

Statement of David R. Shipman, Acting Administrator

Agricultural Marketing Service

U.S. Department of Agriculture

Before the

Subcommittee on Horticulture and Organic Agriculture

House Committee on Agriculture

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Mr. Chairman and members of the Subcommittee, good morning and thank you for the invitation to appear before you today. I appreciate the opportunity to share with you a brief overview of the U.S. Department of Agriculture's (USDA) activities and services that assist the fruit and vegetable industry in meeting U.S. Food and Drug Administration (FDA) and commercial marketplace requirements. The Agricultural Marketing Service (AMS) is the primary USDA agency working in this area.

As you know, FDA is the Federal agency with primary responsibility for the food safety of fruits and vegetables. Within USDA, the Food Safety and Inspection Service holds similar responsibility for meat, poultry, and egg products.

The mission of AMS is to facilitate the strategic marketing of agricultural products in the domestic and international marketplace. AMS is not a food safety agency. The agency does respond to requests from producers to support their product quality control efforts for use as

marketing claims. For example, producers have asked AMS to establish programs to provide independent verification that FDA guidance is being followed.

AMS Audit-Based Programs

AMS has significant experience in the design and delivery of marketing programs that involve inspections for product quality and verification of production processes. At industry's request, AMS has incorporated food safety-related elements into several of its marketing programs.

AMS independent third-party audits provide impartial verification that growers, handlers and processors are following FDA guidance and commodity specific agricultural best practices. The Agency has developed the AMS Industry Services Audit and Accreditation Program to provide a range of audit and accreditation services. AMS auditor qualifications and training are based on International Organization for Standardization (ISO) auditing principles and activities with an emphasis on process-based auditing, program specific training, and annual program-specific refresher training. To maintain Agency credentials, each auditor must complete a minimum of 80 hours of continual professional development and course work every three years, plus meet annual performance criteria according to the U. S. Office of Personnel Management (OPM) Qualification Standards performance criteria as mandated by USDA.

AMS experienced staff in fruit vegetable inspection and agricultural practices have provided the foundation to evolve inspectors into International Standards Organization (ISO) trained auditors. The evolution of inspectors into auditors came at the request of the food industry that was in need of independent third-party verification. Plant sanitation surveys are one of the first audit-based services that assess food processing facility's compliance with FDA's current Good

Manufacturing Practices (GMP's), and ensures their ability to provide consistent quality and wholesome products by verifying food safety systems.

Audit-based programs focus on the management of production and handling systems. They provide a basis for third-party verification of conformance to production and handling standards, methods, or procedures. Through these programs, it is possible to verify that processes are working within established limits. Production and handling systems are documented, specific processes are monitored and measured, and product identity and traceability are required. Processes specifically relating to the management and minimization of food safety hazards may be included.

In the horticultural or specialty crops area, AMS product grading, plant sanitation review, and audit-based programs are conducted with a Federal workforce of some 800 full and part time employees.

Additionally, AMS has cooperative agreements with nearly all State Departments of Agriculture, under which their fruit and vegetable inspectors receive training and are granted Federal licenses to assist in the delivery of AMS services and programs, adding another 3,500 skilled professionals to the agency's deployable workforce.

Good Agricultural Practices and Good Handling Practices Audit Verification Program

One example of an audit-based program fashioned around food handling processes is the Good Agricultural Practices and Good Handling Practices (GAP/GHP) Audit Verification Program. This program assists farms and packinghouses through verification of their adherence to FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* to be used

as a marketing claim. It is a uniform, nationwide program that is voluntary and funded by user fees.

The GAP/GHP Program originated from requests from various state governments and industry organizations. A program was sought that would enable growers and packers to demonstrate adherence to Good Agricultural Practices and Good Handling Practices, as was being required by their retail customers.

As identified in FDA's guidance materials, participants in this program demonstrate control in several areas of their operations to minimize microbial hazards, including water supplies, manure management, worker health and hygiene, sanitary facilities, field and packing area sanitation, transportation, and product traceback.

The minimum audit frequency for GAP and GHP audits is twice each season. Should a facility or growing operation fail to pass either the initial or subsequent audits, additional audits will be undertaken. In addition, in many instances, the same auditors are in and around these facilities in the course of other, routine quality grading activities. This provides many more opportunities to provide feedback on food safety problems that emerge between audits. The initial GAP or GHP audit is scheduled to ensure that the grower or packer has a clear understanding of when they need to have their operation in order. Subsequent audits are unannounced.

Primary users of this program include fresh fruit and vegetable growers, packers, shippers, and others in the marketing chain. For the 2008 fiscal year, AMS audited a total 1,131 separate

farms or facilities with the total number of commodities audited being approximately 105.

Audits were performed in 36 states and Puerto Rico. AMS staff and AMS-licensed and trained State employees perform the on-site audits.

Outreach to Small Farmers

In cooperation with the Department's Office of Civil Rights, AMS conducted three educational outreach sessions for small, disadvantaged farmers in March 2007. These sessions were held in Raleigh, North Carolina, Marianna, Arkansas, and Thomasville, Georgia and were attended by 20-25 farmers at each session.

The purpose of this outreach was to educate the participants in Good Agricultural Practices, Food Defense, and 3rd party audits, specifically the USDA-AMS GAP&GHP audit program. As a direct result of this effort, approximately 25 farms in Arkansas, Mississippi, Georgia, and North Carolina have successfully passed the USDA-AMS GAP&GHP audit over the past 2 years.

AMS staff also participated in training and outreach to small farmers in the New England and Mid-Atlantic regions at over 20 different grower meetings sponsored by the various state extension services over the past three years. These growers are generally participating in regional retail outlets "buy local" farm to store programs. Approximately 800 participants were given an overview of the USDA-AMS GAP&GHP audit program and had the opportunity to ask specific questions regarding the program.

Qualified Through Verification Program

Another example of an audit-based program offered by AMS is the Qualified-Through-Verification (QTV) Program. There are currently seven fresh-cut plants participating in the QTV program.

QTV is a voluntary, user-fee program that provides third-party verification of a fresh-cut processor's adherence to its Hazard Analysis Critical Control Point (HACCP) plan. Under the QTV program, processors identify and document critical points in their production process, measure performance of their operation at these critical points, and position themselves to detect and address any deficiencies as they might emerge.

Third-party verification by AMS involves initial document review and subsequent on-site audits. The frequency of audits begins at two week intervals, with reduced frequency possible based on a firm's performance. AMS auditors performing QTV audits must complete training in HACCP principles (including hazard analysis, preventive measures, critical control point determination, sanitation Standard Operating Procedures, critical limits, monitoring procedures, corrective actions, record keeping), in addition to AMS audit training requirements.

The QTV Program reflects the latest FDA guidelines. For example, with FDA's March 2007 release of its draft final *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (finalized in February 2008), AMS immediately modified its QTV program to incorporate this updated guidance regarding the identification and implementation of appropriate measures to minimize the hazard of microbial contamination during the processing of fresh-cut produce. In addition, participants in the QTV program will be required to source

products only from growers that adhere to Good Agricultural Practices as outlined in FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*.

Impartiality

All AMS' inspectors, including its Federal-licensed State partners, undergo an extensive combination of hands-on training and classroom instruction in commodity grading. In addition, inspectors receive training in ethics, conduct, and customer service. To ensure consistency and integrity in audit-based inspection services, AMS instituted minimum auditor requirements through its Industry Services Audit & Accreditation Program (ISAAP). The ISAAP requirements are based on internationally recognized standards for the training and evaluation of auditors.

Marketing Orders and Agreements

Authorized by the Agricultural Marketing Agreement Act of 1937 (the Act), marketing orders and agreements assist farmers and handlers by allowing them to collectively address marketing problems. These programs are initiated by industries that chose to have Federal oversight of certain aspects of their operations. AMS oversees marketing orders and agreements to ensure that they operate in the public interest and within legal bounds.

Marketing orders and agreements may set minimum quality requirements, standardize packaging, regulate flow of product to market, and implement other regulations including consumer education, research and advertising. Marketing agreements only apply to handlers

who voluntarily sign an agreement, while marketing orders set regulations on all handlers in a specified region once the program is approved in a grower referendum. Fees are collected from handlers to cover the local costs of administering these programs. AMS currently administers 32 fruit and vegetable marketing orders, covering 25 specialty crop commodities.

Food Quality and Safety Issues under Federal Marketing Orders

Section 608c(6) of the Act provides authority to regulate the quality of various commodities through Federal marketing orders and agreements. The presence or absence of harmful pathogens, toxins, or other contaminants is considered a quality characteristic. In response to producer requests, AMS has incorporated food quality-related requirements in marketing agreement and marketing order regulations for many years. For example, testing for *Aflatoxin*, considered a possible human toxin, has been required for U.S. grown peanuts since 1965, originally under a Federal marketing agreement and subsequently through separate legislation administered by AMS.

A large majority of the currently active Federal marketing order programs include minimum grade requirements with most U.S. grade standards having criteria related to food safety (e.g., lack of mold, insects, foreign material, etc.). Since 1961, for example, the marketing order for California prunes has had inspection and fumigation requirements relative to live insect infestations. Beginning in 2005, Pistachio handlers were required to test all nuts destined for human consumption for *Aflatoxin*. Also, starting with the 2007-08 crop, almond handlers were required to treat almonds prior to shipment to reduce the chance of *Salmonella* contamination.

California Leafy Green Marketing Agreement

Following the September 2006 *E. coli* outbreak linked to fresh spinach grown in the Salinas Valley (and subsequent collaboration among industry, FDA, and California Department of Public Health to enhance existing recommendations for the safety of leafy greens), the spinach and related leafy green industries collectively worked with the California Department of Food and Agriculture (CDFA) to begin designing a State marketing agreement that would require adherence to good agricultural practices for most companies involved in shipping leafy greens in the State. The California Leafy Green Marketing Agreement (Agreement) became effective in February 2007. Arizona implemented a similar program in October 2007.

The CDFA Agreement is a voluntary program. This program licenses signatory handlers to use a certification mark to certify the member's use of good agricultural practices on all of the product handled. The use of the certification mark would be denied to those firms found in violation. The Agreement also mandates that handlers source their leafy greens produced in California from growers who comply with a specified set of good agricultural practices. According to CDFA, to date, handlers representing more than 99 percent of the leafy greens produced in California have signed the Agreement.

AMS has cooperated with CDFA in the verification aspects of the Agreement, including the design and delivery of training for the California State auditors who monitor compliance.

AMS worked with the California and Arizona leafy greens industries, the California tomato

industry, and the American mushroom industry to develop a framework for providing audit services. Each industry developed a "best practices" document and requested AMS to develop an audit protocol to monitor compliance with these practices. As a result, AMS is providing auditing services which recognize operator's adherence to industry-defined best practices and FDA guidance targeted to minimize food safety hazards. FDA specialists have interacted with industry as "subject matter experts" in the development of the best practices documents and AMS maintains an active working relationship with these same specialists.

Proposed National Marketing Agreement for Leafy Greens

In response to interests expressed by segments of the leafy green vegetable industries, AMS, in October 2007, published an advanced notice of proposed rulemaking (ANPR) that resulted in the submission and consideration of 3,500 public comments on the need and level of support for a nationwide good agricultural and handling practices program. In short, AMS' review of the comments received indicated public backing for such a measure could be favorable if certain issues, such as the cost and impact on small entities, the need for science-based guidelines and other factors, were addressed in the development and implementation of any Federal regulation.

Subsequent to the publication of the ANPR, a coalition of U.S. produce industry members began drafting a national marketing agreement proposal that would further minimize the hazards of food-borne contamination in leafy green vegetables. The purpose of the proposed marketing agreement would be to verify industry adherence to good agricultural and handling practices. Requirements implemented under the program would be science-based, would conform to FDA's *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* and

would be subject to USDA inspection audit verification and oversight. As a marketing agreement, the proposed program would only be binding to handlers who voluntarily sign the agreement. In addition to good handling practices, the program would require signatories to verify that any product handled comes from producers or other handlers using verified good agricultural and handling practices. The program would authorize unannounced audits and apply to imports, creating the need to audit growing facilities outside of the United States.

The program would license signatory handlers to use a certification mark to certify the member's compliance with the program. As a result of agreement violation, a signatory would be subject to withdrawal of audit services, would lose the privilege of the official certification mark, and may be subject to misbranding or trademark violations. Any product deemed an immediate threat to public health by USDA inspection would be reported by USDA to FDA.

Any requirements under a Federal marketing agreement for leafy greens would reinforce those industries' abilities to meet FDA requirements. Authorities and regulations under such a program would be consistent with FDA guidance and regulations.

AMS anticipates that proponents of the proposal will submit an official request for rulemaking in May 2009. Once the request is received, AMS will proceed with conducting nationwide hearings to gather evidence and advance the rulemaking process accordingly. This process will allow all interested parties the opportunity to provide input. Any future program would include an extensive outreach effort to make businesses, especially small entities, aware of the marketing agreement and audit requirements. AMS has requested \$2.3 million in funding for 2010 to support the marketing agreement.

In both February 2008 and 2009, the Department of Agriculture-chartered Fruit and Vegetable Industry Advisory Committee, a group of 25 members of the U.S. produce industry, expressed strong support for making Federal marketing agreements and marketing orders available to industries to facilitate national adoption and compliance with food safety standards, such as GAPs, GHPs and Good Manufacturing Practices (GMPs).

Microbiological Data Program

In Fiscal Year 2001, AMS implemented the Microbiological Data Program (MDP), a monitoring program to collect information regarding the incidence, number, and species of important foodborne pathogens and indicator organisms on domestic and imported fresh fruit and vegetables. The collection and analysis of samples began in April 2001.

MDP was primarily designed to provide data on microbial presence in order to establish a microbial baseline to assess the risks of contamination, if any, in the domestic food supply. The data are used to establish "benchmarks" by which to evaluate the efficacy of procedures to reduce or eliminate harmful foodborne microorganisms. The data are provided to stakeholders for decision-making purposes (e.g., Federal and State public health agencies, growers, processors, retail stores, and food handlers).

Data collection and testing activities are carried out with the support of 11 states ~ California, Colorado, Florida, Maryland, Michigan, Minnesota, New York, Ohio, Texas, Washington, and Wisconsin ~ through cooperative agreements with their respective Departments of Agriculture. AMS provides quality assurance oversight and laboratory/administrative support to the

program.

Recent examples of the value provided by MDP occurred in April this year during routine monitoring when *Salmonella* was found in alfalfa sprouts and spinach by the Ohio and Wisconsin laboratories testing samples collected by the program. The Centers for Disease Control and Prevention (CDC) and FDA as well as health officials in both States were notified. MDP information was used for trace back and notification to customers who had received the affected products and in both cases, the affected products were voluntarily recalled. The *Salmonella* strain found by Ohio was determined to be linked to a cluster of foodborne illnesses in Arizona and New Mexico. There are no reported illnesses linked to the spinach strain. Since spinach from this lot was distributed in Illinois, FDA is assisting in product recall for that State. Quick intervention by FDA and State officials and voluntary cooperation by distributors reduce risks to consumers' health and minimize economic impact on growers.

In the aftermath of these incidents, the FDA Associate Commissioner for Foods asked for a more interactive approach between the two agencies to develop plans and communication strategies for MDP. Building on their prior programmatic collaboration, FDA and AMS agreed to have designated points of contact always available so that FDA can respond quickly when MDP finds harmful pathogens during routine monitoring. CDC became actively engaged in MDP during the *Salmonella saintpaul* outbreak in 2008 and has continued participating in program planning by providing feedback on foods that need to be monitored by the program. The PFGE fingerprint patterns of enteric bacterial pathogens isolated by MDP are entered into CDC's PulseNet database to be compared with pathogens isolated from humans.

To conclude, Mr. Chairman, I would like to reiterate that Federal food safety policies for fruits and vegetables fall under the jurisdiction of the FDA. AMS has developed significant experience in the design and delivery of marketing programs, including those involving inspections for product quality and verification of production processes. At industry's request, AMS has incorporated food safety-related elements in several of its marketing programs to verify that industries adhere to FDA requirements and guidelines.

I would be pleased to respond to questions.