SUPPLEMENTAL PRELIMINARY REGULATORY IMPACT ANALYSIS FOR 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)

Contents

Analysis of Economic Impacts

FDA has examined the impacts of two proposed rules relating to food importers' foreign supplier verification programs (FSVPs) and accredited third-party audits under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). The proposed rules are:

1. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals ("FSVP proposed rule").

2. Accredited Third-Party Food Safety Audits and Food or Facility Certification ("Third Party Accreditation proposed rule").

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

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $144 million, using the most current (2013) 3Implicit Price Deflator for the Gross Domestic Product. FDA expects that the FSVP proposed rule would result in a 1-year expenditure that would meet or exceed this amount.

I. Revisions to Proposed Rule

The FSVP proposed rule established requirements relating to FSVPs for importers of food for humans and animals. The previously proposed regulations would require 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 proposed regulations would help ensure that imported food is produced in a manner consistent with U.S. standards.

In a Supplemental Notice of Proposed Rulemaking, we are proposing a number of revisions to the proposed rule. The substantive changes that we believe require us to revise the preliminary regulatory impact analysis (PRIA) for the proposed rule are as follows:

1) We are proposing a slightly modified version of what we identified in the previously proposed rule as Option 2 for supplier verification activities requirements. Under Option 1 of the previous proposal, initial and subsequent annual onsite auditing of foreign suppliers would have been required when the foreign supplier controls the hazard in a food and the hazard is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA hazard); in other circumstances, the importer could determine an appropriate verification activity from among several specified methods, which would include onsite auditing, sampling and testing, review of supplier food safety records, and any other appropriate method. Under Option 2, onsite auditing would not have been mandatory under any circumstances; instead, the importer would determine the appropriate verification activity – based on the risk presented by the hazard, the probability that exposure to the hazard will result in serious harm or death, and the food and supplier's compliance status – from among the activities listed above.

2) We changed the criterion for when an importer is not required to conduct supplier verification activities when importing a food from "having no hazards that are reasonably likely to occur" to "having no significant hazards."

3) We effectively reduced the FSVP requirements applicable to importers that are food facilities that would be required to conduct supplier verification under the revised Preventive Controls (PC) proposed rule (importers in compliance with the PC supplier verification provisions would be deemed in compliance with most of the FSVP requirements). The same approach would apply to importers whose customers are in compliance with the PC supplier verification requirements.

4) We effectively combined the requirements to conduct (1) a food and foreign supplier compliance status review and (2) a hazard analysis into a requirement to conduct a more comprehensive evaluation of food and supplier risk. We adopted a two-step process involving a hazard analysis as the first step and then, if significant hazards are identified, a more complete evaluation of risks including an enhanced compliance status review of the supplier. We made several minor edits to the hazard analysis, such as adding consideration of environmental pathogens and formulation. We added certain requirements regarding factors that importers must consider when evaluating supplier risk. In addition, we added a requirement that importers subject to the full risk evaluation approve suppliers based on the proposed risk evaluations and document those approvals.

5) We changed the purpose of supplier verification activity from providing assurance of adequate control of hazards in food to providing assurance that food is produced in a manner consistent with the preventive controls or produce safety regulations, when finalized, if applicable, and is not adulterated or misbranded with respect to allergen labeling. This change, reflecting the newly proposed risk evaluation requirements, required a recalculation of the costs associated with conducting foreign supplier verification activities, which had been based on the costs of verification of hazard control.

6) We changed the requirement that certain importers maintain lists of their suppliers to a requirement that certain importers establish and follow written procedures to ensure they import food only from suppliers they have approved based on their risk evaluation. However, in the case of very small importers (VSI) and importers obtaining food from very small foreign suppliers (VSS) we eliminated the previously proposed requirement that they maintain a list of

their suppliers but have not revised the proposal to require them to establish and follow written procedures to ensure they import food only from approved suppliers.

7) We changed the definitions of "very small importer" and "very small foreign supplier" so that they now involve a limit of $1 million in annual food sales rather than the previously proposed limit of $500 thousand in annual food sales.

8) We revised the supplier verification activity requirements for importers of food from foreign suppliers that are farms that are not subject to the produce safety regulations.

In this supplemental PRIA we discuss the impact of these changes and present the total costs of the revised proposed rule and its component provisions. (This supplemental PRIA does not include any changes concerning the Third Party Accreditation proposed rule because we are not proposing any changes to that proposal at this time.) However, for a detailed analysis of provisions that are not being revised, see the PRIA of the proposed rule (Ref. 1).

Table A illustrates the total costs and benefits of both the previous proposed rule and the revised proposal. As was the case with the summary estimates in the previous PRIA, 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. (In the previous PRIA (see pages 101 to 102), we calculated costs under three different scenarios reflecting different percentages of importers who, under 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.)

Table A. Summary of Previous Proposed Rule and Revised Proposed Rule

	Annual Potential Pool of Benefits[1]	Annualized Total Costs (Domestic + Foreign)[2]	Annualized Potential Net Benefits
Previous PR			
Option 1			
Costs discounted at 3%	$1,175,963,993	$472,971,342	$702,992,651
Costs discounted at 7%	$1,175,963,993	$473,380,038	$702,583,955
Option 2			
Costs discounted at 3%	$1,175,963,993	$461,407,455	$714,556,538
Costs discounted at 7%	$1,175,963,993	$461,821,706	$714,142,287
Revised PR			
Costs discounted at 3%	$1,175,963,993	$396,780,114	$779,183,879
Costs discounted at 7%	$1,175,963,993	$397,478,400	$778,485,593
Difference Relative to Previous Option 1			
Costs discounted at 3%	$0	-$76,191,228	$76,191,228
Costs discounted at 7%	$0	-$75,901,638	$75,901,638
Difference Relative to Previous Option 2			
Costs discounted at 3%	$0	-$64,627,341	$64,627,341
Costs discounted at 7%	$0	-$64,343,306	$64,343,306

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

II. Need for Regulation

[See Previous Preliminary Regulatory Impact Analysis]

III. Regulatory Options

[1] To the extent that the preventive controls and produce safety rulemakings would reduce foodborne illness even in the absence of this rule, the upper bound on the benefits of this rule would be lower than the estimates shown here.

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

We have not revised the feasible regulatory alternatives for the revised proposed rule. For a detailed discussion of the regulatory alternatives of the proposed rule, see the previous PRIA. We have revised what we called the regulatory options in the previous PRIA. In particular, we are now proposing a modified version of Option 2 regarding supplier verification activity requirements.

IV. Revised Costs for the Revised Proposed Rule

In this section we first present a discussion of the changes in the revised proposed rule and how we revised the cost estimates that we presented in the previous PRIA. We then present a series of tables that appeared in the previous PRIA that we have revised to reflect the changes in the revised proposed rule. 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 in this case.

1. Adoption of Modified Option 2

As previously discussed, the proposed rule contained two options for supplier verification activity requirements for foods with SAHCODHA hazards that are to be controlled by the foreign supplier. In Option 1 we proposed to require importers to conduct or obtain documentation of mandatory onsite audits of foreign suppliers under certain conditions and to choose the most appropriate verification activity in other situations. Option 2 would not have

made onsite auditing mandatory in any circumstances but would instead have allowed importers to choose an appropriate verification activity, based on certain factors, in all situations. The revised proposal regarding supplier verification activities corresponds to Option 2 except that we are proposing to require that when a SAHCODHA hazard in a food will be controlled by the foreign supplier, the importer must conduct or obtain documentation of an onsite audit of the foreign supplier unless it determines that some other verification activity is appropriate. We do not expect that these revisions would cause a change in the economic impact of Option 2, so we have not altered the estimates regarding Option 2.

This change renders the discussion of Option 1 in the PRIA of the previous proposal obsolete except as an intermediate step in estimating the impacts of Option 2. In the previous PRIA, we presented most of the explanation of how we estimated costs for the two options in the context of Option 1 and then presented Option 2 as a variation.

2. Revised Criterion for No Supplier Verification Requirement

The previous proposed rule would not have required importers to conduct or obtain documentation on supplier verification activities for food having no hazards that are reasonably like to occur. We defined a "hazard that is reasonably likely to occur" as a hazard for which a prudent importer would establish controls or verify that the supplier controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being imported in the absence of those controls.

In contrast, the revised proposed rule would not require importers to conduct or obtain documentation on supplier verification activities for food having no "significant hazards." We

define a “significant hazard” as a known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis, establish controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections and corrective actions, verification, and records) as appropriate to the food, the facility, and the control.

These provisions are similar but not identical because the provisions in the previous proposal dealt only with the likelihood of a hazard occurring while the revised provision deals with whatever criteria a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would apply to the outcome of a hazard analysis to determine whether or not to establish controls to significantly minimize or prevent a hazard. However, we think the overlap between these provisions is sufficient so that we have not revised the PRIA on this basis.

3. Revised Requirements for Importers and Customers Subject to Any Potential PC Supplier Verification Provisions

Although the previous proposed rule allowed for less demanding verification activity for hazards controlled by importers or importers’ customers, it did not include any special consideration for importers or customers subject to the PC proposed rule per se because the original PC proposed rule did not contain provisions relating to supplier verification. However, the revised PC proposed rule being published in the same issue of the Federal Register now also includes potential supplier verification provisions. Therefore, we have revised the proposed FSVP requirements so that, should the potential supplier verification provisions in the PC

proposal be finalized importers that would be subject to and in compliance with those supplier verification requirements would be deemed in compliance with most of the FSVP requirements and need only comply with the FSVP provision relating to importer identification. In addition, importers' customers that are subject to and in compliance with the PC supplier verification provisions would only need to comply with the FSVP provisions relating to importer identification and maintaining records with respect to those customers (written assurances that the customer is in compliance with any PC supplier verification provisions), although those same importers might of course still need to comply with other FSVP requirements with respect to customers not subject to PC supplier verification provisions. We do not have direct information on importers that would be subject to potential PC supplier verification provisions (or whose customers would be subject to those provisions). Therefore, we assume that imported food that we 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. 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 working with some but not only raw materials and ingredients. In the case of provisions for which this change was relevant and for which the number of importers were not also affected by changes in the definitions of VSI and VSS, this revision resulted in a decrease in the estimated total number of importers covered by the proposed rule of approximately thirty percent based on mean values. In the case of the verification activity provisions, we did not need to adjust the numbers because the group of importers and customers that we estimate is subject to the PC regulations corresponds to the group that we had estimated would control hazards in the PRIA.

4. Incorporation of Compliance Status Review and Hazard Analysis Requirements into Requirement to Conduct Evaluation of Food and Supplier Risks

The proposed rule would have required importers to conduct a hazard analysis for each food they import under certain conditions. The revised proposal would require importers to conduct a hazard analysis and, if significant hazards are identified, conduct a risk evaluation of a food and foreign supplier under those same general conditions. The risk evaluation includes the hazard analysis but also covers some additional issues as follows:

- The entity that will be applying controls for hazards, such as the foreign supplier, the foreign supplier's raw material or ingredient supplier, the importer, or the importer's customer.
- The foreign supplier's procedures, processes, and practices related to the safety of the food.
- Applicable FDA food safety regulations and information regarding the foreign supplier's compliance with those regulations, including whether the foreign supplier is the subject of an FDA warning letter or import alert.
- The foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, and the supplier's record of correcting problems.
- Any other factors as necessary to effectively evaluate risks associated with a food or foreign supplier.

In addition, the revised proposal would implicitly require importers to approve suppliers using these risk evaluations and to document any such approvals as one element of the proposed requirement to establish and follow written procedures ensuring the use of approved suppliers.

The proposed rule did not contain a provision explicitly requiring importers to identify the entity applying controls for hazards. However, the supplier verification requirements varied depending on whether a hazard was controlled by the importer, the supplier, or the importer's customer, so the importer would have needed to determine this already. In addition, the proposed rule required importers to evaluate hazards throughout the supply chain including the suppliers of the foreign supplier. Based on these considerations we have not revised the previous cost estimates based on this new proposed requirement.

The previous proposed rule contained a provision that would have required importers to review the compliance status of the food and the foreign supplier, including whether they are the subject of an FDA warning letter, import alert, or requirement for certification issued under section 801(q) of the FD&C Act relating to the safety of the food. In the PRIA we said that conducting the required supplier compliance status reviews would involve importers reviewing readily-available information to consider the compliance status of every foreign supplier and imported food. We said that FDA warning letters and import alerts are available on the Agency's Web site and that we anticipated that any requirements for certification issued under section 801(q) would also be made available there. However, the previous proposed rule did not explicitly require importers to consider applicable U.S. food safety regulations in this context. This new text combined with the existing text relating to reviewing foreign supplier compliance would require a somewhat more intensive review than we originally proposed. Under the proposed revision, importers would need to understand what regulations apply to the foreign

supplier (e.g., preventive controls, produce safety, dietary supplement CGMP) and review available documents relating to suppliers' compliance with those regulations. Therefore, we have revised the cost of the supplier compliance review to include a review of U.S. food safety regulations relating to the imported food. To avoid unnecessary changes to the format of the PRIA we have maintained supplier compliance review as a separate heading in the analysis but have indicated that it is now part of the required risk evaluation.

In the previous PRIA we said that reviewing the compliance status of the food or foreign supplier would be a relatively simple procedure involving readily available information. We estimated that an importer would need, on average, approximately 2 hours to conduct a review of a foreign supplier or imported food. We assumed the pay level of the personnel conducting this activity would be similar to production managers in the food manufacturing industry. Understanding the applicable U.S. food safety regulations relating to foreign suppliers would probably require additional time; therefore, we have increased the time required for this activity by 1 hour from 2 hours per assessment to 3 hours per assessment. We assume that the same personnel that reviewed the compliance status would also be able to review the regulations relating to imported food and foreign suppliers. We request comments on this estimate.

The previous proposed rule did not contain a provision explicitly requiring importers to consider the foreign supplier's procedures, processes, and practices relating to the safety of the food. The previous proposed rule contained provisions requiring importers to consider, as part of the hazard analysis, many factors relating to foreign suppliers' procedures, processes, and practices relating to the safety of food, including the condition, function, and design of the foreign supplier's establishment and equipment; transportation practices; harvesting, raising, manufacturing, processing, and packing procedures; packaging and labeling activities; storage

and distribution; sanitation, including employee hygiene; as well as a provision addressing any other relevant factors. Analyzing hazards in food involves investigating what hazards are associated with a food and how it is made, including processes that a supplier uses to mitigate those hazards. On the other hand, analyzing safety risks directly associated with a foreign supplier involves assessing the supplier's procedures and answering questions such as, "What do I know about this supplier's ability to mitigate this hazard? What programs are in place and how well are they carried out?"

Similarly, the previous proposed rule did not contain provisions that required importers to consider (1) the foreign supplier's food safety performance history, including results from testing foods for hazards, audit results relating to the safety of the food, the supplier's record of correcting problems, and (2) any other factors as necessary to effectively evaluate risks associated with a food or foreign supplier. These provisions also overlap to some degree with the hazard evaluation element relating to any other relevant factor, which also appears in the revised proposal as an element of the hazard analysis. However, the specification of additional food and supplier food safety risk factors, and the difference between evaluating supplier activity as it relates to hazards in food and as it relates to supplier risk suggest that these risk evaluation provisions would generate additional costs.

Finally, the proposed rule did not require importers to approve suppliers based on a risk evaluation or to document that approval.

Therefore, we have revised the cost of obtaining the required information and conducting hazard analyses and risk evaluations to include these additional requirements and to cover the process of approving suppliers based on risk evaluations and documenting such approvals.

In the previous PRIA we estimated that an importer would need 8 to 16 hours (mean of 12 hours) to obtain the required information and evaluate hazards for particular combinations of products and suppliers in the case of products other than raw agricultural commodities (RACs) that are fruits or vegetables. We reduced the time estimate to 9 hours for RACs that are fruits or vegetables to reflect the fact that we did not require importers to evaluate microbiological hazards in those products. We assumed that the pay level of the personnel conducting this activity would be similar to production managers in the food manufacturing industry.

We do not know the cost for an importer to evaluate the risks associated with a supplier beyond the evaluation of the supplier in the context of a hazard analysis or the cost to approve a supplier based on a risk evaluation or to document that approval when those requirements are triggered by a significant hazard. To reflect these costs, as well as the costs associated with the additional factors we added to the hazard analysis, we have set the average cost to evaluate the risks associated with hazards and suppliers (beyond those analyzed in the previously proposed hazard analysis) and to approve suppliers and to document those approvals as necessary to be the same as the cost we previously estimated for evaluating the hazards in a particular product from a particular supplier to a range of 8 to 16 hours (mean of 12 hours). We multiplied that cost by the number of suppliers defined in terms of combinations of suppliers and importers. Thus, the average cost is defined to cover suppliers that importers have determined supply food that contains significant hazards as well as suppliers that do not. We do not know how many suppliers an importer may evaluate but not approve. To reflect this additional cost we have set the annual cost associated with evaluating suppliers that an importer does not approve to be 0 to 10 percent of the annual cost of evaluating, approving, and documenting the approval of suppliers that an importer does approve. We request comments on this estimate.

5. Revised Purpose of Verification Activity

The previous proposed rule based supplier verification activity on verifying control of hazards in imported food. The revised proposal bases supplier verification activity on more broadly verifying that a foreign supplier is producing food in a manner consistent with the preventive controls or produce safety regulations, if applicable, and that the food is not adulterated or misbranded with respect to allergen labeling. This means that supplier verification activities would involve verifying control of a broader scope of risks relating to both foods and suppliers, compared to the previous proposed rule's focus on verifying control of the hazards in food. In the previous PRIA we assumed 1 to 3 hazards per food when developing our estimate of the number of verification activities. To reflect the changes in the revised proposal, we have increased the number of potential verification actions by adding 2 risks per food (for a total range of 3 to 5 risks per food when combined with 1 to 3 hazards per food) to account for additional risks other than hazards. The number of risks affects the probability that an importer will need to conduct verification activities as discussed in the previous PRIA; however, the number of risks does not increase the number of verification activities on a one to one basis. For example, our current estimate for Scenario 1 is 133,922 triggering risks associated with 7,142 audits as the primary verification activity after accounting for the various factors specified in the analysis, including number of unique suppliers involved, percentage of suppliers already conducting audits, etc. If we hold other factors constant but use the previous assumptions relating to the number of hazards per food, we would have 67,196 triggering hazards associated with 3,923 audits. The relationship of triggering risks and verification activities would be different for the

other verification activities. We request comment on our estimate of the increase in the average number of risks per food that may trigger verification activity.

6. Change from Maintaining List of Suppliers to Written Procedures Ensuring Use of Approved Suppliers

The proposed rule required certain importers to maintain lists of their suppliers. The revised proposal eliminates that requirement for dietary supplement importers, VSI, and importers obtaining food from VSS and has changed the requirement for the remaining importers subject to that requirement to establishing and following written procedures ensuring that they import food only from suppliers they have approved based on their risk evaluations except that, when necessary and appropriate on a temporary basis, those importers may import food from unapproved suppliers if they subject those foods to adequate verification activities before distributing. Note that these written procedures refer only to ensuring the imported food is from approved suppliers and not to the process of approving suppliers. We discussed the cost of approving suppliers in the section on risk evaluations.

We do not know what type of written procedures importers might establish to ensure that they import food only from approved suppliers but it may involve creating and maintaining a database of approved suppliers and then checking the suppliers of incoming material to see if they are on the list. Some of the comments on the previous proposal that addressed this issue suggested such procedures might involve a "corporate-wide system" and "centralized, controlled processes that ensure only approved suppliers can deliver products to their facilities."

We assume that establishing written procedures relating to constructing and maintaining such a database and checking the suppliers associated with incoming supplies against this list

would take 8 hours. We used the same level of employee, production managers, which we previously used to estimate the cost of maintaining lists of suppliers. We assume that following these procedures would involve an average of 10 minutes per day to maintain the database of approved suppliers plus 5 minutes per shipment an importer receives from any given supplier to check that that supplier is on the approved supplier list. We do not know the number of shipments importers receive from suppliers per year. We have estimated the cost of this activity based on a range of 1 shipment per year to 1 shipment per business day per year.

Using unapproved suppliers when necessary and appropriate would be a temporary measure rather than a substitute for regular use of approved suppliers; therefore, we have addressed this element of the provision by assuming that some importers may have some additional costs associated with temporarily using unapproved suppliers. We do not know how many importers would need to use unapproved suppliers or how frequently they might need to do so. We assume that in most cases the adequate verification activity applied to food from these suppliers would take the form of product testing. To reflect this cost we assumed that between 0 and 5 percent of annual shipments will be from unapproved suppliers and will trigger one-time product testing. We used the same testing costs we used to address the supplier verification activity requirements.

7. Change in Definitions of Very Small Importer and Very Small Foreign Supplier

In the previous proposal we based the definitions of VSI and VSS on annual food sales of $500,000. In the revised proposal we use similar definitions but base them on annual food sales of $1 million.

In the previous PRIA we used data from the analysis of the PC proposed rule relating to domestic food manufacturers to estimate that the percentage of foreign suppliers other than farms that would qualify as VSS under the $500,000 limit would be approximately 59 percent. Using the same data we estimate that the percentage of such suppliers qualifying as VSS under the $1 million limit is approximately 76 percent.

In the previous PRIA we used data from the analysis of the produce rule relating to domestic farms to estimate that the percentage of foreign farms qualifying as VSS under the $500,000 limit would be approximately 93 percent. We do not have corresponding data relating to a limit of $1 million, so we have revised our estimate based on the previous estimate plus an additional percentage of suppliers from a range of 0 percent to the entire remaining 7 percent (with a mean of 4 percent after rounding). Therefore, we estimate the percentage of such suppliers qualifying as VSS under the $1 million limit to be 93 percent to 100 percent (with a mean of 97 percent).

8. Revised Requirements for Importers of Food from Foreign Suppliers That Are Farms That Are Not Subject to the Produce Safety Regulations

The revised proposal reduces the verification activity requirements for importers of food from farms that are not subject to the proposed produce safety regulations. If a RAC supplier qualifies as a VSS then it becomes largely irrelevant if it also qualifies for the special requirements relating to farms that are not subject to the produce rule because the implications for verification activity of both sets of special requirements are similar and there is no advantage to qualifying for both. If a supplier qualifies for both the importer working with that supplier would probably invoke VSS status for that supplier because VSS also confers reduced

requirements for the importer in areas other than verification activity. We do not have sufficient information on foreign RAC suppliers to determine the overlap between the VSS special category and the special category of farms that are not subject to the produce rule. To capture the impact of this provision we estimated RAC suppliers that are not VSS and not subject to the produce rule using a uniform distribution going from 0 to that portion of the 0 to 7 percent of RAC suppliers that might or might not be VSS that are not VSS under the uncertainty range we used to address the change in the definition of VSS. The mean or expected value of the resulting range rounded to a whole number is 2 percent of RAC suppliers or 0.8 percent of all suppliers after accounting for the proportion of all suppliers that are RAC suppliers.

For the increase is the cost of written assurances, we assumed the cost of assurances from suppliers not subject to the produce rule would be similar to the cost of assurances from VSS. Therefore, we based our estimate on expressing RAC suppliers that are not VSS and not covered by the produce proposed rule as a percentage of the suppliers that are VSS and adding that percentage to the written assurance cost we estimated for VSS. We used the same approach to estimate the additional cost of documenting that such suppliers are not subject to the produce proposed rule.

For the reduction in the cost of verification activity we used the same approach but expressed RAC suppliers that are not VSS and not covered by the produce proposed rule as a percentage of the suppliers that are not VSS and eliminating that percentage of the verification activity cost we estimated for non-VSS suppliers. We revised the estimated cost of reviewing results of verification activity and corrective actions triggered by verification activity by the same amount.

9. Revised Tables

We have revised the following tables from the previous PRIA to reflect the changes in the revised proposed rule: 1 to 3, 5, 6, 11, 17, 21, 22, 24 to 28, 35 to 38. We indicate briefly after each table why the information in that table has changed; however, the main discussion of how and why we revised the analysis is in the preceding section.

All tables that appeared in the previous PRIA that we have not revised remain applicable to the revised proposal except for the following tables that involved Option 1 only: 12 to 16, 19, and 30 to 31. We did not revise these tables because they are no longer relevant to the revised proposal.

The PRIA for the original FSVP proposal included tables reflecting the cost of FSVP in conjunction with the original preventive controls proposals. The following tables reflect the cost of FSVP based on the supplemental notice of proposed rulemaking, which considers the inclusion of potential supplier verification provisions in the revised preventive controls proposals.

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	$61	$61	$61	$61	
Cost to Hire Third Party	$246	$246	$246	$246	
Importers Subject to Requirement to Hire Qualified Individuals	25,504	7,237	3,838	973	37,552
Percentage of Importers That Would Need to Hire Third Party	50%	50%	50%	0%	
Importers That Would Need to Hire Third Party	12,752	3,618	1,919	0	18,289

Annual Cost for Hiring Third Parties	$3,133,987	$889,271	$471,562	$0	$4,494,819

We revised Table 1 to account for importers who would be subject to the potential PC supplier verification regulations.

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	3	3	3	3	
Cost Per Hour	$61	$61	$61	$61	
Cost to Conduct Review	$184	$184	$184	$184	
Total Number of Reviews of Suppliers	96,072	44,926	23,464	5,533	169,995
Total Cost	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434

We revised Table 2 to account for the additional requirements concerning review of supplier compliance status involving investigating U.S. food safety regulations and for importers and their customers who would be subject to the potential PC supplier verification regulations.

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

	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	9	9	9	9	

From Scratch per Product and Supplier Combination for 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 Supplier'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 Foreign Supplier's Hazard Analysis For RACs	0.9	0.9	0.9	0.9	
Percentage of Required Information and Hazard Analysis For Which Importer Can Review and Evaluate Foreign Supplier's Hazard Analysis, Midpoint	95%	95%	95%	95%	
Cost Per Hour – Importer	$61	$61	$61	$61	
Cost Per Hour – Supplier	$23	$23	$23	$23	
Cost to Produce the Required Information and Analyze Hazards per Product and	$107	$107	$107	$107	

Supplier Combination For Products Other Than RACs					
Cost to Produce the Required Information and Analyze Hazards per Product and Supplier Combination For RACs	$80	$80	$80	$80	
Average Cost to Process Documentation of an Onsite Audit For Transmission to Importer - Foreign Supplier	$5	$5	$5	$5	
Products That Are Not RACs	10,782	28,521	16,375	3,679	59,357
Products That Are RACs	3,658	12,541	5,514	803	22,516
Cost to Analyze Hazards	$1,445,892	$4,054,670	$2,192,656	$457,667	$8,150,886
Number of Hours to Evaluate Risks Associated with Suppliers Beyond Evaluation of Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Risk Evaluation, Mean	12	12	12	12	
Cost to Evaluate Risks Associated with Suppliers Beyond Evaluation of Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Risk Evaluation, Mean	$737	$737	$737	$737	
Adjustment for Suppliers Reviewed But Not Approved	5%	5%	5%	5%	
Suppliers	5,191	38,139	19,812	4,405	67,548
Total Cost to Evaluate Risks Associated with Suppliers Beyond	$4,018,889	$29,525,329	$15,337,464	$3,410,417	$52,292,100

Evaluation of Suppliers in Hazard Analysis and to Approve and Document Supplier Approvals Based on Risk Evaluation, Mean					
Total Cost All Importers Subject To This Requirement	$1,445,892	$4,054,670	$2,192,656	$457,667	$8,150,886
Total Cost for Suppliers	$27,908	$205,030	$106,506	$23,683	$363,127
Total Cost for Importers and Suppliers	$5,492,689	$33,785,029	$17,636,627	$3,891,767	$60,806,112
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	$3,609,675	$21,040,813	$10,993,301	$2,419,443	$38,063,232
Total Cost for Suppliers	$22,388	$164,474	$85,439	$18,998	$291,300
Total Cost for Importers and Suppliers	$3,632,063	$21,205,287	$11,078,740	$2,438,441	$38,354,531

We revised Table 3 to address supplier risk evaluation, approval of suppliers based on supplier risk evaluations, for importers and their customers who would be subject to the potential PC supplier verification regulations, and the change in the definition of VSI and VSS.

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-DS Foods					
Number of Hour to Write Procedures on Non-DS Foods	2	2	2	2	
Cost to Write Procedures	$123	$123	$123	$123	
Total Non-DS Products	14,421	41,040	21,875	4,479	81,815
Number of Risks Per Imported Product	4	4	4	4	
Total Cost Non-DS Hazards	$7,088,047	$20,171,854	$10,752,125	$2,201,563	$40,213,590
Procedures on DS Products					
Number of Hours to Write Procedures on DS Products	2	2	2	2	
Cost to Write Procedures	$123	$123	$123	$123	
Total DS Products That Will Not Be Further Processed	351	665	327	67	1,409
Total Cost DS Products That Will Not Be Further Processed	$43,144	$81,681	$40,140	$8,230	$173,195
Total Cost of Procedures in Year 1	$7,131,191	$20,253,536	$10,792,265	$2,209,794	$40,386,785
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 Foods	$5,826,217	$16,580,815	$8,838,008	$1,809,636	$33,054,676

Procedures on DS Products	$35,463	$67,140	$32,994	$6,765	$142,362
Total Costs in Every Year After Year 1	$5,861,680	$16,647,956	$8,871,002	$1,816,401	$33,197,039

We revised Table 5 to account for additional risks related to suppliers and issues other than hazards in imported food, importers and their customers who would be subject to the potential PC supplier verification regulations, and the change in the definition of VSI and VSS.

Table 6. Estimated Cost for Establishing and Following Procedures for Ensuring Food Is Obtained From Approved Suppliers	
Cost Per Hour	$61
Hours to Establish and Maintain Procedures for Ensuring Food From Approved Suppliers Per Importer	8
Cost to Establish and Maintain Procedures for Ensuring Food From Approved Suppliers Per Importer	$492
Hours to Follow Procedures for Ensuring Food From Approved Suppliers Per Shipment Per Importer Per Supplier	0.08
Cost to Follow Procedures for Ensuring Food From Approved Suppliers Per Shipment Per Importer Per Supplier	$5

We revised Table 6 to account for the switch from the requirement to keep lists of suppliers to the requirement to use procedures for ensuring food is obtained from approved suppliers.

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 Food From Approved Suppliers					
Number of Importers	2,852	6,270	3,443	824	13,389
Number of Suppliers	5,191	38,139	19,812	4,405	67,548

Cost to Establish and Maintain Procedures for Ensuring Food From Approved Suppliers Per Importer	$492	$492	$492	$492	
Cost to Follow Procedures for Ensuring Food From Approved Suppliers Per Shipment	$5	$5	$5	$5	
Shipments Per Supplier	27	27	27	27	
Number of Shipments	137,572	1,010,692	525,022	116,743	1,790,030
Percentage of Shipments from Unapproved Suppliers, Mean	3%	3%	3%	3%	
Cost of Testing Per Testing Occasion	$341	$341	$341	$341	
Total Cost	$2,508,183	$15,169,339	$7,921,229	$1,774,402	$27,373,153
Determining and Documenting the Appropriate Supplier Verification Activities					
Non-DS Products					
Cost Per Risk	$46	$46	$46	$46	
Number of Products	14,421	41,040	21,875	4,479	81,815
Number of Risks Per Imported Product	4	4	4	4	
Total Cost Non-DS Products	$2,658,018	$7,564,445	$4,032,047	$825,586	$15,080,096
DS Products That Will Not Be Further Processed					
Cost Per Product	$154	$154	$154	$154	
Number of Products	351	665	327	67	1,409
Total Cost DS Products That Will Not Be Further Processed	$53,930	$102,102	$50,175	$10,288	$216,494
Total Cost DS and Non-DS Products	$2,711,947	$7,666,547	$4,082,222	$835,874	$15,296,590
Grand Total	$5,220,130	$22,835,885	$12,003,451	$2,610,277	$42,669,743

We revised Table 11 to account for the switch from the requirement to keep lists of suppliers to the requirement to use procedures for ensuring food is obtained from approved suppliers, for additional risks related to suppliers and issues other than hazards in imported food,

for importers and customers subject to the PC regulations, and for the change in the definition of VSI and VSS.

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	$61	$61	$61	$61	
Cost to Review Results of Verification Activity Per Activity, Average	$61	$61	$61	$61	
Number of Verification Activities					
Scenario 1	52,453	148,832	79,307	16,239	296,832
Scenario 2	48,555	137,746	73,398	15,029	274,727
Scenario 3	44,862	127,243	67,799	13,882	253,786
Total Cost to Review Results of Verification Activity					
Scenario 1	$3,222,735	$9,144,244	$4,872,641	$997,707	$18,237,327
Scenario 2	$2,983,214	$8,463,089	$4,509,551	$923,362	$16,879,217
Scenario 3	$2,756,300	$7,817,785	$4,165,570	$852,930	$15,592,585

We revised Table 17 because the changes in the other tables changed the number verification activities.

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					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Assurance Per Customer - Importer	$6	$6	$6	$6	
Cost Per Assurance Per Customer - Customer	$6	$6	$6	$6	

Number of Raw Materials or Ingredients Going to Importers That Are Not Food or Beverage Manufacturers	7,079	15,876	7,689	1,828	32,472
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	19,779	44,356	21,481	5,108	90,723
Total Cost - Importers	$111,922	$251,001	$121,554	$28,902	$513,380
Total Cost - Customers	$111,922	$251,001	$121,554	$28,902	$513,380
Total Cost - Importers and Customers	$223,844	$404,312	$193,100	$45,150	$866,406

We revised Table 21 to account for the switch from assurances from importers' customers that they controls hazards to assurances from importers' customers that they are in compliance with the potential PC supplier verification regulations, for importers who would be subject to the potential PC supplier verification regulations, and for the change in the definitions of VSI and VSS.

Table 22. Estimated Cost of Obtaining Written Assurances From An Importer's Customer Subject to and in Compliance With DS CGMP Specification Requirements

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Assurance Per Customer - Importer	$6	$6	$6	$6	
Cost Per Assurance Per Customer - Customer	$6	$6	$6	$6	
Number of DS Raw Materials Or Ingredients	6,772	1,830	830	175	9,607
Number of Customers of Each Importer to Which a Given Raw Material or Ingredient Is Sold for Further Processing	3	3	3	3	
Number of Assurances	18,920	5,113	2,320	490	26,842
Total Cost - Importers	$107,061	$28,933	$13,128	$2,771	$151,892
Total Cost - Customers	$107,061	$28,933	$13,128	$2,771	$151,892

Total Cost - Importers and Customers	$214,122	$57,865	$26,256	$5,542	$303,784

We revised Table 22 to account for importers who would be subject to the potential PC supplier verification regulations (which might also import DS raw materials to sell to customers who are subject to and in compliance with DS CGMP specification requirements).

Table 24. Estimated Cost of Very Small Importers Obtaining Written Assurances from Foreign Suppliers and Importers of Any Size Obtaining Written Assurances from Very Small Foreign Suppliers or RAC Suppliers That Are Not Very Small Suppliers and Not Subject to the Produce Rule

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Per Unit Costs					
Cost Per Assurance - Importer	$61	$61	$61	$61	
Cost Per Initial Assurance - Supplier	$61	$61	$61	$61	
Cost Per Assurance After Initial Assurance - Supplier	$6	$6	$6	$6	
Very Small Importers					
Number of Very Small Importers	22,041	267	17	9	22,333
Suppliers Selling Food to Very Small Importers (Combinations)	44,411	652	38	20	45,120
Total Number of Assurances	44,411	652	38	20	45,120
Average number of importers per unique supplier	2.8	2.8	2.8	2.8	
Number of Initial Assurances	15,896	233	14	7	16,150
Number of Assurances After Initial	28,515	419	24	13	28,971
Total Cost - Importers	$2,728,586	$40,080	$2,322	$1,210	$2,772,199
Total Cost - Suppliers	$1,137,993	$16,716	$969	$505	$1,156,182
Total Cost - Importers and Suppliers	$3,866,579	$56,796	$3,291	$1,715	$3,928,381
Very Small Suppliers					
Suppliers Of Importers that Import RAC only	15,921	9,597	2,748	26	28,292

Percentage of RAC Suppliers That Are VSS	66%	66%	66%	66%	
Suppliers of Importers That Import No RAC	102,750	39,406	21,300	5,752	169,207
Percentage of Non-RAC Suppliers That Are VSS	52%	52%	52%	52%	
Suppliers of Importers That Import Some But Not Only RACs	23,763	10,563	5,859	1,498	41,683
Percentage of Suppliers of Importers That Import Some But Not Only RACs That Are VSS	59%	59%	59%	59%	
Total VSS	77,602	32,913	16,272	3,873	130,659
Total VSS Corrected for OASIS Totals	60,444	25,636	12,674	3,016	101,770
Total Number of Assurances	60,444	25,636	12,674	3,016	101,770
Number of Initial Assurances	42,807	17,902	8,988	2,187	71,884
Number of Assurances After Initial	17,637	7,734	3,686	830	29,887
Total Cost - Importers	$3,713,696	$1,575,058	$778,696	$185,324	$101,770
Total Cost - Suppliers	$2,729,861	$1,143,650	$573,101	$139,035	$4,585,648
Total Cost - Importers and Suppliers	$6,443,557	$2,718,708	$1,351,797	$324,360	$10,838,422
RAC Suppliers That Are Not VSS and Not Subject to Produce Rule					
Total Cost - Importers	$33,624	$14,261	$7,050	$1,678	$56,613
Total Cost - Suppliers	$24,716	$10,355	$5,189	$1,259	$41,519
Total Cost - Importers and Suppliers	$58,340	$24,615	$12,239	$2,937	$98,132
Grand Total Year 1 - Importers and Suppliers	$10,368,476	$2,800,119	$1,367,327	$329,012	$14,864,934
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	$1,993,816	$29,287	$1,697	$884	$2,025,684
Total Cost - Suppliers	$432,011	$6,346	$368	$192	$438,916
Total Cost - Importers and Suppliers	$2,425,827	$35,633	$2,065	$1,076	$2,464,601
Very Small Suppliers					
Total Cost - Importers	$2,713,649	$1,150,917	$569,004	$135,419	$4,568,990
Total Cost - Suppliers	$587,982	$249,376	$123,289	$237,014	$1,197,661
Total Cost - Importers and Suppliers	$3,301,631	$1,400,293	$692,293	$372,433	$5,766,651
RAC Suppliers That Are Not VSS and Not Subject to Produce Rule					
Total Cost - Importers	$24,569	$10,420	$5,152	$1,226	$41,368
Total Cost - Suppliers	$5,324	$2,258	$1,116	$2,146	$10,844
Total Cost - Importers and Suppliers	$29,893	$12,678	$6,268	$3,372	$52,212
Grand Total Every Year After Year 1 - Importers and Suppliers	$5,757,352	$1,448,604	$700,626	$376,881	$8,283,463

We revised Table 24 to account for the change in the definitions of VSI and VSS, for importers and their customers who would be subject to the potential PC supplier verification regulations, and for foreign RAC suppliers that are not VSS and are not subject to the produce proposed rule.

Table 25. Estimated Cost of Documenting Very Small Importer or Very Small Supplier or RAC Supplier Not Subject to Produce Rule 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	$61	$61	$61	$61	
Cost to Process Documentation	$61	$61	$61	$61	
Number of Very Small Importers	22,041	267	17	9	22,333
Combinations of Importers and Suppliers Involving Very Small Suppliers	60,444	25,636	12,674	3,016	101,770
Total Cost to Process Documentation	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557

We revised Table 25 to account for the change in the definitions of VSI and VSS, for importers and their customers who would be subject to the potential PC supplier verification regulations and for RAC suppliers that are not VSS and not subject to the produce proposed rule.

Table 26. Estimated Cost for Reviewing Complaints for FSVP Per Importer Conducting That Activity					
	Importer Number of Employees				
	<20	20 to 99	100 to 499	> 500	Total
Hours Per Month To Review Complaints for Relation to FSVP, Average	4	8	16	24	
Hours Per Month to Review Complaints For Relation to FSVP as Percentage of Time to Review Complaints for Relation to Food Safety Plan	0.25	0.25	0.25	0.25	
Hours Per Month To Review Complaints For Relation to FSVP	1	2	4	6	
Hours Per Year, Average	12	24	48	72	
Cost per Hour	$61.44	$61.44	$61.44	$61.44	
Cost Per Importer Per	$737	$1,475	$2,949	$4,424	

Year					
Number of Importers	25,504	7,237	3,838	973	37,552
Cost of Reviewing Complaints Per Year	$18,803,920	$10,671,249	$11,317,490	$4,302,320	$45,094,978

We revised Table 27 to account for importers and their customers who would be subject to the potential PC supplier verification regulations.

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	$61.44	$61.44	$61.44	$61.44	
Probability Per Product Per Year That Information About An Imported Product Will Trigger Investigation, Midpoint	2%	2%	2%	2%	
Number of Products Per Importer Per Year, Weighted Average	10	13	13	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	$44	$60	$58	$50	
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	1	1	1	1	

Modification, Midpoint					
Hours to Modify FSVP	2	2	2	2	
Probability That An Investigation Will Trigger a Modification of a FSVP, Midpoint	25%	25%	25%	25%	
Cost Per Importer Per Year to Modify FSVP Due To Investigations Into Adequacy of FSVP	$5	$6	$6	$5	
Total Cost Per Importer Per Year	$49	$66	$64	$56	
Number of Importers	25,504	7,237	3,838	973	37,552
Cost of Reviewing Complaints Per Year,	$1,246,562	$478,627	$246,474	$54,253	$2,025,916

We revised Table 27 to account for importers and their customers who would be subject to the potential PC supplier verification regulations.

Table 28. Estimated Cost of Investigating Problems With Imported Products Per Importer Conducting That Activity

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Cost Per Investigation	$3,511	$3,511	$3,511	$3,511	
Probability Per Product Per Year That Information About An Imported Product Will Trigger Investigation, Average	3%	3%	3%	3%	
Number of Products Per Importer Per Year, Weighted Average	10	13	13	11	
Cost Per Importer Per Year	$842	$1,140	$1,107	$962	
Number of Importers	25,504	7,237	3,838	973	37,552
Cost of Investigating Complaints Per Year,	$21,486,937	$8,250,078	$4,248,466	$935,163	$34,920,644

We revised Table 28 to account for importers and their customers who would be subject to the potential PC supplier verification regulations.

Table 35. Total Cost Summary for All Elements of Proposed Regulation - All Entities, Option 2					
	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$5,492,689	$33,785,029	$17,636,627	$3,891,767	$60,806,112
Writing and Maintaining Procedures Relating to Verification Requirements	$7,131,191	$20,253,536	$10,792,265	$2,209,794	$40,386,785
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Approve Suppliers and Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$10,806,442	$3,262,296	$1,586,683	$379,703	$16,035,125
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$41,537,419	$19,399,954	$15,812,430	$5,291,736	$82,041,539

Obtaining and Providing DUNS Numbers	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Grand Total Year 1					
Scenario 1	$121,716,047	$180,793,941	$102,163,101	$24,257,887	$428,930,976
Scenario 2	$120,800,323	$178,189,778	$100,774,948	$23,973,654	$423,738,703
Scenario 3	$119,932,816	$175,722,739	$99,459,888	$23,704,388	$418,819,831
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$3,632,063	$21,205,287	$11,078,740	$2,438,441	$38,354,531
Writing and Maintaining Procedures Relating to Verification Requirements	$5,861,680	$16,647,956	$8,871,002	$1,816,401	$33,197,039
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Approve Suppliers and Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$6,195,317	$1,910,781	$919,982	$427,573	$9,453,653
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557

Conducting Investigative and Corrective Actions	$41,537,419	$19,399,954	$15,812,430	$5,291,736	$82,041,539
Obtaining and Providing DUNS Numbers	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194
Grand Total Every Year After Year 1					
Scenario 1	$113,937,832	$163,245,058	$93,010,555	$22,457,409	$392,650,855
Scenario 2	$113,022,108	$160,640,895	$91,622,401	$22,173,177	$387,458,581
Scenario 3	$112,154,601	$158,173,856	$90,307,342	$21,903,911	$382,539,710

We revised Table 35 because the changes in the other tables generated changes in this summary table.

Table 36. Sensitivity Analysis, Option 2				
		Mean	**Low**	**High**
Year 1				
Hiring Third Parties With Qualified Individuals	$4,509,998	$1,346,566		$8,667,449
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$31,313,790	$20,427,810		$44,453,490
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$58,201,080	$32,088,790		$91,822,840
Writing and Maintaining Procedures Relating to Verification Requirements	$39,349,160	$19,500,290		$65,504,740
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures Ensure Supplies from Approved Suppliers				
Scenario 1	$177,408,600	$84,618,160		$308,095,700
Scenario 2	$172,430,600	$81,543,940		$301,123,400
Scenario 3	$167,714,700	$77,722,600		$296,155,500
Obtaining Written Assurances	$16,165,130	$10,203,930		$24,202,050
Documenting Very Small Size Status	$7,675,932	$4,037,394		$12,223,620
Conducting Investigative and Corrective Actions	$82,273,350	$54,541,230		$113,098,300
Obtaining and Providing DUNS Numbers	$4,768,517	$4,768,517		$4,768,517
Grand Total Year 1				
Scenario 1	$421,665,600	$271,483,000		$613,176,900
Scenario 2	$416,687,500	$269,050,900		$607,214,700
Scenario 3	$411,971,600	$266,465,700		$601,714,800

Every Year After Year 1			
Hiring Third Parties With Qualified Individuals	$4,509,998	$1,346,566	$8,667,449
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$31,313,790	$20,427,810	$44,453,490
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$36,739,280	$20,347,440	$57,504,110
Writing and Maintaining Procedures Relating to Verification Requirements	$32,345,260	$15,539,350	$55,697,810
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers			
Scenario 1	$177,408,600	$84,618,160	$308,095,700
Scenario 2	$172,430,600	$81,543,940	$301,123,400
Scenario 3	$167,714,700	$77,722,600	$296,155,500
Obtaining Written Assurances	$9,526,566	$5,116,844	$15,270,780
Documenting Very Small Size Status	$7,675,932	$4,037,394	$12,223,620
Conducting Investigative and Corrective Actions	$82,273,350	$54,541,230	$113,098,300
Obtaining and Providing DUNS Numbers	$4,711,194	$4,711,194	$4,711,194
Grand Total Every Year After Year 1			
Scenario 1	$386,504,000	$247,932,600	$565,579,800
Scenario 2	$381,526,000	$245,343,400	$558,836,800
Scenario 3	$376,810,100	$242,317,800	$554,089,900

We revised Table 36 to reflect the changes in Table 35.

Table 37. Alternative 1- Total Cost Summary for All Elements of Proposed Regulation - All Entities

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Writing and Maintaining Procedures Relating to Verification Requirements	$7,131,191	$20,253,536	$10,792,265	$2,209,794	$40,386,785

Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$10,806,442	$3,262,296	$1,586,683	$379,703	$16,035,125
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$20,050,481	$11,149,876	$11,563,964	$4,356,573	$47,120,894
Grand Total Year 1					
Scenario 1	$75,953,594	$129,548,778	$74,267,209	$17,332,689	$297,102,269
Scenario 2	$75,037,870	$126,944,615	$72,879,055	$17,048,456	$291,909,996
Scenario 3	$74,170,363	$124,477,575	$71,563,996	$16,779,190	$286,991,124
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Writing and Maintaining Procedures Relating to Verification Requirements	$5,861,680	$16,647,956	$8,871,002	$1,816,401	$33,197,039
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089

Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$6,195,317	$1,910,781	$919,982	$427,573	$9,453,653
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$20,050,481	$11,149,876	$11,563,964	$4,356,573	$47,120,894
Grand Total Every Year After Year 1					
Scenario 1	$70,072,959	$124,591,682	$71,679,244	$16,987,166	$283,331,052
Scenario 2	$69,157,235	$121,987,519	$70,291,091	$16,702,933	$278,138,778
Scenario 3	$68,289,728	$119,520,480	$68,976,031	$16,433,667	$273,219,907

We revised Table 37 to reflect the changes in Table 35.

Table 38. Alternative 2 - Total Cost Summary for All Elements of Proposed Regulation - All Entities

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$2,746,345	$16,892,515	$8,818,313	$1,945,884	$30,403,056
Writing and Maintaining Procedures Relating to Verification Requirements	$7,131,191	$20,253,536	$10,792,265	$2,209,794	$40,386,785
Following Procedures Relating to Verification Requirements Including					

Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$10,806,442	$3,262,296	$1,586,683	$379,703	$16,035,125
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$20,768,709	$9,699,977	$7,906,215	$2,645,868	$41,020,769
Obtaining and Providing DUNS Numbers	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Grand Total Year 1					
Scenario 1	$98,200,993	$154,201,450	$85,438,573	$19,666,135	$357,507,151
Scenario 2	$83,344,841	$147,445,720	$81,992,174	$19,002,199	$331,784,933
Scenario 3	$96,417,762	$149,130,247	$82,735,360	$19,112,636	$347,396,006
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$1,816,032	$10,602,644	$5,539,370	$1,219,220	$19,177,266
Writing and Maintaining Procedures Relating to Verification Requirements	$5,861,680	$16,647,956	$8,871,002	$1,816,401	$33,197,039

Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$6,195,317	$1,910,781	$919,982	$427,573	$9,453,653
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$20,768,709	$9,699,977	$7,906,215	$2,645,868	$41,020,769
Obtaining and Providing DUNS Numbers	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194
Grand Total Every Year After Year 1					
Scenario 1	$91,353,091	$142,942,438	$79,564,970	$18,592,321	$332,452,820
Scenario 2	$90,437,367	$140,338,274	$78,176,816	$18,308,088	$327,260,546
Scenario 3	$89,569,860	$137,871,235	$76,861,757	$18,038,822	$322,341,675

We revised Table 37 to reflect the changes in Table 35.

V. Benefits

We have not revised our discussion of the potential pool of benefits of this rule that appeared in the previous PRIA.

VI. Summary

This document has detailed the analysis of the revisions to the proposed rule. For detailed analysis of the pieces of the proposed rule that have not changed, see the previous PRIA (Ref.1).

We estimated the change in costs due to the revisions to the proposed rule discussed in section IV of this document. We did not estimate a change in the pool of potential benefits.

Table B (identical to revised Table 35) presents the total costs by provision of the proposed rule as revised in our supplemental notice of proposed rulemaking. As was the case with the summary estimates in the previous PRIA, 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 have fallen from those initially estimated in the previous PRIA.

Table B. Total Cost Summary for All Elements of Proposed Regulation

	Importer Number of Employees				
	<20	**20 to 99**	**100 to 499**	**> 500**	**Total**
Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434
Conducting Information Collection and Risk Evaluations (Other than Reviewing Supplier Compliance)	$5,492,689	$33,785,029	$17,636,627	$3,891,767	$60,806,112

Writing and Maintaining Procedures Relating to Verification Requirements	$7,131,191	$20,253,536	$10,792,265	$2,209,794	$40,386,785
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Approve Suppliers and Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$10,806,442	$3,262,296	$1,586,683	$379,703	$16,035,125
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$41,537,419	$19,399,954	$15,812,430	$5,291,736	$82,041,539
Obtaining and Providing DUNS Numbers	$1,074,891	$929,363	$1,685,907	$1,078,356	$4,768,517
Grand Total Year 1					
Scenario 1	$121,716,047	$180,793,941	$102,163,101	$24,257,887	$428,930,976
Scenario 2	$120,800,323	$178,189,778	$100,774,948	$23,973,654	$423,738,703
Scenario 3	$119,932,816	$175,722,739	$99,459,888	$23,704,388	$418,819,831
Every Year After Year 1					
Hiring Third Parties With Qualified Individuals	$3,133,987	$889,271	$471,562	$0	$4,494,819
Conducting Supplier Compliance Review (Component of Risk Evaluations)	$17,707,936	$8,280,694	$4,324,893	$1,019,911	$31,333,434
Conducting Information Collection and Risk	$3,632,063	$21,205,287	$11,078,740	$2,438,441	$38,354,531

Evaluations (Other than Reviewing Supplier Compliance)					
Writing and Maintaining Procedures Relating to Verification Requirements	$5,861,680	$16,647,956	$8,871,002	$1,816,401	$33,197,039
Following Procedures Relating to Verification Requirements Including Establishing, Maintaining, and Following Procedures to Approve Suppliers and Ensure Supplies from Approved Suppliers					
Scenario 1	$29,729,974	$92,388,078	$49,065,959	$10,199,080	$181,383,089
Scenario 2	$28,814,249	$89,783,914	$47,677,805	$9,914,847	$176,190,816
Scenario 3	$27,946,742	$87,316,875	$46,362,746	$9,645,581	$171,271,945
Obtaining Written Assurances	$6,195,317	$1,910,781	$919,982	$427,573	$9,453,653
Documenting Very Small Size or RAC Supplier Not Subject to Produce Rule Status	$5,101,521	$1,605,721	$786,776	$187,539	$7,681,557
Conducting Investigative and Corrective Actions	$41,537,419	$19,399,954	$15,812,430	$5,291,736	$82,041,539
Obtaining and Providing DUNS Numbers	$1,037,937	$917,317	$1,679,212	$1,076,728	$4,711,194
Grand Total Every Year After Year 1					
Scenario 1	$113,937,832	$163,245,058	$93,010,555	$22,457,409	$392,650,855
Scenario 2	$113,022,108	$160,640,895	$91,622,401	$22,173,177	$387,458,581
Scenario 3	$112,154,601	$158,173,856	$90,307,342	$21,903,911	$382,539,710

Table C. Average Cost per Importer				
	<20	**20 to 99**	**100 to 499**	**>= 500**
Year 1	$3,324	$15,147	$15,400	$15,036
Every Year After Year 1	$3,112	$13,677	$14,020	$13,920

Table D presents a summary of the total costs and the potential pool of benefits estimated to be associated with the revised proposed rule. We estimate the total potential pool of benefits of the revised proposed rule to be $1.18 billion, annually and the annualized costs of the revised proposed rule to be $396.8 million, based on a 3 percent discount rate. This results in $779.2 million in estimated potential net benefits.

Table D. Total Costs and Potential Benefits		
Total Potential Benefits[3]	**Total Annualized Costs**[4]	**Net Potential Benefits**
$1,175,963,993	$396,780,114	$779,183,879

Relative to Option 1 of the previous proposed rule, this represents a cost savings of $76.2 ($472.97 - $396.78) million and an increase in overall potential net benefits of the same amount.

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 current threshold after adjustment for inflation is $144 million, using the most current (2013) Implicit Price Deflator for the Gross

[3] To the extent that the preventive controls and produce safety rulemakings would reduce foodborne illness even in the absence of this rule, the upper bound on the benefits of this rule would be lower than the estimates shown here.

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

Domestic Product. FDA expects that the FSVP proposed rule would result in a 1-year expenditure that would 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 proposed 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/Food/GuidanceRegulation/FSMA/ucm361902.htm.

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 the proposed rule would have no significant impact on a substantial number of small entities. Because of the dynamic nature of food importing, large numbers of importers may enter and exit the market each year. We lack information to predict with certainty whether the proposed rule would have a significant economic impact on a substantial number of small entities. The revisions to the proposed rule on Foreign Supplier Verification Programs (FSVPs) for Importers of Food for Humans and Animals, as set forth in the supplemental notice of proposed rulemaking, modify some requirements that would change the burden for some importers. Thus, this document amends our Initial Regulatory Flexibility Analysis (IRFA) published as Appendix A in the Preliminary Regulatory Impact Analysis (PRIA) of the proposed rule.

1. Revisions to the Proposed Rule that Affect the IRFA

The Preventive Controls (PC) proposed rule includes a proposal for the potential addition of supplier program provisions. Should such provisions be adopted, under the FSVP proposal, importers that are food facilities that comply with any PC supplier program provisions for a food they import, as well as importers whose customer is in compliance with those provisions, would be deemed in compliance with nearly all of the proposed FSVP requirements (the exceptions are the requirement to ensure that the importer is identified at U.S. entry of the food and certain recordkeeping requirements). This revision decreases our estimate of the number of importers who would be subject to the full FSVP requirements.

To reduce the burden on very small importers, the previous FSVP proposed rule included modified requirements for very small importers defined as importers with annual food

sales of $0.5 million or less. In the revisions to the proposed rule, the Agency increases the annual sales limit for very small importers and importers of food from very small foreign suppliers from $0.5 million to $1.0 million. With this higher limit, the number of small entities who would be subject to the standard FSVP requirements would decrease.

Other revisions to the proposed rule increase or decrease the burden of some requirements. For example, we are now proposing modified supplier verification activity requirements for importers of food from foreign suppliers that are farms not subject to the produce safety regulations. Also, instead of having to maintain a list of their foreign suppliers, importers would need to establish and follow procedures for ensuring that they obtain food from approved foreign suppliers (or, in limited circumstances on a temporary basis, from unapproved suppliers), which might result in increased costs. In addition, the revisions to the proposed rule give importers more flexibility to choose appropriate supplier verification activities depending on the results of a broader evaluation of food and supplier risks than was required under the previous proposal. This flexibility would allow importers to choose the most cost-effective activities that accomplish the goal of assuring that imported food is produced in a manner consistent with U.S. requirements.

2. Revised Number of Small Entities

We present a revised estimate of the number of affected importers in Table A1. As shown, fewer importers would be subject to the full FSVP requirements with the revisions to the proposed rule if supplier verification requirements were to be adopted under the PC rule, and more importers would be eligible for certain modified FSVP requirements because they meet the definition of very small importer or import food from very small foreign suppliers or farms that are not subject to the produce safety regulations. 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 and request comment from affected small entities.

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	22,041	267	17	9	22,333	39%
Importers Subject to Other Regulations [1]	11,724	5,399	3,174	780	21,078	37%
Remaining Food & Food Ingredient Importers [2]	2,852	6,270	3,443	824	13,389	24%
Total--All Importers	**36,617**	**11,936**	**6,634**	**1,613**	**56,800**	**100%**

Numbers may not sum due to rounding.

[1] Includes importers subject to the PC regulations (or whose customers are subject to those regulations), importers subject to certain dietary supplement CGMP regulations (or whose customers are subject to those regulations), and importers subject to modified FSVP requirements (e.g., importers of finished dietary supplements or importers of food only from very small foreign suppliers).

[2] Includes importers of food from foreign suppliers that are farms not subject to the produce safety regulations and importers subject to the standard FSVP requirements.

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 proposed rule. In the revisions to the proposed rule, we have increased the annual sales limit for eligibility for very small importer and very small foreign supplier status from $0.5 million to $1.0 million. With this higher ceiling, the number of small entities

subject to the standard FSVP requirements would decrease, thus reducing the burden on these small entities.