

Voluntary Hazard Analysis and Critical Control Point (HACCP) Manuals for Operators and Regulators of Retail and Food Service Establishments

SUPPORTING STATEMENT 0910-0578

A. JUSTIFICATION

1. Circumstances Which Make This Information Collection Necessary

The Centers for Disease Control and Prevention (CDC) Surveillance Report for 1988 – 1992 identifies the most significant contributing factors to foodborne illness. Five of these broad categories of contributing factors directly relate to food safety concerns within retail and food service establishments and are collectively termed by the U.S. Food and Drug Administration (FDA) as “foodborne illness risk factors.” The five foodborne illness risk factors include: Food from Unsafe Sources, Inadequate Cooking Temperatures, Improper Holding Temperatures, Contaminated Equipment, and Poor Personal Hygiene.

Food safety is a priority action item of *Healthy People 2010*, the comprehensive, nationwide set of health promotion and disease prevention objectives designed to serve as a 10-year strategy for improving health in the United States. *Healthy People 2010* objectives include reducing infections caused by foodborne pathogens, reducing outbreaks caused by foodborne illness, and improving food employee behaviors and food preparation practices that directly relate to foodborne illnesses in retail and food service establishments. In response to these objectives, the FDA National Retail Food Steering Committee has established as a goal a 25% reduction in the occurrence of foodborne illness risk factors in institutional foodservice, restaurants, and retail food store facility types by October 1, 2010.

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, FDA has developed two manuals. 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) (Attachment 1). 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 (Attachment 2).

Hazard Analysis and Critical Control Point (HACCP) principles are designed to reduce the occurrence of foodborne illness risk factors through preventive controls. “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. For industry, the rationale for developing and implementing a food safety management system based on HACCP principles is to provide a system of preventive controls to ensure that final products are not contaminated with agents that could cause foodborne illness or injury. By voluntarily implementing food safety management systems, active managerial control - the purposeful incorporation of specific actions or procedures to attain control over foodborne illness risk factors - can be achieved. Any operator of retail or food service is encouraged to voluntarily utilize the methods and procedures presented in the manual. Operators may decide to incorporate some or all of the principles presented in the draft manual into their existing food safety management systems.

“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” (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. In addition, the manual details intervention strategies that can be developed with retail and food service operators to reduce the occurrence of foodborne illness risk factors. It also provides guidance for evaluating voluntarily-implemented food safety management systems if invited to do so by industry.

2. How, By Whom, and the Purpose for Collecting This Information

No information will be collected by FDA or other Federal agencies. The recordkeeping practices discussed in the draft 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 draft manual includes optional worksheets to assist operators in developing and validating a voluntary food safety management system.

The purpose of the information collection in the manuals is to provide a mechanism for industry to achieve active managerial control of foodborne illness risk factors. By maintaining records, operators and regulators of retail and food service establishments can ensure that monitoring, corrective action, and verification occur, which will in turn, provide control over foodborne illness risk factors.

The draft 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 draft 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 draft 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 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 Technology to Reduce the Burden on the Public

The collection of information does not involve the additional use of automated, electronic, mechanical, other technological collection techniques, or other forms of information technology.

4. Identification and Use of Duplicate Information

Since each retail and food service operator and/or regulator will collect their own information and use it for his or her own purpose, duplication with other sources does not apply.

5. FDA's Efforts to Reduce Burden on Small Business

Use of the manuals and information collection related to them is entirely voluntary. FDA will provide information on the use of the manuals through routine national presentations and training courses.

6. Impact of Not Collecting This Information or Collecting Information Less Frequently

Although the collection of information related to these manuals is voluntary, if information is not collected, operators and regulators may not be employing all the tools necessary to achieve more effective control of foodborne illness risk factors. If operators and regulators of the retail and food service establishment do not focus their efforts on integrating methods to properly identify, assess, and control foodborne illness risk factors, FDA's established goal of a 25% reduction in the occurrence of CDC-identified foodborne illness risk factors by October 1, 2010 would be impossible to achieve.

7. Special Circumstances That Occur When Collecting This Information

Use of the manuals and information collection related to them is entirely voluntary. There are no special circumstances that occur as a result of the voluntary information collection.

8. Identification of Outside FDA sources

In accordance with 5 CFR 1320.8(d), in the Federal Register of July 21, 2005 (70 FR 42072), FDA published a 60-day notice requesting public comment on the proposed information collection (Attachment 3). No comments were received in response. In addition, comments have already been received from the Conference for Food Protection (CFP) and have been incorporated into the draft documents. The CFP is composed of regulators, industry, academia, professional organizations, and consumers whose purpose is to identify problems, formulate recommendations, and develop and implement practices that relate to food safety. In 2004, CFP endorsed both draft manuals with a recommendation that industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs.

9. Payment or Gifts Offered to Respondents

No payments or gifts shall be provided to respondents of this information collection.

10. Method of Ensuring Respondent Confidentiality

Since information will be collected by retail and food service operators and regulators (not FDA) and used for their own purposes, respondent confidentiality on the part of FDA does not apply. The handling, storage, and disposition of any information collected in these manuals is governed by rules, regulations, and/or procedures in place in the industry or regulatory entity collecting the information.

11. Use of Sensitive Questions

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

12. Burden Hours Associated With This Information Collection

The likely respondents to this collection of information are operators and regulators of retail and food service establishments.

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, 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.

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

Table 1. -- Estimated Annual Recordkeeping Burden for Operators¹

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Food Safety Management System	50,000 ²	1	50,000	60	3,000,000
Hazard Analysis	50,000 ²	1	50,000	20	1,000,000
Prerequisite Program Records	100,000 ³	365	36,500,000	0.1	3,650,000
Monitoring Records	100,000 ³	365	36,500,000	0.3	10,950,000
Corrective Action Records	100,000 ³	365	36,500,000	0.1	3,650,000
On-going Verification Records (includes calibration records)	100,000 ³	365	36,500,000	0.1	3,650,000
Validation Records	50,000 ³	1	50,000	4	200,000
Total First Year Burden ⁴ :					26,100,000
Annual Burden ⁴ :					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	100,000	90	9,000,000	0.1	900,000

Action Records					
On-going Verification Records (includes calibration records)	100,000	90	9,000,000	0.1	900,000
Annual Burden ⁵					4,600,000
Total Annual Burden for Operators (Excluding First Year)					26,700,000

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

² First year burden only

³ Annual burden

⁴ Burden for developing and implementing a food safety management system based on the Operator's Manual

⁵ 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 food service 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%) of the approximately one million U.S. retail and food service operators implement the recommendations outlined in the two manuals. This target figure is used in calculating the burden in Tables 1 and 2 because the agency lacks data upon which to base an estimate of how many retail and food service 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 food service 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 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 6137 at 6202; January 19, 2001). FDA estimates that during the first year, 20 labor hours are needed to conduct the hazard analysis and 60 labor hours are needed to develop a food safety management system (HACCP plan). Once the system is in place, the annual frequency of records is based on 365 operating days per year. Assuming one recordkeeper per shift of operation, the agency estimates that two (2) 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, and will require a total of 4 labor hours.

The second set of estimates in Table 1 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 (2) 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 Regulators¹

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 food service 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 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. Annual Cost Estimate to Respondents.

There are no annual costs associated with this information collection.

14. Annual Cost Estimate to FDA.

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. Changes from Previous Approval.

This is a new collection; therefore, there are no changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

16. Publishing the Results of This Information Collection

The results of this information collection will not be published.

17. Reason for Not Displaying the OMB Approval Date.

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

18. Explanations to Section 19, "Certification for Paperwork Reduction Act Submissions"

No exceptions to the certification statement were identified.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The collection of information proposed in these draft manuals does not employ statistical methods; therefore, this section does not apply.

ATTACHMENTS

1. Section 311 of the Public Health Service Act (42 U.S.C. 243).
2. Sections 903(b)(2)(A) and (b)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)(A) and (b)(4)).
3. **Federal Register** notice published on July 21, 2005 [Docket No. 2005D-0274].