Foreign Supplier Verification Programs for
Importers of Food for Humans and Animals

RIN 0910-AG64
OMB Control No. 0910-0752

SUPPORTING STATEMENT

## A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA is required to issue rulemaking 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 its 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 information collection request supports new regulatory requirements under 21 CFR Part 1 as promulgated under FDA's final rule for "*Foreign Supplier Verification Programs for Importers of Food for Humans and Animals*."

2. Purpose and Use of the Information Collection

We are requiring that respondents establish and maintain records on their FSVPs and on the 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 responsibilities under the FSVP regulations and will better enable us to monitor importers' compliance with the regulations.

Certain reporting to Customs and Border Protection (CBP) (for subsequent transfer to FDA) relating to FSVP requirements and exemptions is also required under the rule. Persons who wish to import food for research or evaluation purposes must submit a declaration that the food will be used for that purpose. Submission of these declarations enables us to effectively monitor whether the requirements for the FSVP exemption for food for research or evaluation are being met.

The rulemaking also requires 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. This information is needed to effectively monitor importers' compliance with the FSVP regulations. Knowing the identity of the importer for a particular food being imported helps us implement section 421(b) of the FD&C Act. In this way FDA can allocate resources for examining imported products based on certain risk factors, including the rigor and effectiveness of the importer's FSVP. Moreover, obtaining the identity of the importer at entry enables us 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*." (Section 805(g) of the Act.)

3. Use of Improved Information Technology and Burden Reduction

Although the recordkeeping requirements for FSVPs do not require the use of electronic recordkeeping, we encourage this approach. We expect that most of the importers will maintain their records in electronic format. Likewise, the reporting requirements to CBP specify that the information must be provided electronically. This is necessary to ensure the efficient collection of information by CBP and the subsequent transfer of the information to FDA for FSVP monitoring and enforcement purposes. Therefore, we estimate that 100% of respondents will use electronic means to satisfy the information collection provisions under the rule.

4. Efforts to Identify Duplication and Use of Similar Information

The FSVP rule implements food protection provisions not implemented elsewhere and therefore we believe the information collection provisions are not duplicative. While we considered requiring food importers to register and developing a database of importers, not

all importers are required to register under the regulations and thus our current food facility registration system would not be sufficient for FSVP purposes. At the same time, by collecting this information with each entry as required under the rule, we learn the firm's last importation date and receive updated information with each importation (as opposed to periodic updating through the registration process). In turn, this enables us to better assess and allocate our limited inspectional resources.

5. Impact on Small Businesses or Other Small Entities

Most respondents subject to the rule are small businesses. However, the rule establishes requirements specifically for "*very small importers*" and "*very small foreign suppliers*" that differ from the "standard" FSVP requirements. We believe that this approach minimizes burden on small entities while at the same time provides reasonable assurance of protecting the public health by ensuring a safe food supply. As agency guidance is developed to support the FSVP regulations, we intend to include recommendations to assist small entities 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 their proper administration under the regulations, as well as assist with monitoring compliance. Information may be reported or retained on a daily, weekly, monthly, or yearly basis depending on which types of documents are being transmitted and which regulations are applicable. 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. We believe that the reporting and record collection schedules provided for in the regulations are minimal and collecting the information less frequently would undermine our public protection mandate.

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. There are no other special circumstances relating to the information collection request.

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

FDA published a proposed rule regarding FSVP in the Federal Register of July 29, 2013 (78 FR 45730), and published a supplemental notice of proposed rulemaking regarding FSVP in the Federal Register of September 29, 2014 (79 FR 58574). Some comments addressed recordkeeping generally and are addressed in the final rule which published November 27, 2015 (80 FR at 74225, at page 74303). Other comments received in response to the rulemaking did not respond to the four information collection topics solicited but are also addressed in the final rule (at page 74321). All comments are filed under Docket No. FDA-2011-N-0143.

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, respondents include all persons who import food into the United States. We estimate that there are approximately 56,800 respondents who meet the definition of importer as set forth in the regulations.

FDA estimates the burden associated with this final rule below. Our estimates are based on our experience with similar information collections and in consideration of feedback during rulemaking. More detailed information regarding our calculations may be found within the agency's Final Regulatory Impact Analysis (FRIA), filed under Docket No. FDA-2011-N-0143.

Table 1.—Estimated Annual Reporting Burden[1]

| 21 CFR Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Avg. Burden Per Response | Total Hours |
|---|---|---|---|---|---|
| Exemption for Food for research 1.501(c) | 36,360 | 40 | 1,454,400 | 0.083 (5 mins.) | 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 mins.) | 178,352 |
| Total | | | | | 299,067 |

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

Table 2.—Estimated Annual Recordkeeping Burden

| IC Activity; 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| Controls for LACF; 1.502(b) | 2,443 | 4 | 9,772 | 1 | 9,772 |
| FSVP RECORDKEEPING *including hazard determination, written procedures, reevaluation; audits; and corrective actions*: | | | | | |
| Determine and document hazards; 1.504(a) | 11,701 | 1 | 11,701 | 3.5 | 40,954 |
| Review hazard analysis; 1.504(d) | 11,701 | 7 | 81,907 | 0.33 | 27,029 |
| Evaluation of food and foreign supplier; 1.505(a)(2), 1.511(c)(1) | 11,701 | 1 | 11,701 | 4 | 46,804 |
| Approval of suppliers; 1.505(b), 1.512(c)(1)(iii) | 8,191 | 1 | 8,191 | 12 | 98,292 |
| Reevaluation of food and foreign supplier; 1.505(c), 1.512(c)(1)(ii)(A) | 11,701 | 365 | 4,270,865 | 0.25 | 1,067,716 |
| Confirm or change requirements of foreign supplier verification activity; 1.505(c), 1.512(c)(1)(ii)(A) | 2,340 | 1 | 2,340 | 2 | 4,680 |
| Review of other entities assessments; 1.505(d), 1.512(c)(1)(iii) | 3,510 | 1 | 3,510 | 1.2 | 4,212 |
| Written procedures for use of approved foreign suppliers; 1.506(a)(1), 1.511(c)(2), 1.512(c)(3)(i) | 11,701 | 1 | 11,701 | 8 | 93,608 |
| Review of written procedures; 1.506(a)(2), 1.511(c)(2)(ii), 1.512(c)(3)(ii) | 11,701 | 1 | 11,701 | 1 | 11,701 |
| Written procedures for conducting verification activities; 1.506(b), 1.511(c)(3) | 11,701 | 1 | 11,701 | 2 | 23,402 |

| IC Activity; 21 CFR Section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Avg. Burden per Recordkeeping | Total Hours |
|---|---|---|---|---|---|
| Determination and documentation of appropriate supplier verification activities; 1.506(d)(1)-(2) 1.511(c)(5)(i) | 11,701 | 4 | 46,804 | 3.25 | 152,113 |
| Review of appropriate supplier verification activities determined by another entity; 1.506(d)(3) 1.511(c)(5)(iii) | 11,701 | 2 | 23,402 | 0.33 | 7,723 |
| Conduct/review audits; 1.506(e)(1)(i), 1.511(c)(6)(i)(A) | 11,701 | 2 | 23,402 | 3 | 70,206 |
| Conduct periodic sampling/testing; 1.506(e)(1)(ii), 1.511(c)(6)(i)(B) | 11,701 | 2 | 23,402 | 1 | 23,402 |
| Review records; 1.506(e)(1)(iii), 1.511(c)(6)(i)(C) | 11,701 | 2 | 23,402 | 1.6 | 37,443 |
| Document your review of supplier verification activity records; 1.506(e)(3), 1.511(c)(6)(iii) | 11,701 | 6 | 70,206 | 0.25 | 17,552 |
| 1.507(a)(1) | 11,701 | 3.17 | 37,082 | 1.25 | 46,353 |
| Written assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4) | 11,701 | 8.72 | 102,038 | 0.50 | 51,019 |
| Disclosures that accompany assurances; 1.507(a)(2), 1.507(a)(3), and 1.507(a)(4) | 102,038 | 1 | 102,038 | 0.50 | 51,019 |
| Document assurances from customers; 1.507(c) | 36,522 | 2.8 | 102,262 | 0.25 | 25,566 |
| Document corrective actions; 1.508(a) and 1.512(b)(4) | 2,340 | 1 | 2,340 | 2 | 4,680 |
| Investigate and determine FSVP adequacy; 1.508(b), 1.511(c)(1) | 2,340 | 1 | 2,340 | 5 | 11,700 |
| SUBTOTAL for FSVP RECORDKEEPING ITEMIZED ABOVE: | | | 4,984,036 | | 1,917,174 |
| Written assurances for food produced under dietary supplement CGMPs; 1.511(b) | 11,701 | 2.88 | 33,664 | 2.25 | 75,744 |
| Document very small importer/certain small foreign supplier status; 1.512(b)(1) | 50,450 | 1 | 50,450 | 1 | 50,450 |
| Written assurances associated with very small importer/certain small foreign supplier 1.512(b)(3) | 50,450 | 2.8 | 141,084 | 2.25 | 317,439 |
| TOTAL | | | | | 2,370,579 |

12b. Annualized Cost Burden Estimate

FDA estimates that records will be kept by the employee performing the corresponding activity. In most cases, this employee will be, or will 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, therefore is $164,023,050 (2,669,646 burden hours x $61.44/hr).

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

| Table 3- Estimated Annual Operating and Maintenance Costs | |
|---|---|
| 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 will 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 information 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 provided in accordance with proposed § 1.509(c).

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

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.