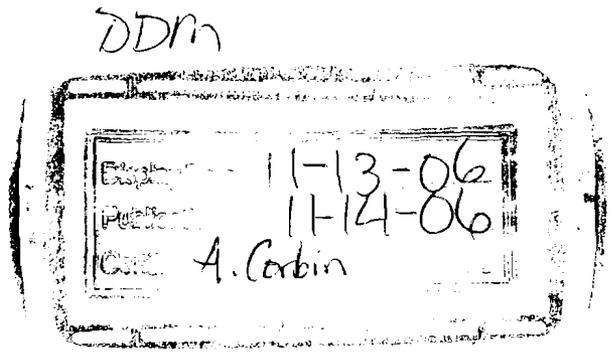


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0419]



Draft Voluntary National Retail Food Regulatory Program Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Voluntary National Retail Food Regulatory Program Standards” (the Program Standards). The Program Standards are intended to help state, local, and tribal regulators design and manage a retail food regulatory program that is focused on the reduction of foodborne illness risk factors.

DATES: Submit written or electronic comments concerning the draft Program Standards document and its recommendations for collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft Program Standards document to Glenda R. Lewis, Center for Food Safety and Applied Nutrition (HFS-626), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2150. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments concerning the draft Program Standards document and its recommendations for collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville,

MD 20852. Submit electronic comments on the draft Program Standards document and its recommendations for collection of information to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft manuals and received comments.

FOR FURTHER INFORMATION CONTACT: Glenda R. Lewis, Center for Food Safety and Applied Nutrition (HFS-626), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-2150.

SUPPLEMENTARY INFORMATION:

I. Background

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 developed draft 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. They capture the best management practices currently in use by those 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.

The incorporation of a risk-based methodology into regulatory inspection programs is an important element in reaching the goals established by the President's Council on Food Safety in the document entitled "Food Safety Strategic Plan" released in January 2001 (available at <http://www.foodsafety.gov/~fsg/cstrpl-4.html>) as well as FDA's food safety program goals.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB

for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Voluntary National Retail Food Regulatory Program Standards

In the **Federal Register** of May 9, 2001 (66 FR 23715), a 60-day notice was published soliciting comments on FDA's collection of information from local, state and tribal authorities concerning their use of or planned use of FDA's Program Standards. No comments were received in response to that notice. The agency has decided to reissue this 60-day notice for further comment because the Program Standards have been revised since the previous notice. The January 2005 revision of the Program Standards is available in draft for comment on FDA's Web site at <http://www.cfsan.fda.gov/~dms/ret3toc.html>.

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 HACCP principles, (4) uniform inspection program, (5) foodborne illness and food security 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 a retail program under 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 the end of each Program Standard by jurisdictions that enroll. 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). All three tasks must be completed within a 3-year time span. 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. 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. The time required to complete the forms is minimal.

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 1–8, shown in chart 1 of this document), FDA considered responses from four state and three local jurisdictions that participated in an FDA Program Standards Pilot study.

Chart 2 of this document shows the estimated recordkeeping burden for the completion of the baseline data collection and chart 3 of this document shows the estimated recordkeeping burden for the verification audit. The overall program improvement cycle is a 3-year period for completion of all three management tasks.

CHART 1.—YEAR ONE—SELF ASSESSMENT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year One)
No. 1 Regulatory Foundation	Self Assessment: (Appendix A ¹) Completion of worksheet recording results of evaluations and comparison on worksheets	16
No. 2 Trained Regulatory Staff	Self Assessment: (Appendix B ¹) Completion of summary worksheet of each employee training records ²	19
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 procedures ²	19
No. 5 Foodborne Illness and Food Security Preparedness and Response	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 and 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
Subtotal		92

¹Or comparable documentation.

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

CHART 2.—YEAR TWO—BASELINE DATA COLLECTION

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

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

CHART 3.—YEAR THREE—VERIFICATION AUDIT

Standard	Recordkeeping Activity	Hours per Recordkeeper (Year Three)
9	Verification Audit (Appendices I and J) ¹	46

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

FDA estimated the annual hours per recordkeeper (i.e., per enrolled jurisdiction) in table 1 of this document by adding the recordkeeping estimates for the management tasks of self assessment, baseline data collection, and verification audit (charts 1, 2, and 3 of this document) that enrolled

jurisdictions must perform during a 3-year cycle, then dividing the total by three to obtain an annual average.

The estimates in tables 1 and 2 of this document are based on the estimated participation of 500 regulatory jurisdictions 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 in the near future. In its 2002 operational plan, the FDA National Retail Food Team established a goal of enrolling 15 percent of eligible agencies, or 450 programs, in the Program Standards by the year 2010. For purposes of this burden estimate, it is reasonable to take into account the possibility that this goal could be exceeded by approximately 10 percent, for a total of approximately 500 participating agencies.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

FDA Worksheets ²	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Appendices A through J	500	1	500	157	78,500
Total Burden Hours					78,500

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

²Or comparable documentation.

Reporting

Based on the number and nature of the items that need to be completed, FDA estimates a total of 12 minutes annually for each enrolled jurisdiction to complete both FDA Form 3519, "FDA National Registry Report," and Form 3520, "Permission to Publish in National Registry." Form 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 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. As explained previously in this document, FDA estimates that 500 regulatory jurisdictions will enroll in the Program Standards. The reporting burden in table 2 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 1 of this document.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3519	500	1	500	6 min	50 hours
3520	500	1	500	6 min	50 hours
Total Burden Hours					100 hours

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

III. Comments

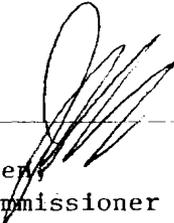
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft Program Standards document and its recommendations for collection of information. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft Program Standards document and received comments

may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft Program Standards document at <http://www.cfsan.fda.gov/~dms/ret3toc.html>.

Dated: 10/31/06
October 31, 2006.



Jeffrey Shuren
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

