour - Importer	$96	$96	$96	$96	
Percentage of Required Supplier Compliance Status Review For Which Importer Can Review and Evaluate Supplier Compliance Status Review from Another Entity, Midpoint	26%	26%	26%	26%	
Cost to Conduct Review, Average	$219	$219	$219	$219	
Total Number of Reviews of Suppliers	4,031	37,461	22,869	5,098	69,460
Total Cost	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097

The initial discussion of Table 2 occurred on pp. 18 to 20 of the PRIA. In the SPRIA, Table 2 appears on p. 24, and the changes to the proposed rule that caused FDA to revise its estimates are discussed on pp. 13 to 17 and 11 to 12. In this final RIA we revised Table 2 to include the additional flexibility to use food and supplier evaluations conducted by other entities, the change in requirements relating to importers obtaining food from certain small foreign suppliers, the updated labor cost calculations, and to align the number of reviews of suppliers with the number of food risk evaluations.

Table 3. Estimated Cost for Obtaining Required Information and Conducting Hazard Analyses, Evaluations of Foods and Suppliers (Other Than Reviewing Supplier Compliance Status), Approving Suppliers Based on Food and Supplier Evaluations, and Documenting Supplier Approvals

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Number of Hours to Produce the Required Information and Analyze Hazards From Scratch per Product and Supplier Combination for Products Other Than RACs, Mean	12	12	12	12	
Number of Hours to Produce the Required Information and Analyze Hazards From Scratch per Product and Supplier Combination for Products for	9	9	9	9	

RACs, Mean					
Number of Hours to Transmit Existing Hazard Analysis	0.25	0.25	0.25	0.25	
Percentage of Hours Required if Importer Can Review Foreign Other Entity's Hazard Analysis as Percentage of Number of Hours To Produce the Required Information and Evaluate Hazards From Scratch	10%	10%	10%	10%	
Number of Hours to Produce the Required Information and Evaluate Hazards From Review and Analyze 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 Analyze Hazards From Review and Analysis of Other Entity's Hazard Analysis For RACs	0.9	0.9	0.9	0.9	
Percentage of Required Information and	95%	95%	95%	95%	

Hazard Analyses For Which Importer Can Review and Evaluate Another Entity's Hazard Analysis, Midpoint					
Cost Per Hour – Importer	$96	$96	$96	$96	
Cost Per Hour - Supplier or Other Entity	$33	$33	$33	$33	
Cost to Produce the Required Information and Analyze Hazards per Product and Supplier Combination For Products Other Than RACs	$140	$140	$140	$140	
Cost to Produce the Required Information and Analyze Hazards per Product and Supplier Combination For RACs	$105	$105	$105	$105	
Average Cost to Process Documentation of an Onsite Audit For Transmission to Importer - Foreign Supplier or Other Entity	$8	$8	$8	$8	
Products That Are Not RACs	5,827	40,204	26,852	6,223	79,105
Products That Are RACs	2,062	16,329	8,127	1,300	27,818
Cost to Analyze Hazards	$783,916	$5,287,238	$3,362,640	$764,775	$10,198,569

Number of Hours to Evaluate Foreign Supplier Performance Beyond Evaluation of Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Food and Supplier Evaluation, Mean	12	12	12	12	
Number of Hours to Evaluate Foreign Supplier Performance Beyond Evaluation of Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Evaluation From Review of Another Entity's Evaluation, Mean	1.2	1.2	1.2	1.2	
Percentage of Required Evaluations For Which Importer Can Review Another Entity's Evaluations, Midpoint	0.3	0.3	0.3	0.3	
Cost to Evaluate Foreign Supplier Performance Beyond Evaluation of	$875	$875	$875	$875	

Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Evaluation, Mean					
Adjustment for Suppliers Reviewed But Not Approved	5%	5%	5%	5%	
Suppliers	3,547	29,801	18,104	4,251	55,703
Total Cost to Evaluate Foreign Supplier Performance Beyond Evaluation of Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Evaluation, Mean	$3,704,776	$34,430,767	$21,019,133	$4,685,733	$63,840,409
Total Cost All Importers Subject To This Requirement	$4,488,692	$39,718,005	$24,381,773	$5,450,509	$74,038,978
Total Cost for Suppliers or Other Entities	$27,547	$231,445	$140,600	$33,014	$432,606
Total Cost for Importers and Suppliers	$4,516,240	$39,949,450	$24,522,372	$5,483,523	$74,471,584
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 Analyses as Percentage of Initial Cost to Produce	10%	10%	10%	10%	
Total Cost for Importers	$3,574,154	$31,336,470	$19,231,093	$4,287,909	$58,429,626
Total Cost for Suppliers Or Other Entities	$22,098	$185,665	$112,789	$26,484	$347,036
Total Cost for Importers and Suppliers or Other Entities	$3,596,252	$31,522,135	$19,343,881	$4,314,393	$58,776,661

The initial discussion of Table 3 occurred on pp. 21 to 27 of the PRIA. In the SPRIA, Table 3 appears on pp. 24 to 27 and the revisions to the proposed rule that necessitated the revised estimates are discussed on pp. 11 to 12, 13 to 17, and 20 to 21. In this RIA, we revised Table 3 to include importers who were formerly excluded from the estimate for the cost of conducting hazard analysis because their customers would be subject to the proposed PC supplier verification regulations, the replacement of the proposed very small foreign supplier provisions with provisions for food imported from certain small foreign suppliers, the change in

the definition of a very small importer, the additional flexibility to use hazard analyses and food and supplier evaluations from other entities, the change in requirements relating to importers obtaining food from certain small foreign suppliers, and the updated labor cost calculations.

Much of the explanation for our cost estimates in Table 3 can be found in the PRIA, and readers who have been following the development of the FSVP rule are therefore already familiar with the basis for many of our calculations. For example, in the PRIA we stated that we did not know how much time an importer would require to gather the required information and evaluate the hazards associated with a given imported product. Despite this uncertainty, we then went on to discuss the information available to us, which caused us to 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. We also tentatively determined that products that are RACs would require less time than other products because importers would not need to consider biological hazards for RACs. We corrected for this factor by reducing the time estimate for RACs by 25 percent (mean of 9 hours). As a result, we estimated in the PRIA that the costs to produce the required information and analyze hazards per product and supplier combination for products other than RACs were $107, and the costs to produce the required information and analyze hazards per product and supplier combination for RACs were $80 (see pp. 22 to 24 of the PRIA). We arrived at those estimates by estimating the average cost of the required information and hazard evaluations per product and supplier combination for products other than RACs to be 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. For products that are RACs, we estimated that the average

cost of the required information and hazard evaluations per product and supplier combination 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 our explanation we inadvertently reversed the percentages. Stated correctly the explanation is as follows: The average cost of the required information and hazard evaluations per product and supplier combination for products other than RACs is 95 percent x 1.2 hours times $61.44 per hour plus 5 percent x 12 hours x $61.44 per hour, which equals $107. For products that are RACs, the average cost of the required information and hazard evaluations per product and supplier combination 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.)

As previously stated, in the final RIA we have revised the analysis to base the labor cost for activity conducted by a qualified individual on the national estimate of the mean hourly wage for SOC 11-3051 Industrial Production Managers in 2013 (Ref. 3) and, consistent with updated DHHS guidelines on the development of RIAs (Ref. 4), we increased wages by 100 percent from $47.78 to $95.56. In addition, in the FSVP final rule we revised the proposed requirements to allow for the additional flexibility to use hazard analyses and food and supplier evaluations from other entities. In light of these revisions, we now estimate that the average cost of the required information and hazard evaluations per product and supplier combination for products other than RACs is 95 percent x 1.2 hours times $95.56 per hour plus 5 percent x uniform distribution from 1.2 hours to 12 (mean of about 6.6 hours) x $95.56 per hour, which equals $140. 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 $95.56.44 per hour plus 5

percent x uniform distribution from 0.9 hours to 9 hours (mean of about 5 hours) x $95.56 per hour, which equals $105.

We did not revise Table 4, which appeared on p. 30 of the PRIA.

Table 5. Estimated Cost for Writing and Maintaining Procedures Relating to Verification Requirements					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Procedures on Non-Dietary Supplement (DS) Hazards					
Number of Hour to Write Procedures on Non-DS Hazards	2	2	2	2	
Cost to Write Procedures	$191	$191	$191	$191	
Total Non-DS Products	4,862	34,845	21,560	4,637	65,904
Number of Risks Per Imported Product	4	4	4	4	
Total Cost Non-DS Hazards	$3,717,140	$26,638,307	$16,482,094	$3,544,524	$50,382,064
Procedures on DS Products					
Number of Hours to Write Procedures on DS Products	2	2	2	2	
Cost to Write Procedures	$191	$191	$191	$191	
Total DS Products Not Subject to Modified Requirements	105	557	305	64	1,031
Total Cost DS Products Not Subject to Modified Requirements	$20,022	$106,436	$58,371	$12,220	$197,049
Total Cost of Procedures in Year 1	$3,737,161	$26,744,744	$16,540,464	$3,556,744	$50,579,113
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	$3,055,406	$21,896,096	$13,547,914	$2,913,520	$41,412,936
Procedures on DS Products	$16,457	$87,488	$47,980	$10,045	$161,970
Total Costs in Every Year After Year 1	$3,071,863	$21,983,584	$13,595,894	$2,923,564	$41,574,906

The initial discussion of Table 5 occurred on pp. 30 to 33 of the PRIA. In the SPRIA Table 5 appears on pp. 25 to 29, and we discuss the revisions to the proposed rule that caused FDA to revise Table 5 on pp. 11 to 12, 13 to 17, and 20 to 21. In this final RIA we revised Table 5 for the replacement of the very small foreign supplier provisions with provisions related to importers of food from certain small foreign suppliers, the change in the definition of a very small importer, and the updated labor cost calculations.

Table 6. Estimated Cost for Establishing and Following Procedures for Ensuring Food Is Obtained From Approved Suppliers	
Cost Per Hour	$96
Hours to Establish and Maintain Procedures for Ensuring Supplies From Approved Suppliers Per Importer	8
Hours to Review and Assess Procedures and Document Review and Assessment	1
Percentage of Required Procedures For Which Importer Can Review Another Entity's Procedures, Midpoint	0.3
Cost to Establish and Maintain Procedures for Ensuring Supplies From Approved Suppliers Per Importer, Weighted Mean	$584

Hours to Follow Procedures for Ensuring Suppliers From Approved Suppliers Per Shipment Per Importer Per Supplier	0.08
Cost to Follow Procedures for Ensuring Suppliers From Approved Suppliers Per Shipment Per Importer Per Supplier	$8

The initial discussion of Table 6 occurred on pp. 36 to 37 of the PRIA. This table originally referred to maintaining a list of suppliers. In the SPRIA Table 6 appears on pp. 29, and we discuss the revisions to the proposed rule that caused us to revise Table 6 on pp. 19 to 20. In this RIA we revised Table 6 for the additional flexibility to establish and follow procedures of other entities, and the updated labor cost calculations.

Table 7. Estimated Cost of Determining and Documenting the Appropriate Supplier Verification Activity	
Non-DS Products	
Hours to Determine and Document Appropriate Supplier Verification Activity Per Hazard, Midpoint	0.75
Hours to Review and Assess Determination of Appropriate Supplier Verification Activity Per Hazard	0.08
Percentage of Required Determinations For Which Importer Can Review Another Entity's Determinations, Midpoint	0.26
Cost Per Hour	$96
Cost Per Hazard, Weighted Mean	$55
DS Products Not Subject to Modified Requirements	
Hours to Determine and Document Appropriate Supplier Verification Activity Per Product, Midpoint	2.50
Hours to Review and Assess Determination of Appropriate Supplier Verification Activity Per Hazard	0.25
Cost Per Hour	$96
Percentage of Required Determinations For Which Importer Can Review Another Entity's Determinations, Midpoint	0.26
Cost Per Product, Weighted Mean	$182

The initial discussion of Table 7 occurred on pp. 37 to 39 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 7 for additional flexibility to use determinations of appropriate verification activity from other entities and the updated labor cost calculations.

Table 8. Estimated Cost of Conducting (and Documenting) Onsite Audit or Obtaining Documentation of Onsite Audit	
Cost of Audit by Unaccredited Auditor	$1,500
Cost of Audit by Accredited Auditor	$5,000
Other Entity Conducting Audits Using Accredited Auditors	13%
Other Entity Conducting Audits Using Unaccredited Auditors	50%
Other Entity Conducting Audits Using Accredited Auditors, Implied Weight	21%
Other Entity Conducting Audits Using Unaccredited Auditors, Implied Weight	79%
Cost of Onsite Audit Excluding Travel Expenses, Weighted Average	$3,250
Travel Expenses per Onsite Audit	$1,000
Cost Per Onsite Audit, Total	$4,250
Hours to Process Documentation of an Onsite Audit From Foreign Supplier or Other Entity – Importer	0.25
Hours to Process Documentation of an Onsite Audit For Transmission to Importer - Foreign Supplier or Other Entity	0.25
Cost Per Hour	$33
Cost to Process Documentation of an Onsite Audit – Importer	$8
Cost to Process Documentation of an Onsite Audit - Foreign Supplier or Other Entity	$8

The initial discussion of Table 8 occurred on pp. 39 to 42 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 8 for the updated audit costs and updated labor cost calculations.

Table 9. Estimated Cost of Conducting (and Documenting) or Obtaining Documentation of Sampling and Testing	
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 or Other Entity	0.25
Cost Per Hour	$33
Cost to Process Documentation of Sampling and Testing – Importer	$8
Cost to Process Documentation of Sampling and Testing - Foreign Supplier or Other Entity	$8

The initial discussion of Table 9 occurred on pp. 43 to 44 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 9 for the updated labor cost calculations.

Table 10. Estimated Cost of Conducting (and Documenting) or Obtaining Documentation of Review of Foreign Supplier Food Safety Records	
Hours Per Foreign Supplier Per Importer Per Year	8
Cost Per Hour	$96
Cost Per Foreign Supplier Per Importer Per Year	$717
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	$33
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year – Importer	$8
Cost to Process Documentation of Review of Foreign Supplier Monitoring Per Foreign Supplier Per Importer Per Year - Foreign Supplier or Other Entity	$8

The initial discussion of Table 10 occurred on pp. 44 to 45 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 10 for the updated labor cost calculations.

Table 11. Estimated Cost of Establishing and Following Procedures for Approving Suppliers and Ensuring Food Is Obtained from Approved Suppliers and of Determining and Documenting Appropriate Verification Activities (Hazard Based and Facility Based)

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Establishing and Following Procedures for Ensuring Supplies From Approved Suppliers					
Number of Importers	1,046	5,949	3,763	943	11,701
Number of Suppliers	4,031	37,461	22,869	5,098	69,460
Cost to Establish and Maintain Procedures for Ensuring Supplies From Approved Suppliers Per Importer	$584	$584	$584	$584	
Cost to Follow Procedures for Ensuring Suppliers From Approved Suppliers Per Shipment	$8	$8	$8	$8	
Shipments Per Supplier	27	27	27	27	
Number of Shipments	106,818	992,726	606,035	135,101	1,840,680
Percentage of Shipments from Unapproved Suppliers, Mean	3%	3%	3%	3%	
Cost of Testing Per	$341	$341	$341	$341	

Testing Occasion					
Total Cost	$2,183,704	$18,928,754	$11,642,256	$2,629,311	$35,384,024
Determining and Documenting the Appropriate Hazard-Based Supplier Verification Activities					
Non-DS Products					
Cost Per Hazard	$55	$55	$55	$55	
Number of Products	4,862	34,845	21,560	4,637	65,904
Number of Risks Per Imported Product	4	4	4	4	
Total Cost Non-DS Products	$1,064,037	$7,625,257	$4,718,025	$1,014,625	$14,421,944
DS Products Not Subject to Modified Requirements					
Cost Per Product	$182	$182	$182	$182	
Number of Products	105	557	305	64	1,031
Total Cost DS Products Not Subject to Modified Requirements	$19,104	$101,559	$55,696	$11,660	$188,019
Total Cost DS and Non-DS Products	$1,083,141	$7,726,816	$4,773,721	$1,026,286	$14,609,963
Grand Total	$3,266,845	$26,655,569	$16,415,976	$3,655,596	$49,993,988

The initial discussion of Table 11 occurred on pp. 46 to 47 of the PRIA. In the SPRIA Table 11 appears on pp. 29 to 30, and we discuss the revisions to the proposed rule that caused us to revise Table 11 on pp. 11 to 12, 19 to 20, and 20 to 21 of the SPRIA. In this RIA we revised Table 11 for the replacement of the proposed very small foreign supplier provisions with provisions for importers of food from certain small foreign suppliers, the modified requirements for importers of food from the certain small suppliers, the additional flexibility to rely on

documentation of use of procedures to ensure use of approved suppliers from other entities, the additional flexibility to use determination and documentation of appropriate supplier verification activities from other entities, the change in the definition of a very small importer, the revised requirements relating to importers obtaining food from certain small foreign suppliers, and the updated labor cost calculations.

We deleted Tables 12 through 16 at the SPRIA stage because they addressed aspects of the original proposed rule that no longer applied to the supplemental proposed rule. The discussion of Tables 12 through 16 appeared in the PRIA on pp. 48 to 66.

Table 17. Estimated Cost of Reviewing Results of Verification Activity

	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	$96	$96	$96	$96	
Cost to Review Results of Verification Activity Per Activity, Average	$96	$96	$96	$96	
Number of Verification Activities					
Scenario 1	21,146	151,307	93,572	20,121	286,145
Scenario 2	19,671	140,734	87,030	18,714	266,149
Scenario 3	18,273	130,718	80,833	17,381	247,205
Total Cost to Review Results of Verification Activity					
Scenario 1	$2,020,706	$14,458,863	$8,941,738	$1,922,748	$27,344,055
Scenario 2	$1,879,723	$13,448,531	$8,316,609	$1,788,312	$25,433,175
Scenario 3	$1,746,160	$12,491,374	$7,724,381	$1,660,952	$23,622,868

The initial discussion of Table 17 occurred on pp. 65 to 66 of the PRIA. In the SPRIA Table 17 appears on pp. 31. Also on page 31, we noted that we revised Table 17 because the changes in other tables in the SPRIA changed the number of verification activities that we anticipated would be conducted. In this RIA we revised Table 17 for the factors that affect verification activity including the deletion of the very small supplier provisions, the addition of the modified requirements for importers of food from certain small foreign suppliers, the change in the definition of a very small importer, and the updated labor cost calculations.

Table 18. Audit Cost Correction for Substitution of Inspection Results

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost of Onsite Audit	$4,250	$4,250	$4,250	$4,250	
Number of Previously Estimated Audits Eliminated	224	1,601	990	213	3,027
Cost Savings (Negative Costs)	-$950,290	-$6,802,397	-$4,207,333	-$904,730	-$12,864,750

The initial discussion of Table 18 occurred on p. 67 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 18 to update the number of FDA inspections that we anticipate can be substituted for audits and for the revised estimate of audit costs.

We deleted Table 19 at the SPRIA stage because it addressed an element of the original proposed rule that no longer applied to the supplemental proposed rule. The initial discussion of Table 19 in the PRIA occurred on pp. 68 to 70.

Table 20. Estimated Cost of Obtaining Written Assurances From Customers or Other

Entities	
Hours to Process Written Assurances Including Control Procedures Per Product Per Customer Per Year – Importer	0.25
Hours to Process Written Assurances Including Control Procedures Per Product Per Customer Per Year – Customer or Other Entity	0.25
Cost Per Hour	$33
Total Cost Per Product Per Customer Per Year – Importer	$8
Total Cost Per Product Per Customer Per Year – Customer or Other Entity	$8

The initial discussion of Table 20 occurred on pp. 70 to 71 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 20 for the updated labor cost calculations.

Table 21. Estimated Cost of Obtaining Written Assurances From An Importer's Customer Or Other Entity That Controls Hazards and Providing Disclosure Documents

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Assurance Per Customer – Importer	$8	$8	$8	$8	
Cost Per Assurance Per Customer – Customer or Other Entity	$8	$8	$8	$8	
Number of Raw Materials or Ingredients Going to Importers That Are Not Food or Beverage Manufacturers	3,564	19,543	10,812	2,603	36,522
Number of Customers to Which A Given Raw Material Or Ingredient Is Sold, Average	2.8	2.8	2.8	2.8	
Number of Assurances	9,958	54,600	30,208	7,273	102,038
Cost of Assurances – Importers	$81,408	$446,353	$246,947	$59,455	$834,163
Cost of Assurances – Customers or Other Entity	$81,408	$446,353	$246,947	$59,455	$834,163
Additional Cost for	$497,911	$2,729,986	$1,510,377	$363,638	$5,101,912

Disclosure Documents					
Total Cost – Importers	$330,364	$1,811,346	$1,002,135	$241,274	$3,385,119
Total Cost – Customers or Other Entity	$330,364	$1,811,346	$1,002,135	$241,274	$3,385,119
Total Cost - Importers and Customers or Other Entity	$660,728	$3,622,692	$2,004,270	$482,548	$6,770,238

The initial discussion of Table 21 occurred on pp. 72 to 73 of the PRIA. In the SPRIA Table 21 appears on pp. 31 to 32, and we discussed the revisions to the proposed rule that caused us to revise this table on pp. 11 to 12 and 20 to 21. In this RIA we revised Table 21 to add the costs associated with the requirement to provide disclosure documents and the updated labor cost calculations.

Table 22. Estimated Cost of Obtaining Written Assurances From An Importer's Customer Subject to DS Specifications Requirements

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Assurance Per Customer - Importer	$8	$8	$8	$8	
Cost Per Assurance Per Customer - Customer	$8	$8	$8	$8	
Number of DS Raw Materials Or Ingredients	8,271	2,433	1,110	235	12,049
Number of Customers to Which a Given Raw Material or Ingredient Is Sold for Further Processing	3	3	3	3	
Number of Assurances	23,108	6,798	3,101	657	33,664
Total Cost - Importers	$188,907	$55,577	$25,349	$5,368	$275,201
Total Cost – Customers	$188,907	$55,577	$25,349	$5,368	$275,201
Total Cost - Importers and Customers	$377,814	$111,154	$50,699	$10,735	$550,402

The initial discussion of Table 22 occurred on pp. 73 to 74 of the PRIA. In the SPRIA Table 21 appears on pp. 32 to 33, and we discussed the revisions to the proposed rule that caused

us to adjust this table on pp. 11 to 12. In this RIA we revised Table 22 for the updated labor cost calculations.

Table 23. Estimated Cost of Obtaining Written Assurances From Foreign Suppliers or Other Entities	
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 or Other Entity	1
Hours to Process Written Assurances After Initial Description of Processes – Supplier or Other Entity	0.25
Cost Per Hour – Importer	$96
Cost Per Hour For Initial – Supplier or Other Entity	$96
Cost Per Hour After Initial – Supplier or Other Entity	$33
Cost Per Assurance – Importer	$96
Cost Per Initial Assurance - Supplier or Other Entity	$96
Cost Per Assurance After Initial – Supplier or Other Entity	$8

The initial discussion of Table 23 occurred on pp. 74 to 75 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 23 for the updated labor cost calculations.

Table 24. Estimated Cost of Very Small Importers Obtaining Written Assurances from Foreign Suppliers and Importers of Any Size Obtaining Written Assurances from Certain Small Foreign Suppliers					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Per Unit Costs					
Cost Per Assurance - Importer	$96	$96	$96	$96	
Cost Per Initial Assurance - Supplier or Other Entity	$96	$96	$96	$96	
Cost Per Assurance After Initial Assurance -	$8	$8	$8	$8	

Supplier or Other Entity					
Very Small Importers					
Number of Very Small Importers	35,080	2,042	65	19	37,206
Suppliers of Very Small Importers (Combinations)	133,021	7,744	247	71	141,084
Total Number of Assurances	133,021	7,744	247	71	141,084
Average Number of Importers Per Unique Supplier	2.8	2.8	2.8	2.8	
Number of Initial Assurances	47,612	2,772	88	26	50,498
Number of Assurances After Initial	85,409	4,972	159	46	90,586
Total Cost - Importers	$12,711,502	$740,017	$23,618	$6,823	$13,481,960
Total Cost - Suppliers	$5,248,011	$305,520	$9,751	$2,817	$5,566,099
Total Cost - Importers and Suppliers	$17,959,513	$1,045,537	$33,368	$9,640	$19,048,058
Special Supplier Categories					
Total Suppliers In Special Categories	2,332	20,344	11,742	2,665	37,082
Total Number of Assurances	2,332	20,344	11,742	2,665	37,082
Number of Initial Assurances	835	7,281	4,203	954	13,273
Number of Assurances After Initial	1,497	13,062	7,539	1,711	23,809
Total Cost – Importers	$222,864	$1,944,025	$1,122,040	$254,628	$3,543,557
Total Cost – Suppliers	$92,011	$802,601	$463,240	$105,125	$1,462,977
Total Cost - Importers and Suppliers	$314,874	$2,746,626	$1,585,280	$359,753	$5,006,534
Grand Total Year 1 - Importers and Suppliers	$18,274,388	$3,792,164	$1,618,648	$369,393	$24,054,592
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	$9,288,472	$540,741	$17,258	$4,986	$9,851,456
Total Cost – Suppliers	$1,984,774	$115,546	$3,688	$1,065	$2,105,073
Total Cost - Importers and Suppliers	$11,273,246	$656,287	$20,945	$6,051	$11,956,529
Suppliers In Special Categories					
Total Cost – Importers	$162,850	$1,420,526	$819,890	$186,061	$2,589,327
Total Cost – Suppliers	$34,798	$303,540	$175,195	$262,877	$776,410
Total Cost - Importers and Suppliers	$197,648	$1,724,067	$995,085	$448,937	$3,365,737
Grand Total Ever Year After Year 1 - Importers and Suppliers	$11,470,893	$2,380,354	$1,016,031	$454,988	$15,322,266

The initial discussion of Table 24 occurred on pp. 76 to 78 of the PRIA. In the SPRIA Table 24 appears on pp. 33 to 35, and we discussed the revisions to the proposed rule that caused us to adjust the table on pp. 11 to 12, 20 to 21, and 21 to 22. In this RIA we revised Table 24 for the change in the definition of very small importers, the replacement of provisions relating to very small foreign suppliers with provisions for certain small suppliers, and updated labor cost calculations.

Table 25. Estimated Cost of Documenting Very Small Importer or Certain Small Supplier Status

	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	$96	$96	$96	$96	
Cost to Process Documentation	$96	$96	$96	$96	
Number of Very Small Importers	35,080	2,042	65	19	37,206
Combinations of Importers and Suppliers Involving Certain Small Foreign Suppliers	1,817	15,846	9,146	2,075	28,883
Total Cost to Process Documentation	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512

The initial discussion of Table 25 occurred on pp. 78 to 80 of the PRIA. In the SPRIA Table 24 appears on p. 36, and we discussed the revisions to the proposed rule that caused us to adjust the table on pp. 11 to 12, 20 to 21, and 21 to 22. In this RIA we revised Table 25 to account for the change in the definition of very small importers, the replacement of provisions relating to very small foreign suppliers with provisions related to certain small suppliers, and updated labor cost calculations.

We deleted Table 26 from this RIA because that table estimated costs for the proposed requirement that importers review complaints and that proposed requirement has been deleted. The initial discussion of Table 26 occurred on pp. 82 to 83 of the PRIA. In the SPRIA Table 26 appears on pp. 36 and 37, and we discussed the revisions to the proposed rule that caused us to adjust the table on pp. 11 to 12.

Table 27. Estimated Cost for Reviewing Adequacy of FSVP Per Importer Conducting That Activity

	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	$96	$96	$96	$96	
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	10	13	12	11	
Number of Investigations Per Importer Per Year	0.1	0.2	0.2	0.2	
Cost Per Importer Per Year To Conduct Investigations Into Adequacy of FSVP	$69	$91	$88	$76	
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	$7	$10	$9	$8	
Total Cost Per Importer Per Year	$76	$101	$98	$84	
Number of Importers	1,046	5,949	3,763	943	11,701

Cost of Reviewing Adequacy of FSVP Per Year, corrected for OASIS totals and raw materials	$7	$10	$9	$8	

The initial discussion of Table 27 occurred on pp. 83 to 86 of the PRIA. In the SPRIA Table 24 appears on pp. 37 to 38, and we discussed the revisions to the proposed rule that caused us to adjust the table on pp. 11 to 12. In this RIA we revised Table 27 to include importers who were formerly excluded because they were deemed in compliance with the FSVP requirements (because their customers would be subject to the potential PC supplier verification provisions), the replacement of the very small foreign supplier provisions with provisions for importers of food from certain small foreign suppliers, and the updated labor cost calculations.

We deleted Table 28 from this RIA because it is no longer relevant to the final rule. The initial discussion of Table 28 occurred on pp. 87 to 88 of the PRIA. In the SPRIA Table 28 appears on p.38, and we discussed the revisions to the proposed rule that caused us to adjust the table on pp. 11 to 12.

Table 29. Estimated Cost of Providing Unique Facility Identifier

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Obtaining Unique Facility Identifier					
Hours to Obtain Unique Facility Identifier	0.25	0.25	0.25	0.25	0.25
Cost Per Hour	$33	$33	$33	$33	$33
Cost of Obtaining Unique Facility Identifier Per	$8	$8	$8	$8	$8

Importer Per Year					
Number of Importers Without High Confidence D&B Record Matches	14,351	4,678	2,600	632	22,261
Cost of Obtaining Unique Facility Identifiers	$117,318	$38,242	$21,255	$5,169	$181,984
Providing Unique Facility Identifier					
Hours to Provide Facility Identifier at Entry per Entry	0.02	0.02	0.02	0.02	
Cost to Provide Facility Identifier at Entry per Entry	$0.8	$0.8	$0.8	$0.8	
Number of Entries	1,908,708	1,734,312	3,210,101	2,064,479	8,917,600
Cost of Providing Facility Identifier	$1,435,539	$1,304,376	$2,414,317	$1,552,695	$6,706,927
Total Costs	$1,552,857	$1,342,618	$2,435,572	$1,557,864	$6,888,911
Every Year After Year 1					
Percentage of New Importers Entering the Industry Every Year	54%	54%	54%	54%	
Cost of Obtaining Unique Facility Identifiers	$63,932	$20,840	$11,583	$2,817	$99,171
Cost of Providing Unique Facility Identifiers at Entry	$1,435,539	$1,304,376	$2,414,317	$1,552,695	$6,706,927
Total Costs	$1,499,471	$1,325,216	$2,425,900	$1,555,511	$6,806,098

The initial discussion of Table 29 occurred on pp. 90 to 91 of the PRIA. We did not revise this table in the SPRIA. In this RIA we revised Table 29 for the updated labor cost calculations.

We deleted Tables 30 and 31 at the SPRIA stage. The initial discussion of Tables 30 and 31 occurred on pp. 91 to 95.

We revised Tables 32 through 34 in the section on benefits, as discussed further below.

Table 35. Total Cost Summary for All Elements of the FSVP Regulations		
	Importer Number of Employees	

	<20	20 to 99	100 to 499	> 500	Total
Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Conducting Supplier Compliance Review (Component of Supplier Performance Evaluations)	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097
Conducting Information Collection and Food and Supplier Evaluations (Other than Reviewing Supplier Compliance)	$4,516,240	$39,949,450	$24,522,372	$5,483,523	$74,471,584
Writing and Maintaining Procedures Relating to Verification Requirements	$3,737,161	$26,744,744	$16,540,464	$3,556,744	$50,579,113
Following Procedures Relating to Verification Requirements Including Establishing,					

Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$19,312,930	$7,526,009	$3,673,617	$862,676	$31,375,232
Documenting Very Small Importer or Certain Small Supplier Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512
Conducting Corrective Actions	$79,787	$600,604	$366,942	$79,364	$1,126,697
Importer Identification	$1,552,857	$1,342,618	$2,435,572	$1,557,864	$6,888,911
Grand Total Year 1					
Scenario 1	$59,189,098	$230,661,632	$142,629,326	$31,957,120	$464,437,177
Scenario 2	$58,856,342	$228,276,980	$141,153,854	$31,639,815	$459,926,991
Scenario 3	$58,541,284	$226,019,161	$139,756,858	$31,339,387	$455,656,690
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Conducting Supplier Compliance Review (Component of Supplier	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097

Performance Evaluations)					
Conducting Information Collection and Food and Supplier Evaluations (Other than Reviewing Supplier Compliance)	$3,596,252	$31,522,135	$19,343,881	$4,314,393	$58,776,661
Writing and Maintaining Procedures Relating to Verification Requirements	$3,071,863	$21,983,584	$13,595,894	$2,923,564	$41,574,906
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$12,509,436	$6,114,199	$3,071,000	$948,271	$22,642,906
Documenting Very Small Importer or Certain Small Supplier Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512

Conducting Corrective Actions	$79,787	$600,604	$366,942	$79,364	$1,126,697
Importer Identification	$1,499,471	$1,325,216	$2,425,900	$1,555,511	$6,806,098
Grand Total Every Year After Year 1					
Scenario 1	$50,746,933	$216,043,945	$133,893,975	$30,238,054	$430,922,908
Scenario 2	$50,414,177	$213,659,293	$132,418,503	$29,920,749	$426,412,722
Scenario 3	$50,099,118	$211,401,474	$131,021,507	$29,620,321	$422,142,421

The initial discussion of Table 35 occurred on pp. 101 to 105 of the PRIA. In the SPRIA Table 35 appears on pp. 39 to 41. Also on page 35, we noted that we adjusted the table because changes in the other tables generated changes in this summary table. In this RIA we revised Table 35 to reflect the change in verification activity requirements relating to entities other than foreign suppliers and the changes in the other preceding tables that relate to this summary table.

As we noted in the PRIA, 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 final rule 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 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).

Table 36. Sensitivity Analysis			
	Mean	**Low**	**High**
Year 1			
Hiring Third Parties With Qualified Individuals			
Scenario 1	$33,954,600	$13,443,260	$62,156,090
Scenario 2	$33,213,660	$12,978,340	$61,458,450
Scenario 3	$32,511,710	$12,571,690	$60,351,080
Conducting Supplier Compliance Review (Component of Supplier Performance Evaluations)	$14,524,570	$7,652,391	$24,102,330
Conducting Information Collection and Food and Supplier Evaluations (Other than Reviewing Supplier Compliance)	$71,758,150	$38,324,710	$120,961,900
Writing and Maintaining Procedures Relating to Verification Requirements	$51,434,060	$18,751,650	$97,713,020
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers			
Scenario 1	$246,185,100	$82,290,620	$500,961,600
Scenario 2	$242,336,900	$79,083,630	$499,997,400
Scenario 3	$238,694,500	$75,580,870	$501,777,500
Obtaining Written Assurances	$32,192,550	$14,906,920	$52,466,960
Documenting Very Small Importer or Certain Small Supplier Status	$6,443,409	$5,210,670	$8,036,169
Conducting Corrective Actions	$1,060,628	$77,617	$2,868,545
Importer Identification	$6,888,911	$6,888,911	$6,888,911
Grand Total Year 1			

Scenario 1	$464,442,000	$226,048,600	$816,256,800
Scenario 2	$459,852,800	$222,615,500	$809,576,000
Scenario 3	$455,508,400	$220,020,100	$801,265,300
Every Year After Year 1			
Hiring Third Parties With Qualified Individuals			
Scenario 1	$33,954,600	$13,443,260	$62,156,090
Scenario 2	$33,213,660	$12,978,340	$61,458,450
Scenario 3	$32,511,710	$12,571,690	$60,351,080
Conducting Supplier Compliance Review (Component of Supplier Performance Evaluations)	$14,524,570	$7,652,391	$24,102,330
Conducting Information Collection and Food and Supplier Evaluations (Other than Reviewing Supplier Compliance)	$56,744,220	$30,714,030	$95,104,220
Writing and Maintaining Procedures Relating to Verification Requirements	$42,248,990	$15,220,870	$82,801,780
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers			
Scenario 1	$246,185,100	$82,290,620	$500,961,600
Scenario 2	$242,336,900	$79,083,630	$499,997,400
Scenario 3	$238,694,500	$75,580,870	$501,777,500
Obtaining Written Assurances	$23,407,410	$10,148,320	$41,324,400
Documenting Very Small Size Status	$6,443,409	$5,178,870	$8,068,577
Conducting Corrective Actions	$1,060,628	$75,309	$2,855,526
Importer Identification	$6,806,099	$6,806,099	$6,806,099
Grand Total Every Year After Year 1			
Scenario 1	$431,375,000	$206,466,700	$778,610,200
Scenario 2	$426,785,900	$202,848,900	$779,172,500
Scenario 3	$422,441,500	$200,862,800	$780,839,100

The initial discussion of Table 36 occurred on pp. 101 to 106 of the PRIA. In the SPRIA Table 36 appears on pp. 41 to 42. Also on page 42, we noted that we adjusted Table 36 to reflect

changes made to Table 35 of the SPRIA. In this RIA we revised Table 36 to reflect the changes in Table 35 of this RIA.

Table 37. Alternative 1- Total Cost Summary for All Elements of Final Rule - All Entities

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Writing and Maintaining Procedures Relating to Verification Requirements	$3,737,161	$26,744,744	$16,540,464	$3,556,744	$50,579,113
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288

Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$19,312,930	$7,526,009	$3,673,617	$862,676	$31,375,232
Documenting Very Small Importer or Certain Small Supplier Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512
Conducting Corrective Actions	$79,787	$600,604	$366,942	$79,364	$1,126,697
Grand Total Year 1					
Scenario 1	$52,237,912	$181,171,762	$110,666,827	$23,800,083	$367,876,584
Scenario 2	$51,905,156	$178,787,110	$109,191,355	$23,482,778	$363,366,398
Scenario 3	$51,590,098	$176,529,291	$107,794,359	$23,182,350	$359,096,097
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Writing and Maintaining Procedures Relating to Verification Requirements	$3,071,863	$21,983,584	$13,595,894	$2,923,564	$41,574,906
Following Procedures Relating to Verification Requirements Including					

Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$12,509,436	$6,114,199	$3,071,000	$948,271	$22,642,906
Documenting Very Small Importer or Certain Small Supplier Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512
Conducting Corrective Actions	$79,787	$600,604	$366,942	$79,364	$1,126,697
Grand Total Every Year After Year 1					
Scenario 1	$44,769,120	$174,998,793	$107,119,639	$23,252,499	$350,140,050
Scenario 2	$44,436,364	$172,614,140	$105,644,167	$22,935,194	$345,629,865
Scenario 3	$44,121,306	$170,356,321	$104,247,171	$22,634,766	$341,359,563

The initial discussion of Table 37 occurred on pp. 107 to 108 of the PRIA. In the SPRIA Table 37 appears on pp. 42 to 44. Also on p. 44, we noted that we revised Table 37 to reflect the

changes in Table 35 of the SPRIA. In this RIA we revised Table 37 to reflect the changes in Table 35 of this RIA.

Table 38. Alternative 2 - Total Cost Summary for All Elements of the FSVP Regulations - All Entities					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Conducting Supplier Compliance Review (Component of Supplier Performance Evaluations)	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097
Conducting Information Collection and Food and Supplier Evaluations (Other than Reviewing Supplier Compliance)	$2,258,120	$19,974,725	$12,261,186	$2,741,761	$37,235,792
Writing and Maintaining Procedures Relating to Verification Requirements	$3,737,161	$26,744,744	$16,540,464	$3,556,744	$50,579,113
Following Procedures Relating to					

Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$19,312,930	$7,526,009	$3,673,617	$862,676	$31,375,232
Documenting Very Small Importer or Certain Small Supplier Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512
Conducting Corrective Actions	$39,893	$300,302	$183,471	$39,682	$563,348
Importer Identification	$1,552,857	$1,342,618	$2,435,572	$1,557,864	$6,888,911
Grand Total Year 1					
Scenario 1	$56,891,085	$210,386,605	$130,184,669	$29,175,677	$426,638,036
Scenario 2	$37,245,399	$200,475,943	$125,035,580	$27,995,696	$390,752,618
Scenario 3	$56,243,271	$205,744,134	$127,312,201	$28,557,944	$417,857,549
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Conducting Supplier	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097

Compliance Review (Component of Supplier Performance Evaluations)					
Conducting Information Collection and Food and Supplier Evaluations (Other than Reviewing Supplier Compliance)	$1,798,126	$15,761,068	$9,671,941	$2,157,197	$29,388,331
Writing and Maintaining Procedures Relating to Verification Requirements	$3,071,863	$21,983,584	$13,595,894	$2,923,564	$41,574,906
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Food Is Obtained from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$12,509,436	$6,114,199	$3,071,000	$948,271	$22,642,906
Documenting Very Small	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512

Importer or Certain Small Supplier Status					
Conducting Corrective Actions	$39,893	$300,302	$183,471	$39,682	$563,348
Importer Identification	$1,499,471	$1,325,216	$2,425,900	$1,555,511	$6,806,098
Grand Total Every Year After Year 1					
Scenario 1	$48,908,913	$199,982,576	$124,038,564	$28,041,176	$400,971,228
Scenario 2	$48,576,157	$197,597,924	$122,563,091	$27,723,871	$396,461,043
Scenario 3	$48,261,099	$195,340,105	$121,166,095	$27,423,443	$392,190,742

The initial discussion of Table 38 occurred on pp. 109 to 111 of the PRIA. In the SPRIA Table 38 appears on pp. 44 to 46 and we noted the revision to account for the changes in Table 35 of the SPRIA. In this RIA we revised Table 38 to reflect the changes in Table 35 of this RIA.

V. Benefits

A. Comment Review

One comment stated that the benefits from FSVP are uncertain and are linked to efficacy of the Preventive Controls and Produce Safety Rules.

We agree that the benefits of the rule are uncertain and that the benefits of this rule are linked, at least in part, to other rules promulgated under FSMA. Because of the uncertainty and interdependency between this final rule-making and other FSMA rule-makings, we have decided that it is inappropriate to estimate separate benefits for this rule-making alone.

One comment asserts that we overstated the benefits of the rule in our previous analyses by incorrectly using information from Scallan et al. (Ref. 5) regarding foodborne illness in the United States.

In our calculation of the burden of unknown illnesses we correctly use the methodology set forth in the Scallan paper. Dr. Scallan confirmed that we had correctly interpreted the data in her paper in a telephone interview (Ref. 6). We also have accounted for, in our illness burden calculation, the likelihood that unknown illnesses are less serious in nature. This is reflected in the weighted average cost of each type of illness; as examples, the average burden of a case of listeriosis is estimated to be well over one million dollars while the burden of an unknown illness is estimated to average about four hundred dollars per illness.

One comment asserts that we underestimated illnesses due to imported foods by using too small of a dataset.

For the final rule we were able to expand our dataset to include illnesses that occurred for the years 2003-2012 rather than illnesses from only 2003-2008. We included all illnesses from outbreaks where the root cause could be attributed to imported foods, and we used data from FDA and the Centers for Disease Control (CDC) to reach our conclusions on which outbreaks and illnesses to include.

One comment claims that we underestimated the value of a statistical life (VSL).

We have updated the VSL that we use for benefits calculations. The updated values are consistent with the values recommended in the draft Guidelines for Regulatory Impact Analysis

published by the U.S. Department of Health and Human Services (Ref. 7). The new mean VSL is now $9 million in 2013 dollars.

One comment asserts that we underestimated the lost quality of life and undervalued the cost from foodborne illness.

We do not agree. We use estimates of the burden of foodborne illness that have been published in the journal *Risk Analysis* (Ref.8). These estimates have been peer reviewed, and include more long-term health outcomes than other published estimates of foodborne illness burden; we include all long-term health outcomes that are supported in the literature. We also include all costs of deaths as appropriate for all identified and unidentified illnesses.

One comment pointed out that we did not include the costs of avoided recalls, outbreak investigations, private litigation, or consumer peace of mind.

We do not have sufficient data to evaluate these costs. Outbreak investigations and private litigation represent transfers of wealth, not benefits to the rule. Instead of spending money on investigations and litigation, we estimate that resources will be spent on food safety measures as required by this rule. Recalls could increase or decrease as a result of this rulemaking; we cannot predict the net effect. We also cannot quantify the extent to which consumers currently lack peace of mind about the safety of their imported food, and the extent to which the final rule will affect their peace of mind.

B. Anticipated Illness Burden Due to Imported Foods

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 regulations. Among other things, FSMA requires us to promulgate regulations to ensure the safety of produce and processed foods by establishing minimum safety standards for both. These regulations 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 rule on importers' FSVPs 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 growing, harvesting, manufacturing, and processing of food, including the preventive controls and produce safety regulations.

The FSVP regulations thus functions as a part of a suite of FSMA and other food safety regulations to help ensure the safety of food consumed in the United States. The FSVP regulations establish 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 potential changes that would make the FSMA regulations more effective or less costly.

Although the FSVP regulations do not themselves establish safety requirements for food manufacturing and processing, they will 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 final rules on preventive controls and produce safety consider and analyze the number of illnesses and deaths that those 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 as they apply to imported food. For this reason, and because we do not have sufficient data to parse out which particular regulations might be responsible for the expected reduction in foodborne illnesses as a result of the FSMA final rules, we account for the public health benefits of the FSVP regulations in the preventive controls rules, produce safety rule, and other applicable food safety rules instead of in this rule.

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. 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 the rules should significantly decrease the chance for contamination and illness from nearly

all imported foods consumed in the United States. Again, we have already accounted for the benefits described below as a part of the produce safety and preventive controls rules. What follows provides a sense of the scope of foodborne illness that is related to FDA-regulated imported food.

To estimate the number of illnesses associated with imported produce and imported processed foods,[2] we begin with illnesses recorded in FDA's outbreak database for the years 2003-2012 (Ref. 9) The data contain information as to the product's origin, which allows us to look only at the outbreaks associated with an imported product. The data do not include any outbreaks linked to handling or storage in retail establishments, restaurants, or homes.

The data span of 2003-2012 is utilized for this analysis because it represents the most current and comprehensive data available. We are unable to consider data from years beyond 2012 because the full outbreak data from CDC has not been completely collected, sorted, cleaned, and made available for public use. We do not review data from earlier years because some regulations whose effect we want to consider had not been adopted by 2003. Additionally, collection of data on foodborne illnesses by both FDA and CDC have improved vastly in recent years, and earlier data may be more subject to underreporting biases.

To determine the percent of illness attributable to the foods, we examine the FDA-specific outbreak data and the whole universe of identified pathogen illnesses, accounting for all outbreaks associated with an identified food vehicle. Dividing the number of observed FDA illnesses by the total, which comes from the CDC's outbreak database (Ref. 10), gives us the

[2] Our analysis addresses only human food, as there is very little data on outbreaks related to animal food.

percentage attributable to FDA-regulated foods. This number is then multiplied by Scallan, et al.'s estimate of the total annual incidence of each specific foodborne pathogen (Ref. 5). 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-regulated products by the annual incidence yields the annual estimated illnesses attributable to FDA-regulated food.

Table 39 summarizes our outbreak data for the illnesses attributed to imported produce and imported processed food. The table presents our estimation of the total annual number of illnesses attributable to foods that would fall under the scope of this rule based on FDA outbreak data combined with CDC outbreak data[3]. It is likely that there are many more unidentified cases of illness than are reported in the FDA database. To deal with this undercounting, we multiply our estimation of the total annual number of illnesses attributable to foods that would fall under the scope of this rule by 4 to obtain a number of unidentified illnesses. This method is consistent with Scallan, et al., who estimated that unidentified illnesses make up about 80 percent of all foodborne illnesses (Ref. 5).

Table 39. Estimated Annual Number of Illnesses Attributable to Food Under the Scope of this Rule					
Imported Processed Foods					
Agent	**FDA Cases (2003-2012)**	**Total Cases (2003-**	**Percentage Attributable to FDA-regulated**	**Estimated Annual Foodborne**	**Estimated Illnesses Attributable to FDA-regulated**

[3] CDC outbreak data does not allow us to differentiate outbreaks by the source of contamination. To that extent, CDC data possibly includes outbreaks related to contamination of FDA-regulated food that were linked to handling or storage in retail establishments, restaurants, or homes.

		2012)	Products	Illnesses (Scallan)	Products
Listeria monocytogenes	71	361	20%	1,680	330
Mycobacterium bovis	35	35	100%	54	54
Salmonella spp.	341	36790	1%	1,072,450	9940
Total Identified					10,325
Total Unidentified					41,299
TOTAL					51,624

Imported Produce

Agent	FDA Cases (2003-2012)	Total Cases (2003-2012)	Percentage Attributable to FDA Products	Estimated Annual Foodborne Illnesses (Scallan)	Estimated Illnesses Attributable to FDA Products
Cyclospora	708	1109	63%	13,906	8,878
E. coli O157 STEC	35	3694	1%	69,972	663
Hepatitis A	919	1250	74%	1,665	1,224
Salmonella spp.	1960	36790	5%	1,072,450	57,135
Total Identified					67,900
Total Unidentified					271,600
TOTAL					339,500

TOTAL Pool of Illnesses Attributable to Imported Foods	391,124

VI. Summary

This document has detailed the analysis of the changes we made in the final rule and the revisions we made to the analysis in response to comments and based on other changes in the final rule. For detailed analysis of the pieces of the final rule that have not changed from the supplemental proposal, see the previous PRIA and SPRIA. (Ref.1 and Ref. 2.)

We estimated the change in costs due to the changes we made in the final rule as well as in response to comments. We also estimated a change in the pool of potential benefits.

Table B (identical to revised Table 35) presents the total costs by provision of the final rule. As was the case with the summary estimates in the previous SPRIA, these summary costs are based on the Scenario 1 assumptions relating to the percentage of importers conducting or obtaining documentation of onsite audits as verification activity. Table C presents a rough estimate of the average cost per importer based on total costs and the total number of importers. The total and average cost per importer has fallen from those initially estimated in the previous PRIA.

Table B. Total Cost Summary for All Elements of Final Regulation					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**

Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$4,516,240	$39,949,450	$24,522,372	$5,483,523	$74,471,584
Writing and Maintaining Procedures Relating to Verification Requirements	$3,737,161	$26,744,744	$16,540,464	$3,556,744	$50,579,113
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998

Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$19,312,930	$7,526,009	$3,673,617	$862,676	$31,375,232
Documenting Very Small Size or Special Supplier Category Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512
Conducting Corrective Actions	$79,787	$600,604	$366,942	$79,364	$1,126,697
Importer Identification	$1,552,857	$1,342,618	$2,435,572	$1,557,864	$6,888,911
Grand Total Year 1					
Scenario 1	$59,189,098	$230,661,632	$142,629,326	$31,957,120	$464,437,177
Scenario 2	$58,856,342	$228,276,980	$141,153,854	$31,639,815	$459,926,991
Scenario 3	$58,541,284	$226,019,161	$139,756,858	$31,339,387	$455,656,690
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals					
Scenario 1	$7,917,234	$14,901,565	$9,068,708	$1,743,525	$33,631,032
Scenario 2	$7,863,192	$14,514,286	$8,829,084	$1,691,993	$32,898,556
Scenario 3	$7,811,995	$14,147,390	$8,602,072	$1,643,174	$32,204,632
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$882,090	$8,197,802	$5,004,555	$1,115,651	$15,200,097
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier	$3,596,252	$31,522,135	$19,343,881	$4,314,393	$58,776,661

Compliance)					
Writing and Maintaining Procedures Relating to Verification Requirements	$3,071,863	$21,983,584	$13,595,894	$2,923,564	$41,574,906
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers					
Scenario 1	$17,664,970	$129,689,477	$80,136,907	$17,357,644	$244,848,998
Scenario 2	$17,386,255	$127,692,104	$78,901,058	$17,091,871	$241,071,288
Scenario 3	$17,122,394	$125,801,181	$77,731,074	$16,840,263	$237,494,911
Obtaining Written Assurances	$12,509,436	$6,114,199	$3,071,000	$948,271	$22,642,906
Documenting Very Small Size or Special Supplier Category Status	$3,525,831	$1,709,362	$880,189	$200,130	$6,315,512
Conducting Corrective Actions	$79,787	$600,604	$366,942	$79,364	$1,126,697
Importer Identification	$1,499,471	$1,325,216	$2,425,900	$1,555,511	$6,806,098
Grand Total Every Year After Year 1					
Scenario 1	$50,746,933	$216,043,945	$133,893,975	$30,238,054	$430,922,908
Scenario 2	$50,414,177	$213,659,293	$132,418,503	$29,920,749	$426,412,722
Scenario 3	$50,099,118	$211,401,474	$131,021,507	$29,620,321	$422,142,421

Table C. Average Cost per Importer				
	Importer Number of Employees			
	<20 employees	**20 to 99 employees**	**100 to 499 employees**	**>= 500 employees**
Year 1	$1,614	$19,262	$21,429	$19,747
Every Year After Year 1	$1,383	$18,037	$20,113	$18,681

Table D presents a summary of the total costs and the potential benefits estimated to be associated with the final rule.

Table D. Total Costs and Potential Benefits		
Total Potential Benefits	**Total Annualized Costs[4]**	**Net Potential Benefits**
Unquantified	$434,737,369	Unquantified

VII. Unfunded Mandates

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

[4] Costs have been annualized with a 7 percent discount rate over a 10-year time horizon.

current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. The FSVP final rule will result in a 1-year expenditure that will meet or exceed this amount.

VIII. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that the FSVP final rule is a major rule for the purpose of congressional review.

Reference List

1. FDA. 7-29-0013. 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) . http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM363286.pdf.

2. FDA. 7-29-0013. Supplemental Preliminary Regulatory Impact Analysis for the supplemental 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) . http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM444229.pdf.

3. Bureau of Labor Statistics. Occupational Employment Statistics, May 2013, 11-3051 Industrial Production Managers. http://www.bls.gov/oes/current/oes113051.htm#ind.

4. Bureau of Labor Statistics. Occupational Employment Statistics, May 2013, 43-6014 Secretaries and Administrative Assisstants, Except Legal, Medical, and Executive. http://www.bls.gov/oes/current/oes436014.htm.

5. Scallan, E, Hoekstra, R. M., Angulo, F. J., Tauxe, R. V., Widdowson, M. A., Roy, S. L., Jones, J. L., and Griffin, P. M. 2011. Foodborne illness acquired in the United States - Major pathogens. 7-15.

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7. U.S.Dpartment of Health and Human Services. 2015. Guidelines for Regulatory Impact Analysis. Draft 2014, updated May 2015.

8. Minor, et al. 2015. The Per Case and Total Costs of Foodborne Illness in the United States. 12015 Jan 2. doi: 10.1111/risa.12316.

9. 2015. FDA Internal Foodborne Outbreak Database. Accessed April 17, 2015. http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/default.htm.

10. 2015. CDC NORS Foodborne Outbreak Online Database. Accessed April 2015. http://wwwn.cdc.gov/foodborneoutbreaks/.

IX. Appendix

Revised Regulatory Flexibility Analysis for the Proposed Rule on Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FDA-2011-N-0143)

The Regulatory Flexibility Act requires a regulatory flexibility analysis (RFA) unless the Agency can certify that a final rule will 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 final rule would have a significant economic impact on a substantial number of small entities. The revisions to the final rule on Foreign Supplier Verification Programs (FSVPs) for Importers of Food for Humans and Animals modify some requirements that would change the burden for some importers. Thus, this document amends our Supplemental Initial Regulatory Flexibility Analysis (SIRFA) published as Appendix A in the Supplemental Preliminary Regulatory Impact Analysis (SPRIA) of the supplemental proposed rule.

1. Revisions to the Final Rule that Affect the IRFA

To reduce the burden on very small importers, the FSVP supplemental proposed rule included modified requirements for very small importers defined as importers with annual food sales of $1.0 million or less. In the final rule, the Agency specifies that the $1.0 million limit applies to annual human food sales and has introduced a second and higher limit for annual animal food sales of $2.5 million or less although these limits now include U.S. market value of animal food or human food imported, manufactured, processed, packed, or held without sale, as appropriate.

The Agency has eliminated the provisions that previously related to importers working with suppliers categorized as very small foreign suppliers; however, it has replaced those provisions with modified requirements for importers working with other categories of small foreign suppliers based on size as follows: 1) farms designated as not "covered farms" under the produce rule (i.e. meet the size criteria for not being a covered farm in the produce rule as opposed to other potential reasons for not being subject to the produce rule); 2) entities that meet the definition of "qualified facilities" in the PC rules, which are facilities subject to the PC rules that are very small businesses based on average value of food sold over the previous three years of $1 million for human food and $2.5 million for animal food, adjusted for inflation and including the sales of affiliate or subsidiary facilities if the average value of the food manufactured, processed, packed, or held at the facility sold directly to "qualified end users" exceeds the average value of food to all other purchases; and 3) suppliers of shell eggs that are not covered by the shell egg safety rule because they have less than 3,000 laying hens.

Other revisions to the final rule increase or decrease the burden of some requirements. For example, we are allowing importers additional flexibility to use existing documentation relating to the verification requirements from other entities in the supply and distribution chain.

2. Revised Number of Small Entities

We present a revised estimate of the number of affected importers in Table A1. As shown, fewer importers are subject to the full FSVP requirements with the revisions in the final rule because they meet the definition of very small importer. As described in the IRFA, costs vary for each type of importer. However, we expect that the relative burden on affected small entities in each employee size category would remain similar to the burden described in the IRFA.

Table A1. Revised 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**
Very Small Importers	35,080	2,042	65	19	37,206	66%
Remaining Importers	2,852	6,270	3,443	824	13,389	24%
Total--All Importers	36,617	11,936	6,634	1,613	56,800	100%

3. Regulatory Flexibility Options

The Regulatory Flexibility Act requires agencies to analyze regulatory options that 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 rule. In the revisions in the final rule, we have increased the annual sales limit for eligibility as a very small importer by providing separate sales limits for human and animal food, setting the sales limit applying to animal food to $2.5 million, and in both cases including U.S. market value of animal food or human food imported, manufactured, processed, packed, or held without sale, as appropriate. With this higher ceiling, the number of small entities subject to the standard FSVP requirements is decreased, thus reducing the burden on these small entities.