**VOLUNTARY HAZARD ANALYSIS AND CRITICAL CONTROL POINT MANUALS FOR OPERATORS AND REGULATORS OF RETAIL AND FOOD SERVICE ESTABLISHMENTS**

**OMB No. 0910-0578**

**SUPPORTING STATEMENT**

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

FDA provides assistance to state, local, and tribal regulatory 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.

Hazard Analysis and Critical Control Point (HACCP) principles are designed to reduce the occurrence of foodborne illness risk factors through preventive controls. FDA has developed two manuals in an effort to assist state, local, and tribal regulatory jurisdictions and the retail and food service entities they regulate with reducing the occurrence of foodborne illness risk factors. "Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments" (Operator's Manual) (available at http://www.cfsan.fda.gov/~dms/hret2toc.html) provides operators of retail and food service establishments with a step-by-step scheme for designing and voluntarily implementing food safety management systems based on HACCP principles. "Managing Food Safety: A Regulator's Manual for Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems" (Regulator's Manual) (available at http://www.cfsan.fda.gov/~dms/hret3toc.html) provides state, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles to assist them with identifying and assessing control of foodborne illness risk factors.

We request OMB approval of the voluntary information collection provisions contained in the Operator's Manual and the Regulator's Manual.

### 2. Purpose and Use of the Information Collection

No information will be collected by or submitted to FDA or other Federal agencies. FDA will not inspect the records that operators and regulators keep pursuant to the practices discussed in the manuals. The Operator's Manual contains information and recommendations for operators of retail and foodservice establishments who wish to develop and implement a voluntary food safety management system based on Hazard Analysis and Critical Control Point (HACCP) principles. Operators may decide to incorporate some or all of the principles presented in the manual into their existing food safety management systems. The recordkeeping practices discussed in the manual are voluntary and may include documenting certain activities, such as monitoring and verification, which the operator may or may not deem necessary to ensure food safety. The manual includes

optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The Regulator's Manual contains recommendations for State, local, and tribal regulators on conducting risk-based inspections of retail and foodservice establishments, including recommendations about recordkeeping practices that can assist operators in preventing foodborne illness. These recommendations may lead to voluntary actions by operators based on consultation with regulators. For example, an operator may develop a risk control plan as an intervention strategy for controlling specific out-of-control foodborne illness risk factors identified during an inspection. Further, the manual contains recommendations to assist regulators when evaluating voluntary food safety management systems in retail and foodservice establishments. Such evaluations typically consist of the following two components: Validation (assessing whether the establishment's voluntary food safety management system is adequate to control food safety hazards) and verification (assessing whether the establishment is following its voluntary food safety management system). The manual includes a sample "Verification Inspection Checklist" to assist regulators when conducting verification inspections of establishments with voluntary food safety management systems.

Types of operator records discussed in the manuals and listed in the following burden estimates include: Food safety management systems (plans that delineate the formal procedures to follow to control all food safety hazards in an operation); risk control plans (HACCP-based, goal-oriented plans for achieving active managerial control over specific out-of-control foodborne illness risk factors); hazard analysis (written assessment of the significant food safety hazards associated with foods prepared in the establishment); prerequisite programs (written policies or procedures, including but not limited to, standard operating procedures, training protocols, and buyer specifications that address maintenance of basic operational and sanitation conditions); monitoring (records showing the observations or measurements that are made to help determine if critical limits are being met and maintained); corrective action (records indicating the activities that are completed whenever a critical limit is not met); ongoing verification (records showing the procedures that are followed to ensure that monitoring and other functions of the food safety management system are being implemented properly; and validation (records indicating that scientific and technical information is collected and evaluated to determine if the food safety management system, when properly implemented, effectively controls the hazards).

**3. Use of Improved Information Technology and Burden Reduction**

The manuals do not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by operators or regulators. Operators are free to use whatever forms of information technology may best assist them in voluntarily implementing food safety management systems based on HACCP principles. Regulators are free to use whatever forms of information technology may best assist them in conducting risk-based inspections based on HACCP principles.

**4. Efforts to Identify Duplication and Use of Similar Information**

To the best of FDA's knowledge, no other federal government agency is engaged in developing manuals to assist state, local, and tribal regulatory jurisdictions and the retail and food service

entities they regulate with reducing the occurrence of foodborne illness risk factors based on HACCP principles.

**5. Impact on Small Businesses or Other Small Entities**

Use of the manuals and information collection related to them is entirely voluntary on the part of both operators and regulators. The procedures in the manuals are no more burdensome for small businesses than for large. FDA provides information on the use of the manuals through routine national presentations and training courses.

**6. Consequences of Collecting the Information Less Frequently**

Although use of the manuals and the recordkeeping related to them is voluntary, operators and regulators who do not follow the recommendations in the manuals may not be employing all the tools necessary to achieve more effective control of foodborne illness risk factors.

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

There are no special circumstances involving this information collection.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of December 19, 2008 (73 FR 77721). No comments were received.

**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**

No information will be collected by or submitted to FDA. FDA will not inspect the records that operators and regulators keep pursuant to the practices discussed in the manuals. Thus, FDA is not responsible for the confidentiality of the information.

**11. Justification for Sensitive Questions**

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

## 12. Estimates of Annualized Burden Hours and Costs

All recommendations in both manuals are voluntary. For simplicity and to avoid duplicate estimates for operator recordkeeping practices that are discussed in both manuals, the burden for all collection of information recommendations for retail and foodservice operators are estimated together in table 1 of this document, regardless of the manual in which they appear. Collection of information recommendations for regulators in the Regulator's Manual are listed separately in table 2 of this document.

Description of Respondents: The likely respondents to this collection of information are operators and regulators of retail and foodservice establishments.

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

Table 1.--Estimated Annual Recordkeeping Burden for Operators[1]

| Types of Records | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| Prerequisite Program Records | 100,000[2] | 365 | 36,500,000 | 0.1 | 3,650,000 |
| Monitoring Records | 100,000[2] | 365 | 36,500,000 | 0.3 | 10,950,000 |
| Corrective Action Records | 100,000[2] | 365 | 36,500,000 | 0.1 | 3,650,000 |
| On-going Verification Records (includes calibration records) | 100,000[2] | 365 | 36,500,000 | 0.1 | 3,650,000 |
| Validation Records | 50,000[2] | 1 | 50,000 | 4 | 200,000 |
| Annual Burden[3]: | | | | | 22,100,000 |
| Risk Control Plan | 50,000 | 1 | 50,000 | 2 | 100,000 |
| Monitoring Records | 100,000 | 90 | 9,000,000 | 0.3 | 2,700,000 |
| Corrective Action Records | 100,000 | 90 | 9,000,000 | 0.1 | 900,000 |
| On-going Verification Records (includes calibration records) | 100,000 | 90 | 9,000,000 | 0.1 | 900,000 |
| Annual Burden[4] | | | | | 4,600,000 |
| Total Annual Burden for Operators | | | | | 26,700,000 |

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

[2] Annual burden.

[3] Burden for developing and implementing a food safety management system based on the Operator’s Manual.

[4] Annual burden for developing and implementing a risk control plan based on the Regulator’s Manual.

The burden for these activities may vary among retail and foodservice operators depending on the type and number of products involved, the complexity of an establishment's operation, the nature of the equipment or instruments required to monitor critical control points, and the extent to which an

operator uses the Operator's Manual and/or the Regulator's Manual. The estimate does not include collections of information that are a usual and customary part of an operator's normal activities. FDA has established as a goal to have 50,000 (1/2 of 1 percent) of the approximately one million U.S. retail and foodservice operators implement the recommendations outlined in the two manuals. This target figure is used in calculating the burden in tables 1 and 2 of this document because the agency lacks data on how to base an estimate of how many retail and foodservice establishments are likely to use one or more of the manuals to voluntarily implement a comprehensive food safety management system based on HACCP principles or a risk control plan for out-of-control processes identified during an inspection. FDA's estimate of the total number of retail and foodservice establishments is based on numbers obtained from the two major trade organizations representing these industries, the Food Marketing Institute and the National Restaurant Association, respectively.

The hour burden estimates in table 1 of this document for operators who follow the HACCP-based recommendations in the Operator's Manual are based on the estimated average annual information collection burden for mandatory HACCP rules, including seafood HACCP (60 FR 65096 at 65178, December 18, 1995) and juice HACCP (66 FR 6138 at 6202, January 19, 2001). FDA estimates that once the system is in place, the annual frequency of records is based on 365 operating days per year. Assuming there is one recordkeeper per shift of operation, the agency estimates that two recordkeepers per day would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the system. The agency further estimates that validation will be conducted once per year, based on menu or food list changes, changes in distributors, or changes in food preparation processes used. The validation will require a total of 4 labor hours.

The second set of estimates in table 1 of this document shows the annual burden for developing and implementing a risk control plan to control specific out-of-control foodborne illness risk factors identified during an inspection by a State, local, or tribal regulatory authority. If an operator decides to use a risk control plan as recommended in the Regulator's Manual, one person from the establishment is needed to work with the regulator to develop the written plan. FDA estimates that two recordkeepers per day (one recordkeeper for each shift) would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the risk control plan. The estimated duration of implementation for a risk control plan is 90 days, which is the minimum recommended time to achieve long-term behavior change.

Table 2.--Estimated Annual Recordkeeping Burden for Regulators[1]

| Types of Records | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|---|---|---|---|---|---|
| Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist) | 50,000 | 1 | 50,000 | 16 | 800,000 |
| Total Annual Burden for Regulators | | | | | 800,000 |

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

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

**13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers**

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

**14. Annualized Cost to Federal Government**

Since each retail and food service operator and/or regulator will collect their own information and use it for his or her own purpose, information relative to these manuals is not collected by FDA. Therefore, no FDA personnel or funding is required.

**15. Explanation for Program Changes or Adjustments**

There is no change in the burden estimate.

**16. Plans for Tabulation and Publication and Project Time Schedule**

The information obtained from this information collection will not be published.

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

Approval to not display the expiration date for OMB approval of the information collection is not being sought.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

n/a