**ADDRESSES:** Submit electronic comments on the collection of information to: *Alice-Lynn.Ryssman@acl.hhs.gov.* Submit written comments on the collection of information to Alice-Lynn Ryssman, U.S. Administration for Community Living, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Alice-Lynn Ryssman, 202–357–3491.

**SUPPLEMENTARY INFORMATION:** Under 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 request 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility; (2) the accuracy of ACL'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.

The OAA Title III–E National Family Caregiver Support Program (NFCSP), with statutory authority contained in Title III sections 302, 372, and 373 of the Older Americans Act (OAA) (42 U.S.C. 3032), as amended by the Older Americans Act Amendments of 2006, *Pub. L. 109–365),* funds a range of comprehensive home- and community-based services supports that assist family and informal caregivers to care for their loved ones at home for as long as possible. ACL is directed under 206(a) of the OAA to conduct evaluations of OAA programs. Thus, this data collection will conduct an evaluation of the NFCSP to fulfill this requirement and understand how well this program is meeting its goals and mission.

The evaluation design is comprised of two primary components:

1. A process study, which examines the strategies, activities, and resources of the program at each level of the Aging Network—State Unit on Aging (SUA), Area Agency on Aging (AAA), and Local Service Provider (LSP); and

2. A client outcome study, which examines the health and social effects of the program on participants compared to non-participants. This study examines the health and social effects on caregivers and also tracks the health outcomes of the care recipients.

The process study will include all 56 SUAs, all of the AAAs (N = 618), a sample of local service providers (N = 1,000), and a sample of program participants (1,250) and non-participants (N = 1,250). The table below provides the information ACL used to estimate the burden of this collection of information:

| Respondent type | Number of respondents | Responses per respondent | Average burden per response (hrs.) | Total average annual burden (hrs.) |
|---|---|---|---|---|
| All SUAs | 56 | 1 | 1.5 | 84 |
| All AAAs | 618 | 1 | 2 | 1236 |
| Stratified sample of LSPs | 1,000 | 1 | 0.33 | 330 |
| Family caregivers participating in NFCSP | 1,250 | 3 | 0.58 | 2175 |
| Family caregivers not participating in NFCSP | 1,250 | 3 | 0.58 | 2175 |
| Total | 4,174 | | | 6,000 |

The proposed data collection tools may be found on the ACL Web site at *http://www.aoa.gov/AoARoot/Program_Results/Program_survey.aspx.*

Dated: November 15, 2013.

**Kathy Greenlee,**

*Administrator and Assistant Secretary for Aging.*

[FR Doc. 2013–27822 Filed 11–19–13; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1432]**

### Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the information collection provisions in the guidance document entitled ''Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables.''

**DATES:** Submit either electronic or written comments on the collection of information by January 21, 2014.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written

comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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:** Under 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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our 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.

**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 (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 (SOP) plan and a Sanitary Standard Operation Procedures (SSOP) 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. An 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.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity | No. of recordkeepers | No. 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 an HACCP system: System development | 10 | 1 | 10 | 100 | 1,000 |
| Preventive control program comparable to an HACCP system: System implementation | 145 | 510 | 73,950 | 0.067 | 4,955 |

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

| Activity | No. of recordkeepers | No. of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Preventive control program comparable to an 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 × 22) 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 x 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 an 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 x 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 an 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: November 14, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–27782 Filed 11–19–13; 8:45 am]

**BILLING CODE 4160–01–P**