



United States
Department of
Agriculture

Agricultural
Marketing
Service

Fruit and
Vegetable
Programs

Fresh
Products
Branch

Good Agricultural Practices and Good Handling Practices Audit Verification Program

User's Guide

April 2011



Audit User's Guide for GAP & GHP

This User's Guide is specifically developed and designed by the United States Department of Agriculture, Agricultural Marketing Service, Fresh Products Branch to provide information about the USDA Good Agricultural Practices & Good Handling Practices (GAP&GHP) Audit Verification Program.

This User's Guide does not establish any substantial rule not legally authorized by official Branch Policy.

Questions about this User's Guide can be directed to the Fresh Products Branch's Audit Management Section in Washington DC.

April 2011

******This publication may be duplicated without authorization from USDA. ******

TABLE OF CONTENTS

GENERAL INFORMATION	1
BACKGROUND	1
AUDITORS	2
DEVELOPMENT OF A FOOD SAFETY PROGRAM	2
PREPARING FOR AN AUDIT	3
INTERNAL AUDIT	4
DOCUMENTATION	4
D=DOCUMENT	4
P=POLICY.....	5
R=RECORDS.....	5
SCHEDULING AN AUDIT	5
PARTICIPATION AGREEMENT.....	5
THE AUDIT	5
INITIAL AUDIT	6
FOLLOW-UP AUDIT.....	6
UNANNOUNCED VERIFICATION VISIT	6
PART 1- FARM REVIEW	7
PARTS 2 THROUGH 6 OF THE GAP&GHP AUDIT.....	7
PERFORMING AN AUDIT FOR A DIVERSIFIED FARMING OPERATION.....	7
NON-CONFORMITY AND CORRECTIVE ACTION POLICY	8
AUDIT SCOPES	9
GENERAL QUESTIONS.....	9
FOOD SAFETY PLAN	10
TRACEABILITY	10
RECALL PROGRAM	10
WORKER HEALTH AND HYGIENE	11
PESTICIDE/CHEMICAL USE	12
FARM REVIEW.....	12
WATER USE	12
SOIL AMENDMENTS	13
ANIMALS/WILDLIFE/LIVESTOCK	14
LAND USE & LAND USE HISTORY.....	14
FIELD HARVEST & FIELD PACKING ACTIVITIES.....	15
PRE-HARVEST ASSESSMENT	15
FIELD SANITATION UNITS.....	16
HARVESTING CONTAINERS & EQUIPMENT	16
WATER USE	17

TRANSPORTATION OF PRODUCE	17
EMERGENCY CLEAN-UP PROCEDURES.....	17
HOUSE PACKING FACILITY	17
WATER USE IN PACKING FACILITY	18
TREATMENT OF PROCESSING WATER.....	18
SANITATION PROGRAM/GENERAL HOUSEKEEPING	19
WORKER HEALTH AND HYGEINE	19
CONTAINERS	20
PEST CONTROL.....	20
STORAGE AND TRANSPORTATION	20
MECHANICAL EQUIPMENT	21
ICE AND REFRIGERATION.....	21
TRANSPORTATION AND LOADING	21
WHOLESALE DISTRIBUTION CENTER/ TERMINAL WAREHOUSE	21
RECEIVING.....	22
SANITATION PROGRAM/GENERAL HOUSEKEEPING	22
WATER USE IN PACKING FACILITY	23
TREATMENT OF PROCESSING WATER.....	23
STORAGE FACILITY/TEMPERATURE CONTROL	23
CONTAINERS	24
MECHANICAL EQUIPMENT	24
PREVENTIVE FOOD DEFENSE PROCEDURES	24
FOOD DEFENSE PLAN	24
PERSONNEL	24
FACILITY PROCEDURES.....	25
KEY/ENTRANCE ACCOUNTABILITY	26
DELIVERIES	26
SEPARATION OF PRODUCTS.....	26
ALLERGENS	27
USDA GAP&GHP PROGRAM AUDIT SCORING.....	27
AUTOMATIC UNSATISFACTORY CONDTION	27
POST AUDIT ACTIVITIES.....	28
APPEALS, COMPLAINTS & DISPUTES	28
ADDITIONAL RESOURCES	29
APPENDIX I – FV-237A AUDIT REQUEST	30
APPENDIX II – FV-651 PARTICIPANT AGREEMENT	31
APPENDIX III – CORRECTIVE ACTION REPORT	33

GENERAL INFORMATION

This User's Guide is intended to provide guidance to the fresh fruit and vegetable industry on the requirements of the USDA Good Agricultural Practices and Good Handling Practices Audit Verification Program (GAP&GHP) and prepare for a successful audit. This Guide does not address every specific question on the USDA GAP&GHP audit checklist, but covers all the major topic areas of the audit.

USDA AMS and state departments of agriculture who work with USDA AMS through cooperative agreements also conduct commodity specific audits for the leafy greens, tomato and mushroom industries. These audits fall under the general guidelines of the USDA GAP&GHP program. Each commodity specific audit has its own set of specific requirements and audit checklists. Please refer to the USDA GAP&GHP website at www.ams.usda.gov/gapghp for links to these commodity specific audit programs.

BACKGROUND

In October 1998, the U.S. Food and Drug Administration (FDA) issued a guidance document for the fresh fruit and vegetable industry which provided general guidelines for reducing the risk of contamination of fresh produce by microbial organisms. The document, "*Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*," (The FDA Guide) provides information about high risk areas for contamination and how to avoid or minimize such contamination. Shortly after the release of The FDA Guide, many wholesale and foodservice buyers of fresh fruits and vegetables began requiring their suppliers to undergo 3rd party audits which provided assurances they were following good agricultural practices (GAP) and good handling practices (GHP).

In response to numerous requests from the fruit and vegetable industry, the USDA Agricultural Marketing Service (AMS) in cooperation with the Association of Fruit and Vegetable Inspection and Standardization Agencies (AFVISA) developed an audit based program to verify conformance to The FDA Guide. In August 2001, USDA AMS approved and conducted a pilot project for the GAP&GHP audit, and in January 2002, USDA AMS formally implemented the USDA Good Agricultural Practices & Good Handling Practices (GAP&GHP) audit verification program. It is offered to the fruit and vegetable industry and assesses an operation's efforts to minimize the risk of contamination of fresh fruits, vegetables and nuts by microbial pathogens. The program does not guarantee the product is free from microbial contamination, but verifies the participant has taken proactive measures to reduce the risk of contamination by adhering to generally recognized best practices. The responsibility for product safety and the continued observance of best practices rests with the operation producing and handling the fresh product.

Additional information and a copy of the current checklist can be found at www.ams.usda.gov/gapghp.

The USDA GAP&GHP audit verification program is a voluntary, user fee funded program. The USDA Agricultural Marketing Service operates under the Agricultural Marketing Act of 1946 [7 U.S.C. 1621], and offers voluntary, user fee funded programs which assists in the strategic marketing of agricultural commodities. The U.S. Food and Drug Administration is the federal agency with regulatory authority for fresh fruits and vegetables.

AUDITORS

All auditors used to perform the USDA GAP&GHP audit are either federal employees of USDA AMS, or state department of agriculture employees who are specifically trained and licensed to perform audits on behalf of USDA AMS. Most auditors are fruit and vegetable inspectors who inspect and grade produce on a daily basis as well as perform audits.

USDA AMS sets the minimum criteria for all AMS personnel used to conduct audits. The following bullets highlight the auditor requirements for the GAP&GHP program:

- Auditors must have a minimum of three years work experience in the area of fruit and vegetable production, handling or marketing; or a Bachelors Degree in an agricultural related field; or a combination of work experience and education.
- Auditors must demonstrate knowledge of the production, handling, distribution and marketing of fresh fruits and vegetables.
- Auditors must undergo formal classroom training as well as on the job training.
- Auditors are evaluated by program management before being licensed as an auditor.
- Auditors must take yearly refresher training specific to the audit program they are licensed.
- Auditors must take yearly ethics training.
- Auditors must complete 80 hours of continual professional development every three years.
- Auditors are evaluated on a yearly basis.

USDA licensed auditors provide impartial, prompt third party services to the fruit and vegetable industry and have no financial interest in the products and services they are auditing. In order to remain impartial, auditors are prohibited from providing specific recommendations to operations on the development of their food safety plan or actions which need to be taken by the operation in order to be compliant with the USDA GAP&GHP program requirements. Auditors may answer general inquiries and refer inquiries to food safety experts such as cooperative extension specialists.

DEVELOPMENT OF A FOOD SAFETY PROGRAM

The development of a food safety program is recommended for any operation which produces or handles fresh fruits and vegetables, not just for operations who wish to participate in the USDA GAP&GHP audit verification program.

A food safety plan is a written document that covers all aspects of the growing and handling processes, and evaluates the potential sources of risk. The plan indicates what steps and procedures the operation will take to reduce the risks of contamination by chemical, physical, or microbial hazards.

To assist operations in the development of a food safety plan the FDA and the fruit and vegetable industry have developed commodity specific guidance documents which outline the best practices of the specific commodity. The FDA has released four commodity specific guidance documents for leafy greens, melons, tomatoes and fresh cut fruits and vegetables. Trade and commodity associations have developed their own set of guidance documents including watermelons, strawberries, mushrooms, leafy greens, tomatoes, and green onions. Other guidance documents are currently in development.

Many university Cooperative Extension programs across the country have developed templates or examples of produce specific food safety plans to assist their constituents develop food safety plans. Operations should contact their state Extension Service program or visit the National GAPs Program website for further information at <http://www.gaps.cornell.edu>.

For operations wishing to participate in the USDA GAP&GHP program, the first step in preparing for an audit should be the development and implementation of a food safety program. The produce food safety program should be written by the operation and shall define specific, measurable steps taken by the operation to reduce the risk of microbial, physical and chemical hazards from contaminating the product. A well-written plan will detail all aspects of the growing and handling processes and shall also outline the corrective actions the operation will take if it is suspected or known product has become contaminated. Typically the food safety program takes the form of a manual to facilitate the easy dissemination and recording of the operations food safety plan. The food safety plan needs to incorporate the USDA GAP&GHP audit verification program requirements and applicable policies. The following points are key items to consider:

- The operation must create a food safety program that accurately reflects their operation.
- The operation shall develop Standard Operating Procedures (SOPs) which outline the policies and procedures for the operation.
- The operation must designate a person that oversees the food safety program.
- The produce food safety program must be implemented and followed.
- The operation must determine what to document and keep records for. The operation must also keep all documents and records current.
- The operation shall document corrective actions taken which verifies adherence to their food safety plan.

PREPARING FOR AN AUDIT

For farming operations/packinghouses wishing to participate in the USDA GAP&GHP program, the operation should implement their produce food safety program

as close to the beginning of the growing season as possible. Starting early in the season allows the operation to make any necessary changes to their policies and procedures, as well as accumulate documents and records verifying their food safety program. Additionally, once the growing season starts, operations may not have the time and/or resources available to develop and implement a viable food safety program.

Wholesale distribution centers/terminal warehouses/commercial storage facilities may implement their food safety program at any point during the year. These operations should take into consideration the time it will take to accumulate documents and records verifying their food safety program before scheduling an audit.

INTERNAL AUDIT

Although not a requirement of the program, it is recommended that the operation conduct a self or internal audit prior to scheduling an official USDA audit. A self or internal audit allows the operation to find areas of improvement and take corrective actions before the actual audit. Some Cooperative Extension programs will work with their growers and assist in performing an internal audit of the operation.

Operations can utilize the USDA GAP&GHP audit checklist to perform the internal audit which is available on the USDA GAP&GHP website or by contacting the local inspection office.

DOCUMENTATION

An important component of any audit based program is the review of documents and records. Since the auditor is not at the operation on a daily basis, documents and records are necessary to verify policies and procedures are in place, and certain tasks have been completed throughout the year.

The operation shall keep records as necessary to document adherence to their food safety program, USDA GAP&GHP program requirements, and local, state and federal regulations. The operation's food safety plan shall address what documents and records shall be maintained and the policies and procedures for managing the documents.

For the purposes of the USDA GAP&GHP program, the audit checklist defines when documents are required and what type of documentation is necessary. These are defined in the last column of the audit checklist as a D, P, or an R. Operations may decide to keep additional documentation than is required by the USDA GAP&GHP program, but at a minimum, those questions on the audit checklist which are identified with a D, P or R require documentation.

D=Document

Any question designated with a D requires a combination of written standard operating procedures outlining company policies and procedures, records of actions taken, and/or other documents which may be necessary to support the food safety plan.

P=Policy

Any question designated with a P requires a written policy or procedure to appear in the operation's food safety plan.

R=Records

Any question designated with a R requires a record which shows a process has been completed or record an action taken.

SCHEDULING AN AUDIT

An operation shall initiate the scheduling of the audit at least two weeks in advance of their anticipated audit date by contacting the local USDA inspection office. The USDA does not automatically contact operations who have participated in previous years to schedule its yearly announced audit. It is the operation's responsibility to schedule the audit.

A list of USDA inspection offices is available on the USDA GAP&GHP website or by calling the Fresh Products Branch at 800-560-7956, Extension 5. In addition, audits may be requested using the FV-237A form, located in the appendix of this User's Guide, and faxing to the local USDA inspection office. When contacting the local inspection office, be prepared with a list of anticipated dates the operation is available for an audit. All services are offered on a first come, first served basis. Once an auditor is assigned, he/she will contact you to make arrangements for the audit. Be prepared to provide the auditor with a point of contact, the contact's information, physical location/address of the audit site and other information necessary for the audit. If the operation has a large non-English speaking workforce, the auditor may ask the operation to provide a translator in order to communicate with the workers during the audit if he/she does not speak the language of the workforce.

PARTICIPATION AGREEMENT

The auditor will provide the operation with USDA form FV-651, the Participation Agreement. An example of the FV-651 form is in the appendix of this guide. The Participation Agreement outlines the expectations of the operation and the USDA in performing the GAP&GHP audit. Form FV-651 must be signed by a management representative of the operation and submitted to the auditor prior to the start of any audit. Without the form, no audit services can be provided.

THE AUDIT

The actual audit is broken down into four main areas:

- Opening Meeting - The lead auditor introduces the audit team, communicates the agenda of the audit, answers questions from the auditee, and explains the audit process so everyone knows what to expect during the audit.
- Conducting the audit - The audit team will review documents and records, interview employees, witness processes and observe the operation to determine compliance to the operations food safety plan and the USDA GAP&GHP program requirements.
- Team Caucus - After the audit team has finished evaluating the operation, the team will meet and discuss any findings, address any concerns among the team members, and finalize the audit.
- Closing Meeting - The lead auditor will meet with the operation's representatives and review the findings of the audit. The audit team will also answer any questions from the auditee and explain any observations.

There are distinct types of audits which may be applicable to the operation during the year; the initial audit, the follow-up audit and the unannounced verification visit.

INITIAL AUDIT

The initial audit is the annual announced audit that verifies the farm/facilities compliance with the requirements of the USDA GAP&GHP audit verification program. A USDA GAP&GHP audit is valid for one year from the date of the initial audit.

FOLLOW-UP AUDIT

A follow-up audit is performed when either the farm/facility's initial audit or unannounced verification visit does not meet the program requirements. If an operation does not meet program requirements, the auditor will create a corrective action report and the operation must address the non-conformities prior to the scheduling of a follow-up audit. For specific instructions, refer to the non-conformity and corrective policy section.

- If the operation fails to meet program requirements due to an "automatic unsatisfactory" condition, the follow-up audit must consist of all scopes originally requested on the initial audit.
- If the operation fails to meet program requirements because of a low score for one or more scopes, only those scopes which failed and the General Section must be completed on the follow-up audit.

UNANNOUNCED VERIFICATION VISIT

An important component of the USDA GAP&GHP audit is the use of unannounced verification visits. Unannounced verification visits are conducted at some point during the season after the operation has successfully passed an initial or follow-up audit. It is used to verify that a farm/facility is in consistent conformance with the requirements of its food safety plan and the USDA GAP&GHP program requirements.

The unannounced verification visit differs from the initial audit in that the auditee does not know specifically when the auditor will be on site to perform the audit. The unannounced review will generally verify conformance through observation but may also require a further review of documentation.

USDA policy sets the following conditions for when and how many unannounced verification visits shall be conducted:

Part 1- Farm Review

For operation which only grow one commodity in a production area during a growing season such perennial crops, potatoes, onions, etc., no unannounced verification visits for the production area are required.* For those operations that grow multiple commodities during the growing season using the same crop production area, unannounced verification visits of the farm are required.

Parts 2 through 6 of the GAP&GHP audit

- For an operation which is in operation for 30 days or less, no unannounced verification visits are required.*
- For an operation which is in operation for 31-90 days, a minimum of one unannounced verification visit shall be conducted.*
- For an operation which is in operation for 90 days or more, a minimum of two unannounced verification visits shall be conducted.*

*Note In all cases, the USDA reserves the right to conduct additional unannounced verification visits if there is specific reason to suspect the operation is not in compliance with the GAP&GHP program requirements or their own food safety program.

PERFORMING AN AUDIT FOR A DIVERSIFIED FARMING OPERATION

It is not a requirement to perform a separate audit for every separate commodity grown on the farm, however operations may choose to do so if they so desire. USDA AMS policy allows diversified farming operations to cover all the commodities grown on the farm under the same audit subject to the following conditions:

- All commodities covered by the audit must be declared during the initial audit and cannot be added later in the season. The food safety plan must address the various risks associated with all the commodities being audited. For instance if a berry grower hand picks strawberries but mechanically harvests blueberries, the food safety plan shall address the potential risks and corrective actions associated with each of these activities.
- The auditor must have the opportunity to observe the crop(s) being grown and harvested during the initial audit or subsequent unannounced verification visits. As an example, if the operation schedules an audit for August 1st, any crops which have been completely harvested prior to August 1st cannot be listed on the

audit. The auditor may not actually witness every commodity listed being harvested, but needs to have the opportunity to observe.

- Operation would be subject to the appropriate number of unannounced verification visits determined by the length of the growing season for all the commodities produced.

The following is an example of how performing a GAP&GHP audit for a diversified operation would work. ABC Fruit and Vegetable Growers Inc. produces a wide variety of fruits and vegetables including asparagus, strawberries, sweet peas, tomatoes, peppers, peaches, nectarines, apples, pears, potatoes, broccoli and cauliflower and wants a USDA GAP&GHP audit. The operation is in production from the start of the growing season on April 1st to approximately October 31st.

- ABC Fruit and Vegetable Growers Inc would call and schedule their initial audit when the spring crops (asparagus, strawberries and sweet peas) are being harvested. However, they would declare all twelve of the commodities grown when scheduling the audit.
- The auditor would perform the initial audit and cover the General Section and Part 1 Farm Review of the entire farming operation. The auditor would also perform Part 2 Field Harvesting and Field Packing Activities on the asparagus, strawberries and sweet peas. In addition because the operation is in production for more than 90 days, the auditor would inform the operation there will be two unannounced verification visits sometime during the rest of the growing season. The auditor would then schedule the first unannounced visit to coincide with the harvest of the tomatoes, peppers, and stone fruit, and the second unannounced visit to coincide with the harvest of the remaining commodities.

NON-CONFORMITY AND CORRECTIVE ACTION POLICY

A Corrective Action Report (CAR) is required for any GAP&GHP audit which fails due to non-conformities from a specific “automatic unsatisfactory” or because a particular scope fails to meet the minimum program requirements.

The auditor will document the non-conformity(s) observed during the audit on the CAR form and submit it with the audit report at the closing meeting. If the operation wishes to continue in the GAP&GHP program, it must review the non-conformity(s) listed on the Corrective Action Report form and develop a plan to fix or address them. Corrective actions are typically taken in two steps, a short term corrective action and a long term corrective action (sometimes referred to as a root cause analysis). Short term corrective actions are taken to immediately address a deficiency. For example, if an auditor observes a restroom without any soap, toilet paper and paper towels, the operation’s short term corrective action is to stock the restroom with the appropriate supplies. A root cause analysis reviews the deficiency if it occurs frequently or requires long term investment. In the example above, if the auditor investigated why the restrooms were always out of supplies and found their food safety program didn’t designate someone to check the bathrooms on a regular basis and restock as needed.

Designating someone to handle the bathroom supplies would be a long term or root cause corrective action.

Once the operation has reviewed and developed a corrective action for the non-conformities listed on the audit, it will submit the corrective actions to the auditor for review. The auditor will review the corrective actions and sign off on the Corrective Action Report if he/she feels the corrective actions listed will reasonably address the non-conformity. Ultimately the corrective actions will be verified during a follow-up audit or unannounced verification visit.

AUDIT SCOPES

The USDA GAP&GHP audit is divided into seven sections or scopes, each which covers a specific portion of the supply chain. The scopes of the audit are:

- General Questions
- Part 1 – Farm Review
- Part 2 – Field Harvesting & Field Packing Activities
- Part 3 – House Packing Facility
- Part 4 – Storage & Transportation
- Part 5 – (No Longer Used)
- Part 6 – Wholesale Distribution Center/Terminal Warehouse
- Part 7 – Preventative Food Defense Procedures

USDA considers a good agricultural practices audit to consist of Part 1 Farm Review and Part 2 Field Harvest & Field Packing Activities and a good handling practices audit to consist of Part 3 House Packing Facility and Part 4 Storage & Transportation for pre farm gate operations or Part 6 Wholesale Distribution Center/Terminal Warehouse for post farm-gate operations. Part 7 Preventative Food Defense Procedures is an optional scope for those operations which need verification of food defense.

The operation shall designate which scopes of the audit the auditor will perform when requesting the audit.

GENERAL QUESTIONS

The General Questions are a mandatory scope of every audit (except for a Part 7 Food Security only audit) and cover overarching food safety issues which are applicable to any audit. In order to successfully pass the USDA GAP&GHP audit, the operation must meet the requirements of the General Questions portion of the audit. The following sections outline the major topics covered by the General Questions.

FOOD SAFETY PLAN

USDA policy requires that an operation develop and implement a documented food safety program. The program must include a food safety manual which includes standard operating procedures (SOP's), and/or documentation which outline the operation's policies and work instructions for adhering to the food safety program. It may also contain information or references pertaining to self audits of the program or management reviews of the program. Other similar documentation may also be applicable and acceptable if it indicates that an established food safety program is in place.

In addition, it is required that the operation has identified a specific person(s) to implement and oversee the food safety program. The person(s) need to be formally identified in the food safety plan, organizational chart, or similar documentation.

TRACEABILITY

The food safety program shall include a documented traceability program. A traceability program in its simplest form is the ability to know where product was received from (one step back) and where product was sent to (one step forward). The operation needs to develop and implement policies and procedures for a traceability program. There are commercially available traceability programs for the produce industry which can assist operations in implementing a traceability program. For further guidance operations can contact their trade/commodity associations, state horticultural associations or county extension agent.

The Bioterrorism Act of 2002 requires certain handlers of foods to keep records which allow the handler to keep track of produce "one step forward" and "one step back" within the food chain. For producers, keeping records and uniquely identifying product moving out of the field to its next destination (packing house, storage cellars, end user, etc.) is an important component of a traceability program. For product moving in bulk from the field to a packing house or storage facility, records such as load tickets, field harvest records that move with the load or other similar records that identify where the product originated are examples of identification. For products that are field packed, the individual cartons or master containers should be clearly identified with the company information including company name and address and other identifying marks as outlined in the company's traceability program.

RECALL PROGRAM

A recall program is defined as the ability to pull product from the marketplace once it has left the operation's control. The operation needs to develop policies and procedures which allow it to recall product by working with their suppliers and customers to track the path the product takes from the farm to the consumer. A recall is a means to return marketed product to its origin or to remove it from the market place and have verifiable evidence that all product being recalled is accounted for. A "mock recall" is a practice exercise that is used to determine where product is shipped and whether or not it can be returned to the origin or removed from the marketing chain.

Operations must have some documented evidence of completing at least one mock recall prior to the audit. Documents must indicate the customers contacted, the amount of product remaining from the original shipment, and the disposition of product which could not be effectively recalled.

The following is an example of a mock recall:

- A packinghouse generated 5,000 cases of apples on January 15th from grower X lot 1234. The packinghouse labeled the apples with their name, address and a lot code of 11511.
- The 5,000 cases of apples were shipped to five different retailers, each receiving 1,000 cases.
- The packinghouse initiates a recall of lot 11511. The individual(s) responsible for performing the mock recall contacts the five retailers who received apples from lot 11511 and informs them they are performing a mock recall. The packinghouse forwards a form to each retailer asking to supply an accounting of the number of cartons from lot 11511 still in their possession and the number of cartons sold. The form will contain instructions on where to send the form when completed and the timeframe when it must be sent back. The recall plan should outline the timeframe required to complete the mock audit.
- The packinghouse summarizes the forms from the five retailers and determines the number of cartons still in the retailers control and the number that are not.

In the event of an actual recall, the operation shall develop a procedure on how they want the product being recalled to be handled. Does the operation want it returned? Will the operation allow the buyer to dispose of it and submit proof the product has been dumped?, etc. This needs to be communicated to the buyer so they can effectively manage their inventory as well.

WORKER HEALTH AND HYGIENE

One of the primary risks associated with fruits and vegetables is the potential introduction of pathogens through poor worker health and hygienic practices. The General Questions section of the USDA audit covers, in great detail, areas which need to be addressed regarding worker health and hygiene. In addition, other scopes of the audit address worker health and hygiene issues related to those scopes such as an operation's glove and jewelry policies, or location of portable sanitation units in the field.

The operation's food safety plan shall address worker health and hygiene issues and develop SOPs which address them. This should include a training program to educate workers on the operation's SOPs. A solid training program is an essential component of a food safety program. Examples of SOPs include:

- Ensuring potable water is available to all workers;
- Ensuring all workers and visitors to the location are required to follow proper sanitation and hygiene practices;
- Providing training on proper sanitation and hygiene practices to all staff;
- Verifying employees and visitors are following good hygiene/sanitation practices;

- Confirming employees are washing their hands before beginning or returning to work;
- Posting readily understandable signs that instruct employees to wash their hands before beginning or returning to work;
- Servicing and cleaning all toilet/restroom/field sanitation facilities; and
- Confining smoking and eating to designated areas separate from where product is handled.

The General Questions section also requires the operation to develop a blood and bodily fluid policy, and a policy which addresses workers who report to work with symptoms of forborne illness.

The USDA GAP&GHP audit requires that all sanitation facilities must be properly supplied with single use towels, toilet paper, and hand soap or anti-bacterial soap and potable water for hand washing. Hand sanitizers are not an acceptable substitute for hand washing and are not to be used as the sole method for hand cleaning. The number and placement of sanitation facilities must comply with all applicable local, state and federal regulations. At a minimum the Occupational Safety and Health Administration (OSHA) requires one bathroom per 20 employees.

PESTICIDE/CHEMICAL USE

The operation shall use all pesticides and other pre or post harvest materials in a manner consistent with prevailing regulations and the labeled instructions. This includes following state licensing requirements for pesticide applicators.

FARM REVIEW

The Farm Review scope of the USDA audit mainly addresses the crop production areas and adjacent lands, domestic and wild animals, as well as the inputs used to produce the crop such as water and soil amendments.

WATER USE

For the purposes of the USDA GAP&GHP program, water use is defined as either agricultural water used for irrigation, frost protection, fertigation, chemical application or other pre-harvest purposes, and post harvest water used on the product after it has been harvested. An example of post harvest water use is water used to wash the product, transport the product through the grading and packing line (dump tanks, flumes, etc.) or apply post harvest chemicals. Operations must have knowledge of the water quality used in order to determine whether or not the product is reasonably likely to become contaminated through the application of or submersion into water.

For agricultural water, the USDA GAP&GHP program requires the operation perform a water quality risk assessment to determine if the water quality is appropriate for the crop(s) it's being used on. The risk assessment should include the water quality, the type of irrigation method, and the crop being irrigated. The results of the risk

assessment shall be used to determine an action level where the operation determines water quality is not suitable for use without taking a corrective action. Water tests are required to be conducted on a scheduled frequency to verify water quality is meeting the operation's action threshold as outlined in their SOPs.

The USDA GAP&GHP program sets the following testing frequency:

- **Municipal water:** Test results are acquired from the local water authority annually or tested by the operation at least annually.
- **Well water:** Water is tested one time during the growing season. If fecal coliforms are present, the well is treated with a sanitizer to reduce pathogen levels and is retested. Wells are monitored to make sure casings are secure and well-maintained and that livestock and manure storage areas are excluded from the well recharge and pumping area.
- **Surface water:** Water is tested three (3) times during the growing season – first at planting, second at peak use, third at or near harvest.

There is not a national irrigation water standard which sets the minimum microbial levels allowable for irrigation water. However, there are many commodity specific guidelines available which give recommendations for water quality. These can serve as a reference source for an operation when determining specific thresholds for their irrigation water. For instance the CA & AZ Leafy Greens Marketing Agreements and the Food Safety Standard for the Tomato Supply Chain identify the microbial requirements of the EPA Recreational Water Standard as the threshold for irrigation water.

For post harvest water applications, the USDA GAP&GHP program requires that the water used meet the microbial requirements of the US EPA Drinking Water Standard. Any post harvest water use which does not meet this standard will result in an “automatic unsatisfactory” assessment on the audit.

SOIL AMENDMENTS

Animal manure and biosolids represent a significant source of potential contamination. However, properly treated manure or biosolids can be an effective and safe fertilizer. Raw animal manure or raw biosolids used as a fertilizer or enters water sources through runoff may contain pathogens of public health significance that can contaminate produce.

The operation shall conduct a risk assessment to determine if and when raw manure or biosolids are appropriate to use. The type of crop and growing conditions are all factors in the risk assessment. For example, raw manure applied to a newly planted orchard is less of a risk than raw manure applied to a vegetable crop grown on the ground. The USDA GAP&GHP Program requirements state that if raw manure is used, it must be applied at least 2 weeks prior to planting and a minimum of 120 days prior to harvest. There are also several commodity specific guidance documents which are more restrictive than the USDA GAP&GHP program and either do not allow the use of raw manure or have a one year restriction on the application of raw manure. Operations shall check to see what the commodity specific recommendations and

prevailing regulations are for their commodities regarding the use of manure and biosolids.

Animal manure or biosolids which are composted require a documented composting process be developed and available for review. If purchasing composed manure, has documentation from the composter listing the process used and test results showing the process effectively controlled the pathogens of concern should be maintained. If an operation has questions regarding proper composting procedures, contact the Cooperative Extension Service in your state. Most all Extension Services have developed proper composting procedures and have this type of information readily available.

ANIMALS/WILDLIFE/LIVESTOCK

Animals pose a potential source of contamination for fruit and vegetable crops. Domestic animals which can be controlled such as livestock or pets need to be excluded from entering crop production areas in order to reduce the potential for contamination. However, when farm service animals (horses, oxen, and mules) are used, an operation shall address potential sources of contamination through a risk assessment and documented SOP's to control hazards caused by these animals and remediation steps which will be taken if they cause contamination.

The USDA GAP&GHP program requires operations to monitor for the presence or signs of animals. Based on the results of the monitoring, if necessary take measures to reduce the opportunity for animals from entering the crop production areas. This does not mean total exclusion; farming operations are never going to be able to completely exclude wild animals from entering crop production areas. However, every effort should be made to limit the access to the production areas. When needed, measures should be taken to reduce the entry into crop production areas by wild animals. This can be accomplished many ways, including such items as noise cannons or scare balloons to scare away birds and migratory water fowl, or fencing /other barriers or deterrents which limit wildlife access.

Operations shall also consider any local, state or federal regulations when developing mitigation strategies for wild animals. Regulations may limit the options for controlling wild animals. Co-management strategies which balance food safety concerns with wildlife control and not just remove riparian areas, grass buffer strips and other conservation practices should also be considered. Operations can contact the local Natural Resources & Conservation Service or their local county extension agent for more information on co-management.

LAND USE & LAND USE HISTORY

The operation must consider the crop production areas and adjacent land use through a documented land use risk assessment. Any risks reasonably likely to cause chemical, physical or microbiological contamination of the produce which are identified by the risk assessment must be addressed and the crop production area tested to validate the hazard has been addressed. While adjacent lands may not be the property

of the operation, the effects they have on the crop production areas needs to be evaluated and mitigation strategies put in place to minimize the impact of the hazard on the ground. For example, if the adjacent ground is uphill houses a concentrated animal feeding operation, proactive steps to minimize the opportunity for runoff to flow through the crop production area must be taken.

Flooding which is caused by the overflow of a body of water shall be documented and if it occurs in season, an assessment is performed to determine if the flooding contaminated the product. The operation should consider testing the product and/or soils before harvesting if sources of contamination are located in the general vicinity of the crop production areas.

The land use risk assessment shall also consider the location of the operation's sewage treatment/septic system or nearby municipal/commercial sewage treatment facilities. The operation shall also verify their sewage treatment/septic system is functioning properly and does not lead to a contamination risk.

FIELD HARVEST & FIELD PACKING ACTIVITIES

The Field Harvest and Field Packing Activities section of the audit covers the harvesting of commodities in either the field or greenhouse operations. It also covers the packing of such commodities for shipment when it occurs directly in the field or greenhouse and is not sent to a packinghouse for further sorting or grading. The emphasis on this scope is the harvesting activities, and the containers and equipment which are used to pack the product. Employee health and hygiene are also an important component of field harvest and field packing and are covered in the General Questions section of the audit.

USDA policy only allows an auditor to perform this scope of the audit when commodities are actively being harvested and there is activity in the crop production area. It is not a requirement that the auditor observe every commodity listed on the audit being harvested, however the food safety plan shall address all the commodities being harvested, and the different risks associated with different harvesting methods. (i.e. mechanically harvested vs. hand harvested). Records for all commodities harvested are maintained for traceability.

PRE-HARVEST ASSESSMENT

The farm operation must have completed a pre-harvest assessment on each production area prior to harvesting any crop being certified by the audit. The assessment may include statements which address known risk that are applicable to the operation such as:

- Are toilet and wash facilities properly located?
- Is potable water available for workers?
- Are harvest containers available, clean, well located and protected?
- Is harvest equipment available and in good condition?

- Is there evidence of unauthorized entry in the crop area and if so, has it been investigated?
- Is there evidence of domestic or wild animal crop damage?
- Is there evidence of physical contamination in the crop area?
- Are fuel and chemicals which might contaminate crop areas isolated?
- If areas are contaminated are they isolated for “no-harvest”?
- Are there any other notable sources of biological or physical contamination such as dump sites, manure, burning debris, water that may affect food safety?
- Is transportation equipment clean and available?

The assessment may include other information as determined by the operation.

FIELD SANITATION UNITS

The number and placement of sanitation facilities must comply with all applicable local, state and federal regulations. Operations shall also have a documented emergency clean-up procedure in case contamination occurs. The procedure should include what will be done to contain the spill and to prevent additional contamination, what will be done to clean up the spill and what will be done with contaminated product.

HARVESTING CONTAINERS & EQUIPMENT

The farming operation shall keep harvest containers (picking buckets, baskets, bulk bins, etc.) as clean as practicable to prevent cross-contamination of fresh produce. These are some key areas to consider which are covered in the GAP&GHP audit:

- Harvest containers used repeatedly during a harvest should be cleaned on a scheduled basis as outlined in the food safety plan.
- If the farming operation stores harvest containers outside, proactive steps shall be taken to minimize harboring rodents and other pests in the harvesting containers.
- Harvesting containers stored outside should be cleaned and sanitized before being used to haul fresh produce.
- Operations shall also instruct workers to only use harvesting containers for their intended purpose, and not to use them for collecting trash or transporting personal items unless they are designated for that use.
- Final packing containers used in field pack operations shall be protected from sources of contamination.
- Only new or sanitized containers are used for packing the product.
- Operation shall repair or discard damaged harvesting containers.
- Harvesting equipment and machinery which comes in contact with the product is in good repair.

- Light bulbs and glass on harvesting equipment are protected and the operation has an SOP in place to address glass or plastic breakage on the equipment during harvest.

WATER USE

See the water use discussion in the Farm Review section.

TRANSPORTATION OF PRODUCE

Products that are transported in bulk from the field or from storage for further packing may be contaminated during this time. Steps should be taken to reduce the possible contamination by other vehicles on the roads, overhead contamination from overpasses, from birds or other means. Using tarps, enclosed trailers or other means to cover loads are examples of good practices. Products being moved in enclosed containers (boxes, cartons, etc.) would be considered covered if they are completely enclosed.

EMERGENCY CLEAN-UP PROCEDURES

The operation shall have a documented emergency clean-up procedure in the event accidental contamination occurs from glass/plastic breakage, chemicals, petroleum, or pesticides contaminating the crop. The procedure should include what will be done to contain the spill and to prevent additional contamination. As well as what will be done to clean it up and what will be done with contaminated product.

HOUSE PACKING FACILITY

This scope covers packinghouses located on or near crop production areas. This scope is not intended for repack operations or distribution operations which may custom pack product for retail or foodservice customers. These types of operations should use the Part 6 Wholesale Distribution Center/Terminal Warehouse section of the USDA GAP&GHP audit.

The main focuses of the House Packing Facility section of the audit are, water, the packing equipment, general housekeeping, worker health and personal hygiene, containers used for packing, and pest control. This scope of the audit can only be performed when the packinghouse is actively handling product. If the audit covers more than one commodity, it is not necessary to see every commodity being packed unless there are major differences in the packing process such as dry run product vs. product which uses a water flume, etc.

WATER USE IN PACKING FACILITY

Source water used in the packing of fresh fruits and vegetables must meet the requirements of the EPA Drinking Water Standard. Also water used to make ice used in the packinghouse must meet these requirements.

Municipal water supplies are regulated by law and are required to meet these requirements. However well water and surface water is subject to various uncontrollable influences and may or may not meet these requirements. The operation must provide documentation verifying the source water meets the EPA Drinking Water Standard requirements.

For commodities which are susceptible to water infiltration such as product with a stem scar; special attention needs to be given to the water temperature in the dump tank and flumes vs. the temperature of the product. Research has shown that a susceptible commodity which is placed in water colder than the pulp temperature of the commodity have a greater chance of internalizing the water and thus carrying any contamination into the product. Operations should refer to commodity specific recommendations or their state extension food safety specialist for more information regarding water infiltration.

TREATMENT OF PROCESSING WATER

Water used during the post-harvest handling of fruits and vegetables often involves a high degree of water-to-produce contact, and if untreated, may serve as a source of contamination or cross-contamination. Re-use of processing water may result in the build-up of microbial loads, including undesirable pathogens. Operations shall consider practices which will ensure and maintain water quality. Such practices may include:

- Monitoring of sanitation chemicals used to prevent cross contamination (i.e. chlorine and pH).
- Perform periodic water sampling and microbial testing.
- Change water as necessary to maintain sanitary conditions.
- Consider developing SOPs (standard operating procedures or sanitary operating plans), including water change schedules.
- For all processes that use water: clean and sanitize water contact surfaces, such as dump tanks, flumes, wash tanks, and hydro coolers, as often as necessary to ensure appropriate water quality.
- Install backflow devices and legal air gaps, as needed, to prevent contamination of clean water with potentially contaminated water (such as between potable water fill lines and dump tank drain lines).
- Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.

SANITATION PROGRAM/GENERAL HOUSEKEEPING

Operations with poor sanitation in the packing environment may significantly increase the risk of contaminating fresh produce and water used on produce. Pathogenic microorganisms may be found on the floors and in the drains in the packing facility and on the surfaces of sorting, grading, and packing equipment. Any of these surfaces could be a potential source of microbial contamination.

Operations shall employ good sanitation practices as a standard operating procedure to maintain control throughout the packing operation. Packing areas should be cleaned minimally at the end of each day. As necessary, clean and sanitize the washing, grading, sorting, and the packing lines to reduce the potential for microbial contamination of fresh produce. The operation shall develop and implement a general sanitation schedule which addresses the cleaning and sanitizing of the packinghouse operation including:

- Food contact surfaces
- Pipes, ducts, fans, and ceilings which are over product flow zones
- Catwalks over food contact surfaces

Ice making facilities may be located on the site of the operation or may be contracted out and supplied by another operation. In either case, the facility must provide records that indicate there is a regular schedule to sanitize the ice production and storage facility and any means of transportation to reduce the microbial population. This would include augers, conveyors and shovels used to transport the ice from one part of the facility to another.

The operation shall use food grade approved lubricants in areas where lubricating agents may come into contact with produce.

The operation shall have a procedure which identifies how product that spilled or comes in contact with the floor is handled. Spilled product that comes in contact with the floor can become contaminated and should not be used without considering a corrective action such as washing /sanitizing or disposing of the product. Commodity specific guidelines offer recommendations regarding the handling of spilled product and should be incorporated into the operation's food safety program.

WORKER HEALTH AND HYGEINE

The questions in the General Section portion of the audit related to health and hygiene are applicable to the House Packing Facility section of the audit as well. In addition, the House Packing Facility has several questions related to worker health and hygiene which are specific to these types of operations.

The operation shall evaluate and develop a hair/beard net policy which is appropriate for the facility. Hair nets and beard nets are worn in order to keep stray hair from entering the food and food containers being packed. In addition, wearing of hairnets when the hair is very long reduces the risk of catching hair in machinery.

The operation shall evaluate and develop a jewelry policy. Jewelry can be both a physical safety and a food safety hazard. Jewelry may fall into the food item or the container or may get caught on machinery and injure the worker.

The operation shall state the hairnet and jewelry policy in the food safety plan even if the policy states that no hairnets or restrictions on jewelry are required.

CONTAINERS

Operations should develop policies and procedures outlining only the use of new or sanitized containers which are clean and in good condition when packing the product. Policies and procedures shall require pallets and packing containers are properly stored to reduce the risk of contamination from pests, rodents, dirt, water, etc. Operation shall outline a sanitation schedule for reusable plastic containers used to pack product.

PEST CONTROL

All packing and storage facilities shall establish a pest control program to reduce the risk of contamination by rodents and other animals, including pets. This program shall include regular and frequent monitoring to accurately assess the program's effectiveness. The pest control program can be either performed by an employee trained to perform pest control or a contracted pest control company.

The operation must maintain a pest control log which records inspection dates, inspection reports, and procedures implemented to eliminate pest infestations. If using a contracted company, they generally supply the records of activity. All traps and bait stations will be marked and flagged by numbers or some type of coding system and recorded on a map which shows the location of such bait stations and traps.

All bait stations containing poison attractants must be located outside the facility. Traps or other non-poison methods should be the only control program located within a structure.

STORAGE AND TRANSPORTATION

This scope covers storage and transportation facilities located on or near crop production areas. This would include storage and transportation areas co-located with a packinghouse or stand alone storage facilities used on or near farms such as potato storage sheds or controlled atmosphere facilities. This scope is not intended for repack operations or distribution operations which may custom pack product for retail or foodservice customers. These types of operations should use the Part 6 Wholesale Distribution Center/Terminal Warehouse section of the USDA GAP&GHP audit.

The topics of worker health and hygiene, water quality, general sanitation & housekeeping and pest control are addressed in the House Packing section of this User's Guide (pages 17-20) and are applicable to this section of the audit as well.

MECHANICAL EQUIPMENT

Any equipment used in the storage facility shall be clean and properly maintained to prevent leaking fluids that could potentially contaminate the product. Loose or broken parts must be repaired to prevent foreign objects from contaminating the product. Any equipment or portions of equipment that directly touches raw product must be maintained so as to not contaminate the product.

ICE AND REFRIGERATION

The operation shall use water which meets the EPA Drinking Water Standards when making ice used for cooling or which comes in contact with the product. Ice or cold water (hydro-cooling) is often used by some commodity packers to reduce product temperature. The operation shall provide records which verify the source water used to make ice meets these requirements, including any ice which is purchased from an outside vendor.

The operation shall develop and implement a procedure for monitoring climate controlled rooms for temperature and keeping a record of temperatures. Climate control systems must be working and thermometers used in cold storage areas and for determining product temperatures should be regularly checked for accuracy and operators must maintain records to validate this procedure.

TRANSPORTATION AND LOADING

The operation shall develop an SOP which outlines the procedures for inspecting transportation conveyances for cleanliness, odors, and debris before the loading with product. The SOP should also include policies for not loading produce with potentially contaminating products such as raw meat or chemicals and policies to ensure adequate transport temperatures and should develop a written policy for transporters and conveyances to maintain specified transit temperatures. Records documenting adherence to the SOPs shall be maintained.

WHOLESALE DISTRIBUTION CENTER/ TERMINAL WAREHOUSE

Even though the *“Guide to Minimize Microbial Food Safety Hazards for Fresh Fruit and Vegetables”* is typically applied to farming operations, it is applicable throughout the marketing chain. Organizations and personnel within the wholesale distribution chain are just as responsible for food safety as organizations and personnel at the farm level. Part 6 of the USDA GAP&GHP audit focuses specifically on the wholesale end of the food distribution chain, and utilizes many of the same principles applied to packinghouses and storage & transportation facilities.

RECEIVING

Operations shall develop a formally approved supplier program for all incoming products which includes verification the supplier has undergone a 3rd party GAP&GHP audit.

The operation shall develop an SOP which outlines the procedures to verify incoming conveyances are checked for cleanliness, objectionable odors, and other potentially contaminating factors prior to accepting a load. The SOP shall also address procedures for monitoring the temperature of incoming loads and verify they meet any temperature requirements specified on the bill of lading or other requirements. The operation shall also have a policy on how to handle loads which do not meet the temperature requirements.

SANITATION PROGRAM/GENERAL HOUSEKEEPING

Operations with poor sanitation in the packing environment may significantly increase the risk of contaminating fresh produce and water used on produce. Pathogenic microorganisms may be found on the floors and in the drains in the packing facility and on the surfaces of sorting, grading, and packing equipment. Without good sanitation practices, any of these surfaces could be a potential source of microbial contamination.

Operations shall employ good sanitation practices as a standard operating procedure to maintain control throughout the packing operation. Packing areas should be cleaned at the end of each day. As necessary, clean and sanitize the washing, grading, sorting, and the packing lines to reduce the potential for microbial contamination of fresh produce. The operation shall develop and implement a general sanitation schedule which addresses the cleaning and sanitizing of the packinghouse operation including:

- Food contact surfaces
- Pipes, ducts, fans, and ceilings which are over product flow zones
- Catwalks over food contact surfaces

Ice making facilities may be located on the site of the operation or may be contracted out and supplied by another operation. In either case, the facility must provide records that indicate there is a regular schedule to sanitize the ice production and storage facility as well as any means of transportation to reduce the microbial population. This would include augers, conveyors and shovels used to transport the ice from one part of the facility to another.

The operation shall use food grade approved lubricants in areas where lubricating agents may come into contact with produce.

The operation shall have a procedure which identifies how product that spilled or comes in contact with the floor is handled. Spilled product that comes in contact with the floor can become contaminated and should not be used without considering a corrective action such as washing/sanitizing or disposing of the product.

WATER USE IN PACKING FACILITY

Source water used in the packing of fresh fruits and vegetables must meet the requirements of the EPA Drinking Water Standard. Water used to make ice used in the packinghouse must also meet these requirements.

Municipal water supplies are regulated by law and are required to meet these requirements. However, well water and surface water is subject to various uncontrollable influences and may or may not meet these requirements. The operation must provide documentation verifying the source water meets the EPA Drinking Water Standard requirements.

For commodities which are susceptible to water infiltration such as produce with a stem scar, special attention needs to be given to the water temperature in the dump tank and flumes vs. the temperature of the product. Research has shown that a susceptible commodity which is placed in water colder than the pulp temperature of the commodity have a greater chance of internalizing the water and thus carrying any contamination into the product. Operations should refer to commodity specific recommendations or their state extension food safety specialist for more information regarding water infiltration.

TREATMENT OF PROCESSING WATER

If applicable to the facility the operation shall verify that water used for processing is treated and monitored including:

- Monitoring of sanitation chemicals used to prevent cross contamination (i.e. chlorine and pH).
- Perform periodic water sampling and microbial testing.
- Change water as necessary to maintain sanitary conditions.
- Consider developing SOPs (standard operating procedures or sanitary operating plans), including water change schedules.
- For all processes that use water: clean and sanitize water contact surfaces, such as dump tanks, flumes, wash tanks, and hydro coolers, as often as necessary to ensure the safety of produce.
- Install backflow devices and legal air gaps, as needed, to prevent contamination of clean water with potentially contaminated water (such as between potable water fill lines and dump tank drain lines).
- Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.

STORAGE FACILITY/TEMPERATURE CONTROL

The operation shall have procedures in place to verify the refrigeration systems are working properly and are monitoring the temperatures of climate controlled rooms. The operation must have temperature recording logs available for review. Thermometers used in cold storage areas and for determining product temperatures

should be regularly checked for accuracy and operators must maintain records to validate this procedure.

CONTAINERS

Operations should develop policies and procedures outlining only the use of new or sanitized containers which are clean and in good condition when packing the product. Policies and procedures shall require pallets and packing containers are properly stored to reduce the risk of contamination from pests, rodents, dirt, water, etc. Operation shall outline a sanitation schedule for reusable plastic containers used to pack product.

MECHANICAL EQUIPMENT

Any equipment used in the storage facility shall be clean and properly maintained to prevent leaking fluids that could potentially contaminate the product. Also loose or broken parts must be repaired to prevent foreign objects from contaminating the product. Any equipment or portions of equipment that directly touches raw product must be maintained so as to not contaminate the product.

PREVENTIVE FOOD DEFENSE PROCEDURES

This section of the USDA GAP&GHP audit covers an operations food defense program. Food Defense is the protection of the food supply by **intentional contamination** by biological, chemical, or physical means by an aggressor. In contrast, the previous sections of the USDA GAP&GHP audit dealt with food safety which is the protection of food products from **unintentional** contamination from biological, chemical, or physical means.

FOOD DEFENSE PLAN

The operation shall develop and implement a documented food defense plan. Similar to a food safety plan, a food defense plan includes a company Food Defense Manual, containing the company's published SOP's and/or documentation. It will also contain information or references pertaining to internal or self audits of the program. Other similar documentation may also be applicable and acceptable if it indicates that a formally established program is in place.

The Food Defense plan shall indicate that there is a person in the operation that has implemented and will oversee the food defense program.

PERSONNEL

Each company should designate a contact person who is responsible for overseeing the plan. This person should be the point of contact for employees to point out potential security problems or issues. This person can also designate another person (for example, a shift supervisor) who can be the contact person for employees.

Food defense training shall be provided for all employees and should cover potential threats and vulnerabilities of the food supply and how they apply to the produce industry. Training should include who employees should contact if they observe a potential food defense issue. Records showing training instructions and training documents that each employee has signed should be available.

The food security plan should address access procedures to identify who has admittance to sensitive areas of the facility. This includes verifying the identity of visitors to the facility and the purpose for the visit. Check in procedures can vary from a formal sign in/sign out procedure in enclosed facilities to visitors checking in with the owner/manager (or designated person) of a small operation.

The operation should determine if any staff should have limited access to certain areas of the operation. The food security plan should address those jobs and the details of how staff will be limited to areas of the operation that are related to their job function, and to general access areas (break rooms, locker rooms, etc.). This type of scenario usually applies to larger packing house facilities or wholesale warehouses. In the case of small operations that only have a limited number of employees who perform all functions, this may not apply. Limiting access to packing/storage areas by unauthorized personnel is one of the most important procedures that can be implemented to reduce the risk of intentional contamination.

Visitors should be accompanied by an employee. A facility may designate exceptions to this for frequent visitors to the facility such as USDA inspectors, health department inspectors, the pest control contractor, etc., provided a documented list of exempted people is maintained.

All vehicles should be subject to inspection to look for any obvious sources of contamination. Documentation that vehicles entering the facility are being searched or that vehicles are subject to search should be available for review.

A policy should be in place that prohibits workers from bringing personal items into the production, handling, or storage areas. This reduces the possibility of an insider from contaminating product. Many packing facilities will allow workers to bring water to the packing line. This is an acceptable practice as long as the water is supplied by the facility and is not brought from outside sources.

Employees should not be allowed to loiter around the grounds and facility after their work hours, especially in sensitive areas of the operation. A work schedule outlining employee's hours and area the employee is assigned to work should be available to all management.

FACILITY PROCEDURES

The Operation shall develop procedures for the following areas:

- Procedure for controlling all items which identify a person as an employee of the company and requiring those items to be returned to the company upon completion of employment. If an employee does not turn over these items, there

is a procedure in place for management/security to be notified that the employee is not allowed access to the facility.

- Policy or Procedure to limit access to the company's computer network so that sensitive information is only accessed by authorized personnel.
- Policy or procedure for verifying the employment eligibility of all new hires in accordance with the Immigration and Nationality Act. In addition, the operation should outline what level of background checks will be performed. This can be a procedure as simple as a reference check, or more detailed such as a credit check for financial personnel. Operations that employ farm workers through an outside contractor should stipulate in their contract that the contractor perform a minimum level of background checks as well.
- Procedure for scheduled checks of the operation. On a farm, critical areas such as the storage barns, pesticide storage areas, and any product storage areas should be checked routinely. For packing sheds and wholesale warehouses that have a more permanent structure, the entire facility should be routinely checked. Including development of a checklist to verify the points of entry into buildings, either on the farm or packing house/wholesale warehouse.

KEY/ENTRANCE ACCOUNTABILITY

There shall be an accountability log showing who is in possession of any keys to enter the facility. Lost keys are documented on the accountability log, and steps are taken if keys to sensitive areas such as chemical storage areas are reported lost or stolen. These steps may include changing the lock or adding additional security measures.

DELIVERIES

The operation shall develop a policy which outlines delivery schedules and the policy for rejecting loads. The policy should include a list of criteria for why the product doesn't meet specified requirements as well as food safety requirements such as evidence of container tampering, evidence of suspicious foreign objects, etc. The receiving department/facility shall never accept incoming product that is from an unknown source. All deliveries should be listed on the delivery schedule, and only deliveries from that schedule should be accepted. The policy should address returned product and outline the returned product should be inspected for obvious signs of tampering or intentional contamination.

SEPARATION OF PRODUCTS

USDA Commodity Procurement purchases require that all domestic products be segregated from any foreign product. Additionally, because foreign product has the potential to be targeted for intentional contamination and shipped to the United States, it should be kept segregated from domestic product.

ALLERGENS

Products that are known allergens, such as peanuts should be segregated for several reasons. First to avoid inadvertent cross contamination with other products, and secondly to minimize the potential for an insider to simply “reach across the aisle” and purposely contaminate other product stored in the same area.

USDA GAP&GHP PROGRAM AUDIT SCORING

The USDA GAP&GHP audit utilizes a scoring system. Each question is given a score of 5, 10 or 15 points and is weighted depending on the relative risk associated with the question. There are no partial points given for any question, each question is either given the total points assigned to the question or zero points.

The USDA GAP&GHP Program requirements state that a minimum of 80% must be scored on each scope of the audit conducted in order to “pass” the audit. In addition no “automatic unsatisfactory” conditions can be present.

AUTOMATIC UNSATISFACTORY CONDITION

In addition to the scoring guideline shown above, there are a set of overarching conditions, which if observed, will result in the issuance of an “automatic unsatisfactory” score on the audit. These conditions are:

- An immediate food safety risk is present when produce is grown, processed, packed or held under conditions that promote or cause the produce to become contaminated.
- The presence or evidence of rodents, an excessive amount of insects or other pests in the production area during packing, processing or storage.
- Observation of employee practices (personal or hygienic) that jeopardize or may jeopardize the safety of the produce.
- Falsification of records.
- Answering of Questions P1 or P2 as “NO”.

Commodity specific audits performed by USDA auditors follow the same general guidelines as outlined above for automatic unsatisfactory conditions; however, they may refer to them in different terms such as “major deficiency” or “flagrant violation”. Refer to the commodity specific audit programs for the policies regarding these conditions.

In addition, if an immediate food safety risk which results in product contamination, the auditor may be required to report the operation to the applicable state Public Health Agency or the Food and Drug Administration.

POST AUDIT ACTIVITIES

Once an operation has successfully met the requirements of the USDA GAP&GHP program, it will receive a USDA certificate and have their information listed on the USDA website. The certificate is good for one year from the date of the initial audit, and the operations information will remain on the USDA website for one year unless the operation fails an unannounced verification audit.

APPEALS, COMPLAINTS & DISPUTES

Operations have the ability to appeal, dispute or lodge a complaint if they so desire. Operations with issues regarding an audit or auditor(s), should refer to the following list for assistance with the process.

- APPEAL: A formal complaint contesting the results or findings of the audit brought before the Branch by applicants or other parties.
- COMPLAINT: Discontent or unhappiness about a situation, interpretation, or performance of an audit, auditor(s), and/or policy brought before the Branch by applicants or other parties.
- DISPUTE: Disagreement or argument about a situation, interpretation or performance of an audit, auditor(s), and/or policy brought before the Branch by applicants or other parties.

If an operation decides to appeal or dispute an audit, there are certain steps that must be followed. The formal request for an appeal must be in writing on company letterhead from the company or person requesting the appeal. Information included in the request should be the date of the audit, location (if different from corporate office), sections on the original audit being appealed, and the specific item(s) being under dispute. Appeals, complaints and Disputes must be submitted to the Fresh Products Branch within three calendar days from the date the audit was performed.

All GAP/GHP audit appeals are performed by the Audit Review Board (ARB), who meet as needed to review all GAP&GHP audit appeals. The ARB has the authority to sustain or reverse the appeal. The results of the appeal will be provided by the ARB to all parties in the appeal process within 14 calendar days. Copies of the appeal results become part of the audit record.

Complaints regarding auditors shall be directed to the auditor's supervisor. Complaints regarding Branch policies and procedures shall be directed to the Audit Management Section.

Additional Resources

Establishing, implementing, and maintaining an effective food safety plan involves the evaluation of many processes. The USDA GAP&GHP website www.ams.usda.gov/gapghp provides links to many resources. State and Federal Agencies, University and Cooperative Extension Programs, Trade and Commodity Associations offer additional guidance for food safety planning.

APPENDIX I – FV-237A AUDIT REQUEST

FORM APPROVED BY OMB No. 0581-0125

	UNITED STATES DEPARTMENT OF AGRICULTURE Agricultural Marketing Service Fruit and Vegetable Programs Fresh Products Branch		REQUEST FOR AUDIT SERVICES	
	(This is the only acceptable form for fax or electronic submission to USDA for audit requests)			
NOTE: Fill in all appropriate blocks. Requested services may be delayed because of incomplete information. Type of service requested must be selected below.				
DATE OF REQUEST:		ANTICIPATED DATE OF AUDIT:		
AUDITEE INFORMATION			FARM/ FACILITY INFORMATION	
Company Name:			Location:	
Street Address:				
City, State & Zip:			Total Acres / Total Sq Feet to be audited:	
Phone Number:				
Contact Person:				
APPLICANT INFORMATION			COMMODITIES TO BE COVERED BY AUDIT (Please List)	
Company Name				
Phone Number:				
Fax Number:				
E-mail:				
Contact Person:				
TYPE OF AUDIT SERVICES REQUESTED				
Type of Audit(s) Requested (Please choose at least one)			Scope of GAP&GHP Audit (Please choose all that apply)	
<input type="checkbox"/> Good Agricultural Practices & Good Handling Practices (GAP&GHP) (Select Audit Scopes)			<input type="checkbox"/> Part 1 – Farm Review	
<input type="checkbox"/> Mushroom Specific GAP Audit (M-GAP)			<input type="checkbox"/> Part 2 – Field Harvest & Field Packing Activities	
<input type="checkbox"/> Tomato Audit Protocol (T-GAP)			<input type="checkbox"/> Part 3 – House Packing Facility	
<input type="checkbox"/> Leafy Greens Audit (LGMA)			<input type="checkbox"/> Part 4 – Storage & Transportation	
<input type="checkbox"/> Identity Preservation Audit (IP)			<input type="checkbox"/> Part 6 – Wholesale Distribution Center / Terminal Warehouse	
<input type="checkbox"/> Other, Specify: _____			<input type="checkbox"/> Part 7 – Preventative Food Defense Procedures	
ADDITIONAL REMARKS				
To download a copy of the USDA Good Agricultural Practices & Good Handling Practices audit checklist, please visit the USDA website at http://www.ams.usda.gov/gapghp .				
Once a request has been received, a USDA representative will make contact within 48 hours of receipt to schedule the audit.				
<small>According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0125. The time required to complete this information collection is estimated average .02 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.</small>				
<small>The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202)720-2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, or call (800)795-3272 (voice) or (202)720-6382 (TDD). USDA is an equal opportunity provider and employer.</small>				
<small>FV-237A (10-10)</small>				

APPENDIX II – FV-651 PARTICIPANT AGREEMENT

	UNITED STATES DEPARTMENT OF AGRICULTURE Agricultural Marketing Service Fruit and Vegetable Programs Fresh Products Branch	FORM APPROVED BY OMB No. 0581-0125 Good Agricultural Practice & Good Handling Practices Audit Program (GAP & GHP) Identity Preservation Program (IP) Partners in Quality Audit Program (PIQ) & Other Audit Programs
AGREEMENT FOR PARTICIPATION IN AUDIT VERIFICATION PROGRAMS		
Company Information		
I _____ a duly authorized representative of (Insert Name)		
_____ (Name of Company) (Street Address, City, State, and Zip Code)		
hereinafter referred to as the applicant, do hereby agree to be audited under the a voluntary USDA, AMS, Fresh Products Branch audit program. The audit shall include verification of the company's farm(s), packing facilities, storage facilities, wholesale distribution centers or other locations as applicable to the audit scope(s).		
1. The applicant agrees that with respect to:		
<p>a. Laws, Regulation, Statutes - To conform with all applicable Federal, State, and local government laws, regulations, or statutes, including, but not limited to: Regulations Governing Inspection and Certification of Fruits and Vegetables and Related Products (7 CFR, Part 52), any other pertinent regulations, and any such instructions covering inspection and certification of the products and verification of the processes as may be issued by AMS.</p> <p>b. Audit Request - To contact and schedule the audit with the appropriate federal or federal-state inspection office (using the FV-237A form). The request for the initial audit will be made no later than two (2) weeks prior to the end of the growing/harvesting/packing season.</p> <p>c. Records - To maintain all records required by the specific audit program including, but not limited to, quality manual, food safety manual, water test results, employee training records, manure use records, laboratory testing results and other records as required by the quality manual, food safety manual or specific audit program requirements. The applicant shall make these records available to USDA federal and/or federal-state auditors.</p> <p>d. Access to Facilities - To grant permission for AMS authorized personnel to enter any and all farms and/or facilities covered by the specific audit program for the purposes of conducting the audit. This includes the initial audit and any unannounced audits as may be required by the program.</p> <p>e. Payment - To pay by credit card, check, draft, or money order drawn to the order of the appropriate federal or federal-state agency for the services covered herein on or before the due date specified on the billing statement. Charges for GAP&GHP audits include, but are not limited to, the audit fee as listed in the fee schedule or Federal Register and travel expenses for the initial audit and any unannounced audits as may be required by the program.</p>		
2. AMS agrees that with respect to:		
<p>a. Perform Audit – To provide objective third-party verification of the applicant's specific audit program using internationally recognized audit principles.</p> <p>b. Opening & Exit Interviews - To discuss the audit prior to and report the results and observations with the applicant after each audit and provide a copy of the completed audit report or checklist.</p> <p>c. Reports - To issue to the applicant reports of all audits and evaluations of the applicant's specific audit program and provide written notification of any deficiencies found, if any.</p> <p>d. Confidentiality - To consider and treat any trade secrets or confidential information as proprietary and confidential. To consider any records and related information provided to AMS as information that is voluntarily submitted to AMS because of their participation in the specific audit program.</p> <p>e. Issuance of Certificate, Posting and Sharing Audit Results - To issue a certificate to the applicant and to post audit results to the USDA website, (with the exception of the Preventative Food Defense Procedures scope), only when the applicant receives at least the minimum passing score for each scope being audited. To provide the specific applicant checklist and results of individual questions to other parties only at the written request of the applicant. NOTE: Reports containing a compilation of generic audit information may be shared with the Food and Drug Administration. Any personal information linking the audit results to the auditee shall be redacted prior to issuance.</p>		

3. It is mutually agreed that with respect to:

- a. Length of Service** - That the audit results for GAP&GHP audits are valid for one year from the date of the initial audit, provided that at least the minimum score is achieved on both the initial audit and any unannounced audits that may be required by the program. For all other audit programs, the length of service is outlined in the specific audit program policy guide. This agreement shall remain in effect for the length of time the auditee remains a participant in the specific audit program.
- b. Maintaining Certification** - That a company's information will only remain 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.

Approved By:

Should AMS personnel be at a facility for other purposes and notice issues that would jeopardize the company's standing on the specific audit program, AMS has the obligation to bring this to the attention of the company representative and, depending on the severity, withdraw certification.

Name of Applicant (Print): _____ **Title:** _____

Signature: _____ **Date:** _____

USDA Agricultural Marketing Service, Fruit & Vegetable Programs/ Federal or Federal-State Inspection Program Supervisor

Name of Representative (Print): _____ **Title:** _____

Signature: _____ **Date:** _____

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0125. The time required to complete this information collection is estimated average 8.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, genetic information, political beliefs, reprisal or because all or part of an individual's income is derived from any public assistance program. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202)720-2600 (voice and TDD). To file a complaint of discrimination, write to USDA, Director, Office of Civil Rights, 1400 Independence Avenue, S.W., Washington, D.C. 20250-9410, or call (800)795-3272 (voice) or (202)720-6382 (TDD). USDA is an equal opportunity provider and employer.

APPENDIX III – CORRECTIVE ACTION REPORT

USDA Fruit and Vegetable Programs Good Agricultural Practice & Good Handling Practices CORRECTIVE ACTION REPORT	Report #: _____ of _____
Company Name/Farm:	Date:
Lead Auditor:	Crop:
Description of Non-Conformity: Notified company staff at time of finding non-conformity: YES or NO	
Checklist question number and/or section of auditee food safety plan non-conformity is associated with:	
Company Representative Signature: <small>SIGNATURE AFFIRMS FACTS CONCERNING NON-CONFORMITY ARE CORRECT</small>	
Corrective Action Proposed and Time Frame for Implementation: (Attach separate sheet if necessary)	
Auditor Signature for Acceptance of Proposed Corrective Action and Timetable for Implementation:	

Top portion for AUDITOR USE ONLY; bottom portion for Company and Auditor use.