

Notices

Federal Register

Vol. 63, No. 172

Friday, September 4, 1998

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[FV-96-328]

Request for Comments on the Qualified Through Verification Program for the Fresh-Cut Produce Industry

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice, request for comment.

SUMMARY: The Department of Agriculture (USDA) is seeking comment on the "Qualified Through Verification" Program (QTV). The program, which began in January 1996, is a pilot program provided under the authority of the Agricultural Marketing Act (AMA) of 1946, as amended. The program provides for voluntary audit-based inspections for wholesomeness and food safety. A new service was requested by representatives of the fresh-cut produce industry that would address wholesomeness in conjunction with food safety under Hazard Analysis Critical Control Points (HACCP) criteria, and Food and Drug Administration (FDA) current Good Manufacturing Practices (cGMPs). Under a "pilot program", the Agricultural Marketing Service (AMS) has found that QTV fosters a proactive approach by the production facility's management for identifying process deficiencies during production rather than after production is completed.

DATES: Comments must be received on or before November 3, 1998.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice. Comments must be sent in duplicate to the Office of the Branch Chief, Processed Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, STOP 0247, P.O. Box 96456, Washington, DC.

20090-6456 or e-mailed to james_r_rodeheaver@usda.gov. Comments should note the date and page number of this issue of the **Federal Register** and would be made available for public inspection in the Office of the Branch Chief during regular business hours at 1400 Independence Avenue, SW, Room 0709, South Building, Washington, DC 20250-0001.

FOR FURTHER INFORMATION CONTACT: Mr. James R. Rodeheaver, Branch Chief, Processed Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, U.S. Department of Agriculture, STOP 0247, P.O. Box 96456, Washington, DC 20090-6456, Telephone (202) 720-4693.

SUPPLEMENTARY INFORMATION: This notice is requesting comments on the QTV program which, since January 1996, has been a pilot program. This service is performed under the Agricultural Marketing Act of 1946 (7 U.S.C. 1621-1627).

The QTV Program was developed in 1995 by AMS in response to a request by the International Fresh-cut Produce Association (IFPA). A notice was published in the **Federal Register** on December 20, 1996 announcing the program. AMS's QTV Program is a voluntary audit and verification service using science-based techniques that helps maintain public confidence in the wholesomeness of minimally processed fruits and vegetables. Minimally processed fruits and vegetables are products that have been freshly cut, washed, packaged, and maintained with refrigeration. IFPA is one of the major trade associations that represents the fresh-cut produce industry. As currently constituted, QTV is directed only toward the fresh-cut produce industry. A producer of bottled water has asked AMS to provide QTV services to them. Although the Agency has declined the request, AMS would welcome input regarding extending QTV to this or other products.

Since January 1996, AMS has offered the QTV pilot program as a voluntary auditing and verification service. The program manual has been revised twice (once in October 1997, with the most recent revisions in July, 1998) based on the agency's experience.

QTV allows AMS to provide services that help food processors develop food safety plans based on sound scientific and objective techniques under HACCP.

HACCP is widely viewed as an effective and rational means of assuring food safety from harvest to consumption. Under HACCP, safe production of food products is guided by identifying, evaluating, and controlling food safety hazards.

Since 1985, the National Academy of Sciences has strongly endorsed HACCP as the most effective and efficient means of ensuring the safety of our food supply. Regulatory agencies such as FDA and the Food Safety Inspection Service (FSIS) have required companies to implement HACCP for seafood, (December 18, 1995 (60 FR 65096)), and meat and poultry, (July 25, 1996 (61 FR 38805)). HACCP is currently being proposed to regulate the fruit and vegetable juice industry, (April 24, 1998 (63 FR 20450 and 20486)). Currently, HACCP is not required for the fresh-cut fruit and vegetable industry.

The principles of HACCP, as provided by the National Advisory Committee on the Microbiological Criteria for Foods (NACMCF) adopted November 1989 and amended in 1992 and 1997 are:

Principle 1: Conduct a hazard analysis.
Principle 2: Determine critical control points.

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

Hazards may be microbiological, chemical, or physical. HACCP uses preventive measures and predetermined corrective actions at specific points in the production process identified as critical control points based on a comprehensive hazard analysis of the food being produced. As defined by the NACMCF, a critical control point is a step in a process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

In addition to the Agency's experience from present audit based programs, AMS processed fruit and vegetable inspectors verify that food processing facilities where AMS has contracted to perform in-plant product certification are conforming to FDA cGMP's and are handling adulterated products in accordance with FDA requirements.

QTV is not a mandatory or regulatory program like other HACCP based programs established or proposed by FDA and FSIS. Participation in QTV does not relieve a facility of its responsibilities with respect to FDA or other food safety regulators. AMS believes that participation in QTV will help firms comply with food safety regulations.

A company that is interested in the QTV pilot program begins by requesting the Agency to perform a program presentation and conduct a plant survey of the company's facilities. At the meeting, AMS seeks commitment to the QTV concept from senior management and recommends HACCP-based training for key plant personnel. Also, any deficiencies in the facility or staff training identified by AMS during the QTV approval process must be addressed satisfactorily before the plant can enter the program.

A QTV plan is developed by a company, then submitted to AMS for review. The QTV plan is then evaluated based on the criteria for the program. When a company submits its draft QTV plan to AMS for review, AMS considers the submission as the firm's application for QTV certification for the facility covered by the plan. The Agency reviews QTV plans in the order in which they are received. Draft QTV plans are generally reviewed within 30 days. Later drafts, if revisions to the QTV plan are necessary, are usually reviewed within two weeks. A company's progress in the QTV Program is based on the speed with which a firm has revised its QTV plan and completed any necessary training or facility modifications.

The QTV plan includes:

(Note: A more detailed list of technical terms and definitions can be found in the QTV Program Manual, entitled "Qualified Through Verification" Program for the Fresh-Cut Produce Industry"; the QTV Program Manual is available on the USDA website at <http://www.ams.usda.gov/fv/qtv.htm> or by contacting the Processed Products Branch Chief, at the address given above. Interested parties are invited to submit comments on the QTV Program Manual to the same address.)

1. *Organizational Chart and Narrative*: A diagram identifying the personnel responsible for developing and implementing the QTV plan; a narrative describing the duties of the identified personnel specific to QTV and HACCP requirements.

2. *Description of Product and Labels*: A list of all major groups of finished processed fruit and vegetable products that are to be covered under the QTV Program. The description includes but

is not limited to product mixes, package sizes, ingredients, and shelf-life. Examples of the primary package labels are to be included in this section of the plan.

3. *Process Flow Charts and Process Flow Narrative*: The flow chart(s) illustrates the operational steps involved with a product or similar products with designations of critical control points and control points. The process flow narrative is a description of each operational step involved with a product or similar products with designations of critical control points and control points.

4. *Hazard Analysis*: This is an evaluation of all the potential hazards that can be associated with the products produced in the facility as well as in the growing, harvesting, transporting and storing of these products. This evaluation is used to determine which hazards must be addressed in the HACCP plan. A thorough hazard analysis is the most important step towards developing an effective HACCP plan for QTV. It requires extensive review by the company HACCP team and, if additional expertise is needed, outside experts.

5. *Critical Control Point (CCP) Narrative and Worksheet*: The worksheet is a description of the following information for each CCP.

- (a) Location of the Critical Control Point
- (b) Hazard(s) to be controlled at Critical Control Point
- (c) Preventive Measures
- (d) Critical Limits
- (e) Monitoring Procedures
- (f) Corrective Actions
- (g) Records
- (h) Verification

6. *Record Keeping*: Record keeping is a method of documenting and filing information relevant to HACCP and the QTV plan. These records must be identified and easily accessible for review by AMS auditors.

7. *Verification Procedures*: These procedures describe methods the company will use daily, monthly, and annually, to determine the overall effectiveness of its QTV plan.

8. *Sanitation Standard Operating Procedures (SSOPs)*: SSOPs are a comprehensive description of the company's program to ensure sanitation compliance. These procedures include listing equipment and structures to be cleaned and/or sanitized, and the sanitation schedule for each. SSOPs should also identify the types of chemicals used, where and how they are stored, materials and methods used, who will perform the cleaning operations, and who will verify that the cleaning was done properly.

9. *Consumer Complaints*: There must be an established procedure for handling, addressing, and recording consumer complaints.

10. *Recall Procedures*: This is a method of positively identifying, locating, and retrieving products that have left the facility.

11. *Microbiological Testing Program and Corrective Procedures*: The microbiological testing program describes the procedures employed by the applicant to ensure that the product and sanitation techniques comply with regulations. This includes testing for specific microorganisms in incoming product, environmental testing of the facility (equipment, drains, etc.), and finished product testing. The QTV plan must specify the corrective procedures that will be undertaken if specific microorganisms are found during testing that could result in product contamination.

12. *Additional Elements as Described in the QTV Program Manual*: These include a pest control program, standard operating procedures, standard testing procedures, an employee training program, and a product coding system.

Once AMS has determined that a firm's QTV plan meets QTV requirements, the company must then implement the AMS-accepted plan for a minimum of 30 days to demonstrate that it can fulfill its plan's requirements. After the 30-day period and when requested by the plant, AMS will perform the validation audit. This is a complete review by AMS QTV auditors of the company's QTV plan in operation. The auditors will follow the Systems Audit Checklist (which may be found in the QTV Program Manual).

The validation audit includes a review of the facility's production records, interviews with employees at CCP's, observation of employee food handling practices during each shift, observation of cleaning and sanitizing of equipment before and during production, review of the microbiological testing program, and review of the employee training program. The plant will be accepted into the QTV Program if a minimum of a Level IV rating is obtained based on the results of the validation audit. A Level IV rating indicates that the facility is following its QTV plan, that the plan is effective, and that the facility qualifies for unannounced AMS QTV audits once it enters a contract for service with AMS.

AMS and the company will then enter into a contract for AMS service which includes periodic unannounced Systems Audits. The company agrees under the contract to conform to the

Regulations Governing Inspection and Certification of Processed Fruits and Vegetables and Related Products (7 CFR 52.1 through 52.83) and instructions covering inspection and certification. The company also agrees to the following:

Records—Maintain and make available for review by AMS all records required by the QTV plan including, but not limited to, hazard analysis, preventive measures, CCP and critical limit documentation, monitoring records of preventive measures associated with CCP's, corrective action reports, and verification records, including consumer complaints relevant to the QTV plan.

Samples—Provide reasonable quantities of product samples while participating in the QTV Program at no cost to the Government.

Surety—At the discretion of AMS, furnish an acceptable surety, effective prior to the date of the first Systems Audit, guaranteeing payment for the services to be rendered in an amount sufficient to cover estimated billings for a period of three months in the form of a properly executed surety bond or advance payment.

Payment—Pay by check, draft, or money order drawn to the order of USDA for the service covered herein on or before the due date specified on the bill.

Plant Access—The applicant is responsible for granting permission for AMS to enter plant premises to perform Systems Audits at any time.

AMS agrees to perform the following:

Systems Audits—Provide objective third-party verification of the applicant's QTV plan.

Verification—Review, evaluate, and verify the effectiveness of the processor's adherence to the QTV plan through on-site inspections, evaluation of production processes identified in the plan, evaluation of product samples, audit of plant records and interviews with plant employees.

Sanitation—Perform sanitation inspections and report to company management any sanitation deficiency which may result in an unsatisfactory rating or cause product contamination.

Sample—Randomly draw and evaluate official samples to verify the effectiveness of the applicant's QTV plan and determine if end items comply with applicable specifications.

Formulation—Verify product formulation. Audit reports and records to determine if documentation of components and quantities used are accurate and complete.

Calibration—Verify procedures used to calibrate scales and measuring devices. Packaging and Labeling—Verify that product packaging and labeling are in compliance with the applicable specifications in the QTV plan.

Record Keeping—Review records associated with and identified in the QTV plan to determine adherence to the plan.

Exit Interview—Discuss and report the results and observations with the firm after each QTV Systems Audit, providing verification reports, sharing data and sample results as necessary, allowing for voluntary follow-up and corrective action, where appropriate. Provide written notification in the event any violative condition is found.

Report—Issue a report to plant management on Systems Audits and evaluations.

Confidentiality—To the extent permitted by law, consider and treat any trade secrets or confidential information as proprietary and confidential and further to consider any QTV records and related information provided to AMS, because of the company's participation in the QTV Program, as information that is voluntarily submitted to the Agency.

Charges—Bill the applicant for Systems Audits on an hourly basis in accordance with the applicable sections of the Regulations.

Systems Audits shall continue until the company has suspended service,

withdrawn, been debarred, or the agreement is terminated by:

Mutual consent—either party giving the other party 30 days advance written notice specifying the date of suspension or termination;

A written notice by AMS if the applicant fails to honor any invoice for fees within 60 days after date of receipt;

Bankruptcy of the applicant or closing out of business, or change in controlling ownership of the firm;

AMS at any time, acting pursuant to any applicable law, rule, or regulation, debarring the applicant from receiving any further benefits of the service; or

Non-performance by the applicant such that the applicant no longer satisfies the requirements for participation in the QTV Program.

Following validation and the signing of the QTV contract, AMS will conduct unannounced audits at scheduled intervals as set forth in the QTV Program Manual. The company may revise its QTV plan at any time, subject to AMS review and approval.

Whenever an AMS auditor identifies a current Good Manufacturing Practice violation under QTV, whether during the Validation Audit or subsequent unannounced Systems Audits, the auditor will first notify the processor. The processor is responsible for taking proper and effective corrective action. The extent of any subsequent actions by AMS, will depend upon the nature of the audit finding and the adequacy of a processor's response.

Traditionally, shields are used by AMS for marketing as an identifying mark of a program service in its voluntary programs. The shields shown in Figures 1 and 2 can be used by facilities that have been successfully validated and have entered into a QTV contract. The processor's name and address or assigned plant number identifies the facility as approved for the QTV plan.

BILLING CODE 3410-02-P



Figure 1

-Blue -
-White-
-Red -



QTV No. 000
Figure 2

BILLING CODE 3410-02-C

AMS welcomes comments on how to improve the design or wording for the shield, whether to provide for an official QTV shield at all, or whether the use of an approved official QTV mark should in some way be limited. The Agency is aware of differing views on the use and design of the QTV mark.

Two types of marks are available under the program for use by a validated company. One shield, Figure 1, includes a QTV facility number within the shield and can be used by a company with only one facility. A company under the same name with multiple facilities can use either Figure 1 or the non-numbered QTV shield provided the QTV facility number is also included on the label in close proximity to the shield in Figure 2. Each plant successfully operating under an approved QTV plan has a separate QTV identifying number. These approved identification marks may only be used on products specified in the QTV plan.

There is no additional charge for use of the QTV shield. Firms may use the shield in their advertising and promotion. This activity must not, however, suggest that products bearing the shield are safer than others or otherwise misrepresent the QTV shield.

QTV facilities that fail to meet acceptable QTV audit levels will be dropped from the pilot program. Products from such facilities may not then bear the QTV shield and the facility must destroy such labels. AMS verifies that the facility has ceased its use of the approved mark. Unauthorized use of the mark may violate the AMA of 1946 and/or the Perishable Agricultural Commodities Act of 1930 (PACA), as amended (7 U.S.C. 499a-499s). Violators may be subject to fines and/or imprisonment, civil penalties, loss of USDA grading and certification, or suspension or revocation of their PACA license.

AMS maintains a copy of a plant's QTV plan and AMS, QTV auditors examine but do not normally, copy or remove from the facility any plant documents during systems audit. QTV plans in AMS's possession remain the property of the company and will be treated as privileged or confidential. AMS will maintain as confidential, QTV related records and plans to the extent permitted by law.

Beyond the costs of AMS audits, the overall cost of participation in QTV will vary depending on a company's facility and staff preparation. The frequency of AMS audits, and hence the Agency's charges for its services, will vary based on a firm's performance as determined by the periodic QTV audits. After validation, all firms begin at Level IV, which requires an unannounced QTV audit every two weeks. Under the original QTV Program requirements dated October 1995, a firm which demonstrates exemplary performance during all audits could advance from Level IV to Level I (which requires the least frequent auditing) in approximately nine months, or seven audits, significantly reducing their audit costs. Firms which perform well will reduce their audit costs since the frequency of AMS unannounced audits decreases when a firm is able to progress from Level IV to Levels III, II, and ultimately to Level I. Level I had required an unannounced audit every six months, but the Agency has adjusted the minimum audit rate to once every three months in the current revision dated July 1998. Under the new revision, a company can advance from Level IV to Level I in seven months or five audits.

Fees for the program would be provided for in the regulations under § 52.51(a). The QTV Program is funded entirely through user fees. The fee currently charged for QTV services under the pilot program is \$41.00 per hour (see 7 CFR 52.42). This fee is

charged for the time required by AMS personnel to travel to and from an audit site, do the audit, and perform associated administrative activities. Currently, the door-to-door cost for a typical eight-hour QTV Systems Audit, based on recently completed QTV Systems Audits by two auditors, has averaged between \$1700.00 and \$2000.00. As the QTV Program continues and AMS knows more precisely the program costs, it will make any necessary fee rate adjustments. Costs for analytical work regularly performed by a firm or an outside provider to support a firm's QTV Program is the firm's responsibility.

There are approximately 300 to 400 fresh-cut processors according to IFPA estimates. This estimate does not include an unknown number of restaurants, produce wholesalers, or retailers that may process fruits and vegetables for salads or other purposes. There are currently seven plants participating in Systems Audits under the program. These plants include small to large-size processors.

AMS has identified a need for participation from the private sector in training, consulting, and microbiological testing for QTV Program applicants. Several private laboratories have taken the initiative to provide these services and are currently working jointly with AMS in training and QTV plan development for several applicants. This cooperation has proven beneficial to all parties.

AMS invites comments on the program, use of the shield, requirements of the program, and quality versus food safety issues.

This notice has a 60-day comment period. All interested parties will have an opportunity to express their views. Once the comment period has closed, AMS will review and consider all comments before making further decisions about the QTV Program.

Dated: August 28, 1998.

Enrique E. Figueroa,

Administrator, Agricultural Marketing Service.

[FR Doc. 98-23903 Filed 9-3-98; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Washington Provincial Advisory Committee Meeting Notice

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Washington Provincial Advisory Committee will meet on Thursday, September 17, 1998, in Stevenson, Washington, at the Rock Creek Center (Rock Creek Drive) in the auditorium. The meeting will begin in 10 a.m. and continue until 5 p.m. The purpose of the meeting is to provide information on (1) the Status of Watersheds on the Gifford Pinchot National Forest, (2) Social and Economic Factors, and (3) Public Open Forum. All Southwest Washington Provincial Advisory Committee meetings are open to the public. Interested citizens are encouraged to attend. The "open forum" provides opportunity for the public to bring issues, concerns, and discussion topics to the Advisory Committee. The "open forum" is scheduled as part of agenda item (3) for this meeting. Interested speakers will need to register prior to the open forum period. The committee welcomes the public's written comments or committee business at any time.

FOR FURTHER INFORMATION CONTACT:

Direct questions regarding this meeting to Linda Turner, Public Affairs Specialist, at (360) 891-5195, or write Forest Headquarters Office, Gifford Pinchot National Forest, 10600 NE 51st Circle, Vancouver, WA 98682.

Dated: August 27, 1998.

Thomas Mulder,

Administrative Officer.

[FR Doc. 98-23847 Filed 9-3-98; 8:45 am]

BILLING CODE 3410-11-M

DEPARTMENT OF AGRICULTURE

Forest Service

Northern Goshawk Habitat Management

ACTION: Proposal to prepare interim direction for Northern Goshawk habitat

management in the Intermountain Region, (R4) U.S. Forest Service.

SUMMARY: Notice is hereby given that the Regional Forester (R4), in cooperation with Bureau of Land Management and the USDI-Fish and Wildlife Service, is reviewing Utah state-wide information (Habitat Assessment and Management Recommendations for the Northern Goshawk in the State of Utah (in press) and USDI-FWS 12-month finding on a petition to list the northern goshawk (FR, June 29, 1998, Volume 63, Number 124, pages 35183 to 35184)) relating to the sustainability of habitat for the northern goshawk. A Conservation Strategy and Agreement for the Management of Northern Goshawk Habitat in Utah is being developed based on the Assessment. The Forest Service is proposing to amend regional direction, Regional Guides, and Forest Plans to incorporate interim direction in the form of goals and objectives, desired habitat conditions, standards and guidelines, and monitoring requirements based on the information in the Assessment and the Strategy. The interim direction will apply to National Forest System Lands throughout Utah.

The purpose and need for the proposed action is to provide state-wide consistency in future project design, implementation and monitoring that will insure long-term goshawk habitat sustainability throughout the state of Utah. The proposed amendment to the Regional Guide and six national forests in Utah would be prospective only, and would not apply to projects that have been approved prior to the effective date of the amendments. This action will provide interim direction to protect habitat and populations of northern goshawks until existing forest plans are revised or suitably amended. Specifically, the proposed action will include National Forest System Lands on the Wasatch-Cache, Uinta, Ashley, Manti-LaSal, Fishlake and Dixie National Forests in the Intermountain Region.

The Forest Service serves notice that the agency is seeking information and comments from federal, state, and local agencies, and other individuals or organizations who may be interested or affected by the proposed action for the sustainability of northern goshawk habitat in Utah. This input will be used in preparing regional direction, Forest Plan amendments and/or Guides, and accompanying environmental analyses.

Written comment should be sent to the agency within 30 days from the date of publication of this notice in the **Federal Register**.

SUPPLEMENTARY INFORMATION: The Forest Service, in accordance with 16 U.S.C. 1604 and 36 CFR parts 219 et seq., develops Land and Resource Management Plans to provide for multiple use and sustained yield of products and services including outdoor recreation, range, timber, watershed, wildlife and fish, and wilderness. At its discretion, the Forest Service may amend Regional Guides (36 CFR 219.8) and/or Forest Plans based on the results of monitoring and evaluation (36 CFR 219.10(f), 219.12(k)). Review of research reports, published professional papers and agency assessments indicates that additional long term programmatic habitat management direction may be warranted for the northern goshawk in Utah. This long-term approach is being developed through the Conservation Strategy and Agreement for the Management of Northern Goshawk Habitat in Utah (to be released in the fall of 1998). This interim direction is being proposed to preserve options for long term management that will be developed during Forest Plan revision. Once the conservation strategy is released that information plus the current policy direction to use the 1992 Reynolds et al., report will be used during project level design and National Environmental Policy Act (NEPA) analysis and disclosure of effects.

A range of alternatives will be considered. One of these will be the "no action" alternative in which current management would continue. Other alternatives could examine the effect of varying approaches to the interim direction.

The Forest Service is seeking information and comments from federal, state and local agencies, and other individuals and organizations who may be interested or affected by the proposed action. This information will be used in determining the scope of the amendments to the Regional Guide, direction, and Forest Plans. Prior to completing these amendments, the Forest Service will publish a Notice of Intent (NOI) in the **Federal Register** to describe the specific proposal and type of NEPA documentation. At the time such a Notice is published, there will be additional opportunities for public comment.

The responsible official will be the Regional Forester for the Intermountain Region; Intermountain Region, Federal Building, 324 25th Street, Ogden, Utah 84401.

The determination of proposed amendments is expected to be completed and available for public review by November 30, 1998. At that time an improved estimate of time for