TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR sections/forms	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
361.1(c)(3)&(4); Form FDA 2914	69	1	69	1	69
361.1(c)(3); Form FDA 2915	48	10	480	3.5	1,680
361.1(d)(8)	10	5	50	0.5 (30 minutes)	25
Total					1,774

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
361.1(c)(2)	69	4	276	10	2,760
361.1(d)(5)	35	18	630	0.75 (45 minutes)	472.5
Total					3,232.5

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

Dated: January 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01463 Filed 1–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1432]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by February 26, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0609. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guide To Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables (OMB Control Number 0910–0609)—Extension

Fresh-cut fruits and vegetables are fruits and vegetables that have been processed by peeling, slicing, chopping, shredding, coring, trimming, or mashing, with or without washing or other treatment, prior to being packaged for consumption. The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the produce in transmitting foodborne illness. Factors such as the high degree of handling and mixing of the product, the release of cellular fluids during cutting or mashing, the high moisture content of the product, the absence of a step lethal to pathogens, and the potential for temperature abuse in the processing, storage, transport, and retail display all increase the potential for pathogens to survive and grow in fresh-cut produce.

Sections 301 and 402 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331 and 342) prohibits the distribution of adulterated food in interstate commerce. In response to the increased consumption of fresh-cut fruits and vegetables and the potential for foodborne illness associated with these products, we recognize the need for guidance specific to the processing of fresh-cut fruits and vegetables. The guidance document entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables,'' which is available at *http://www.fda.gov/FoodGuidances,* provides our recommendations to fresh-cut produce processors about how to avoid contamination of their product with pathogens. The guidance is in addition to the good manufacturing practice (GMP) regulations found in part 110 (21 CFR part 110). The guidance is intended to assist fresh-cut produce processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers and retail establishments in a ready-to-eat form. Accordingly, we encourage fresh-cut produce processors to adopt the general recommendations in the guidance and to tailor practices to their individual operations.

The guidance provides information and recommended procedures designed to help fresh-cut produce processors minimize microbial food safety hazards. The recommended procedures contained in the guidance are voluntary. Both FDA and fresh-cut produce processors will use and benefit from the information collected.

Two general recommendations in the guidance are for operators to develop and implement both a written Standard Operating Procedures (SOPs) plan and a Sanitary Standard Operation Procedures (SSOPs) plan. SOPs and SSOPs are important components to properly implement and monitor GMP, which are required for processed food operations under part 110. Other recommended programs that require documentation and recordkeeping are recall and traceback programs. In the event of a food safety concern, processors who adopt these recommended programs will be prepared to recall products from the marketplace or be able to traceback fresh produce to its source. Fresh-cut produce processors are also asked to consider the application of Hazards Analysis and Critical Control Point (HACCP) principles or comparable preventive control programs to the processing of fruits and vegetables. A HACCP system allows managers to assess the inherent risks and identify hazards attributable to a product or a process, and then determine the necessary steps to control the hazards. FDA, along with other Federal and State food Agencies and industry and food establishments, have found such preventive control programs, when properly designed and maintained by the establishment's personnel, to be valuable in managing the safety of food products.

In the **Federal Register** of November 20, 2013 (78 FR 69684), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two letters in response to the notice, with one containing multiple comments. Those comments outside the scope of the four collection of information topics on which the notice solicits comments are not discussed in this document.

One comment suggested that, to ensure the safety of consumers, FDA should mandate by law the recommendations in the guidance. The comment stated that the Food Safety Modernization Act (FSMA) gave FDA authority ''to require producers to implement prevention based food safety standards.'' In response, we note that Agency guidance documents are issued consistent with our good guidance practices regulations (GGPs) found at 21 CFR 10.115. Guidance documents represent our current thinking on a particular subject, but do not create or confer any rights for or on any person and do not operate to bind FDA or the public. The guidance document entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables'' discusses microbiological hazards presented by most fresh-cut fruits and vegetables and recommends control measures for such hazards in the processing of such produce. Firms are free to adopt as many or as few of the guidance's recommendations as they choose.

At the same time, we continue our rulemaking efforts under FSMA to build a food safety system for the future that makes modern, science-, and risk-based preventive controls the norm across all sectors of the food system. In the **Federal Register** of January 16, 2013 (78 FR 3504), we published a proposed rule proposing to establish science-based standards for growing, harvesting, packing, and holding produce on domestic and foreign farms. In the same issue of the **Federal Register**, we published another proposed rule proposing to amend our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it and to add requirements for domestic and foreign facilities that are required to register under the FD&C to establish and implement hazard analysis and risk-based preventive controls for human food (78 FR 3646).

One comment agreed, generally, that the information collection provisions of the guidance are necessary. Another comment agreed, generally, that our burden hour estimates are accurate, but suggested they did not take into account the financial cost of training required for the HACCP team. With regard to the latter comment, FDA notes that, although only an estimate of reporting and recordkeeping burden is included in **Federal Register** notices announcing agency information collection activities (5 CFR 1320.5(a)(1)(iv)), we have provided an estimate of the cost burden to industry in our supporting statement for this collection, which is available at *www.reginfo.gov.*

One comment suggested that we should require all processors in the fresh-cut industry to electronically upload their SOPs and SSOPs to an FDA Web site for review and audit. The comment maintained that such a system ''would reduce the amount of man hours spend [sic] collecting, reviewing, filing, auditing, and analyzing the written SOPs SSOPS [sic]. It would also make communication, education, and support readily available to the fresh-cut industry.'' Finally, one comment suggested that we should require the fresh-cut industry to use an automated system and standardized templates to scan and submit data to us for review. As an example, the comment referenced the system used by hospitals to submit information to a ''national healthcare regulator.'' The comment also noted the periodic scheduling of audits and inspections of hospitals by the regulator.

As previously discussed, the guidance document entitled ''Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables'' represents our current thinking on the microbiological hazards presented by most fresh-cut fruits and vegetables and provides recommended control measures to protect against these hazards. We may not impose requirements through Agency guidance.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
SOP and SSOP: Maintenance	122	3,315	404,430	0.067	27,097
Traceback development	10	1	10	20	200
Traceback maintenance	290	1	290	40	11,600
Preventive control program comparable to a HACCP system: System development	10	1	10	100	1,000
Preventive control program comparable to a HACCP system: System implementation	145	510	73,950	0.067	4,955
Preventive control program comparable to a HACCP system: Implementation review	145	4	580	4	2,320
Annual burden hours					47,172

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

A. Industry Profile

Estimates of the paperwork burden to the fresh-cut industry are based on information received from a fresh-cut processor who has developed and maintained these programs and information from a fresh-cut produce industry trade association. We estimate that there are 280 fresh-cut plants in operation and that approximately 10 new firms will enter the fresh cut industry over the next 3 years.

B. SOPs and SSOPs

We consider the guidance's recommendation to develop SOPs and SSOPs to be ''usual and customary'' for manufacturers and processors in the fresh-cut industry (see 5 CFR 1320.3(b)(2)). Therefore, we do not calculate this burden.

We recommend that facilities not only develop but also maintain SOPs and SSOPs. Of the 280 fresh-cut processors, we estimate that over half have SOP and SSOP maintenance programs in place. Therefore, for purposes of estimating the annual recordkeeping burden for SOP and SSOP maintenance programs, we assume that 40 percent of the existing processors, or 112 firms, and the 10 new firms do not have SOP and SSOP maintenance programs in place. We estimate the recordkeeping burden for SOP and SSOP maintenance programs by assuming that these 122 firms will choose to implement such a maintenance strategy as a result of the recommendations in the guidance.

A typical fresh-cut processing plant operates about 255 days per year. For an 8-hour shift, assuming the ingredients are received twice during that time, under the recommendations in the guidance, there would be about 13 records kept (2 for inspecting incoming ingredients; 2 for inspecting the facility and production areas once every 4 hours; 3 records for equipment (maintenance, sanitation, and visual inspections for defects); 1 for calibrating equipment; 2 temperature recording audits (1 time for each of the 2 processing runs); and 3 microbiological audits (ingredients, food contact surfaces, and equipment)). Therefore, the annual frequency of recordkeeping for SOPs and SSOPs is calculated to be 3,315 times (255 × 13) per year per firm; 122 firms will be performing these activities to generate a total 404,430 records (3,315 × 122) annually.

The total time to record observations for SOP and SSOP maintenance is estimated to take 4 minutes or 0.067 hours per record, and the number of records maintained is 404,430. Therefore, the total annual burden in hours for 122 processors to maintain their SOP and SSOP records is approximately 27,097 hours (404,430 × 0.067). The maintenance burden for these 122 firms is estimated in row 1 of table 1.

C. Recall and Traceback

The burden to develop a traceback program is a one-time activity estimated to take approximately 20 hours. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry in the next 3 years. We estimate that the 10 new firms will spend 20 hours each preparing a traceback program, for a total of 200 hours (10 × 20). The burden estimate of developing a traceback program is shown in row 2 of table 1.

Firms may test their traceback programs yearly to see if adjustments are needed to maintain traceback capabilities. Evaluating and updating traceback programs is estimated to take 40 hours to complete. The annual burden of maintaining a traceback program is estimated for the 280 existing firms in the industry plus the 10 firms new to the industry. Assuming that each firm completes this exercise once a year, the total maintenance burden of traceback programs is 11,600 hours yearly (290 × 40). This burden estimate is shown in row 3 of table 1.

The guidance refers to previously approved collections of information found in our regulations. The recommendations regarding establishing and maintaining a recall plan, as provided in 21 CFR 7.59, have been approved under OMB control number 0910–0249. Therefore, we are not calculating a paperwork burden for recall plans.

D. Preventative Control Program

Developing a HACCP plan is a one-time activity during the first year that is estimated to take 100 hours based on a trained HACCP team working on the plan full time. Accordingly, we only need to estimate the burden on the 10 new businesses expected to enter the industry in the next 3 years. We estimate that the 10 new firms will spend 100 hours each to develop their individual HACCP plans, for a total of 1,000 hours (10 × 100). This burden estimate is shown in row 4 of table 1.

After the HACCP plan is developed, the frequency for recordkeeping for implementing or maintaining daily records is estimated to be 510 records per year. The total time to record observations is estimated to take 4 minutes or 0.067 hours per record. Of the 280 existing firms, we estimate that approximately 135 firms have not implemented HACCP plans. We assume that these fresh-cut processors (135 existing firms plus 10 new firms) would voluntarily implement a HACCP plan. Therefore, the total annual records kept by 145 firms is 73,950 (510 × 145), and the total hours required are 4,955 (73,950 records × 0.067 hours per record = 4,954.65, rounded to 4,955). This annual burden is shown in row 5 of table 1.

Fresh-cut processors are presumed to review their HACCP plans four times per year (once per quarter). Estimating that it takes each of the 145 firms 4 hours per review each quarter, the total burden of this activity is 2,320 (145 × 4 × 4) hours per year. This annual burden is shown in row 6 of table 1.

Dated: January 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–01423 Filed 1–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–R–2012–N269; FXRS12610200000S3–134–FF02R06000]

Final Comprehensive Conservation Plans and Findings of No Significant Impacts for Environmental Assessments for Four Southwestern Refuges (Ozark Plateau and Wichita Mountains, OK; Buffalo Lake and Texas Mid-Coast, TX)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of four final comprehensive conservation plans (CCPs) and findings of no significant impacts (FONSIs) for the environmental assessments (EAs) for Buffalo Lake National Wildlife Refuge (NWR), Ozark Plateau NWR, Texas Mid-coast National Wildlife Refuge Complex (NWRC), and Wichita Mountains Wildlife Refuge (WR). Additionally, the Texas Mid-coast NWRC final CCP includes a final Land Protection Plan. In these final CCPs, we describe how we intend to manage these refuges for the next 15 years.

ADDRESSES: You will find the final CCPs and the EAs/FONSIs on the planning Web site, at *http://www.fws.gov/southwest/refuges/plan/plansinprogress.html.* Limited numbers of hard copies and CD–ROMs are available. You may request one by any of the following methods:

- *Email: jose_viramontes@fws.gov.* Include ''Final CCPs'' in the subject line of the message.
- *U.S. Mail:* USFWS–NWRS–Division of Strategic Planning and Policy, P.O. Box 1306, Albuquerque, NM 87102.

FOR FURTHER INFORMATION CONTACT: Jose Viramontes, Southwest Regional Chief, Division of Strategic Planning & Policy, National Wildlife Refuge System, 505–248–6473 or *jose_viramontes@fws.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

Buffalo Lake NWR

With this notice, we finalize the CCP process for Buffalo Lake NWR, which we began by publishing a notice of intent in the **Federal Register** (63 FR 33693) on June 19, 1998. For more about the initial process and the history of this refuge, see that notice. We released the draft CCP and EA to the public, announcing and requesting comments in a notice of availability (77 FR 65011) on October 24, 2012. The comment period ended on November 23, 2012. A summary of public comments and the agency responses is included in the final CCP.

Ozark Plateau NWR

With this notice, we finalize the CCP process for Ozark Plateau NWR, which we began by publishing a notice of intent in the **Federal Register** (63 FR 33693) on June 19, 1998. For more about the initial process and the history of this refuge, see that notice. We released the draft CCP and EA to the public, announcing and requesting comments in a notice of availability (78 FR 9410) on February 8, 2013. The comment period ended on March 8, 2013. A summary of public comments and the agency responses is included in the final CCP.

Texas Mid-Coast NWRC

With this notice, we finalize the CCP process for Texas Mid-coast NWRC, which we began by publishing a notice of intent in the **Federal Register** (74 FR 29714) on June 23, 2009. For more about the initial process and the history of this refuge, see that notice. We released the draft CCP and EA to the public, announcing and requesting comments in a notice of availability (77 FR 50523) on August 21, 2012. The comment period ended on September 20, 2012. A summary of public comments and the agency responses is included in the final CCP.

Wichita Mountains WR

With this notice, we finalize the CCP process for Wichita Mountains WR, which we began by publishing a notice of intent in the **Federal Register** (73 FR 65872) on November 5, 2008. For more about the initial process and the history of this refuge, see that notice. We released the draft CCP and EA to the public, announcing and requesting comments in a notice of availability (77 FR 47657) on August 9, 2012. The comment period ended on September 10, 2012. A summary of public comments and the agency responses is included in the final CCP.

Background

The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997 (16 U.S.C. 668dd–668ee) (Administration Act), requires us to develop a CCP for each national wildlife refuge. The purpose in developing a CCP is to provide refuge managers with a 15-year strategy for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System (NWRS), consistent with sound principles of fish and wildlife management, conservation, legal mandates, and Service policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation.

Each unit of the NWRS was established for specific purposes. We use these purposes as the foundation for developing and prioritizing the management goals and objectives for each refuge within the NWRS mission, and to determine how the public can use each refuge. The planning process is a way for us and the public to evaluate management goals and objectives that will ensure the best possible approach to wildlife, plant, and habitat conservation, while providing for wildlife-dependent recreation opportunities that are compatible with each refuge's establishing purposes and the mission of the NWRS.

Additional Information

For each refuge, the final CCP includes detailed information about the refuge unit itself, the planning process, issues, and the management alternative selected. The Web site also includes the EAs and FONSIs, prepared in accordance with the National Environmental Policy Act (NEPA) (43 U.S.C. 4321 *et seq.*). Each EA/FONSI includes a discussion of alternatives for refuge management options. The Service's selected alternatives are reflected in the final CCP for each refuge.

Selected Alternatives for Each Refuge

The selected alternative in each of the CCPs best meets the vision for the future for that refuge; the purposes for which the refuge was established; and the habitat, wildlife, and visitor services