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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0274]

Draft Voluntary Hazard Analysis and Critical Control Point Manuals for Operators and Regulators of Retail and Food Service Establishments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two draft manuals entitled "Managing Food Safety: A Manual for the Voluntary Use of HACCP Principles for Operators of Food Service and Retail Establishments" (the "Operator's Manual") and "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" (the "Regulator's Manual"). The Operator's Manual presents FDA's best advice to retail and foodservice operators for voluntarily implementing food safety management systems based on hazard analysis and critical control point (HACCP) principles to reduce the occurrence of foodborne illness risk factors. The Regulator's Manual is intended to assist State, local, and tribal regulatory authorities in identifying and assessing control of foodborne illness risk factors during routine inspections of retail and foodservice establishments by providing a risk-based inspection methodology.

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

ADDRESSES: Submit written comments concerning the draft manuals and their 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 manuals and their recommendations for collection of information to *http://www.fda.gov/dockets/ecomments.* Submit written requests for single copies of the draft manuals to Margaret Boone, Center for Food Safety and Applied Nutrition (HFS–625), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1559. Send one self-adhesive address label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft manuals and received comments.

FOR FURTHER INFORMATION CONTACT: Alan Tart, Office of Regulatory Affairs, Southeast Regional Office, State Cooperative Programs (HFR–SE670), Food and Drug Administration, 60 8th St., NE., Atlanta, GA 30309, 404–253–1267.

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. Food safety management systems based on HACCP principles are designed to reduce the occurrence of these risk factors through preventive controls. For industry, the rationale for developing and implementing a food safety management system based on HACCP principles is to ensure that final products are not contaminated with agents that could cause foodborne illness or injury. In an effort to assist State, local, and tribal regulators and the retail and foodservice entities they regulate, FDA has developed two draft manuals for the voluntary use of HACCP principles in retail and foodservice establishments.

The Operator's Manual provides operators of retail and foodservice establishments with a step-by-step scheme for designing and voluntarily implementing food safety management systems based on HACCP principles. By voluntarily implementing food safety management systems, active managerial control of foodborne illness risk factors can be achieved. Any operator of a retail or foodservice establishment is encouraged to voluntarily utilize the methods and procedures presented in the draft manual.

The Regulator's Manual provides State, local, and tribal regulatory authorities with a step-by-step scheme for conducting risk-based inspections based on HACCP principles. In addition, the draft manual details intervention

strategies that can be developed with retail and foodservice operators to reduce the occurrence of foodborne illness risk factors. It also provides a methodology for evaluating voluntarily-implemented food safety management systems, if invited to do so, by retail or foodservice operators.

Comments received from the Conference for Food Protection (CFP) have been incorporated into the draft manuals. The CFP is composed of regulators, industry, academia, professional organizations, and consumers. Its 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 both industry and regulatory entities consider implementing the principles of the documents into their respective food safety programs.

The utilization of voluntary food safety management systems by industry, as well as the incorporation of a risk-based methodology into regulatory inspection programs, are important elements in reaching the goals established by the President's Council on Food Safety and also FDA 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 these topics: (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 HACCP Manuals for Operators and Regulators of Retail and Food Service Establishments

The draft 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 HACCP principles. Operators may decide to incorporate some or all of the principles presented in the draft manual into their existing food safety management systems. 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 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 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).

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 per 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
Ongoing 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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR OPERATORS[1]—Continued

Types of Records	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
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 Action Records	100,000	90	9,000,000	0.1	900,000
Ongoing 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 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. FDA seeks comments on this estimate.

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 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 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 per 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft manuals and their 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 manuals 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

An electronic version of these draft manuals is available on the Internet at *http://www.fda.gov/*.

Dated: 7/13/05
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Jeffrey Shuren,
Assistant Commissioner for Policy.

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