Proposed Rule on Foreign Supplier Verification Programs for
Importers of Food for Humans and Animals

RIN 0910-AG64

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA is required to issue this proposed rule under section 301 of the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353), signed into law on January 4, 2011. Section 301 of FSMA adds section 805 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a) to require persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying the following: (1) The food is produced in compliance with section 418 (concerning hazard analysis and risk-based preventive controls) or 419 (concerning standards for the safe production and harvesting of certain fruits and vegetables that are raw agricultural commodities (RACs)) of the FD&C Act (21 U.S.C. 350g and 350h), as appropriate; (2) the food is not adulterated under section 402 of the FD&C Act (21 U.S.C. 342); and (3) the food is not misbranded under section 403(w) of the FD&C Act (21 U.S.C. 343(w)) (concerning food allergen labeling).

Section 805(c) of the FD&C Act directs FDA to issue regulations on the content of foreign supplier verification programs (FSVPs). Section 805(c)(2)(A) states that these regulations shall require that the FSVP of each importer be adequate to provide assurances that each of the importer's foreign suppliers produces food in compliance with processes and procedures, including risk-based preventive controls (PC), that provide the same level of public health protection as those required under sections 418 and 419 of the FD&C Act and in compliance with sections 402 and 403(w) of the FD&C Act. Section 805(c)(2)(B) states that these regulations shall include such other requirements as FDA deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

In addition to the authority specified in section 301 of FSMA (adding section 805 of the FD&C Act) to issue these proposed regulations, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to promulgate regulations for the efficient enforcement of the FD&C Act. Also, some aspects of the proposed FSVP regulations are being issued under section 421(b) of the FD&C Act (21 U.S.C. 350j(b)).

This is a new information collection for 21 CFR Part 1.

2. Purpose and Use of the Information Collection

Federal Government: We are requiring that importers establish and maintain records on their FSVPs and on their performance of certain activities under those FSVPs, including the identification of hazards that are reasonably likely to occur with a food and verification that these hazards are being adequately controlled by the foreign supplier or other appropriate entity. These recordkeeping requirements will help ensure that importers are meeting their responsibilities under the FSVP regulations and will better enable us to monitor importers' compliance with the regulations.

We also are requiring certain reporting to Customs and Border Protection (CBP) (for subsequent transfer to FDA) relating to FSVP requirements and exemptions. We propose to require persons who wish to import food for research or evaluation purposes to submit a declaration that the food will be used for that purpose. Submission of these declarations is needed to enable us to effectively monitor whether the requirements for the FSVP exemption for food for research or evaluation are being met.

We also propose to require that the name and Dun and Bradstreet Universal Numbering System (DUNS) number of the importer be provided for each line entry of food product offered for importation into the United States. We need this information to effectively monitor importers' compliance with the FSVP regulations. In addition, knowing the identity of the importer for a particular food being imported would help us carry out section 421(b) of the FD&C Act. This provision, also added by FSMA, requires FDA to allocate its resources for examining imported products based on certain risk factors, including the rigor and effectiveness of the importer's FSVP. Finally, obtaining the identity of the importer at entry also could help us meet the requirement, stated in section 805(g) of the FD&C Act, to "publish and maintain on [our] Internet Website . . . a current list that includes the name and location of, and other important information deemed necessary by [FDA] about, importers participating under this section [i.e., section 805]."

3. Use of Improved Information Technology and Burden Reduction

The proposed recordkeeping requirements for FSVPs would not require the use of electronic recordkeeping, but we encourage this approach. We expect that most of the importers will maintain their records in electronic format; it would be difficult to stay competitive in today's global market without the use of information technology.

The proposed requirements concerning the reporting of information to CBP specify that the information must be provided electronically. We believe that electronic submission is necessary to ensure the efficient collection of information by CBP and subsequent transfer of this information to FDA for FSVP monitoring and enforcement purposes. Therefore, we estimate the electronic submission to be 100%.

4. Efforts to Identify Duplication and Use of Similar Information

Because the FSVP proposed rule would establish new requirements for importers, the recordkeeping requirements associated with the proposed rule would not duplicate any existing recordkeeping requirements. Similarly, the requirement to provide an electronic declaration to CBP that a food will be used for research or evaluation purposes so that the food is eligible for exemption from the FSVP requirements would not duplicate any existing reporting requirement.

With respect to the proposed requirement to provide the name and DUNS number of the importer when a food is offered for entry into the United States, while we currently receive information identifying the "importer" as part of entry and as part of prior notice under section 801(m) of the FD&C Act, the entities identified under those procedures are not necessarily the "importer" for the purposes of FSVP. We also considered requiring food importers to register with FDA to develop a database of importers. Some, but not all, importers currently register with FDA as food facilities and are assigned registration numbers under 21 CFR part 1, subpart H (§§ 1.225-1.243). Because not all importers are required to register, the current food facility registration system would not be sufficient for FSVP purposes. Moreover, obtaining the identity of the importer at the time of entry, as proposed, would enable us to both carry out section 421(b) of the FD&C Act and develop a database of importers without creating a new or revised registration system. By collecting this information with each entry, we would know the firm's last importation date and would receive "fresh" information with each importation (as opposed to, with a registration system, when the firm updates its registration or periodically re-registers). With the information gathered at the time of entry, our database would be able to include the types of food the firm is importing, which would better enable the Agency to assess and allocate its inspectional resources.

5. Impact on Small Businesses or Other Small Entities

Most food importers that would be subject to the proposed rule are small businesses and would need to begin performing various activities that they currently do not perform. However, the proposed rule would establish FSVP requirements for "very small importers" that differ from the "standard" FSVP requirements. The proposed rule defines a "very small importer" as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. Very small importers would be exempt from many of the standard FSVP requirements, including those concerning hazard analysis, foreign supplier verification, investigation of adulteration or misbranding, and FSVP reassessment. The only verification activities required of very small importers would be maintaining a list of foreign suppliers and obtaining written assurance from suppliers (every 2 years) of compliance with applicable U.S. food safety requirements. We estimate that there are about 25,000 very small food importers, which represents about 44 percent of all food importers.

Under the proposed rule, corresponding modified FSVP requirements would apply to food that is imported from very small foreign suppliers. The proposed rule would define a "very small foreign supplier" as a foreign supplier, including any subsidiary, affiliate,

or subsidiaries or affiliates, collectively, of any entity of which the foreign supplier is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than $500,000, adjusted for inflation. Very small foreign suppliers would not be subject to the standard requirements for supplier verification activities.

We do not have information on the size characteristics of foreign suppliers. However, we estimated the number of such suppliers by using the size information on domestic suppliers that we used in the preliminary regulatory impact analysis (PRIA) of the preventive controls (PC) proposed rule (issued January 16, 2013) and assuming that foreign suppliers would have similar size characteristics to domestic suppliers. Based on this approach, we estimated that 59 percent of foreign suppliers of food products that are not fruit or vegetable RACs and 93 percent of foreign suppliers of RAC products would qualify as very small suppliers. Using this information, we estimated in the PRIA for the FSVP proposed rule that there are about 127,000 combinations of importers and suppliers involving very small suppliers.

When we issue draft guidance on the FSVP regulations, we intend to include recommendations to assist small businesses, including those who meet the definition of "very small importers," in establishing FSVPs and complying with the FSVP regulations.

6. Consequences of Collecting the Information Less Frequently

Written FSVP procedures and records of implementation of those procedures are necessary to ensure proper adoption and implementation of FSVPs as well as Agency monitoring of compliance with the FSVP regulations.

It is necessary that information submitted to CBP concerning food imported for research or evaluation be provided when filing entry with CBP so that we can effectively monitor whether the requirements for the FSVP exemption for food for research or evaluation are being met. Similarly, it is necessary that identification of importers be provided for each line entry of food product offered for importation into the United States so that we can use the information to effectively monitor importers' compliance with the FSVP regulations.

Information may be given or retained on a daily, weekly, monthly, or yearly basis depending on which types of documents are being transmitted. Some information from respondents will be needed every time a food is imported into the United States while other information may not be needed every time. For example, a DUNS number will be provided to CBP with every entry line; shipments could occur regularly (e.g., on a weekly basis) between the same importer and foreign supplier or they could happen once a year or sporadically. As another example, audit results of a supplying facility could be transmitted to the importer once annually for a relationship between a specific supplier supplying the same product to the same importer over the course of the year.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The reporting requirements concerning (1) declarations of food for research or evaluation (in § 1.501(c)) and (2) identification of the importer when a food is offered for importation into the United States (in § 1.509(c)) must be made when filing entry for the food with CBP. Consequently, this reporting must occur as frequently as the food is offered for importation, which could be as often as multiple times in a single day.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   The proposed rule published in the FEDERAL REGISTER on July 29, 2013. (78 FR 45729.)

9. Explanation of Any Payment or Gift to Respondents

   This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

    This regulation does not specify confidentiality. However, records that may be reviewed during FDA inspections of food importers are subject to FDA regulations on the release of information in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

    This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

    Description of Respondents: Generally, all persons who import food into the United States. We estimate that there are approximately 56,800 persons who meet the definition of importer set forth in the proposed regulations.

    However, the proposed rule would exempt the importation of certain foods from the FSVP requirements, including certain juice and seafood products, food for research or evaluation (exempt but subject to a reporting requirement), food for personal consumption, certain alcoholic beverages, food that is transshipped, and food that is imported for further processing and future export.

    In addition, the proposed rule would establish modified FSVP requirements for the following: (1) importers of dietary supplements; (2) very small food importers and importers of food from very small foreign suppliers; and (3) importers of food from suppliers in countries whose food safety systems FDA has officially recognized as comparable or determined to be equivalent to that of the United States.

The proposed rule also would affect persons who import food for research or evaluation purposes.

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

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

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

Table 1 of this document provides an estimate of the annual reporting burdens associated with the proposed rule. Table 2 and 2b of this document provides an estimate of the annual recordkeeping burdens associated with the proposed rule. Option 1 includes Table 1 and Table 2. Option 2 includes Table 1 and Table 2b. Since FDA is only able to upload one option into as part of the ICR in ICRAS we chose to upload Option 2 (Tables 1 and 2b).

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

(Included in both Options 1 and 2 and uploaded into ICRAS/ROCIS.)

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

The "number of respondents" is multiplied by the "number of responses per respondent" to equal the "total annual responses." The "total annual responses" is multiplied by the "average burden per response" to equal the "total hours."

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

(Included only in Option 1 ***not*** *uploaded into ICRAS/ROCIS.)*

21 CFR Section	No. of Record-keepers	No. of Records per Record-keeper	Total Annual Records	Average Burden per Record-keeping	Total Hours
Controls for LACF 1.502(b)	2,443	4	9,772	1	9,772
Review compliance status for food and supplier 1.504, 1.511(c)(1), 1.512(b)(2)	53,291	5	266,455	2	532,910
Determine and document hazards 1.505(a)	27,829	1	27,829	3.7	102,967
Review hazard analysis 1.505(d)	27,829	7	194,803	1	194,803
Written list of	56,800	1	56,800	1.50	85,200

suppliers 1.506(a), 1.511(c)(2), 1.512(b)(3)					
Written procedures for verification 1.506(b), 1.511(c)(3)	27,829	7	194,803	2	389,606
Written assurances from suppliers 1.506(f)	23,715	5	118,575	1	118,575
Conduct/Review audits for SAHCODHA hazards 1.506(g)(1), 1.506(h)	5,947	1	5,947	14	83,258
Determine and document type of verification activities 1.506(g)(2)	23,742	8	189,936	0.75	142,452
Conduct/Review audits non-SAHCODHA hazards 1.506(g)(2)(i), 1.511(c)(5)(i)	59	1	59	14	826
Conduct periodic sampling/testing 1.506(g)(2)(ii), 1.511(c)(5)(ii)	23,742	5	118,710	4	474,840
Review records 1.506(g)(2)(iii), 1.511(c)(5)(iii)	23,742	5	118,710	1.6	189,836
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	10,658	1	10,658	14	149,212
Investigate and determine FSVP adequacy 1.507(d),	10,658	1	10,658	5	53,290

1.511(c)(1)					
Written assurances for food produced under dietary supplement (DS) CGMPs 1.511(b)	3,509	6	21,054	2.25	47,372
Determine and document verification activities for importers of DS 1.511(c)(5)	1,822	2	3,644	2.50	9,110
Document very small importer/very small supplier status 1.512(b)(1)	152,395	1	152,395	1	152,395
Written assurances from very small importer/very small supplier 1.512(b)(4)	56,800	2	113,600	2.25	255,600
Total					2,992,024

TABLE 2b. ESTIMATED ANNUAL RECORDKEEPING BURDEN

(Included only in Option 2 and uploaded into ICRAS/ROCIS.)

21 CFR Section	No. of Record-keepers	No. of Records per Record-keeper	Total Annual Records	Average Burden per Record-keeping	Total Hours
Controls for LACF 1.502(b)	2,443	4	9,772	1	9,772
Review compliance status for food and supplier 1.504, 1.511(c)(1), 1.512(b)(2)	53,291	5	266,455	2	532,910
Determine and document hazards 1.505(a)	27,829	1	27,829	3.7	102,967
Review hazard analysis 1.505(d)	27,829	7	194,803	1	194,803
Written list of suppliers 1.506(a), 1.511(c)(2), 1.512(b)(3)	56,800	1	56,800	1.50	85,200
Written procedures for verification 1.506(b), 1.511(c)(3)	27,829	7	194,803	2	389,606
Written assurances from suppliers 1.506(f)	23,715	5	118,575	1	118,575
Determine and document type of verification activities 1.506(g)(1)	23,742	8	189,936	0.75	142,452
Conduct/Review audits 1.506(g)(1)(i), 1.506(h), 1.511(c)(5)(i)	4,936	1	4,936	14	69,104
Conduct periodic sampling/testing 1.506(g)(1)(ii),	23,742	5	118,710	4	474,840

1.506(h), 1.511(c)(5)(ii)					
Review records 1.506(g)(1)(iii), 1.506(h), 1.511(c)(5)(iii)	23,742	5	118,710	1.6	189,936
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	10,658	1	10,658	14	149,212
Investigate and determine FSVP adequacy 1.507(d), 1.511(c)(1)	10,658	1	10,658	5	53,290
Written assurances for food produced under DS CGMPs 1.511(b)	3,509	6	21,054	2.25	47,372
Determine and document verification activities for importers of DS 1.511(c)(5)	1,822	2	3,644	2.50	9,110
Document very small importer/very small supplier status 1.512(b)(1)	152,395	1	152,395	1	152,395
Written assurances from very small importer/very small supplier 1.512(b)(4)	56,800	2	113,600	2.25	255,600
Total					2,977,144

12b. Annualized Cost Burden Estimate

FDA estimates that these records would be kept by the employee performing the activities on which the records are being kept. In most cases, this employee would be, or would be similar to, a production manager in the food manufacturing industry. The mean wage for Standard Occupations Classification (SOC) 11-3051 Production Managers in

North American Industry Classification System (NAICS) code 311000 Food Manufacturing in 2010 was $40.96. (Bureau of Labor Statistics, Occupational Employment Statistics, May 2010, National Industry-Specific Occupational Employment and Wage Estimates for NAICS 31100 - Food Manufacturing, http://bls.gov/oes/current/naics3_311000.htm.) We increased this wage by 50 percent to $61.44 to account for overhead. The overall estimated cost incurred by the respondents under Option 1 is $183,829,955 (2,992,024 burden hours x $61.44/hr) and $182,909,583 (2,977,044 burden hours x $61.44/hr) under Option 2.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

Table 3- Estimated Annual Operating and Maintenance Costs Under Option 1 *(**not** uploaded into ICRAS/ROCIS)*	
21 CFR Part 1	Operating and Maintenance Costs
Conduct/Review audits for SAHCODHA hazards 1.506(g)(1), 1.506(h)	$3,716,875
Conduct/Review audits non-SAHCODHA hazards 1.506(g)(2)(i), 1.511(c)(5)(i)	$36,875
Conduct periodic sampling/testing 1.506(g)(2)(ii), 1.511(c)(5)(ii)	$158,240,430
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	$6,661,250
Total annual costs	$168,655,430

Table 3b- Estimated Annual Operating and Maintenance Costs Under Option 2 *(uploaded into ICRAS/ROCIS)*	
21 CFR Part 1	Operating and Maintenance Costs
Conduct/Review audits 1.506(g)(1)(i), 1.506(h), 1.511(c)(5)(i)	$3,085,000
Conduct periodic sampling/testing 1.506(g)(1)(ii), 1.506(h), 1.511(c)(5)(ii)	$158,240,430
Investigate adulteration or misbranding 1.507(b), 1.511(c)(1)	$6,661,250
Total Annual Costs	$167,986,680

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its routine or for cause establishment inspection activities. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review

and evaluation to be $16.33 to $55.46 per hour, the GS-5/Step 1 rate to the GS 13/Step 10 rate for the Washington-Baltimore locality pay area for the year 2012. To account for overhead, this cost is increased by 50 percent, making the total cost $24.50 to $83.19 per hour. The midpoint of this range is $53.85 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $269.25 per review ($53.85/hour x 5 hours). FDA estimates that it will review records for an average of 500 inspections per year. Thus, FDA estimates that the total annual cost to the Federal Government for reviewing records during inspections would be $134,625 ($269.25 x 500 inspections).

15. Explanation for Program Changes or Adjustments

    This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    We are considering using the information that importers would provide to CBP in accordance with proposed § 1.509(c) to help us meet the requirement, stated in section 805(g) of the FD&C Act, to "publish and maintain on [our] Internet Web site . . . a current list that includes the name and location of, and other important information deemed necessary by [FDA] about, importers participating under this section [i.e., section 805]." The meaning of the phrase "importers participating under this section" is ambiguous. Among other things, it could mean the list must include all importers subject to section 805 or only those subject to section 805 and in compliance with that provision. If so, FDA needs a way to know the identity of these importers. One way to gather this information would be to obtain from CBP the importer information that would be provided in accordance with proposed § 1.509(c) -- i.e., for each line entry of food product offered for importation into the United States, the importer's name and DUNS number.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

    We are not seeking approval not to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.