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

OMB Control No. 0910-0609

SUPPORTING STATEMENT

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.

The Federal Food, Drug, and Cosmetic Act (the act) prohibits the distribution of adulterated food in interstate commerce (21 U.S.C. 331 and 342). 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 implemented and monitored 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, which might be implicated in a foodborne illness outbreak, 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 accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 11, 2010 (75 FR 48692). FDA received no 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 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

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[1]

Activity	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
SOP and SSOP: Maintenance	122	3,315	404,430	0.067	27,097
Traceback Development[2]	10	1	10	20	200
Traceback Maintenance	290	1	290	40	11,600
Preventive control program comparable to a HACCP system: System development[2]	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.

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. Because of the small number of fresh-cut processors, the agency is able to extrapolate data from industry programs to calculate the total estimated upper bound burdens (see table 1 of this document).

The burden to industry of developing and maintaining the activities recommended in FDA's fresh-cut guidance will vary considerably among fresh-cut processors, depending on the type and number of products involved, the sophistication of the equipment or instruments (e.g., those that automatically monitor and record food safety controls), and the type of controls monitored under any individual preventive control program, such as critical control points (CCPs) monitored under a HACCP program.

In 2007, FDA estimated that there were 250 fresh-cut plants in operation in the United States, and that approximately 10 new firms enter the fresh cut industry each year (72 FR 11364, at 11366). Using these figures, we estimate that in 2010 there are 280 fresh-cut plants in operation and that approximately 10 new firms will enter the fresh cut industry each year, over the next three years. Many of the existing firms in the fresh-cut industry already make use of current good manufacturing practices-related, recall, HACCP, and other activities. FDA estimates that the burden of this fresh-cut guidance will fall on both existing and new firms entering the industry who may follow the recommendations in the guidance.

SOPs and SSOPs

Two general recommendations in this guidance are for operators to develop and implement both a written SOPs plan and a written SSOPs plan. SOPs describe in writing the performance of the day-to-day operations of a processing plant. Examples of activities that would fall under SOPs would be developing written specifications for agricultural inputs, ingredients, and packaging materials; production steps for the processing and packaging operations; instructions for packaging and storage activities; and procedures for equipment maintenance, calibration, and replacement and facility maintenance and upkeep; and maintaining SOP records on product processing and distribution activities.

SSOPs provide written instructions or procedures for sanitary practices developed for each specific sanitation activity in and around the facility. Sanitation activities include procedures for cleaning equipment, food-contact surfaces and plant facilities; chemical use and storage; cleaning equipment maintenance, use, and storage; pest control; and maintaining SSOP records for the activities. From communication with the fresh-cut industry, we know that existing fresh-cut processors already have developed SOPs and SSOPs. We therefore consider the development of SOPs and SSOPs to be "usual and customary" for manufacturers and processors in the fresh-cut industry (see 5 CFR 1320.3(b)(2)). Thus, we do not calculate this burden for existing firms or new firms entering this industry.

FDA recommends that facilities not only develop but also maintain SOPs and SSOPs. Implementation and maintenance of SOPs and SSOPs include maintaining daily records for each of the firm's operational days for the following activities: Inspection of incoming ingredients, such as the fresh produce and packaging material; facility and production sanitation inspections; equipment maintenance, sanitation, and visual safety inspections; equipment calibration, e.g., checking pH meters; facility and premises pest control audits; temperature controls during processing and in storage areas; and audits of ingredients, food contact surfaces, and equipment for microbiological contamination. Of the 280 fresh-cut processors, we estimate that well 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, the agency assumed 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. FDA estimates 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 this fresh-cut guidance document.

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, assuming all firms choose to follow the recommendations on keeping records.

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, along with the annual maintenance burden of audits or testing, is estimated in row 1 of table 1 of this document. Again, these figures assume that all firms choose to follow the recommendations on recording observations.

Recall and Traceback

We recommend that fresh-cut processors establish and maintain written traceback procedures to respond to food safety hazard problems when they arise and establish and maintain a written contingency plan for use in initiating and effecting a recall. In order to facilitate tracebacks and recalls, we recommend that processors establish a program that documents and tracks fresh-cut products back to the source of their raw ingredients, and keep records of product identity and specifications, the product in inventory, and where, when, to whom, and how much of the product is shipped.

Traceback programs are used for those times when a food safety problem has been identified or a product has been implicated in a foodborne illness outbreak. The burden to develop a traceback program is a one-time activity estimated to take approximately 20 hours. In 2007, we previously estimated that firms in the industry would choose to begin a traceback program after the guidance was made available and estimated that the 250 existing fresh cut firms and the 10 new businesses expected to enter the industry annually from 2007 to 2010 would spend 5,200 hours (250 x 20) on this activity. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry annually 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 x 20). The burden estimate of developing a traceback program is shown in row 2 of table 1 of this document.

Traceback program adjustments or revisions may, or may not, be needed annually. 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 that may decide to implement this type of program. 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 of this document.

This fresh-cut guidance refers to previously approved collections of information found in FDA regulations. The recommendations in this document regarding establishing and maintaining a recall plan, as provided in 21 CFR 7.59, have been approved under OMB control number 0910–0249. Therefore, FDA is not calculating a new paperwork burden for recall plans.

Preventative Control Program

When properly designed and maintained by the establishment's personnel, a preventive control program is a valuable program for managing the safety of food products. A common preventive control program used by the fresh-cut industry is a HACCP system. 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. Monitoring and verification steps, which include recordkeeping, are included in the HACCP system to ensure that potential risks are controlled. We use HACCP as an example of a preventive control program that a firm may choose based on the recommendations in the guidance to estimate the burden of developing, implementing, and reviewing a preventive control program.

FDA estimated the paperwork burden of developing and implementing a HACCP plan based on a plan with two CCPs. The number of CCPs may vary depending on how the processor chooses to identify the CCPs for a particular operation. Developing a HACCP plan is a one-time activity that is estimated to take 100 hours based on a trained HACCP team working on the plan full time. The HACCP team identifies the CCPs and measures needed to control them, and then identifies the approach needed to verify the effectiveness of the controls. During this plan development period, the firm chooses the records to be kept and information and observations to be recorded. This is a one-time process during the first year.

In 2007, we previously estimated that, of the estimated 250 fresh-cut processors, approximately 50 percent of the firms already have HACCP plans in place. We therefore assumed that the remaining fresh-cut processors (125 existing firms plus the 10 new firms), would voluntarily develop a HACCP plan, and estimated that 135 processors would spend 13,500 hours (135 x 100) to develop their individual HACCP plans. Accordingly, we only need to estimate the burden of this one-time activity on the 10 new businesses expected to enter the industry annually 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 of this document.

After the HACCP plan is developed, the frequency for recordkeeping for implementing or maintaining daily records is estimated to be 510 records per year. (This is based on a firm choosing to maintain daily records for 2 CCPs for one 8–hour shift per day for each of the estimated 255 operational days per year.) The total time to record observations for the CCPs was estimated to take 4 minutes or 0.067 hours per record. Therefore, the total annual records kept by 145 firms (the 135 firms plus the 10 new businesses expected to enter the industry) 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 of this document.

After the HACCP plan has been developed and implemented, we recommend that the plan is reviewed regularly to ensure that it is working properly. Fresh-cut processors are estimated to review their HACCP plans four times per year (once per quarter). Assuming that it takes each of the 145 firms 4 hours per review each quarter, the total burden of this activity, for firms that choose to review their plans annually, is 2,320 (145 x 4 x 4) hours per year. This annual burden is shown in row 6 of table 1 of this document.

12 b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage for respondents' workers involved in recordkeeping is equivalent to a GS-5-1 level in the locality pay area of Washington-Baltimore in 2010, approximately $16.33 per hour. Doubling this wage to account for overhead costs, FDA estimates the average hourly cost to respondents to be $32.66 per hour. The overall estimated cost incurred by the respondents is $1,540,638 (47,172 burden hours x $32.66/hr = $1,540,637.50, rounded to $1,540,638).

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 $42.66 per hour, the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2010. To account for overhead, this cost is increased by 100 percent, making the total cost $85.32 per hour. Thus, FDA estimates the cost to the Federal Government for the review of records to be $426.60 per review ($85.32/hour x 5 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 $42,660 ($426.60 x 100 inspections).

15. Explanation for Program Changes or Adjustments

FDA estimates that the total annual burden has decreased from 47,838 hours to 47,172 hours (a reduction of 666 hours). This adjustment is the net result of 1) removing 6,233 one-time burden hours associated with the issuance of the new guidance document, and 2) increasing the number of respondent recordkeepers to reflect the growth of industry in the last three years, which adds 5,567 hours, a net decrease of 666 hours.

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.