Supporting Statement

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

A. Justification

1. Circumstances Necessitating Information Collection

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) (Attachments A and B). 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 Food Safety Hazards for Fresh-cut Fruits and Vegetables," 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 designed to help fresh-cut produce processors minimize 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 is requesting OMB approval of the voluntary information collection provisions contained in the guidance document entitled, "Guide to Minimize Food Safety Hazards for Fresh-cut Fruits and Vegetables."

2. How, by Whom, Purpose of Collection

This is a new 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 Good Manufacturing Practices (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.

3. Consideration Given to Information Technology

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. 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.

4. Identification of Duplicative 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. Small Businesses

FDA recognizes that some of fresh-cut produce processing firms 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.

6. **Less Frequent Information Collection**

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.

7. Information Collection Circumstances

The recommended procedures contained in the guidance do not involve submission of information to the agency, written responses to the agency, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA, or require the disclosure of trade secrets or other confidential information.

8. Consultations with Persons Outside FDA

In the Federal Register of March 6, 2006 (71 FR 11209), FDA published a Notice of Availability of the draft guidance document with a 60-day notice requesting public comment on the collection of information provisions. FDA received a number of comments on the draft guidance but received no comments regarding the information collection provisions.

9. Payment or Gift

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality Provisions

Company records describing manufacturing procedures may be consulted during FDA plant inspections. 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, would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Privacy

This information collection does not involve any questions of a sensitive nature.

12. Burden of Information Collection

FDA estimates the burden of the collection of information described in the above programs as follows:

Table 1--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	Annual Frequency of Record Keeping	Total Annual Records	Hours per Record	Total Hours
SOP & SSOP: Maintenance	110	3,315	364,650	0.067	24,432
Traceback Development[2]	260	1	260	20	5,200
Traceback Maintenance	260	1	260	40	10,400
Preventative control program comparable to a HACCP system: System development[3]	135	1	135	100	13,500
Preventive control program comparable to a HACCP system: System implementation	135	510	68,850	0.067	4,613
Preventive control program comparable to a HACCP system: Implementation review	135	4	540	4	2,160
First Year Activity (one-time burden)					18,700
On-going Burden					41,605
Total Annual Estimated Recordkeeping Burden					60,305

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

[2] First year activity (one-time burden): the No. of Recordkeepers annualized over a three-year period is 86.66. The total first year activity for “traceback development” totals 1,733.

[3] First year activity (one-time burden): the No. of Recordkeepers annualized over a three-year period is 45. The total first year activity for “preventative control program comparable to a HACCP system: system development” totals 4,500.

Industry Profile

Estimates of the paperwork burden to the fresh-cut produce processing industry that may result from the publication of FDA's guidance document are based on information from FDA's relationship with a fresh-cut produce processor who has developed and maintained these programs and information from the fresh-cut produce industry trade association. Because of the small number of fresh-cut produce processors, the agency is able to extrapolate data from industry programs to calculate the total estimated upper bound burdens that may result from the issuance of this guidance (see Table 1).

The burden to industry of developing and maintaining the activities recommended in FDA's fresh-cut produce guidance will vary considerably among fresh-cut produce 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 monitored under a HACCP program.

Currently, the fresh-cut produce industry trade association estimates that there are 250 fresh-cut produce processing plants in operation in the U.S. While most of the recent growth in the fresh-cut produce industry has been due to mergers between already existing firms, there are approximately 50 fresh-cut produce plants that did not exist in 2001. This implies that about 10 new firms are entering the fresh-cut produce industry each year. Many of the existing firms in the fresh-cut produce industry already make use of CGMP-related, traceback, HACCP, and other activities. Therefore, FDA estimates that most of the burden of this guidance will fall on the new firms entering the industry who may use this guidance as a way to solidify their business practices.

SOPs and SSOPs

Two general recommendations in this guidance are for operators to develop and implement both a written Standard Operating Procedures (SOPs) plan and a written Sanitary Standard Operation Procedures (SSOPs) plan. SOPs and SSOPs are important components to properly implemented and monitored Current Good Manufacturing Practices (CGMPs), which are found in 21 CFR 110.

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; procedures for equipment maintenance, calibration, and replacement; 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 produce industry, we know that existing fresh-cut produce processors already have developed SOPs and SSOPs. Therefore, we 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)). This 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 250 fresh-cut produce processors, the fresh-cut produce industry trade association estimates that well over half have SOP and SSOP maintenance programs in place. Therefore, for purposes of estimating the annual record keeping burden for SOP and SSOP maintenance, the agency assumed that 40 percent of the existing processors, or 100 firms, and the 10 new firms do not have SOP and SSOP maintenance in place. FDA estimates the recordkeeping burden for SOP and SSOP maintenance by assuming that these 110 firms will choose to implement such a maintenance strategy as a result of the issuance of this 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 draft guidance, there would be about 13 records kept (two for inspecting incoming ingredients; two for inspecting the facility and production areas once every 4 hours; three records for equipment (maintenance, sanitation, and visual inspections for defects); one for calibrating equipment; two temperature recording audits (one time for each of the two processing runs); and three 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; 110 firms will be performing these activities to generate a total 364,650 records (3,315 x 110) 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 four minutes or 0.067 hours per record, and the number of records maintained is 364,650. Therefore, the total annual burden in hours for 110 processors to maintain their SOP and SSOP records is approximately 24,432 hours. The maintenance burden for these 110 firms, along with the annual maintenance burden of audits or testing, is estimated in row 3 of Table 1. 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. Firms in the industry may choose to begin a traceback program after this guidance is made available. The total annual estimated burden for this activity for the 250 existing fresh cut firms and the 10 new businesses expected to enter the industry annually is 5,200 hours. 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 250 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 10,400 hours yearly. This burden estimate is shown in row 3 of table 1 of this document.

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

Preventive 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 Hazards Analysis and Critical Control Point (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 draft

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. Of the estimated 250 fresh-cut processors, the fresh-cut industry estimates that approximately 50 percent of the firms already have HACCP plans in place. Therefore, assuming that the remaining fresh-cut processors voluntarily decide to develop a HACCP plan, 125 existing firms plus the 10 new firms, will develop a HACCP plan.

Developing a HACCP plan is a onetime 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. Therefore, the total time for 135 processors to develop their individual HACCP plans is approximately 13,500 hours. This onetime burden 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 two 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 the 135 firms choosing to implement the HACCP plan is 68,850, and the ‘‘Total Hours’’ required are 4,613. 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 135 firms 4 hours per review each quarter, the total burden of this activity, for firms that choose to review their plans annually, is 2,160 hours per year. This annual burden is shown in row 6 of table 1 of this document.

FDA estimates the burden of the collection of information described in the previous paragraphs as follows: Summing the ‘‘Total Hours’’ column, the estimated one-time recordkeeping burden for firms that choose to follow the recommendations is 18,700 hours; the annual burden for firms, existing and new, is estimated to be 41,605 hours. The total annual estimated recordkeeping burden is 60,305.

13. Cost to Respondents

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

14. Annualized Cost to the Federal Government

There are no annualized costs to the Federal Government as a result of this guidance.

15. Reason for Change

This is a new collection. The new burden hours result from the recommendation that fresh-cut produce processors develop and implement written procedures designed to minimize microbial food safety hazards.

16. Statistical Reporting

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

17. Display of OMB Approval Date

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", of OMB Form 83-I

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.