

Request for OMB Review
Supporting Statement
0910-XXXX
Adoption of the FDA Food Code by Local, State, and Tribal Governments

Submitted by:

Office of Regulatory Affairs
Office of Regional Operations
Division of Federal-State Relations
Food and Drug Administration
Public Health Service
Department of Health and Human Services

**ADOPTION OF THE FDA FOOD CODE BY LOCAL, STATE, AND TRIBAL
GOVERNMENTS**
Supporting Statement for Information Collection Request

Approval is requested for the collection of information from local, state, and tribal governments regarding the adoption of the FDA Food Code, a voluntary model of food safety regulatory standards in the retail setting. The Association of Food and Drug Officials (AFDO) has been asked by FDA to contact local, state, and tribal officials to obtain information about the status of Food Code adoptions in their respective jurisdictions. Telephonic and electronic means will be used wherever possible. AFDO will compile this information to construct for FDA an active data-base and produce reports on the nationwide progress toward adoptions of the Code. A list of questions to be used in the information gathering has been developed in cooperation with AFDO officials and is attached to this request. (Attachment 1)

A. JUSTIFICATION

A. 1. Necessity for the Information Collection

The Food and Drug Administration (FDA) has major responsibilities for assuring the safety of the nation's food supply. Among these responsibilities, FDA has the lead federal food safety inspection role for foods prepared and sold at retail and works cooperatively with local, state and tribal government agencies that operate retail food safety regulatory programs within their respective jurisdictions. FDA also works closely with the Food Safety and Inspection Service/U.S. Department of Agriculture (FSIS/USDA), which has the lead federal food safety role for meat and poultry.

The FDA, FSIS, and CDC, in collaboration with the Conference for Food Protection, state and local public health and food control agencies, industry representatives, academia, and

consumers have updated the 1999 Food Code to reflect the most current science and the best strategies to ensure a safer food supply in the United States. The Food Code assists and promotes consistent implementation of national food safety regulatory policy among the several thousand local, state and tribal governments that have primary responsibility for the regulation or oversight of retail level food operations. The FDA Food Code provides a scientifically sound technical and legal basis for regulating the retail segment of the food industry. However the Food Code is neither federal law nor federal regulation and it is not preemptive, but may be adopted and used by agencies at all levels of government that have responsibility for managing food safety risks at retail.

Authority for providing such assistance is derived from section 311(a) of the Public Health Service Act (42 U.S.C. 243) and delegation of authority from the Public Health Service to the Commissioner of Food and Drugs relative to food protection is contained in 21 CFR 5.10(a)(2) and (a)(4). Under 31 U.S.C. 1535, FDA provides assistance to other Federal agencies such as the Indian Health Service. (Attachment 2)

A. 2. Use of the Information

Nationwide adoption of the model FDA Food Code is an important step to further the goals of the President's Council on Food Safety for consistent, scientifically sound, and risk-based food safety standards and practices and to work more effectively with partners in state, local and tribal governments and with other federal agencies. To help achieve these aims and FDA's Food Safety Initiative goals, FDA needs a comprehensive, accurate, and current inventory of Food Code adoptions to monitor the effectiveness of FDA's assistance to these agencies and to identify gaps where additional assistance may be needed.

FDA has established a site on the Internet at <http://www.cfsan.fda.gov> under "Federal/State Food Programs" and "Retail Food Safety References" to list agencies that have reported adoptions of the FDA Food Code. Because it is self-reported, the current list is incomplete and those codes adopted have not been evaluated for consistency with the model FDA Food Code. FDA has obtained the services of the Association of Food and Drug Officials (AFDO) to develop and implement an active surveillance system to track and report on the adoptions of the Food Code by state and local agencies and tribal nations of Native Americans.

AFDO will develop an active computer data base that will capture adoptions of the Food Code; identify and periodically contact State, local and tribal food safety program administrators to determine the current status of Food Code adoptions; collect information to identify consistency of adopted Codes with the FDA Food Code focussed only on the CDC identified risk factors and the FDA Food Code interventions; and provide quarterly progress reports to FDA from the data base in tabular and graphic form. Reports may be placed on the Internet at <http://www.cfsan.fda.gov>.

The scope of the project is not intended to include a detailed assessment by AFDO regarding absolute "equivalency" of the adopted codes. Equivalency determinations are much more detailed in nature and are made by each jurisdiction in evaluating its program under Standard

1 of the Voluntary National Retail Food Regulatory Program Standards. Under the design of the Program Standards, those determinations are then subject to confirmation via FDA audits.

A. 3. Use of Information Technology

Initial contacts by AFDO to local, State and tribal program administrators will be by telephone and/or e-mail to minimize the burden on respondents. A uniform set of questions will be used to elicit information on whether or not the FDA Food Code has been adopted in the respondent's jurisdiction; which version of the Food Code is in effect (the FDA Food Code is revised on a biennial basis); areas of difference in CDC risk factors and interventions from the Food Code; applicability of the adopted Code to all retail establishments and if not, what types of establishments are excluded; numbers of retail establishments subject to the Code and population served by the Code; scope of the code to all local jurisdictions; identification of any local jurisdictions where the Code does not apply; efforts aimed at adoption if the Food Code is not in effect; and the status and expected dates of promulgation.

Responses by telephone and/or e-mail will be encouraged unless the respondent wishes to provide documents and other information in printed form.

Periodic follow-up contacts by telephone and/or e-mail with jurisdictions in the process of adopting the Food Code will be made by AFDO semi-annually to assure that the information on hand is current.

A. 4. Efforts to Identify Duplication

FDA is unaware of any comprehensive inventory of Food Code adoptions from other sources. The only comment received on our Federal Register Notice of April 6, 2000 noted the existence of a list of adoptions published on FDA's web site. As noted in A.2 above, that list is self-reported and therefore is incomplete and not comprehensive for all potential levels of adopting jurisdictions. FDA disagrees with the comment that the comprehensive list to be provided by this data collection will not help the agency in any meaningful way. A comprehensive list will enable the agency to determine where gaps exist, what jurisdictions may need assistance and assist the agency in applying resources to encourage Food Code adoptions based on confirmed data rather than on estimates and guesswork.

A. 5. Method to Minimize Burden on Small Business

No small businesses will be involved in this collection.

A. 6. Consequence of Not Conducting the Collection

Without this data collection, FDA will be unable to have an accurate inventory of Food Code adoptions throughout the United States and will be unable to measure progress toward the goal of nationwide adoption. As planned, the information will allow FDA to identify

areas where additional assistance is needed and permit allocations of resources to meet those needs. Nationwide adoption is also necessary to achieve the goal of uniform, scientifically sound and risk-based standards, that is a key goal of the President's Council on Food Safety.

A. 7. Special Circumstances Explanation

This collection fully complies with 5 CFR 1320.5

A. 8. Public Comment and Consultation Outside the Agency

In accordance with 5 CFR 1320.8(d) on April 6, 2000, in Volume 65, Number 67, page 18110, a 60-day notice for public comment was published in the Federal Register. One comment was received which questioned the necessity for the information and criticized the funding mechanism for obtaining the information. FDA disagrees with the commentator on both points. The necessity for the information is addressed specifically in A.2 and A.4 above. On the commentator's second point regarding propriety of funding the project, the purchase requisition for services was well within the limits and fully compliant with regulations for purchasing the services of the Association of Food and Drug Officials to conduct the information gathering.

9. Payment or Gifts to Respondents

Respondents will not receive any type of payment or gift for responding to the request for information.

A. 10. Assurance of Confidentiality

No information of a personal nature is requested. Therefore, no confidentiality assurances are deemed necessary. The information to be provided is public in nature, and it may be necessary to follow-up with the respondents to clarify responses and/or to track the progress of anticipated Food Code adoptions. Thus, the identification of the respondents will be necessary for AFDO to perform the desired information gathering.

A. 11. Sensitive Questions

No questions of a sensitive nature are included in this information gathering.

A. 12. Hour Burden Estimates

FDA based its estimates on the number of State agencies (100) involved in Food Code-related regulatory programs, 300 local agencies with local ordinance authority and 100 tribal agencies that may consider Food Code adoption in any one year. Estimating the number of local agencies is difficult before the start of this project because in some States, adoption by a State agency automatically applies to all local jurisdictions in that state. In other States, some metropolitan and county jurisdictions may adopt the FDA Food Code individually.

Similar circumstances may apply to tribal nations' agencies that may be adopting the FDA Food Code. When the initial information gathering is completed, FDA will be able to identify more accurately the number of local and tribal agencies for which tracking adoption of the FDA Food Code will be necessary.

Frequency of reporting will range from once per year to quarterly for any one jurisdiction. This is because agencies that have already adopted the Food Code will require less frequent contact, perhaps only annually, than those that are in the process of adopting the Food Code. An average of two contacts in one year, therefore, was selected. Because most reporting will be done telephonically or electronically, reporting times often will be much less than one hour. These estimates will fluctuate from year to year as agencies adopt, revise or consider adoption of the FDA Food Code. This project is expected to operate over a five year period during which the frequency of contacts should decrease as jurisdictions adopt the FDA Food Code.

The project is expected to take five years because the adoption process in some States can extend to two years or more. For example, some States have biennial legislative sessions. Others have extensive notice-and-comment administrative rulemaking procedures that can extend well beyond one year.

| No. Of Respondents | Estimated Annual Reporting Burden | | | Total Hours |
|--------------------|-----------------------------------|------------------------|--------------------|-------------|
| | Annual Frequency per Response | Total Annual Responses | Hours per Response | |
| 500 | 2 | 1,000 | 1 | 1,000 |
| Total Hours | | | | 1,000 |

A. 13. Total Annual Cost Burden to Respondents Excluding Hours Burden Shown in Sections A.12

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

A. 14. Annual Cost to the Federal Government

The estimated annual cost to the Federal government for this information collection is \$75,000 for AFDO to contact, collect, collate, and periodically report results to FDA.

A. 15. Explanation of Program Changes or Adjustments

This is a new collection of information.

A. 16. Project Schedule and Plan for Analysis

Initially, there are two phases to this project. In phase one, AFDO is compiling existing information from FDA internal files on Food Code adoptions, compiling contact lists, gathering and establishing files on existing local and state codes and developing a process for contacting, processing and recording initial contacts with local, State and tribal officials and developing reporting formats to FDA.

Phase two will begin after OMB approval of the survey instrument (questions) that will be posed to the respondents. This is estimated to begin in about November, 2000 with follow-up contacts for non-respondents and for clarifications by April, 2001.

Each year, over an estimated 5 year period, subject to funding, AFDO will be contacting jurisdictions to determine the status of Food Code adoptions and contacting additional local jurisdictions not included in previous years' gatherings. At the end of this period, we estimate that all potential adopting jurisdictions will have been identified, contacted and included in the quarterly status reports regularly provided to FDA. Reports will be in both tabular and graphic format to include detailed and summary information on the progress of Food Code adoptions, nationwide. Reports will be available on FDA's internet web-page and in other appropriate printed and electronic formats for ready access by any interested party.

A. 17. Displaying the OMB Approval Expiration Date

No exemption is requested.

A. 18. Exceptions to the Certification Statement of OMB Form 83.I

No exception is requested.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no collections of information employing statistical methods. The intention is to contact all local, State and tribal government agencies that have or may adopt the FDA Food Code.

ATTACHMENTS:

1. Questions for Food Code Adoption Survey
2. Authority(s) for Project:
 - a. 311(a) Public Health Service Act (42 U.S.C. 243) (assistance to States)
 - b. 21 CFR 5.10(a)(2) and (a)(4) (delegation of authority)
 - c. 31 U.S.C. 1535 (assistance to other federal agencies)

ATTACHMENT 1:

QUESTIONS FOR FOOD CODE SURVEY:

Date:

Jurisdiction & Address:

Name and Title of Respondent:

Phone:

Fax:

E-Mail:

1. Have you adopted a new food code applicable to retail food establishments since 1993?
2. If so, did you model your new food code after the FDA Food Code? If yes, which edition ('93, '95, '97, or '99)
3. Did you amend the food code as part of the adoption process? If yes, which specific areas the CDC-identified risk factor and interventions of the FDA Food Code were not adopted and which sections of the retail code were modified or added?
4. Do you have a side-by-side comparison of your food code with FDA's Food Code? If yes, please provide. If not, please identify any modifications to the FDA Food Code ('99 edition), relative to the CDC risk factors and Food Code interventions. (encourage response by e-mail or fax)

| | | |
|--|-------------------|-----------|
| State/Local/Tribal Modifications of the FDA Food Code: | | |
| Food Code Provision (99 Edition) | Code Modification | Rationale |
| | | |

5. If you adopted a version of the FDA Food Code, what barriers or obstacles did you encounter during the adoption process? If so, did this result in a failure to adopt certain elements of the FDA Food Code that you believe are essential? Please identify those.

6. Does your food code apply to all retail food establishments within your jurisdiction? If not, what types of establishments are excluded?
7. If your code does not apply to any of the following, please specify the agency that has jurisdiction and if possible, the name of a contact who can provide information about their system's retail food regulatory requirements:
 - a. schools
 - b. nursing homes
 - c. hospitals
 - d. day-care
 - e. bed & breakfast
 - f. mobile food vendors
 - g. temporary food establishments
8. Approximately how many retail food businesses are covered by your code?
9. Approximately how many populations are served by these businesses?
10. If you **have not** adopted a version of the FDA Food Code, are you in the process of adoption? If yes, what is your estimated time line for adoption?
11. Will your code be adopted as law or by rule-making (regulation) by your agency?
12. If you **have not** adopted a version of the FDA Food Code, have you done a comparison of your current code with the FDA Code? If yes, please provide a copy.

For State Officials only:

13. Does your code:
 - a. Automatically apply to all local jurisdictions within your state?
 - b. Apply to local jurisdictions as "minimum standards" only which the local agency is permitted to strengthen?
 - c. Not apply to local jurisdictions because they are autonomous within your state?
 - d. Apply to most local jurisdictions but not all since some are autonomous?
14. Do you have a list of all local jurisdictions within your state which are not automatically required to follow the state code? If yes, please provide names, addresses and phone numbers of key contact persons who can provide information about their system's retail food regulatory requirements.
15. If local jurisdictions in your state autonomously adopt their own codes, do you know the status of possible adoption of a new food code since 1993 in those jurisdictions? If so, do you have copies of those codes?
16. Does another agency in your state have authority over retail establishments to which your Food Code does not apply? If yes, please provide the name(s), phone numbers and addresses of key staff contacts at the other agency(s) who can provide information about their system's retail food regulatory requirements.

ATTACHMENT 2:

(DFSR/ORR to provide copies of the sections of respective statutes/regs listed on page 6)