

# **Guide to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables**

**0910-0609**

## **SUPPORTING STATEMENT**

**Terms of Clearance:** None.

### **A. Justification**

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

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 enhance 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) 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, the Food and Drug Administration (FDA) recognizes 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 FDA’s recommendations to fresh-cut produce processors about how to avoid contamination of their product with pathogens. This guidance is in addition to the good manufacturing practices (GMPs) provided in part 110 of FDA’s regulations (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, FDA encourages fresh-cut produce processors to adopt the general recommendations in the guidance and to tailor practices to their individual operations.

FDA requests extension of OMB approval of the information collection provisions contained in the guidance document entitled, “Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables.”

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

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 GMPs that are required for processed food operations under part 110.

Other recommended programs that require documentation and record keeping 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 market place or be able to trace back 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. FDA, other Federal and state food agencies, 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.

*Description of Respondents:* The respondents to this information collection are processors of fresh-cut fruits and vegetables. Respondents are from the private sector (for-profit businesses).

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

The guidance does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by fresh-cut produce processors. Companies are free to use whatever forms of information technology may best assist them in voluntarily developing recordkeeping as recommended in the guidance. Many of the observations recommended are amenable to modern data acquisition and processing technology. The agency encourages the application of information technology for monitoring and recordkeeping operations to minimize the paperwork burden and labor costs, and also to enhance the organization of records and to facilitate their retrieval. The agency estimates that about twenty five percent (25%) of the responses would be collected electronically.

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

As this is a guidance document, no firm is required by regulation to develop or maintain any of the suggested strategies for pathogen mitigation, except, as noted above, SOPs and SSOPs, which are important components to GMPs required for processed food operations under part 110. It is likely that many existing fresh-cut produce processors already follow the strategies suggested in the guidance document. FDA expects that firms new to this industry are the most likely to benefit from this fresh-cut produce guidance. There should be no duplicative information collection as a result of this guidance.

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

FDA estimates that some of the fresh-cut produce processing firms (twenty-five percent (25%)) are small businesses, and has kept their particular needs in mind throughout the development of this guidance document. Estimates of the paperwork burden associated with the guidance are based on FDA's voluntary, working relationship with a fresh-cut produce processor who has developed and maintained standards as recommended in the guidance and are also based on the agency's

relationship with the fresh-cut produce industry trade association. The burden for activities recommended in the guide has been estimated using typical fresh-cut produce processing firms as a model. There is no known way to reduce the burdens on a small business wishing to implement the recommended procedures to minimize microbial food safety hazards. FDA notes, however, that the recommended procedures contained in the guidance are voluntary. FDA aids small businesses in complying with its recommendations through the agency's Regional Small Business Representatives and through the administrative and scientific staffs within the agency. FDA has provided a Small Business Guide on the agency's website at <http://www.fda.gov/oc/industry/>.

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

Data collection occurs daily. The recommended procedures contained in the guidance represent the current thinking of FDA on a number of food safety hazards and management practices common to the processing of most fresh-cut fruits and vegetables. Less frequent information collection would decrease the ability of firms to minimize microbial food safety hazards through the identification of trends, documentation of procedures, and corrective actions. The agency would not "collect" records or plans as a routine matter. Records would remain on file at each processing facility and would be examined there periodically by the agency.

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

There are no special circumstances associated with this collection of information.

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

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

(Comment 1) 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 the authority "to require producers to implement prevention based food safety standards."

(Response) As is the case with all of FDA's guidance documents, per our good guidance practices regulations (GGPs), the guidance represents our current thinking on the microbiological hazards presented by most fresh-cut fruits and vegetables and the recommended control measures for such hazards in the processing of such produce. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public, thus, this guidance cannot impose mandatory requirements. Firms are free to adopt as many or as few of the guidance's recommendations as they choose.

In contrast, failure to comply with our regulations may be cited during an FDA plant inspection and could lead to an enforcement action. The provisions are discussed in the guidance to show the operation of a comprehensive approach to minimizing microbial food hazards.

We have taken action under FSMA. 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 modernize our regulation for CGMPs In Manufacturing, Packing, or Holding Human Food and to add requirements for domestic and foreign facilities that must register under the FD&C to establish and implement hazard analysis and risk-based preventive controls for human food (78 FR 3646). The proposed rules are intended 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.

(Comment 2) One comment agreed, generally, that the information collection provisions of the guidance are necessary.

(Response) We agree that the information collection provisions are necessary. With 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 is intended to help 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.

(Comment 3) Another comment agreed, generally, that our burden hour estimates are accurate but argued that the time estimates did not take into account the financial cost of the training required for the HACCP team.

(Response) We agree that the burden hour estimates are accurate. However, we disagree with the comment's suggestion that the financial cost of training for the HACCP team should be included in the burden hour estimates. Per OMB's implementing regulations (5 CFR 1320.5(a)(1)(iv), only an estimate of a recordkeeping hour burden is published in the Federal Register notice. However, we report our estimate of the cost burden to industry in the Supporting Statement that we submit to OMB, which is available on the website for OMB's Office of Information and Regulatory Affairs (<http://www.reginfo.gov>).

(Comment 4) One comment suggested that we should require all processors in the fresh-cut industry to electronically upload their SOPs and SSOPs to an FDA website for review and audit. Another comment suggested that we require the fresh-cut industry to use an automated system and standardized templates to scan and submit data to us for review.

(Response) The November 20, 2013 notice requested public comment on the proposed extension of OMB approval of the information collection provisions of the existing guidance document. The changes sought by these comments would require us to engage in rulemaking. Consequently, the comments' request goes beyond the scope of the existing guidance and the scope of the four collection of information topics on which the notice sought comments.

## **9. Explanation of Any Payment or Gift to Respondents**

FDA does not provide any payment or gift to respondents.

## 10. Assurance of Confidentiality Provided to Respondents

Company records describing manufacturing procedures, which may be consulted during FDA plant inspections, and any SOPs, SSOPs, testing, auditing, or HACCP records that the agency may copy or take possession of, such as in the event of a traceback or recall, often contain trade secret and confidential commercial information. Confidential commercial information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), by Section 301(j) of the FD&C Act, and by part 20 of the agency’s regulations (21 CFR part 20).

## 11. Justification for Sensitive Questions

This information collection does not involve questions that are of a personally sensitive nature.

## 12. Estimates of Annualized Burden Hours and Costs

*Description of Respondents:* The respondents to this information collection are processors of fresh-cut fruits and vegetables. Respondents are from the private sector (for-profit businesses).

### 12 a. Annualized Hour Burden Estimate

FDA’s fresh-cut guidance represents the agency’s recommendations to industry based on the current state of science. Following the recommendations set forth in the fresh-cut guidance is the choice of each individual fresh-cut operation, plant, or processor. FDA estimates the burden of this guidance on industry by assuming that those in the fresh-cut industry who do not currently follow the recommendations put forth in the guidance will find it of value to do so. Therefore, the estimates of the burden associated with the issuance of this guidance represent the upper bound estimate of burden, the burden if every fresh-cut plant, processor, or operation that does not follow the recommendations of the guidance should choose to do so.

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

Table 1.--Estimated Annual Recordkeeping Burden <sup>1</sup>					
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 <sup>2</sup>	10	1	10	20	200
Traceback Maintenance	290	1	290	40	11,600
Preventive control program comparable to a HACCP system: System development <sup>2</sup>	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	145	4	580	4	2,320

system: Implementation review					
Annual burden hours					47,172

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

### 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 three years.

### 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); one 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 x 13) per year per firm; 122 firms will be performing these activities to generate a total 404,430 records (3,315 x 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 x 0.067). The maintenance burden for these 122 firms is estimated in row 1 of Table 1.

### 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 three years. We estimate that the 10 new firms will spend 20 hours each preparing a traceback program, for a total of 200 hours (10 x 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.

#### 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 three 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 a HACCP plan. Therefore, the total annual records kept by 145 firms is 73,950 (510 x 145), and the total hours required are 4,955 (73,950 records x 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 x 4 x 4) hours per year. This annual burden is shown in row 6 of Table 1.

### **12 b. Annualized Cost Burden Estimate**

FDA estimates that the average hourly wage for respondents' workers involved in recordkeeping is equivalent to a GS-5/Step-1 level in the locality pay area of Washington-Baltimore in 2014, approximately \$16.49 per hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be \$32.98 per hour. The overall estimated cost incurred by the respondents is \$1,555,733 (47,172 burden hours x \$32.98/hr = \$1,555,732.56, rounded to \$1,555,733).

### **13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs**

There are no capital, start-up, operating, or maintenance costs associated with this collection.

**14. Annualized Cost to the Federal Government**

FDA's review of the retained records would generally occur as part of its routine or for cause establishment inspection activities. FDA estimates that its review of the retained records would take five hours per inspection. FDA estimates the hourly cost for review and evaluation to be \$43.09 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2014. To account for overhead, this cost is increased by 100 percent, making the total cost \$86.18 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be \$430.90 per review ( $\$86.18/\text{hour} \times 5 \text{ hours}$ ). FDA estimates that it reviews records for an average of 100 inspections per year. Thus, FDA estimates that the total annual cost to the Federal Government would be \$43090 ( $\$430.90 \times 100 \text{ inspections}$ ).

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

The hour burden is unchanged.

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

The agency has no plans for publication of information from this information collection.

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

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

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

There are no exceptions to the certification.