Voluntary National Retail Food Regulatory Program Standards

0910-0621

SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

While the responsibility for regulating retail and foodservice establishments lies primarily with state, local, and tribal jurisdictions, FDA provides assistance to these jurisdictions through multiple means including, but not limited to, training and technical assistance. Authority for providing such assistance is derived from section 311 of the Public Health Service Act (42 U.S.C. 243). In addition, FDA's mission under section 903(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 393(b)(2)(A)) includes ensuring that foods are safe, wholesome, and sanitary, and section 903(b)(4) of the Act directs FDA to cooperate with food retailers, among others, in carrying out this part of its mission.

The Centers for Disease Control and Prevention has identified the major contributing factors associated with foodborne illness outbreaks. Five of these contributing factors directly relate to retail and foodservice establishments and are called "foodborne illness risk factors" by FDA. In an effort to assist state, local, and tribal regulators and the retail and food service entities they regulate, FDA has developed a Program Standards document entitled, "Voluntary National Retail Food Regulatory Program Standards."

The Program Standards were developed to address the need for national uniformity among retail food regulatory programs, to promote uniform application of the FDA Food Code, and to reduce the occurrence of foodborne illness risk factors. The Program Standards were developed with extensive input from state, tribal, and local regulatory authorities and are intended to help those authorities design and manage a retail food regulatory program that is focused on the reduction of foodborne illness risk factors. They are intended to capture the best management practices currently in use by state, tribal, and local regulatory authorities. The Program Standards initiative represents a comprehensive strategic approach that will help ensure the safety and security of the food supply at the retail level.

FDA requests OMB approval of information collection provisions of the Voluntary National Retail Food Regulatory Program Standards and the draft revision, which is available at: www.fda.gov/retailfoodprotection, as well as Form FDA 3519, "FDA National Registry Report" and Form FDA 3520, "Permission to Publish in National Registry."

2. Purpose and Use of the Information Collection

The Program Standards define nine essential elements of an effective regulatory program for retail food establishments, establish basic quality control criteria for each element, and provide a

means of recognition for those state, local, and tribal regulatory programs that meet the Program Standards. The program elements addressed by the Program Standards are as follows: (1) Regulatory foundation, (2) trained regulatory staff, (3) inspection program based on Hazard Analysis and Critical Control Point (HACCP) principles, (4) uniform inspection program, (5) foodborne illness and food defense preparedness and response, (6) compliance and enforcement, (7) industry and community relations, (8) program support and resources, and (9) program assessment. Each standard includes a list of records needed to document compliance with the standard (referred to in the Program Standards document as "quality records") and has one or more corresponding appendices that contain forms and worksheets to facilitate the collection of information needed to assess the retail food regulatory program against that standard. The respondents are state, local, and tribal government Agencies. Regulatory Agencies may use existing, available records or may choose to develop and use alternate forms and worksheets that capture the same information.

In the course of their normal activities, state, local, and tribal regulatory Agencies already collect and keep on file many of the records needed as quality records to document compliance with each of the Program Standards. Although the detail and format in which this information is collected and recorded may vary by jurisdiction, records that are kept as a usual and customary part of normal Agency activities include inspection records, written quality assurance procedures and records of quality assurance checks, staff training certificates and other training records, a log or database of food-related illness or injury complaints, records of investigations resulting from such complaints, an inventory of inspection equipment, records of outside audits, and records of outreach efforts (e.g., meeting agendas and minutes, documentation of food safety education activities). No new recordkeeping burden is associated with these existing records, which are already a part of usual and customary program recordkeeping activities by state, local, and tribal regulatory Agencies, and which can serve as quality records under the Program Standards.

State, local, and tribal regulatory Agencies that enroll in the Program Standards and seek listing in the FDA National Registry are required to report to FDA on the completion of the following three management tasks outlined in the Program Standards: (1) Conducting a program self assessment, (2) conducting a baseline survey of the regulated industry, and (3) obtaining an independent outside audit (verification audit). The results are reported to FDA on Form FDA 3519, "FDA National Registry Report" and Form FDA 3520, "Permission to Publish in National Registry." These forms are located in Appendix I of the Program Standards document. If a regulatory Agency follows all the recordkeeping recommendations in the individual standards and their appendices, it will have all the information needed to complete the forms.

In April 2010, the Conference for Food Protection approved changes to the Program Standards. The changes have been incorporated into a draft 2011 revision, which is available at: www.fda.gov/retailfoodprotection. One change was to provide an extension of time for completion of the three management tasks. Another change was the inclusion of clarifying language in Standard 9 that a jurisdiction may use its inspection data to conduct its study of risk factor occurrence. Although this was always the intent in Standard 9, it was not clear to jurisdictions that this was a viable option.

Description of Respondents: The respondents are State, local, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry.

3. Use of Improved Information Technology and Burden Reduction

The respondents submit their information to FDA on Form FDA 3519, "FDA National Registry Report," and Form FDA 3520, "Permission to Publish in National Registry," both of which are available electronically online and on CD for download. The agency estimates that about twenty-five percent (25%) of the submissions will be submitted electronically in the next three years.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is unaware of any comprehensive inventory of Program Standard enrollment from other sources. There are no similar data that can be used or modified for use. No public comments were received that identified any other sources. Thus, there is no duplicative collection of information.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that none of the respondents are small businesses. Respondents are State, local, and tribal regulatory agencies. No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally, i.e., upon enrollment in the Program Standards and within a 12 month to 60 month period thereafter. Although the collection of information related to the Program Standards is voluntary, if information is not collected, regulators may not be employing all the tools necessary to achieve more effective control of foodborne illness risk factors. The information allows FDA to assist regulatory programs to improve the services they provide to consumers and their regulated industries through the use of the continuous improvement model specified in the Program Standards.

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

There are no special circumstances associated with this collection of information.

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

In accordance with 5 CFR 1320.8(d), in the Federal Register of January 12, 2011 (76 FR 2124), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six comment letters in response to the notice. One comment was

generally supportive of the necessity of the information collection and its practical utility. Five letters contained comments outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here.

9. Explanation of Any Payment or Gift to Respondents

FDA does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection does not request any information of a personal nature, or trade secret or commercial confidential information. The information to be provided is public in nature. Thus, FDA provides no assurances of confidentiality.

11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Respondents are State, local, and tribal regulatory agencies that enroll in the Program Standards and seek listing in the FDA National Registry.

12 a. Annualized Hour Burden Estimate

As noted in section 2 above, in April 2010, the Conference for Food Protection approved changes to the Program Standards. The changes have been incorporated into a draft 2011 revision, which is available at: www.fda.gov/retailfoodprotection. One change was to provide an extension of time for completion of the three management tasks. Another change was the inclusion of clarifying language in Standard 9 that a jurisdiction may use its inspection data to conduct its study of risk factor occurrence. Although this was always the intent in Standard 9, it was not clear to jurisdictions that this was a viable option.

FDA analyzed whether incorporation of these changes alters its estimate of the recordkeeping and reporting burdens. FDA concluded that the changes will lessen the annual recordkeeping burden estimate because the management tasks will be conducted on a less frequent basis annually. Thus, based on its experience with the Program Standards over the past 3 years, FDA has reduced its estimate of the hours per record to 94.29, from the previously estimated 157 hours per record in 2008. The reduced recordkeeping burden hour estimates are shown in table 4 of this document. FDA notes that jurisdictions that choose to analyze their inspection data per the Standard 9 criteria will enjoy a less resource intensive method for tracking risk factor trends over time. However, the Agency has not reduced its estimate of 333 hours for Standard 9 shown in table 2 of this document. The Agency will consider reducing this estimate in a future information collection request based on supporting data it expects to receive in the future from participating jurisdictions. The two noted changes had no effect on the reporting burden hour

estimates shown in table 2 of this document.

Recordkeeping

FDA's recordkeeping burden estimate includes time required for a state, local, or tribal Agency to review the instructions in the Program Standards, compile information from existing sources, and create any records recommended in the Program Standards that are not already kept in the normal course of the Agency's usual and customary activities. Worksheets (Appendices) are provided to assist in this compilation. In estimating the time needed for the program self-assessment (Program Standards 1 through 8, shown in table 1 of this document), FDA considered responses from four state and three local jurisdictions that participated in an FDA Program Standards Pilot study. Table 2 of this document shows the estimated recordkeeping burden for the completion of the baseline data collection and table 3 of this document shows the estimated recordkeeping burden for the verification audit.

Table 1.--Self Assessment

Standard	Recordkeeping Activity	Hours per Record
No. 1 Regulatory Foundation	Self Assessment: (Appendix A) Completion of worksheet recording results of evaluations and comparison on worksheets[1]	16
No. 2 Trained Regulatory Staff	Self Assessment: (Appendix B-2 and B-4)[1] Completion of CFP Field Training Manual and Documentation of Successful Completion--Field Training Process; completion of summary worksheet of each employee training records[2]	19.3
No. 3 HACCP Principles	Self Assessment: (Appendix C[1]) Completion of worksheet documentation	4
No. 4 Uniform Inspection Program	Self Assessment: (Appendix D[1]) Completion of worksheet documentation of jurisdiction's quality assurance	19
No. 5 Foodborne Illness Investigation	Self Assessment: (Appendix E[1]) Completion of worksheet documentation	5
No. 6 Compliance Enforcement	Self Assessment: (Appendix F[1]) Selection and review of 20 to 70 establishment files @ 25 minutes per file. Estimate is based on a mean number of 45. Completion of worksheet	19
No. 7 Industry & Community Relations	Self Assessment: (Appendix G[1]) Completion of worksheet	2
No. 8 Program Support and Resources	Self Assessment: (Appendix H[1]) Selection and review of establishment files	8

Total		92.3

[1] Or comparable documentation.

[2] Estimates will vary depending on number of regulated food establishments and the number of inspectors employed by the jurisdiction.

Table 2.--Baseline Data Collection

Standard	Recordkeeping Activity	Hours Per Record
No. 9 Program Assessment	Baseline Data Collection (Appendices I & J) Selection and inspection of randomly selected statistical sample of 9 to 87 establishments from each of 9 facility types[1]	333

[1] Calculation based on mean sample size of 39 and average FDA inspection time for each establishment type. Estimates will vary depending on number of regulated food establishments within a jurisdiction and the number of inspectors employed by the jurisdiction.

Table 3.--Verification Audit

Standard	Recordkeeping Activity	Hours per Record
No. 9	Verification Audit (Appendices I & J)[1]	46.15

[1] We estimate that no more than 50% of time spent to complete self assessment of all 9 Standards is spent completing verification audit worksheets. Time will be considerably less if less than 9 standards require verification audits.

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

Table 4.--Estimated Annual Recordkeeping Burden[1]

FDA Worksheets[2] Appendices A through J	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average burden per recordkeeping (in hours)[3]	Total Hours
	500	1	500	94.29	47,145
Total					47,145

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

[2] Or comparable documentation.

[3] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

FDA bases its estimates of the number of recordkeepers and the hours per record on its experience with the Program Standards over the past 3 years. FDA estimates that approximately 500 regulatory jurisdictions will participate in the Program Standards. There are approximately 3,000 jurisdictions in the United States and its territories that have retail food regulatory programs. Enrollment in the Program Standards is voluntary and, therefore, FDA does not expect all jurisdictions to participate.

FDA bases its estimate of the hours per record on the recordkeeping estimates for the management tasks of self assessment, baseline data collection, and verification audit (tables 1, 2, and 3 of this document) that enrolled jurisdictions must perform a total of 471.45 hours (92.3 + 333 + 46.15 = 471.45). As noted, based on its experience with the Program Standards over the past 3 years, FDA has reduced its estimate of the number of recordkeeping hours that enrolled jurisdictions will perform annually to 94.29, from the previously estimated 157 hours per record in 2008. FDA estimates that, annually, 500 recordkeepers will spend 94.29 hours performing the required recordkeeping for a total of 47,145 hours.

Reporting

FDA requires regulatory jurisdictions that participate in the Program Standards to submit two forms annually: Form FDA 3519, "FDA National Registry Report," and Form FDA 3520, "Permission to Publish in National Registry." Form FDA 3519 requires the name and address of the jurisdiction; completion dates for the self assessment, baseline survey (original and update), and verification audit; names of the person(s) who completed the self-assessment, verification audit, baseline survey, baseline survey update, and action plan; signature of the program manager; and date the form was completed. Form FDA 3520 requires the name of the jurisdiction, completion date of the self assessment, date of the verification audit report, name of the auditor, signature and title of the official completing the form, and date the form was completed.

The reporting burden in table 5 of this document includes only the time necessary to fill out and send the forms, as compiling the underlying information (including self-assessment reports, baseline surveys, outside audits, and supporting documentation) is accounted for under the recordkeeping estimates in table 4 of this document.

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

Table 5.--Estimated Annual Reporting Burden[1]

Form FDA No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)[2]	Total Hours
3519	500	1	500	6/60	50
3520	500	1	500	6/60	50

Conference for Food Protection Training Plan and Log	500	3	1,500	6/60	150
Total					250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

FDA bases its estimates of the number of respondents and the hours per response on its experience with the Program Standards over the past 3 years. As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both forms. FDA bases its estimate on the small number of data elements on the two forms and the ease of availability of the information. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3519 for a total of 500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit one Form FDA 3520 for a total of 500 annual responses. Each of these submissions is estimated to take 0.1 hour per response for a total of 50 hours. FDA estimates that, annually, 500 regulatory jurisdictions will submit three requests for documentation of successful completion of staff training using the CFP Training Plan and Log for a total of 1,500 annual responses. Each submission is estimated to take 0.1 hour per response for a total of 150 hours. Thus, the total reporting burden for this information collection is 250 hours.

12 b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage for the employees engaging in recordkeeping and submitting information to FDA is $15 per hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $30/hour. Thus, the overall estimated cost incurred by the respondents is $1,421,850. (47,395 burden hours X $30/hr = $1,421,850).

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

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The estimated annual cost to the Federal Government for this information collection is $24,999 for AFDO to contact, collect, collate and periodically report results to FDA.

15. Explanation for Program Changes or Adjustments

Based on its experience with the Program Standards over the past 3 years, FDA has reduced its estimate of the number of recordkeeping hours that enrolled jurisdictions will perform annually to 94.29, from the previously estimated 157 hours per year in 2008. This change reduces the recordkeeping burden hours. Thus, we are reporting an adjustment (decrease) in total burden hours of 31,405 hours (78,800 hours – 47,395 hours = 31,405 hours).

16. Plans for Tabulation and Publication and Project Time Schedule

The agency lists regulatory agencies that have enrolled in the Draft Voluntary National Retail Food Regulatory Program Standards on the web and updates the list quarterly, including the enrolled jurisdictions' contact information, enrollment dates, and self-reported and verified status of each of the program standards.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.