

Hearing Testimony-USDA Agricultural Marketing Service Fruit and Vegetable Programs National Leafy Greens Marketing Agreement

Introduction

Good Day ladies and gentlemen of the leafy greens industry, interested individuals, and government officials:

My name is Anthony Souza. The spelling is SOUZA. My address is 3355 Myrtle Avenue, Suite 240, North Highlands, CA 95660. I serve as one of eight Federal Program Managers within the USDA, Agricultural Marketing Service, Fruit and Vegetable Programs. I have 21 years of experience as a fruit and vegetable inspector with a Bachelor of Science degree in agriculture education. The primary responsibility of a Federal Program Manager is to ensure uniformity and integrity in the inspection and audit services performed by state personnel. I am in the western region which includes Arizona, California, Hawaii, Nevada and Utah. I have counterparts in other territories of the U.S. that have similar responsibilities.

The purpose of this testimony is to describe USDA's experience and expertise in providing impartial inspection and audit services that verify Food and Drug Administration guidelines and regulations for good agricultural practices, good handling practice and Current Good Manufacturing Practices.

AMS Services

The mission of Agricultural Marketing Service, referred to as AMS, is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace through the use of market news information, marketing orders and agreements, research and promotion activities, commodity purchases for school lunch and other government feeding programs, and standardization, training, auditing and inspection activities. AMS, Fruit and Vegetable Programs has over 90 years of experience providing certification and verification services for fruits, vegetables, and other specialty products. Inspection services include product sampling and analysis according to federal or state grades or specifications, marketing order requirements, import requirements, industry grades, or contract specifications. Auditing services include verification programs for quality assurance to marketing order requirements, identity preservation of value-added commodities, and good agricultural and handling practices, and Hazard Analysis Critical Control Point, referred to as HACCP, plans based on industry specifications or marketing order requirements.

Inspection and audit services are performed by a combination of federal and state personnel. Through the use of cooperative agreements, AMS trains and authorizes state departments of agriculture employees to perform inspection and auditing services. This partnership with state departments of agriculture allows AMS to provide inspection and auditing services at or near specialty crop production areas and major terminal market/wholesale distribution centers across the country. Fruit and Vegetable Programs

have 2,650 federal and state personnel who provide inspection and audit services. Currently there are approximately 250 auditors and 150 auditors-in-training.

In the course of providing inspection and audit services we are on farms and in packinghouses and processing facilities. The Food Drug Administration, referred to as FDA, recognizes that our presence at these operations helps to ensure adherence with food safety guidelines and regulations, contributes to the protection of consumers and aids FDA in enforcement of pertinent regulations. A Memoranda of Understanding between FDA and AMS defines each agency's responsibilities related to inspection and standardization activities for food products. We have inspection personnel in fruit and vegetable processing plants across the country who help assure that these processing facilities adhere to GMPs. All processed products must meet the requirements of the Food, Drug and Cosmetic Act before a U.S. Grade can be assigned. Inspectors perform tests to assure that products do not exceed FDA's Defect Action Levels. AMS personnel will report to FDA if a product or a practice is observed which has a reasonable probability of causing serious adverse health consequences or death to humans or animals. AMS personnel, specifically in the Processed Products Branch are authorized to tag product to be held for FDA to take action.

From this point forward, I am going to speak specifically about AMS' audit based services for Good Agricultural Practices (GAP), Good Handling Practices (GHP), Current Good Manufacturing Practices (CGMP) and related commodity specific programs.

An important component of third-party auditing is the retail and foodservice, which is increasingly demanding that its suppliers provide verification that they are conforming to recognized good agricultural practices, good handling practices, or good manufacturing practices.

At industry's request, AMS has incorporated food safety elements into several of our programs, and has established programs such as the Qualified Through Verification and the GAP&GHP Audit Verification Program to provide independent verification that growers and handlers are following FDA guidelines and commodity specific best practices.

AMS actively communicates with retailers and foodservice companies to provide information on AMS audit based programs. The results of these contacts are increasingly favorable, as many buyer groups have recognized that AMS audit programs offer a viable solution in verifying their suppliers have implemented GAPs, GHPs and GMPs. Retailers have requested our assistance when they implemented GAP requirements for their ~~for their~~ buy local programs which are made up of primarily small to medium sized growers. We worked with the retailers and local Cooperative Extension agents and provided training to these growers on an overview of the role auditing plays in a food safety program.

The audit programs were developed with the cooperation and assistance of USDA Agricultural Research Service, state departments of agriculture, and the National Good Agricultural Practices program, which is a group of academic and scientific faculty from across the U.S. These groups, in addition to others, continue to provide scientific expertise as the GAP, GHP and GMP programs evolve when newer science formulates specific best practices. Additionally, AMS works closely with FDA and incorporates any final FDA commodity specific guidelines into our audit programs, such as when the draft guidance recently released for leafy greens, melons, and tomatoes is issued in "final."

Since the beginning of the GAP&GHP Audit Verification Program, over 4,000 GAP&GHP audits on 100 different commodities have been completed in 45 states, Puerto Rico, Washington, D.C., and Canada. As the demand for verification of GAP, GHP, and GMP has increased, commodity groups have approached AMS for assistance with the development of commodity specific audit programs. In 2008, a commodity specific program for tomatoes was implemented for the California Tomato Farmers Cooperative, as well as a commodity specific program for mushrooms. These programs are used by producers of both commodities. We are actively assisting the citrus, potato and apple commodity groups as they develop commodity specific best practices and request our assistance to verify conformance with commodity specific best practices.

AMS is involved with the California and Arizona State Leafy Greens Marketing Agreements. Through our cooperative agreement with these two states, AMS provides the training and oversight of the state personnel conducting the audits. Both state departments of agriculture and state marketing agreement boards requested that AMS provide oversight and technical assistance to their programs. As a federal program manager for these two states, I work very closely with the California Department of Food and Agriculture staff on the auditing aspect of this program, and attend the board meetings and technical review meetings to share AMS policy on matters under our oversight.

Audits

AMS Industry Services Audit and Accreditation Programs (ISAAP) is an internal quality management system that defines how AMS develops, manages and provides audit and accreditation programs. AMS audit programs follow generally recognized International Organization for Standardization, referred to as ISO audit principles and activities.

The audit process begins with a farm or facility representative requesting a voluntary GAP, GHP or GMP audit. AMS requires that they sign an agreement for participation in the audit program. This agreement grants permission for the auditor to have access to the farm and/or facilities for the purposes of conducting the initial audit, any unannounced and follow-up audits. Audits are scheduled for a time when the farm and/or facility are in production. For clarity, the initial audit, which the firm knows the date and time of the audit, is the first audit that is intended to verify adherence to program requirements; the unannounced audits, may be one or more, this audit is scheduled but not announced to the company ahead of time, it is intended to verify continued, ongoing adherence to program

requirements; and the follow-up audits, also unannounced are to verify that any corrective actions have been implemented. The participation agreement also requires that an applicant agrees to maintain all records required by the audit program including but not limited to a food safety manual, all records as required by the firm's food safety manual, water test results, and employee training records. These records are required to be available to AMS auditors for review.

The audit begins with an opening meeting; the auditor explains the audit activities to the farm or facility representative. The audit consists of a physical visit to the farm and/or facility which involves a review of records and documentation, interviews of employees, observation of practices, and a closing meeting. An audit checklist is used by the auditors to verify that the farm or facility is adhering to GAPs, GHPs and GMPs.

During the closing meeting, the auditor provides the company representative with a copy of the audit report and discusses the results of the audit and any nonconformities found. We have established procedures for the resolution of complaints, appeals and disputes received from the grower, handler or other parties about the verification audits.

If at any time during an audit, the auditor observes an immediate food safety risk; it is our obligation as a federal agency subject to the public's trust to report an immediate food safety risk to the appropriate public health authority and/or FDA.

The audit results are valid for one year from the date of the initial audit, provided that at least a passing score is achieved on both the initial audit and any unannounced audits. A company's information will be posted on the USDA website if any and all unannounced audits show satisfactory adherence to the program. If the minimum passing score is not achieved, the company's information will be removed from the website until a follow-up audit is conducted by AMS verifying that effective corrective actions have been taken and the company attains the minimum score on all appropriate scopes of the audit. AMS retains audit reports for a period of three years.

Auditor Training and Oversight

AMS auditor qualifications are modeled after internationally recognized auditor competence and auditing principles. To be qualified as an AMS auditor, federal and state inspectors must successfully meet the auditor qualifications and complete auditor training requirements. AMS's requirements for auditor independence, integrity, objectivity and the auditor qualification and training requirements assure the reliability of the auditing Staff. AMS auditors are held to the highest ethical standards, and the strict conflict of interest policies of government employees.

The auditor qualification criteria are reviewed on a regular basis and if it is determined that additional training requirements are needed, the auditor criteria is revised. Consistency between auditors is a critical component of third-party audits. AMS Auditor Criteria establishes auditor qualifications to ensure that audit programs are provided professionally and uniformly.

AMS qualifications and requirements must be met to become an AMS qualified auditor. (AMS ISAAP Auditor Criteria attached as an Exhibit)

First, a potential auditor candidate must meet the education and agricultural work experience requirements and be recommended by a supervisor as a viable candidate for auditor-in-training. The candidate must be open-minded, diplomatic, observant, perceptive, tenacious and decisive and demonstrate strong written and oral communication skills.

The second step is for the auditor-in-training to successfully complete the AMS approved fundamental training courses which are: ISO 19011 *Guidelines for quality and/or environmental management systems*, Section 4 Principles of Auditing and Section 6 Audit Activities; a Process Based Audit course; and, a Specific Audit Program training course, GAP, GHP, GMP, HACCP or Better Process Control School. Training is provided by a combination of AMS training specialists, state food safety regulatory officials, food safety experts from academia and FDA Office of Regulatory Affairs University online courses.

The next step is for the auditor-in-training to participate in a minimum of three audits, acting as the team leader on two of them, under the supervision of an evaluator. The evaluator is a Federal Program Manager, Audit Program Manager, supervisor or senior auditor who is an AMS qualified auditor and has completed ISO 9001 Lead Auditor training.

An auditor-in-training is not permitted to perform audits independently, without supervision until they can demonstrate the ability to manage and coordinate audits, has received a satisfactory rating on evaluations and has been determined to be qualified by a supervisor.

To maintain the status of an AMS qualified auditor they must maintain a satisfactory rating on the annual Auditor Performance Evaluation; complete annual ethics and program specific refresher training; and participate in a minimum of two complete audits each year as a team leader. Qualified auditors must also complete 80 hours of continual professional development every 3 years. This requirement ensures that auditors maintain their auditing knowledge and skills. The professional development training may include: online college courses, FDA training courses, extension presentations, and attendance at workshops, conferences, and seminars related to audit services.

AMS auditor criteria recommends, although does not require, that auditors become certified by the American Society for Quality in the appropriate auditing field. A number of our auditors are American Society for Quality certified quality auditors and/or certified HACCP auditors.

Location of Auditors

AMS auditors are located in approximately 75 field offices around the country, primarily in the specialty crop production regions. We have reviewed which areas have the highest leafy green production in the U.S, and have determined that we have adequate staffing in those areas to handle the potential increased demand for auditors if the proposed National Leafy Green Marketing Agreement is implemented. California and Arizona, which account for approximately 80% of U.S. leafy green production, use 6 to 10 state auditors for the verification audits. AMS has the capability to train additional federal and state personnel as the requests for audits increase.

The proposed National Leafy Greens Marketing Agreement states “*that no signatory handlers subject to the provision of this agreement shall receive leafy green vegetables produced in foreign countries that have not been subject to GAP verification audit by USDA licensed inspectors.*” According to data from USDA’s National Agricultural Statistics Service, the majority of leafy greens imported into the U.S. come from Mexico, primarily from the states along the U.S. border and two provinces in Canada; Quebec and Ontario. AMS does not foresee any difficulty in providing service in these two areas as we have offices located in close proximity.

Audit Fees

The Agricultural Marketing Act of 1946, which is one authority under which AMS operates, requires that services are provided on a cost recovery basis. The fees for all inspection and auditing activities are established to cover the costs of operating the program. The current fee for audit based services is \$92.00/hour per auditor. Domestically this rate includes all travel expenses; internationally, the fee is set at \$92.00/hour per auditor plus all travel expenses. In accordance with the cooperative agreements, our state cooperators can set their fees to recover the cost of providing services so fees for some audit services can vary slightly from state to state.

Conclusion

AMS has over a 90 year history of providing impartial, efficient, uniform certification and verification services to the produce industry. Our personnel have experience in fruit, vegetable and specialty crop production and handling and understand the complexity of agricultural production and processing practices. We are committed to ensuring that AMS auditors are qualified and well trained to ensure the consistency of auditors. Our nationwide availability of qualified, independent auditors ensures that we can provide service across the U.S. as well as internationally. AMS is prepared to provide impartial, consistent audit verification services so that industry can demonstrate adherence to the best practices that FDA, industry, and the scientific community developed.

Thank you.