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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0079]

Draft Guidance for Industry: Guide to Minimize Food Safety Hazards of Fresh-Cut Fruits and Vegetables; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables" (the draft fresh-cut guidance). This document complements FDA's current good manufacturing practices (CGMP) regulations by providing specific guidance on the processing of fresh-cut produce. The draft fresh-cut guidance and the CGMP regulations are intended to assist processors in minimizing microbial food safety hazards common to the processing of most fresh-cut fruits and vegetables sold to consumers in a ready-to-eat form.

DATES: Submit written or electronic comments on the draft guidance and the collection of information provisions by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables" to the Office of Plant and Dairy Foods (HFS–306), Center for Food Safety and Applied Nutrition, 5100 Paint

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Branch Pkwy., College Park, MD 20740, 301–436–1400, FAX: 301–436–2651. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance. A copy of the draft guidance is available for public examination in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Submit written comments on the draft guidance and the proposed collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amy Green, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy. (HFS–306), College Park, MD 20740, 301–436–2025, FAX: 301–436–2651, e-mail: *amy.green@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

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.

With this notice, FDA is announcing the availability of the draft fresh-cut guidance. This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's 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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed in the following paragraphs.

With respect to the following collection of information, FDA invites comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's 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.

Title: Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables.

Description: 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). The methods by which produce is grown, harvested, and processed may contribute to its contamination with pathogens and, consequently, the role of the food in transmitting foodborne illness. The potential for pathogens to survive or grow may be enhanced in fresh-cut produce due to the release of plant cellular fluids during cutting or chopping, the high moisture content of many of the products, the absence of a process lethal to pathogens, and the potential for temperature abuse during processing, storage, transport, and retail display. In response to the increased consumption of fresh-cut fruits and vegetables and the potential for foodborne illness associated with these products, FDA recognizes the need for guidance specific to the processing of fresh-cut fruits and vegetables. Accordingly, FDA encourages fresh-cut produce

processors to adopt the general recommendations in the guidance and to tailor practices to their individual operations.

FDA's fresh-cut draft 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 draft 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.

A. Industry Profile

Estimates of the paperwork burden to the fresh-cut industry that may result from the publication of FDA's draft guidance are based on information from FDA's relationship with 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 that may result from the issuance of this draft guidance (see table 1 of this document).

The burden to industry of developing and maintaining the activities recommended in FDA's fresh-cut draft 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 hazard analysis and critical control point (HACCP) program.

Currently, the fresh-cut trade association estimates that there are 250 fresh-cut plants in operation in the United States. While most of the recent growth in the fresh-cut industry has been due to mergers between already existing firms, there are approximately 50 fresh-cut plants that did not exist in 2001. This implies that about 10 new firms are entering the fresh-cut industry each year. Many of the existing firms in the fresh-cut industry already make use of CGMP-related, recall, HACCP, and other activities. FDA estimates that the burden of this draft guidance will fall on both existing and new firms entering the industry who may follow the recommendations in this draft guidance.

B. SOPs and SSOPs

Two general recommendations in this draft 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 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 250 fresh-cut processors, the fresh-cut 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 recommendations in this draft guidance document, if finalized.

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 4 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 1 of table 1 of this document. Again, these figures assume that all firms choose to follow the recommendations on recording observations.

C. 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.

D. 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 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 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. Therefore, the total time for 135 processors to develop their individual HACCP plans is approximately 13,500 hours. This one-time 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:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
SOP and 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
Preventive control program comparable to a HACCP system: System development[2]	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
One-time burden hours					18,700
Annual burden hours					41,605

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

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.

III. Comments

Interested persons may sumbit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/guidance.html.*

Dated: 2/27/06
February 27, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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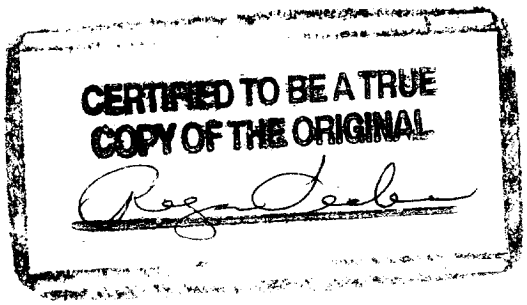
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